

**The Place of Informed Consent and Community Assent in International Public Health
Interventions**

INAUGURAL-DISSERTATION

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von

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Basel, den 10. Mai 2011

Dekan: Prof. Dr. Albert Urwyler

I dedicate this dissertation to my mother,
and to the memory of my father and step-father.

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SUMMARY

What should the role and place of individual informed consent and community assent be in international public health interventions in order to support an intervention, whilst satisfying the appropriate ethical standards? In responding to this research question, the reflections will cover public health interventions and public health ethics in international settings, with particular attention being given to transcultural interventions in developing countries. The example will be used of public health interventions targeted towards the threat to public health represented by malaria in Africa. The focus will be on research-oriented interventions, although public health practice will also be touched upon. The dissertation will not be questioning informed consent in medical and clinical research and practice; the concerns are limited to informed consent and community assent in public health, particularly in developing country contexts.

The epistemic position outlined in *Chapter 1* is that the relationship between theoretical and empirical work in ethics should be one of a mutually supportive feedback. Therefore the dissertation will contain a deductive, theoretical, normative-descriptive tranche, as well as an explorative, exemplary empirical, inductive tranche, as reflected in the Deductive – Inductive Feedback Structure that has been developed. The motivation for this approach is that the research question arose from concerns raised by public health practitioners; therefore an approach was necessary that addresses concrete experiences, as well as the theoretical, normative aspects of consent and assent in public health.

The position taken in the moral relativism-ethics universalism debate is described as being that neither extreme relativism nor absolutism are satisfactory positions to guide practical ethics research and reflection. A weak universalist position is adopted, that holds that moral acts are capable of being reasonably argued, and judged as being right or wrong. There exists, however, a plurality of reasonably argued values and principles that apply to many situations; a plurality of justifiable judgments can exist. Thus even holding that principles and acts are capable of being reasonably argued, it should not be assumed that we are (yet) aware of what should universally be done in every situation.

This epistemic, methodological structure has stimulated the adoption of a 'System – Driving Force – Target – Transformation Knowledge' analytical framework in addressing the research question. This approach was originally developed as a tool to organise information in complex systems, and focuses on cause-effect relationships between interacting

components. Systems knowledge is status quo knowledge that comprises the theoretical status of informed consent and community assent, existing guidelines, and empirical knowledge. Driving force knowledge deals with the forces that stimulate, drive, or exert pressures that challenge and change the status quo. Target knowledge is ethical, prescriptive knowledge about the aims or targets that are right, appropriate (and also practical). Transformation knowledge covers how to get from the status quo to the targeted end.

Having established this foundation and structure, *Chapter 2* differentiates and defines the terms health, medicine, public, public health and epidemiology. The determinants of the health of the public are then considered; a sketch is given of public health actors; reflections are made on globalization and public health, and the perspective of seeing public health as a public good is reviewed. The variety of aims and goals of public health according to context are then noted, and an overview made of the interface of health, public health, and human development concepts and activities. Given the complexity involved, the public health of a population at any one time is concluded as best being seen as the product of a thick, non-linear bundle of trajectories, situated along the timeline of history. These trajectories include cultural, historical, economic, health system and political factors.

Chapter 3 commences the deductive, normative ethics tranche by reviewing the various definitions, history, and background of the development of informed consent. Time-lines of major documents codifying informed consent and community level assent are developed. It is interesting to note that informed consent has been codified in international 'hard' law such as the Council of Europe Convention on Human Rights and Biomedicine from 1997; in international 'soft' laws, for example the UNESCO Universal Declaration on Bioethics and Human Rights from 2005, as well as in various national laws. A United States Court found in 2009 in the TROVAN[®] case that the prohibition of non-consensual medical experimentation on humans is binding under customary international law.

The foundations of informed consent in medicine and public health are then outlined, starting with the substantive basis that is usually held as justifying the need to obtain informed consent, followed by considering procedural aspects of consent and assent processes. The open questions on informed consent in public health are outlined, with the main issue being: what should the central principles be that underlie and shape the informed consent process in public health; what is the appropriate theoretical basis for evaluating if individual consent is needed in a particular public health situation? Is a deontological, individualistic approach (the status quo in medicine and epidemiology guidelines) always appropriate?

Chapter 4 provides an introduction to the complex notion of ‘community’, looking at the various definitions, the various dimensions, and its moral status. It is noted that some communities need to be protected, and many deserve respect. Protection might be needed to prevent discrimination; segregation or exploitation, especially if a community is politically or economically disadvantaged, and therefore vulnerable.

The contents of major exemplary normative laws, guidelines, codes and commentaries (the Texts”) that deal with various aspects of informed consent on the individual and community level are outlined in *Chapter 5*. Although this dissertation addresses consent in public health, Texts that cover medicine as well as public health are considered. The reasons for this are that firstly the history of the development of consent in medicine and public health are strongly intertwined; secondly is the scarcity of normative texts covering public health, especially public health outside developed countries, and finally because it is hypothesized that guidelines developed with a medical context in mind are often applied to public health.

Reflective, analytical work on the Texts is undertaken in *Chapter 6*. The analysis reveals a status quo of the primacy of deontological – duty based – principles that protect and respect the individual person, and a widespread acceptance of the default position of the obligation to obtain an individual’s prior informed consent. This position is found in the Texts that cover the research and practice of medicine, as well as the few guidelines on epidemiology (a core discipline of public health). However, another set of population level principles is found that includes respect for community, respect for diversity, and sensitivity to local traditions, for example, the tradition of obtaining community leader permission or assent before approaching individuals for consent. A reasonably coherent position is found in the Texts on the relationship between the individual and community focused sets of principles. This favours the primacy of the duty to respect and uphold the principles of the individual informed consent, with deviations from this default position requiring justification, and the satisfying of various criteria.

Bearing in mind that the majority of the Texts are aimed at medical, clinical settings, the question arises whether the principles underlying consent in public health should, in addition to the predominantly deontological position, apply consequentialist theories or other approaches. It is interesting to see that a close reading of the few texts that deal with public health reveals the inclusion of some limited consequentialist reasoning, and a reference to human rights.

Yet the community level principles are not completely overridden. Further analysis of the Texts reveals that although the principle of respect for persons as expressed in informed consent takes precedence on a substantive level, respecting diversity can require on a procedural level that some kind of community assent be obtained before approaching individuals if traditions so require it. This situation results in the drafting of a two-stage MIICCA structure – **Model for Integrated Informed Consent and Community Assent** – in which an opening community assent stage precedes an individual consent stage. However, this is only one of the possible roles that ‘community’ can play. The other roles and functions are the following:

- a) A community representative may be required to give surrogate consent on behalf of individuals if it is impossible to pursue individual consent because of the nature of the intervention, e.g. a public health promotional campaign;
- b) Conducting some form of community involvement can be a condition for a research ethics review committee agreeing to waive individual informed consent;
- c) A community representation may be needed to act in a consultative capacity to review a project, and providing inputs on matters that may include the design of the informed consent process, representing thereby the rights and interests of the community;
- d) Community engagement can have the function of implementing the principle of respect for communities as partners in a project into practice;
- e) Conducting a community consultation can confer political and moral legitimacy.

In addition to these principle-driven roles of ‘community’, practical reasons can motivate the involvement of the community, such as creating an amicable relationship between researchers and the communities in order to facilitate trial recruitment and compliancy.

By the end of Chapter 6, a picture starts to crystallize of a disconnect existing between the normative, descriptive Texts that primarily take a deontological position in justifying and structuring informed consent, and theoretical reflections suggesting that a more pluralist position might be appropriate in public health. The closing reflections of Chapter 6 note the differentiated picture that starts to emerge of the different roles that ethics theory must take in planning informed consent and informed assent in public health interventions. Firstly is the ‘meta’ role at the start of any intervention in evaluating if a consent or assent process is required. If it is decided that consent and assent is relevant and necessary, the second level use of ethical theory is to decide what form and kind of consent and assent is applicable: individual informed consent; community assent; MIICCA, and /or community consultation, or a mixture? Finally, is the use of theories in order to decide on the details of a consent or

assent process, e.g. the application of a consequentialist approach to evaluate if the level of formalities in a consent process can justifiably be varied.

Chapter 7 leaves theoretical, normative reflections temporarily to one side, and develops two exploratory models for public health based on the contents of the Texts, one for individual consent, and one for community assent. The models aim to provide concrete guidance for public health practitioners, and include minimum standards. This task is undertaken although the position is hardening that the status quo individualistic deontological understanding of consent principles found in the Texts is less than satisfactory when applied to public health interventions. The reason for nevertheless drafting models on a questionable basis is that public health practitioners need practical guidance, and the only available basis is the status quo found in documents such as the 2009 CIOMS epidemiology guidelines. However, the models also include elements that try to account for important aspects of public health interventions in developing countries, e.g. economic, political and cultural factors. The models do not question the principles held as underlying individual consent, but seek to add refinements in implementation and interpretation.

Chapter 8 closes the deductive, theoretical, normative-descriptive tranche by reviewing a selection of articles on public health ethics ('the Literature'). The need to draw upon public health ethics to consider the research question arises because there is no clear set of appropriate ethical standards covering consent issues in transcultural public health interventions. The central question being asked of public health ethics is what theories, what principles should be applied to consent and assent questions? The review shows that the task of developing a public health ethics is a work-in-progress that is not able to give a clear answer to the research question. The Literature displays a pluralist approach; various theories and approaches are found, including human rights; deontological principles (some of which refer to the individual, and some to a societal level), and various references to consequentialist positions that are particularly applied to resolve conflicts between individual and community rights and interests. Thus the disconnect located at the end of Chapter 6 between the normative, descriptive Texts that primarily take a deontological position, and theoretical reflections suggesting that a more pluralist position is confirmed. Clusters of principles are extracted and distilled from the Literature, and modeled to form a Public Health Ethics Array of Clusters of Principles and Approaches Framework ("the Cluster Framework") that is aimed at supporting public health interventions in developed, developing and transition country contexts.

In addition to developing the Cluster Framework, Chapter 8 sees the generation of the hypothesis that historical events can act as driving forces that impact on public health ethics in several ways. Therefore, public health ethics should be open to revision in the light of inter alia critically considering historical influences on its past and on-going development. The question is then: is it *now* historically the time to reconsider public health ethics regarding the treatment of consent and assent? An affirmative answer is found in the literature, with the opinion being expressed that the swing towards the status quo of the default position favouring the individual rights holder needs to be revisited (without, however, taking then too strong a corrective tilt towards the primacy of the public good). A neutral opening stance should be taken in applying the Cluster Framework to questions of informed consent and assent, allowing for the consideration of consequentialist analysis, community based principles, a human rights discourse, as well as protecting and respecting individual rights and principles when evaluating and designing the appropriate process for an intervention.

The inductive, descriptive ethics empirical tranche of the dissertation then commences. This comprises three public health case studies, and the exemplary, exploratory expert interviews that have been conducted. The main aim of this tranche is to validate the understanding of informed consent and assent as prescribed in guidelines such as CIOMS. This concept of a validation process is introduced; criteria and indicators are developed. The three case studies are the KINET social marketing bednet (malaria prevention) project; an IPTi (Intermittent Preventive Treatment in infants) randomized, placebo-controlled prophylactic drug study for malaria, and an IPTi acceptability trial that examined the reception in an African community of the IPTi program. The cases illustrate the very different kinds of public health interventions within which consent and assent issues require consideration. Firstly the KINET project tested the application of a social marketing approach to meeting the aim of increasing insecticide treated bednet usage in Tanzania. Although non-invasive, the success or failure of KINET in increasing bednet usage has a health impact at the level of individual users, and on the level of community. The use of well-maintained bednets has a herd or mass epidemiological effect, meaning that the accumulated use by individuals brings benefits at the level of the community of reducing the incidence of malaria. Secondly, the randomized, placebo controlled invasive drug study had a complex risk-benefit profile with repercussions at both the individual and community levels, with one of the risks being the possible negative community impact of IPTi of speeding-up the rate of development of parasite drug resistance to anti-malarials. Finally the IPTi acceptability trial methodology included in-depth interviews, focus groups, and participant observation data collection methods.

The results of the case studies and interviews are presented in *Chapters 9 and 10*; and some of the major findings are now outlined. They raise a central question that is the mirror image of that raised in the theoretical, deductive tranche: what are the standards that ethics review committees and researchers should apply to consent and assent in public health? The exploratory, empirical results show that support is required, with a particular problem being coping with situations where seeking individual informed consent is impossible due to the nature of the intervention, as will often be the case in public health. Can and should the absence of individual consent be compensated by the interactions with the community? Problems can arise when social science methodologies such as participant observation are applied, and regarding consent issues in social marketing interventions. To summarize, guidance is needed on the following issues:

- a) When individual consent and community assent processes are required;
- b) When they can be waived;
- c) When elements in the process can be simplified to avoid unconstructive complexity;
- d) When and what consent elements must remain as absolute minimal standards?

The exploratory, exemplary, empirical results confirm both the importance of ethics review committees and the problems that exist. The experts find the review processes to be unwieldy; the decisions made to lack coherency, with the review process and the requirements for consent being thought to have negative impacts such as delaying or even halting the research agenda in an unacceptable way. Consent and patient information forms are too long, complex, and sometimes inappropriate for the context in which they must be applied. The expert interview findings suggest that researchers do not always comply with the informed consent requirements when working in the field. Is non-compliance due to the inappropriate nature of the requirements; to how the requirements and guidelines are communicated to the researchers, or to systemic problems that hinder the application of the norms – or a mixture of all these possible reasons? To what extent are problems arising from either the wrong, or rather an incomplete set of principles being applied and interpreted in regulating the consent and assent processes in public health?

One of the criteria included in the consent process validation concept is if consent and assent are operationalized in an intervention so that the underlying principles are upheld and fulfilled, i.e. that persons are respected, or the right to diversity observed according to the perception of those affected. Although difficult to measure, the IPTi acceptability trial case

study illustrates that complex processes can be negatively perceived as being disrespectful, as they confuse rather than inform.

Regarding the subject of how 'community' was treated by the experts, a pragmatic approach towards involving community leaders or representatives is found in the expert interviews to be a standard practise. There is a lack of clarity, however, on what the relationship between community assent and individual consent should (normatively) be with the misunderstanding existing that community assent can replace individual consent. The reason for this situation requires attention. Is again the problem that the contents of the guidelines are perceived as being inappropriate; is it one of weak communication of the guidelines, or of differences in opinions on the role and importance of consent and assent? Both the case studies and the expert interviews illustrate that more work is needed to explicate the complex interplay of individual consent with community assent and involvement on a practical and ethical theoretical level in public health. The ethical analysis must integrate an understanding of pragmatic aspects of community permission and involvement.

The conclusion of the empirical inductive tranche is that the cases and interviews support the need for revisiting the guidance that is required for public health interventions, and to protect the rights and interests of all stakeholders particularly the individual and communities involved (although the exploratory, hypothetical findings do not justify asserting that informed consent and assent *must* be revised). The main findings that lead to this conclusion include instances of non-compliance with the admittedly unsatisfactory guidelines, and that complying with the need to obtain informed consent is sometimes knowingly disregarded, possibly because of the perception of the inappropriate nature of the guidelines for public health intervention. Another finding is that some consent processes are so complex that they may confuse rather than inform participants, and therefore fail to show respect for the involved persons or communities.

The final synthesis tranche then starts, the main task of which is to draw together the system, driving force and target force knowledge in order to address the research question. After a reiteration of the systems knowledge that has been generated, the driving forces are summarised. Driving forces exert pressure, drive forward a change process, and challenge the status quo of a phenomenon. The main forces located in the work of the deductive tranche are now listed:

- a) The standards derived from the Texts are not wholly adequate for public health, resulting in uncertainty as to what the theoretical foundation should be in public health interventions conducted in developing countries;
- b) The Texts focus on developed countries and pay little attention to other contexts. This is a problem because factors such as history, culture, the economy, and political situation are ethically relevant when considering consent and assent in international public health;
- c) A disconnect was revealed between the theoretical, descriptive normative basis of consent found in the Texts that was primarily deontological, and the reflections, general principles, theories and approaches located in the articles on public health ethics;
- d) No internationally accepted ethics of public health exists that can provide a framework of principles for consent and assent;
- e) Different roles and functions of 'community' in consent and assent in transcultural contexts have been identified, with there being no clarity on which role and function community should play in the multi-faceted consent and assent processes that arise in public health interventions in developing country contexts;
- f) The role of history (such as economic, political, military, social and scientific factors and forces) is asserted as being a major driving force in forming informed consent, as shown by the reflections and time-lines developed in Chapter 3. This role was emphasised again in Chapter 8, with the hypothesis being developed that an awareness of past and on-going historical influences on theory development and application should be a part of the work in developing standards for consent and assent.

The driving forces arising from the case studies and interviews include the following:

- a) The tentative conclusion that the informed consent process as prescribed in guidelines such as CIOMS cannot be validated for various reasons including that they are not necessarily complied with;
- b) Although the exploratory, hypothetical findings do not have the power to support an argument that informed consent and assent should be revised, they support revisiting the guidance that is needed to support public health interventions, and protect the rights and interests of all stakeholders, particularly the individuals and communities involved;
- c) There are grounds for doubting if guidelines prepared for developed countries can be transferred onto developing countries, or that any guidelines developed interventions, or that guidelines for epidemiology should be widely applied in public

health fields outside epidemiology. Medical research and practice can be simply transferred onto public health.

Having reviewed the systems knowledge – the status quo – and located the driving forces, the next question is what should be done with these pressures for change; what responses are appropriate? Target knowledge is the knowledge that should address these questions; target knowledge is prescriptive knowledge concerning the aims or targets that are right, appropriate, and also practical. The need to identify or generate target knowledge results from the pressure of driving forces that justifiably stimulate and demand change. Although target knowledge production should be an interdisciplinary exercise, this dissertation has produced some exploratory, hypothetical contributory target knowledge that can be divided into knowledge of a more theoretical nature, and that with a more practical slant. The main theoretical target knowledge generated includes the following:

- a) The proposal that ethics theory must be applied on three different levels when analysing informed consent and community assent in public health;
- b) The hypothesis that historical events (such as economic, political, military, social and scientific factors and forces) have had an impact on public health ethics, therefore public health ethics should be open to revision in the light of inter alia critically considering these influences on its past and on-going development;
- c) The suggestion of a revised approach to assent and consent in public health that takes a neutral position in applying the public health ethics clusters;
- d) A draft decision making framework for public health interventions (see Chapter 8);
- e) The hypothesis that an individual consent and community assent process for a public health intervention should not be designed and evaluated as if consent was a self-contained activity, but seeing consent and assent as being processes that are embedded in the structure and context of a particular intervention.

The practical focused, exploratory, hypothetical target knowledge includes:

- a) The notion of validating a consent process (Chapter 9);
- b) The identification of the various roles of community that need to be integrated into designing an informed consent and assent process in public health transcultural interventions;
- c) Certain aspects of the community assent and individual consent models developed for public health, transcultural interventions (Chapter 7);

- d) The following bundle of target knowledge on the important but problematic role of research ethics committees (RECs):
- i. The proposal that the ethics of public health (including aspects related to consent and assent) needs to be revisited, implying that the basis on which RECs currently make their decision also needs revision;
 - ii. The need to acknowledge when RECs in developing and developed countries will be limited in their ability to meet the expectations made of them, and to acknowledge such shortcomings and account for it in the design of quality assurance aspects of an intervention;
 - iii. If the central duty of RECs in medical research is to act as a guardian of the rights and dignity of research subjects, the question needs to be addressed: who is acting as advocate for the public when evaluating public health interventions? Is some kind of instance required to act on the collective's behalf?
 - iv. An appreciation that the vetoing role, or even vetoing responsibility of local review committees in adjudicating appropriate consent and assent can be important (as indicated in the standard of care debate); their capabilities and empowerment to perform this role based on balanced and informed criteria must be strengthened.

The synthesis then asks the central question of this dissertation: have the inductive and deductive tranches resulted in knowledge being produced that enables the research question to be answered: *what should the role and place of individual informed consent and community assent be in public health interventions in order to support an intervention, whilst satisfying the appropriate ethical standards?* The conclusion is that this is not the case; a satisfactory answer cannot be given. There are two main reasons for this failure. One is that the ethics of public health is at an early stage of development, especially when compared to the rapid developments in the fields of medical and clinical ethics; therefore no 'appropriate ethical standards' are yet available. As long as they do not exist, the research question cannot be answered. The second reason is that there is no clarity in the Literature, the Texts, or in the minds of public health experts on what the relationships between informed consent, community assent, and community participation should be in transcultural public health interventions.

However, although the research question remains unanswered, paradoxically the objectives of the dissertation have been tentatively achieved: *"to offer a support from the field of ethics for transcultural public health interventions in developing countries, and add*

to the emerging ethics of public health in developing countries with respect to questions concerning community assent.”

The final part of the dissertation seeks to offer a response to a) the failure to answer the research question and b) the need to locate ‘appropriate ethical standards.’ It is suggested however that in view of the complexity disclosed in the dissertation, the task should be formulated as being the establishment of a framework within which the appropriate standards for consent and assent can be selected for a particular intervention, rather than the locating the ‘appropriate standards.’

To this end, to close the dissertation, a 5-Step Plan is introduced that applies much of what has been learnt. The task of Step 1 is to deepen the work started in this dissertation of ascertaining the status quo of consent and assent by conducting more research on inter alia what is done in the field.

The content of Step 2 is to enter into a discourse with experts from developed, developing, and transitional countries coming from the following groups: researchers, regulators, ethics review committees members, sponsors/funding institutions and ethicists. The aim is to establish from these expert’s perspectives what the problem areas with consent and assent are.

Step 3 aims to locate the causal chains that have led to the problematic aspects of informed consent and community assent in public health. The analysis should identify the historical events that have acted as driving forces, and locating the responses to the events, e.g. a law, a regulation, a legal case, that resulted in the status quo.

Step 4 is a follow-up of locating driving force response chains; it comprises analysing why a particular response was made to a driving force (that then led to the status quo). One approach to this question is based on accepting that various roles and functions have been allocated over time to the basic idea of ‘consent’. The allocation of these roles and functions has been in response to historical events and processes. The tentative hypothesis is that individual informed consent has become overloaded with roles and functions, some of which are necessary, and some of which can, and some of which must be delegated or abandoned in some situations. On the other hand, community assent and community involvement processes have remained ‘under-loaded’. The reason suggested for the overload is that a ‘preventive ethics’ approach has been applied to the development and implementation of informed consent and community assent. A reason

for the under-use of community assent (in its many guises) is that the issue of consent in public health has been derived from the individualistic medical field which is characterized by a Hippocratic, i.e. individualistic tradition.

Step 5 suggests continuing the interdisciplinary discourse with the aim of agreeing on the relevant target knowledge, i.e. what the stakeholders think informed consent and assent should be (normatively and practically). One part of this work is to unravel the functions loaded onto informed consent over time, and decide which roles and functions are necessary, and which must be delegated or abandoned in some situations. A framework, or 'scaffolding' for this discourse is suggested that is illustrated in Figure 22 (Upstream and Downstream Scaffold for Embedding Consent and Assent Processes). This is based on the hypothesis that individual consent and community assent processes for a public health intervention should be designed and evaluated not as being a self-contained event, but as considering how a process is embedded in the structure and context of a particular intervention.

This scaffold approach views informed consent and community assent in public health as being elements in a cascade of measures that take place at various stages of an intervention. Informed consent and assent is one part of quality assurance, respecting and protecting measures that take place through all stages of the life cycle of research, development, and use in individual and population health care interventions. The hypothesis acknowledges the limits of a consent and assent process to perform the many legal, ethical and practical roles and functions that are often expected of the processes.

Thus the 'doctrine of informed consent' often referred to in the medical context is transformed in public health into a maxim of transparent planning, and an approach of being open to combine informed consent, community assent, and community multi-level engagement, all in pursuit of protecting individuals and communities, whilst supporting international public health research and practice.

Limitations

Regarding the general limitations of the dissertation, it is appreciated that although Chapter 3 indicates the complexity of the term 'community,' the term is thereafter used in a general way. The further research programme outlined in Chapter 11 should take this into account. It

is also appreciated that many issues surrounding consent, assent, and community will vary according to whether an intervention is taking place in a rural or urban setting, and that family dynamics and gender issues can play a role. Dealing with these issues is outside the scope of this dissertation. The limitation is also acknowledged that the historical matters that are touched upon take a 'western' perspective; an interesting endeavour would indeed be to take a more intercultural view of how informed consent has developed. In general, an analysis of cultural differences regarding 'personhood,' and the concept of 'autonomy' and 'consent' would be an important additional line of inquiry. It would also have been interesting when developing the Cluster Framework in Chapter 8 to have made a shadow-model that considers inputs from other world-view positions. Again, this endeavour would be outside the scope of this dissertation.

Furthermore as will be laid out in Chapter 1, the term 'public health' covers a vast area of activities. This dissertation focuses on a very small area of this vast field. Regarding the geographical focus of the dissertation being on developing countries, it also deals with a narrow setting (mainly Tanzania). Tanzania does not represent Africa, and Africa does not represent all developing countries.

The term 'empirical' is used to refer to the expert interviews and case studies. It is appreciated that this posterior work is exemplary and explorative; no claims are made that 'knowledge' has been produced that is representative, generalizable, justified true belief. All references to results, findings, and knowledge that come from this empirical work should be seen in this light. However the 'knowledge' forthcoming does form a basis for generating hypotheses.

Notwithstanding these limitations, it is hoped that this dissertation will succeed in making a small contribution to the subject of consent and assent in public health, developing country contexts.

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List of Abbreviations and Nomenclature

ALPHA	American Public Health Association
AMA	American Medical Association
BCC	Behaviour change communication
CAB	Community advisory boards
CIOMS	The Council for International Organizations of Medical Sciences
DDT	Insecticide: dicholoro-diphenyl-trichloroethane
DoH	Declaration of Helsinki
EGE	European Group on Ethics
EPI	Expanded Program on Immunization (WHO)
EUROPH	Public policies, law and bioethics : a framework for producing public
EN	health policy across the European union by examining concepts of European and universal ethical guidelines
FPIC	Free, prior informed consent
GCP	Good Clinical Practice)
GEP	Good Epidemiological Practice
GMAP	Global Malaria Action Plan (Roll Back Malaria Partnership)
HPIN	HIV Prevention Trials Network
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IEA	International Epidemiologists Association
IPTi	Intermittent preventive treatment of malaria in infants
MIICCA	Model for Integrated Informed Consent and Community Assent
MRCC	Medical Research Coordinating Committee (Tanzania)
NBAC	National Bioethics Advisory Committee (USA)
RBM	Roll Back Malaria Partnership (global framework to implement coordinated action against malaria)
REC	Research ethics review boards/ethics committees
SP	Sulphadoxine-pyrimethamine (SP)
WHO	World Health Organization
WMA	World Medical Association

PART I: INTRODUCING THE PROJECT

CHAPTER 1

RESEARCH QUESTION, OBJECTIVES, STRUCTURE, METHODOLOGY, EPISTEMIC POSITION

*“Health matters to everyone:
to ourselves, our families and our communities.”¹*

1.1 Introduction

After many years of hopes raised and hopes dashed, the WHO 2010 World Malaria Report stated that progress is finally being made in improving malaria control.² The number of deaths due to malaria is estimated to have decreased from 985,000 in 2000, to 781,000 in 2009, with the largest absolute decreases in deaths being seen in Africa.³ In particular, the massive scale-up in malaria control programmes between 2008 and 2010 resulted in providing insecticide-treated mosquito nets to more than 578 million people at risk in sub-Saharan Africa. However, even with this progress malaria remains a serious public health problem (as do many other diseases). Malaria still kills one child every 45 seconds, nearly 90 per cent of them in Africa.⁴ Eradicating malaria is the only morally acceptable end-goal – albeit one that will take many years to achieve⁵ – and there is increasing talk of this goal being now ‘back on the table’. However, the challenges remain formidable, with efforts being needed to develop better tools as well as maximising the synergistic effectiveness of currently available technologies.⁶

¹ Nuffield Council on Bioethics, *Public health: ethical issues*, 2007: 3.

² WHO, *World Malaria Report*, 2010: xi-xv.

³ Margaret Chan, *Progress seen in world malaria report*,” Statement to the press at the launch of the World malaria report, 2010.

⁴ UN, *Fact Sheet Millennium Goals*, 2010.

⁵ Robert Newman, “Learning to outwit malaria,” *Bulletin of the World Health Organization*, 2011; 89: 10-11.

⁶ Marcel Tanner, Don de Savigny, “Malaria eradication back on the table,” *Bulletin of the World Health Organization*, 2008;86: 81-160, 82.

What is the connection between the above and the subject of informed consent in public health? The volume of literature that deals with 'informed consent' is considerable. A Google search brings 9,310,000 hits; Pubmed finds 42,000 documents.⁷ Has not everything been said that there is to say on the subject? Perhaps not; the RBM Global Malaria Action Plan (GMAP) identified three types of research that are necessary to support effective malaria control and elimination. Firstly, the research and development needed to create new or improved anti-malarial interventions. Secondly, research that informs policy decisions most relevant to informed consent and thirdly, operational and implementation research to understand the use and effectiveness of interventions in the field.⁸ It is within this third area of research on the transition from intervention efficacy to effectiveness that this dissertation is positioned. It is based on the understanding that for instance "delivery of effective malaria treatment will not occur unless attention is also focused on the broader socio-cultural, economic, technical, and political environments in which it will be implemented."⁹

Another reason for reflecting on the need for informed consent in public health is that the scientific developments in the field of malaria (and other critical diseases) include innovations such as genetic control of mosquito vectors of diseases, new synthetic insecticides, fungi biocontrol agents for adult malaria mosquito control, and genetically modified maize expressing insecticidal toxins etc. that require analysis from a public health ethics, population level perspective.¹⁰ For example, an article from November 2010 in "Science" reported the world's first outdoor trial in which a private company released transgenic *aedes aegypti* mosquitoes in 2009 designed to fight human disease in the Grand Cayman. Scientists, regulatory authorities, ethicists and pressure groups have long debated if, how, and when to carry out the first test release of transgenic mosquitoes in view of the well-known opposition to genetic engineering, with the expectation being that any such

⁷ Google and Pubmed searches, search parameter: "informed consent," (accessed 22 January 2011).

⁸ Roll Back Malaria, *Global Malaria Action Plan*, 2008: 15.

⁹ D N Durrheim, H A Williams, "Assuring effective malaria treatment in Africa: drug efficacy is necessary but not sufficient," *Journal of Epidemiology and Community Health*, 2005; 59: 178-179, 178.

¹⁰ Wen L Kilama, "Health research ethics in public health: Trials and implementation of malaria mosquito control strategies," *Acta Tropica*, 2009 Nov;112 suppl. 1: 37-47.

research must be preceded by extensive interactive public groundwork. The article reported that there were no town hall meetings or public debates, as the government of the Cayman Islands did not consider this necessary.¹¹ The question arises: was this trial ethically acceptable? Should not some form of community process have been conducted?

This dissertation is placed against this background of global public health issues, increasingly complex and scientifically sophisticated interventions, and the partnerships between governments, intergovernmental organizations, academia and NGOs that have a vital role to play in international public health. The aim is not to examine or question the theoretical justification, guidelines, or manner of implementing informed consent in medical or clinical research or practice. The concerns are limited to informed consent (on the individual level), and community assent in public health in transnational contexts.

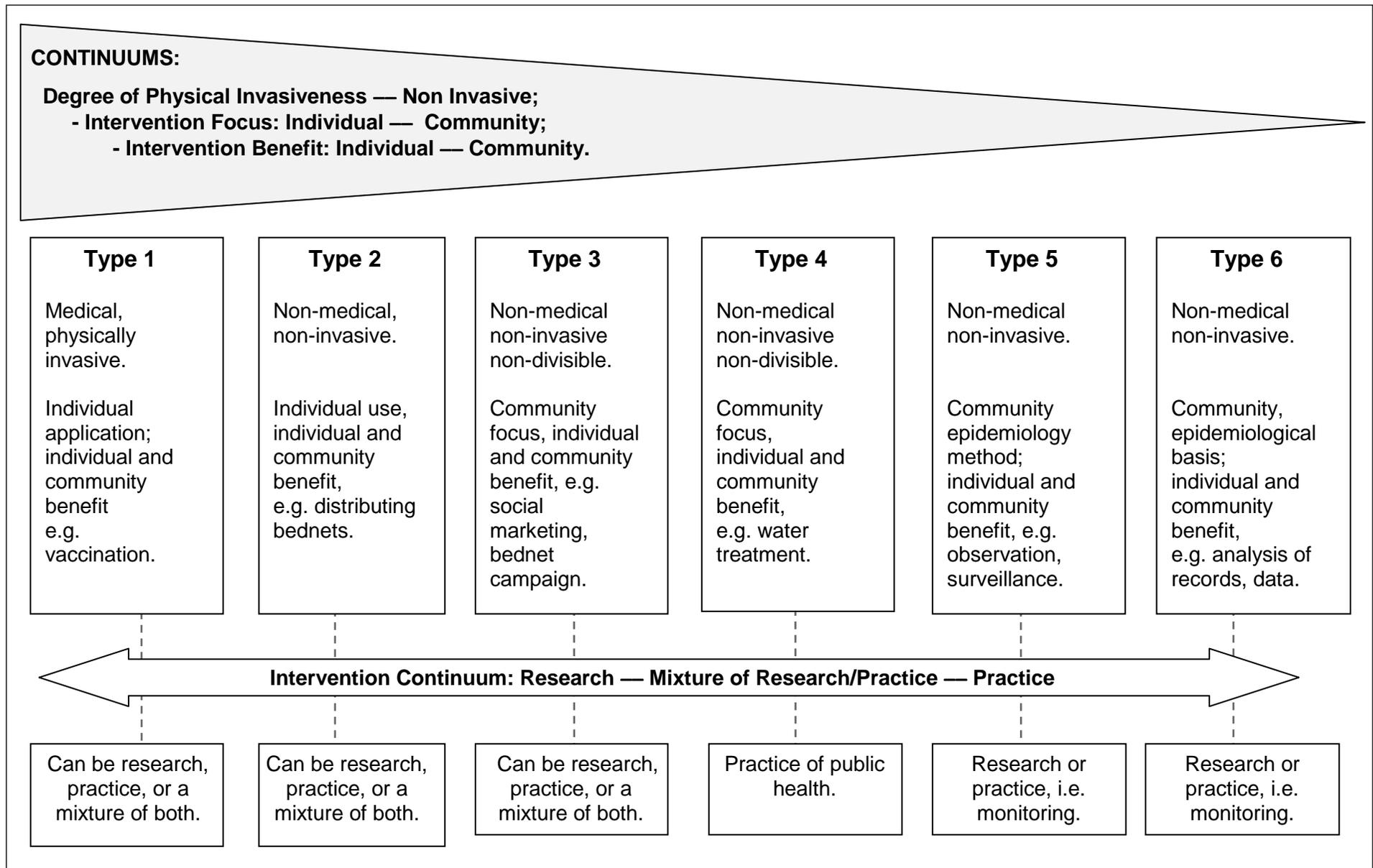
1.2 Research Question, Objective and Scope

The research question is: what should the role and place of individual informed consent and community assent be in public health interventions in order to support an intervention, whilst satisfying the appropriate ethical standards? The objectives of the project are to offer support from the field of ethics for multinational and transcultural public health interventions, and to add to the emerging ethics of public health with respect to questions concerning informed consent and community assent. The reflections will cover public health interventions and public health ethics in international settings, although particular attention will be given to transcultural interventions in developing countries using malaria as an exemplary area of activity. The kinds of actions that can fall under the label 'public health' are extremely diverse, as are the possible contexts in which informed consent and community assent can take place. It is also often difficult to classify many public health interventions as being either research or practice, with many being a mixture of both.¹² This complexity is shown in the Figure 1. The focus of this dissertation is on interventions of the type 1, 2, 3 that tend to be a

¹¹ Martin Enserink, "GM Mosquito Trial Alarms Opponents, Strains Ties in Gates-Funded Project," *Science*: 19 November 2010:Vol. 330 no. 6007: 1030-1031.

¹² D Gitau-Mbura, "Should Public Health be Exempt from Ethical Regulation? Intricacies of Research Versus Activity," *Africa Journal of Public Health*, 2008 Dec;5(3):160-2, 160.

Figure 1: The Complexity of Public Health



mixture of research and practice as exemplified by interventions targeted towards threats to public health presented by malaria, e.g. testing malaria treatment regimes and bednet campaigns, with the stronger focus being on the ethics of research.

1.3 Definition of Terms

'Public health' is defined as being the process of mobilizing local, state, national and international resources to solve the health problems affecting populations and communities.¹³ The term 'intervention' means any activity aimed towards testing, maintaining or achieving an intentional change in the physical health status of an individual or community, i.e. administration of a vaccine, a health education programme, as well as procedures to acquire data such as conducting an interview or taking a blood sample undertaken by a researcher or practitioner. The term 'international public health intervention' is used to refer to interventions in either a developed, developing or transitional country. By 'transcultural intervention' is meant an intervention in which a host country and external institutions (parties outside the host country) are involved, where the host is a developing country that will typically have weak health systems. 'Community' is defined as a group of people who participate in a research or non-research intervention, or who are the target of a research or non-research intervention, or who will be affected by or have an influence on the conduct of such interventions.

1.4 Definition of the Problem

The research question arose from the experiences of practitioners of public health interventions in international, particularly transcultural contexts. It is based on the premise suggested in the introduction that the application of reflections coming from the field of ethics can make a practical contribution to the acceptance and sustainable success of an intervention in the form of planning appropriate informed consent and community assent processes. There has been considerable work since the latter stages of the 20th century in developing medical ethics. However, an ethics of public health is at an early stage of development. The intellectual energy devoted to the ethics of public health is scant,¹⁴

¹³ Roger Detels et al., *Oxford Textbook of Public Health*, (Oxford: Oxford University Press, 2009).

¹⁴ S. R. Leeder, "Ethics and public health," *Internal Medicine Journal*, Vol. 34 Issue 7 2004: 435-439.

especially when compared to the rapid developments in the fields of medical and clinical ethics since the end of World War II.^{15, 16, 17, 18} The valuable work that has been done in public health has focused on epidemiology, with much of it being set against a developed country background. It is therefore necessary that bioethics extends the ethical debate into the arena of international public health.¹⁹

1.5 Epistemic Position, Methodology, and Structure

Before deciding on an approach to address the research question from the perspective of practical ethics, the underlying epistemic position needs to be established. Ethics can be defined as being the branch of philosophy concerned with the evaluation of human conduct. Philosophers commonly distinguish between normative ethics (the development of theories that systematically provide and justify proposals as to how live and act), metaethics (the careful analysis of the meaning and justification of ethical claims) and practical ethics. Practical (or applied) ethics is generally defined as being the use of normative and metaethics to form judgments regarding practical, controversial cases.²⁰ The field of descriptive ethics is increasingly seen as being a part of ethics; 'descriptive ethics' is here understood as being the field in which empirical data about moral issues are gathered, such as information on the morals, the norms of the actors in a situation.²¹ The term 'empirical data' is used here to cover knowledge or evidence obtained by following scientific sound

¹⁵ James F Childress et al., "Public health ethics: mapping the terrain," *Journal of Law, Medicine & Ethics*, 30 (2002): 70-78, 70.

¹⁶ Marc J Roberts, Michael R Reich, "Ethical analysis in public health," *Lancet* 2002 Mar 23;359(9311): 1055-9.

¹⁷ James F Childress et al., "Public health ethics: mapping the terrain," *Journal of Law, Medicine & Ethics*, 30(2002): 70-78.

¹⁸ Marc J Roberts, Michael R Reich, "Ethical analysis in public health," *Lancet* 2002 Mar 23;359(9311): 1055-9,1055.

¹⁹ Wen L Kilama, "Health research ethics in public health: Trials and implementation of malaria mosquito control strategies," *Acta Tropica*, 2009 Nov;112 Suppl 1: 37-47.

²⁰ James Fieser, *The Internet Encyclopedia of Philosophy* (IEP); URL: <http://www.philosophypages.com/>.

²¹ Pascal Borry et al., "The Birth of the Empirical Turn in Bioethics," *Bioethics* vol. 19, Number 1 (2005):49-71, 60.

observational or experimental research. This is in comparison to the reflective, analytical methods of generating ethical, normative knowledge (on what should be done to live a good life for example). Descriptive ethics include empirical studies about what humans believe; identifying consequences; 'testing' normative theories or models in the sense of how they can be applied in reality, and in providing case reports for consideration.

What is then the relationship between this empirical data and normative ethics? It is accepted that empirical evidence is required as input to allow for sound moral reasoning, with most decision making models containing the step of obtaining and understanding the necessary fact.²² However, there is a more contested methodological debate at the 'meta' level in regard to what extent reliance should be placed on theories to prescribe and justify an action, and what the role of descriptive, empirical evidence should be in prescribing what we should do. Two positions can loosely be identified: a) that only rationalistic, deductive, theoretical, a priori methodologies can justify normative, prescriptive assertions, and b) a position favouring a posteriori belief in empiricism and inductive research as being the only or a main way of justifying an answer to a normative, ethical research question. The position taken in this practical ethics dissertation is that the relationship between the normative (what should be done), and descriptive work (what is done) in practical ethics should be one of a two-way feedback. The methods of inquiry (deductive, theoretical, empirical and inductive) are mutually supportive,²³ although normative theoretical ethics should be the core of ethical reflection. Although the prescriptive nature of ethics means that inferences from facts to values – deriving an 'ought' from an 'is' – must be avoided, empirical work should contribute to medical and public health ethics in the form of descriptive ethics.²⁴ Ethics and empirical data should more specifically "challenge each other mutually and in a step-wise manner."²⁵ These reflections have resulted in the Deductive – Inductive Feedback Structure.

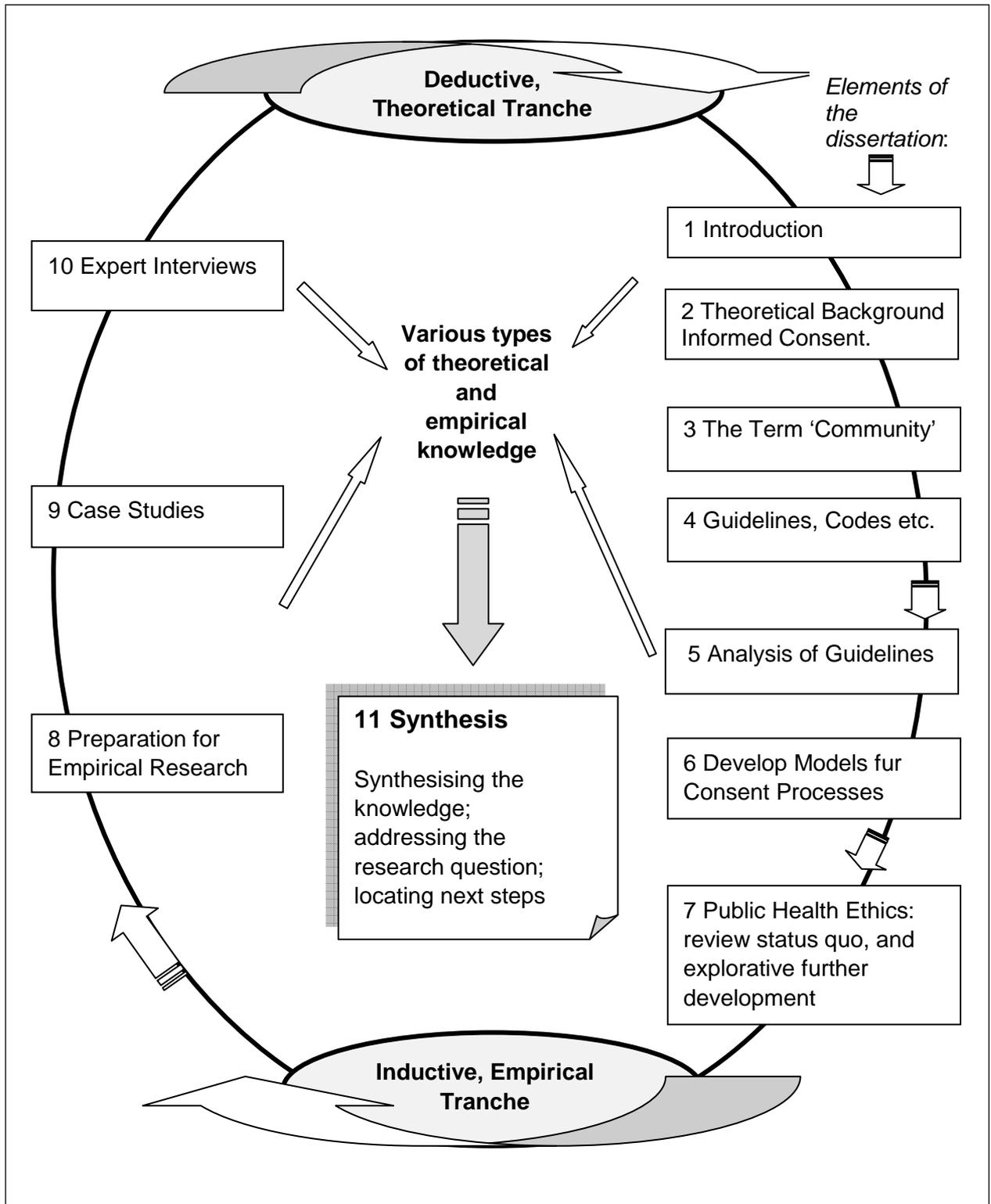
²² Jeremy Sugarman, Daniel P. Sulmasy (Eds.). *Methods in medical ethics* (Washington DC: Georgetown University Press, 2001): 4-15.

²³ Ibid. 10-15.

²⁴ Ibid.

²⁵ Stella Reiter-Theil, "What does empirical research contribute to medical ethics? A methodological discussion using exemplary studies," in review, *Cambridge Quarterly of Healthcare Ethics*, 2011.

Figure 2: Deductive – Inductive Feedback Structure



This is illustrated in Figure 2 above.²⁶ This structure illustrates the two tranches and various stages of this dissertation. The inclusion of an empirical tranche does not aim at creating a hierarchy of the descriptive determining the normative. Facts or evidence do not prescribe what we should do. There should be a dialogue between the two with the development of a richer interdisciplinary research culture formed by bringing them together.²⁷ The motivation for developing this methodological framework to structure the dissertation is that the research question came from practitioner's experiences in undertaking public health interventions. A methodological approach is therefore necessary that integrates both concrete experiences and ethical reflections. This model and the underlying epistemic assumptions form the foundation for the dissertation structure and methodology.

1.6 Designing the Work Program

The first step in designing the work program is to deconstruct the research question bearing in mind the epistemic position. The research question takes an ethical, normative form: what should the role and place of individual informed consent and community be in public health. There are two possible responses: one derived from the status quo of normative, ethical reflections on consent, and the other from the contents of codes and guidelines. The second part of the question makes the assumption that compliance with these ethical standards will support – or certainly not hinder – a public health intervention that addresses the public health problems in a justifiable way. This assumption should however be examined. Therefore, an optimal work program needs to address the following issues:

- a) If ethical standards for public health especially regarding informed consent exist;
- b) If the existing standards are followed;
- c) Can the standards be validated from the following theoretical and pragmatic points of view:

²⁶ Loosely based on a model in Trochim W K, *The Research Methods Knowledge Base* (Cincinnati: Atomic Dog Publishing 2001).

²⁷ Stella Reiter-Theil, "Does empirical research make bioethics more relevant? The embedded researcher as a methodological approach," *Medicine, Health Care and Philosophy*, 2004;7(1): 17-29, 18.

- i) Can they be theoretically validated, i.e. do the standards that guide the actions in the field operationalize the ethics principles that underlie informed consent and community assent in a way that results in the principles being upheld when implemented in the field;
- ii) What are the practical repercussions for the intervention of following the standards;
- d) If they are not followed, the reason for non-compliance and what are the repercussions of this non-compliance;
- e) Whether the responses to the above lead to the conclusion that the ethical standards are appropriate or need revision;
- f) If action is needed, what is the way forward to ensure that the role and place given to individual informed consent and community assent support and avoid unjustifiably hindering an intervention, whilst satisfying the appropriate ethical standards?

Placing these questions and the responses within the Deductive – Inductive Feedback Structure recommends adopting a ‘systems – driving force – target – transformation knowledge’ framework in order to address the research question (see Figure 3).²⁸ This approach was originally developed as a tool to organise information in complex systems, looking especially at cause-effect relationships between interacting components, helping thereby to formulate interventions that will resolve issues.²⁹

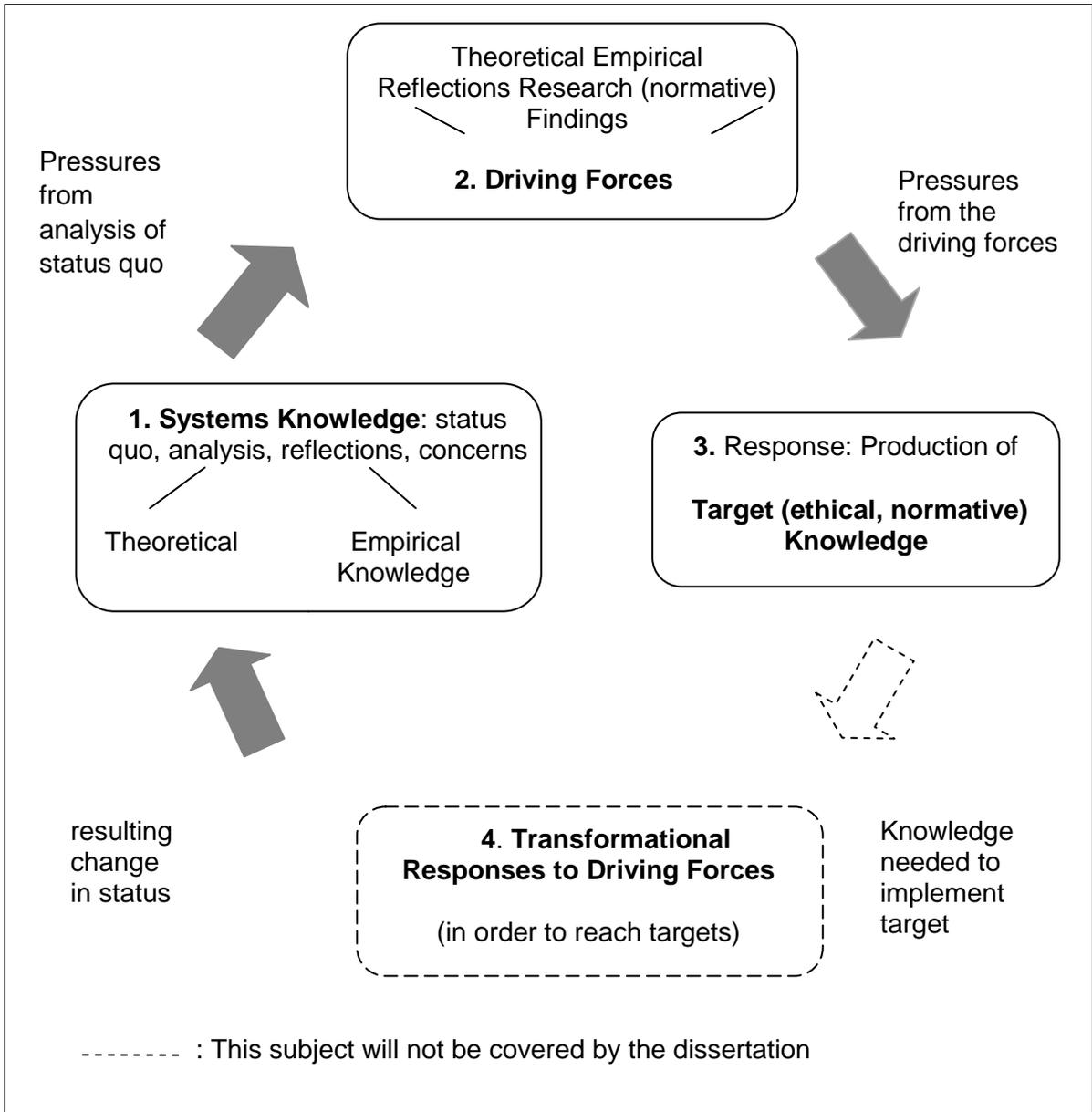
Applying this framework to a problem requires that the following kinds of knowledge be generated: systems – status quo – knowledge that comprises: a) knowledge of the current theoretical status, b) existing guidelines, and c) the status quo of what is done in reality life. ‘Systems knowledge’ optimally includes knowledge of the causes or determinants of the status quo. Driving force knowledge is knowledge about forces that stimulate, drive, or exert pressures that challenge the status quo. Driving force knowledge usually arises by analysing the theoretical or empirical status quo. ‘Target knowledge’ is ethical, prescriptive knowledge about the aims or targets that are right, appropriate (and also practical). The need to produce target knowledge results from driving forces that justifiably stimulate change. Its generation requires interdisciplinary reflection and empirical research. Transformation knowledge is practical knowledge about to make the transition from the current to the target status.

²⁸ ProClim Forum for Climate and Global Change, *Research on Sustainability and Global Change – Visions in Science Policy by Swiss Researchers*, 1997.

²⁹ Ibid.

Effective transformation instruments must be based on knowledge of the system and knowledge of the desired end.³⁰ They can include new codes, guidelines, laws or conducting legal cases, also by undertaking research. The production of this kind of knowledge is not extensively addressed in this dissertation.

Figure 3: Systems – Driving Force – Target – Transformation – Knowledge Analysis of Informed Consent / Community Assent



³⁰ Ibid.

1.7 Moral Relativism – Universalism Debate

The position taken in the Moral Relativism – Ethics Universalism Debate will now be established. A main challenge for practical ethics is to form and operationalize a justifiable position that enables decisions and actions to be taken in the real world, while respecting the philosophical complexities of this universalism-relativism debate, noting that applied ethical reflection on this subject needs to give equal attention to both procedural and substantive aspects. The practical ethics concept at the centre of this dissertation is informed consent. There has been considerable debate on what, if any role cultural differences should play in ethical issues associated with medical and public health ethics. The debate has at its extremes accusations of ‘moral imperialism’ on the one hand (forcing the adoption of non universal norms coming from the West), and advocating ‘double standards’ on the other, by allowing some principles such as respect for persons to be disregarded in some countries.³¹

Can the principles, values and standards underlying and expressed in sophisticated renditions of informed consent be claimed to be universal in the face of the cultural diversity that undoubtedly exists? For example, if the need for informed consent is based on respect for individuals, how should these principles be applied in a collectivistic society where the individual is subordinate or of equal value to the community? Is the argument that such standards have been upheld by international institutions and codified in their guidelines a valid and sufficient argument for their universality? The complexity is further highlighted by the human rights movement that claims universality, but also claims “diversity” as being a human right. The UNESCO Universal Declaration on Cultural Diversity raises cultural diversity to the level of the common heritage of humanity and makes its defence an ethical imperative which is robustly linked to, and cannot be separated from, respect for the dignity of each individual person.

There are essentially two positions that can be taken in this debate: an absolute universal position and secondly, a relativistic position. Moral relativism is a position that the truth or falsity of a moral judgment, and accordingly the justification given for a judgment, is not absolute or universal, but is relative to a particular context. Only with a given context can a judgment be accorded normative force. According, for example, to the relativist position, it

³¹ EGE European Group on Ethics in Science; *Opinion n°17 - 04/02/2003 - Ethical aspects of clinical research in developing countries*: 12.

would be allowed, or even required to follow traditions that would condone female genital mutilation, or that allow tribal leaders to give consent for females to take part in research without the females having to also give their individual consent. An argument that supports moral relativism is the purported empirical or descriptive assertion that deep and fundamental moral disagreements exist when comparing societies, where disagreements are more profound than any agreements that may exist. This argument can be expressed as follows:

- Premise: Different cultures have different moral codes (the premise being derived from asserted descriptive or empirical evidence).
- Conclusion: Therefore, there is no objective "truth" in morality. Right and wrong are only matters of opinion that vary from culture to culture. Since cultures and individuals differ in certain moral practices, there are no objective moral values.³²

However, this argument is not sound as the conclusion does not follow from the premise. The existence of different moral codes is not evidence that no objective truth exists. The fact that people disagree about something does not mean there is no objective truth. This argument is also questionable based on the doubtful verity of the premise that different cultures have different moral codes. Descriptive research increasingly questions the existence of differences in fundamental norms. For instance, the international human rights movement can be seen as indicating substantial moral agreement. Hans Küng has maintained that there is a common "global ethic" across the world's major religious traditions regarding respect for human life, distributive justice, truthfulness, and the moral equality of men and women.³³ Anthropological literature dealing with differences between societies characterised by collectivist and individualist values does not for instance, support the conclusion that collectivist societies are uniformly devoid of concepts relating to individuality and personal autonomy, or that individuality is unconditionally rejected.³⁴

³² This argument is based on an approach in "The Challenge of Cultural Relativism," James Rachels.

³³ See the website "Global Ethics Foundation" (project Weltethos). URL: <http://www.weltethos.org/index1.htm>.

³⁴ Linda Richter et al., "Guidelines for the development of culturally sensitive approaches to obtaining informed consent for participation in HIV vaccine-related trials," Medical Research Council (Durban) Commissioned by UNAIDS1999: 8.

The phrase 'different moral codes' also requires differentiation. It can hardly be disputed that moral behaviour varies from culture to culture. But what is the reason for this? What is it that differs? Is it necessarily due to disagreement on fundamental moral values? A distinction should be made between traditional practices and manners, and fundamental values. The following example from James Rachels is helpful to differentiate this issue:

“Consider a culture in which people believe it is wrong to eat cows. This may even be a poor culture, in which there is not enough food; still, the cows are not to be touched. Such a society would appear to have values very different from our own. But does it? We have not yet asked why these people will not eat cows. Suppose it is because they believe that after death the souls of humans inhabit the bodies of animals, especially cows, so that a cow may be someone's grandmother. Now do we want to say that their values are different from ours? No; the difference lies elsewhere. The difference is in our belief systems, not in our values. We agree that we shouldn't eat Grandma; we simply disagree about whether the cow is (or could be) Grandma.”³⁵

This illustrates that it does not follow from the fact that cultures and individuals differ in *practices* that they do not share common *values*. Cultures may differ about how they manifest a value. It should also be noted there are various levels of values. A further issue that throws doubts on empirical evidence supporting a relativist position is that social sciences increasingly hold “culture” not to be a fixed, closed, static or homogenous entity with its own moral norms and standards, but rather as being dynamic, flexible, porous, and often hybrid in nature.

A strong metaethical argument against moral relativism is the self-referential inconsistency argument. This addresses the problem that relativists typically wish to preserve for themselves the very principle that they seek to deny to others. Relativism is presented as being a *true* doctrine that excludes its opposites. If relativists apply their own theory to themselves, they must however agree that relativism itself precludes holding the opinion that their own position must be universally true.

Is there a middle or moderate universalistic position on the continuum moral relativism – absolutist universalism that can credibly be argued, and be used as a basis to seek resolution when intercultural ethical conflicts arise? A basis for this could come from

³⁵ This anecdote is based on an approach in “The Challenge of Cultural Relativism,” James Rachels.

empirical evidence that a small set of universal values or principles on which ethical judgments can be based seems to exist, that may form a basis for those open and willing to enter into a discourse based on rational discussion. Such a basis was argued by Sissela Bok in her book “Common Values.”³⁶ She opined that there are three categories of moral values that are necessary for the survival of all human societies that form a core, minimal basis: positive duties of mutual care and reciprocity; negative injunctions concerning violence, deceit, and betrayal, and norms for certain rudimentary procedures and standards for what is just.

Hinman argues for such a “middle ground between relativism and absolutism that combines the attractions of both without their attendant liabilities.” His middle position “recognizes the importance of understanding other cultures and respecting their autonomy, yet it also acknowledges that we live in an increasingly shared world in which moral differences often cannot simply be left unresolved.”³⁷ The risks of taking a universal position should be combated by adopting the following rules: firstly, we should seek to understand the meaning of practices within the culture as a whole, although understanding does not imply and moral necessity for agreeing or acceptance of a position as having any truth value; we should show tolerance to leave different cultures as much room as possible to pursue their own moral vision whenever possible, whilst still “standing up against evil”; we should be humble and when examining moral differences between ourselves and other cultures be open to admit our fallibility in finding that it is we, not the other who are found morally wanting. The principle of fallibility urges us toward moral humility but does not mean that we should never act with commitment in moral issues.³⁸

Although there may be less diversity in fundamental issues than often assumed, with the diversity being largely issues of interpretation, belief systems, behavior and manners, a respect for diversity should be a part of intercultural communications. However, in the event that ‘diversity’ is put forward as an argument for tolerating actions that infringe core principles

³⁶ Sissela Bok, *Common Values* (University of Missouri Press University of Missouri Press. 1995): 16, 57.

³⁷ Lawrence M. Hinman, *Ethics: A Pluralistic Approach to Moral Theory*, Fourth Edition (Thomson Wadsworth, 2008): 29.

³⁸ *Ibid.* 30.

and values, it should be questioned if this diversity justifies overturning core principles. Respect for diversity can also be shown by formulating sound argumentation and entering into a discourse, rather than tolerating positions that are averse to core values. The work of UNESCO including the intercultural Universal Ethics Project agreed of the UNESCO Division of Philosophy and Ethics makes an important contribution to the relativism debate in the field of practical ethics. The aim of the project is to identify basic ethical principles for the emerging global society of the 21st century by putting together a set of ideas, values and norms that would help humanity to deal with such global problems as poverty and underdevelopment.³⁹ The methodology that has been developed is that the ethical values and principles that form the core of universal ethics should be identified by empirical and reflective methods (analogue with Figure 2 above). The empirical approach taken is to search for values and principles that are widely and factually held in diverse cultures and religions. However applying reflective methods are an indispensable complement to the empirical approach. The project has debated the conceptual issue of “Universality in Diversity,” noting the “deep roots of suspicion regarding all universalistic projects, as well as the alliance of universalistic claims with the hegemonic intentions of certain powers. The notion of universality must therefore be able to respond to suspicions of political ambitions. A universalistic framework needs to integrate diversity within its structure. The project has considered the relationship between universal ethics and existing documents on universal human rights, values and norms. A consensus exists among the participants of the project that these documents should form the starting point of the search for universal ethics, resulting in the project producing a “Common Framework for the Ethics of the 21st Century.” It is not expected that this will receive the unanimous consent of the international community, but is rather seen as “the starting point of a long and arduous evolutionary process of intercultural debate and consensus-building.” However, in spite of these modest expectations, the UNESCO Universal Ethics Project has developed three Declarations: the 1997 Universal Declaration on the Human Genome that was the first legal and ethical framework at the global level; this was followed in 2003 by the International Declaration on Human Genetic Data, and in 2005 by the Universal Declaration on Bioethics and Human Rights.⁴⁰ The Universal Declaration was a response to the mandate of setting

³⁹ Yersu Kim, *A Common Framework for the Ethics of the 21st Century*, UNESCO, 1999.

⁴⁰ UNESCO, *Universal Declaration on Bioethics and Human Rights*, 2005. Paris, France.

universal standards in the field of bioethics with due regard for human dignity and human rights and freedoms, in the spirit of cultural pluralism inherent in bioethics.⁴¹ The drafting process included collaborating with NGOs, national bioethics committees, intergovernmental organisations, with hearings also taking place from religious and spiritual perspectives.⁴²

The position here taken is that neither extreme relativism nor absolutism is satisfactory to guide practical ethics research and reflection. A weak universalist position regarding fundamental principles shall be adopted. This holds that moral acts are capable of being reasonably argued, and reasonably judged as being right or wrong. There exists a plurality of reasonably argued values and principles that apply to many situations. A plurality of justifiable judgments regarding one situation can exist side-by-side. It can also occur that the same conclusion is reached, but based on different principles, or that the application of the same principle leads to different courses of action due to different interpretation. Thus even holding that principles and acts are capable of being reasonably argued, it should not be assumed that we are (yet) aware of what should universally be done in every situation. Problems arise when competing justifiable positions can reasonably be applied to a situation that would result in different incommensurable actions being recommended. In such cases, the justifiable positions should be open to amendment, re-interpretation, and realignment of the various interpretations.

As the Cameron philosopher Godfrey Tangwa expresses it: “I am a cultural pluralist. I perceive great value in the remarkable diversity and variety of human cultures, which seems to me remarkably analogous to the biodiversity of the living world, in which I find equal value.”⁴³ However, Tangwa also declares himself to be a moral universalist, believing in “the absolute moral equality of all human beings, no matter their particularising and individuating characteristics, no matter their situation or condition in life, no matter what culture they belong to.” Tangwa denies “arbitrary double standards in morality, in spite of not knowing of

⁴¹ UNESCO, General Conference 2003, 32 C/Res. 24.

⁴² See the UNESCO website that details the background of the Universal Declaration on Bioethics and Human Rights.

⁴³ Godfrey B. Tangwa, “Bioethics, Biotechnology and Culture: A Voice From The Margins,” *Developing World Bioethics*, 2004 Dec;4(2):125-38, 126-127.

any extant moral theory that would be universally accepted without question or one that would explain away, to everybody's satisfaction, divergence of moral opinion."⁴⁴ His explanation of divergency is that:

"Divergence of moral opinion, whether inter or intra societies and cultures, moreover, seems to me to be connected with human epistemological limitations and intellectual weaknesses and with human egoism and self-centredness. In other words, I do not think that we need to be searching for the reasons for moral divergence within morality itself. There is nothing wrong with morality; but there is something wrong with human beings, with human epistemological capacities and capabilities, with prejudice and human perception, with human feelings and desires, with human motivations, emotions and ambitions ... I believe that every genuinely valid and uncontaminated particular moral judgement is universalisable, although not every such judgement is necessarily absolutely exceptionless. To assume absolute exceptionlessness for any particular moral judgement is to presume a degree of epistemological comprehensiveness not possible with human knowledge."⁴⁵

To conclude, the application of ethical principles that are insensitive to morally significant features of its object of concern is a problem that needs to be taken seriously.⁴⁶ However, the existence of a set of moral norms embedded in a culture does not mean that it must be either accepted uncritically, or rejected outright. Acknowledging differences, and being sensitive to the values inherent in local practices, be they from developed, developing or transitional countries, does not require uncritical acceptance of them.⁴⁷

1.8 Limitations of the Dissertation

Regarding the general limitations of the dissertation, it is appreciated that although Chapter 3 will indicate the complexity of the term 'community,' the term will be used thereafter in a general way. It is also appreciated that many issues surrounding consent, assent, and community will vary according to whether an intervention is taking place in a rural or urban

⁴⁴ Ibid.

⁴⁵ Ibid.

⁴⁶ Michael Parker, "Ethnography/ethics," *Social Science & Medicine*, Volume 65, Issue 11, (2007): 2248-2259, 2249.

⁴⁷ Nuffield Council on Bioethics, "*The Ethics of Research Related to Healthcare in Developing Countries*," 2002: 52.

setting, and also that family dynamics and gender issues can play a role. Dealing with these issues is outside the scope of this dissertation although their importance is recognised. The limitation is also acknowledged that the historical matters that are touched upon take a 'western' perspective; an interesting endeavour would indeed be to take a more intercultural view of how informed consent has historically developed. It would also be of interest to enlarge on cultural differences regarding 'personhood,' and the concept of 'autonomy' and 'consent'; it would also have been interesting when developing the Cluster Framework in Chapter 8 to have made a shadow-model that considers inputs coming from other world views. Again, the values of such endeavours are noted, although they are outside the feasible scope of this dissertation.

Furthermore, as will be laid out in Chapter 2, the term 'public health' covers a vast area of activities. This dissertation focuses on a very small area of this vast field. Likewise regarding geographical focus, this dissertation considers conceptually the category 'developing countries', whilst limiting itself to one continent (Africa), and then to primarily one country: the United Republic of Tanzania. Tanzania does not represent Africa; nor should Africa be seen as representing all developing countries. Notwithstanding this limitation, it is hope that this dissertation offers some insights that are of wider interest in other developing country settings, in transitional countries, as well as in so-called developed countries.

The term 'empirical' was defined above as referring to knowledge or evidence obtained by following scientific sound observational or experimental research; it will be used in this dissertation to include the expert interviews that have been conducted, together with the case studies. It is appreciated that this 'empirical' work is exemplary and explorative; no claims are made that 'knowledge' has been produced that is representative, generalizable, justified true belief. All references to results, findings, and knowledge that come from this empirical work should be seen in this light. However, although the 'knowledge' forthcoming is explorative and exemplary, it is held as representing the kind of empirical knowledge or inputs that forms a fruitful approach for generating hypotheses.

Notwithstanding these limitations, it is hoped that this dissertation will succeed in making a small contribution to the subject of consent and assent in public health, developing country contexts.

CHAPTER 2

THE TERM 'PUBLIC HEALTH'

2.1 Reflections on the Term Health

The term 'health' has evolved from meaning the absence of diagnosable disease, to the WHO offering in 1998, a contested four dimensional definition of health being a dynamic state of complete physical, mental, spiritual and social wellbeing and not merely the absence of disease or infirmity,⁴⁸ although when this term is non-specifically used, it is generally assumed that physical health is primarily meant. Such a wide definition has advantages and drawbacks. An advantage can be that it helps to avoid an over-medicalization and a one-sided understanding of health in its physical manifestations, drawing attention to the social, relational meanings of health. A disadvantage is that operationalizing such a complex concept is problematic, and it can result in over-socializing health.

The right to health was first articulated in the WHO 1946 Constitution which states that: "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being" without distinction of race, religion, political belief, economic or social condition."⁴⁹ From an ethical point of view it is important to emphasise that the 'right' applies to attainable, and not to perfect health. Granting health the status of a human right provides a basis for claims to be made by individuals and groups for social justice regarding access to the means to maintain or re-install health, and a fair distribution of health burdens and benefits.

There is a relationship between the right to attainable health and other human rights, with promoting and protecting health and respecting, protecting and fulfilling other human rights being inextricably linked. 'Health', understood in any of its dimensions, can represent both, an independent variable (a cause or a resource), or a dependant variable (a state resulting from another variable). Health as a causal factor affects the ability to work, enabling societal and individual life goals to be chosen and pursued. When referring to health as dependant

⁴⁸ WHO Executive Board, 101st session, 1998, resolution EB101.R2 proposed the amendment of the Constitution Preamble to read: "Health is a dynamic state of complete physical, mental, spiritual, and social well-being and not merely the absence of disease and infirmity." The Fifty-second World Health Assembly, May 1999, rejected this amendment.

⁴⁹ WHO, Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, 100) and entered into force on 7 April 1948.

variable, i.e. as result, effect, or outcome, the issue is often what determines health, and how health can be promoted.

Neither physical nor mental health (either individual or collective) should be seen as a moral virtue. Nor should health be lightly classified as a moral good. Although we are fortunate to enjoy health, and may be sensible to take care of our health, we are not ethically a better person for being healthy. Poor health does not indicate questionable ethical standards, or render an individual or a population less deserving of respect. Therefore, arguments that hold health to be a virtue or a good are problematic, and can be connected with the belief that illness is a punishment, and that illness is deserved. Such arguments also tend to discriminate against those with physical or mental attributes that are outside definitions of normality. What is seen as normal or healthy is subjective decision. Situations can arise where different cultures and traditions will understand 'health', or healthy behaviour differently; the importance of the dimensions of health can be prioritized differently, with for instance, local social and spiritual norms being given more importance than physical health.

2.2 Differentiating and Defining Medicine, Public Health and Epidemiology

It is helpful before defining public health to differentiate between medicine and public health. Medicine focuses on the treatment or diagnosis of individuals. In contrast public health (that includes epidemiology), has as addressee a community or population; the focus of interventions is not an individual person but a group. Although the focus of public health is the population level, the relationship between the action of the individual and the well-being of a population cannot of course be ignored. For example, in some cases taking preventive actions to create and maintain herd immunity requires that public health focuses keenly on the individual level.

There are a number of definitions of public health with one of the most quoted being that of the Institute of Medicine from 1988: "Public health is what we, as a society, do collectively to assure the conditions in which people can be healthy."⁵⁰ The Nuffield Council on Bioethics in common with the Institute of Medicine have a definition that has a strong focus on the collective, societal nature of public health activities, defining public health as being "the

⁵⁰ Institute of Medicine, Committee for the Study of the Future of Public Health, Division of Health Care Services, *The Future of Public Health* (Washington, D.C.: National Academy Press, 1988).

science and art of preventing disease, prolonging life and promoting health through organized efforts of society.”⁵¹ The Dictionary of Epidemiology defines public health as “one of the efforts organized by society to protect, promote, and restore the people’s health. It is the combination of sciences, skills, and beliefs that is directed to the maintenance and improvement of the health of all the people through collective or social actions.”⁵² When considering public health in transcultural and multinational settings, the Oxford textbook of public health offers an appropriate definition: “Public health is the process of mobilizing local, state, national and international resources to solve the major health problems affecting communities.”⁵³

Although there is no agreement on what ‘public health’ means, definitions tend to imply normative criteria, typically expressing a desirable goal.⁵⁴ Definitions share the common element that public health involves a population not individual focus, and that public health interventions require some kind of collective, orchestrated action. In addition to the various definitions, how to operationalize ‘public health’ is confusing, with the term being used in a number of non-exclusive ways: to denote the state of the health of the public as supplied by epidemiologic data; to denote interventions undertaken to achieve a desired situation regarding the health of a population; as a normative goal (for instance, pursuing health because it is a human right), and to label the collective outcome of specific actions or interventions.

The term ‘public’ is also a complex concept with several interpretations.⁵⁵ It can refer in a numerical sense to a population; it can indicate the recipient of state organised activities in terminology such as ‘public policy’, ‘public services’ etc.; it also has a directly political meaning of what we collectively do through government - what our publicly elected representatives do in our name. Another meaning is more inclusive of the members of a

⁵¹ Nuffield Council on Bioethics, *Public health: ethical issues*, 2007: 3.

⁵² John M Last, *The Dictionary of Epidemiology* (Oxford: Oxford Press, 2001).

⁵³ Roger Detels et al., *Oxford Textbook of Public Health*, (Oxford: Oxford University Press, 2009).

⁵⁴ European Public Health Ethics Network (EUROPHEN), “*Public policies law and bioethics: a framework for producing public health policy across the European Union*,” 2006: 2.

⁵⁵ James F Childress et al., “Public health ethics: mapping the terrain,” *Journal of Law, Medicine & Ethics*, 30(2002): 70-78.

society and includes forms of social and community action.⁵⁶ The 'public' is often referred to as if it were a moral agent, so that rights and obligations can be ascribed to it.

Another approach to examining the meaning of 'public' is to consider what it means to label something as being a public health issue. Accepting a definition of public health as being a process of mobilizing various resources to solve the major health problems affecting communities,⁵⁷ the shared nature of the problem is suggested, that the determinants are broad, widely spread factors, suggesting that the responsibility for action is collective, through possible elected representatives.⁵⁸ Labelling something a public health issue is a political action, and "often serves implicit normative or political purposes."⁵⁹ What is important from the point of view of ethical analysis is to be aware of and make transparent "normative arguments and value statements," when using the term public health.⁶⁰

Epidemiology is sometimes referred to as the science of public health. A common definition is that it is "the study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to control health problems."⁶¹ Public health practice often relies on research findings from epidemiology to protect, prevent or control health issues or problems in a population.⁶² Therefore, epidemiology is "the 'glue' that holds public health's many professions together;" the 'mother science of public health.' It takes a population as the unit of study, and is a corner stone of modern public health practice, providing a quantitative foundation for public health policy and clinical research, as well as a basis for preventive approaches in medicine and public health. In order to make a contribution to resolving health problems on a population level, epidemiology conducts

⁵⁶ Ibid.

⁵⁷ Roger Detels et al., *Oxford Textbook of Public Health*, (Oxford: Oxford University Press, 2009).

⁵⁸ Marcel Verweij, Angus Dawson, "A The Meaning of 'Public' in 'Public Health', in *Ethics, prevention and public health*, eds. Marcel Verweij, Angus Dawson (Oxford: Oxford University Press, 2007): 13-29.

⁵⁹ Ibid. 29.

⁶⁰ Ibid.

⁶¹ John M Last, *The Dictionary of Epidemiology* (Oxford: Oxford Press, 2001).

⁶² Council for International Organizations and Medical Sciences (CIOMS) *International Ethical Guidelines for Epidemiological Studies* (2009): 14-16.

various kinds of studies that can be broadly divided into observational and experimental studies. It focuses on research related to the distribution and determinants of both positive and adverse health states and events, and on application of knowledge gained to improve and promote public health in communities.⁶³ The results of epidemiologic research studies contribute to generalizable knowledge by elucidating the causes of disease; by combining epidemiologic data with information from other disciplines such as genetics and microbiology; by evaluating the consistency of epidemiologic data with etiological hypotheses, and by providing the basis for developing and evaluating health promotion and prevention procedures.

Given the wide, complex, and multi-layer scope of public health, it is helpful to see public health as a thick, linear bundle of activities that follow a process of pursuing health in a particular dimension (physical, mental, or societal), according to the intervention to hand. The activities in this bundle include medical interventions; providing health related infrastructures; promotional activities designed to influence or change behaviour, as well as the work of valuating and monitoring activities to maintain the preventive aims of furthering the health of a population. Thus public health activities include a wide range of preventive, promotional, protective and improving activities. The broad tasks are proactive and preventive, aiming to understand, ameliorate, or improve the health of a population or prevent its deterioration. The question also arises with all definitions as to whether the term refers to physical, or also other dimensions of health. Public health is irrevocably connected to the political system in place; what is meant by 'public health' in a dictatorship is different from that in a democracy. Both public health research and practice need to be inter- and multidisciplinary, involving inter alia the medical, epidemiological and social sciences, as well as seeking practical ethics inputs.

2.3 The Aims and Goals of Public Health

It was noted above that the definitions of public health tend to include or imply normative criteria, being typically in the form of expressing aims and goals. Empirical research has identified that various interpretations of the aims or goals that public health should pursue exist side-by-side in, for instance, Europe. The Europhen project identified firstly that the traditional public health goal is improving the health of the population. A further aim is

⁶³ Steven Coughlin, "Ethical issues in epidemiologic research and public health practice," *Emerg Themes Epidemiol*, 2006; 3, 16: 1.

promoting health related autonomy. In Sweden for example, the goal is to provide the citizens with equal societal preconditions and opportunities to allow them to choose to take actions and decisions that further good health, with citizens being free to accept or reject healthy options. Finally, the goal of public health can be equality-oriented, focusing on the health of a disadvantaged segment of the population. These variations in goals have an interface with differences in political theories and political realities, specifically regarding the relationship between the state, society and its citizens. It is also suggested that the various goals have an implicit interface with economic status.

Can it be argued that one goal is universally preferable? Is it rather that different types of priorities and goals are appropriate for different countries depending on factors such as the status of the political system, the economic picture, actual health levels etc?⁶⁴ If this be the case, what goals are appropriate for transcultural public health interventions in a developing country context, or in a transitional country setting?

2.4 Determinants of the Health of the Public

In order to tackle a health problem (whatever dimension of health is involved), what determines or influences the issue must be identified in order to design an intervention that has a chance of achieving the aim. Understanding the determinants of a problem is also necessary to develop indicators to monitor a situation, both before, during and after an intervention. Even if one focuses on the physical dimension of health, the determinants of public health are manifold, context specific, and dynamic. The determinants of population health occur at various levels: global, international, national and local. In a globalizing world, problems and solutions reach across national borders, resulting in a growing need for international collective action. The actions of developing country institutions have consequences that have far-reaching impacts for developing countries.⁶⁵

⁶⁴ European Public Health Ethics Network (EUROPHEN), "*Public policies law and bioethics: a framework for producing public health policy across the European Union*," 2006, 22: 37-239.

⁶⁵ Thomas W. Pogge, "Relational Conceptions of Justice: Responsibilities for Health Outcomes," in: *Public Health Ethics and equity*, eds. Sudhir Anand, Fabienne Peter, Amartya Sen (Oxford: Oxford University Press, 2004): 136-141.

Determinants can be classified into six main groups: epidemiological, demographic, scientific, social, structural and political.⁶⁶ To these categories must increasingly be added ecological, environmental and climate factors. Climate shifts may increasingly change patterns of infectious diseases, demanding therefore the continuing need for surveillance of communicable disease as a central public health skill.⁶⁷ A fundamental and critical determinant for the health of a population is the national public health system. Health issues, and proposed resolutions are perceived and can also be influenced by cultural, tradition driven norms and understandings. Aiming to change such health influences or determinants is, from an intercultural, development ethics point of view, problematic. Another kind of determinant is intellectual property; knowledge: its generation, distribution, application, transfer (or non transfer) and occasionally questionable misallocation, e.g. bio-piracy. Both the medical and social sciences have contributed to an increase in knowledge and understanding of the determinants of physical and mental health. The recent area of knowledge arising from the human genome project could also have significant repercussions for public health.

The determinants of health that are at the forefront for change in order to improve public health vary according to context. For instance, determinants in a Western context will typically include a focus on the responsibilities of the individual for their own health.⁶⁸ Many of the issues discussed in the context of public health arise from what some commentators call 'lifestyle diseases', such as obesity- and smoking-related conditions. Implicit in the use of the term 'lifestyle' is the idea that a disease is simply a result of individuals' choices about how to live their lives (although what determines the choices made deserves attention). However, focusing on such determinants is in many developing countries inappropriate, as socio-economic conditions, i.e. poverty, paucity of education, may render assumptions of individual choice and responsibility less than meaningful.

⁶⁶ Rosalind Stanwell-Smith, Deidre Hine, "Public health medicine in transition", *J R Soc Med.* 2001 July; 94(7): 319-321.

⁶⁷ Ibid.

⁶⁸ European Public Health Ethics Network (EUROPHEN), "*Public policies law and bioethics: a framework for producing public health policy across the European Union,*" 2006, 20: 249.

Various epidemiological and demographic transitions are underway in various regions, in accordance with which of the determinants that are impacting on the health of the public are in flux. The transition long held to be in the natural order of human development is the move away from the priority health issues being infectious pandemics, towards the prevalence of chronic, age related diseases. With this transition comes a shift in health priorities. However, reverse-transitions are being increasingly observed, with for instance a resurgence of familiar infections once thought to be conquered accompanied by an array of novel diseases, the danger of which has the potential to spread rapidly due to globalization.⁶⁹

To understand the status-quo of public health when planning an intervention an appreciation of historical factors is recommended; indeed history can be seen as a determinant of public health. The historical determinants of physical, social and mental health – both positive and negative – for individuals and populations include major social, economic and scientific movements such as industrialization, urbanization, globalization, and changes in political systems. Primary positive determinants have been improvements in sanitation, hygiene, occupational safety, nutritional adequacy, food safety, and education. Negative determinants are wars, disease, slavery, poverty, and increasingly environmental problems such as pollution and climate change (especially relevant for patterns of disease transmission).

2.5 Globalization and Public Health Actors

Various complex interwoven international economic, political, cultures and military movements, changes and trends associated with the expression 'globalization' have, and still do, impact and influence public health.⁷⁰ Health issues are increasingly understood as being global as well as local phenomena from the point of view of both causes and resolutions. In a globalized world, health problems are increasingly international.⁷¹ Issues such as HIV- AIDS, potential threats from bio-weapons, atomic power, ecological environmental risks and dangers, drug trade, terrorism etc., all call for measures that go beyond traditional forms of

⁶⁹ Kristin Harper, George Armelagos, "The Changing Disease-Scape in the Third Epidemiological Transition," *Int J Environ Res Public Health*. 2010 February; 7(2): 675-697.

⁷⁰ Solomon Benatar, "Public Health and Public Health Ethics," *Acta Bioethica*, año IX, NO 2 (2003): 196.

⁷¹ Judith Asher, *The Right to Health: A Resource Manual for NGOs*. American Association for the Advancement of Science, (undated): 64.

state control. Global, collective responses to health dilemmas (as well as local and national) are called for that require international cooperation in designing and implementing appropriate responses. A global public health ethics is required to consider global responses to global threats, and to ensure that global public health goods (and health as a global public good) are generated and fairly distributed.

If globalization has opened-up the scale of the canvas on which public health needs to be addressed, it also raises the question of who is empowered to act on this global level. Although there is some degree of consensus regarding the public health activities that would be necessary to maintain at least the physical health of a population, there is by no means agreement on who should do the work. As the definition of public health adopted illustrates, the possible actors are multifarious and include the state, local and international NGOs, and international quasi-governmental organisations. State agencies are often granted public health powers in order to protect the public's (physical) health, and are expected to undertake a wide range of public health measures including monitoring and reporting. The routine collection of highly confidential and sensitive personal and medical information can be involved, as are a range of emergency measures. The state (if democratically elected and upheld) can be held to be in such a special situation of legitimacy that it can be seen as having the authority to act to serve the aim of population health without acting to obtain act specific informed consent.⁷² Regarding what dimensions of health, and concerning what determinants of public health those with power and authority are empowered to act is a complex political and normative question. The question arises to what extent a state should be concerned to change the determinants of public health such as the equitable distribution of social and economic resources. Should the state have responsibility for issues such as "social capital": social networks such as family and friends, associations, religion, civic organizations, these being important determinants of the social well-being dimension of public health that may well in turn impact on physical and mental health? In a transcultural public health context, the legitimacy of external parties to take action in planning and implementing an intervention is a fundamental question of ethical importance.

Globalization has "greatly increased the influence of powerful non-governmental bodies and corporations around the world; diminished the influence of governments; and has created an

⁷² Paul J. Amoroso, John P. Middaugh, "Research vs. public health practice: when does a study require IRB review?" *Preventive Medicine*, 36 (2003): 250-253.

unprecedented interdependence between states and the non-governmental sector.”⁷³ Nongovernmental organizations (NGOs) have become increasingly important agents of the development process in not only developing countries and countries in transition, but also in poor communities in developed countries. States increasingly rely on non-state organisations (profit and non-profit) for the local management and delivery of health systems.⁷⁴ Public health interventions in developing countries and countries in transition are increasingly collaborations or partnerships between players from the state, private and academic sectors (often referred to as private-public partnerships).

In the ‘globalized’ contemporary world, health issues are epidemiologically increasingly global not local. If the threats to public health are global, then the actions necessary to promote and maintain health need to have a global reach. Although there is increasing talk of global public health goods, who is empowered to act; to what extent and under what circumstances do international institutions such as the WHO and UN agencies have moral and political legitimacy to intervene on public health issues on a global level? The extent of the power of international quasi-governmental organisations such as the UN and the WHO, economic groupings such as the WTO and NGOs is not always clear, and is contested. Do they have any power to act against the will of a people or against a state? The Westphalian principle of sovereignty and territorial integrity says that external actors should not interfere in national, domestic issues, and that developed country agents desiring to be active in a developing country must respect its sovereignty and territorial integrity.⁷⁵ This position dates back to the Peace of Westphalia in 1648 and although it still holds considerable sway in the 21st century, it is sometimes challenged using both descriptive and normative arguments. These include arguments of economic globalization; normative just-war theory of interventions; the threats to nations purported to be posed by failed states; the duty to halt human right infringements, as well as public health issues.

⁷³ A non-governmental organization (NGO) is any non-profit, voluntary citizens' group which is organized on a local, national or international level.

⁷⁴ Judith Asher, *The Right to Health: A Resource Manual for NGOs*. American Association for the Advancement of Science, (undated): 3-4.

⁷⁵ Dan Philpott, "Sovereignty", *The Stanford Encyclopedia of Philosophy* (Summer 2003 Edition), Edward N. Zalta (ed.).

2.6 Public Health as Public Good

Many public health determinants such as clean drinking water can be classified as public goods. The original economical definition of public goods requires that the conditions of non-exclusion (no one can be excluded from benefiting from the good), and non-rivalry be met.⁷⁶ Fresh air might be considered a public good because one person breathing it outdoors does not affect other people's ability to do so (non-rivalry), and because it is practically impossible to prevent everyone from doing so (non-excludability). Most public goods are of fundamental importance for the wellbeing of all people, i.e. peace and security. The issue of who is responsible for their provision, and how public goods are to be provided has therefore an ethical aspect. In an extended use of the term 'public good', the health of the public can be seen as a public good upon which individual health and economic prosperity is built. The essential, non-divisible, nature of some goods also has an interface with consent issues, as their provision cannot be made to be contingent on individual consent.⁷⁷

Jeffrey Sachs has stated anti-malarial commodities – such as drugs, diagnostic methods, insecticides, bednets – should be seen as being public goods. Sachs' assertion (that stretches to the limits an understanding of what 'public goods' are) was then that public goods should be available free of charge for mass distribution. Yet although public goods typically have a value for individuals and society that is beyond that of a commodity, their supply can sometimes be left to a regulated market. Research suggests that there are benefits from the creation of a vigorous and competitive market supported by public sector demand creation initiatives such the removal of tax and tariff barriers in securing the provision of such public goods.⁷⁸ However, if the market fails to secure their provision, responsibility is generally attributed to the state for securing and ensuring their provision. A public goods approach is valuable for public health analysis because it draws attention to free-rider problems that come with the nature of some quasi-public goods such as a

⁷⁶ A non- rival good means that unlike privately owned goods, use by one consumer does not prevent another consumer from access. Non-excludable means that access to the good cannot be withdrawn i.e. air.

⁷⁷ Onora O'Neill, "Informed consent and public health," *Phil. Trans. R. Soc. Lond. B* 2004 359: 1133-1136, 1135.

⁷⁸ WHO / RBM, *Scaling-up insecticide-treated netting programmes in Africa. A strategic framework for coordinated national action*, 2 ed. 2005: 5.

vaccination for a communicable disease. Until eradication, people who refuse vaccination (assuming the number refusing is at a very low level), will benefit from all those who agree to be vaccinated, and who take a risk upon themselves or their children to do so. Furthermore, with this kind of public good, an individual's decision has repercussions that extend beyond personal consequences because the maintenance of a certain level of vaccination is necessary to control and pursue the goal of eradication in the community.

2.7 Human Development Concepts and the Place of Health

The theory and practice of human development is concerned with the normative question: what is the good life; what are the legitimate and reasonable aims of developmental work in less developed countries; what aims should "development" include, and what should it exclude? Although there is a general normative understanding amongst development ethicists that social and economic change that alleviates human deprivation in poor contexts (including the aim of improving health) are desirable aims,⁷⁹ exactly how these aims should be interpreted and achieved are complex and contentious issues. The pioneer in the field of development ethics Denis Goulet has proposed that conflicts occur in four different arenas that form the core subject matter of development ethics: debates over goals; divergent notions of power, legitimacy, authority, governance, competing political systems; competition over resources, and conflicts between modern modes of living. For instance, social and economic aims can be in conflict with development being variously seen as an array of competing images of the 'good life' (in material terms), or as a process of social change, with the conceptions posing conflicts between the values underlying each approach.⁸⁰

A variety of approaches and ethics discourses addressing the question of how development should be understood have arisen since World War II. One dominant approach applied by major actors such as the World Bank, was that development should best be understood and pursued in economic, monetary terms. Recipient countries of development aid were required to adopt free market "Western" economic structures as a condition for receiving aid.

However, "most discussions now acknowledge that income per capita is a necessary but

⁷⁹ David A Crocker, "Deliberative Participation in Local Development," *Journal of Human Development*, 8, 3 (2007): 431-455.

⁸⁰ Denis Goulet, "Development ethics: a new discipline", *International Journal of Social Economics*, (1997) Vol. 24 No. 11: 1160-1171, 1160-1165.

insufficient proxy of well-being.”⁸¹ Furthermore requiring free market structures with minimal public sector involvement proved to be disruptive to local economies. In reaction to these failures, new accounts of development and normative theories have arisen. These discourses can be catalogued under various labels as illustrated in Figure 4⁸² that shows that the development ethics field comprises various streams of practice and traditions of theorizing. The core of all the discourses is to move the development debate towards a multidimensional understanding of human development, and to acknowledge the complexity of promoting development. One important factor that all the discourses have in common however, is that they are a departure from, and largely a reaction to models and goals of development that were measured solely by materialistic, financial endpoints such as GNP. Development should be human development that is concerned with “the basic development idea: namely advancing the richness of human life, rather than the richness of the economy in which human beings live, which is only a part of it”; development must be concerned with enhancing the lives we lead and the freedoms we enjoy, not only with wealth creation.⁸³ However as the human development index (HDI)⁸⁴ and the work of the economist Amartya Sen illustrates, development discourse, theories and practice cannot sensibly disregard economic issues or deny that financial resources have an impact on human flourishing, or disregard the positive role that trading on relatively free markets can make to development.⁸⁵

⁸¹ Sabine Alkire, “Dimensions of Human Development.” *World Development* Vol. 30, No. 2, (2002): 181–205, 183.

⁸² Ibid. 186.

⁸³ Amartya Sen, *Development as Freedom* (Oxford, Oxford University Press, 1999): 15.

⁸⁴ UNDP index comprising life expectancy at birth, knowledge, as measured by the adult literacy rate / education level and standard of living, as measured by GDP.

⁸⁵ Amartya Sen, *Development as Freedom* (Oxford, Oxford University Press, 1999): 14, 25, 27.

Figure 4: Areas of Development Ethics⁸⁶

		APPLICATIONS OF THEORIES			
		Socio-Economic Development Policy	Human Rights Activism And Practice	Emergency Relief, Conflict, Humanitarian Intervention	Corporate Responsibility
THEORETICAL DIRECTIONS	Critiques of Mainstream Economics	Sen & Capability approach	Rights-based approaches' to development	Entitlements approach	Triple bottomline
	Well-Being Research	Participatory assessment; building autonomy	Autonomy and participation	Promoting autonomy in relief programs	Autonomy in work
	Moral Philosophy	Nussbaum's capabilities, O'Neill's approach to justice	Rights of women aged, children, workers, disabled	Kantian ethics of obligations, Pogge obligations i.e. Red Cross	Western moral philosophy too abstract to contribute
	Religions	Liberation theology; Buddhist economics	Liberation theology	Christian relief agencies; Red Crescent	Catholic social thought
	Humanism	Goulet, Berger, Illich, Max-Neef	Universal Declaration of Human Rights	Oxfam relief work; Medicine san Frontier	UN Global Compact
	Human Rights Theory and Law	Right to work, basic income	Human rights; judicial activism	Doctrines of (non-) intervention	Labour rights, child labour
	Professional / Practical Ethics	Professional guidelines, codes of practice	Striving to apply formally avowed rights	Codes of relief ethics	Business codes; social entrepreneurship

Amidst the complex array of development approaches, Amartya Sen's capability approach has emerged as a leading alternative to standard economic frameworks for evaluating, analysing that thinking about poverty, inequality and human development. Development according to the capability approach should mean that people are treated as the subjects of their own lives, and not just passive objects of social welfare policies or development

⁸⁶ Based on Sabine Alkire, "Dimensions of Human Development." *World Development* Vol. 30, No. 2, (2002): 181-205: 186.

interventions.⁸⁷ The UNDP embraces “capacity development” which they define as being the process through which individuals, organisations and societies obtain, strengthen and maintain the capabilities to set and achieve their own development objectives over time.⁸⁸

Many of the relevant texts on development theories and approaches provide a catalogue or list of the items or dimensions of development that the authors consider to be central to the good life. Alkire has gathered together these reflections and distilled the contents in order to produce a representative list of dimensions of value that human communities globally have supported from the work of activists, basic needs theorists, human development psychologists, cross-cultural psychologists and philosophers (see Table 1 below).⁸⁹ Alkire comments that “there may be tremendous practical value in referring deftly, with a mental glance, to a set of dimensions of human development, in order to spark conversations about objectives or to make sure that no obvious negative side-effect of a proposed initiative is overlooked.”⁹⁰

2.8 Summary of Overview of ‘Public Health’

A suitable definition for public health in transcultural contexts is that public health is the process of mobilizing local, state, national and international resources to solve the major health problems affecting communities is adopted. Health can be seen as having four dimensions: physical, mental, spiritual and social, with at least the physical dimension of attainable health being a fundamental right. Public health interventions can focus on prevention in the areas of either physical, mental, or social health, although a social focus usually has as end-goal an aspect of physical health. The meaning of the term “public” within this definition is also complex, with any meaningful understanding being connected to the political system in place.

⁸⁷ Gabriel Ferrero y de Loma-Osorio, Carlos Salvador Zepeda, “*Operationalizing the Capability Approach with Participatory and Learning Process Approaches.*”

⁸⁸ See the UNDP Capacity Development website.

⁸⁹ Sabine Alkire, “Value Construction in Sen’s Approach,” in Kaufman, Alexander ed. *Capabilities Equality: Basic Issues and Problems*, London: Routledge, 2006: 133-154.

⁹⁰ Sabine Alkire, “Dimensions of Human Development,” *World Development*, Volume 30, Issue 2: 181-205.

Table 1: Core Dimensions of Value for the Poor

	Dimension	Content Elaboration
1	Life	Its maintenance and transmission – health and safety
2	Knowledge	Practical and useful education, understanding, wisdom.
3	Aesthetic Experiences	Beauty and whatever intensely engages our capacities to know and feel
4	Meaningful Work	
5	Recreation/Play	Relaxation, resting, entertainment etc.
6	Relationships	Harmony between and among individuals and groups – friendship, living at peace, neighbourliness, social capital.
7	Inner Peace	The harmony of one’s inner feelings with one’s judgments and choices
8	Participation	The ability to make decisions that matter, to plan and shape one’s life.
9	Religion	Harmony with some more-than-human source of meaning and value etc.

The range of interventions that fall under the term ‘public health’ are extremely wide. Rather than there being one universal goal of public health, different goals may be appropriate for different contexts. What priority goals and aims are appropriate in a developed country may differ from those suitable for a developing or transitional country, although there are also global pressures and the need for a global approach to causes and solutions of some public health problems. The major health problems that public health needs to address will vary according to context, and addressing them requires the identification and understanding of the determinants in order to design effective interventions. Calling a health issue a public health problem has political repercussions, as does designing an approach to a public health question.

In summary of the above: given this complexity, the public health of a population at any one time should be seen as the result of a thick, non-linear bundle of trajectories, situated along the time-line of history. These trajectories include cultural, historical, economic, and political factors. The various economic, political, cultural and military movements associated with the expression ‘globalization’ have impacted and influenced public health. Globalization has opened-up the scale of the canvas on which public health needs to be addressed, it also

raises the question of who is empowered to act on this global level. State agencies are often granted public health powers. Globalization has greatly increased the influence of powerful non-governmental bodies and corporations around the world. Public health interventions in developing countries and countries in transition take increasingly a collaborative or partnership form between players from the state, private and academic sectors (often referred to as private-public partnerships). In an extended use of the term “public good,” the health of the public can be seen as a public good upon which individual health and economic prosperity is built. As public goods are of fundamental importance for the well-being of all people, the issue of who is responsible for their provision, and how public goods are to be provided has therefore an ethical aspect.

Reflections on public health issues in developing countries can benefit from drawing on thoughts and practise from the normative aspects of human development. The dimensions of development such as contained in Table 1 above can be a contribution to public health transcultural intervention evaluation by helping to identify unintended impacts of an intervention so that they should be anticipated and factored into a decision-making process.

PART II: DEDUCTIVE, THEORETICAL TRANCHE

CHAPTER 3

INTRODUCTION TO INFORMED CONSENT

3.1 History of Informed Consent

Discourses on informed consent have taken place not only in medical and health fields, but also in contractual theory, economics, and sustainable development, with the legal and moral validity of a transaction depending on the involved individuals freely participating; having access to information, and being aware of the central features of their actions.⁹¹ Regarding the level of community rights and participation, discourses exist as part of the ecological, sustainable development debate. Transcultural projects such as mining and dam building have received considerable attention, with the principal being established that local communities and indigenous peoples must be informed about development projects in a timely manner, and given the opportunity to approve or consent (or reject) a project. A commonly found abbreviation is FPIC – free, prior informed consent – that is found in the context of development projects and business co-operations in connection with the protection of both material and immaterial property such as traditional knowledge. The requirement for FPIC has been codified in various agreements at national and international level. One example is the Convention on Biological Diversity that protects the use of the traditional knowledge of indigenous peoples.⁹² In addition to the terminology ‘indigenous people’ (which defines a very specific kind of group), the terminology ‘local community’ is often used to prescribe who should be involved in decision-making on development issues that will directly affect their lives, culture and livelihoods. Stakeholder models of transnational corporations have also brought consent issues into business ethics regarding for instance “social license to operate” concepts.⁹³

The UN Commentary on the Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights reads that

⁹¹ Onora O’Neil, “Some limits of informed consent,” *J. Med. Ethics* 2003;29: 4-7, 4.

⁹² The Convention on Biological Diversity (CBD), signature 1992, UN Conference on Environment and Development (UNCED) in Rio de Janeiro, ratified in 1993.

⁹³ See the United Nations “Supply Chain Sustainability – A Practical Guide for Continuous Improvement” document for an application of this concept.

“Transnational corporations and other business enterprises shall respect the rights of local communities affected by their activities and the rights of indigenous peoples and communities consistent with international human rights standards. Corporations shall also respect the principle of free, prior and informed consent of the indigenous peoples and communities to be affected by their development projects.”⁹⁴

These discourses stress that indigenous peoples and other affected parties have the right to participate and to give their free, prior and informed consent throughout each phase of a project cycle.⁹⁵ This has not always been the case of course; in past centuries, feudal, colonial authorities, invaders, and cultural or religious authorities often had sole, authoritarian decision making powers.

To turn now to consent in health care, the definitions of informed consent coming from various medical and health contexts are very similar. One representative definition coming from research is that

“Informed consent is a decision taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence, inducement, or intimidation.”⁹⁶

Another definition coming from the therapeutic, treatment-oriented practice of medicine is that “consent to medical treatment is the voluntary and continuing permission of the patient to receive a particular treatment based on an adequate knowledge of the purpose, nature and likely risks of the treatment including the likelihood of its success and any alternatives to it; permission given under any unfair or undue pressure is not ‘consent’.”⁹⁷ A definition from the few texts available on public health is that regarding epidemiology, voluntary informed

⁹⁴ UN, “*Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights*,” U.N. Doc. E/CN.4/Sub.2/2003/12/Rev.2 (2003).

⁹⁵ See *The Extractive Industries Review* (EIR) report to the World Bank Group for discussions on applying FPIC.

⁹⁶ CIOMS, *International ethical guidelines for biomedical research involving human subjects*, 2002, Guideline 4: 35-44.

⁹⁷ The Medicines and Healthcare products Regulatory Agency (MHRA) / Department of Health (UK) definition: URL: <http://www.mhra.gov.uk/>.

consent is a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation.⁹⁸

In addition to the definitions of informed consent offered above, a functional approach can be taken. In a seminal paper from 1974, Alexander Capron outlined 6 functions of informed consent: (1) to promote individual autonomy, (2) to protect the patient-subject's status as a human being worthy of respect, (3) to avoid fraud and duress, (4) to encourage self-scrutiny by the physician and researcher, (5) to promote rational decision making, and (6) to involve the public in important questions about health care policy and research.⁹⁹ Dworkin suggests that the special role that autonomy plays in healthcare and in the doctrine of informed consent is related to the embodied nature of people: "the care of our bodies is linked with our identities as persons and whatever goals or values we have are tied up with the fate of our bodies."¹⁰⁰ Dworkin further says that as "one's body is irreplaceable and inescapable... failure to respect my wishes concerning my body is a particularly insulting denial of autonomy."¹⁰¹ This supports special sensitivity being necessary regarding the actions of the state regarding the physical health of the public, compared to its activities that deal with other goods, resources, or services. Dworkin's thoughts in connecting the bodily integrity with our identity suggest that what is being protected (even when dealing with a decision regarding a direct, physical intervention) by the normative underpinnings of the ethical doctrine of consent is not only bodily integrity, but also intangible attributes, values and rights such as dignity and privacy. Thus the question of what kinds of public health interventions require consent needs to consider interventions that have an intangible impact, as well as those with a physical interface.

⁹⁸ Council for International Organizations and Medical Sciences (CIOMS); World Health Organization, *International Ethical Guidelines for Epidemiological Studies* (WHO: Geneva, Switzerland: World Health Organization, 2009); Guideline 4: 35-44.

⁹⁹ Alexander Capron, "Informed Consent in Catastrophic Disease Research and Treatment," *University of Pennsylvania Law Review*, 1974 Dec;123(2): 340-438.

¹⁰⁰ G. Dworkin, *The theory and practice of autonomy* (Cambridge: Cambridge University Press, 1988): 113.

¹⁰¹ Ibid.

Informed consent can be sought in a number of situations in the medical and health sectors: from individual patients and from healthy volunteers as part of a research project; from a patient in the therapeutic, treatment-oriented practice of medicine in a clinical or non clinical context, or from an individual or population in the practice of public health. These categories of research practice are not however clear-cut, with interventions in public health often being in a grey area of being a mixture of research and practice. In a public health context, consent can be sought from various communities: those who have statistically a normal health status distribution (the general public); who have a diagnosed health issue, or who have a high risk of developing a health problem. Therefore informed consent can involve the healthy, the chronically ill, or the acutely sick. The degree and nature of their vulnerability can greatly vary, with one factor determining vulnerability being the standard of the health system in place. Vulnerability does not however mean the vulnerable are not competent to give informed consent.

The issue of informed consent as expression of the right to autonomy has had a central role in the development of both medical ethics and research ethics since World War II,¹⁰² although the basic idea is to be found prior to this time.¹⁰³ Seeking and securing prior free and informed consent is now widely held to be essential for both ethically acceptable medical research, and is even occasionally held (erroneously) as being sufficient therefore.¹⁰⁴ A timeline of the 'progress' of consent is shown below, acknowledging however the limited nature of the events and documents selected to mark the development: indeed the laws, codes and guidelines only express the understanding at one point in time of the normative status of informed consent.

¹⁰² Z. A. Bhutta, "Beyond Informed Consent," *WHO Bulletin* 2004 Oct;82(10): 771-772.

¹⁰³ A.M. Moulin, "Medical Sciences and Ethics Before 1947." in *Ethics codes in medicine. Foundations and achievements of codification since 1947*. Eds. Tröhler U., Reiter-Theil S., Herych E., *Ethics codes in medicine*. (Aldershot: Ashgate; 1998): 24-25.

¹⁰⁴ Onora O'Neill, "Informed consent and public health," *Phil. Trans. R. Soc. Lond. B* 2004 359: 1133-1136, 1133.

Figure 5: Timeline of Major Documents Codifying Individual Informed Consent

Year	Event
1946	Constitution of the World Health Organization
1947	Nuremberg Code
1948	General Assembly of the United Nations Universal Declaration of Human Rights
1964	The World Medical Association Declaration of Helsinki recommendations to guide physicians in biomedical research involving human subjects
1975	Helsinki Revision introduced independent research ethics committees
1979	The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research U.S.
1982	CIOMS/WHO Proposed International Ethical Guidelines for Biomedical Research Involving Human Subjects
1983	Helsinki Revision
1989	Helsinki Revision
1991	International Guidelines for Ethical Review of Epidemiological Studies CIOMS
1993	CIOMS / WHO International Ethical Guidelines for Biomedical Research Involving Human Subjects
1996	ICH Guidelines Good Clinical Practice
1997	Universal Declaration on the Human Genome
1997	EU Convention on Human Rights and Biomedicine Oviedo
2000	Revision of Declaration of Helsinki
2002	CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects
2005	UNESCO Universal Declaration on Bioethics and Human Rights
2005	Additional Protocol (2005) to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (Oviedo Convention)

The status of the moral and legal doctrine of informed consent in research as understood at the end of the first decade of the 21st century is generally attributed to events that

commenced with the Nuremberg Code of 1947.¹⁰⁵ This Code covers human experimentation, and resulted from the Nuremberg Trials of doctors who performed experiments in the concentration camps during World War II. The Code was the first international document to provide guidelines on research ethics, and was adopted by the United Nations General Assembly in 1948. It reads *inter alia* that the voluntary consent of the human subject is absolutely essential, with the person involved having sufficient knowledge and comprehension of the elements of the research as to enable him to make an understanding and enlightened decision, and that the experiment should yield fruitful results for the good of society.¹⁰⁶ Continuing the work of codifying the need for informed consent in medical research, it was followed by the issuing of many guidelines and codes, notably the Declaration of Helsinki that is directed toward physicians.¹⁰⁷ Over the years, various often contentious amendments have been made to the Helsinki Declaration. Many other codes and guidelines have been issued that cover consent; national consultative activities such as those of the Nuffield Council for Bioethics in the United Kingdom, and the National Bioethics Advisory Commission in the USA have regularly taken place. These documents will be introduced in Chapter 5 below, with extracts being shown in Annex I. The issue of research in developing countries was eventually taken up by the Council for International Organization of Medical Sciences (CIOMS), which, in collaboration with the WHO, proposed guidelines for international research in 1982. The guidelines were further amended in 1993 and 2002, with the issue of International Ethical Guidelines for Biomedical research involving human subjects.

To turn now to informed consent in the field of clinical and medical *practice*: this has been widely acknowledged, but less codified. Although the events and document on the timeline may have had some influence, issues in the practice of medicine have been guided primarily by the (national) professional ethos of physicians. The development of the requirement in professional codes for informed consent is usually seen within a wider framework of the changes in the physician – patient relationship, and the question if or to what extent patients

¹⁰⁵ Nuremberg Code (1947), Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2, p. 181-182. Washington, D.C.: U.S. Government Printing Office, 1949 (see Annex I).

¹⁰⁶ *Ibid.*

¹⁰⁷ World Medical Association, *Declaration of Helsinki: ethical principles for medical research involving human subjects*, 1964; last revised 2008.

should be involved in treatment decisions.¹⁰⁸ The move to accept the principle of respect for autonomy, rather than a beneficence model (according to which the primary obligation of a physician is to provide medical benefits according to an assessment made by a physician), has been gradual. The reasons for this shift in attitudes in the US and Europe came partly from the changes in the second half of the 20th century in social forces such as the civil rights movement. Such social (and socio-economic) movements have gradually influenced developments of informed consent in the practice of medicine, its inclusions in professional codes, and the codification of patient rights.¹⁰⁹ These developments have also been supported and stimulated by a number of legal cases based on claims of assault and battery because physicians failed to obtain the patient's informed consent to an intervention (particularly in the field of surgery). One case widely quoted is the US negligence case *Canterbury v. Spence* (1972) in which informed consent emerged as a legal right with full legal redress equivalent to assault and battery if informed consent was not provided.

A newer development in the relationship between physicians and informed consent can be called 'the general therapy stage.' This is based on research showing the therapeutic benefits of informed consent with patients who are effectively informed and able to exert knowledgeable control over their own treatment decisions and therapy processes have improved recovery rate, a stronger immune system, better pain tolerance, less depression, and improved compliance. It has been asserted that as the medical community has absorbed these findings, informed consent has been recognized as both ethically essential and therapeutically sound.¹¹⁰

However, the timelines above should not be interpreted as suggesting a smooth, incremental progression towards the development of a sophisticated informed consent process being both widely accepted and applied in medical research and practice. For instance, the Nuremberg Code was in some respects weakened by the subsequent Helsinki Declaration; the reason why this was so may be found in the medical profession's attempt to retain control

¹⁰⁸ Ezekiel J. Emanuel, Linda L. Emanuel, "Four Models Of The Physician-Patient Relationship," *JAMA*, Vol. 267, 1992 Issue 16: 2221-2226.

¹⁰⁹ R.R. Faden, T.L. Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986): 59-97.

over its own activities.¹¹¹ Indeed historically, the primary original goal of the Helsinki Declaration can be seen as being not to protect human subjects, but to create a normative framework within which experimentation could continue.¹¹² The medical profession has historically strived to be self-regulating, and free from state and legislative interference.¹¹³

In spite of the documents listed in the timeline, the progress made in how research was actually conducted up until the start of the seventies is questionable, as illustrated by the Tuskegee scandal that came to light only in 1972.¹¹⁴ In the Tuskegee scandal, public health researchers started to conduct studies in 1932 on African – American patients with syphilis (at which time there was no proven treatment for syphilis). But even after penicillin became a standard cure for the disease in 1947, the medicine was withheld from study participants as the scientists wanted to continue to study how the disease spreads, and kills. The experiment lasted until 1972 when public health workers leaked the story to the media. The analysis of the role of the Helsinki Declaration as reported above might explain why Tuskegee was possible (although nota bene it was in essence a public health intervention). It can be argued that it was only such scandals, and the resulting pressure from the general public, that stimulated change in the practice of informed consent.

In spite of these scandals, codes and declarations, problems still arise, particularly surrounding the research activities of pharmaceutical companies. Events such as the UK Alder Hey hospital controversy in the 1990's (in which consent to remove tissue from children's cadavers was interpreted as approving organ removal and storage¹¹⁵), and the TROVAN[®] affair (see Annex VIII) suggest that much remains to still be achieved.

¹¹¹ D. Sprumont, P. Arnold, "The Nuremberg Code: Rules of Public International Law," in *Ethics codes in medicine. Foundations and achievements of codification since 1947*, eds. U. Tröhler, S. Reiter-Theil, E. Herych (Aldershot: Ashgate; 1998): 84-93.

¹¹² Ibid.

¹¹³ Jeff Blackmer, "Professionalism and the Medical Association." 2007: 18.

¹¹⁴ R.R. Faden, T.L. Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986): 186.

¹¹⁵ Whilst parents had given their 'tick-box' consent to the removal of tissue, they had not understood this as including the removal of whole organs (which was the interpretation that the pathologist had questionably made of the consent form's scope of authorization).

In contrast with the research and practice of medicine, there has been much less attention paid specifically to the subject of how to justify, apply or as necessary amend theories of informed consent in public health. Indeed there has been comparatively little attention paid to the ethics of public health in general, and especially to public health ethics outside developed country contexts. Documents often widely assume the same kind of genesis of informed consent, and apply essentially the same principles of informed consent found in medicine to public health. Recalling the very varied nature of public health activities outlined in Chapters 1 and 2, this may be appropriate for some public health activities, but are guidelines developed primarily for clinical individual investigations appropriate for all public health, community-based interventions?¹¹⁶ Considering this question will be a central theme in this dissertation. Regarding the history of the few considerations of informed consent and community assent in public health, the main texts are quoted in Annex III, and a timeline shown below in Figure 6. One of the earliest references on an international level is to be found in the 1991 CIOMS epidemiology guidelines (relatively late when compared to the medical field), under the heading “Community agreement”:

“When it is not possible to request informed consent from every individual to be studied, the agreement of a representative of a community or group may be sought, but the representative should be chosen according to the nature, traditions and political philosophy of the community or group. Approval given by a community representative should be consistent with general ethical principles. When investigators work with communities, they will consider communal rights and protection as they would individual rights and protection. For communities in which collective decision-making is customary, communal leaders can express the collective will. However, the refusal of individuals to participate in a study has to be respected: a leader may express agreement on behalf of a community, but an individual's refusal of personal participation is binding”.¹¹⁷

¹¹⁶ Richard R. Sharp, Morris W. Foster, “Community Involvement in the Ethical Review of Genetic Research: Lessons from American Indian and Alaska Native Populations,” *Environmental Health Perspectives*, Volume 110, Number S2, 2002: 145-146.

¹¹⁷ Council for International Organizations and Medical Sciences (CIOMS); World Health Organization, *International Guidelines For Ethical Review Of Epidemiological Studies* (WHO: Geneva, Switzerland: World Health Organization, 1991).

Figure 6: Timeline History of Development of Informed Consent on a Population, Community Level (as Illustrated by Epidemiology)

Year	Event
1991	CIOMS International Guidelines for Ethical Review of Epidemiological Studies
1997	Human Genome Diversity Project Proposed Model Ethical Protocol for Collecting DNA Samples
2000	UNAIDS Ethical considerations in HIV preventive vaccine research guidance document
2001	NBAC US National Bioethics Advisory Commission Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries
2002	Nuffield Council On Bioethics report The ethics of research related to healthcare in developing countries
2002	CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects
2003	EGE European Group on Ethics in Science Opinion Nr 17 clinical research in developing countries
2005	UNESCO Universal Declaration on Bioethics and Human Rights
2005	Nuffield Bioethics Council report follow-up The ethics of research related to healthcare in developing countries
2007	UNAIDS/ WHO Ethical Considerations in HIV Preventive Vaccine Research; Ethical Considerations in Biomedical HIV Prevention Trials
2007	Nuffield Bioethics Council report “Public health – ethical issues
2008	CIOMS International Guidelines for Ethical Review of Epidemiological Studies
2008	Revision of Declaration of Helsinki

3.2 Normative Substantive Foundation of Informed Consent

There now follows an outline of the normative foundation of informed consent in medicine and public health, starting with considering the substantive basis that is usually held as justifying consent. The procedural foundation will then be sketched. Finally, the open questions on informed consent in public health from this theoretical point of view will be outlined.

The term “substantive” refers to reflections on moral theories such as consequentialism, deontology, principlism, casuistry, virtue ethics, care ethics etc.; the practice of substantive ethics entails reflections on their applicability and application in justifying a particular judgment and decision. Substantive ethical questions include issues such as the moral status of an embryo, or moral dilemmas that rise between having to choose between two principles (such as respect for an individual and duties of furthering the common good).

An influential substantive approach to grounding the principles that underlie informed consent was articulated in the 1979 Belmont Report that was directed towards research in medicine. The Report identifies three basic ethical principles that are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice.¹¹⁸ The central principle underlying and shaping the informed consent is the first of these principles: respect for persons. This principle has equal relevance for research and practice in medicine; its role in public health is less clear. One ethical consideration flowing from this principle is respect for autonomy, with the Belmont Report reading that “respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection.”¹¹⁹ The Belmont Report thus introduced an accessible middle level theoretical deontological basis, i.e. that treating individuals as autonomous agents is an ethical necessity. Deontological theories judge the morality of an action based on the action's adherence to a rule or duty such as the right to have autonomy respected, paying no heed to the consequences that result from adhering to the duty. (This is in contrast to a consequentialist approach that determines the rightness of an action according to its consequences). An autonomous person is an individual capable of deliberation about personal goals, and of acting under the direction of such deliberation. Respecting the right to autonomy requires that those who are capable should be treated with respect for their capacity for self-determination; respecting autonomy means giving weight to autonomous persons' considered opinions and choices, whilst refraining from obstructing

¹¹⁸ National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Washington, D.C.: Department of Health, Education, and Welfare, 1979.

¹¹⁹ Ibid.

their actions unless they are clearly detrimental to others.¹²⁰ To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, and to deny an individual the freedom to act on those considered judgments.¹²¹ The principle of freedom, respect for persons and the derived right and duty to respect autonomy are reflected and expressed in health care and research in the informed consent process. This process protects the individual's freedom of choice and respects the individual's autonomy and respects his or her personhood and dignity.^{122, 123} In addition, informed consent should reduce the chances of exploitation.¹²⁴

Other deontological – a priori - principles that contribute to the requirement that individuals be offered the chance to grant or withhold their informed consent include truth telling, and the right to know. Stephen Wear (talking about non research) offers a “trump card” argument to support the informed consent doctrine: the doctrine supports freedom in the sense of what it means to be a member of a free society; the right to be protected from capricious external monitoring and the right to be left alone.¹²⁵ It should also be recalled that the review above of human development ethics revealed that the ability to make decisions and plan and shape one's life is considered to be of considerable value.

The picture that emerges from the sources quoted above is widely accepted, but is still subjected to some challenges. Although the greater part of efforts to improve regulatory frameworks for research ethics has focused on the design, codification and regulation of informed consent procedures, a “recalcitrant uncertainty”¹²⁶ exists in the minds of some on

¹²⁰ Ibid.

¹²¹ Ibid.

¹²² National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Belmont Report: Ethical principles and guidelines for the protection of human subjects of research* (Washington (DC): Government Printing Office; 1988. GPO: 887-809).

¹²³ CIOMS, international ethical guidelines for biomedical research involving human subjects, 2002, Guideline 4.

¹²⁴ National Bioethics Advisory Commission, “*Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*,” 2001, Chapter 3: 36.

¹²⁵ Stephen Wear, *Informed consent: patient autonomy and physician beneficence within clinical medicine*, (Dordrecht: Kluwer Academic Publishers 1993): 3.

the moral foundation of informed consent: is it an implication of respect for autonomy, beneficence, or some combination of these or other moral values?¹²⁷ Why also is it important to respect individual autonomy (understood as being given the opportunity to deliberate and choose what shall or shall not happen to us)? One response is that it is of intrinsic, deontic value, meaning that it is of value irrespective of the repercussions of how or if this autonomy is used, what decisions are taken, or what are the consequences that arise therefrom. This intrinsic value entails a right to informed consent,¹²⁸ noting however, that this must include the possibility of undertaking an “informed refusal.”¹²⁹ Respecting autonomy also recognises that individuals or a community have certain inalienable rights – which are usually characterized as human rights – respected, thus the principle can be seen as an extension of the doctrine of human rights.¹³⁰

Another approach to justifying informed consent that departs from the deontic Belmont Report, is to perceive the development of personal autonomy not only in the sphere of self-referential decisions and well-being, but also as having an instrumental value in creating social progress.¹³¹ J.S. Mill provided a utilitarian, consequentialist justification for respecting human liberty of action and thought, claiming that individuality is “one of the principal ingredients of human happiness, and quite the chief ingredient of individual and social progress.”¹³²

¹²⁶ Becky Cox White, Joel Zimbelman, “Abandoning Informed Consent: An Idea Whose Time Has Not Yet Come,” *Journal of Medicine and Philosophy*, 23: 5,(1998): 477- 499.

¹²⁷ Kristinsson Sigurdur. “Autonomy and informed consent: A mistaken association?” *Medicine, Health Care and Philosophy* (2007) 10: 253-264, 261.

¹²⁸ Christopher Agulanna, “The Requirement of Informed Consent in Research Ethics: Procedure for Implementing a Crucial Ethical Norm in African Communal Culture,” *European Journal of Scientific Research* Vol.44 No.2 (2010): 204-219.

¹²⁹ T L Beauchamp, J F Childress, “Principles of Biomedical Ethics,” 5th edn. (Oxford: Oxford University Press, 2001): 80.

¹³⁰ Christopher Agulanna, “The Requirement of Informed Consent in Research Ethics: Procedure for Implementing a Crucial Ethical Norm in African Communal Culture.” *European Journal of Scientific Research* Vol.44 No.2 (2010): 204-219, 205.

¹³¹ Kristinsson Sigurdur. “Autonomy and informed consent: A mistaken association?” *Medicine, Health Care and Philosophy* (2007) 10: 253-264, 261.

¹³² J. S. Mill, 1989/1859, ‘On Liberty’, in: S. Collini (ed.), *On Liberty and Other Writings*, (Cambridge University Press), 1-115.

The philosophy of Kant is often called upon to justify informed consent. The appropriateness of this is however questionable as the term “autonomy” used by Kant does not mean the possibility for self-determination, but is a quality that our will should possess. In Kant’s ethical theory, autonomy is a desirable property of rational practical reasoning. Practical reasoning is autonomous if it is free from any external influences. Only such autonomous ‘internal’ reasoning can be a legitimate source of moral authority.¹³³ According to Kant, exercising reasoning results in the formulation and acceptance of a categorical imperative that commands us to exercise our *will* in a particular way. Kant’s first formulation of the imperative reads that one should “act only in accordance with that maxim through which you can at the same time will that it become a universal law.”¹³⁴ Another formulation is the humanity formulation that states that we should never act in such a way that we treat humanity, whether in ourselves or in others, as a means only but always as an end in itself. Thus Kant’s version of “autonomy” does not prescribe being free to decide for ourselves; on the contrary, we are bound to exercise our rational autonomous will by applying the *categorical imperatives* in deciding how we should act. This is in strong contrast to the Belmont use of the term autonomy in the sense of exercising self-determination without prescribing how this autonomy should be used – what principles an individual uses when exercising the right to ‘autonomy.’ Kant prescribes the content – what we decide – when using our autonomous will. O’Neil considers that “contemporary accounts of autonomy have lost touch with their Kantian origins, in which the links between autonomy and respect for persons are well argued; most reduce autonomy to some form of individual independence, and show little about its ethical importance.”¹³⁵ According to O’Neill, rather than inflating informed consent to solve various moral problems, the application of Kantian thought to informed consent would limit its relevance to being a safeguard by which individuals can protect themselves against coercion and deception.¹³⁶ However, in spite of doubts as to the applicability of Kant, one less controversial application is the means-and-ends version of his categorical imperative that states that we should not treat any rational being merely as a means to an end (in a solely

¹³³ Immanuel Kant, *Kritik der reinen Vernunft (Critique of Practical Reason)*, (Hamburg: Felix Meiner Verlag, 1990, first published 1781).

¹³⁴ Immanuel Kant, *Grundlegung zur Metaphysik der Sitten (Groundwork for the Metaphysic of Morals)*, (Hamburg: Felix Meiner Verlag, 1990, first published 1785).

¹³⁵ Onora O’Neill, “Some limits of informed consent,” *J Med Ethics* 2003;29: 4-7, 5.

¹³⁶ *Ibid.*

instrumental fashion); we may only act so that a person is also an end in itself.¹³⁷ The purely instrumental use of human beings as a means to the ends of others without their knowledge, and without their freely granted permission constitutes exploitation and is unethical.¹³⁸

Conducting an informed consent process should help to prevent such exploitation.

A question then arising is if in addition to our having negative duties to avoid exploitive behaviour, whether respecting the right to autonomy brings positive duties to support moral self-development in using the right to make well-reasoned decisions (thus making an interesting connection with development ethics and the capability approach)?

Is too much importance given to informed consent? The Belmont Report says that respect for persons incorporates at least two ethical convictions, one of which is treating individuals as autonomous agents. This suggests that there are other ways to respect persons: what might these be? How important is autonomy; should it have the significance that warrants the high moral status that informed consent is typically thought to enjoy? Accepting that Belmont's autonomy principle has value: how should this be balanced with other principles and values such as beneficence? The dominant position of the substantive principle of patient autonomy and self-determination can be seen as overshadowing principles such as medical beneficence. However medicine is, according to O'Neil, the human activity aimed at healing and restoration of health. O'Neil asks if medicine can continue to serve the patient if cleansed totally of all benevolent motivation?¹³⁹ Is there a price for exercising the right to override medical advice for the sake of freedom that may be too high?¹⁴⁰ As counter argument, it can be convincingly argued that autonomy precedes beneficence; it is precisely the right of an autonomous person or community to choose a set of goals, values, and beliefs that say what a benefit is that form the basis for their autonomous choices.¹⁴¹ Indeed O'Neil

¹³⁷ Immanuel Kant, *Grundlegung zur Metaphysik der Sitten (Groundwork for the Metaphysic of Morals)*, (Hamburg: Felix Meiner Verlag, 1990, first published 1785).

¹³⁸ National Bioethics Advisory Commission, "*Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*," 2001, Chapter 3: 36.

¹³⁹ J. J. Chin, "Doctor-patient Relationship: from Medical Paternalism to Enhanced Autonomy," *Singapore Med J* 2002 Vol. 43(3): 152-155, 152-53.

¹⁴⁰ Candace Cummins Gauthier, "Moral responsibility and respect for autonomy: meeting the communitarian challenge," *Kennedy Inst Ethics* Volume 10, Number 4, December 2000: 337-352, 338.

¹⁴¹ Becky Cox White, Joel Zimelman, "Abandoning Informed Consent: An Idea Whose Time Has Not Yet Come," *Journal of Medicine and Philosophy*, 23: 5,(1998): 477-499, 490.

represents a body of opinion that is sceptical of the high value and prominent place given to informed consent in medical practice or research, doubting if 'informed consent' has any value derived from supporting individual autonomy.¹⁴² O'Neil holds that the claim that that consent is the key to respecting autonomy is "endlessly repeated but deeply obscure with some of the commonly cited reasons for thinking that informed consent is of great importance being quite unconvincing."¹⁴³ A better founded reason for taking informed consent seriously is not its connection to furthering autonomy, but that it provides assurance that patients and others are neither deceived nor coerced and sanctions the waiving of prohibitions, i.e. physical assault, that otherwise apply.

3.3 Procedural Aspects of Informed Consent

The term 'procedural ethics' is used here to refer to normative reflections on the methodological process that should be followed and promoted in decision-making. Applying this understanding when describing informed consent as a 'process' is not making a connection between the process, and the ethical acceptability of an informed consent decision that is the result of this process.

A central aspect of procedure necessary to adhere to the substantive principles underlying informed consent is the form and content of a communicative process: "informed consent is more than simply getting a patient to sign a written consent form. It is a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention."¹⁴⁴ Most descriptions of informed consent contained in laws and guidelines focus on procedural, not substantive matters: it is the steps and procedural content that is usually detailed; what substantive principles should be applied when exercising one's right to autonomy, e.g. deciding if to give consent is not a part of normative texts. The aims of the process can be seen as ascertaining and protecting voluntariness and competence, and actively furthering understanding and the active use of reason – it can be interpreted as needing to consider both positive and negative duties.

¹⁴² Onora O'Neill, "Some limits of informed consent," *J Med Ethics* 2003; 29: 4-7, 5.

¹⁴³ Ibid.

¹⁴⁴ American Medical Association Website Patient Physician Relationship Topics: Informed Consent.

Granting consent should be expressed in the sense of leaving no doubt as to the will of the person, although there are different ways and perceptions of expressing consent according to circumstances, cultures and different regions of the world.¹⁴⁵

3.4 Normative Foundation of Consent and Assent in Public Health

The scant normative international texts on public health (that mostly cover epidemiology) suggest that the theoretical foundation (and the high level of priority) given to consent in public health is essentially the same as that quoted above for the medical context. For example, the CIOMS epidemiology guidelines list the same general ethical principles that they include in their guidelines for biomedical research: the principles of respect of persons, beneficence and justice. Guideline 4 on consent states that for all epidemiological research involving humans, the investigator must obtain the voluntary informed consent of the prospective subject. This is perhaps surprising when considering the difference between biomedical therapeutic activities, and the preventive population nature of public health that no other principles are mentioned; public health is the societal approach to protecting and promoting health; it is concerned with societal-oriented strategies, rather than individual-oriented actions.¹⁴⁶ This is in contrast to the individual therapeutic nature of biomedical research and practice. Does this not call for the application of an ethics of public health, not just the ethics developed in medicine? Interestingly a text contained in the defunct 1991 version of the CIOMS epidemiology guidelines (regretfully not included in the revised 2008 version), is that the general ethical principles may be applied at individual and community levels:

“At the level of the individual (microethics), ethics governs how one person should relate to another, and the moral claims of each member of a community. At the level of the community, ethics applies to how one community relates to another, and to how a community treats each of its members (including prospective members) and members of other groups with different cultural values (macroethics).”¹⁴⁷

¹⁴⁵ UNESCO, Report of UNESCO International Bioethics Committee on Consent, 2008.

¹⁴⁶ Nancy Kass, “Public health ethics: from foundations and frameworks to justice and global public health,” *J Law Med Ethics*, 2004 Summer;32(2), 90.(2004): 232-242, 232.

¹⁴⁷ Council for International Organizations and Medical Sciences (CIOMS); World Health Organization, *International Guidelines For Ethical Review Of Epidemiological Studies* (WHO: Geneva, Switzerland: World Health Organization, 1991).

It was then asserted that procedures held to be unethical at one level cannot be justified because they are considered acceptable on the other level.

One of the few international, normative documents to fleetingly address the subject of informed consent in public health is the UNESCO Universal Declaration on Bioethics and Human Rights. The Declaration reads that any limitation of the principles of the Declaration are to be limited, it must be covered by law, including laws in the interests of public safety, although any such law must be consistent with international human rights law,¹⁴⁸ can be justified by serving the interests of public safety and the protection of public health, or for the protection of the rights and freedoms of others, although any such law needs to be consistent with international human rights law and be laid down in legal instruments to, presumably try to avoid an arbitrary use of a state's monopoly on legitimate violence.¹⁴⁹ Thus a general principle of public safety as limiting factor to informed consent 'doctrine' is introduced, but is placed within the boundaries of compliance with human rights.

3.5 The Transcultural Authority of Informed Consent Principles

The dominant value that informed consent affirms is that of individual self-determination, a value said to derive from the Western ethos of liberal individualism. Does the assumption that this value is universally upheld amount to some form of cultural imperialism? Is the perspective of the individualist nature of a person as expressed in informed consent appropriate in all cultures and contexts? The question raised especially by the social sciences is that informed consent is premised on autonomous individuals and their rights, with too little attention being given to the social aspects of society. Such an understanding of informed consent in bioethics has been criticized as being an 'empty ethics' model, that not only reduces the significance of other ethical principles, but also ignores the cultural and social context within which the process of consent takes place.¹⁵⁰ According to such views,

¹⁴⁸ UNESCO, Universal Declaration on Bioethics and Human Rights, 2005. Paris, France. Article 27

¹⁴⁹ Ibid.

¹⁵⁰ Oonagh Corrigan, "Empty Ethics: the problem with informed consent," *Sociology of Health and Illness*, Vo 25 No 3 (2003): 768-792, 770.

there is a need for more socially nuanced concepts of freedom, autonomy and consent with it being important to recognise that decisions do not take place in isolation.¹⁵¹

The position taken above in the universalism – relativism debate (outlined in Chapter 1 above), was that a weak universalist position regarding fundamental principles is adopted, holding that moral acts are capable of being reasonably argued, and judged as being right or wrong. However, it should not be assumed that we are (yet) aware of what should universally be done in every situation. This may be the case with some aspects of informed consent; the validity of the principle of respect for persons is not here doubted, but other (community-based) principles may need to be respected in some situations. It was also suggested that in the case of disagreement in transcultural contexts, any empirical evidence of a core basis of shared values would provide a basis for discourse. What evidence is available regarding informed consent? The NBAC found “that there is a great deal of support in developing countries for the requirement of voluntary, individual informed consent,” care being necessary to avoid however, committing the is-ought fallacy. This assertion lends considerable support to the view that both developed and developing country researchers view the requirement to obtain voluntary informed consent as a necessary ethical standard.¹⁵² Some consider also that scholars exaggerate the idea of African collective decision-making, with the evidence being that “while community may have a strong hold on its members, it would be wrong to suppose that individuals totally lack the power of choice over matters that affect their lives or existence. In as much as all societies contain some sense of community, the famed community-feeling is not something that is Africa-specific.”¹⁵³ What however strong norms of community are met, these should not be crudely overridden. Ways of blending the principle of voluntary informed consent which emphasizes individual choice with the ideals of a culture that stresses the value of group choice or collective decision-making need to be developed, without discounting the belief in the need to respect persons.

¹⁵¹ Ibid. 771.

¹⁵² National Bioethics Advisory Commission (NBAC). *Ethical and Policy Issues in International Research: clinical trials in developing countries*, 2001, Chapter 3: 50.

¹⁵³ Christopher Agulanna, “The Requirement of Informed Consent in Research Ethics: Procedure for Implementing a Crucial Ethical Norm in African Communal Culture,” *European Journal of Scientific Research* Vol.44 No.2 (2010): 204-219, 216.

3.6 Summary and Open Questions

The central deontological principle that underlies and shapes the informed consent process is widely seen as being the principle of respect for persons, with one ethical consideration flowing from this principle being respect for autonomy. One way of giving voice to this principle is informed consent. The principles are important irrespective of the repercussions of how or if this autonomy is used, what decisions are taken, or what consequences arise therefrom. On the poorly covered public health level, public safety is introduced as a justificatory basis for limiting the principle of autonomy as expressed in informed consent, but only if placed within the boundaries of a corridor containing compliance with human rights.

There seems to be an open question (or at least room for doubt), on what the central principles should be that underlie and shape the informed consent process in public health; what is the appropriate theoretical basis for evaluating if individual consent is needed in a particular public health situation? Is a deontological approach as applied in the Belmont Report (that then influences the form and content of consent processes), or a consequentialist approach appropriate? If one accepts the centrality of a deontological approach and the principles of respect for persons: the Belmont Report agrees that there are different ways to respect persons; what might these be in public health? Even accepting the central role given to the principle of respect for persons, are deontological, consequentialist or other theories relevant in public health? What respect is due to non-individualist perspective of society; what respect is due to cultural and social context. In considering these questions, is a specific ethics of public health necessary and if yes, does it exist? The work of addressing these theoretical questions will commence in Chapter 5 by considering the contents of a few major exemplary laws, guidelines, codes and commentaries (“the Texts”) that deal with various aspects of informed consent on the individual and community level. The importance of agreeing to a normative foundation is that it leads to an understanding of what informed consent should achieve in real life; what its aims and its functions are, thus facilitating making grounded judgements when it can be waived or varied, or must be applied.

CHAPTER 4

COMMUNITY LEVEL APPROACH TO INFORMED CONSENT

4.1 Introduction

Can an emphasis on individual autonomy and informed consent mask the importance of considering ethical aspects of communities in public health interventions? In addition to the principle of respect for persons as individuals, an ‘umbrella’ principle increasingly under discussion is that respect should be shown not only for the individual, but also for the community, and that not only individuals, but also communities have rights. Such principles can take the form that one should be sensitive to local cultural traditions, and have respect for cultural diversity and pluralism.¹⁵⁴ Other assertions of community rights include their right to sovereignty over their natural resources, or the prohibition of genocide that exists to protect a group (in addition to rights and duties existing that protect individuals).¹⁵⁵ Ethical principles applicable to communities are often “designed to protect human dignity, integrity, self-determination, confidentiality, rights, and health of populations and the people comprising them.”¹⁵⁶ According to Weijer, when research involves communities, new issues arise; the same comment can be applied to a public health practice applied on a community level, such as fluorinating water. Taking due account of community context can be important to the success of an intervention.¹⁵⁷ Particular attention is needed to involve the community if the intervention originates outside that community or even outside the country in which the community is located.¹⁵⁸ An example of the practical importance of considering community is seen in the increasing application in public health of phase IV surveillance trials. These gather information on a new intervention in the everyday context of the target market, providing not only clinical and medical data but also social, cultural and behavioral public health information.¹⁵⁹

¹⁵⁴ UNESCO Universal Declaration on Bioethics and Human Rights, 2005.

¹⁵⁵ UN Convention on the Prevention and Punishment of the Crime of Genocide, 1948.

¹⁵⁶ Lawrence Gostin, “Ethical principles for the conduct of human subject research: population-based research and ethics,” *Law.Med Health*, 1991 Fall-Winter;19(3-4): 191-201, 191.

¹⁵⁷ Kathleen MacQueen, James W. Buehler, “Ethics, Practice, and Research in Public Health,” *Am J Public Health*, 2004;94: 928-931, 931.

¹⁵⁸ CIOMS *International Ethical Guidelines for Epidemiological Studies* 2009, Guideline 3: 33-35.

¹⁵⁹ Jacqueline L. Deen, John D. Clemens, “Issues in the design and implementation of vaccine trials in less developed countries,” *Nature Reviews Drug Discovery* 2006 5,11: 932-940.

The practical reason why it is important to reflect on 'community' rights with respect to consent is that if a reasonable formulation of the principle of respect for community can be justified, it confers obligations to respect the values and interests of the community and wherever possible, to protect the community from harm.¹⁶⁰ This would include duties regarding informed consent that the parties involved in an intervention will need to heed.

4.2 Moral Status of Community

In considering 'community' as being a kind of entity that can hold rights and that deserves respect or requires protection, the question arises what the moral status of a community is. Can a community have a moral status and identity that is distinct from that of the constituent individuals? Can a community be granted a moral status so that it is capable of having special so-called collective rights and duties attributed to it, that are more than and different from the rights and duties of individuals? Or can only individuals have a moral status; can only individuals have rights; can we only have duties towards individuals? One differentiation that helps an analysis is between collective individual rights and collective group rights.¹⁶¹ Collective individual rights are a bundling of the rights held by individuals that are claimed collectively, for instance a claim to freedom of thought that a collective, e.g. a religion, might assert. With such collective individual rights, the intention is to assert individual rights, not to assert that the community is a moral agent. In contrast are collective group rights that are held and borne by a group qua the group.¹⁶² Examples are the right to self-determination, sovereignty over natural resources, or the prohibition of genocide that exists to protect a group (in addition to rights and duties existing that protect individuals). With collective group rights, the individual may still be an object of protection, but the group itself is the fundamental element.¹⁶³ The holding of collective group rights implies that the

¹⁶⁰ Charles Weijer et al., "Protecting communities in research: current guidelines and limits of extrapolation," *Nature Genetics* 23, (1999): 275-280.

¹⁶¹ Peter Jones, "Human Rights, Group Rights, and Peoples' Rights." *Human Rights Quarterly*-Volume 21, Number 1, (1999): 80-107.

¹⁶² Ibid.

¹⁶³ Margot E Salomon, Sengupta Arjun, *The right to development: obligations of states and the rights of minorities and indigenous peoples, 2003*, Minority Rights Group International, London, UK. URL: <http://www.minorityrights.org>.

community is a moral agent, i.e. an entity capable of actions that can be subjected to moral evaluation. When considering the wide range of communities that exist (as outlined in Figure 7 below), is it reasonable to assert that all these communities are moral agents? This is most surely not the case. If some forms of communities are not moral agents, can one speak of them as having rights – and other moral agents having duties towards them?

Another approach to justifying granting a community rights that does not depend on arguing successfully that they have the status of moral agent, is to make a distinction between a moral agent (the subject; the actor), and ‘community’ as object or moral patient of ethical reflection.¹⁶⁴ The term moral patient is often used with reference to non-human entities, e.g. animals, trees, but can also be used to denote humans. Granting a community the status of ‘moral patient’ has the repercussion that what is done to a moral patient can be evaluated as being right or wrong; it is not a matter devoid of moral content. Moral patients can exist at different levels: the individual, communal, societal or globally. The appropriate level or category of moral patient varies according to the principle under discussion. For instance the appropriate category of patient for the human dignity principle is the human being; in the framework of respect for cultural diversity it is a community or society; in the framework of solidarity and equity, it is humanity in its entirety that is addressed by the principle.¹⁶⁵

It is concluded that although it may be difficult to justify granting some communities the status of moral agents, many communities can reasonably be argued as being a moral patient. However, the question remains regarding what specific principles and rights can claims be reasonably made, and what exactly is a ‘community’?

4.3 Defining, Categorizing, and Evaluating Community

‘Community’ is defined in different ways, by different disciplines, and is widely used in an indeterminate fashion to delineate a variety of human associations that have different characteristics. Communities can be local or national; global communities aided by modern technology and global NGOs are an increasing reality. A community in a public health

¹⁶⁴ Mark H Bernstein, *On Moral Considerability: an essay on who really matters*. (Oxford University Press 1998), 119-124.

¹⁶⁵ *Ibid.*

intervention can exist at various levels: it can be the entire population that is the target of the intervention or the population targeted by an intervention may contain one or more communities. A widely accepted definition of community is a group of people with diverse characteristics who are linked by social ties, share common perspectives, and engage in joint action in geographical locations or settings.¹⁶⁶ The WHO definition is that a community is a group of people understood as having a certain identity due to the sharing of common interests or to a shared proximity. A community may be identified as a group of people living in the same village, town, or country and, thus, sharing geographical proximity, or as a group of people sharing a common set of values, interests, or a common condition such as a disease.¹⁶⁷ The HIV Prevention Trials Network HPTN have an interesting definition (echoing stakeholder theories in business ethics) that a community is a group of people who will participate in the research or are likely to be affected by or have an influence on the conduct of the research.^{168, 169} A slightly amended version of this definition is here adopted, being that a community is a group of people who participate in, are targeted, or who are likely to be affected by or have an influence on an intervention.

Communities can be categorized according to origin (family relationships, geographical areas, cultural, ethnic, or religious groups in which one is born or raised), or by circumstance. Communities of circumstance would include groups in which one finds oneself either by choice or by chance. In the health care field this can include disease based communities.^{170, 171} A framework to classify the different kinds of community is that of Weijer and Emanuel illustrated in Figure 7 below.¹⁷² This model focuses on communities in

¹⁶⁶ Kathleen MacQueen, James W. Buehler, "Ethics, Practice, and Research in Public Health," *Am J Public Health*, 2004;94: 928-931, 931.

¹⁶⁷ WHO 2000 Operational Guidelines for Ethics Committees That Review Biomedical Research Glossary.

¹⁶⁸ See HPTN website: http://www.hptn.org/community_program/CommunityFAQs.htm.

¹⁶⁹ UNAIDS, Good participatory practice: guidelines for biomedical HIV prevention trials, 10 Core Principles, 2007.URL.:
http://data.unaids.org/pub/manual/2007/jc1364_good_participatory_guidelines_en.pdf.

¹⁷¹ HUGO Ethics Committee, "Statement on Benefit Sharing," 2000.

¹⁷² Charles Weijer et al., "Protecting communities in research: current guidelines and limits of extrapolation," *Nature Genetics* 23, (1999): 275-280.

research, but can equally be applied to practice. It supports an analysis of a community according to different characteristics, illustrating that a community can be “arrayed along a spectrum of cohesiveness.” Not all kinds of community are equally cohesive, with the spectrum ranging from a highly cohesive aboriginal community to looser forms such as a virtual-community.¹⁷³

Having identified and analysed the different kinds of community, the actions that can practically be undertaken in order to protect and respect can be identified. Following Weijer,¹⁷⁴ there are essentially five areas in which action needs to be taken in order to respect and protect communities: consultation in protocol development, information disclosure and informed consent, involvement in research conduct, access to data and samples and dissemination and publication of results. By mapping possible protections against community characteristics, it becomes clear that a community must have certain characteristics in order to practically enjoy a given protection. There are substantial problems with applying protections to other less cohesive communities, for instance when trying to implement concepts of community level consent. Some communities are clearly delineated, such as aboriginal communities, and their involvement is the subject matter of guidelines that seek not only to lay out measures designed to respect and protect them, but that also contain conditions and undertakings that potential researchers or practitioners must agree to regarding local culture and tradition.

Many communities do not have clearly authorized representation, being dispersed, with attenuated cultural traditions, without having established forums or modes of communication.¹⁷⁵

¹⁷³ C. Weijer, E J *Emanuel*, “Protecting Communities in Biomedical Research,” *Science* 18 August 2000: Vol. 289. no. 5482: 1142-1144.

¹⁷⁴ *Ibid.*

¹⁷⁵ Charles Weijer et al., “Protecting communities in research: current guidelines and limits of extrapolation,” *Nature Genetics* 23, (1999): 275-280.

Figure 7: Characteristics of Types of Communities in Biomedical Research¹⁷⁶

Community Characteristics	Type of Community						
	Aborig-inal	Geo-Political	Religion	Disease	Ethnic/Racial	Work Related	Virtual
Common history, traditions, knowledge	++	+	++	+/-	+	++	+
Shared culture	++	+/-	++	-	+	+/-	-
Health-related common culture	++	+	++	++	+	+/-	-
Legitimate political authority	++	++	+/-	-	-	+/-	-
Representative group/ individuals	++	++	++	+	+	+/-	+/-
Mechanism for priority setting in health care	+	+	+/-	+	+/-	+/-	-
Geographic localization	+	++	+/-	+/-	+/-	-	-
Common economy / shared resources	++	++	+/-	+/-	+/-	-	-
Communication network	++	+	+	+/-	+/-	+	++
Community self-identification	++	++	++	+/-	+	+/-	+

Symbol key:
 '++': community nearly always or always possesses the characteristic; '+' community often possesses the characteristic; '+/-': community occasionally or rarely possesses the characteristic; '-' community rarely or never possesses the characteristic.

¹⁷⁶ Drawn from Charles Weijer et al., "Protecting communities in research: current guidelines and limits of extrapolation," Nature Genetics 23, (1999): 275-280.

However, although some forms of protection are practically not possible or available, this should not be taken as necessarily meaning that the community does not have rights, or that the principles of respect for diversity and self-determination are not relevant. The implication may rather be that flexibility is needed in finding ways to express a principle. A particular situation in which seeking some form of community consent would be ethically appropriate but impossible is regarding a fully anonymised research project cohort, such as virtual community.¹⁷⁷ Figure 7 also invites analysis and reflection on the question if all forms of community should be granted a full status of moral patient, and if some formal criteria must be met in order to have rights attributed.

An important ethically relevant dimension when considering what rights and interests should be attributed is to reflect on who is defining a 'community', and why they are making this classification; a community can be defined by those outside the group, or by the group itself. This differentiation is relevant because "community is a term that can never be dissociated from the social perceptions of the members themselves or those people outside the community."¹⁷⁸ Both the act of those outside a group, and the act of a group defining itself as a community are actions involving power; defining a community involves exclusion and inclusion; labelling excluding and including differences as being cultural can involve power, prestige and resources.¹⁷⁹ The fact of including and excluding a group of people by labelling them (or accepting their own label) as being a 'community' can involve allocating advantages and disadvantages to the 'community.'

Should all claims coming from a group for special treatment as a 'community' based on rights, interests, traditions or culture be recognized? On the other hand, should externally labelled communities benefit from all community rights (and duties)? The act of externally creating and defining a group may result in a community that needs special treatment. An example is a community formed by recruiting for a clinical trial if the research reveals a special medical condition not hitherto understood. Such communities created by research results may be rendered vulnerable to employment, insurance discrimination or some other

¹⁷⁷ Ibid.

¹⁷⁸ HUGO Ethics Committee, " *Statement on Benefit Sharing*," 2000.

¹⁷⁹ Linda Richter et al., "Guidelines for the development of culturally sensitive approaches to obtaining informed consent for participation in HIV vaccine-related trials," Medical Research Council (Durban) Commissioned by UNAIDS1999: 9.

such issues. It can also be that a 'community' is externally identified, but the members will not willingly acknowledge that they belong to the community for fear of stigma and (perceived or real) disadvantage or harm. For example, regarding the community at risk for HIV, some at-risk groups may not want to see themselves as being part of any such community.¹⁸⁰

4.4 Concluding Reflections on 'Community'

The reflections above on the subject of 'community' have showed the complexity of the term. The CIOMS 1991 epidemiology guidelines contained the statement that the definition of a community or group may be a matter of ethical concern, with investigators needing to be sensitive as to how a community is constituted and defined (a comment not included in the 2009 revised version). Difficulties with community decision making, representation and consent can be exacerbated by the nature of many communities (such as disease based communities), with some kind of representative proxy process being necessary.

As will be often noted in this dissertation, some communities need to be protected, and many are deserving of respect. Protection might be needed to prevent discrimination; segregation or exploitation. Such problems are heightened if a community is politically or economically disadvantaged and therefore vulnerable.¹⁸¹ Communities can bear risks that are different from, and not simply aggregates of individual risks. Showing respect for a community can involve the negative duty of non-interference, or positive duties such as securing their ability to make decisions. The role that informed consent can play to both protect and respect a community will be a recurring theme in this dissertation.

¹⁸⁰ N Dickert, C Grady, "What's the price of a research subject? Approaches to payment for research participation," *N Engl J Med* 1999; 341: 198-203.

¹⁸¹ For a definition of 'vulnerable' see CIOMS *International Ethical Guidelines for Epidemiological Studies* 2009: Vulnerable persons are those who are relatively (or absolutely) may be competent but incapable of protecting their own interests due to lack of power, education or resources (Guideline 13).

CHAPTER 5

LAWS, GUIDELINES, CODES AND COMMENTARIES

5.1 Introduction

In order to consider the questions raised at the end of Chapter 3, the contents of a few major exemplary laws, codes, declarations, guidelines and commentaries ('the Texts') that deal with individual and community consent in medical and public health (primarily epidemiology) research and practice will be considered (for more details of the documents, see Annexes I, II and III). Although the subject of this dissertation is public health, in view of the intertwined history and normative developments of consent in medicine and public health, Texts that cover both areas will be considered.

As this dissertation focuses on international public health interventions, examples from international law will first be taken. Before starting the review by looking at legal instruments, the relationship between law, medicine, professional codes, public health and ethics will be considered. The next categories of documents that will be outlined are the Nuremberg Code and Helsinki Declaration. International medical research guidelines will then be considered, taking CIOMS as an example. Thereafter a commercial, regulatory pharmaceutical guideline will be outlined; two exemplary national developing country medical research codes, and then a medical professional (non-research) code of conduct. To close the medical overview, a Nuffield Council report on research in developing countries will be outlined.

Texts that deal with public health (in which area only few documents exist), will then be outlined, starting with CIOMS international epidemiology research guidelines. Some professional codes of conduct for epidemiological research and the practice of public health will be considered, before then looking at public health professional's codes. Following this, the Nuffield report on public health in the UK will be outlined. Finally, as work in public health needs to draw on knowledge produced not only by the medical sciences and epidemiology, but also by the social sciences, two ethics of social science documents will be outlined. Thereafter sections of the Texts on the topic of when individual consent can be dispensed with (waived) in medicine and public health will then be considered (see Annex IV for more detail). The focus will then move to what the same groups of Texts say about 'community.' This starts by reviewing the general references (see Annex II), before examining what is said about community consent and its relations to individual informed consent (see Annex III).

5.2 The Relationship Law, Medicine, Professional Codes, Public Health and Ethics

Taking the central enquiry that practical ethics addresses as being: What is it that I or that we should do in order to be 'good' or just, the question that then follows is: How should we identify and justify what the right action is; what are the possible sources of the norms, principles, rules, etc., that we should follow?

The discipline of practical ethics supplies one source: The reflection and analysis of theories and the principles derived therefrom, e.g. a Kantian application of the free will, and our ability to reason, the categorical imperative (in all its versions). Another approach is to look at applicable ethics codes or guidelines. A code of ethics is a document that typically attempts to clarify and guide the conduct of a group or a profession, elucidating the values and principles it holds as being most important; the application of these values and principles can then result in guidelines for action being formulated.^{185, 186} Professional ethics codes can perform various purposes; they can express fundamental principles in an aspirational manner and set standards the infringement of which will result in moral criticism (and possible professional sanction).¹⁸⁷ A deeper consideration of what grants a code or guideline such as the Declaration of Helsinki its ethical legitimacy would be outside the scope of this dissertation, but it is a question that deserves reflection.

To what extent do legal instruments provide us with an answer to the question: what is it that we should do in order to be 'good' or just? Laws are undoubtedly a source of normative guidance, that is, they are concerned with setting a standard of behaviour. Laws do not, however, necessarily tell us what we should do to be a good person; their normative force is focused on instructing what we should do in order to be a law-abiding citizen, and avoid incurring sanctions. The relationship between law and ethics is complex; there is no necessary one-to-one correspondence between a legal and ethical norm; "it would not be

¹⁸⁵ CIOMS, *Ethical Guidelines for Epidemiological Studies*, 2009.

¹⁸⁶ Brian Hurwitz, "Clinical guidelines and the law: advice, guidance or regulation?" *Journal of Evaluation in Clinical Practice*, 1 (1995): 49-60.

¹⁸⁷ W. Winslade, T. L. Krause, "The Nuremberg Code turns fifty," in *Ethics codes in medicine. Foundations and achievements of codification since 1947*, eds. Tröhler U., Reiter-Theil S., Herych E., (Aldershot: Ashgate; 1998): 40-162.

correct to say that every moral obligation involves a legal duty; but every legal duty is founded on a moral obligation.”¹⁸⁸ A law may reasonably be regarded as unethical (yet have passed into law as the result of a democratic process); ethical norms may also call for an action that infringes a law.¹⁸⁹

Regarding the relationship between the medical profession and the legislature, the medical profession has historically strived to be self-regulating, believing that issuing and adhering to their own internal professional codes and guidelines is sufficient, with state intervention being undesirable and unnecessary.¹⁹⁰ Thus internally drafted professional codes play a central role in medicine; references are often found to contracts between a physician and the patient and to a social contract with physicians existing.¹⁹¹ The privilege of a profession as being independent from State intervention depends on it proving itself as being capable of responsible self-regulation by not only issuing, but also and adhering to their professional codes and guidelines.¹⁹²

Regarding compliance with laws that interact with their professional roles in spite of this self-regulation, although physicians are obliged to respect the law, it can also be asserted that they are required to “recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.”¹⁹³ Physicians might on some occasion have a duty not to follow the law as reflected in the following quote:

¹⁸⁸ Lord Chief Justice Coleridge *R v Instan* [1893] 1 QB at 4532. *A B and Others v Leeds Teaching Hospital NHS Trust, Cardiff and Vale NHS Trust* [2004] EWHC 644, (2004) 77 B.M.L.R. 145.

¹⁹⁰ D. Sprumont, P. Arnold, “The Nuremberg Code: Rules of Public International Law,” in *Ethics codes in medicine. Foundations and achievements of codification since 1947*, eds. Tröhler U., Reiter-Theil S., Herych E., (Aldershot: Ashgate 1998): 84-96.

¹⁹¹ E. Lepicard, “Ethical Conduct and Ethical “Norms” up to 1947,” in *Ethics codes in medicine. Foundations and achievements of codification since 1947*, eds. Tröhler U., Reiter-Theil S., Herych E., eds., (Aldershot: Ashgate 1998): 40-49.

¹⁹² D. Sprumont, P. Arnold, “The Nuremberg Code: Rules of Public International Law,” in *Ethics codes in medicine. Foundations and achievements of codification since 1947*, eds. Tröhler U., Reiter-Theil S., Herych E., (Aldershot: Ashgate 1998): 84-96.

¹⁹³ American Medical Association, The Council on Ethical and Judicial Affairs (CEJA) Principles of Medical Ethics, 2001 E-1.02. The Relation of Law and Ethics.

“Ethical values and legal principles are usually closely related, but ethical ligitations typically exceed legal duties. In some cases, the law mandates unethical conduct. In general, when physicians believe a law is unjust, they should work to change the law. In exceptional circumstances of unjust laws, ethical responsibilities should supersede legal obligations. The fact that a physician charged with allegedly illegal conduct is acquitted or exonerated in civil or criminal proceedings does not necessarily mean that the physician acted ethically.”¹⁹⁴

What role does legislation and its political context, codes of ethics and guidelines play in the field of public health? The extremely wide nature of public health professionals has led to there being no clear internationally accepted code of professional ethics in either research or practice, although some national codes exist for public health, and particularly for epidemiology (also the international CIOMS Guidelines). Regarding the role of legislation and its political context, bearing in mind that the mandate of public health professionals concerns the health of a population, the political context of a particular intervention from the perspective of political philosophy has a role to play in providing legitimacy and ethical justification. It is, for instance, widely held that a public health intervention carried out by a government authority in a democracy has a high level of legitimacy because the preservation of the public health can be seen as being among the most important goals of government, with the enactment and enforcement of law being the primary means with which government can further the health of the public¹⁹⁵ (see Chapter 7.2.2 for more reflections on legitimacy and consent).

There is however another level of the relationship between ethics, ethical codes and the law whereby the existence of an ethical code or guideline is seen as a first step on the aspirational road of (a) it progressing to being seen as have the force of law, and (b) to it being actually integrated into legislation (with then the possibility to impose sanctions if not adhered to). This more complex relationship is illustrated by making a review of the various forms of international law, one source of which are treaties – agreements between states – that once signed and ratified are legally binding; these are sometimes referred to as ‘hard law’. As an example, the Council of Europe Convention on Human Rights and Biomedicine from 1997 will be outlined below, together with an example of a national binding document,

¹⁹⁴ Ibid.

¹⁹⁵ Lawrence Gostin, *Public Health Law and Ethics: A Reader*, 2002.

the Swiss Constitution from 2010. Another source of international law are instruments such as declarations, recommendations, charters, resolutions, etc., that are sometimes referred as non-binding or soft laws, that have particularly been developed in sensitive fields such as bioethics.¹⁹⁶ These so-called 'soft laws' do not have per se a binding effect, and have been widely criticized and even dismissed as being irrelevant.¹⁹⁷ However, soft laws such as those issued by UNESCO are based on a mandate that intends them to be part of a gradual process with their representing on the short term a moral or political commitment (but not a binding commitment), but on the longer term being hoped to have (albeit in an indirect and persuasive way), an influence on governments which is not very different from that of legally binding treaties."¹⁹⁸ As an example of a soft law, the UNESCO Universal Declaration on Bioethics and Human Rights from 2005 will be outlined in Chapter 5.

Further sources of international law are legal principles common to all civilised countries,¹⁹⁹ and finally is the possibility that customary law can be a source of international law. Customary law is derived from a continuous practice of a norm by state legislatures, motivated by a sense of legal obligation. A US Court found in the TROVAN[®] case that the prohibition of non-consensual medical experimentation on humans is binding under customary international law (a decision that the defendants Pfizer are appealing).²⁰⁰ It is into this customary law aspect of international law (and national law, the principle of customary law also existing in most national legal systems), that ethical, particularly professional codes can fall, Although they are not formal legal instruments, codes of ethics

¹⁹⁶ Roberto Andorno, "The Invaluable Role of Soft Law in the Development of Universal Norms in Bioethics." Ein Beitrag zum Workshop "Die Umsetzung bioethischer Prinzipien im internationalen Vergleich". 2007.

¹⁹⁷ Kenneth W Abbott, Duncan Snidal, "Hard and Soft Law in International Governance," *International Organization*. (2000), 54: 421-456.

¹⁹⁸ Roberto Andorno, "The Invaluable Role of Soft Law in the Development of Universal Norms in Bioethics." Ein Beitrag zum Workshop "Die Umsetzung bioethischer Prinzipien im internationalen Vergleich". 2007.

¹⁹⁹ E. Lepicard, "Ethical Conduct and Ethical "Norms" up to 1947," in *Ethics codes in medicine. Foundations and achievements of codification since 1947*. eds. Tröhler U, Reiter-Theil S, Herych E, Ethics codes in medicine. (Aldershot: Ashgate; 1998): 40-49.

²⁰⁰ See the website <http://www.business-humanrights.org> for general information.

can be reference points on which to base civil or criminal liability suits.²⁰¹ If a code is cited in a legal action, this acknowledges on the one hand the high moral standing of the code, and forms a legal basis for claims that it is part of public national or international law.²⁰²

5.3 Medical Research and Practice

5.3.1 Binding 'Hard' Laws

Informed consent is not only a moral requirement, but also a legal doctrine that is included in many national laws as well as in international soft non-binding and binding (hard) law. One example of hard law is the Swiss Constitution that since 2010 includes a clause covering research on humans, stating that all research on humans must be based on the participants giving their consent after being adequately informed.²⁰³ Another example of a legal instrument that covers consent is the Council of Europe Convention on Human Rights and Biomedicine from 1997, that contains the general rule regarding consent in Article 5 that reads that “an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention, as well as on its consequences.”²⁰⁴

The relationship between hard law and ethics is complex and contentious in the field of medicine. Although physicians are obliged to respect the law, an ethical principle can also be asserted that they are required to “recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.”²⁰⁵ Physicians might on some occasion have a duty not to follow the law, as reflected in the following quote:

²⁰¹ W. Winslade, T. L. Krause, “The Nuremberg Code turns fifty,” in *Ethics codes in medicine. Foundations and achievements of codification since 1947*, eds. Tröhler U., Reiter-Theil S., Herych E., (Aldershot: Ashgate, 1998).

²⁰² Ibid.

²⁰³ Federal Constitution of the Swiss Confederation of April 18, 1999.

²⁰⁴ Council of Europe Convention on Human Rights and Biomedicine, 1997, Article 5.

²⁰⁵ The Council on Ethical and Judicial Affairs (CEJA) American Medical Association AMA Principles of Medical Ethics, 2001 relationship ethics – law , E-1.02 The Relation of Law and Ethics.

“Ethical values and legal principles are usually closely related, but ethical ligations typically exceed legal duties. In some cases, the law mandates unethical conduct. In general, when physicians believe a law is unjust, they should work to change the law. In exceptional circumstances of unjust laws, ethical responsibilities should supersede legal obligations. The fact that a physician charged with allegedly illegal conduct is acquitted or exonerated in civil or criminal proceedings does not necessarily mean that the physician acted ethically.”²⁰⁶

5.3.2 Soft Laws

An example of soft law is the UNESCO Universal Declaration on Bioethics and Human Rights from 2005 (that is not without its controversial aspects). This represents an important step in the search for global minimum standards in biomedical research and clinical practice, being only the instrument in international law that comprehensively deals with the linkage between human rights and bioethics.²⁰⁷ It has a wide scope; addressing ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions.²⁰⁸ Its aims (Article 2) include guiding the actions of groups as well as individuals, and fostering multidisciplinary and pluralistic dialogue on bioethical issues between all stakeholders. In spite of its wide focus, the subject of consent has a prominent role. It holds that any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information.²⁰⁹ Restrictions on the right can be, however, made in some circumstances that include the protection of public health.

²⁰⁶ Ibid.

²⁰⁷ Roberto Andorno, “*The Invaluable Role of Soft Law in the Development of Universal Norms in Bioethics.*” Ein Beitrag zum Workshop “Die Umsetzung bioethischer Prinzipien im internationalen Vergleich”. 2007.

²⁰⁸ UNESCO Universal Declaration on Bioethics and Human Rights, 2005.

²⁰⁹ Ibid.

5.3.3 The Nuremberg Code and Helsinki Declaration

The next descriptive, normative documents to be outlined are the Nuremberg Code and Helsinki Declaration. These are not legally binding, and unlike soft laws, are not conceived in a way that allows them to act as intergovernmental agreements. Nevertheless, they have become very influential, so much so that the Helsinki Declaration is sometimes held too approximate legislation.²¹⁰ The Helsinki Declaration claims for itself a sovereign role, stating that no national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects that the Declaration contains.²¹¹

The Nuremberg Code from 1949 originated in the post-World War II American military tribunals that tried the physicians held to have conducted inhumane experiments that violated fundamental principles of law and justice.²¹² The focus is on the protection of the rights and integrity of the research subject and it is directed towards the conduct of scientists experimenting on human subjects. The Code states that the voluntary consent of the human subject is absolutely essential. Accordingly the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to be able to make an understanding and enlightened decision.²¹³ The information that must be provided includes the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon health or person which may possibly come from participation in the experiment.²¹⁴ It was drafted as a part of a court's decision in a trial that

²¹⁰ Paula Kokkonen, "Medicine, the Law and Medical Ethics in a Changing Society," *World Medical Journal*, VOL. 50 NO 1, March 2004: 6.

²¹¹ World Medical Association. Declaration of Helsinki: ethical principles for medical research involving human subjects, 1964; last revision 2008.

²¹² Nuremberg Code, *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*, Vol. 2: 181-182, Washington, D.C.: U.S. Government Printing Office, 1949.

²¹³ Ibid.

²¹⁴ Ibid.

prosecuted a group of physicians; it presented a list of criteria, the breaking of which imposed liability on physicians; it can indeed be seen as primarily being a “liability creating document.” Its function has therefore historically been to set the boundaries of where legal liability occurs (and where not), rather than protecting and respecting research participants.²¹⁵ It can be argued that the subsequent characterization by the medical profession of the Nuremberg Code (that was essentially a legal document) as being a code of medical ethics was an attempt to free the profession from being bound by it, allowing them to retain their quasi monopoly position in medical matters.²¹⁶

The full title of the Helsinki Declaration is “Ethical Principles for Medical Research Involving Human Subjects.” It was first issued by the World Medical Association in 1964. The Declaration of Helsinki is addressed primarily towards physicians although the current 2008 version newly reads that the WMA encourages other participants in medical research involving human subjects to adopt the principles. It has become increasingly controversial, and is fighting to maintain its position as a fundamental document in the field of ethics in biomedical research that influences the formulation of international, regional and national codes and laws. Although often referenced as gold standard by other documents, it is increasingly the case that not all bodies accept all the revisions made to the Declaration. The American Food and Drug Administration announced in May 2008 that they are ending the need for clinical trials conducted outside of the US to comply with the Declaration of Helsinki in order to be accepted as being part of drug applications.²¹⁷ The Declaration has been held to approximate legislation,²¹⁸ and it claims for itself a sovereign role, stating that no national

²¹⁵ W. Winslade, T. L. Krause, “The Nuremberg Code turns fifty,” in *Ethics codes in medicine. Foundations and achievements of codification since 1947*, eds. Tröhler U., Reiter-Theil S., Herych E., (Aldershot: Ashgate; 1998): 14-162, 55.

²¹⁶ D. Sprumont, P. Arnold, “The Nuremberg Code: Rules of Public International Law,” in *Ethics codes in medicine. Foundations and achievements of codification since 1947*, eds. Tröhler U., Reiter-Theil S., Herych E., (Aldershot: Ashgate; 1998): 84-96, 91.

²¹⁷ It should however be noted that the American Food and Drug Administration announced in May 2008 that they are ending the need for clinical trials conducted outside of the US to comply with the Declaration of Helsinki in order to be accepted as being part of drug applications.

²¹⁸ Paula Kokkonen, “Medicine, the Law and Medical Ethics in a Changing Society,” *World Medical Journal*, Vol.. 50 No.1, March 2004: 5-6.

ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects that the Declaration contains. It states that the responsibility for the human subject must always rest with a medically qualified person, and never rest on the subject of the research, even though the subject has given consent. Consent must be voluntary and informed. Each potential subject must be adequately informed of the aims; methods; sources of funding; any possible conflicts of interest or institutional affiliations of the researcher; the anticipated benefits and potential risks of the study, and any discomfort the intervention might entail. The subject should be informed of the right to abstain from participation in the study, and to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.²¹⁹ The Declaration continues to be revised and reviewed. Annex I contains a table that compares the essential contents regarding consent as it has developed over the years.

5.3.4 International Medical Research Guidelines

The medical research guidelines of the Council for International Organizations of Medical Sciences - CIOMS – will now be outlined. CIOMS is an international nongovernmental organization, in official relations with the World Health Organization (WHO). CIOMS has been active in research ethics for many years. The CIOMS Guidelines have neither the binding quality of hard or soft law, although they have (like the Nuremberg Code and Helsinki Declaration), become influential, particularly in international contexts. CIOMS issued the first guidelines for research on humans in 1982. The period that followed saw rapid advances in medicine and biotechnology, the growth of multinational clinical trials and of research involving children and other vulnerable groups, a shift in attitudes toward regarding human subjects research as largely beneficial rather than threatening as evidenced by the outbreak of the HIV/AIDS pandemic, and an increase in large-scale trials in developing countries. CIOMS Guidelines aim to address how the ethical principles that should govern the conduct of biomedical research involving human subjects as laid out in the Declaration of Helsinki can be applied especially in developing countries, “particularly in

²¹⁹ World Medical Association. Declaration of Helsinki: ethical principles for medical research involving human subjects, 1964; last revision 2008.

developing countries, given their socio-economic circumstances, laws and regulations, and executive and administrative arrangements.²²⁰ Taking the Declaration of Helsinki as a 'gold standard' has meant that major revisions in Helsinki have required that CIOMS also revise their guidelines.

The CIOMS 2002 International Ethical Guidelines for Biomedical Research Involving Human Subjects states regarding individual informed consent that "for all biomedical research involving humans the investigator must obtain the voluntary informed consent of the prospective subject." The commentary to the Guideline reads that informed consent is a decision to participate in research, taken by a competent individual who has received, understood and considered the necessary information and arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation. The underlying principle is that competent individuals are entitled to choose freely whether to participate or not. Informed Consent protects the individual's freedom of choice and respects the individual's autonomy but must always be complemented by independent ethical review. The Guideline understands informed consent to be a process "that is begun when initial contact is made with a prospective subject and continues throughout the course of the study." Regarding the language used to provide the information, it must not be simply "a ritual recitation of the contents of a written document." The investigator must then ensure that the prospective subject has adequately understood the information.²²¹ The documents in Guideline 5: "Obtaining informed consent: Essential information for prospective research subjects," details a list of 26 items of information that must be provided in language or another form of communication that the individual can understand before requesting an individual's consent to participate in research.

²²⁰ CIOMS, *International ethical guidelines for biomedical research involving human subjects*, 2002.

²²¹ Ibid.

5.3.5 Commercial, Regulatory Pharmaceutical Research Guideline

A set of guidelines that have arisen from the commercial pharmaceutical corner are the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Documents ('ICH').²²² Established in 1990, ICH "is a unique project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration." The ICH terms of reference include contributing to the protection of public health from an international perspective. Its purpose is to make recommendations "on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration", with the objective of harmonization being a more economical use of human, animal and material resources, and the elimination of unnecessary delay in the global development and availability of new medicines whilst maintaining safeguards on quality, safety and efficacy.²²³

ICH have issued standards for Good Clinical Practice (GCP) covering ethical and scientific quality standards for designing, conducting, recording and reporting trials that involve the participation of human subjects with the objective of providing a unified standard for the European Union (EU), Japan and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions. ICH names the Declaration of Helsinki as a gold standard: clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki.²²⁴ Compliance with this standard is hoped to provide public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible. The guidelines cover requirements for informed consent that must be complied with in order that the data resulting from clinical trials can be accepted. ICH defines informed consent as a process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been

²²² International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). E6(R1). *Good clinical practice: consolidated guideline*.

²²³ Ibid. Section 2.1.

²²⁴ Ibid.

informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent needs to be documented by means of a written, signed and dated informed consent form, and should be obtained from every subject prior to clinical trial participation. The guidelines say that the language in the oral and written information and consent form should be understandable, and as non-technical as is practical.

5.3.6 Exemplary National Developing Country Medical Research Code

Many developing countries do not have local research codes, with one exception being the Ugandan National Guidelines for Research Involving Humans as Research Participants issued by the Uganda National Council for Science and Technology in 2007.²²⁵ This document states that the purpose of informed consent is to ensure that individuals control whether or not they wish to enrol in the study, “and participate only when the research project is consistent with their values, interests and preferences.”²²⁶ To “provide informed consent”, individuals must be accurately informed of the purpose, methods, risks, benefits and alternatives to research; understand this information and its bearing on their own situation, and make a voluntary and uncoerced decision whether or not to participate. It further reads that “respect for persons requires that research participants be given the opportunity to make choices about what should be done to them.” The process aspect of informed consent is emphasized: “consent is not just a form or a signature/mark but a process of information exchange between the researcher and research participants on the whole research process.”²²⁷

5.3.7 Medical Professional Codes of Conduct

The role of professional codes is central in guiding the activities of a profession and maintaining the privileges that most professions claim. They are usually issued on a national level, although the Declaration of Helsinki is an example of a professional code that has

²²⁵ Uganda National Council for Science and Technology, *National Guidelines for Research involving humans as research participants*, 2007 (Kampala Uganda UNCST).

²²⁶ Ibid. 22.

²²⁷ Ibid. 23.

international aspirations, and that has acquired power beyond the ordering of its professional members. One national example is the American Medical Association, who issued a document entitled “Principles of Medical Ethics”, as well as a document that applies the principles. Such a code does not have legal standing, but sets a “standards of conduct which define the essentials of honourable behaviour for the physician.”²²⁸ The AMA comment regarding consent that “the patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The patient should make his or her own determination on treatment. The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care.”²²⁹ The document continues by stating that the physician should then make a recommendation for managing the health issue that is in accordance with good medical practice, with the physician having an ethical obligation to help the patient make choices from among the therapeutic alternatives that are consistent with good medical practice.²³⁰

Another national professional code is the Pakistan Medical and Dental Council Code of Ethics for Medical and Dental Practitioners from 2001.²³¹ Consent is the “autonomous authorization of a medical intervention by individual patients.” Patients are entitled to make decisions about their medical care, and have the right to be given all available information relevant to such decisions. The code draws attention to the cultural variations – and similarities – of the medical profession around the world, and how national associations regulate their profession. In addition to referencing Helsinki, the Code contains a chapter on medical ethics and Islam. This states that

“... in Islam, human beings are the crown of creation and are Allah’s vice regents on earth. They are endowed with reason, choice and responsibilities, including stewardship of other creatures, the environment and their own health. Muslims are expected to be moderate and balanced in all matters, including health. Illness may be seen as a trial or even as a cleansing ordeal,

²²⁸ The Council on Ethical and Judicial Affairs (CEJA) American Medical Association AMA Principles of Medical Ethics, 2001 relationship ethics – law E-1.02 The Relation of Law and Ethics.

²²⁹ CEJA, American Medical Association PDA E-8.08 1981 (application of principles).

²³⁰ Ibid.

²³¹ The Pakistan Medical and Dental Council, *Pakistan Medical and Dental Council Code of Ethics*, 2006, section 18.

but it is not viewed as a curse or punishment or an expression of Allah's wrath. Hence, the patient is obliged to seek treatment and to avoid being fatalistic."

Islamic bioethics is said to be closely linked to the broad ethical teachings of the Holy *Qur'an* "and the tradition of the Prophet Muhammad (Peace be upon him), and thus to the interpretation of Islamic law." Bioethical deliberation is accordingly inseparable from the Islamic religion, "which emphasizes continuities between body and mind, the material and spiritual realms and between ethics and jurisprudence. The *Qur'an* and the traditions of the Prophet Muhammad (Peace be upon him) have laid down detailed and specific ethical guidelines regarding various medical issues."²³² The code reads furthermore that If secular Western bioethics can be described as rights-based, with a strong emphasis on individual rights, Islamic bioethics is based on duties and obligations (e.g. to preserve life, seek treatment), although rights (of Allah, the community and the individual) do feature in bioethics, as does a call to virtue (Ihsan).²³³

5.3.8 Report on Research in Developing Countries

Problems regarding the ethical and scientific standards of research in developing countries have stimulated a number of commentaries, most notably the work of the Nuffield Bioethics Council. Their report "The ethics of research related to healthcare in developing countries" focuses on externally-sponsored research conducted in developing countries, and comments on a range of issues that arise when seeking consent in that context.²³⁴ It comments that respect for persons is a fundamental moral duty that is widely recognised in national and international guidance and laws. No health care action is to be taken against a person's wishes; therefore prior consent must be obtained. Nuffield comments that the three essential elements of consent are that it must be informed, be given voluntarily, and be given by a person competent to do so. The report affirms the need for an awareness of the social and

²³² Ibid.

²³³ Ibid.

²³⁴ Nuffield Council on Bioethics, "*The Ethics of Research Related to Healthcare in Developing Countries*," 2002.

cultural setting in which the research is to be conducted, mentioning for instance the need to be sensitive to the cultural issues.²³⁵

5.4 Public Health

5.4.1 International Epidemiology Research Guideline

One of the few guidelines in the area of public health research will now be outlined: the CIOMS guidelines in the field of epidemiology. The first guidelines were issued in 1991, with the new 2009 version “International Ethical Guidelines for Epidemiological Studies” being a response to the growing recognition of the importance of epidemiological research to improving the health of the public, a fact that highlighted the importance of bringing the guidelines into line with current thinking on ethics and human rights.²³⁶ Surprisingly, in spite of the population focus of epidemiology, the “General Ethics Principles” are identical to the CIOMS 2002 International Ethical Guidelines for Biomedical Research Involving Human Subjects (respect for person; beneficence, and justice defined as the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her). No community or population focused principles are mentioned. Regarding consent, the 1991 document stated that when individuals are to be subjects of epidemiological studies, their informed consent will usually be sought. The position has become more stringent, with the 2009 revision stating that for all epidemiological research involving humans, the voluntary informed consent of the prospective subject must be obtained.²³⁷ The Guidelines focus on issues in developing countries dealing with issues such as process, language, comprehension, and documentation of consent. It provides a comprehensive list of 26 items (see Annex V) of the information that should be provided “in language or another form of communication that the individual can understand.” The obligations or duties of sponsors and investigators are also listed.

²³⁵ Ibid.

²³⁶ CIOMS, *International Ethical Guidelines for Epidemiological Studies*, 2009.

²³⁷ Ibid.

5.4.2 Professional Codes of Conduct for Research in Epidemiology

There are also several professional codes in public health that regulate epidemiological research. One such is the American College of Epidemiology 2000 “Ethics Guidelines.” These state that epidemiologists should obtain the prior informed consent of research participants.²³⁸ The elements of informed consent are stated as being that information should be provided about: the purposes of the study; the sponsors; the investigators; the scientific methods and procedures; any anticipated risks and benefits; any anticipated inconveniences or discomfort, and the individual's right to refuse participation or to withdraw from the research at any time without repercussions.

Another normative document is the IEA International Epidemiologists Association “Good Epidemiological Practice (GEP) Guidelines For Proper Conduct In Epidemiologic Research.”²³⁹ According to the Guidelines, respect for individuals in research entails accepting an individual's right to refuse to participate; to be informed about the research subject, and to be properly equipped to make a decision based on the best possible information. It reads that written informed consent should be obtained when the research involves risks, but that formal written consent is unnecessary if: the research is carried out in settings that pose no threat to the potential participants, if taking part is voluntary, and if no benefits are at risk of being lost if potential participants refuse to take part.

5.4.3 Practice of Public Health: Professional Codes of Conduct

There are few normative documents covering the practice of public health, possibly because public health professionals include not only physicians but also a wide range of other backgrounds. One of the main (national) organisations is APHA, the American Public Health Association. APHA was founded in 1872, and “aims to protect all Americans and their communities from preventable, serious health threats and strives to assure community-based health promotion and disease prevention activities and preventive health services are

²³⁸ American College of Epidemiology, *Ethics Guidelines 2000*.

²³⁹ International Epidemiological Association (IEA), *Good Epidemiological Practice – IEA Guidelines for proper conduct of epidemiological research*, 2007..

universally accessible in the United states.”²⁴⁰ APHA takes an advocacy, politically active, normative role, and “builds a collective voice for public health, working to ensure access to health care, protect funding for core public health services and eliminate health disparities, among a myriad of other issues.”²⁴¹ They have a set of “Principles of the Ethical Practice of Public Health.”²⁴² Principle 6 reads regarding consent that “public health institutions should provide communities with the information they have that is needed for decisions on policies or programs and should obtain the community’s consent for their implementation.”²⁴³ The APHA comments that this statement is the community-level corollary of the individual-level ethical principle of informed consent. More details are however not given.

5.4.4 Nuffield Council Report on Public Health Practice

One of the few general commentaries in the area of public health practice is another report from the Nuffield Bioethics Council entitled “Public health – ethical issues.” Focusing on the practice of public health, the role of the state, and the question whether we need more state interference the report contributes to the emerging field of ‘population-level bioethics.’ It acknowledges that public health raises special issues compared to bioethics, and seeks to offer an ethical framework for the scrutiny of public health policies. Regarding issues of individual consent, the report supports the concept of consent as being at the centre of clinical medicine, as well as being important in public health medical interventions such as vaccination.²⁴⁴ It questions however its importance and “moral relevance” in non-medical public health activities if no substantial health risks are involved. In such situations, it might be reasonable to dispense with individual consent, and be satisfied with a ‘procedural justice’ approach that relies on conventional democratic decision-making processes as being sufficient to authorise measures. Key elements of such an approach, which has also been described under the concept of ‘accountability for reasonableness’ are: transparency of

²⁴⁰ See the American Public Health Association, APHA website, URL: <http://www.apha.org/>.

²⁴¹ Ibid.

²⁴² APHA, *Principles of the Ethical Practice of Public Health*, URL: <http://www.apha.org/>.

²⁴³ Ibid.

²⁴⁴ Nuffield Council on Bioethics, “*Public health: ethical issues*,” 2007. 2.24: 19, 24.

decision-making processes; a focus on rationales that those affected recognise as being helpful in meeting health needs fairly; and the involvement of individuals and stakeholder groups in decision-making processes with opportunities to challenge interventions in preparation and in practice.²⁴⁵ Because the report concerns public health issues in a country such as England that enjoys a democratic political system, its applicability to countries at other stages of development should not be assumed. However, the theoretical reflections are of interest.²⁴⁶

5.5 Place of Informed Consent in Social Science Research and Practice

The applicability of practical ethics considerations such as the informed consent precept in social science research and practice is a contentious and passionately debated question. No consensus (possibly because of the widely differing nature of the social sciences) has been reached; no widely accepted international guidelines exist. One little known Code of conduct on social science research issued by the UNESCO is detailed in Annex I. This states that the Code is concerned to draw the attention of all researchers to certain areas in which conflicts between ethical principles and aims of the research might arise, and has therefore developed a framework to guide research practice. The principles to which researchers should adhere include that freely given informed consent should be obtained from all human subjects. Potential participants should be informed, in a manner and in language they can understand of the context, purpose, nature, methods, procedures, and sponsors of the research. Research teams should be identified and contactable during and after the research activity. At a national level, various professional codes have been issued by national associations, for instance the Association of Social Anthropologists of the UK and the Commonwealth Ethical Guidelines for Good Research Practice from 1999. The principles include the following text regarding informed consent:

“Negotiating informed consent: following the precedent set by the Nuremberg Trials and the constitutional laws of many countries, inquiries involving human subjects should be based on the freely given informed consent of subjects. The

²⁴⁵ Ibid. 19.

²⁴⁶ Ibid.

principle of informed consent expresses the belief in the need for truthful and respectful exchanges between social researchers and the people whom they study.”

The code continues by stating that “negotiating consent” entails communicating information likely to be material to a person's willingness to participate. The long period of time over which anthropologists make use of their data, and the possibility that unforeseen uses or theoretical interests may arise in the future should be conveyed to participants, as should any likelihood that the data may be shared (in some form) with other colleagues, or be made available to sponsors, funders or other interested parties, or deposited in archives.

5.6 Waiving Individual Consent

The subject of waiver of consent is mentioned in many normative Texts; the main points to be found are now outlined, with a selection of Texts dealing with waiver being shown in Annex IV. Before looking at what the guidelines and commentaries say, what is or should be understood under ‘waiver’; what should be seen as being waived with respect to consent or assent? The hypothesis is that what is being waived – dispensed with – is conducting a *process* of informed consent; what are not being waived are the rights and principles that underlie consent. Waiver is here understood as a situation where sound arguments are made that an intervention is justified although no individual informed consent informed consent is obtained from those directly involved or affected.

Firstly it is generally accepted that in public health interventions in emergency and critical situations such as investigating serious disease outbreaks, the need for informed consent can justifiably be put to one side. Otherwise the Texts show that waiving informed consent requirements can occur in exceptional circumstances and only if certain criteria are fulfilled although there is no clear picture of the precise criteria or situations. One justificatory condition mentioned in the Texts is that seeking individual-level informed consent is impossible or impracticable, with informed consent procedures being then without any use or relevance.²⁴⁷ What “impractical” or “impossible” means is not that it is merely tedious or time consuming to pursue consent; under impracticable or impossible should be understood that

²⁴⁷ Onora O'Neill, Some Limits of Informed Consent. *J Med Ethics* 2003;29: 4-7.

pursuing individual consent cannot be done because the person to be approached cannot be identified, or where it would be so time consuming, costly or burdensome so as to render the research or practice unfeasible or nonsensical (with the fulfilment of its aims being null and void). This situation often arises in public health research and practice. Such impossibility is mentioned as a necessary criteria for waiving consent (although the use of the term 'waive' in connection with something that is not possible is problematic),^{248, 249, 250} but is rarely an adequate condition on its own.²⁵¹

The Europhen report considers that the requirement to obtain consent before a health professional gives a treatment is a "very clinically orientated instruction;" it is impossible to inform every member of a community or obtain each person's consent for most public health interventions.

Another aspect of the impossibility situation found in the Texts is that in situations when "individualized consent is not feasible, investigators may be asked by the ethical review committee to ascertain the views of representative members of the relevant community on the proposed research."²⁵² These activities are not to be equated to obtaining permission from community leaders but are aimed at "obtaining the views of people who are in effect proxies for the potential subjects."²⁵³ The Tanzania Guidelines on Ethics for Health Research regarding epidemiological studies also acknowledge that there are circumstances where it may not be feasible to obtain informed consent from all participants. In such situations "an agreement of the community representation may have to be sought, with care being taken that the representative selection should be carried in a manner that conforms to the traditions

²⁴⁸ U.S. Department of Health & Human Services Office for Protection from Research Risks URL <http://www.hhs.gov/> Summary of Basic Protections for Human Subjects 1997.

²⁴⁹ CIOMS, International guidelines for biomedical research involving human subjects, 2002.

²⁵⁰ National Health and Medical Research Council (NHMRC), *National statement on Ethical Conduct in Research Involving Humans*, 2007.

²⁵¹ American College of Epidemiology Ethics Guidelines 2000 2.6.3 Conditions under which informed consent requirements may be waived.

²⁵² CIOMS; *International Ethical Guidelines for Epidemiological Studies*, 2009.

²⁵³ Ibid.

and culture of the community.” However these Tanzanian Guidelines require that any approval given by the community has to be assessed, and should conform to ethical norms (these are however not identified), and it may be needed to establish the authenticity of the community approval.²⁵⁴

Interesting is the statement in the US American College of Epidemiology guidelines that the requirement to obtain the informed consent of research participants may be waived if it is not feasible to do so; in such cases however participants will need protection in other ways, such as through measures that safeguard confidentiality.²⁵⁵ One special form of impossibility is the use of personally non-identifiable materials in which the individuals concerned would be unknown, and hence are not contactable.²⁵⁶ What should however be considered is that even regarding non identifiable data, the use of data can bring risks of harms or benefits to a group or community.

A central criterion for waiver is that research ethics review boards or committees (REC) have given their approval. It should however be recalled that REC approval is only required for research interventions, and that state-run interventions are often exempt from obtaining REC approvals. In addition to REC approvals, another necessary but not sufficient criteria for waiving consent is that the intervention carries only a minimal risk (physical risk being assumed as being here meant). The subject of risk needs special consideration when public health interventions are being considered. This will take place in Section 7.2.6 below. Some commentaries associate risk with the degree of invasiveness; any invasive intervention must obtain consent (unless it is an emergency procedure); a non-invasive public health intervention is automatically assumed to be low risk (with waiver being acceptable). Another condition for justifying waiver is that there should be no known or likely reason for thinking

²⁵⁴ The Tanzania Guidelines on Ethics for Health Research, 2001. Chapter 6, Ethical Issues regarding epidemiological studies.

²⁵⁵ American College of Epidemiology, *Ethics Guidelines 2000 2.6.3 Conditions under which informed consent requirements may be waived* ..

²⁵⁶ CIOMS, *International Ethical Guidelines for Epidemiological Studies*, 2009.

that participants would not have consented if they had been asked,²⁵⁷ a thought that it seems reasonable to extend to cover a community or population.

An issue especially relevant for public health is that consent may be waived for any intervention performed within the scope of regulatory authority.²⁵⁸ A central argument is that consent will have been granted to the state for them to undertake a range of actions on behalf of the public to the putative good of society. Does, however, this argument only hold true in a democracy? This highlights a central difference between the subject of waiver in a medical and public health context in that in public health, a state agency rather than an ethics review committee will often be the institution that decides if a waiver is reasonable.

5.7 General References to Community

A selection of the various references to ‘community’ will firstly be reviewed (see Annex II for details) in order to obtain an overview of how ‘community’ is seen, before moving on to the references dealing with community assent (see Annex III).

The UNESCO Universal Declaration on Bioethics and Human Rights that addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, makes mention of communities in several respects. The preamble recognizes that decisions regarding ethical issues in medicine, life sciences and associated technologies may have an impact on individuals, families, groups or communities and humankind as a whole, and that “ unethically scientific and technological conduct has had a particular impact on indigenous and local communities.” In article 15, the principle of benefit sharing is established: benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries.²⁵⁹

²⁵⁷ National Health and Medical Research Council (NHMRC), *National statement on Ethical Conduct in Research Involving Humans*, 2007.

²⁵⁸ CIOMS, *International Ethical Guidelines for Epidemiological Studies*, 2009.

²⁵⁹ UNESCO Universal Declaration on Bioethics and Human Rights, 2005.

The influential and increasingly controversial Helsinki Declaration mentions for the first time 'community' in its 2008 revised version, with Paragraph 17 reading that medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community, and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research. This replaces a clause in the 2000 version that research is only justified if there is a reasonable likelihood that the population in which the research will be carried out stand to benefit. 'Community' is also mentioned in 2008 in clause 18 as being a bearer of risks: "every medical research study involving humans should be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation."²⁶⁰

Annex II includes extracts from the The Human Genome Diversity Project Model Ethical Protocol for Collecting DNA Samples.²⁶¹ The developments surrounding the mapping of the genome, genetics and the coding of DNA sequences have stimulated new areas of reflection regarding community.²⁶² The Protocol states that three principles guided their consideration of the ethical issues raised by the project: informed consent, respect for the participating population's culture, and adherence to international standards of human rights. The protocol advocates a community-researcher partnership, and community involvement in the design, conduct and publication of a study.

Another important area of input and reflection on communities in cross cultural, public health interventions comes from guidelines on public health, preventive interventions to combat HIV-AIDS in developing countries, particularly in the necessary research to develop a vaccine. HIV-AIDS patients are a very particular community formed by a disease category,

²⁶⁰ World Medical Association. Declaration of Helsinki: ethical principles for medical research involving human subjects, 1964; last revision 2008.

²⁶¹ Human Genome Diversity Project, *Proposed Model Ethical Protocol for Collecting DNA Samples*, 1998..

²⁶² Richard Sharp, Foster Morris W. "Community Involvement in the Ethical Review of Genetic Research: Lessons from American Indian and Alaska Native Populations." *Environmental Health Perspectives Supplements*, Vol. 110, No. S2, 2002.

possibly through self-identification, and occasionally being formed by external discriminatory labels.

Guidelines that deal with epidemiology (with its population focus) are a rich level of reflection regarding 'community.' For instance the CIOMS International Ethical Guidelines for Epidemiological Studies under the heading of "community review of, and permission for, studies" read that investigators carrying out epidemiological research sometimes include a process of review by representatives of the community in which it is proposed to conduct the study, particularly in situations where the research originates outside that community.²⁶³ Such review "can take the form of a 'dialogue' with the community about the proposed study and its potential implications, or a more structured consultation that would document the concerns of a socially identifiable group."²⁶⁴

As an example of how developing countries deal with 'community', the Ugandan research guidelines are an example of references made to the importance of community advisory boards (CAB) that should be established by study investigators as a forum for facilitating dialogue between community members, study volunteers and researchers. CAB members shall be largely identified from communities where research is to be undertaken through a stake holder consultative process. The establishment of a CAB is "an opportunity to adopt a relationships paradigm that enables researchers to anticipate and address the context in which communities understand risks and benefits, and individuals give consent."²⁶⁵ A CAB should provide a mechanism for community consultation that contributes to protecting communities, and fostering meaningful research particularly when no fairly chosen genuine representative exists for a population.²⁶⁶

The American College of Epidemiology Ethics Guidelines provide insights regarding the importance of community also relevant for developed countries, stating that to the extent

²⁶³ CIOMS, *International Ethical Guidelines for Epidemiological Studies*, 2009.

²⁶⁴ Ibid.

²⁶⁵ Sanda Quinn, "Protecting Human Subjects: the Role of Community Advisory Boards." *Am J Public Health*. (2004);94: 918-922.

²⁶⁶ Ibid.

possible and whenever appropriate, epidemiologists should also involve community representatives in the planning and conduct of the research through for example community advisory boards. Obligations are held as existing towards communities; epidemiologists should meet these obligations “by undertaking public health research and practice activities that address health problems, including questions concerning the utilization of health care resources, and by reporting results in an appropriate fashion.”²⁶⁷ Epidemiologists should also respect cultural diversity in carrying out research and practice activities, and in communicating with community members. They should help to build and maintain public trust, with “providing community service (for example, providing scientific expertise to community-based organizations) being “an epidemiologic virtue.”²⁶⁸

5.8 General References to Consent on a Community Level

A selection of references to consent, agreement or permission on a community level (with a more complete selection being shown in Annex III) will now be made. The UNESCO Universal Declaration on Bioethics and Human Rights states that in cases of research carried out on a group of persons or a community, the additional agreement of the legal representatives of the group or community concerned may be sought.²⁶⁹ Both the CIOMS biomedical research and epidemiology guidelines contain the clause that: “in some cultures an investigator may enter a community to conduct research or approach prospective subjects for their individual consent only after obtaining permission from a community leader, a council of elders, or another designated authority. Such customs must be respected; the CIOMS epidemiology guidelines note that in some cases, formal approval may be legally required, for example regarding research in the US involving Native American communities.”²⁷⁰

²⁶⁷ American College of Epidemiology, *Ethics Guidelines*, 2000 2.6.3 Conditions under which informed consent requirements may be waived.

²⁶⁸ Ibid.

²⁶⁹ Ibid.

²⁷⁰ CIOMS, *International Ethical Guidelines for Epidemiological Studies*, 2009, Guideline 5 Commentary.

The Helsinki Declaration revision of 2008 addresses in clause 22 for the first time the need to involve communities: “participation by legally competent individuals in medical research involving humans must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual should be enrolled in a research study unless he or she freely agrees.”²⁷¹

Commentaries and reports on developing countries have given considerable attention to consent issues and the community consent. The National Bioethics Advisory Commission (NBAC) 2001 Clinical Trials in Developing Countries²⁷² report made a number of recommendations, one of which reads that “where culture or custom requires that permission of a community representative be granted before researchers may approach potential research participants, researchers should be sensitive to such local requirements.”

The European Group on Ethics in Science have commented that “developing countries differ from industrialised countries regarding economic and social contexts. In addition, cultural differences may also exist regarding traditions, family or community structures and moral values.” Therefore according to the local situation, it may be appropriate to seek agreement on the implementation of a research project from persons representative of or invested with a certain authority within the community.

²⁷³ The Nuffield Council 2002 report points out that a characteristic of externally-sponsored research carried out in developing countries is that there are often cultural differences between those organising or funding the research and the research workers and participants in the host country, with the moral significance of these differences requiring special attention.²⁷⁴ For instance, decisions about an appropriate course of action are in some

²⁷¹ World Medical Association. Declaration of Helsinki: ethical principles for medical research involving human subjects.

²⁷² National Bioethics Advisory Commission (NBAC) *Ethical and Policy Issues in International Research: clinical trials in developing countries*, Volume I (2001) and Volume II (2002).

²⁷³ EGE European Group on Ethics in Science; *Opinion n°17 - 04/02/2003 - Ethical aspects of clinical research in developing countries*, 1,8: 6-7.

²⁷⁴ Nuffield Council on Bioethics, *The Ethics of Research Related to Healthcare in Developing Countries*, 2002.

settings made within a hierarchy of customary roles in the family and community, with the general duty of respect implying a duty to be sensitive to other cultures.²⁷⁵

²⁷⁵ Ibid.

CHAPTER 6

ANALYSIS OF EXEMPLARY LAWS, GUIDELINES, CODES AND COMMENTARIES

6.1 Differentiating the Terms Consent and Assent

Before commencing the analysis of the Texts, the use of the terminology 'consent' and 'assent' needs to be considered. The opinion exists that the word 'consent' should be reserved for the exercising of autonomous choice by an individual; when referring to the community, the use of a term such as 'assent' is preferable. Henceforth, use of the term 'consent' will be reserved only for processes conducted with an individual (or their duly appointed representative). Where the agreement or approval is being sought on a community level qua the interest of the community, the term 'assent' will be used. If however, agreement is being sought on a community level from representatives as proxy for individuals who cannot consent, the term 'community consent' will apply. The Texts will now be analysed and reflected upon to see if they help answer the questions raised in Chapter 3 in order to progress responding to the research question.

6.2 Essential Elements of Informed Consent

The Texts reveal that conducting an informed consent process is seen as being a duty in international and national professional codes, regulations and guidelines. Similar approaches are met regarding consent in research, non research, medicine or epidemiology. The default position in medicine and epidemiology is that an informed consent is required; deviations from this standard require justification and the satisfying of various criteria. Dispensing with the requirement is to be regarded as exceptional. Informed consent is widely seen as being based on the principle of respect for persons and their dignity as expressed in respecting an individual's autonomy and right to self-determination, and fulfilling the resulting duty to ensure that competent individuals choose freely whether to participate in an intervention or not. There are a number of common themes, as well as a few variations. Consent must be free from coercion, undue influence, inducement, or intimidation, and that it must be given by a competent individual. The consent must be informed. Regarding the extent of the information needed to be given, the Texts variously describe this as being adequate information; the information relevant to the decision, or the information that is necessary. The information given must in any case be in a form comprehensible for the recipient. Consent should be given based on understanding, or an adequate understanding of the information received. An authorisation must clearly be given. Explicit consent relies on documentation, signatures and formal statements; it may require witnesses who confirm that proper procedures for

consenting have been followed. The formal procedures are typically designed to create enduring records, thereby reducing later uncertainty about the consent given, and perhaps forestalling dissatisfaction, complaint or litigation. Individuals who consent explicitly may not later be able to claim that they were injured or wronged, and may not have a sound basis for complaint or litigation.²⁷⁶

A core set of obligatory (minimal) steps in the consent process can be derived from the Texts as being the following:

- a) Undertaking the threshold elements of assuring the competence and voluntariness of the individuals (the absence of coercion, undue influence, inducement, or intimidation, a step that requires preparatory investigations into the targeted population);
- b) Providing the information that is necessary and adequate for the decision being taken, including as minimum information: the purpose of the intervention; the risks for the individual involved; any benefits for individual and community, what will happen to the individual in the intervention, and for non-research, information on any alternatives. The information must be provided in culturally and context appropriate ways, and in a form and language understandable for the targeted individuals;
- c) Conducting a culturally appropriate consent process by allowing the individual or representative the appropriate time to take a decision, and then documenting this consent in a culturally appropriate way.

Regarding the step sometimes mentioned in guidelines of assuring that the information has been understood, this is not included as a core activity because of the difficulty in conducting any meaningful process to control and measure 'understanding' or comprehension.²⁷⁷

Nothing should be included in a minimum standard set that is not feasible to perform, even though striving for understanding is an important aspirational goal.

However, the Texts on which the statements above are based cover medicine and only one field of public health: epidemiology. There are no internationally accepted guidelines that

²⁷⁶ Onora O'Neill, "Informed consent and public health." *Phil. Trans. R. Soc. Lond. B* 359,(2004):1133-1136,1134.

²⁷⁷ Patricia Marshall, *Challenges in Study Design and Informed Consent for Health Research in Resource-poor Settings*. Geneva, Switzerland: WHO/TDR, 2007: 24-25.

cover consent in public health outside of epidemiology. Two of the documents that make any references to public health and consent are the International Bioethics Committee of UNESCO (IBC) report on consent,²⁷⁸ and the references made in the UNESCO Universal Declaration on Bioethics and Human Rights as quoted above in Section 3.4.²⁷⁹ The Nuffield report on public health in the UK introduces other principles to those listed above into discussions of the moral relevance of individual informed consent in public health interventions. It suggests that although the concept of consent is rightly at the centre of clinical invasive medical or invasive public health interventions, it is not relevant for non-invasive public health measures such as preventing excessive consumption of tobacco and alcohol.²⁸⁰ Taking a consequentialist position, actions of the state that interfere with choices (rather than more onerous infringements such as enforced isolation) can be justified by Mills' 'harm principle' without needing consent.

If we consider public health interventions such as vaccination programs, prophylactic antimalarial treatment for infants, and social marketing programs (that may be a mixture of research and practice), what is the situation regarding the requirement to obtain individual informed consent in the light of the above? Firstly, regarding a medical, physically invasive intervention such as a vaccination: the default position according to the Texts is that individual informed consent is required e.g. for a prophylactic antimalarial treatment in the IPTi program. In emergency situations such as a communicable pandemic (a subject outside the scope of this dissertation), another situation may however pertain. Regarding a non-medical, non-invasive social marketing campaign aimed at behavioural change such as bednet usage, the situation is less clear. A problem is that the guidelines and criteria have not yet been developed that have wider situations of public health in different contexts in mind. Whilst the Nuffield report might readily dispense with consent in such situations, the transference of this line of thought to other political contexts regarding transcultural interventions is questionable.

²⁷⁸ UNESCO, *Report of UNESCO International Bioethics Committee (IBC) on Consent*, 2008.

²⁷⁹ UNESCO, *Universal Declaration on Bioethics and Human Rights*, 2005.

²⁸⁰ Nuffield Council on Bioethics. "Public health: ethical issues," 2007: 19.

6.3 Waiving Individual Informed Consent

It is generally accepted that in public health interventions in emergency and critical situations such as investigating serious disease outbreaks, it is justifiable to put the requirement for informed consent to one side, a situation generally referred to as a waiver of consent. A selection of texts dealing with waiver is shown in Annex IV. Before looking at what the guidelines and commentaries say, what is or should be understood under 'waiver'; what should be seen as being waived with respect to consent or assent? The hypothesis is that what is being waived – dispensed with – is the *process* of conducting an informed consent process that expresses underlying rights and principles. What is not being waived (or ignored), are the rights and principles that underlie the consent and assent doctrines. Waiver is here understood as a situation where sound arguments are made that an intervention is justified although no individual informed consent informed consent is obtained from those directly involved or affected. The texts show that waiving informed consent requirements can occur in exceptional circumstances and only if certain criteria are fulfilled, although there is no clear picture of the precise criteria or situations. One justificatory factor mentioned in the texts (that often occurs in public health research or practice) is that seeking individual-level informed consent is impossible or impracticable, with informed consent procedures being then without any use or relevance.²⁸¹ What is sufficiently "impractical" or "impossible" that justifies waiving the requirement to seek individual informed consent does not merely mean that to do so would be time consuming; under impracticable or impossible should be understood that pursuing individual consent cannot be done because the person to be approached cannot be identified, or where it would be so time consuming, costly or burdensome so as to render the research or practice unfeasible or nonsensical in that it could no longer fulfil its aim. Such impossibility is mentioned as a necessary criteria for waiving consent (although the use of the term 'waive' in connection with something that if not possible is problematic). It is rarely stated as an adequate condition on its own.²⁸² The Europhen report considers that the requirement to obtain consent before a health professional gives a treatment is a "very clinically orientated instruction;" it is impossible to inform every member of a community or obtain each person's consent for most public health

²⁸¹ Nuffield Council on Bioethics. "*Public health: ethical issues*," 2007: 19.

²⁸² American College of Epidemiology, *Ethics Guidelines* 2000 2.6.3 Conditions under which informed consent requirements may be waived.

interventions.²⁸³ The Tanzania Guidelines on Ethics for Health Research regarding epidemiological studies also acknowledge that there are circumstances where it may not be feasible to obtain informed consent from all participants. In such situations “an agreement of the community representation may have to be sought, with care being taken that the representative selection should be carried in a manner that conforms to the traditions and culture of the community.”²⁸⁴ However the Guidelines require that any approval given by the community has to be assessed and to conform to ethical norms (these are however not identified), and there may be need to establish the authenticity of the community approval.²⁸⁵ Interesting is the statement in the US epidemiologists guidelines that the requirement to obtain the informed consent of research participants may be waived if it is not feasible to do so, in such cases however participants will need protection in other ways, such as through confidentiality safeguards.²⁸⁶ One special form of impossibility as justification for waiving individual informed consent is the use of personally non-identifiable materials in which the individuals concerned would be unknown and hence could not be contacted to obtain consent.²⁸⁷ What should however be considered is that the use of non- identifiable data can bring risks of harms or benefits to a group or community. Another aspect of the impossibility situation found in the waiver texts is that in situations when “individualized consent is not feasible, investigators may be asked by the ethical review committee to ascertain the views of representative members of the relevant community on the proposed research.”²⁸⁸ These activities are not to be equated to obtaining permission from community leaders but are aimed at “obtaining the views of people who are in effect proxies for the potential subjects.”²⁸⁹

²⁸³ European Public Health Ethics Network (EUROPHEN). “*Public policies law and bioethics: a framework for producing public health policy across the European Union.*” 2006: 41.

²⁸⁴ NHREC (Tanzanian) National Health Research Ethics Committee, *The Tanzania Guidelines on Ethics for Health Research, 2002*, Chapter 6 Ethical Issues regarding epidemiological studies 6.2 Consent of the community.

²⁸⁵ Ibid.

²⁸⁶ American College of Epidemiology, *Ethics Guidelines 2000*; 2.6.3 Conditions under which informed consent *requirements may be waived*.

²⁸⁷ CIOMS, *International Ethical Guidelines for Epidemiological Studies*, 2009, Guideline 4: 40.

²⁸⁸ Ibid. 38.

²⁸⁹ CIOMS, *International Ethical Guidelines for Epidemiological Studies*, 2008: 38.

A central criterion for waiver is that research ethics review boards or ethics committees (REC) have given their approval to an intervention taking place without obtaining informed consent. It should however be recalled that REC approval is only required for research interventions, and that state run interventions are often exempt from obtaining REC approvals. In addition to REC approvals, another necessary but not sufficient criteria for research is that the intervention carries only a minimal risk. It is generally not explicated regarding what dimension of health the risk refers; physical risk may well be the assumption. The subject of risk needs special consideration when public health interventions are being considered. Associated with risk is that some commentaries link the degree of invasiveness of a public health practice intervention with the acceptability of waiving consent. Unless an emergency or extremely critical threat exists, a highly evasive intervention cannot be carried out without consent.

Another condition for justifying waiver is held in some texts to be that there should be no known or likely reason for thinking that participants would not have consented if they had been asked.²⁹⁰ It seems reasonable to extend this thought to cover a community or population, as well as applying to research, practice, or a typical mixture that is found in public health.

An issue especially relevant for public health work in any form is that consent may be waived for any intervention performed within the scope of regulatory authority.²⁹¹ Indeed one central difference between the subject of waiver in a medical and public health context is that in public health a state agency rather than an ethics review committee will often be the institution that decides if a waiver is reasonable. A central argument is that consent will have been granted to the state for them to undertake a range of actions on behalf of the public to the putative good of society. Does however this argument only hold true in a democracy? This highlights a central difference between the subject of waiver in a medical and public health context: in public health, a state agency rather than an ethics review committee will generally be that party to decide that a waiver is reasonable.

²⁹⁰ NHMRC, *Australian National Statement on Ethical Conduct in Research Involving Humans*, 2007.

²⁹¹ CIOMS, *International Ethical Guidelines for Epidemiological Studies*, 2009, Guideline 4: 42-43.

6.4 Implicit and Tacit Consent

In delineating waiver criteria in public health, the distinction made in medical ethics between express ways in which autonomous (individual) consent can be shown and granted, and other kinds of consent that can be labelled as implicit and tacit consent are of interest.²⁹² Explicit consent typically relies on a set of actions and documents designed to create enduring records, with one motive for conducting an explicit process being to reduce future uncertainty about if consent was given, to perhaps forestall dissatisfaction, complaint or litigation.²⁹³ In contrast is implicit or implied consent, where the 'consenter' has undertaken some activity or some action that leads to the consent being clearly inferable.²⁹⁴ For example, agreement to blood being taken or to having an injection is generally signified by extending one's arm for the doctor to take the blood or give the injection.²⁹⁵ More risky interventions will generally call for express or explicit consent; the more invasive the intervention is and the more severe physical, psychological and/or socio-economic consequences are, the more express and formalized the consent will need to be.²⁹⁶ Tacit consent is when no dissent is given to a proposal; it is expressed silently or passively by omission.^{297, 298} The acceptability of tacit consent is only reasonable regarding a routine, simple, low risk, non-invasive intervention such as occurs in daily medical practice, the nature of which can be assumed to be known by the ordinary patient.

There is a clear parallel between the above and the considerations in public health of when the political context justifies assuming that an implicit or tacit consent has been given.

²⁹² T L Beauchamp, J F Childress, *Principles of Biomedical Ethics*, 5th edn.(Oxford: Oxford University Press, 2001): 65.

²⁹³ Patricia Marshall, *Ethical Challenges in Study Design and Informed Consent for Health Research in Resource-poor Settings*, (Geneva, Switzerland: WHO/TDR, 2007): 24-25.

²⁹⁴ T L Beauchamp, J F Childress, *Principles of Biomedical Ethics*, 5th edn. (Oxford: Oxford University Press, 2001): 65.

²⁹⁵ Onora O'Neill, "Informed consent and public health." *Phil. Trans. R. Soc. Lond. B* (2004) 359: 1133-1136.

²⁹⁶ UNESCO, Report of UNESCO International Bioethics Committee (IBC) on Consent, 2008: 6.

²⁹⁷ T L Beauchamp, J F Childress, *Principles of Biomedical Ethics*, 5th edn.(Oxford: Oxford University Press, 2001): 65.

²⁹⁸ UNESCO, *Report of UNESCO International Bioethics Committee (IBC) on Consent*, 2008: 6.

However, the parallel works less well in an intercultural interventions because tacit and implicit consent rely on knowledge that cannot be assumed to be known in all settings. What knowledge can be assumed as existing needs the support of cultural epidemiologists and anthropologists. Seeking to expand arguments that justify an intervention based on some kind of tacit or implied consent (rather than explicit consent) is unsatisfactory as passivity can signal agreement, but can also signal other phenomena such as extreme illness or despair.

6.5 Community Assent and Community Level Principles

As well as showing a wide spread acceptance of the principles that underlie the doctrine of individual informed consent, and of the obligation to perform a consent procedure, the Texts also exhibit a degree of acceptance of a range of principles regarding communities or collectives, notably the principle of respect for community; sensitivity to local cultural traditions, respecting cultural diversity, and the need to respect self-governance of communities. One example of cultural diversity is the various forms of community level decision making that can be found in some societies, a collectivist decision making tradition pertains. This is in strong contrast to the individual approach of informed consent. For example the Texts speak of traditions existing that before entering into a community to conduct research or approach prospective subjects for their individual consent, permission or assent should be obtained from a community leader, a council of elders, or another designated authority. Such customs are widely held as deserving respect.²⁹⁹

6.6 The Roles and Meaning of Community

The complexity of the term 'community' was outlined in Chapter 4 above; no documents examine in any detail, how the term is being precisely used. The Texts suggest that communities may need protection; may deserve to be respected, and should often be involved in interventions. Communities can seemingly be put into various roles: as beneficiary, as a bearer of needs, bearer of risks, and as the holder of rights. The Texts use different terminology to denote who should decide on behalf of a community with the following being mentioned: a council of elders, a village council; the designated authority, the community leader and the community representative or a community proxy acting as a

²⁹⁹ CIOMS, *International Ethical Guidelines for Epidemiological Studies*, 2009, Guideline 4: 42-43.

representative in decision making.³⁰⁰ The Texts also refer to different degrees of power that a community should have, and different types of relationships between a community and the management of an intervention. The Texts variously refer to a community having the power to agree, to approve, to assent, to grant or to withhold permission. A question not touched upon is on the basis of what considerations should assent or dissent optimally be given or rejected: based on principles of the common good, or some other motive? What information should be provided to support a decision: regarding both individual and community benefits and risks of the intervention?

References are also made to more interactive relationships between a community and the intervention team are described as being: a partnership; a consultation, a participatory process, a shared responsibility, working jointly together, a community participation, entering into consultation, including communities in negotiations, entering into a dialogue, and ascertaining views of the community on various aspects of an intervention. There are different opinions on the timing and contents of the community involvements, with some documents suggesting that the community gives input throughout all stages of an intervention.³⁰¹ Community leaders or community members can be asked prior to the start of an intervention to comment on the proposed individual informed consent process. An important involvement is to ensure that community interests qua community are taken into account, such as ensuring that the intervention is responsive to the health needs and priorities of the community, and that benefits should be shared or made reasonably available after the intervention.³⁰² A particular role of 'community' was discovered in the Texts in connection with the waiver of consent: a community representation can be chosen to act as surrogate or proxy for individuals whose consent cannot be asked for. In addition to community rights and interests, the UNAIDS document states that communities also have

³⁰⁰ CIOMS *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, 2000, Guideline 4: Individual informed consent, commentary: Cultural considerations.

³⁰¹ Uganda National Council For Science And Technology, *National Guidelines For Research Involving Humans As Research Participants*, 2007: clause 3.5.3 Community Advisory Boards.

³⁰² See especially UNESCO Universal Declaration On Bioethics And Human Rights, 2005 , article 15 that reads: Article 15 – Sharing of benefits: Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries.

responsibilities; they should “assume appropriate responsibility for assuring the successful completion of the trial and of the programme.”³⁰³

Dickert and Sugarman propose a set of general goals for community consultation that should provide a framework for investigators, sponsors, institutional review boards, and communities to evaluate community consultation processes that is outlined in Figure 8³⁰⁴ Particularly relevant is the assertion that community consultation can help to confer ethical and political legitimacy on a project because granting an entity the opportunity to speak “has significant justificatory power,” especially when individuals are unable to provide consent. Thus, carefully planning, consultations and assent processes with community leaders and community members can play an important role in supporting an intervention’s legitimacy, especially in situations in which seeking individual consent is not possible.

Figure 8: Ethical Goals of Community Consultation³⁰⁵

Ethical Goal	Definition
Enhanced protection	Enhance protections for subjects and communities by identifying risks or hazards that were not previously appreciated, and by suggesting or identifying potential protections.
Enhanced benefits	Enhance benefits to study participants, the population for which the research is designed, or the community in which the study is conducted.
Shared responsibility	Consulted communities may bear some degree of moral responsibility for the research project and may take on some responsibilities for conducting the study.
Legitimacy	Confer ethical/political legitimacy by giving relevant parties the opportunity to express their views and concerns at a time when changes can be made to the research protocol.

³⁰³ UNAIDS, *Ethical considerations in HIV preventative vaccine research*: 19, 2004.

³⁰⁴ Neal Dickert, Jeremy Sugarman, Ethical goals of Community consultation in research,” *America journal of Public Health*, Vol. 95, No 7. (2005): 14-18.

³⁰⁵ Adapted from Neal Dickert, Jeremy Sugarman, Ethical goals of Community consultation in research,” *America journal of Public Health*, Vol 95, No 7, (2005): 14-18.

6.7 Relationship Individual Informed Consent and Community Assent

Section 6.2 reported the widespread acceptance found in medical and epidemiological research Texts and practice of the fundamental principle of respect for persons as expressed in the individual informed consent doctrine; Section 6.5 identified the acceptance of principles such as respect for community; sensitivity to local cultural traditions and respecting cultural diversity. What should the relationship be between the two sets of principles? How should informed consent with its focus on the rights of the individual be prioritized if it conflicts with respecting diversity and traditions that may not support the individualistic consent process? A reasonably coherent deontological position is found in the Texts in favour of the primacy of the duty to respect and uphold the principles of informed consent. The duty to respect and be sensitive to other cultures may not override the central requirement of respect for persons (which requires that we refrain from conducting research without consent); although the importance of cultural diversity and pluralism should be given due regard, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms.³⁰⁶ Community agreement or the consent of a community leader or other authority cannot be a substitute for an individual's informed consent, nor does the right of self-determination entitle a community to disregard the principle of individual respect for persons as expressed in individual informed consent. Not complying with the procedure of informed consent for competent adults would be held as violating dignity, rights and freedoms. Genuine consent to participate in research must be obtained from each participant even in diverse cultural contexts.^{307, 308}

³⁰⁶ Universal Declaration on Bioethics and Human Rights, 2005 article 12: Article 12 – “Respect for cultural diversity and pluralism. The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.”

³⁰⁷ Declaration of Helsinki, 2008 revision, para. 8 reads: Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.

³⁰⁸ CIOMS International Ethical Guidelines For Epidemiological Studies 2009, Guideline 4 Individual Informed Consent, Commentary: “In no case, however, may the permission of a community leader or other authority substitute for individual informed consent.”

6.8 Respecting Diversity: Procedural Flexibility

However, although cultural diversity should not be invoked to infringe upon fundamental principles expressed in the informed consent processes, the *prima facie* principle of respecting diversity, culture and tradition should not be ignored. The differentiation made in Chapter 3 above between the substantive and the procedural dimensions of informed consent should now be recalled: although the substantive principles of individual consent should have precedence over the substantive principles of diversity and traditions, the Texts agree that the principle of respect for diversity should be respected on a procedural level. Respecting cultural diversity can justify or even require the amendment of procedural aspects of the informed consent process, by for instance requiring that a community level permission be obtained (if so required by tradition) before approaching prospective subjects for their individual consent.³⁰⁹

6.9 Theoretical Approach to Consent and Assent

Chapter 3 above outlined the various theoretical underpinnings of informed consent found in the literature, with a preponderance of deontology approaches being found. The Texts also refer almost exclusively to deontological principles. However, an open question raised at the end of Chapter 3 (that is at the heart of many issues surrounding consent in public health and different cultural contexts), is whether decisions surrounding informed consent should additionally, or alternatively apply consequential theories, or other approaches, e.g. human rights. A close reading of the few documents that deal with public health reveal the inclusion of some consequentialist reasoning. These references are of two kinds: a) firstly the use of a consequentialist approach in evaluating if seeking consent is necessary in all public health interventions, e.g. applying the criteria from Section 6.3 above such as evaluating according to the level of risk; b) secondly is the use of consequentialist arguments to justify limiting or amending the contents and structure of an informed consent process, e.g. how much information must be supplied, and what kind of formalities must be adhered to (noting that changes will generally need to received ethic committee approval).³¹⁰ One example of this

³⁰⁹ EGE European Group On Ethics In Science, *Opinion Nr 17 Clinical Research In Developing Countries*, 2003, reads in Para 2.7 Free and Informed Consent: "Consent of family or community leader may be required in addition to individual consent".

³¹⁰ CIOMS, *International Ethical Guidelines for Epidemiological Studies*, 2009: 48.

use of consequentialist approach would be to evaluate criticisms of overly legalistic and bureaucratic approaches to consent caused by the need perceived by some physicians and researchers to legally protect themselves against litigation based on claims of assault and battery.^{311, 312} The results of this bureaucracy are held as including “contortions that are irrelevant or inimical to a more substantive notion of informed consent,” that unnecessarily complicate and delay interventions.³¹³ If these negative impacts of a deontological informed consent approach can be confirmed, taking a consequentialist approach would justify amending some aspects of the informed consent process.

6.10 Variations in the Relationship Individual Consent and the Community

An analysis of the Texts indicate that there are essentially three types of community involvement that will now be outlined.

6.10.1 Dual Model Individual Consent and Community Assent

One type of involvement is that although the principle of respect for persons as expressed in informed consent takes precedence on a substantive level, respecting diversity can require that some kind of community assent be obtained before approaching individuals if traditions so require. The modification of procedures to take tradition into account should be supported to an extent necessary to respect local culture, without however infringing fundamental individual rights. This situation results in a two-stage structure – Model for Integrated Informed Consent and Community Assent MIICCA, see Figure 9 – in which an opening community assent stage precedes an individual consent stage.

MIICCA addresses the criticism that informed consent processes often take a one-sided assumption of the nature of humans, and expresses a more socially nuanced concept of freedom, autonomy and consent, recognising that consent or dissent decisions do not take place in isolation; MIICCA allows space to take cultural context into account. However what

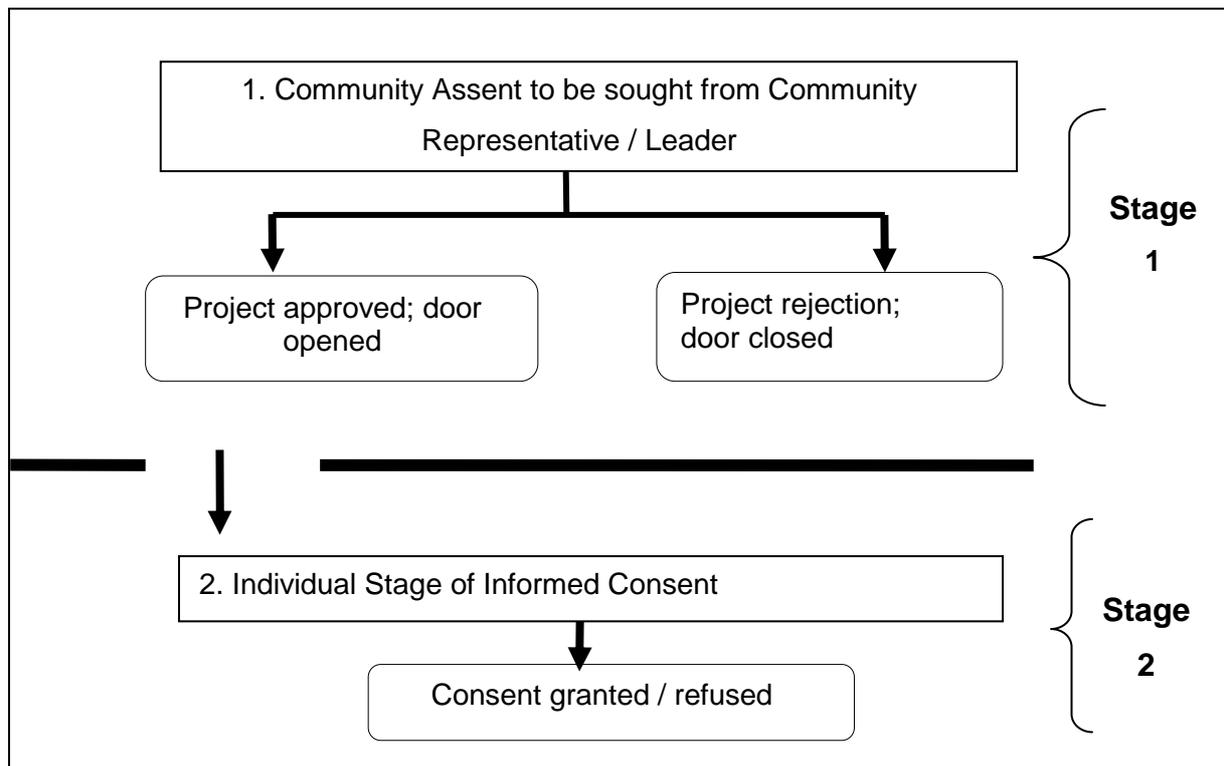
³¹¹ AMA informed consent as Legal Issue <http://www.ama-assn.org/ama/pub/category/4608.html>.

³¹² Michael M. Burgess, “Proposing modesty for informed consent.” *Social Science & Medicine*,” 65 (2007): 2284-2295, 2286.

³¹³ Ibid. 2288.

steps should be followed in the individual and community stages of the dual process in public health, international contexts?

Figure 9: MIICCA Model for Integrated Informed Consent and Community Assent



6.10.2 Community ‘Assent’ Process as Surrogate and Condition for Waiver of Individual Consent

Another type of community involvement is if a representative coming from the targeted community is asked to give a surrogate or proxy consent in the event that seeking informed consent on an individual basis is impossible, for instance in a social marketing bednet promotional intervention. The task of the surrogate will be to represent the position of an individual, not the community. Pursuing such a process can be one of the criteria that allows an intervention to take place without informed consent. The task of the surrogate will be to represent an individual’s rights and interests.

6.10.3 Community Representatives in a Consultative Capacity

The Texts also refer to interactive relationships with a community such as partnership or consultation, with special attention being needed to involve the community if the intervention originates outside the country in which the community is located.³¹⁴ This is congruent with the accepted norm of development ethics that developed country agents must act in a collaborative, capacity and capability building manner with host countries. Support is given for the approach shown in MIICCA by reading the African Charter on Human and Peoples' Rights.³¹⁵ This document came into force in 1986, and has been ratified by more than forty African states. Article 18 states that the family shall be the natural unit and basis of society. It is unusual when compared to similar 'Western' documents because not only are individual rights laid down, but also duties are established towards the community. Article 27 reads that every individual shall have duties towards his family and society, the state and other legally recognized communities and the international community, and that the rights and freedoms of each individual shall be exercised.

6.11 Closing Reflections

A differentiated picture starts to emerge of the place that ethics theory should play in informed consent and informed assent in public health. Firstly is the 'meta' question that arises at the start of any intervention of evaluating if a consent or assent process is prescribed. This requires that a set of 'waiver' criteria be available that has been developed for public health in varying international contexts. This is not available. Formulating these criteria would require that the appropriate ethical theoretical basis be identified: deontological approach (that then influences the form and content of consent processes), or a consequentialist approach according to which the rightness of an action is determined by its consequences appropriate, or another approach, i.e. human rights or a mixed approach? If it is decided that consent /assent is relevant for an intervention, the second level decision is to decide what form and kind of consent and assent is applicable: individual informed consent;

³¹⁴ CIOMS, *International Ethical Guidelines for Epidemiological Studies*, 2009 Guideline 3, external sponsored research: 33-35.

³¹⁵ Organization of African Unity. *African [Banjul] Charter on Human and Peoples' Rights*. entered into force Oct. 21, 1986. URL <http://www.umn.edu/humanrts> entered into force Oct. 21, 1986.

community assent; the dual model; and /or community consultation, and which should have priority? In all these questions, the inputs of local cultural experts will be needed. It is suggested that this decision will be a mixture of context dependent tradition, culture and practical factors, as well as theory-driven principles. Finally is the use of different theories on a level of deciding on the details of a consent or assent process, i.e. if and to what extent a consequentialist approach should be taken in amending and simplifying the level of formalities in a process.

A picture has also started to emerge of the dual position of 'community' in an intervention. Firstly working on the community level can be a vital source of information and practical support for an intervention; secondly are the obligations that may exist towards communities that may need protection, may deserve to be respected, and should often be involved in interventions. Communities can be put into various roles, with different terminology being used to denote *who* should decide on behalf of a community. Different degrees of power are also accorded to a community. There are different opinions on the contents of the community involvements. A particular role of 'community' was discovered in the Texts in connection with the waiver of individuals consent: a community representation can be chosen to act as surrogate or proxy for individuals whose consent cannot be asked for. There is also the opinion that community consultation can help to confer ethical and political legitimacy to a project.

It is concluded that more work is needed to analyse the various roles of community in public health in general, and specifically its place in consent and assent. Further work that draws on public health ethics is particularly required because a disconnect starts to emerge between the primary focus in both the guidelines on a deontological position in informed consent, and reflections suggesting that a more pluralist position is appropriate that includes consequentialist and community level principles such as the public good. The multilayer scope of public health when seen as a thick, linear bundle of activities that follows a process of pursuing the health of a population in a particular context or dimension (physical, mental, or societal), suggests that a more pluralist theoretical approach might be called for. Finally the complexity of the possible roles and relationships between individual consent and community assent suggest that practitioners would benefit from guidance on what to do in the field.

CHAPTER 7

DEVELOPING PRACTICAL MODELS FOR CONSENT AND ASSENT IN PUBLIC HEALTH INTERNATIONAL CONTEXTS

7.1 Introduction

It has been proposed above that in view of the complexity of the possible relationships between individual consent and community assent, the work of practitioners could benefit from having practical guidance available. The ambitious aim of this chapter is to develop models that give this support, including establishing the minimum standards that should be followed. To this end, two models will now be developed: one for individual consent in public health, transcultural settings, and a second for community representative assent – stages 1 and 2 of MIICCA, starting with individual consent (stage 2).

Although it has been suggested above that the status quo derived from medicine is less than satisfactory when applied to public health transcultural interventions, this is the only ‘official’ guidance available, and will presumably be the norms applied by ethics review committees. The basis for the exploratory models will therefore be the status quo as shown in the normative Texts outlined on Chapter 5. However, the models are designed to support the practitioners in the field by drawing attention to how the status quo could or should be amended to take account of public health transcultural contexts, noting that the various aspects of context that need to be considered include the cultural, economic and political.

Before starting the work on the steps of an individual consent process, a set of preliminary, preparatory building blocks will be introduced that cover themes and issues that should be looked at in public health, and which form the foundation on which the appropriate process can be established and designed.

7.2 Preliminary Stage Building Blocks

The following are the topics of these preliminary blocks: making a general review of the planned intervention; establishing the specific cultural and tradition context; considering the political background; understanding resource availability status; considering risk; understanding the role of community; drafting a communication strategy, and finally preparing the submission to the REC (that must detail the consent processes to be followed).

7.2.1 Waiver Criteria, Political Context, and Legitimation

The first preliminary step is the “meta’ question outlined in Section 6.11 above: evaluating if a consent and / or assent process is required. This would require that a set of ‘waiver’ criteria be available that has been developed for public health in varying international and transnational contexts. As this is not available, the criteria identified in Chapter 6 above will be used a basis for this work.

One of the criteria identified that is particularly important in transcultural projects is the nature of the political environment: the status quo opinion is that individual consent can be waived if a public health intervention is carried out by a state authority.^{316, 317} Much of the literature on medical and public health ethics assumes that an intervention takes place in a democratic context. For instance the Institute of Medicine definition “public health is what we, as a society, do collectively to assure the conditions in which people can be healthy,”³¹⁸ implies in the use of the word “we” the existence of a collective representation, and suggests that the state has been authorized in democratic political processes to undertake public health interventions.³¹⁹ Democracy is widely seen as the preferred system for organizing society that allows for some form of collective decision-making. This is illustrated in the UN 2002 development report entitled “Deepening democracy in a fragmented world” that took the position that democracy has proven to be the system of governance most beneficial for inter alia the development of health.³²⁰ This indicates the considerable trust generally placed in the political and moral legitimacy granted to a public health action if carried out by a state authority. However, these arguments for waiving consent are not automatically transferable onto transcultural and international interventions for several reasons. Firstly, democracies do not universally exist. Secondly, it is questionable if the external party in transcultural

³¹⁶ CIOMS *International Ethical Guidelines for Epidemiological Studies*, 2009: 40-44.

³¹⁷ Nuffield Council on Bioethics. *Public Health: Ethical Issues*, 2007: 19.

³¹⁸ Institute of Medicine, *The Future of Public Health* (Washington, D.C.: National, Academy Press, 1988): 1.

³¹⁹ James Childress et al., “Public health ethics: mapping the terrain,” *Journal of Law, Medicine & Ethics*.30 (2002): 170-178, 171.

³²⁰ UNDP *Human Development Report 2002: Deepening democracy in a fragmented world*, 2002: 4.

collaborations can claim legitimation for their actions because of the political system that exists in the partner country. Can this legitimacy and trust only exist based on the argument that a community has already provided their implicit or tacit consent (or dissent) by the existence of a democratic system? This question raises the wider issue of the legitimation of the external party's actions in a transcultural intervention when the host is a developing country that will typically have weak health systems. Pressures have been applied to external agents in development work to broaden and deepen their notion of accountability and responsibility, and address the questions of the "legitimacy" of their activities.³²¹ Legitimacy can be defined as "the particular status with which an organisation is imbued and perceived at any given time that enables it to operate with the general consent of peoples, governments, companies and non-state groups around the world."³²² Partnership with a host country entity that has political legitimacy as granted by democratic processes is one route. Chapter 6 above touched upon the role of community consultation, assent, and indeed individual consent in conferring ethical and political legitimacy: consent and assent processes planned with the participation of local communities can play a role in supporting an intervention's legitimacy. A case for moral legitimacy can also be argued if an intervention furthers values such as equality, dignity, and health that can reasonably be held to be universal values that resonate with the moral reasonableness of people across the world.³²³ Another kind of legitimacy (assuming that aim of the project is not controversial), is if an organisation is effective in achieving the goals it sets itself; another argument is that acting to empower, e.g. capacity building a community and supporting in general the participation of the host country grants legitimacy.³²⁴

³²¹ Ian Atack, "Four Criteria of Development NGO Legitimacy." *World Development* Vol. 27, Issue 5, (1999): 855-864.

³²² Hugo Slim, "By What Authority? The Legitimacy and Accountability of Non-governmental Organisations," *The Journal of Humanitarian Assistance* (2002): 6.

³²³ *Ibid.* 7.

³²⁴ *Ibid.* 7.

7.2.2 The Role of Culture and Traditions in Establishing Appropriate Consent Structures

If the meta level decision is that a consent /assent process is necessary for an intervention, the second level preparatory decision is to locate the appropriate process type and structure. This decision should be based on a mixture of context dependent traditional, cultural and practical factors, as well as theory-driven, practically-oriented ethical principles.

Therefore obtaining specialist advice is a necessary preliminary step in designing a consent and assent strategy, as well as being a longitudinal activity that should accompany the whole consent process. An appreciation of the social and cultural context is crucial in developing culturally sensitive intervention strategies, especially in non-Western settings.

Interdisciplinary collaborations between epidemiology and anthropology have resulted in a new field: cultural epidemiology, being developed. This acknowledges the importance of both etic and emic knowledge in public health work. The terms emic and etic indicate the two perspectives that can be employed in the study of a society's cultural system: the point of view of either the insider (emic), or the outsider (etic). The etic perspective is derived from the concepts and categories that have meaning for the (western) scientific perspective and body of knowledge. The emic perspective focuses on the intrinsic cultural distinctions that are meaningful to the members of a given society. For instance applying an etic perspective to the question of what health is, and what leads to health problems will reveal that these can be culturally defined. In some regions, Gods, spirits and ancestors are a part of a medical dialogue; according to the Yorùbá beliefs, spirits are part of moral conduct with spiritual beings in this moral theory having a role similar to those of the lawmakers of most democratic societies.³²⁵ Therefore, if one does not pay adequate attention to the role of the spiritual realm in the practice of medicine in Yorùbá society, some aspects of medical ethics in that context cannot be understood. Cultural epidemiology has a methodological framework of qualitative and quantitative approaches, it prioritizes researching the nature and distribution of an illness as experienced from an emic point of view in contrast to the etic nature of epidemiology. The interfaces between the emic and etic knowledge generated by cultural epidemiology and the normative and reflective discipline of ethics can be found in the

³²⁵ Kola Abimbola, *West Africa Review* (2001) *Spirituality And Applied Ethics: An African Perspective.* *West Africa Review.*"

branch of ethics called “descriptive ethics”: the field in which empirical data about moral issues are gathered, such as information on the morals, the norms of the actors in a situation.³²⁶ What should be avoided however (in order to preserve the normative nature of ethical reflections) is that ethics analysis derives value judgments from observing what is actually done.³²⁷

7.2.3 Identifying the Appropriate Role of ‘Community’

The analysis and reflection on the Texts has shown that ‘community’ can play various roles in various informed consent and assent situations and models: the dual community assent and individual consent MIICCA model; community process as surrogate or a condition for waiver of individual consent, and some form of community representatives in a consultative capacity. These various processes can make a contribution towards the complex web of responsibilities to protect, respect, inform and involve. Showing respect can be expressed in various ways, including granting a community veto rights to assent or dissent; informing a community, or by involving or consulting a community. Particular attention is needed to involve the community if the intervention originates outside that community or even outside the country in which the community is located.³²⁸ These points tie in with the accepted norm of development ethics that developed country agents must act in a collaborative, capability building manner with host countries. There are also solid practical reasons to involve communities: it is asserted that the comprehension of informed consent is enhanced when researchers provide the study community or individuals with information prior to obtaining consent, and when study communities are engaged in discussions about the research through meetings with local leaders or public forums.³²⁹ Also a “community engagement

³²⁶ Pascal Borry et al., “The Birth of the Empirical Turn in Bioethics,” *Bioethics* vol. 19, Number 1, (2005): 49–71, 60.

³²⁷ *Ibid.*

³²⁸ CIOMS, *International Ethical Guidelines for Epidemiological Studies* 2009: 33-35, 40-44.

³²⁹ Patricia A Marshal, “Informed Consent in International Research,” *Journal of Empirical Research on Human Research* (2006) Volume 1 (1): 27-29.

approach will help ease whatever tension that may arise in the conduct of research in local communities.³³⁰

Therefore, for all the principle-based and practical reasons mentioned above, the preliminary stage building blocks should include the step of consulting and involving the community. This step should also be a longitudinal activity that accompanies the whole consent and assent process.

7.2.4 Repercussions of Resource Limitation for Consent and Assent Processes

Economic weakness results in limited access to health care and undermines public health infrastructures. This affects informed consent in a number of ways, and on a number of levels. One particular condition that transcultural interventions are required to comply with when working in resource impoverished settings is that every effort must be made to ensure that the intervention is responsive to the health needs and the priorities of those who will be involved, and that benefits will be made reasonably available to the population or community.³³¹ This stipulation has been stimulated by the need to prevent the exploitation of impoverished populations, and opens-up the need to see the assent and consent processes as being as an integral part of the whole intervention, with this process being extended to also include post intervention follow-up activities of controlling that knowledge transfer and benefit sharing is occurring.

Another interface of resource limitation with consent and assent is illustrated by the standard of care debate (see Annex VIII). This debate illustrates the ethical questions that arise in developing countries as to whether economic weakness can justify, or even necessitates, varying substantive or procedural ethical principles. The standard of care debate provides a paradigm on which to address the analogue question if working in a disadvantaged community allows or even requires the alteration of consent and assent substantive and procedural principles?

³³⁰ Christopher Agulanna, "The Requirement of Informed Consent in Research Ethics: Procedure for Implementing a Crucial Ethical Norm in African Communal Culture," *European Journal of Scientific Research* Vol.44 No.2 (2010):204-219, 217.

³³¹ CIOMS, *International Ethical Guidelines for Epidemiological Studies* 2009: 23-33.

7.2.5 Risk in Public Health Context: Questioning the Research – Practice Dichotomy

The need to assess, evaluate and communicate the risk of an intervention arises at various stages in the ‘development → testing → application → monitoring’ life cycle of medical and public health interventions. The results of risk assessments determine what regulatory, professional and legal controls must be exercised, and more fundamentally, if an intervention can be commenced, continued, or must be dropped. What however is the meaning of ‘risk’? Risk is a multidimensional concept. The risk of an event can be assessed and measured in terms of the probability of the event occurring, multiplied by the severity of its harmful impact for individuals or a community. A third factor in calculating ‘risk’ is the level of vulnerability of the target community to the negative impacts of an event.³³² In addition to this mathematical view of risk, a ‘social construct view’ exists in which ‘risk’ is seen as being a perception framed by inbuilt personal (or community) biases, and by social, cultural conventions and norms. Factors that influence risk perception include the degree to which a risk is familiar or unknown, how the risk is presented, and whether the risk is seen as being voluntarily entered into or as being imposed.³³³

An important approach to deciding when and what kind of risk assessment is required is according to whether an intervention is classified as being research or non research. This classification has repercussions regarding the stringency of the laws, codes and norms that must be applied, particularly as review board approval is generally only needed for a research project. In view of the importance of the differentiation, the meaning behind the terms research and non research (practice) will now be illuminated. Research in its various forms has been a valued endeavour that has brought benefits, and arguably also harms. Although research is not a homogenous activity, what all forms of research have in common is the aim of producing generalizable knowledge by testing, exploring or generating new, unproven activities, substances or measures. Because research on humans involves undertaking unproven, unknown measures, it inherently involves uncertainty and some elements of (measurable) risk for the participants: “however noble an investigator’s intentions

³³² Charles Weijer, “The Ethical Analysis of Risks and Potential Benefits in Human Subjects Research: History, Theory, and Implications for U.S. Regulation,” in: *Ethical and Policy Issues in Research Involving Human Participants. Volume II National Bioethics Advisory Commission 2002*: 1-10.

³³³ The Nuffield Council on Bioethics, *Public health: ethical issues*, 2007: 34.

may be, the uncertainties that are inherent in any research study raise the prospect of harms that may be difficult to fully anticipate.³³⁴ This inherent uncertainty and risk of harm for participants explains why a main focus of research ethics is ensuring that in placing some people at a risk of harm for the good of others, research subjects are treated with respect.³³⁵ 'Practice' can be defined as interventions that are undertaken with a high level of expectation that they will enhance the well-being of an individual or community. The reason for this expectation of success is that the intervention is a standard, proven measure that has already passed through testing and regulatory approval procedures including ethical reviews. Once an intervention has become a standard practice, it is largely freed from further formal ethics and regulatory approvals. Further quality assurance may come from the professional ethos and codes of those involved in the practice, and by the education and training they will have received, although this may well not be adequate according to some commentators.³³⁶ However although the practice of medicine involves less uncertainty compared to research, it can still however involve considerable (calculable) risk.

Regarding risk in public health and its categorization according to the research-practice dichotomy, the CIOMS epidemiology guidelines suggest that epidemiologists need to apply careful judgment to determine whether the activity should be classified as research or practice. It does not necessarily follow that all research is problematic and requires stringent controls such as complex informed consent, or that all practice is low risk. Some activities that are routinely carried out by epidemiologists raise ethical issues "that may benefit from careful scrutiny or even reconsideration, even if they have long traditions and are sanctioned by regulations or statutes."³³⁷ The risks in public health practice with its preventive, population focus are less immediate, possibly more elusive compared to clinical research and practice. Risks occur in public health transcultural interventions on the individual, community and population level; 'risks' can also occur in all the dimensions of health: mental, physical and social. What is seen as a risk can vary according to cultural context. To this list

³³⁴ NBAC, *Ethical and Policy Issues in Research Involving Human Participants*. Report and Recommendations of the National Bioethics Advisory Commission, 2001, Volume 1: 2.

³³⁵ J Ezekiel et al., "What Makes Clinical Research Ethical?" *JAMA*, May 24/31, 2000, Vol. 283, No. 20: 2701-2703.

³³⁶ Daniel Callahan et al., "Public Health: Forging a Strong Relationship," *American Journal of Public Health*, February 2002, Vol. 92, No. 2: 1747.

³³⁷ CIOMS, *International Ethical Guidelines for Epidemiological Studies* 2009: 15.

of risk categories should perhaps be added economic risk and ‘risks of principle’: the risks of non-adherence to ethical principles. One approach to identifying such immaterial ‘risks of principle’ is to look at the principles and rights that are applicable in a situation, and consider the chances that these rights and principles will be infringed by an intervention, and what harms could result there from. One example is the “dignitary harm” that can arise if informed consent is not sought.³³⁸ This idea is reflected in the human rights impact assessment (HRIA) concept. HRIA comprises a process of locating and analyzing the potential consequences of a proposed policy, program or project on the enjoyment of human rights.³³⁹

The hypothesis is proposed that the relationship research-practice in public health transcultural interventions is a continuum rather than a black-and-white dichotomy. The research – practice schema is not solely adequate or reliable in identifying the necessary stringency of protective, approval and control measures in public health interventions. The nature of public health interventions is that the activities will often be difficult to classify; they may well be a mixture of research and practice. Regarding for example vaccines, it is becoming more usual to use trials to also guide vaccine introduction, and to provide information to support the introduction of vaccines into public-health programmes.³⁴⁰ Thus rather than assessing the risk profile of an intervention according to a black and white dichotomy of research – practice, a case-by- case, nuanced approach should be taken to avoid both problems of over-regulation and control, and of under-regulation and arbitrary application.³⁴¹

³³⁸ The concept of ‘dignitary harm’ is found inter alia in ICH GCP 1.31 Institutional Review Board (IRB).

³³⁹ See the human rights impact resource centre website at: <http://www.humanrightsimpact.org/hria-guide/overview/>.

³⁴⁰ Jacqueline L. Deen, John D. Clemens, “Issues in the design and implementation of vaccine trials in less developed countries,” *Nature Reviews Drug Discovery* 5:11: 932-940.

³⁴¹ Steven S. Coughlin, “Ethical issues in epidemiologic research and public health practice,” *Emerg Themes Epidemiol.* 2006; 3, 3, 16: 4.

7.2.6 Communication Strategy

A communication strategy should be developed before starting an intervention. This should take into account the linguistic and cultural setting in order to develop appropriate ways to communicate the information that is necessary for adherence to the standards required in the informed consent process. In settings where concepts of respect for the family and community are important, one way of informing individuals might be through more open communal discussion, followed by consultation with family units including women members, although these processes require time and extensive local knowledge.³⁴² In some settings individuals may not feel comfortable in a one-to-one dialogue, preferring to discuss and ask questions within a meeting of the local community.³⁴³ The question is that if a community approach is taken to communicating information, is it realistic to still talk of an individual consent being sought and granted?

7.2.7 Preparing the Submission to Research Ethics Committees

The primary responsibility of ethics review committees is to review research projects in order to safeguard that the research protocol evidences that the rights, safety, and well-being of the research subjects will be protected and respected.³⁴⁴ The importance of independent ethics review can be attributable to past and continuing problems with research suggesting that not all decisions can be left solely to the researchers, and that an independent review process is necessary to oversee the management and “balancing of risks and benefits to individuals and research communities.”³⁴⁵ Another purpose of reviewing research protocols in addition to ensuring adherence to ethical standards is to also ensure that the research meets internationally acceptable scientific standards; it would be unethical for poorly designed research involving human beings to be approved and undertaken because individuals and

³⁴² Nuffield Council on Bioethics. “*The Ethics of Research Related to Healthcare in Developing Countries*,” 74.

³⁴³ Ibid. 6.

³⁴⁴ CIOMS, *International Ethical Guidelines for Epidemiological Studies*, 2009: 27-28.

³⁴⁵ Richard Cash et al. (eds.), *Casebook on Ethical Issues in International Health Research*. (Geneva: World Health Organization, 2009): 40.

communities would then to be subjected to uncertainty and risk without an expectation of benefit.³⁴⁶ The substantive principles that research ethics committees (RECs) should follow are generally held to be those found in major prescriptive document, e.g. respect for persons, beneficence and justice.³⁴⁷

It is not always clear if epidemiological and public health activities should be subjected to REC review and approval because many public health interventions are a mixture of research and practice, and due to many activities being undertaken by the government. The CIOMS epidemiological guidelines recommend that when the research team are in doubt about whether a study warrants ethical review, they should consult the appropriate committee. Even when an exemption is claimed, the research protocol should provide justification for the claimed exemption.³⁴⁸ Regarding the content of a review, this should include scrutinizing the proposed informed consent documents and procedures; the WHO Operational Guidelines For Ethics Committees that Review Biomedical Research suggest that the following information regarding the informed consent process be submitted and considered by REC: a full description of the process; details of the written and oral information that will be provided; the provisions made for receiving and responding to queries and complaints that arise during the course of a project; information on community considerations, e.g. the impact and relevance of the research for the involved community; the steps taken to consult with the concerned communities whilst designing the research; the influence of the community on the consent of individuals; any proposed community consultation during the course of the research, and the extent to which the research contributes to capacity building.³⁴⁹ The composition of RECs should include persons who are thoroughly familiar with the customs and traditions of the population or community concerned and who can thus be sensitive to issues of human dignity.³⁵⁰ Including representatives of the population that will be targeted and affected by the proposed research would also be optimal

³⁴⁶ CIOMS, *International Ethical Guidelines for Epidemiological Studies*, 2009: 27-28.

³⁴⁷ See general comments on the WHO website on the principles that the WHO applies when making its own reviews at: http://www.who.int/rpc/research_ethics/en/index.html.

³⁴⁸ CIOMS, *International Ethical Guidelines for Epidemiological Studies* 2009: 28.

³⁴⁹ WHO, *The WHO Operational Guidelines For Ethics Committees That Review Biomedical Research*, (WHO Geneva 2000): 7-9.

³⁵⁰ CIOMS, *International Ethical Guidelines for Epidemiological Studies* 2009: 29-30.

to show respect for the culture and the dignity and self-reliance of the community, and to assist achieving community members understanding of the study.³⁵¹

There are various opinions regarding which RECs should review a multi-centre project although most normative texts suggest that ethical committees from all countries involved should make a review. Some guidelines suggest that the external and host committees should each have special responsibilities. Committees in the host country would for example focus due to their local knowledge on controlling if the objectives of the research are responsive to their health needs and priorities, and considering the acceptability of the proposed means of obtaining informed consent, including inducement strategies in the light of a community's gift-exchange and other customs and traditions.³⁵²

Do all countries have the necessary facilities and resources to undertake such work? Committees may be ineffective for a variety of reasons, including a lack of financial and human resources, and a lack of training and experience.^{353, 354} Concerns have been raised that the role of such ethical review boards in developing countries may fall short of promoting high ethical standards for human subject research, as they are poorly funded and lack properly trained staff.³⁵⁵ Research conducted in 2007 showed improvement in the number of institutions that have RECs in sub Saharan Africa, but that training and resources shortages still exist and that committees may not be functioning independently. Research published in 2004 conducted with health researchers in developing countries reports that forty four per cent of the respondents reported that their studies did not undergo any review (technical,

³⁵¹ Ibid.

³⁵² Ibid. 34.

³⁵³ Nuffield Council on Bioethics. "*The Ethics of Research Related to Healthcare in Developing Countries*," 2002: 103-107.

³⁵⁴ There are a number of initiatives working internationally on issues ensuring and strengthening competent and independent reviews of research. One such is the European and Developing Countries Clinical Trials Partnership EDCPT, that has African populations and research communities in mind as the major beneficiaries UNESCO has initiated a program to support the establishment and operations of bioethics committees (ABC project – Assisting Bioethics Committees). Other projects are : the African Malaria Network Trust (AMANET), FERCAP, and the South African Research Ethics Training Initiative (SARETI).

³⁵⁵ A. A. Hyder et al., "Ethical review of health research: a perspective from developing country researchers," *J. Med. Ethics* 2004; 30: 68-72, 69-70.

scientific, or ethical) by a Ministry of Health in the developing country where the research was conducted.³⁵⁶ One issue can be that the regulatory authorities are weak, resulting in ethics committees often having to fill the role of local regulators.³⁵⁷ Yet the work of building local ethical committees is vital.³⁵⁸ A number of programmes are being established to develop expertise in the field of medical ethics and/or conducting ethical review in developing countries. The World Health Organization (WHO) Regional Committee for Africa, in 1998, passed a resolution (AFR/RC48/R4) which urged its member states in the region to develop national research policies. The conclusions to be drawn from these comments is that in spite of their important role, ethics review committees in developing, transitional and developed countries may be limited in their ability to meet these expectations. This raises the question whether this reality should be acknowledged and reflected in the design of quality assurance aspects of an intervention including assent and consent process design? Another question is that accepting that “the role of RECs is to act as guardians of the dignity of research subjects, who is acting as advocate for the community and for the good of society when evaluating public health interventions?

7.2.8 Model for Preliminary Stage Activities in Consent and Assent Processes

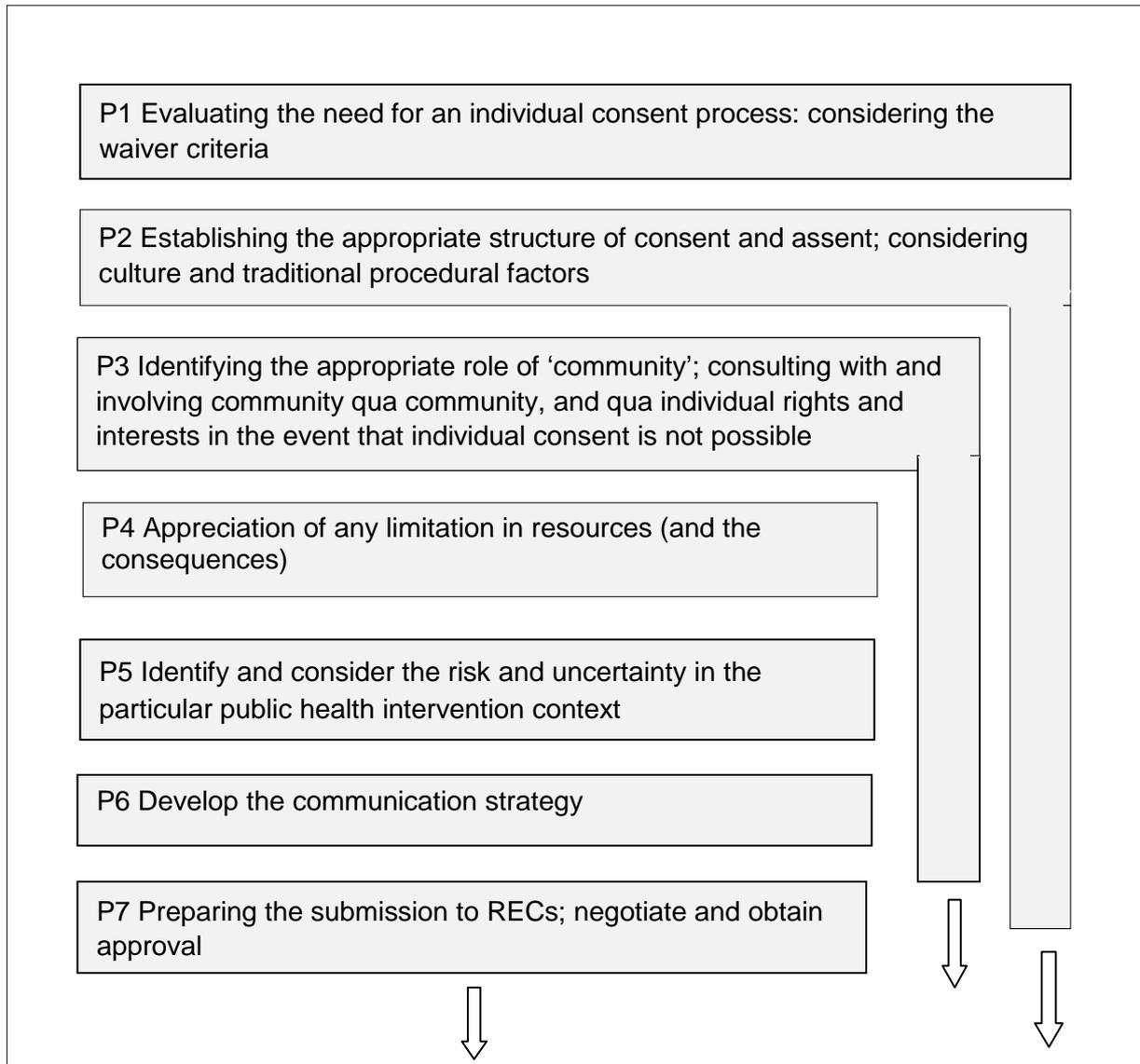
The model that results from the reflections above is shown in Figure 10 below, with the preliminary stage 2 and 3 being longitudinal activities that accompany the whole process.

³⁵⁶ Irene Kuepfer, Christian Burri, “Reflections on clinical research in sub-Saharan Africa,” *International Journal for Parasitology*,” 39 (2009): 947-954, 949-950.

³⁵⁷ Ibid.

³⁵⁸ EGE European Group on Ethics in Science, *Ethical aspects of clinical research in developing countries*, Opinion No.17, 04/02/2003.

Figure 10: Preliminary Stage Investigations: Building Blocks



7.3 Operationalizing Individual Informed Consent in Public Health

Noting that there is a lack of work that specifically addresses public health, the next step as a preparation for designing a transcultural individual consent process is to consider the existing models that operationalize the individual informed consent processes in medical contexts.

These existing models will then be expanded to better fit public health in a variety of MIICCA stage 2 contexts. One representative model is Beauchamp and Childress' model of an

informed consent process first developed in 1979 for use in the medical field. This focuses on the patient-physician relationship, viewing the informed consent process as a benchmarking model of autonomous choice, not merely a legalistic obligation concerning the authorization by an individual of a professional's intended actions.³⁵⁹ The model centres around three topics that each contains various elements:

Figure 11: Beauchamp and Childress Model of Informed Consent³⁶⁰

I. Threshold Elements, preconditions being:

1. Possessing the competence to understand and decide
2. Voluntariness in deciding

II. Information Elements such as:

3. Disclosure and clarification of medical facts: in cases of therapeutic research or the practice of medicine: information on current health status, diagnosis, prognosis
4. Recommendation by the professional of a plan of action (this element not however being appropriate in research)
5. Understanding: ensuring that the disclosure and recommendation have been understood

III. Consent Elements:

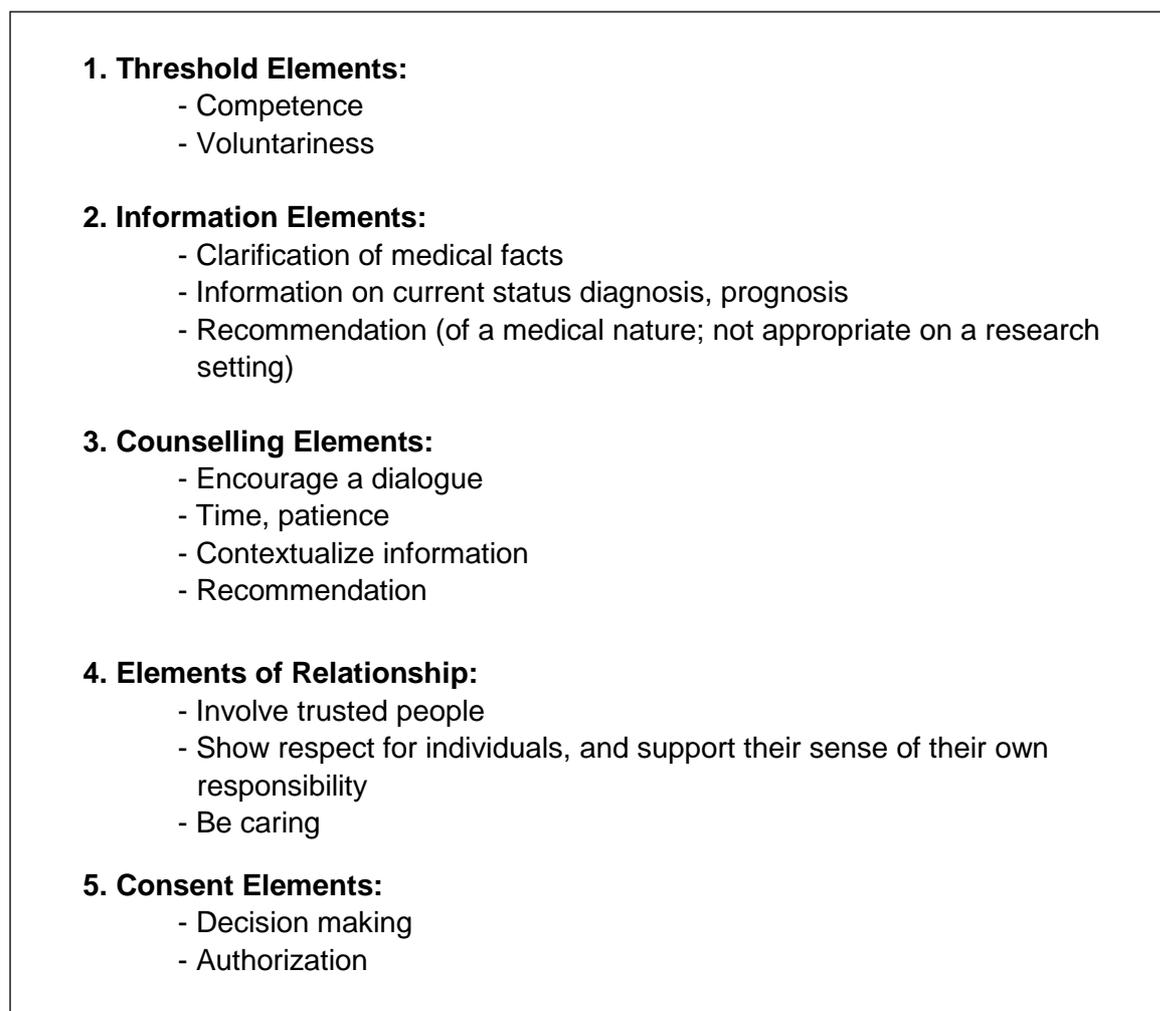
6. Decision making (in favour of or against a recommendation)
7. Authorization

³⁵⁹ T L Beauchamp, J F Childress, *Principles of Biomedical Ethics*, 5th edn. (Oxford: Oxford University Press, 2001): 79-80.

³⁶⁰ Ibid.

A more sophisticated model is found in “The Enriched Model”³⁶¹ (see Figure 12).

Figure 12: Enriched Model of Informed Consent³⁶²



The enriched model was developed with the health care practice end-of-life decisions in mind, but provides a basis for other medical and public health situations.^{363, 364} It has a

³⁶¹ Stella Reiter-Theil, "Ethische Aspekte der Patienten-Verfügung. Eine Chance zur Gestaltung des Sterbens," *Forum Deutsche Krebsgesellschaft*, 1998, 13: 262-268.

³⁶² Ibid.

³⁶³ Ibid.

strong focus on process and communication, as taking a procedural ethics approach to informed consent is paramount as it is only by following an appropriate process that the outcome – be it consent or dissent – can be genuinely informed and considered. It is the process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention.”³⁶⁵

7.4 MIICCA Stage 2: Enriched Public Health Model of Informed Consent

A model for individual consent will now be developed that account for: a) public health, and b) different cultural, political and economic contexts. This is primarily intended to provide a basis for MIICCA stage 2, but should also be applicable to other individual consent processes in public health interventions such as surrogate assent given on behalf of individuals if it is impossible to pursue consent. Thus the below should be seen as comprising building blocks that cover the themes and activities that may be relevant for different situations. The model will draw on the existing models outlined above and the contents of the Texts outlined in Chapter 5, especially the core set of minimal steps identified that contain: the threshold elements of assuring the competence and voluntariness; providing the information that is necessary and adequate in culturally and context appropriate ways, and in a form and language understandable for the targeted individuals; the aspirational goal of securing understanding, and finally conducting a culturally appropriate consent process and documenting in a culturally appropriate way.

However, are all the steps outlined in the Figures 11 and 12 processes that were designed for a medical context applicable to consent in public health, international interventions; should some elements be disregarded to avoid unnecessary bureaucracy, or should others be added? The counselling element is suggested as not being relevant for the population, non-therapeutic, preventive public health, and will be removed from the public health model. The terminology of ‘counselling’ in a transcultural context is also problematic: is an external party authorized to “counsel” in a local environment? The ‘recommendation’ step that both

³⁶⁴ Stella Reiter-Theil, Nicola Stingelin Giles, Ethical Aspects of Screening and Preventive Diagnosis with Radiological Imaging. In: *Reiser M. F. et al. (eds.) Screening and Preventive Diagnosis with Radiological Imaging* (Berlin: Springer 2007): 137-146.

³⁶⁵ American Medical Association Website Patient Physician Relationship Topics: Informed Consent.

the Beauchamp and Childress and Reiter-Theil models refer to (that is not relevant in research), will also not be included.

7.4.1 Threshold Elements Voluntariness and Competence

The characteristics of an individual necessary for them to be able to take an informed binding decision to consent or dissent to a proposition are voluntariness and competence. These characteristics should be established at the start and throughout a consent process.³⁶⁶

Judgements regarding whether an individual has decision making competence are complex and have been the subject of considerable discussion. What defines 'competence'; should the standard of competence be the same regarding all types of intervention; should the standard vary according to the risk involved in a particular intervention?³⁶⁷

There are varying degrees and forms of impairment: fluctuating, prospective, limited, and a complete limitation.³⁶⁸ Researchers and health practitioners should be sensitive to the differing levels of competency, and assessment methods tailored to the specific situation.³⁶⁹ Individuals in a wide variety of situations may have impaired decision making competency; age is just one – although an important – possible determinant of competency. Being disadvantaged need not impede competency. Illness can permanently or temporarily impair competence. The factors that affect the competency to take a decision at a moment in time are manifold. For example, impairment may occur at times of great stress but can then be relieved. Impaired competency can result from neurologic, psychiatric, or substance abuse; conversely, individuals with such problems should not be presumed to be (permanently) decisionally impaired.

One set of criteria or abilities coming from Switzerland that helps assess decision making competency is the following:

³⁶⁶ T L Beauchamp, J F Childress, *Principles of Biomedical Ethics*, 5th edn. (Oxford: Oxford University Press, 2001): 93.

³⁶⁷ Ibid. 75.

³⁶⁸ Ibid.

³⁶⁹ National Bioethics Advisory Commission (NBCA). *Research Involving Persons with Mental Disorders That May Affect Decision-making Capacity: Report and Recommendations of the National Bioethics Advisory Commission* (Rockville, MD: NBAC, 1998, Vol. 1): 51-60.

- The competence to understand information in relation to the decision that is to be taken.
- The competence to be able to appropriately weigh-up a situation and the consequences that would arise from alternative courses of action.
- The competence to rationally weigh-up and place information that is given in the context of a coherent value system.
- The competence to express an own decision.³⁷⁰

Flowing from these reflections is the important question whether individuals have a positive right to have their capability for autonomous decision making furthered, or just a negative right not to have it neglected or damaged? Do public health professionals have a duty to improve and nurture capabilities; would such an idealistic position be feasible or have a purely idealistic role, with their non-attainment being without sanction? To conclude, there is a growing acknowledgement that the characteristic of competency cannot be judged by applying an absolute black-white schema. Competency is a complex, thick concept. Just as 'competency' in young people gradually and individually develops, so can competency according to a number of determinants decline, improve or become irregular.

To turn now to the threshold element voluntariness: Beauchamp and Childress echo Kant's understanding of autonomy by defining a voluntary act in informed consent according to the degree that he or she "wills the action without being under the control of another's influence." What counts as 'influence' includes persuasion, manipulation and coercion.³⁷¹ A person is coerced when choices are unfavourably narrowed by someone who is trying to get him or her to do something he or she would not otherwise do.³⁷² Coercion and manipulation in a consent process are not acceptable; persuasion can arguably be justified when dealing with fully informed competent individuals. Voluntary participation depends, in part, upon an

³⁷⁰ Swiss Academy of Medical Science Guidelines: Care of Patients at the End of Life, 2004. URL: www.samw.ch: 4.

³⁷¹ T L Beauchamp, J F Childress, *Principles of Biomedical Ethics*, 5th edn. (Oxford: Oxford University Press, 2001): 93, 94.

³⁷² Jeniffer Hawkins et al., "Clarifying confusions about coercion." *The Hastings Center Report*, Sept – Oct (2005):16-19, 17.

accurate understanding not only of the purpose of the study, but also of the possibility to withdraw from a study without repercussion.

Some aspects of voluntariness are influenced when conducting consent processes in economically deprived health systems. Factors such as limited access to health care resources can reduce the meaning of concepts of freedom of choice, and therefore voluntariness, and result in the therapeutic misconception. This occurs when people who have limited access to health care misinterpret an invitation to participate in research as an opportunity to receive medical care.³⁷³ This is especially problematic if adults are asked to give consent for dependents. This problem is illustrated in the law suits against Pfizer that resulted from Pfizer conducting a drug trial in Nigeria in 1996 during an epidemic of bacterial meningitis. Pfizer tested an experimental antibiotic drug TROVAN® on children, without it would appear the necessary authorization and consent procedures being fully completed. The Text of one of the law suits reads that the families involved in the trial understood that Pfizer “was providing their children with volunteer relief, not that their children were ‘being volunteered’ to help Pfizer.”³⁷⁴

Another problem with voluntariness that results from economic weakness is how to differentiate between reasonable reimbursement and unreasonable incentives to participate in research. It is difficult to judge the point where inducements become inappropriate, although the payment of reasonable expenses incurred or remuneration for loss of earnings is acceptable (and may even be necessary in developing countries). One guideline is to apply the principle of proportionality, meaning that inducements must be in proportion to the risks and costs to the participant appropriate to the local context.³⁷⁵

A final issue that can impair voluntariness is the situation where a prior assent of a community leader has occurred. Are individuals really free thereafter to decide to participate or desist, or does an explicit or implicit unreasonable pressure (or even coercion) exist, and if so, how relevant is this for the validity of the informed consent process?

³⁷³ Steven S Coughlin, “Ethical issues in epidemiologic research and public health practice, *Emerging Themes in Epidemiology*, 2006; 3, 3,16: 2.

³⁷⁴ New York Times, August 30, 2001, Families Sue Pfizer on Test Of Antibiotic, Tamar Lewin.

³⁷⁵ Nuffield Council on Bioethics, “*The Ethics of Research Related to Healthcare in Developing Countries*,” 2002: 78-79.

7.4.2 Providing Information: Balancing Sufficiency and Overload

If competence and voluntariness can be established, the next element in a valid consent process is that there must be an adequate clarification and disclosure of the facts relevant to the decision, and at least an adequate understanding of what has been disclosed. Disclosure is central to informed consent, reflecting concepts of the 'inviolability of persons' and "the power of thought and the mental component of humanness that should be protected."³⁷⁶

Many laws, guidelines and codes give lists of the information that should be supplied in an individual consent process. Annex V shows one such list with 26 items taken from the CIOMS guidelines. This states, however, that according to the specifics of the study design, the investigator can try to justify to the ethical review committee why a particular item from the list of necessary information will be omitted from the consent process. An important item on most lists of information to be given is the risk for the individual. The hypothesis should be recalled that the risk of a public health intervention needs a case-by-case assessment.

Although international guidelines for informed consent require that all potential risks must be disclosed to individuals, the application of this standard for culturally diverse communities may be challenging for both researchers and participants.³⁷⁷ What is seen as a risk may also vary according to cultural context. Although the lists omit information on the community level, should not individuals be informed of risks on both an individual and community public health level, and of the repercussion of an individual's decision for the community (positive and negative)? Should the harm that needs to be communicated include not only damage to physical health but also immaterial harm such as principles and negative rights being infringed such as freedom from discrimination, freedom from interference with individual autonomy, and the right to participation, privacy and information? It was commented in Section 6.9 above that consent processes are sometimes criticised for being overly legalistic and bureaucratic, resulting in unnecessary complications and delays.³⁷⁸ RECs and sponsors often request that complex lists of the information be followed that lead to long, detailed and

³⁷⁶ Alexander Capron, "Informed Consent in Catastrophic Disease Research and Treatment," *Pennsylvania Law Review*, 1974 Dec; 123(2):340-438, 366.

³⁷⁷ Patricia A. Marshall, "Informed Consent in International Research," *Journal of Empirical Research on Human Research* (2006) Volume 1 (1): 27-28.

³⁷⁸ Michael M. Burgess, "Proposing modesty for informed consent," *Social Science & Medicine*, 65 (2007): 2284-2295, 2285-2289.

arguably “overly legalistic” consent forms that are intimidating difficult to understand.³⁷⁹ In unravelling this criticism, two functions of informed consent can be identified: the *formalistic*, *legalistic*, and the *philosophical*. The *formalistic* function refers to the aspects of informed consent such as ensuring that they have legal effect, e.g. to reduce the liability of those responsible for an intervention. The *philosophical* refers to the principles such as respect for persons, protecting the vulnerable, the dignity of the individual, and duties to respect diversity. A problem can be seen in the expansion of informed consent away from the implementation of substantive principles towards the role of informed consent being to fulfil formalistic legal requirements. The overloading of the informed consent process makes it counterproductive as a means to protect rights and interests,³⁸⁰ with the over-legalization reducing the process to an overwhelming recitation of a list of facts that may hinder rather than support an informed decision.³⁸¹ The legal issues of liability are not here being suggested as being without substance. However packaging them together with a concept that has its roots in the Nuremburg process and civil rights movements is questionable.

One issue that need special attention in multicultural interventions is that in some settings it is customary to withhold information. For instance clinicians often provide diagnoses (as well as prognoses) of cancer or other serious conditions to family members, but they withhold such information from patients. As a result, the patient's consent to certain procedures, if sought, may not be fully informed.³⁸² Nigerian researchers for instance have identified that consent documents attached to certain research protocols included information that potential participants might find extraneous, irrelevant, or culturally inappropriate. In some cultures communicating the possibility of harm is vital; according to other cultural norms, disclosing all

³⁷⁹ Patricia A Marshal, “Informed Consent in International Research,” *Journal of Empirical Research on Human Research* (2006) Volume1 (1): 33.

³⁸⁰ Alan Buchanan, “Assuring Adequate Protections in International Health Research: A Principled Justification and Practical Recommendations for the Role of Community Oversight.” *Public Health Ethics*, Vol, Number 3 (2008): 246-257, 248.

³⁸¹ T L Beauchamp, J F Childress, *Principles of Biomedical Ethics*, 5th edn. (Oxford: Oxford University Press, 2001): 79.

³⁸² N Kass, A A Hyder, Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries in *National Bioethics Advisory Commission; 2001*. Attitudes and experiences of U.S. and developing country investigators regarding U.S. human subjects regulations; pp. B1–B189 :10-11, 17.

possible risks is held as being unnecessarily alarmist. Must rules of complete disclosure be adhered to? The conclusion often reached is that cultural norms do not justify deviation from the substantive ethical standard of informed consent. Enrolling individuals in research who are not given the opportunity to understand such important information represents a deviation from the substantive ethical standard of disclosure required for adequate informed consent, and should not be condoned.³⁸³

Once agreement has been reached on what information should be communicated, the communication strategy developed in the preliminary stage can be implemented. Depending on the intervention and context, a written or spoken communication or a mixture of both may be appropriate. If information is spoken, giving a take-home figurative or written leaflet is often recommended. Culturally appropriate ways of disclosing information about the research should be found.³⁸⁴ Language issues can complicate the communication; the information may need to be contextualized by intercultural experts. Problems can arise with understanding unfamiliar concepts as the belief system of potential research participants may not explain health and disease using the concepts and terms of modern medical science and technology. Therefore requirements of particular relevance to externally-sponsored research conducted in developing countries include the need to ensure that participants be provided with information about the study using terms that they can understand.³⁸⁵

Although the obligation to disclose information that is important for an individual is widely accepted, disclosure leads to further ethical reflection being necessary. The receipt of knowledge can bring benefits and burdens, particularly when linked with the expectation that the information will be absorbed and understood, and the right to autonomy exercised and a rational decision reached. How knowledge is dealt with will be a function of an individual's

³⁸³ NBAC National Bioethics Advisory Commission. *Ethical and Policy Issues in Research Involving Human Participants*. Report and Recommendations of the National Bioethics Advisory Commission, 2001.

³⁸⁴ Richard Cash et al. (eds.), *Casebook on Ethical Issues in International Health Research*. (Geneva: World Health Organization, 2009): 86.

³⁸⁵ Nuffield Council on Bioethics. "The Ethics of Research Related to Healthcare in Developing Countries," 2002: 70-75.

preferences, history, personal situation, and will also be influenced by their personal social network, and the wider 'ethical resources' in place in a society.³⁸⁶

The final information element is the question of the aspirational aim of controlling that the nature of the intervention and its consequences have been sufficiently understood, so that it is reasonable to speak of an informed consent or dissent. Concerns are often cited in the literature of the difficulty of achieving adequate understanding of the disclosed information. Describing risks and uncertainties may generate a sense of fear in communities that are unfamiliar with scientific and medical data, especially in developing countries. Studies have shown that participants in research too often do not have an 'adequate' understanding of the purpose of the research they are being asked to consent to, nor of its potential harms and benefits, and that the degree of understanding must be assessed.³⁸⁷ CIOMS and Nuffield states that the information must be conveyed (whether orally or in writing) in a language that suits the individual's level of understanding, avoiding a ritual recitation of a written document.³⁸⁸ What is a sufficient or adequate understanding? Should the aim of informed consent be to achieve a level of understanding of a 'reasonable person'? Might a realistic and appropriate level of understanding vary according to whether consent is being sought for participation in a research project, or a therapeutic intervention?³⁸⁹ Is a level that includes achieving understanding of the nature of the scientific rationale and procedure realistic? Studies have shown that motivations to join a study are often based on often misplaced expectations about the possibility of obtaining medical care or drugs or better medical care; many people participate in research for reasons that vary from those that researchers or ethics committees prioritise and find important, but that they should nonetheless be held as having exercised their right to autonomous decision making in a legitimate way.³⁹⁰ Is it

³⁸⁶ Stella Reiter-Theil, "The role of predictive medicine in adult health care. Ethical considerations." *Proceedings, "Conflicts of Interest - Ethics and Predictive Medicine"*, 20.-21.2.2003. (British Council, Berne): 22-29.

³⁸⁷ Richard Cash et al. (eds.), *Casebook on Ethical Issues in International Health Research* (Geneva: World Health Organization, 2009): 86.

³⁸⁸ CIOMS, *International Ethical Guidelines for Epidemiological Studies* 2009: 36.

³⁸⁹ T L Beauchamp, J F Childress, *Principles of Biomedical Ethics*, 5th edn. (Oxford: Oxford University Press, 2001): 88.

³⁹⁰ Mary Dixon-Woods, "Beyond 'misunderstanding': Written information and decisions about taking part in a genetic epidemiology study." *Social Science & Medicine* 65 (2007): 2212–2222, 2213.

possible that legitimate decisions can be made that do not require the full understanding of the scientific account of an intervention? Is it necessary that participants' accounts of their reasons and understanding be identical to the scientific/ ethical account in order for them to make a legitimate decision about participation?

An interesting approach is to differentiate between two aspects of understanding. First is the comprehension of essential technical or 'objective' information (although exactly what is 'essential' may be debatable). Second, is understanding the essential personal issues and implications of the intervention for the individual concerned.³⁹¹ In any event, what is important is avoiding misunderstanding of issues that if they were correctly 'understood' would have led to consent not being given. Oral or written "tests" to verify comprehension of the elements of informed consent are often recommended.³⁹²

To conclude, collaborators with local knowledge are required to ensure that information is provided to participants in a comprehensible manner, in a language that can be understood, that is pitched at an appropriate level of comprehension. Thus a longitudinal, process-accompanying element is introduced into the consent model to reach this aim. Resources will be needed to ensure that the informed consent or dissent is valid in the light of a particular cultural, educational, linguistic and cultural setting.³⁹³

7.4.3 Elements of Relationship

The element of relationship in public health has three perspectives, being firstly concerned with building-up a relationship with the individual who is involved in the consent process. The relationship that is to be offered (but not imposed in a culturally inappropriate way), should also last for the duration of the informed consent procedure. It cannot rely on cognitive information alone, but has to take into account other aspects of the individual's life situation.

³⁹¹ G. Lindegger, L.M. Richter, "HIV vaccine trials: critical issues in informed consent," *South African Journal of Science* 96, June 2000: 315-317.

³⁹² Patricia A Marshal, "Informed Consent in International Research," *Journal of Empirical Research on Human Research* (2006) Volume 1 (1): 29, 35.

³⁹³ CIOMS, *International Ethical Guidelines for Epidemiological Studies* 2009: 19.

The second perspective is to be aware of the one-to-one relationships that are important to the individual, and of the advisability of drawing trusted people into the process in a culturally appropriate way. To make this practical, consent needs to be seen as a process that takes place over several encounters.³⁹⁴ Thirdly, is that even when dealing with individual consent, when the context is one of: a) public health, and b) a cultural and set of traditions that may give the community a high priority, another element of relationship is that of communal ties that may need to be respected. Again, rather than being a one-time event, the element of relationship should be an accompanying longitudinal element that should last for all stages of the consent process. Furthermore, resources will need to be available to include these levees of consideration into a consent process.

7.4.4 Consent Elements

It is important to differentiate between the two elements of consent: the individual's decision making process (be it to consent or dissent), and the act of giving the appropriate authorization that reflects a positive decision. In spite of the importance given in the dual consent and assent model to community considerations and to traditions, all efforts should be taken to secure that the decision is freely and clearly given. Regarding the act of giving the appropriate authorization, researchers should consider carefully the need for verbal rather than or written consent, and any culturally appropriate strategies for witnessing consent. There are societies in which the formal act of signature does not exist; there are also political contexts where signing documents is associated with military oppression and dictatorship. Therefore, being asked to sign a document has negative connotations that stimulate mistrust.³⁹⁵ The question of the appropriate way of authorization and documentation in various cultural and linguistic settings needs to be examined with the help of local experts, and hopefully with support of the local ethical review committee (who may approve the waiver of some formalities such as signing a consent form if the intervention carries no more than minimal risk).

³⁹⁴ Patricia A Marshal, "Informed Consent in International Research," *Journal of Empirical Research on Human Research* (2006) Volume 1 (1): 34.

³⁹⁵ Nuffield Council on Bioethics, "*The Ethics of Research Related to Healthcare in Developing Countries*," 2002: 82.

7.4.5. Post Intervention Phase Responsibilities

The responsibilities involved in consent and assent in public health international contexts extend beyond the duration of an intervention. For instance the position of trust should be upheld with respect to issues such as continuing confidentiality of data and benefit sharing. Relationship building should continue over time, as should activities that contribute to local capability and capacity building. Such responsibilities have become important normative requirements of human development interventions.

7.4.6 Minimum Standards and Core Steps in Public Health Individual Consent

The ambitious aim is to draft a model that serves as a guide for planning a consent process that is based on minimum (obligatory) ethics principles, and that takes into account the particularities of public health in international contexts. Practitioners are often interested in having 'minimum ethics standards' in order to plan acceptable interventions; it seems reasonable that the field of practical ethics should enter into the necessary interdisciplinary work of providing these minimum standards. There are, however, difficulties in providing such a model due to the thinness of the available public health ethics frameworks regarding consent issues. The best that can be done for the moment is to look towards the 'common morality' as indicated by the Texts outlined in Chapter 5 to indicate what the minimum ethical standards are (with the 'common morality' being understood as being the set of norms or principles shared by all persons committed to the objectives of morality).³⁹⁶ The core set of minimal steps identified in Chapter 6 have in this chapter been slightly modified and specified to account for a public health, transcultural context; the set has been expanded by the addition of the elements of relationships taken from the Reiter-Theil model, with the relationship elements being widened to the consideration of culture and traditions that may give the community a high priority.

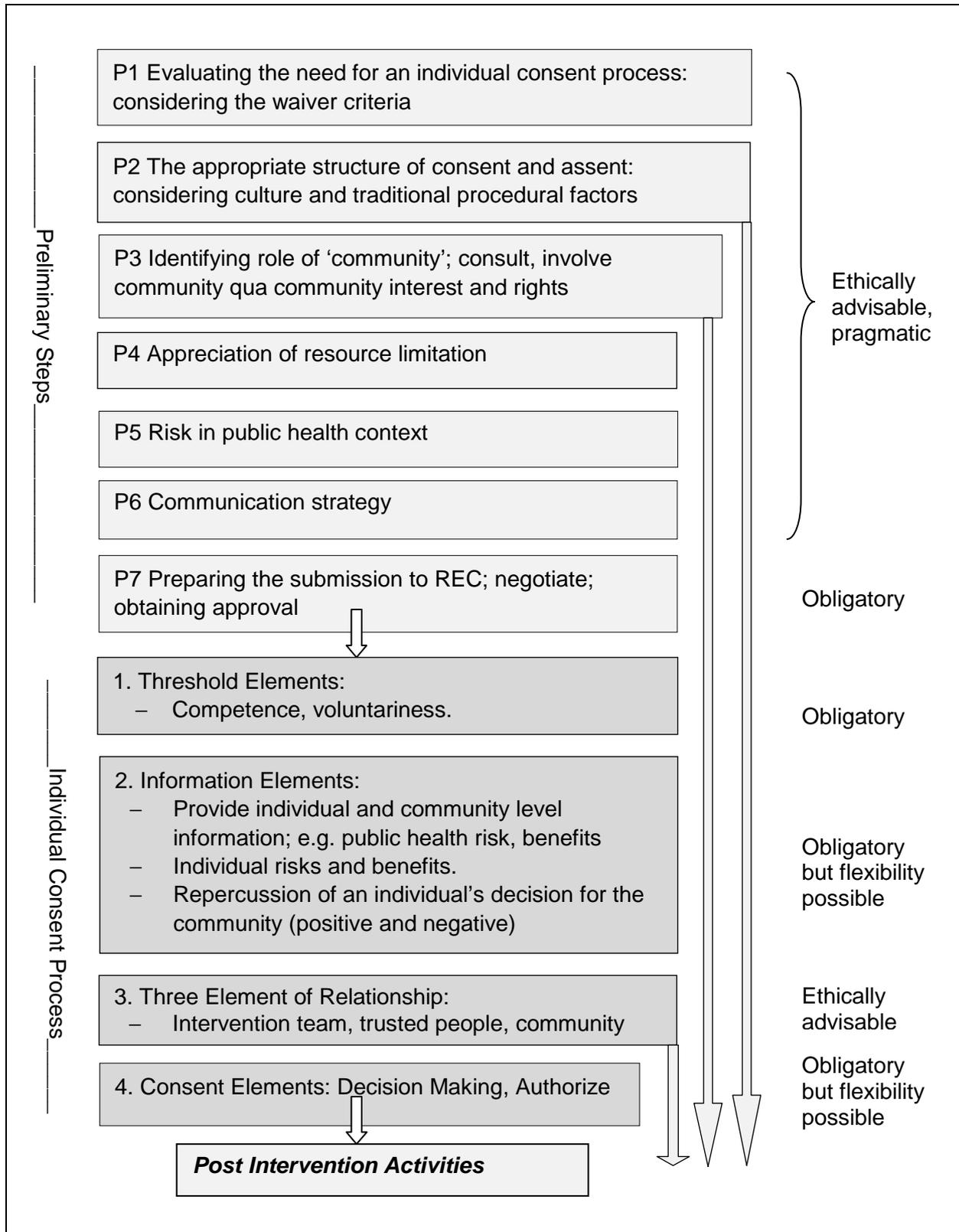
Based on all these reflection, a provisional model is now illustrated in Figure 13 that contains a column of comments on whether a particular element is ethically obligatory – a minimum requirement – or rather ethically or pragmatically advisable. The elements are also labelled

³⁹⁶ Tom L Beauchamp, "A Defence of the Common Morality," *Kennedy Institute of Ethics Journal*, - Volume 13, Number 3, September 2003: 259-274, 265.

to indicate if their interpretation and implementation is open (according to existing guidelines) to a degree of flexibility being exercised to take context and culture into account.

This MIICCA stage 2 has been enhanced by adding the preliminary steps, as well as noting that in a public health setting, the Information Elements need to include both individual and community level information; e.g. public health, community level risks and benefits, as well as (controversially) information on the repercussion of an individual's decision for the community (both positive and negative).

Figure 13: Model for Informed Consent in Public Health Interventions



7.5 Community Assent

7.5.1 Introduction

The Texts revealed that a 'community' has a range of roles to play in consent and assent processes. This section will deal with the situation in which a community leader may be required by tradition to give their assent to the intervention, and to give their agreement before individuals can be approached. The basis for MICCA community stage 1 is the principle of respecting diversity in the event that local traditions require that some kind of community assent be obtained before approaching individuals. The comments above should be recalled that assent given by a community leader does not necessarily mean that the basis for the leader consenting or dissenting are principles and arguments that intend primarily to protect or respect the community, i.e. the common good, or improvements in the health of the public, although this might be an aspirational way of seeing the role of community assent.

7.5.2 Threshold Elements

Whilst the issue of voluntariness of a community leader will rarely arise, establishing competency in the sense of legitimacy, as well as cognitive ability is problematic. A number of issues arise:

- a) Should a judgement be made if a leader, forum, or representative can legitimately grant or refuse assent on behalf of a community?
- b) Should limits be set on the power of a community leader to bind the members of the community – should they be able to accept or veto all kinds of interventions, whatever the consequences?
- c) Should conditions be set in order that community assent be valid, such as there being some form of legitimate political system in place (understood in the meaning of a western democracy), or would such a requirement render the principles of right to diversity, and the duty to respect cultural variation meaningless?
- d) Regarding cognitive abilities of the community leaders, should it be controlled that an individual is capable of rational thought and reflection, or would this be an elitist setting of a too high, unrealistic standard, and be particularly inappropriate in transcultural interventions?

Buchanan et al. comment that only decisions made according to the source of legitimate authority that are accepted by a community should be considered; one should (pragmatically) work within the existing system of power and authority at both the national and local levels in the host community.³⁹⁷

7.5.3 Element of Relationship

The quality of the relationship between the person acting on behalf of the (external) intervention who is requesting assent and the community representative will need special care and attention. Building a relationship of trust is at the centre of conducting a community assent process. Taking a wider perspective, working at the level of conducting community-wide public discussions can be an effective and culturally appropriate way to inform a community and gain their trust that is often applied in the field (assuming that the leader has given prior agreement). Such processes require time and knowledge of the local political structure, language, customs and local moral systems. One structure for collaborating would be to establish a community advisory board that should provide a mechanism for community consultation that contributes to protecting communities, and ensuring that an assent or consent process be amended to fit the context.

7.5.4 Information Elements

What information is necessary for assent or refusal of the community leader to be sufficiently informed? Lists provided by CIOMS are a good starting place, although much more information on the risks and benefits on the community level will be required. Should the aim of the information be to provide what a reasonable person would consider material to making a decision, or should a higher standard be set as the community representative will be taking a decision for not only him or herself, but also for a whole community? Can it be assumed that a leader empowered to represent a community can or should be expected to have (as part of the qualifications for the position), a greater depth of understanding, or the resources to acquire more understanding compared to an individual who decides only for themselves? Accepting that the offering of a recommendation is not appropriate in a research setting

³⁹⁷ David Buchanan et al., "Assuring Adequate Protections in International Health Research: A Principled Justification and Practical Recommendations for the Role of Community Oversight," *Public Health Ethics* Vol. 1 Number 3 2008: 246-257, 253.

when dealing with the individual or at a community level, it is surely also not appropriate when approaching a community representative whether an intervention is research, practice or a mixture.

7.5.5 Assent Elements

The same comments apply to assent elements as were made on the elements of consent for the individual model above. The question of the appropriate way of authorization and documentation needs to be examined, but it should be given and documented in a clear manner; possibly less flexibility should be allowed compared to the individual level.

7.5.6 The Exit Strategy

The community level model introduces a new longitudinal element of 'an exit strategy.' This element signifies the need to bear in mind at each stage of the process that situations may arise that require that plans to conduct the intervention should be stopped. There may be situations in which processes of consent and community assent are so seriously discredited so as to question whether the intervention can be pursued, or whether to do so would infringe core ethical principles (a HRIA approach might be taken to make this judgement).

7.5.7 A Six Step Model of Wide Community-Based Assent

Although the importance of community assent or permission is increasingly recognized, there is a shortage of published articles about experiences with obtaining community permission.³⁹⁸ In one report however on a practical experience with community consent, Diallo et al. have described a malaria vaccine study in Mali, Western Africa. A process is described that was applied to obtain community permission that had 6 steps: (1) a study of the community, (2) an introductory meeting with leaders, (3) formal meetings with leaders, (4) personal visits with leaders, (5) meetings with traditional health practitioners, and (6) recognition that obtaining permission is a dynamic process.³⁹⁹ These steps should also be

³⁹⁸ D. A. Diallo et al., "Community permission for medical research in developing countries," *Clin Infect Dis.*, 2005, 41: 255-259, 257.

³⁹⁹ *Ibid.*

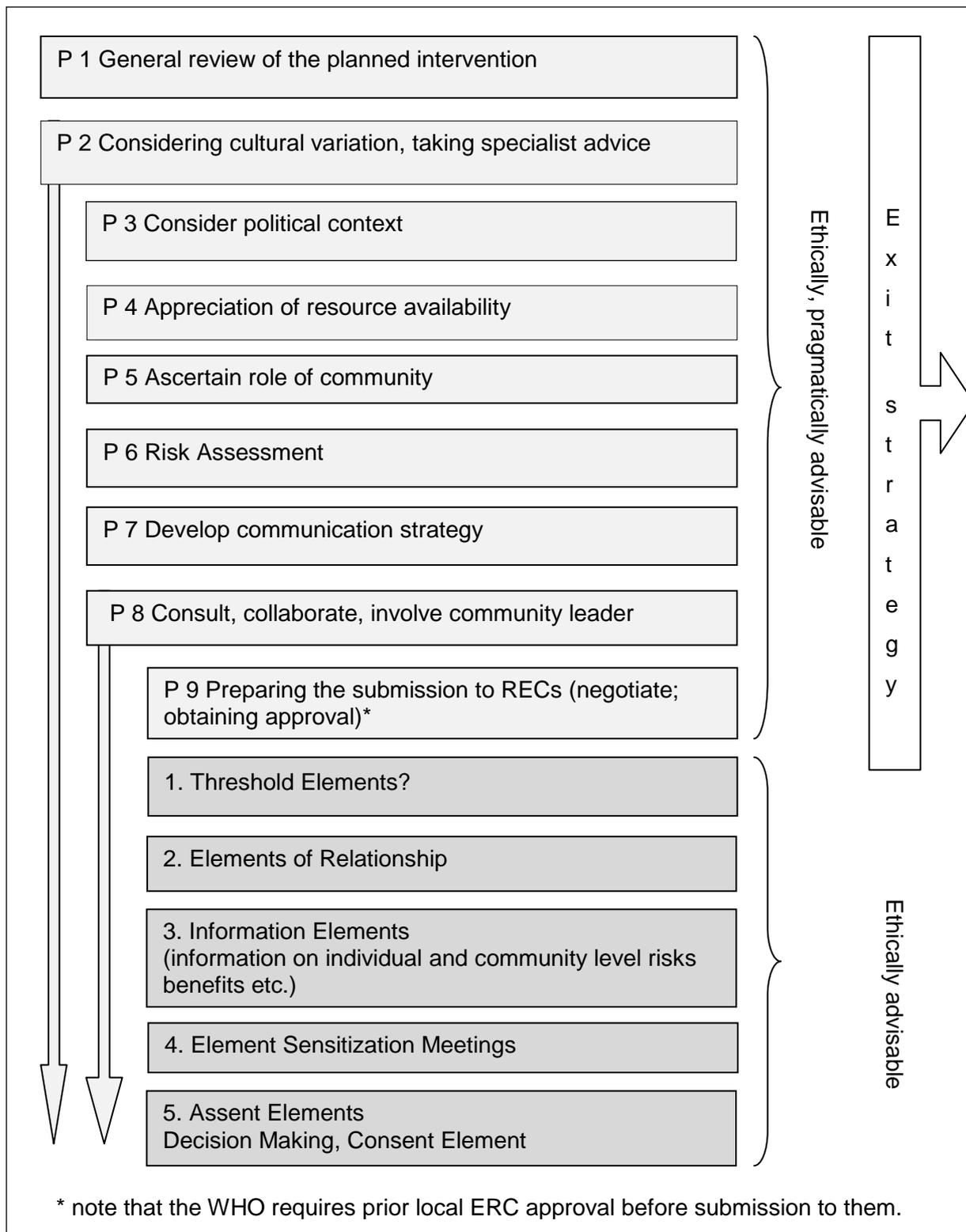
built into the new framework for application as appropriate (also in developed countries for a public health intervention in a culturally diverse community).

7.5.8 The Community Assent Model

To conclude, the enriched model outlined at the start of this chapter needs considerable change to fit a community assent situation. Diallo et al. comment that “far from competing with the individual informed consent process, the process of obtaining community permission both initiated and facilitated the process of disclosure for individual informed cones.” They also consider that a community permission process is able to fill four requirements for the ethical conduct of clinical research in developing countries (points that would also be appropriate in a non-research medical and public health context): the need to establish a collaborative partnership; the minimization of risks to the community; disclosure of information, and evidencing and demonstrating respect for subjects.⁴⁰⁰ The model shown in Figure 14 attempts to meet these goals. This again contains a column containing comments on minimal standards. However, as conducting a community assent process is only required if tradition requires it, all elements are categorized as being ethically advisable rather than obligatory. The only element that may be ethically required is to be aware of situations where the intervention should be dropped – where an exit strategy should come into force.

⁴⁰⁰ Ibid.

Figure 14: Model for Community Assent in Public Health Interventions



7.6 Review of Progress with the Research Questions, and Identification of Next Step

The progress made in answering the research question will now be reviewed. Chapters 1 and 2 considered the terms and themes that frame this dissertation. Chapter 3 looked at the normative foundations of informed consent and community assent in medicine and public health research and practice, and gave timelines of major codifications of consent and community level assent, with the Chapter closing with the identification of issues that need to be addressed and refined. Chapter 4 then considered the term 'community'; its moral status; the various definitions, and the various analytical approaches to understanding and evaluating 'community.' It concluded by noting the complexity of the use of this term, and that the role that informed consent can play to protect, respect and involve a community. Chapter 5 continued the focus on system knowledge (the status quo), by reviewing the contents of major exemplary laws, guidelines, codes and commentaries ('the Texts') that deal with various aspects of informed consent on the individual and community level. The key findings elucidated in Chapter 6 were the following: the Texts show the primacy of principles protecting the individual and a widespread acceptance of the default position of obtaining an individual informed consent. Another set of such principles found in the Texts include the principle of respect for community and sensitivity to local cultural traditions. One example of cultural diversity is the tradition of obtaining community leader permission or assent before approaching individuals for consent. A reasonably coherent position on the relationship between these two sets of principles has been arrived at with the primacy being upheld of the duty to respect and uphold the principles of individual informed consent. Deviations from this default position of seeking informed consent or from the minimum standard content of consent found in the Texts require justification by the satisfying of various criteria. A waiver criteria catalogue was derived based on the Texts developed (having, however, only medical and limited epidemiological normative texts available). The prima facie principles of respecting culture and tradition should not, however, be ignored but should be respected on a procedural level.

The reflections that closed Chapter 6 noted that a differentiated picture has started to emerge of the place of ethics theory in informed consent and informed assent in public health. Firstly is the 'meta' question that arises at the start of any intervention of evaluating if a consent and / or assent process is prescribed. This requires that a set of 'waiver' criteria be

available that has been developed for public health in varying international and transnational contexts. This is not available. In order to develop it, there would need to be agreement on the appropriate ethical theoretical basis for public health consent and assent.

The decision is then needed for each intervention on what form and kind of consent and assent is applicable: individual informed consent (individual informed consent); community assent; community consultation, or a mixture? It is suggested that this decision will be a mixture of context dependent tradition and practical factors as well as theory-driven, practically oriented principles. Finally, is the use of different theories on a level of deciding on the details of a consent or assent process, i.e. if and to what extent a consequentialist approach can be taken that would justify limiting the steps, contents, or level of formalities of a consent process.

The further work on consent and assent that is needed must draw on public health ethics ; disconnect starts to emerge between the focus in both the literature and the guidelines on a deontological position in informed consent, and the theoretical reflections suggesting the application (also) of consequentialism, community level principles, and human rights in public health interventions. Accordingly, the wider field of public health ethics needs to be looked at, in order to progress work on consent and assent in public health. It is doubted whether the systems knowledge noted above derived from current normative Texts related to medicine and epidemiology is fully satisfactory for international public health interventions, recalling also that the breadth of public health interventions is extremely large. The tendency of the status quo to focus on developed countries is also problematic with respect especially to assumptions made of political and economic context. The wide, complex, and multilayer scope of public health as a thick, linear bundle of activities that follow a process of pursuing the health of a population in a particular dimension (physical, mental, or societal) suggests that a more pluralist theoretical approach might be called for.

Another issue to be tackled is the interface of community and consent and assent in public health in various settings. There are different roles of 'community' in consent and assent that need to be carefully differentiated. The role of 'community' in situations in which seeking individual consent is not possible also starts to emerge as being an important aspect of public health interventions.

Notwithstanding, or perhaps because of all this uncertainty, it was considered that developing draft models for consents and assent in public health to support practitioners might be well received. This was covered in this Chapter 7. Although the status quo is less than satisfactory when applied to public health transcultural interventions, these models are built on the status quo systems knowledge outlined in Chapter 5 (with expansion to account for public health, international contexts). Developing the models drew attention to the important role of ethics review committees, although they may be limited in their ability to meet expectations made of them due to a lack of resources, with their tasks being made more difficult if supporting guidelines are not available. The question was then raised if REC shortcomings that cannot be simply resolved should be acknowledged, with this limitation being factored into quality assurance aspects of an intervention? Also accepting that RECs are the guardian of the dignity of research subjects, who is acting as advocate for the good of society when evaluating public health interventions? Nevertheless, the models hope to improve the situation of practitioners in the field by inter alia drawing attention to the possibilities for flexibility contained within the current guidelines. Optimally, developing these models further would be discussed with representatives from ethics review committees from various countries and with researchers coming likewise from developed, developing and transitional countries.

To conclude, no clear set of appropriate ethical standards covering consent and assent issues in public health has yet been located. The next step will be to look at the wider canvas of public health ethics to see if any help can be found. The findings also suggest the need for research into the question if ethically unnecessary or overly complex consent processes are being undertaken in public health, and if the application of a deontological approach to the principles can spill-over into a rigid practice of informed consent that is no longer justified by the principles? Are criticisms of overly legalistic and bureaucratic approaches to consent justified or, is the complexity needed for quality assurance and to protect individuals and communities? In addition to possible over-use of informed consent as doctrine, could the lack of clear guidance on consent in public health result in an under-use and lack of attention in some kinds of interventions?

This progress review stimulates the proposal of the hypothesis that an individual consent and community assent process for a public health intervention should be designing and

evaluating not as being free-standing event, but when considering how it is embedded in the structure and context of a particular intervention. The reason for this hypothesis is to acknowledge the limits of a consent and assent process to perform functions such as protecting and respecting the rights and interests of individuals and communities.

CHAPTER 8

INTERNATIONAL PUBLIC HEALTH ETHICS

8.1 Introduction

This chapter pursues the need identified at the end of Chapter 7 of looking at the wider canvas of public health ethics in order to consider what theories, principles and approaches should be applied when designing consent and assent processes in public health, international interventions. The plan of action is firstly to address the question if there is really a need for a specific 'ethics of public health.' Assuming that the answer is 'yes', as there are no international guidelines on public health ethics, the next step will be to examine some of the more prominent articles ('the Literature') that proposes and discusses the ethics of public health. These articles will then be analysed, and the major theories and approaches they contain collated, and worked together to form a Cluster Framework. Finally, exploratory work will be undertaken to expand this Cluster Framework for use in international public health interventions.

8.2 The Need for 'Public Health Ethics'?

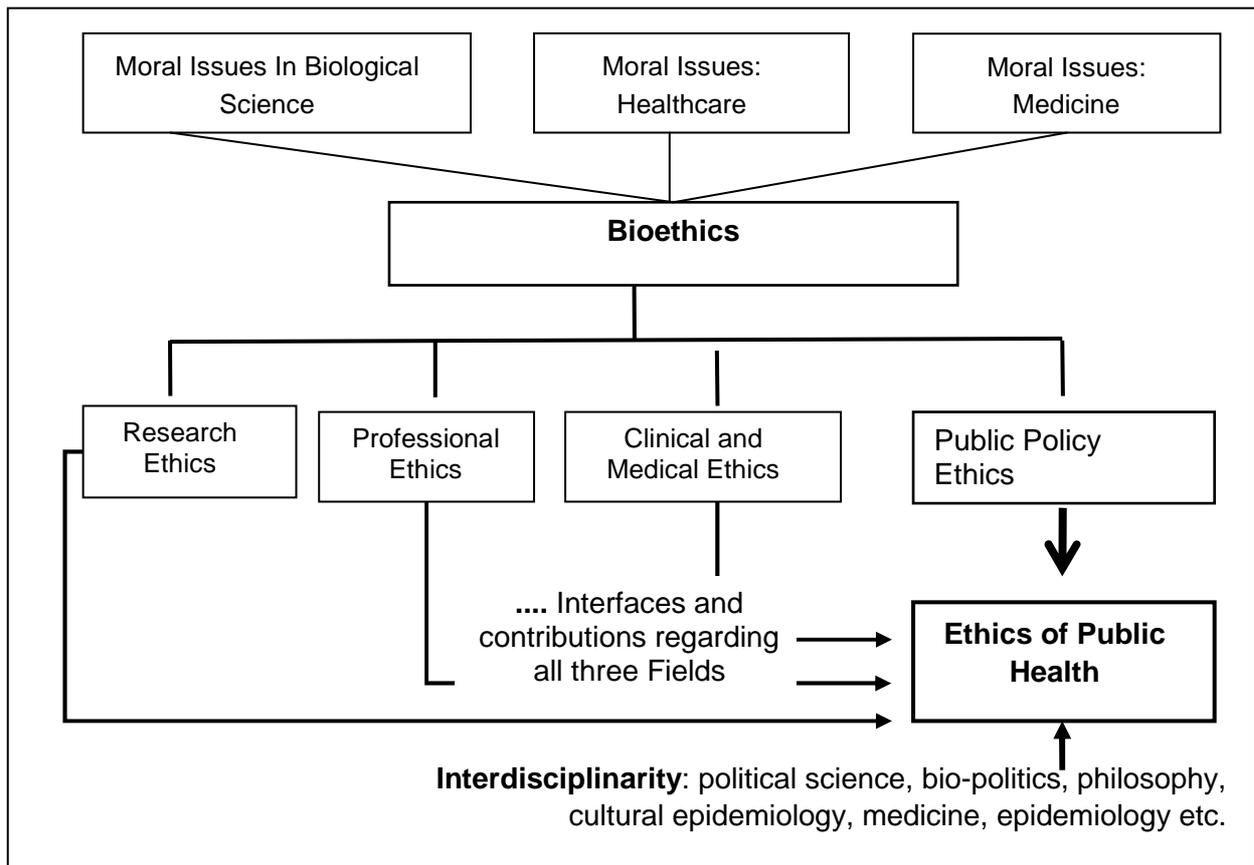
The terms bioethics, medical ethics and public health ethics are all encountered in the field of practical ethics. In order to clarify the relationship between these fields, the taxonomy of the World Medical Association (WMA) will now be used. The WMA defines bioethics as being the study of moral issues that occur in medicine, healthcare and the biological sciences. Bioethics has four major subdivisions: clinical ethics; research ethics; professional ethics, and public policy ethics, which deal with the formulation and interpretation of laws and regulations on bioethical issues.⁴⁰¹ To this taxonomy has been added public health ethics, as illustrated below in Figure 15.

The question will now be considered if public health is sufficiently distinct from medical and clinical practice so as to require its own branch of ethics; can one not simply take theories and principles from medical ethics, professional and research, and transfer them onto public health? In order to justify developing an ethics of public health, two criteria need to be

⁴⁰¹ World Medical Association, Medical Ethics Manual 2005, Glossary: 120.

satisfied. Firstly, a subject area should exist that covers a specific, descriptively distinct class of actions. Secondly, this class of actions must give rise to a specific, distinct, own class of normative problems.⁴⁰²

Figure 15: Relationship Bioethics and Public Health Ethics



As was outlined in Chapter 2, the difference between medicine and public health is that medicine focuses on the treatment, diagnosis or palliative care of individuals. In contrast to this the tasks of public health are proactive and preventive rather than therapeutic; public health operates at the level of a population. It aims to understand, ameliorate, or improve the health of a population or prevent its deterioration. Whilst clinical and medical ethics are dominated by the obligation to respect the individual patient’s right to autonomous decisions

⁴⁰² J Nida-Rümelin, „Theoretische und angewandte Ethik: Paradigmen, Begründungen, Bereiche,“: *Angewandte Ethik. Die Bereichsethiken und ihre theoretische Fundierung*. Nida-Rümelin ed. (Stuttgart: Alfred Körner, 1996).

and actions, public health is concerned with actions in relation to a population. The core 'classical' activities of public health, e.g. sanitation, monitoring disease outbreaks, are being expanded in several ways. Firstly, the parties active in public health are increasingly not only state agencies, but also international, quasi-governmental bodies such as the WHO, NGOs, and parties from the private for-profit sector, as well as academia. Endpoints of public health increasingly include indirect health aims such as improving the equitable distribution of the determinants of public health, i.e. economic resources and social capital.^{403, 404} Public health must increasingly deal with issues of fiduciary responsibility towards a population (including issues of distributive justice), and is expected to uphold standards of accountability and transparency. One concern central to public health ethics (that is less often an issue in medicine except in psychiatry), is the subject of coercion. The actions of public health officers are generally authorized by laws that grant them rights and duties to exercise the power of the state to use force, including in extreme circumstances powers of physical coercion. The relationship between patient and physician is a main focus of medical and clinical ethics; this is not so in public health, where the critical relationship is rather the triangle formed by: a) population or community; b) a public health authority and c) the constituent individuals. Another fundamental difference between public health and medical and clinical ethics is the dimensions of the canvas of ethical reflections. Following on from the individual versus population difference, public health tends to have a wider regional, national and international geopolitical context when compared to the individual and local focus of clinical and medical ethics. Finally, it is also morally relevant that the affected parties of public health activities are often healthy or asymptomatic. In the light of the above, can it be said that public health covers a specific, descriptively distinct class of actions, and gives rise to a specific, distinct, own class of normative problems? The argument does have value that a clear, distinct class of public health activities does not exist. However, arguments that this admittedly fuzzy group of public health tasks do not differ from those of medical ethics are not convincing. It is concluded that it is reasonable to talk of an ethics of public health, although its borders are dynamic. It is also concluded that subject matter, issues and questions arise in the field of public health ethics that are distinct from conventional clinical and medical ethics medicine and that if one took the values developed by Beauchamp and Childress in their individual

⁴⁰³ L. O. Gostin, "Public Health Ethics: Tradition, Profession, and Values," *Acta Bioethica* 2003; IX, NO 2:178-179.

⁴⁰⁴ For a sophisticated treatment of such issues see: Christian Munthe, "The Goals of Public Health: An Integrated, Multidimensional Model," *Public Health Ethics* Vol. 1 No. 1, (2008): 39-52.

focused 'principlism', and transferred them to a public health context, this would fall short of what an ethics of public health needs to be. However, this being said, medical and bioethics provide important inputs and reflection into the developing field of public health ethics.

8.3 The Development of Public Health Ethics

It is often said that an ethics of public health is at an early stage of development, especially when compared to the rapid developments in the fields of medical and clinical ethics since the end of World War II,^{405, 406} and that the intellectual energy devoted to the ethics of public health has been scant compared with that spent on clinical ethics.⁴⁰⁷ Only two commentators and one collection of cases are reported as being available before 2000 that invoked either the language or the clear themes of a distinctive notion of 'public health ethics.'⁴⁰⁸ The time line of the development of references to informed consent on a population, community level starts late (in 1991), and is largely illustrated by texts on epidemiology. Although a detailed examination of why public health ethics lags behind medical ethics would be outside the scope of this project, a few reflections now follow. One reason that may contribute to the tardiness of developing national or international codes of public health ethics is that there is no distinct public health profession, no equivalent to medical schools that allow for focused ethics training. Another hypothesis is that developments in a field of ethics are stimulated if society is confronted with a serious moral problem with clear contours. For instance regarding medical ethics, the events of the Second World War, the Nuremberg Trials and their aftermath, in particular the realization that heinous behaviour of physicians continued after the war outside the German context, provided the tragic impetus to develop research, clinical, and medical ethics. Can it be said that such events have been lacking in the field of public health? This seems implausible when considering the public health tragedies of ill

⁴⁰⁵ James F Childress et al., "Public health ethics: mapping the terrain," *Journal of Law, Medicine & Ethics*, 30 (2002): 70-78, 70.

⁴⁰⁶ Marc J Roberts, Michael R Reich, "Ethical analysis in public health," *Lancet* 2002 Mar 23;359(9311): 1055-9: 1055.

⁴⁰⁷ S. R. Leeder, "Ethics and public health," *Internal Medicine Journal*, Volume 34 Issue 7 (2004): 435-439, 435.

⁴⁰⁸ Nancy E Kass, "Public health ethics: from foundations and frameworks to justice and global public health." *J Law Med Ethics*, 2004 Summer; 32(2), 90 (2004): 232-420, 236.

health, injustice and wars that continue to decimate populations in poorer parts of the world such as the African continent, and recalling that the Tuskegee scandal involved a public health research project. What may, however, be a crucial difference to explain why developing a public health ethics has lagged behind medical ethics, is not the absence of ethically troubling events, but the lack of empowerment of weaker populations to call for action, and the absence of sufficiently powerful advocates to represent the interests of the vulnerable. The tardiness in the development of public health ethics seems in any event to be over; a resurgence of public visibility for public health has arisen stimulated by reasons including reminders that infectious disease has not been conquered in developing countries, and by the recognition that the health of populations is a function more of good public health measures and socioeconomic conditions, than of biomedical advances.⁴⁰⁹

Just as the borders of public health are fuzzy, so consequently are those of public health ethics; “just as public health is broad in its scope, the range of ethical issues in the field is uncommonly wide, encompassing ethics in public health as well as the ethics of public health.”⁴¹⁰ Some scholars have thought about public health ethics in three overlapping ways: professional ethics (the values that help public health professionals to act in virtuous ways); applied ethics (the values that help to illuminate hard problems in public health policy and practice, and advocacy ethics (the overarching value of population health and social justice).⁴¹¹ Problematic when developing a public health ethics are also the various views on what the normative goals of public health should be (see Section 2.3). An important task of public health ethics will be to support finding solutions to such questions as to how to reconcile public interests and the common good with private rights and interests.^{412, 413} Interventions planned to improve the common – population – good, can risk bringing harm to some individuals and communities.

⁴⁰⁹ Daniel Callahan, Bruce Jennings, “ Ethics and Public Health: Forging a Strong Relationship,” *American Journal of Public Health*, February 2002, Vol 92, No. 2.

⁴¹⁰ Ibid.

⁴¹¹ L. O. Gostin, “ Public Health Ethics: Tradition, Profession, and Values,” *Acta Bioethica* 2003; IX, NO 2: 178-179.

⁴¹² Stephen Holland, *Public Health Ethics*, (Polity Press, 2007): introduction: ix.

⁴¹³ European Public Health Ethics Network (EUROPHEN). “*Public policies law and bioethics: a framework for producing public health policy across the European Union*,” 2006.

8.4 Review of Existing Approaches to Public Health Ethics

The selection criterion for the Literature that will now be reviewed is that it specifically covers the development of public health ethics (regarding which no international guidelines exist). The following are the publications (arranged chronologically) which will be reviewed: an article from Nancy Kass, “An Ethics Framework For Public Health” from 2001; REG Upshur’s text “Principles for the justification of public health intervention” dated 2002; James Childress et al 2002 publication “Public health ethics: mapping the terrain”; Larry Gostin’s 2003 article “Public Health Ethics: Tradition, Profession, and Values”; Solomon R. Benatar’s text also from 2003 entitled “Public Health And Public Health Ethics”; “Public Health Principlism” from C M Klugman, published in 2007; Bruce Jennings’s “Public Health and Civic Republicanism: Toward an Alternative Framework for Public Health Ethics,” published in 2007; Peter Schröder-Bäck’s “Principles for public health ethics: a transcultural approach” from 2007; the Nuffield Council Bioethics 2007 Report “Public health: ethical issues”, and finally “A Relational Account of Public Health Ethics” from Françoise Baylis et al, published in 2008.

8.4.1 An Ethics Framework for Public Health

Kass develops a framework for an ethics analysis in her article that provides practical guidance for public health professionals, and highlights the defining values of public health.⁴¹⁴ According to Kass, the current absence of a framework means that public health professionals must ‘muddle through’, an unfortunate situation considering the power (including physical coercion) usually vested in public health professionals. A framework should delineate both negative rights (to non-interference), as well as emphasising positive rights of citizens, including the reduction of social inequities. Kass proposes a 6-step framework as an analytical tool designed to help public health professionals consider the ethics implications of proposed interventions, policy proposals, research initiatives, and programs. Her model has a strong focus on the decision making processes. The first step is to identify what are the public health goals of the proposed program, noting that goals are generally expressed in terms of public health improvement, for instance, a reduction in morbidity or mortality or a social benefit.

⁴¹⁴ Nancy E Kass, “An ethics framework for public health,” *American Journal of Public Health*, 91 (2001): 1776-1782.

The next step is to evaluate the likely effectiveness of the planned program in achieving its stated goals; the questions to be asked include what are the assumptions that lead to a belief that a program will achieve its goals; does data exist to substantiate this assumption? This step is considered by Kass as often being neglected in public health. The importance of addressing the issue of what quantity of data is enough to justify a program's implementation increases according to the burdens posed by an intervention; the greater the burden, the stronger the evidence must be to demonstrate that the program will achieve its goals. The third step is to identify the known or potential burdens or harms of an intervention. These can include: risks to privacy and confidentiality, especially in data collection activities; risks to liberty and self-determination, and risks to justice in the event that an intervention targets only certain groups. The fourth element of the framework is the question whether the burdens associated with a particular planned intervention can be minimized, and whether there are alternative less burdensome approaches? Once a burden has been identified it must be minimized without greatly reducing the program's efficacy. Step five is whether a program will be fairly implemented, a question corresponding to the ethics principle of distributive justice. It requires the fair distribution of benefits and burdens. Kass argues that public health has a positive responsibility to engage in programs and interventions that seek to lessen societal inequalities particularly when those inequalities relate to health outcomes. The final step is how the benefits and burdens of a program can be fairly balanced. This requires reaching a non-discriminatory decision about whether the expected benefits justify the identified burdens. There will often be differing opinions over how burdensome various programs are, depending on the context and perspective taken. If further generations are taken into account, the analysis will become even more complex. Seeking a resolution to disagreements requires that a system of fair procedures – procedural justice – be applied. This requires that a society “engage in a democratic process to determine which public health functions it wants its government to maintain, recognizing that some infringements of liberty and other burdens are unavoidable.” In balancing values and interests, the greater the burden imposed by a program, the greater must be the expected public health benefit.

Kass concludes the framework by commenting that public policy is based on many factors in addition to public health goals and ethical reasoning. However, an ethical analysis should always be conducted. The involvement of communities will help identify the public health

threats that divergent groups face and will create, Kass hopes, a reasonable amount of trust.⁴¹⁵

8.4.2 Principles for the Justification of Public Health Intervention

Upshur's article from 2002 has the objective of discussing principles relevant to ethical deliberation in justifying a public health intervention, using the methods of conceptual analysis and literature review.⁴¹⁶ According to Upshur, the focus of public health should include social and environmental influences on health. Public health ethics must offer a basis to reason through issues relating to social political and cultural contexts. Upshur's analysis identified the following principles that must be met in order for public health to contemplate an autonomy-limiting strategy. Firstly, the Millsian harm principle must be met, meaning that there should be clear and measurable harm to others should an action not be undertaken. Secondly, the proportionality, or least-restrictive-means, principle should be observed. Thirdly, reciprocity must be upheld. If society asks individuals to curtail their liberties for the good of others, society has a reciprocal obligation to assist them in the discharge of their obligations. The final principle is the transparency principle. This holds that public health authorities have an obligation to communicate clearly the justification for their actions and should allow for a process of appeal. If all the above conditions are met, there is a prima facie justification for an intervention taking place, in spite of the fact that it will infringe individual rights.⁴¹⁷

8.4.3 Mapping the Terrain of Public Health Ethics

The Childress et al article: "Public health ethics: mapping the terrain" suggests a loose set of general moral considerations that are relevant to public health that roughly capture the moral content of public health ethics.⁴¹⁸ The general moral considerations include: producing

⁴¹⁵ Ibid.

⁴¹⁶ REG Upshur, "Principles for the justification of public health intervention." *Canadian Journal of Public Health*, 93(2) (2002): 101-103.

⁴¹⁷ Ibid.

⁴¹⁸ James F Childress et al., "Public health ethics: mapping the terrain," *Journal of Law, Medicine & Ethics*, 30 (2002): 70-78.

benefits; avoiding, preventing, and removing harms; utility, maximize benefits over harms; distribute benefits and burdens fairly (distributive justice); respecting autonomous choices and actions, including liberty of action; protecting privacy and confidentiality; keeping promises and commitments; disclosing information, honesty (transparency); building and maintaining trust, and ensuring participation (procedural justice). The relevance of this set has been established by looking at the kinds of moral appeals that public health agents make when justifying their actions, and by looking at debates about moral issues in public health. Several of these “general moral considerations” – especially benefiting others, preventing and removing harms, and utility – “provide a prima facie warrant for many activities in pursuit of the goal of public health.”⁴¹⁹ The article suggests not only that the considerations justify an intervention, but also identifies ‘public health’ as a major benefit that societies and governments ought to pursue.⁴²⁰ The considerations are not absolute, and may conflict with another. One of the conflicts most commonly discussed in the literature is a situation in which population based actions that are justified by being necessary to promote or maintain public health are in conflict with other considerations such as individual liberty. The article proposes five ‘justificatory conditions’ that should help determine whether promoting public health warrants overriding such values as individual liberty or justice in a particular case. The conditions are: effectiveness, proportionality, necessity, least infringement, and public justification. Effectiveness means that if an intervention infringes moral considerations, it is essential to show that it will protect public health. Proportionality means that it is essential to show that the probable public health benefits outweigh the infringed general moral considerations. As an example, a policy may breach autonomy or privacy and have undesirable consequences. To be acceptable, the positive features and benefits must be balanced against the negative features and effects. The principles of necessity acknowledged that not all effective and proportionate policies are necessary to reach the goal. If an intervention infringes a general moral consideration, a morally less troubling strategy should be sought.

If a project satisfies the justificatory conditions of being effective, proportionate, and essential, the principle of least infringement should be applied, with public health agents

⁴¹⁹ James F Childress et al., “Public health ethics: mapping the terrain,” *Journal of Law, Medicine & Ethics*, 30 (2002): 70-78, 70.

⁴²⁰ Ibid.

seeking to minimize the infringement of general moral considerations. Finally, is the condition of public justification: “when public health agents believe that one of their actions, practices, or policies infringes one or more general moral considerations, they also have a responsibility ... to explain and justify that infringement, whenever possible, to the relevant parties, including those affected by the infringement.”⁴²¹ Transparent public justification should be given in terms that fit the overall social contract in a liberal, pluralistic democracy. It is advisable to conduct processes of public accountability that involve “soliciting input from the relevant publics ... in the process of formulating public health policies, practices, and actions, as well as justifying to the relevant publics what is being undertaken.” As a minimum, public accountability requires transparency in openly seeking information from those affected, and honestly in disclosing relevant information to the public. The article acknowledges that its focus is on public health ethics in the United States, although the general moral considerations that it presents may find support in various societies and cultures.⁴²²

8.4.4 Justifying Diminishing Personal and Economic Interests

In his article “Public Health Ethics: Tradition, Profession, And Values,” Lawrence O. Gostin writes that public health ethics may be defined as being the principles and values that help guide the actions of public health system actors that are designed to promote health and prevent injury and disease in the population.⁴²³ Gostin considers that the principal values to be pursued are: population health, safety, and welfare; fairness and equity in the distribution of services, and respect for the human rights of individuals and groups. Although Gostin considers that the field of biomedical ethics has richly informed practice and policy in medicine and health care, “biomedical ethics has often stressed the importance of individual interests“, with insufficient attention being given to the equally strong values of partnership, citizenship and community.⁴²⁴

⁴²¹ Ibid.

⁴²² Ibid. 70-78.

⁴²³ L. O. Gostin, “Public Health Ethics: Tradition, Profession, and Values,” *Acta Bioethica* 2003; IX, NO 2 (2003).

⁴²⁴ Ibid.

Gostin asks the question how society should determine whether to intervene to protect the public's health and safety, when doing so will it diminish a personal or economic interest? Gostin develops a framework of factors and steps to achieve this. The first step is to look at the risk that is to be averted: it must be demonstrated that a risk exists; the duration of the risk that is being prevented must be considered; the probability that the risk will actually occur must be noted, and finally, the severity of harm should the risk materialize must be drawn into the analysis. Step two should demonstrate the intervention's effectiveness. Effectiveness includes the reasonable likelihood of reducing risk, and whether the primary aim of prevention will be achieved. The third step is to assess the economic cost. The criterion to prefer cost-effective measures does not mean that society must wait until there is unassailable scientific evidence before it can intervene. Step four calls for the assessment of the burdens on human rights if an intervention be undertaken. Sometimes even cost-effective policies should not be undertaken if they disproportionately burden human rights. Human rights do not always trump public health, but they certainly need to be weighed carefully. Step five requires the assessment of the fairness of the intervention. Policies should be implemented in just ways, with a fair distribution of benefits and burdens. In summary, a public health intervention can be evaluated using several criteria: a) the nature, probability and severity of the risk; b) the likelihood that it will be effective in meeting its objectives; c) the economic costs entailed, including opportunity costs; d) the burdens on human rights, and e) the fairness, including a just allocation of benefits and burdens.⁴²⁵

8.4.5 A Global, Social Justice Approach to Public Health Ethics

Solomon R. Benatar in "Public Health and Public Health Ethics" takes a global view. He promotes the need for global social economic justice, and the creation of a moral global community that focuses on resolving global injustice, and developing a public health ethics discourse capable of reshaping how we think and act.⁴²⁶ The positive effects of globalization are enjoyed by only about 20% of the world's population. The negative effects (the status in 2002), include widening economic disparities between rich and poor both within and between nations, and increases in both absolute and relative poverty. It is against this background

⁴²⁵ L. O. Gostin, "Public Health Ethics: Tradition, Profession, and Values," *Acta Bioethica* 2003; IX, NO 2 (2003).

⁴²⁶ Solomon Benatar, "Public Health And Public Health Ethics," *Acta Bioethica*, año IX, NO 2 (2003).

that a resurgence of interest in public health has occurred, in a world that at best can be described as amoral, and at worst “morally depraved,” particularly with respect to an unstable “economic system that generates vast wealth but increases poverty.”⁴²⁷ The risks of terrorism are growing, as are the risks of the emergence of new infectious diseases, and other biological threats together with environmental degradation.

Benatar considers that the dominant values that have problematically shaped this polarized world include an erroneous belief in scientific progress and economic growth as being the answers to poverty, and the absence of the re-distribution of wealth. A further aggravation is the exclusive focus on ‘human rights’ as a modern civilizing moral agenda. Although this approach has great potential, it has been diminished by a narrow focus on “uninhibited individual freedom with little sincere attention paid to the whole range of human rights as an indivisible whole.”⁴²⁸ Finally, a “disproportionate belief in the pursuit of short-term self-interest, fostered by market fundamentalism, emphasizes production of goods for consumption by individuals while long-term interests and the production of public goods are undervalued.” Benatar then criticises the uncoupling of the aetiology of disease from its social roots, and a narrow definition of public health with its practitioners focusing on statistics, epidemiology and measurable risk factors. In response to this, a broad definition of public health is advocated by Benatar that addresses upstream causes of widening health disparities. This perspective has intellectual merit because it identifies fundamental causes of public health problems, and provides a better explanatory model compared to narrow direction in which only proximate health risk factors are considered.⁴²⁹

The bioethics discourse must be expanded. Although Benatar agrees that the existing focus on individual rights is vital and necessary, it is not sufficient. What is needed is an improved balance between the needs and rights of individuals on the one hand, and the requirements for advancing public health on the other. This will require a shift in mind-set away from strong individualism towards respect for individuals within the context of a sense of duty towards the community. Realistically a middle ground will have to be forged, because according to

⁴²⁷ Ibid.

⁴²⁸ Ibid.

⁴²⁹ Ibid.

Benatar the choice is not between polar extremes, but rather about achieving an optimal balance between competing goods. Benatar argues that the application of human rights must extend beyond civil and political rights to include social, cultural and economic rights, and their close integration with the reciprocal responsibilities required to ensure that rights are honoured and basic needs are met. 'Human rights', as a secular concept for promoting human dignity, has the potential to transcend religions, national borders and cultures and although widely accepted in the rhetorical sense, continue to be debated regarding their nature and extent. Today many countries consider access to basic health care as a basic human right that nation states should be committed to providing for their citizens. Any movements towards the privatization of medical care can be a threat to this right being realized.⁴³⁰

According to Benatar, it is vital to understand that in a globalizing world, "public health ethics should extend well beyond parochial considerations to include considerations of global social justice and the nature of the 'social contract' within a broader interdependent global society struggling to achieve sustainable development."⁴³¹ Values such as a concern for the common good must be promoted. New and acceptable ways of achieving economic redistribution in order to reduce the rich-poor gap must be constructed, including improving access to public goods. The other values that need to be promoted in a new ethics of public health include a sense of solidarity with others, acknowledging that solidarity is a contested concept although its importance should not be diminished by conceptual difficulties. Finally, the value that needs to be promoted in a new ethics of public health is enlightened long-term self-interest. Benatar does not suggest that adopting a global mind-set must be based solely on altruism, but allows that enlightened long-term self-interest can also play a role.

Benatar concludes that public health and social justice are complex notions. While there is no satisfactory theory of social justice, injustice is easy to recognize and much progress could be made through new scholarly approaches and the application of common sense conceptions of what could be done. While achieving justice may be impossible, a reduction of injustice is feasible according to Benatar if we focus on global injustice and develop a public health ethics discourse capable of reshaping how we think and act.

⁴³⁰ Ibid.

⁴³¹ Ibid.

8.4.6 Public Health Principlism

Craig Klugmann has developed a public health principlism that is based on the idea of common citizenship in the community.⁴³² Klugman's approach was to review various existing public health frameworks and guidelines in order to identify the main common ideas. These are identified as including: solidarity, efficacy, dignity and integrity. The author suggests a 'public health principlism' based on the idea of common citizenship that is derived from these four guiding principles that should be seen as tools for moral deliberation. Under solidarity is understood the coming together of a community as a result of common needs and interests to improve its aggregate health by reducing morbidity and mortality. Efficacy refers to the requirement that a program should be scientifically sound, and have a significant chance of being successful in achieving its goals of improving a community's health and wellness. This principle is based on the philosophical notion that ought implies can. An efficacious program is one that is feasible in regard to social, political, and cultural climates. Having passed the solidarity test, efficacy asks if the program or proposal can be successfully completed. The idea of dignity contains the recognition that human life is vulnerable and needs to be protected. All people are equally worthy of moral respect and consideration. Therefore, dignity says, according to Klugmann, that one should respect people as members of the interconnected community, and choose the least restrictive alternative. Finally, the principle of integrity holds that cultural communities have value and are deserving of respect. This leads to an obligation to preserve the nature and character of a cultural community; to include the community in program development; to provide interventions that match community values, and finally to explain the interventions in terms of local knowledge.

These principles should be viewed as *prima facie*, with greater weight given to solidarity and efficacy than integrity and dignity. The goal is to provide for the aggregate health and well-being of the community, and to acknowledge both community and individual interests. However, care should be taken not to establish a fixed set of principles, as public health ethics is a nascent, emerging discipline, therefore approaches must remain dynamic and avoid rigidity.⁴³³

⁴³² Craig M. Klugman, "Public Health Principlism," *Online Journal of Health Ethics*, Vol. 4, No. 1 (2007).

⁴³³ Stephen Holland, *Public Health Ethics*, (Polity Press, 2007), introduction: ix.

8.4.7 Civic Republicanism

Bruce Jennings has critically noted that the language of liberalism has been predominant in public health ethics, as signalled by the use of terms and concepts such as rights, liberties, autonomy, utilities, and risk-benefit analysis.⁴³⁴ He proposes that public health needs “a paradigmatic shift in moral sensibility, and an additional second language to supplement liberalism.” If this is not acknowledged, “public health will not be able to fully grasp its distinctive vocation as a profession of public service.” To grasp and approach public health one must have recourse to the concept of a “public thing,” noting however that ‘the public’ is not only a statistical concept, nor purely an aggregate of individuals but is a community of individuals intertwined through complicated institutional and cultural systems in and through which they act out their lives. ‘Public’ is a normative concept that provides an account of how the system should be structured and how our lives in common ought to be composed and lived. According to Jennings, public health ethics must have recourse to values associated with individuals acting as citizens, and not only to individuals acting solely in their own interests. To this end, a historical resource is to be found in “civic republicanism,” an approach that has a connection with communitarianism. Jennings defines civic republicanism as a form of communal and social living from which arbitrary power and domination is absent. The individual is not atomistic but relational, and may reasonably be held to certain reasonable justifiable rules of behaviour by a proper authority, with notions of equity, reciprocity, mutuality, solidarity, and balance being central to what constitutes a morally acceptable relationship. There are in particular four principle concepts that the tradition of civic republicanism has to offer public health ethics: the notion of freedom as life in the absence of arbitrary power and domination; the notion of relationships of mutuality and reciprocity wherein individuals can flourish and grow; the idea of civic virtue, and fourthly, the concept of ‘public’. Under civic virtue Jennings understands “a way of living and being in the political world; it is the excellence pursued in the practice of citizenship.”⁴³⁵ The term ‘public’ should accept that individuals have a dual identity: a private and a civic identity. According to Jennings, the place of the tensions and conflicts is not so much between the state and the

⁴³⁴ Bruce Jennings, “Frameworks for Ethics in Public Health,” *Acta Bioethica*, 2003; 9(2).

⁴³⁵ *Ibid.*

individual, but exists rather within the individual agent: between the private will, and the civic will of individuals.⁴³⁶

8.4.8 A Transcultural Approach

In his article “Principles for public health ethics: a transcultural approach,” Peter Schröder-Bäck argues that a framework for public health ethics is needed that contains a set of prima facie mid-level principles.⁴³⁷ Although public health ethics has to “emancipate from bioethics”, and theoretically sharpen its focus, some aspects such as the bioethics principlism methodological approach of Beauchamp and Childress can be learnt from. The principles Schröder-Beck proposes are: social utility, respect for human dignity, social justice, efficiency and proportionality. Schröder-Beck illustrates the relationship between these five principles in tabular form – see Figure 16 below.⁴³⁸ Social utility refers to the utilitarian principle of trying to generate the good, e.g. the health of the population. This principle is the equivalent in social ethics of the place of beneficence in individual bioethics. The principle of respect for human dignity can counter-balance any problematic aspects of the utilitarian approach of the social utility principle. It serves to remind us of the duty not to instrumentalize individuals and respect their free wills. Under social justice should be understood a second level principle that serves as a constraint to the social utility principle. It is concerned with the distribution of benefits and burden; with the question which inequalities are justified and which are unacceptable, and with preventing public health interventions from discriminating, stigmatizing and excluding. Efficiency is complementary to social utility, and deals with the use of resources. It requires that instruments such as cost-benefit analysis and evidence based medicine (EBM) approach should be applied, it being a moral duty to be efficient. The principle of proportionality demands that the probable benefits must be weighting against any moral considerations that will be infringed.

Schröder-Bäck is aware that several norms are missing that might be expected to appear.

⁴³⁶ Bruce Jennings, “Frameworks for Ethics in Public Health,” *Acta Bioethica*, 2003; 9(2).

⁴³⁷ Peter Schröder-Bäck, “Principles for public health ethics: a transcultural approach,” *Eubios J Asian Int Bioethics* 2007: 104-108.

⁴³⁸ Ibid.

Non-maleficence, for instance, is a reasonable member of the individual bioethics toolbox, but in a public health context is not at the forefront. Regarding ‘solidarity’, this according to Schröder-Bäck is a problematic norm as it is often an expression of mutuality and reciprocity, and is therefore, rather prudential than ethically normative. ‘Solidarity’ (as a term that expresses what we owe to our fellow beings) is covered by Schröder-Bäck’s use of the term ‘social justice.’⁴³⁹

Figure 16: Transcultural Approach to Public Health Ethics

	Moral Aim: Maximizing Good Consequences (consequentialism)	Moral Aim: Respecting Rights (deontological)
Individual Level		Respect for Human Dignity
Social Level	Social Utility and Efficiency	Social Justice

Proportionality

8.4.9 Nuffield Council on Bioethics Report “Public health: ethical issues”

The terms of reference of the Nuffield Council’s 2007 report include identifying and considering the issues that arise when deciding on measures to improve public health in England (with its own very particular nationalized public health system).⁴⁴⁰ Although directly translating the report’s findings into other contexts would be inappropriate, the ethical reflections are of interest. The report argues that a Millian liberal harm principle is not solely adequate for the complexity of public health ethics; the responsibilities of a state go further than upholding this principle. The approach developed is the stewardship model.⁴⁴¹ Nuffield’s concept of ‘stewardship’ intends to convey the idea that liberal states have a duty to look

⁴³⁹ Ibid.

⁴⁴⁰ Nuffield Council on Bioethics. *Public Health: Ethical Issues* (Nuffield Council on Bioethics, London 2007).

⁴⁴¹ Ibid. 13.

after important needs of people individually and collectively. Public health programmes carried out according to this model should aim to reduce the risks of ill health that people might impose on each other; aim to reduce causes of ill health by issuing regulations that ensure good environmental conditions; pay special attention to the health of children and other vulnerable people; promote health not only by providing information and advice, but also by programmes to help people overcome unhealthy behaviours; aim to ensure that it is easy for people to lead a healthy life; ensure that people have appropriate access to medical services, and aim to reduce health inequalities.⁴⁴²

In terms of constraints, a state's public health activities should not attempt to coerce adults to lead healthy lives. The state should minimise interventions that are introduced without the individual consent of those affected, or without procedural justice arrangements (such as democratic decision-making procedures) which provide an adequate mandate. The state should seek to minimise interventions that are perceived as unduly intrusive and in conflict with important personal values. Nuffield concludes that rather than having a fixed set of public health rules, a more open framework is appropriate. Nonetheless, the report does identify several principles that are of special importance in public health: the classical harm principle, care of the vulnerable, autonomy and consent.

The report observes, however, that the concept of individual consent has a different meaning in the context of population-level ethics, with it being wrong to require explicit individual consent for all public health interventions. If consent requirements were interpreted stringently, "a considerable amount of important healthcare data might not be accessible, and effective control of highly infectious diseases could be jeopardised."⁴⁴³ In situations of conflict, both consent and autonomy may have to be accorded less importance in public health ethics; other theoretical frameworks and principles that reasonably justify personal restrictions or inconveniences in the interest of the wider population may need to be applied. Existing bioethics frameworks are often, therefore, not well suited to address the problems that arise in public health. In public health ethics, discussions should take ethical issues arising at the level of the population equally seriously as those at the individual level. It is not

⁴⁴² Ibid. 26.

⁴⁴³ Nuffield Council on Bioethics. *Public Health: Ethical Issues* (Nuffield Council on Bioethics, London 2007): 145.

in order that all considerations of the “greater good” are disregarded because they are viewed as incompatible with respect for individuals and their autonomy.⁴⁴⁴

8.4.10 Relational Ethics Approach to Public Health

Relational ethics bases ethical actions on relations and commitments between people. It is sensitive to different life circumstances and perspectives of individuals, families and communities.⁴⁴⁵ Françoise Baylis et al consider that the moral insights necessary to do justice to public health needs to extend further than a liberal (individual focused) framework. Yet Baylis observes that regarding public health themes such as pandemic planning, the values that predominate are paradoxically the rights and interests of individuals, with particular attention being given to such issues as restrictions on individual liberty and freedom, potential social stigma, and isolation.⁴⁴⁶ This focus, Baylis observes, “is an odd and limited list of ethical concerns - a list that likely would not have been generated but for the fact that the analysis remains steeped in an individual rights discourse inherited from clinical ethics and research ethics, and consonant with the dominant moral and political culture.” Baylis expresses the opinion that the ethics framing public health issues should be an ethics of public health, not a slightly modified version of clinical or research ethics; “an appropriate ethic for public health should be grounded first and foremost in the nature of public health, which is generally understood to refer to what society does collectively to assure the conditions for people to be healthy... such an ethics must be differentiated from the theoretical tools that frequently emerge from autonomy-driven mainstream bioethics.”⁴⁴⁷ Public health requires a richer framework that is attentive to the communal aspects that should be at the core of public health ethics. Public health ethics should do more than simply identify the tensions between individual benefit and community benefit: “it must make clear the complex ways in which individuals are inseparable from communities and build on the fact that the interests of both are interrelated.”⁴⁴⁸ The core values of public health ethics

⁴⁴⁴ Ibid.

⁴⁴⁵ Françoise Baylis et al., “A Relational Account of Public Health Ethics.” *Public Health Ethics* (2008) 1 (3): 196-209, 1-14.

⁴⁴⁶ Ibid. 2.

⁴⁴⁷ Ibid. 4.

⁴⁴⁸ Ibid. 5.

should draw on theoretical work on relational personhood (including relational autonomy and social justice) and relational solidarity.⁴⁴⁹

8.5 Intermediary Report: Contribution of Public Health Ethics to Designing Consent and Assent Procedures

The Literature displays a pluralist approach. Each author makes reference to different theories and approaches. A variety of deontological principles are mentioned, some of which refer to the individual, and some to a societal level, including global justice, fairness, procedural justice, solidarity and the value of the community. The various consequentialist theories referenced include the utilitarian approach of balancing benefits and harms. The other theories and approaches include human rights, communitarianism, and relational ethics. Various references are made to the work of Mill and to responsibilities. The community perspective and community based rights and interests identified as minority in previous chapters have been echoed and supported (with references being made to the involvement of communities; a sense of duty towards communities, the need for greater weight given to solidarity), although the weight given to the communal compared to the individual varies.

The disconnect located at the end of Chapter 6 between the normative, descriptive texts that primarily take a deontological position and theoretical reflections suggesting a more pluralist position for public health has been confirmed. In view of the complex, multi-layer, multi-professional nature of public health, it would be unreasonable to expect that the ethics of public health could be based on one theory alone, or that a fixed set of ethical norms would solve the central ethical problems of public health in all contexts.⁴⁵⁰ The Nuffield report on public health concluded in a similar vein: although it would have been “neat” to be able to set out a hierarchical ordering of ethical principles, but there is no fixed set of ethical norms that will always be the appropriate tool for solving the central ethical problems of public health.⁴⁵¹

⁴⁴⁹ Ibid. 9-11.

⁴⁵⁰ Daniel Callahan, Bruce Jennings, “Ethics and Public Health: Forging a Strong Relationship,” *American Journal of Public Health*, February 2002, Vol. 92, No. 2.

⁴⁵¹ Nuffield Council on Bioethics. *Public Health: Ethical Issues* (Nuffield Council on Bioethics, London 2007).

The suitability of a pluralist approach is supported by the opinion that consulting various normative theories and principles helps develop our moral perceptual capacities in complementary directions. When approaching a complex issue," we should actively seek out moral perspectives that help to identify and explore as many moral dimensions of the problem as possible."⁴⁵²

Regarding the approaches taken in the different articles to the question that is central to much of public health ethics of how to balance individual rights with societal interests, several texts (Gostin, Childress et al, Nuffield Council) take a default position that the rights and interests of the individual take priority over societal interests. This position echoes that found in the texts on informed consent. The articles acknowledge, however, that there are occasions when the individualistic default position can or must be overridden so that the individual is secondary to the societal. Several authors give considerable attention to identifying the criteria that must be met and the questions that must be asked when seeking to justify a public health intervention that limit individual rights. These questions, considerations and justifications are compiled in Table 2 below.

Criticisms do however also abound of this tendency to focus on individualistic 'liberalism' in public health ethics, meaning the focus on the rights and interests of individuals being at the centre of public health ethics discourse.

Benatar refers to the need to reshape how we think and act, and move away from this strong individualism; Jennings writes of the need for a paradigmatic shift in moral sensibility, with public health ethics having recourse to values associated with individuals acting as citizens.

⁴⁵² Susan Sherwin, "*Towards an Adequate Ethical Framework for Setting Biotechnology Policy*," Canadian Biotechnology Advisory Committee, 2001.

Table 2: Summary of Justificatory Conditions for Limiting Individual Autonomy in Public Health Interventions

➤ Effectiveness: the planned intervention must be effective in protecting public health and reduce risk.
➤ It must evidence solidarity.
➤ The benefits of the intervention should outweigh the infringed moral considerations: the benefits must be in proportion to the negative aspects.
➤ The intervention must be necessary to prevent or limit a proven significant risk of harm.
➤ There should be no option available but to infringe moral considerations; there is no alternative that brings a less onerous infringement of individual rights.
➤ The intervention must be justified before the public; standards of transparent public accountability must be upheld.
➤ Reciprocity: if the intervention expects individuals to accept the curtailing of their liberties for the good of others, society has obligation to assist them in discharging this obligation.
➤ Economic cost must be assessed, with only cost-effective measures being undertaken.
➤ The fairness of the intervention must be given; policies should be formed and implemented so that benefits and burdens are fairly balanced.
➤ The burdens of an intervention on human rights must be reviewed and considered.

The discussions on developing a public health ethics often refer to the perspective of time; to the shifts in social, economic, health related factors that occur; to the changes in political philosophy, and the effects over time of global trends such as globalisation. References are made to how determinants of health are altering; to changes in risks of terrorism and the emergence of new infectious diseases etc. The idea of place of history in public health ethics will accordingly be expanded below.

However, the same issue arises with the Literature as arose when examining the normative Texts that cover consent and assent: the articles slant towards focusing on public health in a developed country context, with an assumption of public health state-led systems being in place that are typical of developed countries. Work is indeed needed to develop a public health ethics that has taken different contexts, e.g. cultural, political and economic more into account.

8.6 Overview of Public Health Ethics Theories, Approaches and Concepts

The next step is to collate the Literature by extracting the main theories and concepts so that an orderly array of public health theories principles and approaches that form a public health ethics framework can be proposed.

8.6.1 Consequentialist Theories

In contrast to the primacy of deontological theories underlying informed consent, the theories often held as justifying public health interventions are teleological (end- oriented), consequentialist theories, with the health of the public being the primary end that is sought, and the primary outcome for measuring success.⁴⁵³ Consequentialism was defined above as being a category of moral theory that states that the moral value of an action is determined according to its consequences, e.g. whether the balance of the consequences of the act are good or bad. Under 'moral value' can be understood being right, obligatory or supererogatory⁴⁵⁴ Utilitarianism is one theory within consequentialism that provides a rule that defines what is good. As the name suggests, good or bad is measured by the utility or benefit – a non-moral criterion- that an action produces. Utility can mean various positive things such as happiness, pleasure, welfare or the health of the public. The action that is recommended is the one which maximises utility or benefit. When assessing utility, what counts is the utility of an action for all those affected, with all individuals counting equally. As health is a benefit, public health should maximise health; any interventions that meet this maxim is the required course of action.⁴⁵⁵ One example of use of utilitarian theories is to justify quarantining an individual (depriving them of their right to autonomy) if they might have contracted an infectious disease based on the argument of the benefits to the health of a population gained by halting the spread of the disease.

Consequentialist, utilitarian approaches are controversial for a number of reasons. The most serious in the context of public health is that utilitarian justification allows or even

⁴⁵³ James F Childress et al., "Public health ethics: mapping the terrain," *Journal of Law, Medicine & Ethics*, 30 (2002).

⁴⁵⁴ Stephen Holland, *Public Health Ethics*, (Polity Press, 2007): introduction: ix.

⁴⁵⁵ Ibid. 10-11.

recommends that the interests of some people are explicitly not served, or are even damaged or sacrificed, in order to achieve an increase in overall welfare. A fundamental question is, however, whether utilitarian theories (that treat all individuals as equal moral subjects) can provide an appropriate framework for public health with its population focus bearing in mind the existence of collective or community rights. Can the aggregated utility of individuals be weighed up and balanced against the utility that seems to be increasingly accepted as belonging to a collective or a community; are these two types of goods and consequences commensurable?

8.6.2 Deontological Theories

Deontological theories or arguments have been briefly defined as judging the morality of an action based on the action's adherence to a rule or duty. The definition will now be expanded. The word deontology derives from the Greek words for duty (*deon*) and science (or study) of (*logos*). Deontology comprises various moral theories that guide and assess our choices of what we ought to do, claiming that value is not dependent on consequences but on the nature of the action itself, insisting on the central role of invariable rules.⁴⁵⁶ Moral duties must be respected without considering the consequences – indeed even negative consequences should be disregarded, as deontologists hold that no matter how morally good their consequences, some choices are morally forbidden. What makes a choice right is its conformity with a moral norm. How are these norms, duties or principles to be identified? There are various kinds of deontology including a group that are rights-based rather than duties-based. The most well-known duty-based approach is that of Immanuel Kant that has been referenced in previous sections. Of special relevance to public health in this respect is the means-and-ends version of Kant's categorical imperative that reads that we should not treat any rational being merely as a means to an end (in a solely instrumental fashion: any public health intervention that sacrifices the well-being or rights of individual in a way that treats then as mere means in order to benefit the population is problematic. This captures the essence of the dilemma between the individual and populations.⁴⁵⁷

⁴⁵⁶ Ibid. 18.

⁴⁵⁷ Ibid. 18-19.

Criticism of deontological theories include that they require the acceptance of heavy burdens of consequences. Another is that a strict application of principles of protecting human subjects can have difficult repercussions such as slowing research or the acquisition of knowledge.⁴⁵⁸ However, applying a deontological approach can also provide an important corrective to the use of a consequentialist approach by setting limits to what consequences should be accepted.⁴⁵⁹ Therefore, although public health has a clear utilitarian or consequentialist component, with its aim being to promote human welfare and reduce human misery, it should also be limited by a Kantian or deontological considerations, such as respects for persons and their rights.⁴⁶⁰

The form of deontological argument most commonly encountered in public health ethics is not, however, the approach of 's perfect duties, but rather Ross's 'rule deontology', the theory of prima facie (or conditional) duties.⁴⁶¹ This means that an obligation arising from a principle is absolute, e.g. respect autonomy, unless it comes into conflict with another principle, e.g. protect the common good of the health of the public. If this happens, the obligations arising from one principle must yield to the principle that is more pressing in the specific situation in which the conflict arises. A question is then when principles such as the respect for persons expressed as a right to autonomy are absolute (a Kantian position), and when prima facie, and which principles should yield in which situation.

8.6.3 Threshold Deontology

The threshold deontology position holds that deontological norms should govern situations up to a point, but when the consequences become so dire that they cross a stipulated threshold, a consequentialist analysis of the action to be taken should be applied.⁴⁶²

⁴⁵⁸ Steven Coughlin, "Ethical issues in epidemiologic research and public health practice." *Emerg Themes Epidemiol*, 2006; 3: 6: 2.

⁴⁵⁹ Stephen Holland, *Public Health Ethics*, (Polity Press, 2007): introduction: 23.

⁴⁶⁰ Beauchamp D.E., Steinbock (Eds.) "Introduction: Ethical theory and public health." In: *Ethical theory and public health* (Oxford University Press, New York, 1999): 3-23.

⁴⁶¹ W.D. Ross, *The Right and the Good*, 1930.

⁴⁶² Larry Alexander, Michael Moore, "Deontological Ethics", *The Stanford Encyclopedia of Philosophy* (Fall 2008 Edition), Edward N. Zalta (ed.).

There are two varieties of threshold deontology. A simple version holds that there is some fixed thresholds of awfulness beyond which morality's categorical norms no longer have overriding force. Such a threshold is fixed in the sense that it does not vary with the stringency of the categorical duty being violated. The alternative is what might be called "sliding scale threshold deontology." In this version of threshold deontology, the threshold varies in proportion to the degree of wrong being done — the wrongness of stepping on a snail has a lower threshold (over which the wrong can be justified) than does the wrong of stepping on a baby. A risk is that threshold deontology threatens to collapse into a kind of consequentialism.⁴⁶³

8.6.4 Political Philosophy: Communitarianism

The breadth and depth of the ethics of public health requires an interdisciplinary approach embracing various disciplines, one of which is political philosophy (recalling that declaring an issue to be a public health matter is a decision with political repercussions). One such area of interdisciplinary thought is communitarianism. Communitarianism is a label that is an indistinct and vague descriptor. Its genesis is that it is necessary to develop alternatives to the contemporary overly liberalistic individualistic conceptions of self, with its absence of accounting for social context and community. The bases for criticisms of liberalism are "pressing political concerns, namely, the negative social and psychological effects related to the atomistic tendencies of modern liberal societies."⁴⁶⁴ Communitarianism questions the focus on autonomy; should not an individual be rather conceived as a thickly constituted self that is shaped in its very being by its traditions and attachments?⁴⁶⁵ Is not 'community' a precondition for moral autonomy? Should not, furthermore, the model of an autonomous individual be an expression of a debt to one's society, and hence represent social obligations? Communitarianism questions the claim that private autonomous choices should be exempt from moral analysis with this position being "the death of ethics."⁴⁶⁶

⁴⁶³ Ibid.

⁴⁶⁴ Daniel Bell, "Communitarianism," *The Stanford Encyclopedia of Philosophy (Spring 2005 Edition)*, Edward N. Zalta (ed.).

⁴⁶⁵ European Public Health Ethics Network (EUROPHEN), "Public policies law and bioethics: a framework for producing public health policy across the European Union." 2006.

⁴⁶⁶ Daniel Callahan, "Individual Good and Common Good," *Perspectives in Biology and Medicine*, volume 46, number 4 2003: 496-507.

The individualistic ideology has led to a marginalization of theories according to Callahan that have at their normative centre the common good. Callahan contends that “liberal individualism needs a strong competitive voice, one that can be found in communitarianism.” Liberal individualism does not have the intellectual strength or penetration to deal effectively with the most important bioethical issues. Its “thin theory” of the good is not adequate for the future of bioethics (nor for the future of a public health ethics). “The inescapable reality of the kinds of changes that biomedical progress introduce is that they affect our collective lives, our social and educational and political institutions, as well as those tacitly shared values that push our culture one way or the other.”⁴⁶⁷

In reaction to this perceived tendency to over focus on the individual, communitarianism such as Etzioni emphasize social responsibility (see below), and the need for communal life in an increasingly fragmented society.⁴⁶⁸ His position, however, is not to disregard the rights of individuals, but to pursue a responsive communitarianism that seeks to balance individual rights with social responsibilities, and individuality with community.⁴⁶⁹

8.6.5 Social Responsibility

The notion of social responsibility has mainly emerged from business ethics where it defines the moral duties that companies have within the societies in which they are rooted (and in which they both generate and distribute profit and pay taxes). It extends the notion of responsibility beyond individuals to groups, communities, institutions and corporations. Commercial corporations are held, like individuals, to have moral duties that go beyond what is legally required. In other words, institutions and corporations have both a legal and a moral identity, and should assume moral duties beyond those determined by law and their

⁴⁶⁷ Ibid.

⁴⁶⁸ Daniel Bell, "Communitarianism," *The Stanford Encyclopedia of Philosophy (Spring 2005 Edition)*, Edward N. Zalta (ed.).

⁴⁶⁹ Amitar Etzioni et al. (eds.), *The Communitarian Reader: Beyond the Essentials* (Lanham, Maryland: Rowan and Littlefield Publishers, 2004): 2.

shareholders. These include so-called 'duties of good citizenship',⁴⁷⁰ and are arguably more onerous when a corporation trades in a public good (see Chapter 2).

The issue of 'responsibility' and 'social responsibility' is mentioned by various authors in discussions of public health ethics in connection with various theoretical approaches. Benatar, for instance, considers that inadequate attention has been paid to the fact that responsibilities, rights and duties are intimately connected. Human rights discourses are impoverished if the focus is hyper-individualistic, with civic and collective responsibilities being neglected. According to Benatar, a shift is required from an excessively liberal human rights paradigm to a social model of human rights that links benefits and entitlements with the acceptance of a series of responsibilities - the starting point for such rights being the principle of respect for all persons in the context of community.⁴⁷¹

Another application of the concept of responsibility is to reconcile the individual and the societal, using the virtue of moral responsibility as a bridge between autonomy and community based values.⁴⁷² This approach argues that although a right exists to have autonomy protected, obligations exist to reflect on how this freedom is used, and regarding what decisions social or community responsibilities should be taken into account. The problem is not an overly individualized society but "the exercise of self-determination without the guidance of an internalized sense of moral responsibility."⁴⁷³

8.6.6 Mill's Theory of Liberty: The Harm Principle

The thoughts of John Stuart Mill (1806-1873), philosopher, economist, moral and political theorist have arisen in several places in this dissertation. In his essay from 1859 entitled "On liberty," Mill wrote that his object was to assert one very simple principle that should govern

⁴⁷⁰ UNESCO Division of Ethics of Science and Technology, IBC (International Bioethics Committee (IBC): *Draft Report on Social Responsibility and Health*, SHS/EST/CIB-15/08/CONF.502/3 REV 2009.

⁴⁷¹ Solomon Benatar, "Public Health And Public Health Ethics," *Acta Bioethica*, año IX, NO 2 (2003).

⁴⁷² Candace Cummins Gauthier, "Moral Responsibility and Respect for Autonomy: Meeting the Communitarian Challenge." *Kennedy Institute of Ethics Journal*, Volume 10, Number. 4, December 2000: 337-352.

⁴⁷³ Ibid.

the relationship between the state and the individual and the state's use of its physical powers and the use of moral coercion of public opinion. The principle is that "the sole end for which mankind are warranted, individually or collectively in interfering with the liberty of action of any of their number, is self-protection. That the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others."⁴⁷⁴ Mill further said that acting to the good of the coerced individual, either physically or morally, is not a sufficient justification to constrain liberty; no one can be rightfully compelled to do or omit an action because it would be better for him to do so, nor because it will make him happier, or because in the opinions of others, to do so would be wise, or even right. Mill agrees that: "these are good reasons for remonstrating with him, or reasoning with him, or persuading him, or entreating him, but not for compelling him, or visiting him with any evil, in case he do otherwise." The only justification is to prevent or deter someone from harming someone else.⁴⁷⁵ This principle has been very influential in political culture in general, and in public health regarding how to justify government policies.⁴⁷⁶ Its main focus is on protecting individuality, and the exercise of freedom in the construction of one's personal life.⁴⁷⁷ For example, interventions to prevent smoking even against the will of the smokers can be justified if the action is necessary to stop non-smokers being subjected against their will to 'passively' inhaling nicotine smoke. Actions to prevent smoking in a private setting if no one else is affected are not supportable, however, imprudent smoking may be.

8.6.7 Human Rights Approach

The human rights discourse is contested in moral philosophy based on epistemological arguments that human rights lack an objective foundation and justificatory power. Human rights are subjected to further criticisms of being too vague, weak and ambiguous to be of

⁴⁷⁴ J S Mill, (1859) On liberty, in *On Liberty and Other Essays* (1989) Collini S, (Editor) (Cambridge: Cambridge University Press): 13.

⁴⁷⁵ Ibid.

⁴⁷⁶ Stephen Holland, *Public Health Ethics*, (Polity Press, 2007): 53.

⁴⁷⁷ Nuffield Council on Bioethics. *Public Health: Ethical Issues* (Nuffield Council on Bioethics, London 2007): 16.

practical use, and that they can be in conflict with another.⁴⁷⁸ Notwithstanding these issues, the texts from Gostin, Benatar and Childress et al refer to rights, especially human rights. Therefore, whilst acknowledging these issues, some reflections on human rights now follow. A central premise of the human rights discourse is that all humans possess inviolate rights purely by means of being humans.⁴⁷⁹ Although human rights deal with individuals whilst public health activities are concerned with populations, human rights have been increasingly held as having “profoundly influenced the field of public health in various ways,” with some scholars and practitioners seeing human rights as essential tools in public health activities.⁴⁸⁰ The international human rights framework is held by some public health commentators to be “one potential path of synthesis” among conflicting ethical perspectives, and the struggle to balance community health needs and individual rights.⁴⁸¹

The interface and relationship between human rights and public health can be described in different ways: firstly, that public health interventions based on policies that prioritize the health of society over the rights of individuals can violate individual human rights. Secondly, the infringement of human rights directly and indirectly affects health; poor health will hinder pursuing and enjoying human rights. If human rights are not respected, individuals or communities are open to coercion; groups may fear taking part in public health interventions due to possible discrimination or disadvantage. Another viewpoint on the relationship is that human rights can be seen as having a positive, affirmative relationship with public health. Respecting human rights will result in both individuals and communities being empowered to freely grant their consent or assent or to decide not to do so. Policies promoting both human rights and public health result in positive, mutually reinforcing outcomes for persons and society as there is a synergistic relationship between health and human rights, so that one supports the other.⁴⁸² The WHO comment that “promoting and protecting health and

⁴⁷⁸ Stephen Holland, *Public Health Ethics*, (Polity Press, 2007): xiii, xiv.

⁴⁷⁹ T L Beauchamp, J F Childress, *Principles of Biomedical Ethics*, 5th edn. (Oxford: Oxford University Press, 2001): 356.

⁴⁸⁰ L. O. Gostin, “Public Health Ethics: Tradition, Profession, and Values,” *Acta Bioethica* 2003; IX, NO 2: 178-179.

⁴⁸¹ Daniel Callahan, Bruce Jennings, “Ethics and Public Health: Forging a Strong Relationship,” *American Journal of Public Health*, February 2002, Vol. 92, No. 2.

⁴⁸² L. O. Gostin, “Public Health Ethics: Tradition, Profession, and Values,” *Acta Bioethica* 2003; IX, NO 2.

respecting, protecting and fulfilling human rights are inextricably linked: violations or lack of attention to human rights can have serious health consequences ... vulnerability to ill-health can be reduced by taking steps to respect, protect and fulfil human rights.”⁴⁸³

It should be recalled that attainable health has been asserted as being a human right (as mentioned in Chapter 2). The Special Rapporteur on the right to health defines it as the “right to an effective and integrated health system, encompassing health care and the underlying determinants of health, which is responsive to national and local priorities and accessible to all.”⁴⁸⁴ The UNESCO Universal Declaration of Human Rights provides a guideline for operationalization, stating that “everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services.”⁴⁸⁵

Working with the human rights discourse has a number of advantages and applications in the context of an intercultural, international public health project. One reason is found in the more controversial third generation rights that are concerned with solidarity and group and collective rights, a development especially relevant for issues surrounding consent and assent in public health. Collective rights include the right to self-determination, the right to development, right to environmental quality, right to live in peace, right to natural resource control – and perhaps increasingly in the future the collective right to public health. Arguably this concept of collective human rights is important for reflections in the public health field with its focus on wellbeing on the level of the population. Indeed, the potential of human rights should not be diminished by taking a too narrow focus on uninhibited individual freedom⁴⁸⁶ (Human rights are often divided between first generation that protect civil and political rights (e right to life, liberty, and security of person), and economic, social, and

⁴⁸³ See WHO Linkages Between Health and Human Rights at: <http://www.who.int/hhr/en/>

⁴⁸⁴ United Nations Commission On Human Rights, Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, and Indicators for Human Rights Based Approaches to Development in UNDP Programming: A Users' Guide 2006. Paul Hunt March 2006.

⁴⁸⁵ UNESCO, Universal Declaration on Bioethics and Human Rights.

⁴⁸⁶ Solomon Benatar, “Public Health And Public Health Ethics,” *Acta Bioethica*, año IX, NO 2 (2003).

cultural, second generation rights). Benatar comments that: “human rights, as a secular concept for promoting human dignity, has the potential to transcend religions, national borders and cultures. In recent decades the human rights movement has flourished and more countries seem to be accepting universal human rights as a “civilizational” standard.”⁴⁸⁷ Economically, socially or politically weak groups may be at risk of not having their rights and interests respected when public health interventions are carried out and in reflection of this, human rights “have a particular preoccupation with vulnerable individuals and groups.”⁴⁸⁸ Not only has the human right discourse focused on developing countries, but representatives of developing countries including the African continent take part in the human right discourse. This is evidenced by documents such as the African Charter on Human and Peoples' Rights that includes rights such as self-determination as well as duties towards society, so that the exercising of individual freedoms must take due regard of the common interest.⁴⁸⁹

8.7 Forming the Clusters: A Pluralist Approach to Public Health Ethics

The theories and approaches outlined above now need to be organized into clusters with the aim of making them accessible as a public health ethics tool and analytical framework. The method and terminology used here borrows heavily from Beauchamp and Childress' approach to resolving biomedical ethical issues.⁴⁹⁰ Although their work is labeled ‘principlism,’ the ‘principles’ are in their own words ‘clusters of principles’ that should function as an analytical framework for decision making in the medical profession.⁴⁹¹ Beauchamp and Childress consider, with reference to Rawls,⁴⁹² that in order to avoid

⁴⁸⁷ Solomon Benatar, “Public Health And Public Health Ethics,” *Acta Bioethica*, año IX, NO 2 (2003).

⁴⁸⁸ UN document E/CN.4/2003/58 dated 13 February 2003: 13.

⁴⁸⁹ African [Banjul] Charter on Human and Peoples' Rights, adopted June 27, 1981, OAU Doc. community assentB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982), entered into force Oct. 21, 1986.

⁴⁹⁰ T L Beauchamp, J F Childress, *Principles of Biomedical Ethics*, 5th edn.(Oxford: Oxford University Press, 2001).

⁴⁹¹ Ibid. 12.

⁴⁹² John Rawls, “Outline of a Procedure for Ethics,” *The Philosophical Review*, 60, No. 2 1951: 177-197.

infinite regression one should start moral reasoning by accepting the considered judgments: the judgments that morally serious people share.⁴⁹³

Beauchamp and Childress' derived their shared considered judgments from an examination of the pre-theoretical common morality. The common morality and considered moral judgments are not arbitrary lists, but require (with reference again to Rawls) that those who work with their principlism approach meet the kind of conditions that Rawls requires for competent moral judges.⁴⁹⁴ These conditions rely on the existence of competent moral judges who should have the following characteristics: normal intelligence; reasonable knowledge of world affairs; a capacity to 'reason', i.e. see both sides of a question and make allowance for personal bias, and possessing an imaginative appreciation of the predicaments of other individuals.⁴⁹⁵ Beauchamp and Childress' distillation of the judgments resulted in four universal clusters of norms that should serve as guidelines for decision making. The clusters of prima facie norms include principles, rules, and rights that express the values that underlie the common morality.⁴⁹⁶ Beauchamp and Childress argue that their middle level clusters are universal in biomedicine: they are supported by being found in all major theories.⁴⁹⁷ Beauchamp and Childress admit that unsettled issues remain with their appeal to common morality, and make no claim to have developed an approach that resolves all issues. Importantly, the common morality must be open to revision.

Critics of Beauchamp and Childress' work are troubled by the normative, moral foundational role given to the 'common morality' (that is basically descriptive, although its sources have a certain intellectual pedigree), with the point being made that this 'common morality' should rather be seen as a source of well-established moral insights and experiences, which have proved generally valid, rather than being attributed with the qualities of a foundational concept. Beauchamp and Childress do in fact not claim that their work

⁴⁹³ T L Beauchamp, J F Childress, *Principles of Biomedical Ethics*, 5th edn.(Oxford: Oxford University Press, 2001): 398.

⁴⁹⁴ John Rawls, "Outline of a Procedure for Ethics," *The Philosophical Review*, 60, no. 2 1951: 177-197.

⁴⁹⁵ Ibid.

⁴⁹⁶ Prima facie: referring to an obligation that must be fulfilled unless it is in conflict with another prima facie obligation).

⁴⁹⁷ T L Beauchamp, J F Childress, *Principles of Biomedical Ethics*, 5th edn. (Oxford: Oxford University Press, 2001): 404.

represents a philosophic construction.⁴⁹⁸ In applying this approach to this analysis of public health ethics, the texts and theories outlined above are distilled to derive a pre-theoretical common morality (that is open to revision), and a set of considered moral judgements (the judgments that morally serious people share). The resulting public health array of principles that contains six clusters illustrated in Figure 17 below. The outer circle outlines a common morality. The inner circle seeks to group this morality into 'families' or clusters of the theoretical approaches outlined in this chapter. This model is offered as an additional piece in the mosaic of work underway in the nascent development of public health ethics as well as being a tool and analytical framework for supporting the resolution of public health ethics questions.

This model acknowledges that in contrast to the focus on the individual in medicine, the public health perspective is concerned with the health of the entire population; thus rather than a fiduciary duty to the individual patient, public health ethics must be founded (also) on societal responsibility to protect and promote the health of the population as a whole. This moral obligation to protect population health holds important implications for identifying appropriate ethical norms to guide public health research ethics and the ethics of the practice of public health, including that conducted in international settings.⁴⁹⁹

This array is more complex than the Beauchamp and Childress structure, reflecting perhaps the added complexity in public health caused by the involvement of two levels: the individual and the population, and the emerging nature of an ethics for public health. Just as with Beauchamp and Childress' approach, this array is not static but should be seen as being constantly under development and revision, and has no claim to provide a finished immutable ethics of public health. Just as with principlism, how the principles are interpreted and how the judgements are argued – using what theoretical approach – can vary; the same judgments can be arrived at using, for example, a rights based, deontological or consequentialist approach; the principles may be shared, although the arguments and theory supporting the principles can vary. The pluralist position has according to Beauchamp and

⁴⁹⁸ Ibid.

⁴⁹⁹ David Buchanan et al., "Assuring Adequate Protections in International Health Research: A Principled Justification and Practical Recommendations for the Role of Community Oversight." *Public Health Ethics* Vol. 1, No. 3 (2008): 246-257.

Childress the advantage that if one theory is weak in accounting for some part of the moral life, another theory is strong; all types of theory clash in some situations with other deeply held moral convictions, but also in another situation articulate a norm that is held to be of value. Beauchamp and Childress “reject the assumption that one must defend a single type of theory that is solely principle-based, virtue-based, rights based, case-based, and so forth. In moral reasoning we often blend appeals to principles, rules, rights, virtues, passions, analogies, paradigms, parables, and interpretations. To assign priority to one of these factors as the key ingredient is a dubious project.”⁵⁰⁰ The pluralist approach of the model is supported by Michael J Selgelid’s suggestion that there are a number of theories that are of importance in public health, with each theory emphasizing different values including utility, liberty, equality, solidarity etc. Each value or principle is independently valuable in certain situations. However, each of them can in another situation place an “implausibly extreme weight on the values they emphasize.” It is, however, difficult – even unreasonable - to have to choose between these theories if they can all be right, and can all be wrong in different situations. Selgelid proposes a ‘moderate pluralism’ approach to public health decisions and policy that starts with the aim of promoting the values as independent legitimate social goals, and striking a balance or making trade-offs between them in cases of conflict.⁵⁰¹ Selgelid proposes that the weight or importance given to the values will depend on context (this being placed at the centre of the cluster model shown above).

8.8 Context and History

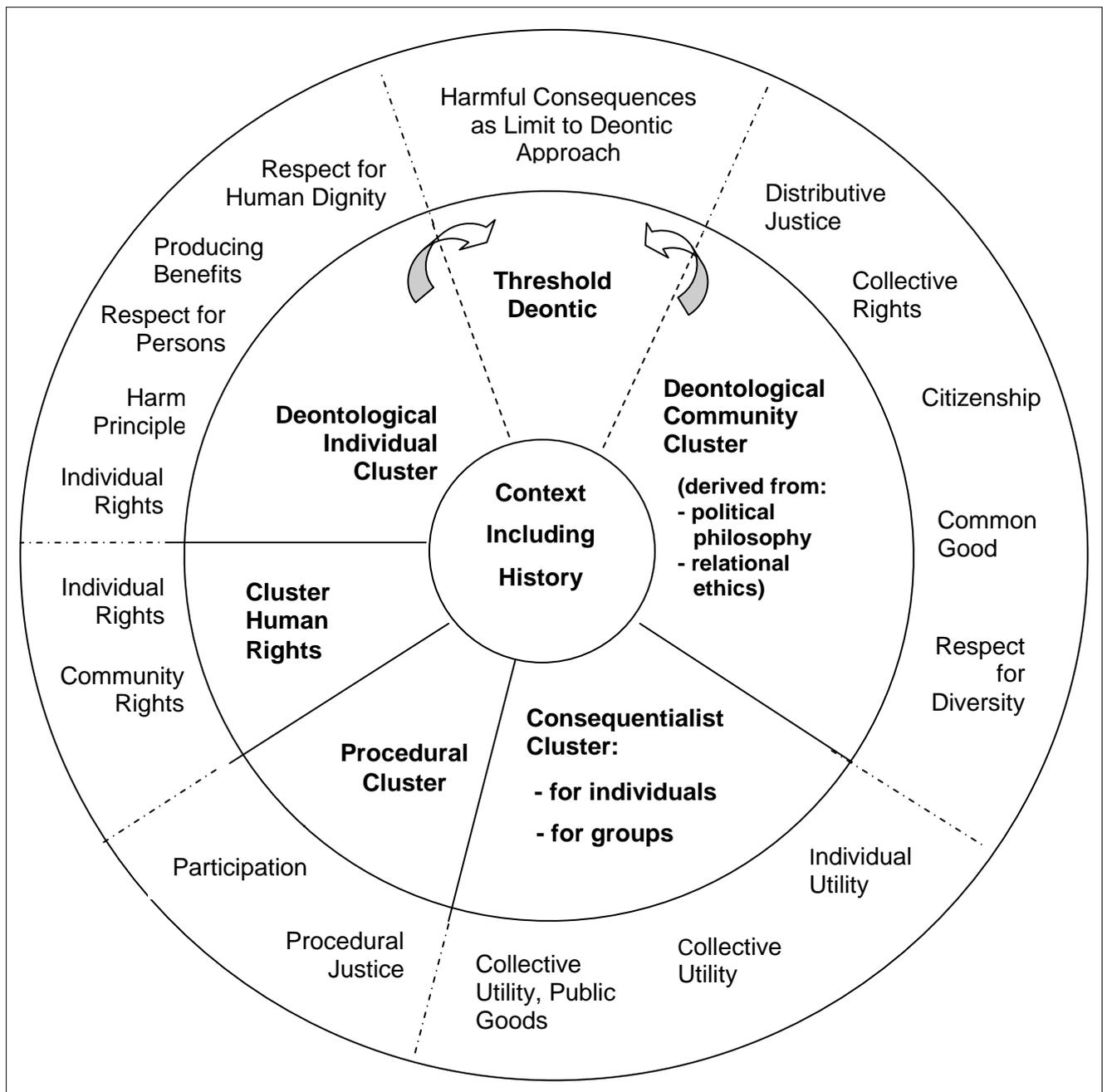
It has been observed that a historical perspective is often mentioned when developing health ethics. The hypothesis is now examined that developing or applying ethical theories, principles or rules should be open to analysis and revision in the light of inter alia critically considering the influences of history in its development.⁵⁰²

⁵⁰⁰ T L Beauchamp, J F Childress, *Principles of Biomedical Ethics*, 5th edn. (Oxford: Oxford University Press, 2001): 111.

⁵⁰¹ J. Selgelid, “A Moderate Pluralist Approach to Public Health Policy and Ethics,” *Public Health Ethics* Vol. 2, No. 2 (2009): 195-205.

⁵⁰² This hypothesis might benefit from the contents of ongoing discussions on the limits of informed consent in medical research, a subject outside the scope of this dissertation.

Figure 17: Public Health Ethics Array of Cluster of Principles and Approaches



It is not proposed that any inference be made that historical facts justify normative conclusions; deriving an 'ought' from an 'is' must be avoided.⁵⁰³ However, historical context

⁵⁰³ Jeremy Sugarman, Daniel P. Sulmasy, *Methods in medical ethics* (2001 Georgetown University Press Washington D.C.): 4.

(including recent history), is a fruitful perspective to evaluate the moral status quo,⁵⁰⁴ with the relevant historical factors including economic, political, military, social and scientific events.

Historical events impact on public health ethics in the following four ways. Firstly, history stimulates moral reflection, and stimulates ethical development. For example, the development of medical and clinical ethics is often explained in terms of the importance of events such as the holocaust, scandals involving research on humans, and the civil rights.

Another reason for critically considering the influences of history in public health ethics is that looking at historical context helps to understand how cultures act and react to the implementation of a process such as informed consent. This is illustrated by the reference made in Chapter 6 to fears of signing documents because of the association with violent coercive actions of corrupt authorities. Past events can affect how public health interventions are perceived and received, and if a sustainable benefit arises. Thus the acceptance, compliancy, and sustainability of a public health intervention (and, therefore, ultimately the health status of the target populations) will be improved by considering the historical context.

On a more analytical level, historical background of a situation can be relevant in interpreting and applying an ethical theory or principle, e.g. Ross's prima facie principles of fidelity, reparation, gratitude and justice in ex-colonial countries. Furthermore, when applying consequentialist theories, awareness of historical background can affect the expected or likely consequences of a given course of action. An example can be found in the polio eradication campaign in some regions of Africa where problems have arisen caused by history influencing the concept of harm, with the belief arising that western polio vaccines were designed to transmit AIDS, and make Muslim women infertile.

These fears that were influenced by political historical events, led to a refusal of polio vaccines, and a new wave of children being infected with polio.⁵⁰⁵

Finally, most relevant to the work being here undertaken of developing an ethics of public health is the 'selection hypothesis.' This holds that history has influenced which principles are

⁵⁰⁴ Ibid. 10-15.

⁵⁰⁵ Samuel Jegede Ayodele, "What Led to the Nigerian Boycott of the Polio Vaccination Campaign," *PLoS Med.* March; 4(3) (2007): e73.

developed and selected today in resolving an ethical issue; historical events stimulate shifts in moral values that guide every-day behaviour, and bring shifts in theoretical problem resolution models. For instance, historical events are held to have strongly influenced the emphasis on individual rights; this individualistic focus on the right to have autonomy respected is arguably as much a reaction to historical events, as a reflection of a philosophical movement.

8.9 Need to (Re) Visit Normative Status Quo on Consent in Public Health?

Accepting and applying the hypothesis and that any proposal for a public health ethics should be open to revision and critical consideration in the light of the influences of history, is it appropriate in the on-going work of developing public health ethics to develop an awareness and sensitivity of how history is influencing our theory and principle selection? It is then necessary to evaluate this influence; what shifts in values are positive moral developments; are any negative; do any need readjustment? An example of a questionable development is that in the wake of the September 11th 2001 attacks, the U.S. government questionably authorized and justified in the Bybee Memo a revision in the definition of torture by excluding the application of “enhanced interrogation” techniques, i.e. prolonged sleep deprivation or forced nudity, although such measures had been previously held as being torture, an infringement of human rights, and therefore not justifiable under any circumstances.^{506, 507}

Timelines of the development and application of consent and assent were outlined in Chapter 3; the role of events such as the physician’s trial at Nuremberg suggests why the default position of the priority of the individual autonomy is omnipresent and codified in so many normative documents. The question is whether the status quo default position of the priority of individual consent in public health ethics needs to be revisited by drawing back, and taking a historical perspective. To continue applying the history hypothesis, have any recent events stimulated (justifiably) the reconsideration of which theories and principles

⁵⁰⁶ Vincent Iacopino et al., “Bad Science Used to Support Torture and Human Experimentation,” *Science* 7 January 2011: Vol. 331 No. 6013: 34-35.

⁵⁰⁷ J. Bybee, Assistant Attorney General, Office of Legal Counsel, DOJ, memorandum for A. Gonzales. Counsel to the President, 1 August, 2002.

should guide public health ethics decision-making (including questions of consent and assent)?

An affirmative answer is supported by many comments in the Literature quoted in this chapter that refer to an over-focus that has developed on liberalism and individualism. In the aftermath of 11th September 2001, it has been suggested that there is a need to readjust attitudes towards public health, and reconsider how the pursuit of the health of the population should be balanced with respecting the rights and interests of individuals as the public and scholarly discourse in the late twentieth century became highly oriented toward 'rights'. The importance of individual freedoms have been stressed at the expense of the health, security, and well-being of the community; "the balance between individual interests and common goods needs to be recalibrated in an age of terrorism ... the current focus on individualism should be seen not as fixed and authoritative, but rather as transient and culturally derived."⁵⁰⁸

A line of thought labelled as being "new communitarian" direction offers an analysis of why some of the shifts in values stimulated by historical events occur and can become problematic. New communitarianism holds that societies tend historically to move from positions that lean too much towards one direction that then requires a move towards the other direction: optimal would be to come to rest in an equilibrium position. Historically (at least in the western world), the balance seen in the literature quoted above can now be seen as leaning too much towards individual rights, therefore requiring re-balancing.^{509, 510} The new communitarian point of view suggests that the perception of how best to balance the individual and the collective varies over time, being sometimes in the directions of individual rights (the status quo), and sometimes towards the primacy of social responsibilities. What is needed is a "carefully crafted balance between these two core values." When the position has tilted too far in one direction, it needs to be pulled in the opposite direction to maintain a balance. The individualistic excesses of the previous generation (1960–1990) need now to be 'trimmed' and room made for more public interest in general and for shoring up public health

⁵⁰⁸ Lawrence O Gostin, "Public Health Law In An Age Of Terrorism: Rethinking Individual Rights And Common Goods," *Health Aff.* Vol. 21, No. 6 (2002): 79-93, 81.

⁵⁰⁹ Ibid.

⁵¹⁰ Ibid.

in particular.⁵¹¹ It can be argued that the justificatory aspects of balancing the individual in public health ethics with the pursuit of the health of the population are undergoing a 'population turn' in which the emphasis needs to shift from the individual to the population level.⁵¹² However, too strong a tilt towards exclusively considering the public good is also undesirable.

The position here supported is a moderate strain of communitarian thinking that recommends "seeking to balance individual rights with social responsibilities; individuality with community; and that connects principles of responsible decision-making to the principle of autonomy" is appropriate.⁵¹³ It should not be assumed that the primacy of individual consent over the public good should be thrown overboard in its entirety, with this being "too much of a valuable part of our culture to simply throw out in favour of an alternative ideology."⁵¹⁴ Applying this position means that in developing and applying an ethics of public health regarding issues of consent and assent, the way forward should be that no default position should be assumed: the preferred position should neither be individualistic or societal. A neutral position is a good basis for collaboration and discussion in transcultural contexts. Each intervention should be looked at afresh, and the question asked what consent and assent approach is appropriate. The Cluster Framework may help with task.

8.10 Public Health Ethics Decision Making Framework

The Cluster Model presents possible theories and approaches as a contribution to the ongoing work of developing a global public health ethics. As a final contribution to these reflections on further developing a public health ethics is the outline that now follows of a public health ethics decision-making process regarding how to apply the Clusters in the

⁵¹¹ Amitai Etzioni, "Public Health Law: A Communitarian Perspective," *Health Affairs* November 2002 vol. 21 No. 6, 102-104: 103.

⁵¹² Harald Schmidt "Bioethics, Human Rights and Universalisation: a Troubled Relationship?" in: Silja Vöneky et al. (eds), *Legitimation ethischer Entscheidungen im Recht - Interdisziplinäre Untersuchungen*(Berlin, Heidelberg, New York: Springer Verlag, 2008).

⁵¹³ Amitai Etzioni et al., (ed.), *The Communitarian Reader: Beyond the Essentials* (Lanham, Maryland: Rowan and Littlefield Publishers, 2004): 2.

⁵¹⁴ Daniel Callahan, "Individual Good and Common Good," *Perspectives in Biology and Medicine*, volume 46, Number 4 2003: 496-507.

event that uncertainty exists. This is intended to be used as part of a forward looking project of undertaking a revision of normative basis of consent in public health, and not necessarily as a tool for the daily work of practitioners. The work will again closely draw on Beauchamp and Childress approach to bioethics. They appreciate that their principles (and indeed the underlying theories), and the clusters as a whole, are abstract and general, e.g. the principle of respect for persons. The generality has the advantage that it leaves room for application in a particular case, but also the disadvantage that they do not easily act as a precise guide to action. Therefore, the abstract principles need to be 'specified' in order that they be applied to practical issues, and then finally balanced.⁵¹⁵ The specification and balancing of prima facie principles should leave room for compromise, mediation, negotiation, and moral growth and progress.⁵¹⁶ Principles also need to be specified and balanced in the light of new cases; emerging sciences can produce new possibilities that need rules to be newly specified. Situations can however arise in which upon examination and specification a principle is judged as being absolute, not prima facie.⁵¹⁷ More usual is a situation where even after specification, conflicts, dilemma, or lack of clarity remains.⁵¹⁸

The question that 'specification' should address is how to find out what general principles should be applied to a particular case, and how to reduce the generality of principles. Specification includes three kinds of rules that are more restrictive in scope, and more specific in content compared to principles. These rules specify a principle in a way that provides guidance for action; the principle should remain intact but should become specific to the case at hand. The process of specification comprises analysing three rules: substantive rules; authority rules (indicating who should perform a certain action), and procedural rules.⁵¹⁹ The procedural rules establish the procedures to be followed when, for instance,

⁵¹⁵ T L Beauchamp, J F Childress, *Principles of Biomedical Ethics*, 5th edn. (Oxford: Oxford University Press, 2001): 15,16.

⁵¹⁶ Ibid. 405.

⁵¹⁷ Ibid. 19.

⁵¹⁸ Ibid. 18.

⁵¹⁹ 'Authority rules' indicate who should perform a certain action. They include (a) rules of surrogate authority (who should decide in the name of an incompetent person); (b) rules of professional authority (who is authorized to make decision whether the patients decisions should be accepted or overridden); (c) rules of distributional authority (who is the proper person to decide on the allocation of medical resources).

making decisions regarding the distribution of medical resources.⁵²⁰ Beauchamp and Childress comment that procedural rules are often resorted to in situations where substantive rules and authority rules are inconclusive and incomplete.

The next step is ‘balancing’, which consists of deliberation and judgment regarding the weight of strength of a principle in a given situation. Beauchamp and Childress list a set of conditions that guide the balancing process by listing the following conditions that must be met in order to justify infringing a prima facie principle:⁵²¹

- a) “Better reasons” for asserting one norm as overriding another, such as a right existing;
- b) The moral aim underlying the infringement must have good chance of being met;
- c) There is no preferable moral option – the action is necessary;
- d) The option brings the least infringement compared with other possible actions;
- e) Negative effects must be minimized;
- f) The decision must be taken impartially taking only morally relevant information regarding all parties into account.

It is interesting to compare these balancing conditions with the individual consent waiver criteria identified in Chapter 6 above, noting the considerable similarities.

Beauchamp and Childress propose that if a prima facie principle is overridden in a particular case, it does not simply evaporate, but that ‘residual obligations’ may be generated that need to be considered.⁵²² This rule has importance in situations where local norms may be at variance with the common morality regarding informed consent.

Drawing on this Beauchamp and Childress framework, a draft public health decision-making structure is now presented – see Diagram 17 – that has public health transcultural contexts in mind. The first Level 1 reflects the importance of not only obtaining information immediately surrounding the intervention, but looks further afield to the context of a particular intervention, the intervention design, and the relevant medical and epidemiological facts. Particular when dealing with consent issues, obtaining knowledge of cultural and traditional

⁵²⁰ T L Beauchamp, J F Childress, *Principles of Biomedical Ethics*, 5th edn. (Oxford: Oxford University Press, 2001): 14.

⁵²¹ Ibid. 19.

⁵²² Ibid. 405.

factors that interface with community assent and community involvement is important (see Chapter 6).

Level 2 contains the issue of establishing the appropriate 'authority rule' for the case to hand that determines who is the appropriate party to take decisions and perform actions. This step needs to be given a prominent place in transcultural public health intervention, as acting on behalf of a population needs special clarification of who has the authority (and why) to act. The importance of this step is to show in the need to conduct a MIICCA process in some cultural contexts.

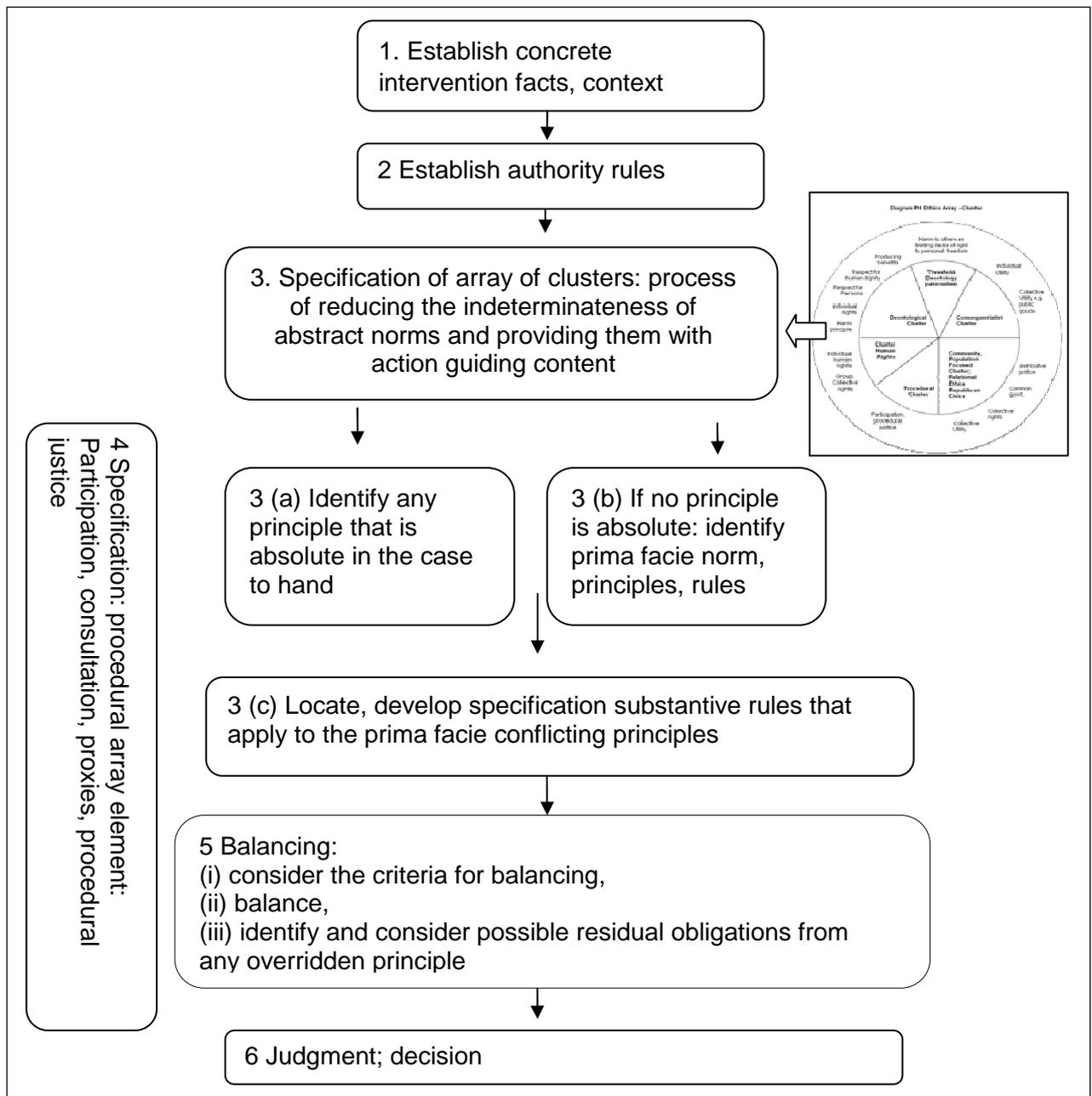
Level 3 is the process of reducing the indeterminateness of the identified principles, and provide them with action guiding content by identifying "specification rules" that should render applicable and usable the principles so that they fit the case to hand. An example of a rule that explicates a theoretical basis into a practical guide for action are informed consent process models. Another example is the specification rule that when applying the principle of respect for diversity, no cultural norm or tradition should be applied if to do so infringes human dignity, human rights or fundamental freedoms. In case of conflict, the Cluster Framework model should be engaged.

The Level 4 procedural specification 'rule' is a longitudinal process that should accompany all the activities of Levels 3 and 5, drawing attention in public health international interventions to remain aware of procedural obligations. Level 5 contains the balancing process of accessing the weight and strengths of specified principles that come into conflict, with finally in Level 6 a decision being formulated.

8.11 Conclusions: An Explorative Ethics Framework for Public Health

This Chapter 8 has pursued the need identified to look at public health ethics in order to consider informed consent and assent issues. It has shown that the task of developing a public health ethics is a work-in-progress. Opinions were noted that a revised public health

Figure 18: Decision Making Process: Paradigmatic Public Health Interventions



ethics framework is needed because of the overly individualistic focus that has emerged as being canonical in the bioethics literature over recent decades,⁵²³ with the need being for a

⁵²³ Tom Baldwin, "Stewardship, Paternalism and Public Health: Further Thoughts," *Public Health Ethics* Vol. 2, No. 1 2009 2: 113-116, 114.

public health framework that takes into consideration the interplay of ethical principles and rules at individual, community, national, and global levels.⁵²⁴ A pluralistic Public Health Ethics Array of Cluster of Principles and Approaches was developed.

The hypothesis has been developed that historical events (such as economic, political, military, social and scientific factors and forces), have had an impact on public health ethics in several ways. Therefore public health ethics should be open to revision in the light of inter alia critically considering these influences on its past and on-going development. It was hypothesized that it is now time to reconsider the treatment of consent and assent using the Cluster Framework. Regarding how the Cluster Framework should be applied to questions regarding consent and assent: a neutral position should be taken in applying the public health ethics clusters to questions on informed consent and community assent. This would allow for the consideration of all aspects of the cluster, allowing inter alia space to address the many questions regarding the place of community in consent and assent that have been located, and for the inclusion of a consequentialist and human rights analysis. Community principles should be considered, as should individual rights and principles. Indeed all elements of the clusters may be appropriate for consideration, especially when addressing the many open questions regarding the place and role of community.

This Chapter 8 closes the deductive, theoretical tranche. One main conclusion is that there are two responses to the ethical standards mentioned in the research question: one is that based on standards derived from the codified status quo although reflections have questioned if this is wholly adequate for public health. Therefore, the step was taken to look at consent and assent from the public health ethics perspective. This resulted in the exploratory response being developed that is a tentative part of the on-going project of working on developing a framework for public health ethics.

⁵²⁴ Steven Coughlin, "How many principles for public health ethics," *The Open Public Health Journal*, 2008, 1: 8-16, 8.

PART III: THE EMPIRICAL, INDUCTIVE TRANCHE

CHAPTER 9

EMPIRICAL TRANCHE PREPARATIONS

9.1 Introduction

The inductive, descriptive ethics tranche of the dissertation will now commence that is the last step towards addressing in Chapter 11 the research question: what should the role and place of individual informed consent and community assent be in public health interventions in order to support an intervention, whilst satisfying the appropriate ethical standards This chapter contains the three public health case studies; chapter 10 will cover the exemplary, exploratory expert interviews that have been conducted. .

Recalling the epistemic position taken that the relationship between normative and descriptive work should be one of two way feedback,⁵²⁵ with empirical research and case studies being able to contribute inter alia to ‘testing’ ethics theories, a main aim of this tranche is to test or validate the informed consent and assent processes that are prescribed in the normative descriptive guidelines by looking at how they are implemented, and how they perform in the field. The aim is to consider in the light of the empirical work if the processes can be internally validated in as much as they achieve (according to their underlying ethical principles) what they aim to achieve.

9.2 Plan of Work

Firstly, the exploratory use of the term ‘validation’ in the field of practical ethics with regard to informed consent will be elaborated. In view of the first step in the decision process illustrated in Figure 18 (Chapter 8) being to gather the relevant facts (which may well involve collaborating with experts), background information to the case studies will then be presented. Thereafter, each case will be outlined, being immediately followed by application of the validation criteria to that case. Chapter 9 closes with conclusions on the validation of the status quo of informed consent.

⁵²⁵ Jeremy Sugarman, Daniel P. Sulmasy (Eds.). *Methods in medical ethics* (Washington DC: Georgetown University Press, 2001): 4-15.

9.3 'Validating' an Informed Consent and Assent Processes

A definition of process validation coming from the FDA is that it is the collection and evaluation of "scientific evidence that a process is capable of consistently delivering quality product."⁵²⁶ 'Validating' a particular informed consent process (focusing on a retrospective validation), requires therefore, a definition of the product, and a set of criteria or indicators to measure its 'quality.' The understanding of the informed consent process 'product' that is to be validated is a consent process such as foreseen in the CIOMS epidemiology guidelines. Reflections now follow on the groups of criteria that would measure the quality of this process when applied in practice.

Firstly is the criterion of validating the underlying theory of consent. One set of indicators would be to examine if the steps of the process laid down by the current guidelines are carried out. An associated question in the event that the guidelines are not followed is why they are not heeded. A more theory-oriented criterion is to take a definition of informed consent (or community assent); select key characteristics contained in the definition that can be used to judge quality and then test adherence. For example, taking the definition that informed consent is a decision taken by a competent, informed person who has adequately understood the information, and has arrived freely at a decision, the indicators that would test 'quality' would be a) if an individual was truly competent in a particular intervention; b) if the necessary information was provided; c) if it was adequately understood, and d) that coercion, undue influence, inducement or intimidation were all absent. Another criterion would be to analyse if the actions in the field operationalize the principles that underlie informed consent and community assent in a way that the process does actually uphold the principles, i.e. that persons and diversity really are respected. A further validation criterion would be the identification of the practical repercussions (both positive and negative) for an intervention of compliancy and non-compliancy with the standards. The dissertation research question was based on the implicit premise that complying with ethical standards on consent and assent will support a public health intervention. Is this however necessarily the case? A vital step in the validation process is to conduct impact assessments. An impact assessment is the process of identifying consequences – impacts – of a past, current or proposed policy or action by using indicators,^{527, 528} with the general objective being "to improve knowledge

⁵²⁶ GMP News, 02/02/2011 "Detailed Analysis of FDA's New Process Validation Guidance."

about the potential impact of a policy or programme, inform decision-makers and affected people, and facilitate adjustment of the proposed policy in order to mitigate the negative and maximize the positive impacts.⁵²⁹ For example, some research has been done to see if informed consent processes are barriers to people agreeing to undergo HIV testing.⁵³⁰ Another potential negative impact that has been investigated is the indicator that having to conduct informed consent processes threatens the validity of results from observational studies by leading to selection bias (only those prepared to consent and undertake the process are included in the sample).⁵³¹ Another serious impact of consent, concerning which some research has also been undertaken, is the assertion that the complexity of informed consent processes result in an undesirable limitation of the research projects that are undertaken.⁵³²

In conclusion, validation will involve undertaking research on a particular informed consent process. Developing indicators will be challenging, with one source being the work of the UN, UNESCO and UNDP in developing indicators for human rights based approaches to development, and indicators for the right to health.⁵³³ The work might also profit from looking at instruments such as the Human Rights Impact Assessment that predicts the potential consequences of a proposed policy, programme or project on the enjoyment of human rights.⁵³⁴

⁵²⁷ See the website: <http://www.humanrightsimpact.org/hria-guide/overview/> for details.

⁵²⁸ European Centre for Health Policy. *Gothenburg Consensus Paper: Health Impact Assessment, Main Concepts and Suggested Approach WHO Regional Office for Europe 1999.*

⁵²⁹ Ibid.

⁵³⁰ Wing Cody, "Effects of Written Informed Consent Requirements on HIV Testing Rates: Evidence From a Natural Experiment." *American Journal of Public Health*, 9 Jun;99(6); (2009): 1087-92.

⁵³¹ Y. Hama et al., "Impact of Written Informed Consent on the Number of Intravenous Contrast-Enhanced CT and MR Studies." *Acad Acad. Radiol*, Feb;13(2) (2006): 258-61.

⁵³² Ibid.

⁵³³ See UNITED NATIONS COMMISSION ON HUMAN RIGHTS Sixty-second session, Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Paul Hunt March 2006 and Indicators for Human Rights Based Approaches to Development in UNDP Programming: A Users' Guide UNDP March 2006.

⁵³⁴ Paul Hunt, Gillian MacNaughton, "*Impact Assessments, Poverty and Human Rights: A Case Study Using The Right to the Highest Attainable Standard of Health*," UNESCO, Paris (2006).

9.4 Developing Provisional Validation Criteria for Case Studies

In view of the complexity of validation, developing a fully reflected and tested set of criteria and indicators would be outside the scope of this dissertation. However, on the basis of the findings and reflections of this deductive tranche, the following are the indicators that will be applied (if data is available) when analysing the case studies:

- a) Were the appropriate ethics approval(s) obtained, e.g. from both sponsoring and host y countries (the CIOMS requirement).
- b) If no REC (research ethics committee) approval was obtained, was the intervention performed within the scope of regulatory authority in a political environment that allows an assumption that at least the majority of the community gave tacit or implicit consent.
- c) Was an individual informed consent process undertaken? If yes, did it conform to the minimal elements located in Section 6.2.
- d) If no individual informed consent process was undertaken: was the waiver justified by using the waiver criteria located in Chapter 6.
- e) Regarding community: was the principle of respect for community and sensitivity to local cultural traditions observed? What was the relationship between informed consent and community; was priority given to individual informed consent whilst respecting traditions for diversity on a procedural level (as the status quo of what the normative texts require)?
- f) Finally in the light of the above, can it be concluded that unnecessary energy was expended on conducting informed consent and assent processes – would obtaining a waiver have been conceivable? Or are there any indications that not enough attention was given to consent and assent issues?

Examining these indicators will make a start in validating or discrediting the current 'doctrine' of informed consent when: a) applied to public health interventions, and b) as practiced in developing countries. As the material on which the valuations are based is limited to what was included in publications that reported the research findings, and to reliable sources such as the IPTi website, this does not necessarily give a full picture of all aspects of an intervention as it was carried out in the field.

9.5 Malaria

Malaria is a complex and potentially deadly disease, with anaemia being a severe complication especially for small children. A very simplified representation of the various stages of the malaria life cycle is shown in Figure 19 (after Vickerrman and Cox, 1967⁵³⁵). The cycle is characterized in some settings by the added complication of a marked seasonality in transmission. The life cycle of malaria parasites presents (theoretically) various opportunities for breaking the cycle, two of which are indicated on the Figure 19 below: bednets and therapeutic drugs. Currently no single intervention has alone the level of efficacy necessary for a complete interruption of the lifecycle. A combination of interventions aimed at different stages of the life cycle are needed to maximize their combined impact in controlling, if not eradicating, malaria.⁵³⁶ The following is the mixture of tools recommended by the World Health Organization (WHO): indoor Residual Spraying with insecticides, primarily with DDT; access to diagnosis and treatment of clinical malaria; access to and use of insecticide-treated nets; intermittent preventive treatment for pregnant women, and since 2010 intermittent preventive treatment for infants. The tools when combined present an opportunity for large-scale malaria control,^{537, 538} Malaria contributes to the cycle of poverty and limits economic development. For example, Africa alone is estimated to lose at least US\$ 12 billion per year in direct losses, (e.g. illness, treatment, premature death), and many times more than that in lost economic growth.⁵³⁹ Pregnant women are a high-risk group for malaria morbidity and mortality in endemic areas as are infants and children.

⁵³⁵ K Vickerman, E E G Cox, „Merozoite formation in the erythrocytic stages of the malaria parasite” in *Transactions of the Royal Society of Tropical Medicine*, Vol 61, Issue 3 1967: 303-308.

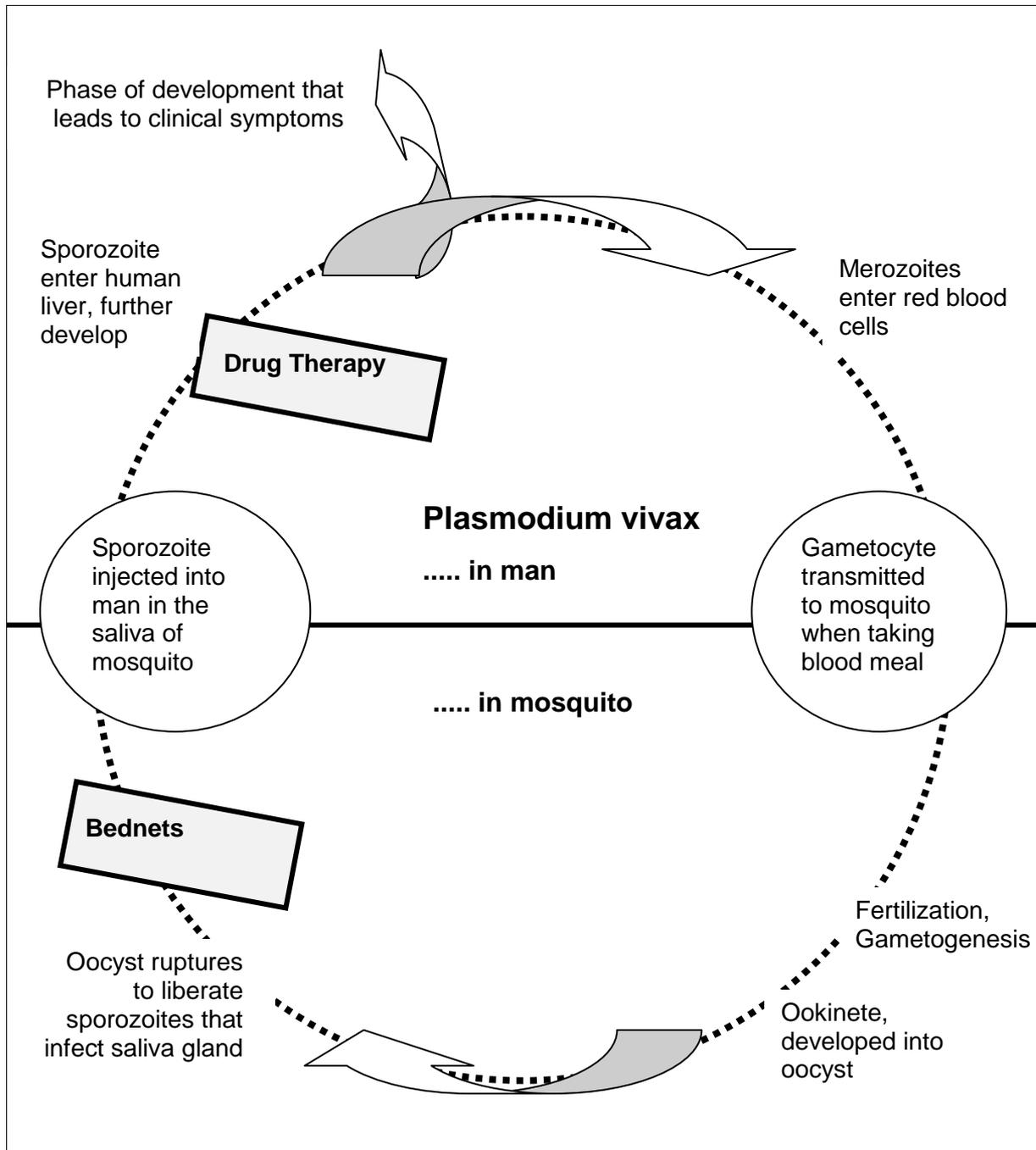
⁵³⁶ NSAID, *NIAID Strategic Plan for Malaria Research Efforts to Accelerate Control and Eradication of Malaria Through Biomedical Research*, 2008.

⁵³⁷ WHO, *World Malaria Report 2010*, URL: http://www.who.int/malaria/world_malaria_report_2010.

⁵³⁸ Roll Back Malaria Partnership, *Global Malaria Action Plan 2008*.

⁵³⁹ Ibid.

Figure 19: Life cycle of Plasmodium Vivax in Man and Mosquito
(after Vickerrman and Cox, 1967)



The number of deaths due to malaria is estimated to have decreased from 985,000 in 2000, to 781,000 in 2009, with the largest absolute decreases in deaths being seen in Africa.⁵⁴⁰ However, even with this progress malaria remains a serious public health problem that kills one child nearly every 45 seconds, with 90 per cent of them being in Africa.⁵⁴¹

There have been a number of efforts and drives to control, limit or even eradicate malaria in the last 60 years. Regional malaria elimination campaigns were first conducted in the late 1940s, preparing the ground for the Global Malaria Eradication Programme in 1955. This campaign succeeded in eliminating malaria from Europe and North America although no major success occurred in sub-Saharan Africa.⁵⁴² The WHO commenced in 1955 a campaign called the Global Malaria Eradication that was focused on vector control by the wide spread application of the insecticide dichloro-diphenyl-trichloroethane (DDT). The efforts then faltered and insecticide-resistant mosquitoes and drug-resistant parasites began to emerge. Eventually, funding slowed and by the end of the 1960s malaria eradication was abandoned for the less ambitious goal of eliminating the disease where possible and controlling it where it could not be eliminated.⁵⁴³

Set against a background of the lack of sustainable success of previous campaigns, great hopes have been placed in the “Roll Back Malaria” (“RBM”) campaign launched in 1998 by the WHO. Roll Back Malaria is an international alliance of more than 90 organisations including WHO, UNICEF, and the World Bank. This initiative was supported by the progress made in the first decade of the 21st century that has seen the mobilization of substantial funding at the global and national levels. In 2007 Bill and Melinda Gates called for the world to launch a new campaign to eradicate the disease. The Swiss Malaria Group was founded in 2007, being made up of Swiss actors from the public and private sectors and civil society.⁵⁴⁴

⁵⁴⁰ Margaret Chan, “Progress seen in world malaria report.” Statement to the press at the launch of the World malaria report, 2010.

⁵⁴² Marcel Tanner, Don de Savigny, “Malaria eradication back on the table.” *Bulletin of the World Health Organization* Organ vol.86 no.2 Geneva, February 2008.

⁵⁴³ Editorial: “Is malaria eradication possible?” *The Lancet*, 2007, 370(9597)(2007): 1459.

⁵⁴⁴ The members are: Swiss Tropical and Public Health Institute, Novartis, Mepha, Medicines for Malaria Venture, Syngenta, Vestergaard Frandsen, Direktion für Entwicklung und Zusammenarbeit (DEZA), Schweizerischen Roten Kreuz, SolidarMed, Novartis Stiftung für Nachhaltige Entwicklung.

The ambitious aim of these combined efforts is malaria eradication.⁵⁴⁵ A WHO 60th anniversary commemorative WHO Bulletin Editorial from 2008 noted that this aim of eradication is once again back on the table, commenting that much has been learnt: “we now know so much more about the biology of parasite-host responses, the determinants of endemicity and transmission dynamics, the social, economic and cultural implications of malaria at household, community and national levels, and the demands made upon health systems in endemic countries. What has yet to be achieved is how to “synthesize and integrate this knowledge to achieve elimination in different settings,” with one barrier to eradication is the state of many health systems that must be improved.⁵⁴⁶ Developing a strategy needs to take account of the situation that although funding has improved, relatively little investment has been made improving the health systems so that the goods can be effectively delivered to those in need.⁵⁴⁷ However, improving health systems is a slow business, and it is increasingly recognized that actions cannot be delayed until sustainable systems are built.⁵⁴⁸ Some commentators remain concerned that although international donor funding for malaria control in Africa has increased, it remains inadequate.⁵⁴⁹ In a Lancet Editorial from late 2008 a major challenge in countries with high malaria mortality was held to be the lack of human capacity and health systems to deliver interventions, and how to transform this need into practice, criticizing that “too frequently, donors tend to be commodity-driven and would rather invest in bed-nets and medicines.”⁵⁵⁰

In their factsheet issued for the World Malaria Day 2009, the RBM Group commented on the paradox that although there exists proven interventions and treatments, between 350 and 500 million people become infected each year (mainly in sub-Saharan Africa, and over one million people die, mainly small children and pregnant women. The work of improving the

⁵⁴⁵ C. C Campbell, Editorial “Malaria Control — Addressing Challenges to Ambitious Goals,” *N Engl J Med*, Volume 36, Nr. 5 (2009).

⁵⁴⁶ Marcel Tanner, Don de Savigny, “Malaria eradication back on the table,” *Bulletin of the World Health Organization*, 2008;86: 81-160, 82.

⁵⁴⁷ WHO / RBM, *Scaling-up insecticide-treated netting programmes in Africa. A strategic framework for coordinated national action*, 2 ed.2005.

⁵⁴⁹ Abdisalan M Noor et al., “Insecticide-treated net coverage in Africa: mapping progress in 2000-07,” *The Lancet*, Vol. 373, Issue 9657, 3 January 2009: 58-67.

⁵⁵⁰ Editorial: Rolling back malaria—the next 10 years, *The Lancet*, Volume 372, Issue 9645, 4 2008: 1193.

situation makes but slow progress, with the poorest carrying most of the burden. If the ambitious goal of eradication is to be achieved, all involved parties must align their energies and resources behind a common approach.⁵⁵¹ It must also be taken into account that if the aim of eradication is finally approached, malaria will transition through a variety of states, requiring the adjustments of strategic approaches and the anticipation of the evolving epidemiology in order to perform effectively and efficiently.⁵⁵² Other challenges that need to be met on the shorter term are counterfeit drugs, ensuring accurate and timely diagnosis, and drug resistance of the mosquito and parasite. Nevertheless, the WHO World Malaria Report from 2010 reported on very encouraging trends in the fight against malaria.

9.6 Understanding the Science: a Basis for Locating Ethical Issues

One of the historical factors that determines the status of public health, and that also interfaces with the development of public health ethics (see Chapter 8 above), are developments in science and technology in the health field. This has been the case since classical time; for instance In Roman cities, silver coins were placed in water supplies in order that the water quality should benefit from the antimicrobial properties of silver,⁵⁵³ (although the moral reasoning and motivations for such actions have hopefully changed from treating a population as primarily a military or labour force, towards humanitarian, human rights based motivation). Science and technology is constantly evolving. The knowledge produced brings forth new possibilities for public health interventions in a multitude of ways, such as the work of Basel's mathematician Daniel Bernoulli (1700-1782), with his first mathematical model of an infectious disease and epidemiological cost-benefit analysis of smallpox immunization from 1766.

The KINET and IPTi cases illustrate that locating ethical issues requires an understanding of the science underlying an intervention, particularly so that any risks of harm can be assessed, and the possibilities of benefits appreciated (this applies to both research and practice interventions). An appreciation is also needed of when the available evidence does

⁵⁵¹ R. Feachem, O Sabot, "A new global malaria eradication strategy," *Lancet*, 008 May 10;371(9624): 1633-5.

⁵⁵² NIAID, "Strategic Plan for Malaria Research Efforts to Accelerate Control and Eradication of Malaria Through Biomedical Research," 2008.

⁵⁵³ WIPO World Intellectual Property Organisation, homepage at: <http://www.wipo.int/pctdb/>.

not allow for risk to be assessed, so that a situation of uncertainty exists. The importance of risk was outlined in Section 6.3 above. Many interventions such as bednets have four dimensions of possible benefits and risks: the impact for individuals, for the community, with both existing on the short and long term. An example is that the public health potential of a new anti-malarial medication can only be reached if the product is used by an individual correctly, with the detrimental outcome of incorrect use including the long term negative community impact of speeding the emergence of drug resistant parasites. Another example is that in addition to providing protection to individual users, a second positive impact (especially over time) of well-maintained impregnated bednet usage is the 'herd' effect: that individual net use has an accumulating knock-on positive effect for the immediate household, reaching beyond the individuals to the community itself^{554, 555, 556} If individuals do not make use of the anti-malarial interventions that are within their reach, they miss an opportunity to have benefits in the long term not only for themselves, but also for their family and the wider community. The herd effect will, however, only arise if well maintained nets are widely and consistently used throughout a community, not only by people deemed as being especially vulnerable.⁵⁵⁷ A final example of the importance of understanding the science in order to appreciate the ethics is the case of net impregnated with excitorepellent insecticides. It has been suggested that the use of such bednets could increase malaria risk for those not sleeping under a net, because the repelled mosquitoes will be stimulated to look with added vigour for an alternative blood feed, focusing on the unprotected. If using bednets brings any increase in risk of malaria to those not using nets, arguments justifying the use of social marketing strategies based on individual and community benefits become rather complicated. Studies have, however, demonstrated that the protection of impregnated nets

⁵⁵⁴ Urs Heierli, Christian Lengeler, *Should bednets be Sold, or given free? The role of the private Sector in malaria control* (Swiss Agency for Development and Swiss Tropical Institute, 2008).

⁵⁵⁵ J Teklehaimanot et al., "Malaria control needs mass distribution of insecticidal bednets," *The Lancet*, Volume 369, Issue 9580, 2007: 2143-2146.

⁵⁵⁶ T J John, R Samuel, "Herd immunity and herd effect: new insights and definitions". *Eur. J. Epidemiol.* 16 (7), 2000: 601-6.

⁵⁵⁷ J Teklehaimanot et al., "Malaria control needs mass distribution of insecticidal bednets," *The Lancet*, Volume 369, Issue 9580, 2007: 2143-2146.

outweighs any shift of risk to the unprotected unless there is a lack of alternative hosts such as cattle (which may occur in an urban setting).⁵⁵⁸

One example of the impact of science on ethical argumentation is that evidence of long term community, epidemiological effects adds to arguments that an intervention should be provided free on a community wide basis. This then lends support for the application of communitarian, republican and relational (also consequentialist) arguments in justifying the application of public health methods that infringe individual rights.^{559, 560} Such evidence also makes credible a position that parallel to individuals having a right to have their autonomy respected, individuals *have a duty as to how they exercise this autonomy*, and a responsibility to elect to sleep under treated bednets (assuming that they are available and accessible).

9.7 Applying a Social Marketing Approach and the Resulting Ethics Issues

Recalling that obtaining and understanding the applicable facts is an important step in a decision making process, what 'social marketing' means (a methodology that was applied to two of the case studies) will now be addressed.

There are various definitions of the term 'social marketing.' One of the first uses of the term is accredited to Philip Kotler and Gerald Zaltman in 1971 who defined it as: "social marketing is the design, implementation, and control of programmes calculated to influence the acceptability of social ideas and involving considerations of product planning, pricing, communication, distribution, and marketing research."⁵⁶¹

⁵⁵⁸ Tanya L Russell et al., "Impact of promoting longer-lasting insecticide treatment of bednets upon malaria transmission in a rural Tanzanian setting with pre-existing high coverage of untreated nets," *Malaria Journal* 2010, 9: 187.

⁵⁵⁹ Jayne Webster et al., "Scaling-up ITN access and use in sub-Saharan Africa: Estimated LLIN requirements and coverage outcomes based on the global delivery strategy mix," Department for International Development Health Resource Centre, 2008.

⁵⁶⁰ WHO / RBM, *Scaling-up insecticide-treated netting programmes in Africa. A strategic framework for coordinated national action*, 2 ed.2005.

⁵⁶¹ Philip Kotler, Gerald Zaltman, "Social Marketing: An Approach to Planned Social Change," *Journal of Marketing*, 1971 Jul;35(3): 3-12.

The definition here adopted is that social marketing is the systematic application of marketing, alongside other concepts and techniques, to achieve specific behavioural goals, for a social good. The term indicates a broad strategic approach that can be applied by a state authority, or an NGO. One of the fundamental differences between marketing and social marketing is that the aim of social marketing is not profit maximization, but generating a social benefit. Success will be measured not monetarily, but whether a change of socially important behaviour has been sustainably stimulated. A social marketing approach is often applied in public health interventions in developing and developed countries, not only in interventions such as KINET and IPTi, but also in anti-smoking, weight reduction and healthy diet programmes.

The features and concepts derived from classical marketing that are key to social marketing are: conducting market research; the principles of voluntary exchange theory; the central role of the customer or consumer and their behavioural determinants; a constructive use of the forces of competition, and market segmentation and targeting.⁵⁶² The key elements find their practical expression when planning an intervention by applying the classical marketing mix of the four interconnected 'P' elements: Place, Promotion, Product and Price. 'Place' includes the actual physical location of the intervention: its general attractiveness, comfort, and accessibility, and also the facilitation of the intervention by providing information, associated goods and services and other functions that facilitate the exchange process.⁵⁶³

The targeted use of promotional activities is a key part of social marketing, being responsible for stimulating demand for a product by the use of persuasive communications to convey product benefits. Firstly social marketers must identify behavioural determinants that can be modified in order to change behaviour, and to change the underlying knowledge, awareness or beliefs about an issue. The techniques used include methods drawn from behavioural theory, persuasion psychology, exposure theories, and marketing science. They are built on applying knowledge of human reactions to messages and message delivery in a way that targets the behaviour that risks damaging health.⁵⁶⁴ Thus a social marketing promotional

⁵⁶² Carol A Grier, A. Bryant, "Social Marketing In Public Health," *Annual Review of Public Health* Vol. 26: 3 9-339 (2005).

⁵⁶³ Ibid.

⁵⁶⁴ W. Douglas Evans, "What social marketing can do for you." *BMJ* Vol. 332, No. 20 (2006): 1207-1209.

strategy will comprise a carefully designed set of activities intended to influence and stimulate change, all designed with a well-researched target audience in mind. Promotional activities may encompass advertising, public relations, printed materials, promotional items, special events, face-to-face selling, and entertainment media.⁵⁶⁵ Promotion in a health context has a special role and responsibility to communicate effectively and provide high quality information. The importance of this promotional communication is shown by the WHO position on malaria control and elimination recommending IEC (information, education, communication) strategies that can be used sustainably to communicate the message of correct use and maintenance.^{566, 567}

Product refers both to a concrete product, i.e. a bednet, as well as the set of benefits (material and immaterial) associated with the desired behaviour that is proposed. Social marketers must convince the target market that the product provides a solution to problems that consumers consider important; that their product offers them a benefit that they value. A process of branding (developing a trademark), and image creation takes place in order to sell a desired behaviour by suggesting an acceptable or desirable set of values or lifestyle that is acquired when consumers buy the product. Another function of branding (that is particularly important for public health with the ethical aspect of its public good status), is that the strategy can be used to establish and maintain a quality aspect of a product. Maintaining a high quality reputation can help the sustainability of a bednet's position in the market place if it is backed-up by a quality assurance programme.

Regarding 'price,' a common misunderstanding is that there must be a physical price for the product that is set by market forces when applying a social marketing strategy. This is not necessarily the case. Considerable research has been undertaken on the use of economic marketing approaches in improving sustainable access to malaria prevention products such as bednets, particularly on the interface of price and equitable access to products and

⁵⁶⁵ Carol A Grier, A. Bryant, "Social Marketing In Public Health," *Annual Review of Public Health* Vol. 26 (2005): 319-339.

⁵⁶⁶ WHO, *World Malaria Report 2010*, Global Malaria Programme: Position Statement on ITNs.

⁵⁶⁷ Urs Heierli, Christian Lengeler, *Should bednets be Sold, or given free? The role of the private Sector in malaria control* (Swiss Agency for Development and Swiss Tropical Institute, 2008).

services in vulnerable populations, for instance the access to treated bednets for pregnant women and infants.⁵⁶⁸ The possible pricing strategies and approaches include: allowing the market mechanisms of supply and demand to set the price; distributing free of charge; partially subsidizing by using funds from the private, public purse, civil or NGO sector, and refined systems involving the selected distribution of vouchers. However, irrespective of the pricing strategy chosen, the commercial framework of a market has an important impact on price, with many African countries having waived taxes and tariffs on nets, netting materials and insecticides.⁵⁶⁹

A consensus among malaria specialists has formed that the appropriate approach to malaria is to combine the complementary 'catch-up' pricing strategies, with 'keep-up' strategies.⁵⁷⁰ The possible bednet delivery strategies of selling nets as a commodity using commercial approaches; distributing free of charge, using the state health care system, and using the private sector are complementary, rather than mutually exclusive approaches. Substantial public subsidies to guarantee access to treated bednets for the most vulnerable are required, but also important is building economic, market based systems and structures that will ensure a sustainable community-wide coverage.⁵⁷¹

In addition to the classical 4 Ps of marketing, it is suggested to add to two further 'Ps' to social marketing: Participation and Partnership. Although neglecting community involvement in the programme design and implementation might decrease the chances of a programme succeeding,⁵⁷² the criticism is made that national malaria programmes often fail at the community level because insufficient attention is being paid to participatory methodologies, especially in the development of messages and interventions.⁵⁷³ Taking an approach of perceiving communities not only as consumers, but also as active partners, benefits the

⁵⁶⁸ WHO / RBM, *Scaling-up insecticide-treated netting programmes in Africa. A strategic framework for coordinated national action*," 2 ed.2005.

⁵⁶⁹ Ibid.

⁵⁷⁰ Ibid.

⁵⁷¹ Ibid.

⁵⁷² Global Malaria Action Plan Part IV: The Role of the RBM Partnership: 211- 212.

⁵⁷³ Ibid.

effectiveness of malaria intervention efforts.⁵⁷⁴ Participation is also a central part of development ethics, constituting perhaps a new orthodoxy in development circles (although some would also say a new tyranny). 'Participation' is included in the public health ethics Cluster Framework developed in Chapter 8. The importance given to participation is that it is thought to lead to an emancipatory empowerment of communities as being participants in the development process. This construction is based on the (questionable?) perception of a target community as being a passive agent, who waits for the emancipatory intervention of development organizations,⁵⁷⁵ and on the assumption that there is a causal relation between 'participation' and 'empowerment,' although this assumption has yet to be critically examined and confirmed. It is also questionable whether transferring participatory ideas such as conducting workshops from developed to developing countries really empowers local communities in any meaningful way.⁵⁷⁶

Connected with participation is the wide use of the term partnership between external development agencies and local entities. Partnerships in social marketing often take place between the public, private sector and NGO sector, with a valuable use of partnership being if each sector focuses on contributing their special fields of competency.⁵⁷⁷

What are then the ethical concerns in applying a social marketing approach to public health issues, such as encouraging communities to use bednets or have their children vaccinated? Markets and the work of marketing can play a role in providing non-essential and essential social goods related to health in prosperous, democratic societies, in an economically efficient and ethically acceptable manner. In profit oriented marketing in developed countries, a morally acceptable marketing campaign will take place by targeting consumers who are competent to take part in market transactions, e.g. being competent to determine differences in quality; possessing awareness of their legal rights; having the possibility to inform

⁵⁷⁴ Pallab Mozumder, Achla Marathe, "Role of information and communication networks in malaria survival," *Malaria Journal* 2007, 6:136:8.

⁵⁷⁵ Participatory Development and the Appropriation of Agency in Southern Tanzania Maia Green *Critique of Anthropology* Vol 20(1): 67-89.

⁵⁷⁶ Maia Green, "Participatory Development and the Appropriation of Agency in Southern Tanzania." *Critique of Anthropology* Vol. 20 (2000): 67-89.

⁵⁷⁷ J R Schellenberg et al., "Effect of large-scale social marketing of insecticide-treated nets on child survival in rural Tanzania," *The Lancet*, Vol. 357, No. 9264 (2001): 1241-1247.

themselves of the product, and have the resources to enter into market relations. It is assumed that those who fulfil these conditions are able to protect their own interests.

However, many public health social marketing interventions in developing countries involve situations of moral market failure: the issue is not using marketing techniques to satisfying wants in a free market, but rather that a society is not able to meet basic needs such as basic health care and nutrition. Many communities and individuals are disadvantaged and vulnerable, and thus limited in their competency to enter into market transactions.

'Vulnerable' is understood to mean susceptible to a harm; the term 'disadvantaged' means "those who are unequal in the marketplace because of characteristics that are not of their own choosing, including their age, race, ethnic minority status, gender (as well as economic factors)."⁵⁷⁸ The application of social marketing techniques in public health in such contexts brings ethical issues caused by an uneven playing field between marketers and consumers.⁵⁷⁹ This results in the question: what moral responsibilities do developed country marketers have when they work in developing countries? Should they avoid targeting the vulnerable and disadvantaged? Certainly marketing to the vulnerable should not trade upon their vulnerabilities (as illustrated by the generally accepted limitations on direct marketing to children). Just as we have a doctrine of product liability, should social marketers be held morally liable for the manner in which they market to consumers, particularly when conducting social marketing?⁵⁸⁰ To continue this line of thought, can it be argued that social marketers have a moral responsibility to "qualify" (e.g. inform) and render competent those they propose to target in a marketing campaign?⁵⁸¹ Regarding the political context, directing social marketing techniques towards population that cannot participate in democratic

⁵⁷⁸ A. R. Andreasen, A. R., "Revisiting the Disadvantaged: Old Lessons and New Problems," *Journal of Public Policy & Marketing*, 1993, 12: 270-275.

⁵⁷⁹ Carol A Grier, A. Bryant, "Social Marketing In Public Health," *Annual Review of Public Health* Vol. 26: 3 9-339 (2005).

⁵⁸⁰ George G. Brenkert, "Marketing And The Vulnerable," *Business Ethics Quarterly* p7-20 special issue no1, 1998.

⁵⁸¹ Ibid.

processes is also ethically questionable, as those whose behaviour is to be changed will not enjoy “a rights-based voice in matters of significant concern to them.”⁵⁸²

An issue underlying all marketing is the acceptability of marketing methods that go in the direction of psychological coercion, and seeking to compromise individual autonomy.⁵⁸³ Are there limits to the means that are acceptable to pursue an aim such as pursuing public health; should the limits be more restrictive in transcultural public health interventions, compared to marketing Coca-Cola® in developing countries? Will the aim of attainable health justify all social marketing techniques? Trying to change behaviour usually means changing underlying values. The more deeply and fundamentally the values and normative statements being promulgated by the intervention are in conflict with norms of the target market, the greater the issues involved in justifying a cross cultural intervention.⁵⁸⁴ The justification for an intervention such as KINET is a particular understanding of social welfare,⁵⁸⁵ with the main justification in such a public health intervention being the importance of physical health for social and individual welfare, i.e. preventing damage to the physical health of those most vulnerable to malaria. Recalling that health has more than the purely physical dimension, questions can arise whether a focus on physical health has always the justificatory power to legitimize public health interventions that apply social marketing techniques if social and ‘cultural health’ aspects of a society are in conflict with an intervention (a situation found in HIV-AIDS work).

The above suggests that the development of social marketing interventions would benefit from ethics inputs, also coming from marketing ethics.⁵⁸⁶ The question is then whether mainstream marketing ethics can be transferred to social marketing in transcultural interventions, noting that marketing ethics codes have been developed with functioning,

⁵⁸² George Brenkert, “Ethical Challenges of Social Marketing,” *Journal of Public Policy and Marketing* Vol. 21, No. 1 (2002): 14-25.

⁵⁸³ N Craig Smith, “Social Marketing and Social Contracts” in: *Ethics in Social Marketing*, ed. Andreasen, Alan R. (Washington, D.C.: Georgetown University Press, 2001): 125-159.

⁵⁸⁴ George Brenkert, “The Ethics of International Social Marketing,” in: *Ethics in Social Marketing* ed. Andreasen, Alan R. (Washington, D.C.: Georgetown University Press, 2001): 26-69.

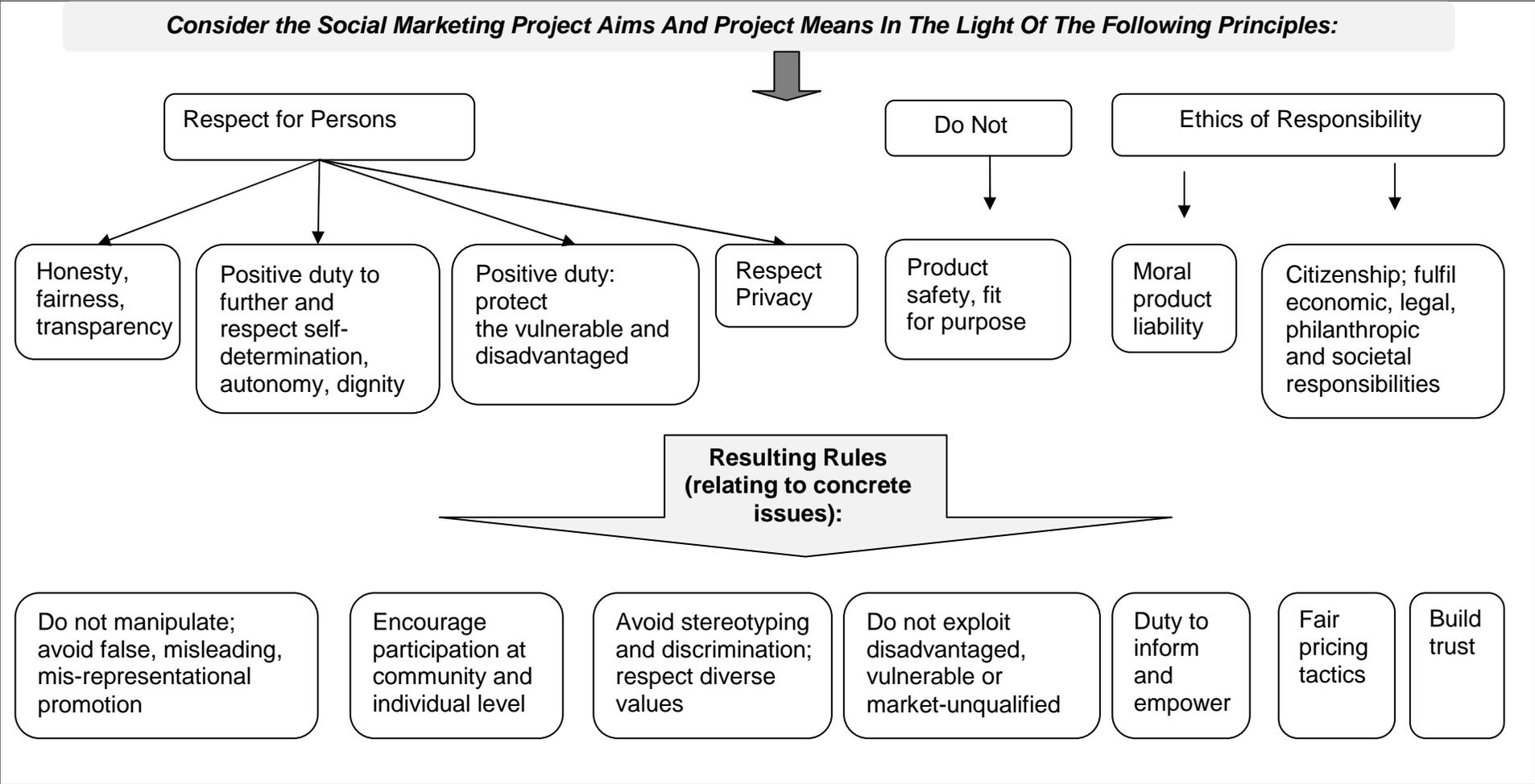
⁵⁸⁵ *Ibid.*

⁵⁸⁶ Gerald Hastings. “Relational Paradigms in Social Marketing,” *Journal of Macromarketing* Vol. 23, No.1 (2003): 6-15.

economically mature democracies in mind. There is indeed a lack of dialogue on the issues of ethics in social marketing; no international code of ethical standards has yet been developed; most social marketing interventions do not include statements of ethical principles.⁵⁸⁷ As a contribution to filling this gap, Figure 20 below is based on the Canadian and American Marketing Codes with some expansion for social marketing in international public health interventions (see Annex VII for details of these documents).

⁵⁸⁷ Alan Andreasen, (ed.) *Ethics in Social Marketing* (Washington, D.C.: Georgetown University Press):1.

Figure 20: Development of an Ethics of Public Health Social Marketing



To conclude, it is increasingly recognizable that if social marketing is to mature as a profession, its practitioners must pay careful attention to ethical standards and practices; social marketing interventions with their claimed social benefit justification need special attention to ethical reflections, even requiring a morally higher basis than commercial marketing on which to build mutual respect with the public.⁵⁸⁸ The main ethical concerns in applying a social marketing approach to public health are encapsulated in the following: a) should social marketing be used in connection with research projects (in which benefits and risks are a priori now fully known; b) taking care to protect the vulnerable and disadvantaged from exposure to the marketing techniques where they are not able to protect their own interests; c) being aware of situations where marketing methods that go in the direction of psychological coercion should be curtailed (analogue to preventing children being exposed to cigarette advertising); d) acknowledging that not all ends justify all means, and d) being aware that in some contexts, the social dimension of health has a high level of importance compared to the physical: not all communities consider that the end result of physical health has first priority.

The importance of addressing these issues is heightened because in the majority of social marketing interventions, seeking individual consent will not be possible. A consequence of this is arguably that undertaking some form of community assent and community consultation process is vital prior to starting a social marketing intervention.

9.8 Introduction to the Case Studies

The three case studies that will be analysed are the KINET social marketing project; an IPTi (Intermittent Preventive Treatment in infants) randomized, placebo-controlled prophylactic drug study for malaria, and an IPTi acceptability trial. Figure 1 in Chapter 1 illustrated the wide variety of public health interventions in which questions of consent and assent require consideration; the differences between these three case studies illustrates the breadth of variety of public health intervention even within this small corner of public health. The KINET project (1996-1999) applied a social marketing approach to treated bednets; the randomized, placebo controlled invasive drug study on infants (1999-2000) had possible impacts (both

⁵⁸⁸ Gerald Hastings, "Relational Paradigms in Social Marketing." *Journal of Macromarketing* Vol. 23, No.1 (2003): 6-15.

positive and negative) for the physical health of the infants, and the non-invasive IPTi acceptability study (2005-2007) that applied social science methods to investigate the implementation of the invasive IPTi program. These three cases will now be presented, with each presentation being immediately followed by its evaluation.

9.9 KINET Social Marketing Treated Bednet Intervention

Bednets, especially insecticide-treated nets play a primary role in global malaria control activities, and their use has been one of the most efficacious and cost-effective means of contributing to the prevention and control of malaria.⁵⁸⁹ However, the transition from efficacy to effectiveness cannot be taken for granted.⁵⁹⁰ The health impact of treated nets occurs on several levels: firstly as protection for those individual users sleeping under the net from mosquito bites, with the protective efficacy of bednets resulting from the quality of the physical barrier they represent; the specific properties of the insecticide used; the species of mosquito and how it reacts to the insecticide, e.g. whether it is killed or repelled (and reacts in then seeking a new host). The second level of impact reaches out over time beyond the individual into the community.^{591, 592} Indeed “with moderate ITN coverage of the population, the herd or ‘mass effect’ is at least as important as the personal protection provided to the user.⁵⁹³ Acting upon epidemiological arguments of the importance of wide coverage needs to be backed-up by sufficient resources to cover (sustainably) the percentage of malaria threatened populations necessary to achieve and maintain community protection.⁵⁹⁴

⁵⁸⁹ WHO / RBM, *Scaling-up insecticide-treated netting programmes in Africa. A strategic framework for coordinated national action*, 2 ed.2005.

⁵⁹⁰ JR Schellenberg et al., “Effect of large-scale social marketing of insecticide-treated nets on child survival in rural Tanzania,” *The Lancet* Vol. 357, No. 9264 (2001): 1241-1247.

⁵⁹¹ Urs, Lengeler, Christian. *Should bednets be sold, or given free? The role of the private Sector in malaria control*, Swiss Agency for Development and Swiss Tropical Institute, 2008.

⁵⁹² J Teklehaimanot et al., “Malaria control needs mass distribution of insecticidal bednets,” *The Lancet*, Volume 369, Issue 9580, 2007: 2143-2146.

⁵⁹³ Tanya L Russell et al., “Impact of promoting longer-lasting insecticide treatment of bednets upon malaria transmission in a rural Tanzanian setting with pre-existing high coverage of untreated nets,” *Malaria Journal* 2010, 9: 187.

⁵⁹⁴ Urs Heierli, Christian Lengeler, *Should bednets be sold, or given free? The role of the private Sector in malaria control*, Swiss Agency for Development and Swiss Tropical Institute, 2008.

KINET was a large-scale social marketing program for malaria control undertaken in the period 1996-1999 in the rural Kilombero Valley in Tanzania, a region that is home to a wide mix of ethnic groups.⁵⁹⁵ It applied a social marketing approach to promote and distribute the products to a rural population of 480,000 people. KINET had two tangible products: insecticide-treated bednets and sachets of insecticide to retreat the nets. The main *intangible* product was, however, 'selling' to the community the advantageous habit of using and maintaining bednets, with a central part of the intervention being a promotional campaign that is an example of an intervention for which seeking individual consent would be highly impractical. The aims were to achieve substantial and sustainable use of insecticide-treated bednets in the target markets of young children and pregnant women,⁵⁹⁶ and to gain experience on social marketing as a tool in the fight against malaria in a rural African setting as inputs for developing a Tanzanian national treated net.⁵⁹⁷

The benefits that were being sold were individual as well as communal protection against malaria. Regarding any risks or uncertainties connected to the intervention: a concern at the time of the research was the uncertainty if an increasing use of treated bednets at community level would force the usual night-biting behaviour of the main malaria vector to change to peak in the early evening and early morning, times when few people are in bed (and therefore, few people would be protected by bednets). If the intervention failed, there were no additional direct risks of harm, but the potential benefits of bednet usage would not accrue to individuals, households, or the community.

KINET was a collaboration between public entities and the private sector, with each sector making a contribution according to their strengths. KINET received support from a number of sources including the Swiss and UK state development agencies, the Government of the

⁵⁹⁵ J R Schellenberg et al., "KINET: a social marketing programme of treated nets and net treatment for malaria control in Tanzania, with evaluation of child health and long-term survival." *Transactions of the Royal Society of Tropical Medicine and Hygiene* Vol. 93, No. 3 (1999): 225-231.

⁵⁹⁶ Ibid.

⁵⁹⁷ J R Schellenberg et al., "Effect of large-scale social marketing of insecticide-treated nets on child survival in rural Tanzania," *The Lancet* Vol. 357, No. 9264 (2001): 1241-1247.

United Republic of Tanzania and private foundations.⁵⁹⁸ Descriptions of the project suggest it to have been a mixture of public health preventive research and practice.

Regarding ethics approvals obtained, the main publication of the study in 1999 did not indicate what approvals were obtained. In a private communication with the project leader, the information was provided that KINET obtained Ifakara Health Institute, Tanzania, as well as local MRCC and COSTECH approvals, with the project coordinator having also secured approval from the Swiss Tropical Institute in Switzerland.⁵⁹⁹ Foreign investigators in Tanzania are expected to secure approval for research protocols from the Medical Research Coordinating Committee MRCC as well as the COSTECH Commission for Science and Technology who is responsible for granting research permits to foreign investigators.

Regarding the intervention location, the education and promotional campaign was directed towards the state maternal and child health clinics, in order to 'capture' the target market of young children and pregnant women. It aimed to provide information in a persuasive, context appropriate way to a population in order to remove obstacles to behavioural change created by misconceptions about the causes of malaria, and how it can be prevented.⁶⁰⁰ The importance of such information campaigns is shown by the WHO position on the use of bednets that recommends the adopting of locally appropriate effective communication and advocacy strategies to promote effective use of treated bednets.⁶⁰¹

A flexible distribution system was chosen in conjunction with community leaders and community members in a series of open meetings. The agents nominated by the villagers included health workers, parish priests, community leaders and shopkeepers.⁶⁰² Training seminars were given and a reward system for reaching certain sales targets was used, and

⁵⁹⁸ Ibid.

⁵⁹⁹ Personal communication from Dr J Schellenberg.

⁶⁰⁰ Sohail, Agha et al., "The impact of a hybrid social marketing intervention on inequities in access, ownership and use of insecticide-treated nets." *Malaria Journal* Vol. 6, No. 13 (2007).

⁶⁰¹ WHO Global Malaria Programme: Position statement on ITNs Undated.

⁶⁰² Kara Hanson et al., "Cost-effectiveness of social marketing of insecticide-treated nets for malaria control in the United Republic of Tanzania," *Bull. World Health Organ*, 2003;81(4): 269-76.

agents who did not keep the terms of the contract were replaced.⁶⁰³ However, the distribution and sale of the nets and insecticide relied largely on using the skills of local retail shops.⁶⁰⁴

Concerning pricing strategy, subsidies were used to reduce the price of the bednets, with a price control being exercised by the selling price being clearly visible on the net packaging and mentioned in advertising. At the start of the campaign the price of the ex-factory bednets was subsidized by approximately 25% and the treatment kits by 83%. However, the effects of developments in the market and falling commodity prices resulted in the nets being later sold without a subsidy, and the subsidy on the treatment kits being reduced to 40%.⁶⁰⁵ In order to better reach and serve the target market of young children and pregnant women, a discount voucher system was introduced that was distributed at health care clinics.⁶⁰⁶ All women attending antenatal clinics and those attending for routine immunizations were entitled to this voucher which gave a price reduction for a treated mosquito net.⁶⁰⁷ Thus the pricing strategy tried to take account of questions of equity and affordability to the poor and vulnerable.

The first preparatory step was holding meetings in 1996 and 1997 in 18 villages to introduce the project, and discuss health problems with a focus on malaria and its prevention. These sensitization meetings took the form of an open discussion between project and community leaders, covering issues such as the health problems of the community, ways to prevent malaria including using nets and the need for retreatment, and how to get bednets into the community in a sustainable way.⁶⁰⁸ Based on this market research, the KINET team developed an information, education and communication (IEC) campaign that drew on basic

⁶⁰³ J R Schellenberg et al., "KINET: a social marketing programme of treated nets and net treatment for malaria control in Tanzania, with evaluation of child health and long-term survival." *Transactions of the Royal Society of Tropical Medicine and Hygiene* Vol. 93, No. 3 (1999): 225-231.

⁶⁰⁴ J R Schellenberg et al., "Effect of large-scale social marketing of insecticide-treated nets on child survival in rural Tanzania," *The Lancet* Vol. 357, No. 9264 (2001): 1241-1247.

⁶⁰⁵ Kara Hanson et al., "Cost-effectiveness of social marketing of insecticide-treated nets for malaria control in the United Republic of Tanzania." *Bulletin of the World Health Organization*, 2003;81(4): 269-76.

⁶⁰⁶ Ibid.

⁶⁰⁷ J R Schellenberg et al., "Effect of large-scale social marketing of insecticide-treated nets on child survival in rural Tanzania," *The Lancet* Vol. 357, No. 9264 (2001): 1241-1247.

⁶⁰⁸ Ibid.

principles of social marketing, namely that certain messages should be promoted together with a product carrying an appealing brand name and logo, and that the marketing should be consumer-oriented and targeted to specific segments of the society.⁶⁰⁹ A range of materials were developed including posters, leaflets and billboards.⁶¹⁰ The brand name and logo were developed together with an advertising agency in Dar-es-Salaam, and were tested locally. The treated nets and insecticide treatment service were launched in 1997 with a celebration that included community theatre, songs, a raffle and speeches from community leaders. The results of the KINET project provided data on the costs and consequences of applying a social marketing approach to malaria control in children, with cost data being collected and analysed so that the cost per death averted, and disability-adjusted life year averted could be calculated, by comparing net usage and non usage on children.⁶¹¹ Even with subsidies for promotion, distribution, and insecticide costs, charging for insecticide-treated nets creates barriers for very poor people. Social marketing was concluded, however, as being a useful approach for malaria control in a rural African setting.⁶¹²

Validating Consent and Assent in KINET

The validation indicators listed in Section 9.4 above will now be systematically applied.

- a) It appears that the appropriate ethics approval was obtained.
- b) Regarding if an individual informed consent process undertaken, at the heart of the KINET project was the execution of IEC campaign, regarding which no individual informed consent process could (feasibly) be pursued. This being the case, the question is whether this 'waiver' was justified according to the exploratory criteria located in Chapter 6

⁶⁰⁹ H. Minja et al., "Introducing insecticide-treated nets in the Kilombero Valley, Tanzania: the relevance of local knowledge and practice for an Information, Education and Communication (IEC) campaign." *Tropical Medicine and International Health*, volume 6 (2001): 614-623.

⁶¹⁰ Ibid.

⁶¹¹ Kara Hanson et al., "Cost-effectiveness of social marketing of insecticide-treated nets for malaria control in the United Republic of Tanzania." *Bulletin of the World Health Organization*, 2003;81(4): 269-76.

⁶¹² J R Schellenberg et al., "Effect of large-scale social marketing of insecticide-treated nets on child survival in rural Tanzania," *The Lancet* Vol. 357, No. 9264 (2001): 1241-1247.

(notwithstanding that criteria needs to be developed with public health in different political and economic settings in mind):

- i) The waiver criterion that seeking individual level informed consent must be impossible is met.
- ii) Approval of ethics committees was secured. It would be necessary to check what ethical issues were addressed to and by the RECs to fully evaluate the REC approval situation. Although they were not in force at the time of the intervention, it is interesting to note that the Tanzania Guidelines on Ethics for Health Research from 2001 read that “there are circumstances where it may not be feasible to obtain informed consent from individual subjects recruited for epidemiological studies.” Such studies should be strictly scrutinized, and the researchers should provide satisfactory reasons to RECs why the proposal should be granted ethical clearance in the absence of informed consent.⁶¹³
- iii) Can KINET meet the criterion of having a low – minimal – level of risk? The approval processes should have reviewed the risk profile of the intervention; the fact that approvals were obtained suggests that the risk profile of KINET was judged to have been acceptable. Notwithstanding this, in public health transcultural contexts, not only individual, but also community and population level risks can arise; ‘risks’ can occur to all dimensions of health: mental and physical health and social well-being. “Dignitary harm” can arise if informed consent is not sought, and what is seen as being a risk can vary according to cultural context. Especially complex will be making an ethics analysis of programmes that have a community impact aspect – as is the case with KINET.
- iv) Was the intervention performed within the scope of regulatory authority and in a political environment that allows for an assumption that at least the majority of the community gave tacit or implicit consent? This question is relevant for transcultural social marketers who undertake interventions in countries of which they are guests.⁶¹⁴ An additional issue is if transcultural marketers use marketing techniques in a population that may have only limited capacity to participate in democratic processes, and who will not

⁶¹³ NHREC (Tanzanian) National Health Research Ethics Committee, *The Tanzania Guidelines on Ethics for Health Research*, 2002, Chapter 3 and 6.

⁶¹⁴ George Brenkert, “The Ethics of International Social Marketing,” in *Ethics in Social Marketing*. Ed. Alan R. Andreasen (Washington, D.C.: Georgetown University Press, 2001): 45.

enjoy “a rights-based voice in matters of significant concern to them.”⁶¹⁵ KINET was a collaboration with the Government of the United Republic of Tanzania, some degree of legitimation can be taken as being granted to the KINET team. Observer reports of the 2010 Tanzanian elections suggest that the Republic of Tanzania is an emerging democracy.⁶¹⁶

v) Regarding the condition for justifying waiver that there should be no known or likely reason for thinking that participants would not have consented if they had been asked,⁶¹⁷ cultural-historical expert evaluation would be needed to look at this question, although the participatory nature of the KINET project indicates that no such reason existed.

vi) Was the agreement of representative members of the relevant community obtained? The 1991 version of the CIOMS epidemiology guidelines in place at the time of the intervention stated that when it is not possible to request informed consent from every individual to be studied, the agreement of a representative of a community or group may be sought, but the representative should be chosen according to the nature, traditions and political philosophy of the community or group with the approval given by a community representative being consistent with general ethical principles.⁶¹⁸ The Tanzanian Guidelines (that admittedly came into force only after the research was completed),⁶¹⁹ now echo this position, stating that “there are circumstances where it may not be feasible to obtain informed consent from individual subjects recruited for epidemiological studies.” In such cases “an agreement of the community representation may have to be sought from the community where the planned study is to take place,” although selection of the representative should be carried in a manner that conforms with the traditions and culture of the community and that the approval provided for by the community has to be assessed and should conform with ethical norms.⁶²⁰ There is no evidence in the KINET publications

⁶¹⁵ George Brenkert, “Ethical Challenges of Social Marketing,” *Journal of Public Policy and Marketing* Vol. 21, No. 1 (2002): 14-25.

⁶¹⁶ See comments by the UNDP at the website: <http://www.tz.undp.org/>.

⁶¹⁷ National Health and Medical Research Council, Australian Government “National Statement on Ethical Conduct in Research Involving Humans,” 2007.

⁶¹⁸ CIOMS, *International Ethical Guidelines for Epidemiological Studies*, 2009.

⁶¹⁹ National Health Research Ethics Committee (NHREC). “The Tanzania Guidelines on Ethics for Health Research.”

⁶²⁰ Ibid.

that any such formal community surrogate assent was knowingly undertaken. However, the participatory nature of the KINET project may compensate for this omission.

A final reflection is the UNESCO criterion that consent can be waived if an intervention is vital to protect public health and the rights and freedoms of others so long as it does not infringe international human rights law. Although a detailed consideration is outside the scope of this dissertation, an open question is whether this criterion can apply to research, or only the practice of medicine or public health (as the benefits of research are not proven at the time of the intervention)?

c) To return now to the validation indicators surrounding the role, rights and interests of 'community': was the principle of respect for community and sensitivity to local cultural traditions observed? The holding of village meetings and sensitization meetings with community leaders showed that KINET engaged with various local stakeholders at various stages of the project. Local knowledge was also called upon in various ways: the distribution system was chosen in conjunction with community leaders and community members in a series of open meetings, with the appointed agents coming from the community. Local advice was also sought in developing branding.

d) Regarding if there are indications that not enough attention, or too much time was unnecessarily given to consent and assent issues, an indication of a lack of attention may be seen in the absence of references being made in the publications to the ethics approvals, and the apparent weak compliancy with the 1991 CIOMS guidelines. However, at the time of the intervention and the publication, the awareness of research ethics, and the journal requirement for acceptance of an article that reference be made to ethic committee approvals were not yet developed.

To conclude, the analysis suggests that conducting the intervention although individual consent had to be 'waived' was justifiable although a clear community level assent thereto is required (and may indeed have been obtained, but not reported in the publication). Analysing KINET draws attention to the need for, and the absence of guidelines supporting public health, social marketing interventions. The main questions suggested above that need to be asked of KINET is whether the vulnerable and disadvantaged were exposed to marketing techniques where they were not able to protect their own interests, if any marketing techniques that go unreasonably in the direction of psychological coercion occurred, and

whether both the means and ends were acceptable. It is reasonable to assume in KINET that none of these problems arose.

9.10 The Background of the IPTi Project

Before outlining the two case studies that took place within the IPTi project, the background to IPTi will now be outlined. Because the signs of falciparum infection in younger children tend to be the non-specific, early stage malaria infection is often unrecognised, and remains, therefore, untreated. Hence a preventive, rather than curative approach for infants is appealing. Intermittent Preventive Treatment in infants (IPTi) is a promising new tool for malaria control that has successfully been pushed forward in the first decade of the 21st century. IPTi involves the administration of a course of an anti-malaria drug - chemoprophylaxis - delivered alongside the expanded programmes on immunisation (EPI). EPI is given at the ages of 2, 3, and 9 months and is one of a few major public-health success strategies, delivering millions of doses of vaccines to infants worldwide every year. It is often the only system of routine contacts between health services and infants in many parts of the world.⁶²¹ Delivering IPTi (irrespective of whether malaria is suspected or has been diagnosed), at the same time as the standard vaccinations is hoped to reduce the negative impacts of poor access to curative services. The candidate anti-malaria drugs used in the research have already received marketing approval as malaria therapeutic agents (with testing, however, usually conducted on adults, not infants).

The IPTi Consortium was founded after the positive results of the case study that will be presented below: the first safety and efficacy trial conducted in Ifakara, Tanzania of IPTi with sulfadoxine-pyrimethamine (SP) delivered through the EPI.⁶²² The Consortium, together with the WHO developed a 5 year programme of studies in Africa that commenced in 2004.⁶²³ The programme was designed to generate evidence on the safety, efficacy, acceptability, effectiveness, cost effectiveness, and implementation strategies to enable the scaling-up of

⁶²¹ David Schellenberg et al., "Intermittent treatment for malaria and anaemia control at time of routine vaccinations in Tanzanian infants: a randomised, placebo controlled trial," *The Lancet* Vol. 357, No. 9267 (2001): 1471-1477.

⁶²² Ibid.

⁶²³ See IPTi Consortium website at <http://www.ipti-malaria.org/>.

IPTi in a range of settings and to monitor any risks or disadvantages that might occur. The aim of all this work was to present the project to the WHO for their evaluation and decision if IPTi should become a WHO recommended policy for malaria control. This was a complex decision in view of the following open scientific and ethical issues⁶²⁴ that surrounded the development and implementation of IPTi:

- a) The fact that the research subjects would be doubly vulnerable: vulnerable by their place of birth, and intrinsically vulnerable because of their age.
- b) The risk of the negative impact of speeding-up the rate of parasite drug resistance to anti-malarials especially SP. Can this risk be justified by the use of the drug as a prophylaxis (on infants who may be infected)? Might this risk be justifiable in endemic regions? In any event, continuous surveillance of parasite resistance to SP must accompany the implementation of SP-IPTi.^{625, 626}
- c) Uncertainty whether adverse effects would result from IPTi on attitudes and uptake of standard EPI interventions. Or conversely, whether the addition of a new intervention enhances the perceived value of EPI and clinic attendance?
- d) Lack of evidence whether the anti-malarial drugs could interact negatively with the infants serological response to EPI vaccines.
- e) Uncertainty if an intermittent programme in infants might bring a loss or retardation of acquired immunity, resulting in a rebound period of increased clinical malaria upon cessation of the prophylaxis? During acute infections, many individuals develop an antibody mediated immunity directed against the parasites in the mosquito, with the immunity being capable of conferring some protection against morbidity and mortality due to the disease.⁶²⁷
- f) Lack of clarity of the risk-benefit ratio of the use of SP on infants in endemic settings in view of the adverse-reaction profile of SP resulting in its withdrawal as a prophylactic agent in non-immune adult travellers.^{628, 629}

⁶²⁴ The case of IPTi illustrates well why RECs need to evaluate (or have evaluated) the science of the project under review and the scientific-medico context of the project.

⁶²⁵ WHO, Technical Expert Group on Preventive Chemotherapy.

⁶²⁶ The WHO report Global report on antimalarial drug efficacy and drug resistance: 2000–2010 published in 2010 drew attention to the increasing problem of parasites developing drug resistance.

⁶²⁷ K N Mendis et al., "Malaria transmission-blocking immunity induced by natural infections of *Plasmodium vivax* in humans," *Infect Immun*. 1987 February; 55(2): 369-372.

After completion of the intensive and extensive research programme, the WHO were satisfied in 2010 that it was appropriate to issue a policy recommendation on Intermittent Preventive Treatment during infancy with sulphadoxine-pyrimethamine (SP-IPTi) for *Plasmodium falciparum* malaria control in Africa, in addition to the key interventions recommended by the WHO.⁶³⁰

9.11 The IPTi Randomised, Placebo-Controlled, Safety and Efficacy Trial

The first of the two IPTi trial case studies that will now be outlined is the safety and efficacy trial conducted for Intermittent Preventive Treatment in infants that was reported in the *Lancet* in 2001,⁶³¹ that took place during the period 1999-2000 in Ifakara, Tanzania. This was the first of the safety and efficacy trials that laid a foundation for the IPTi Consortium. It was a randomised, placebo-controlled, double-blind study delivering intermittent doses of sulphadoxine-pyrimethamine (SP) alongside routine EPI vaccinations at the ages of 2, 3, and 9 months.

At the time of the trial, although no new chemical entity was being tested, equipoise was claimed in that it was unknown to what, if any, extent prophylaxis intermittent treatment might prevent malaria and anaemia in infancy. The risks and unknown factors involved in the trials were listed in 9.10 above that would necessitate careful approval processes from scientific and ethical points of view, especially considering the placebo design. According to the publication in the *Lancet*, the study protocol was approved by the Ifakara Health Research & Development Centre's Scientific and Ethical Review Committees, the Tanzania Medical Research Co-ordinating Committee, and the WHO. The trial intervention design was that the

⁶²⁹ David Schellenberg et al., "Intermittent treatment for malaria and anaemia control at time of routine vaccinations in Tanzanian infants: a randomised, placebo controlled trial." *The Lancet* Vol. 357, No. 9267 (2001): 1471-1477.

⁶³⁰ The recommendation stated however that programmes implementing the SP-IPTi strategy should regularly monitor and evaluate the impact on immunization services and performance, and that pharmacovigilance systems monitoring potentially serious adverse reactions to SP should be strengthened. Surveillance of parasite resistance to SP should accompany the implementation of SP-IPTi as a surrogate measure of its efficacy. See the recommendation at https://www.who.int/malaria/news/WHO_policy_recommendation_IPTi_032010.pdf.

⁶³¹ David Schellenberg et al., "Intermittent treatment for malaria and anaemia control at time of routine vaccinations in Tanzanian infants: a randomised, placebo controlled trial." *The Lancet* Vol. 357, No. 9267 (2001): 1471-1477.

first dose of sulphadoxine-pyrimethamine or placebo was given at age 2 months crushed and mixed with water on a tablespoon. Children were observed for 30 min, and a repeat dose was given if vomiting occurred. The second dose was given immediately after the standard 3 month infant EPI vaccination programme, with the third dose of the study drug being given at the time of measles vaccination (age 9 months). Iron supplements were dispensed to all children, and compliance was assessed when children attended routine clinic visits. At each consultation a detailed standardised questionnaire was completed that documented signs and symptoms. Costs of treatment for children in the study were covered by the project. Blood samples were collected throughout the trial to assess seroconversion to EPI vaccines.⁶³²

Infants were recruited at the mother and child clinics in the time scale August 1999 to April 2000, with the intervention being explained to parents or guardian. Their understanding was assessed with a set of standard questions, and written informed consent was obtained.⁶³³ After written consent was given, a recruitment questionnaire was completed, and the child was assigned an identification number and allocated to a placebo or active substance group. Of the 701 included at the start of the trial, 40 children dropped out as the trial progressed, 12 due to parents withdrawing consent.⁶³⁴

Validating the IPTi Randomised, Placebo-controlled, Safety and Efficacy Trial

The validation of the consent and assent processes in the IPTi safety and efficacy trial will now be considered.

a) Firstly, the appropriate ethics approvals were obtained. In addition to the approvals mentioned above, each project underwent review by the Gates Foundation. The Consortium also undertook to assure that all trials were conducted to Good Clinical Practice (GCP) levels, underwent regular clinical data and safety monitoring, and all were registered at the

⁶³² David Schellenberg et al., "Intermittent treatment for malaria and anaemia control at time of routine vaccinations in Tanzanian infants: a randomised, placebo controlled trial," *The Lancet*, Vol. 357, No. 9267 (2001): 1471-1477.

⁶³³ Ibid,

⁶³⁴ Ibid.

data base www.clinicaltrials.gov to add to transparency (also regarding trials that were not completed, and irrespective of the findings).⁶³⁵ Regarding the potentially controversial placebo nature of the trial, the 1996 version of the Declaration of Helsinki valid at that time required that every patient enrolled in a medical study be assured of receiving the best proven diagnostic and therapeutic methods; placebo controls were only being permitted in studies where no proven diagnostic or therapeutic method existed. The Lancet publication of the trial results comments that the investigators argued that the use of a placebo was necessary since the safety and efficacy of intermittent treatment has not previously been assessed in infants. The 2001 Guidelines on Ethics for Health Research in Tanzania state that with trials involving drugs with known side effects, the trials should be conducted with patients suffering from the illness, who are more likely to benefit from the trial (to counterbalance the risk of harm).

b) To turn to the question of whether an individual informed consent process was undertaken? The answer is yes. Did this conform to the minimal elements located in Section 6.20? Regarding assuring the competence and voluntariness, there is no reason to suppose from the published article that mothers at the clinic who enrolled their infants in the EPI vaccination campaign were not competent, nor any suggestion of coercion, although there will be pressures if one lives in a region of endemic malaria area with a weak health system. Concerning if the appropriate information was provided, the protocol and the documents submitted to the REC would need to be reviewed to control that the appropriate information elements were planned to be communicated, with post intervention research needing to confirm that the approved process was followed. Whether a culturally appropriate consent process was followed cannot be judged. It seems from the research article, however, as if there was little time for reflection and discussion with trusted people, as infants were recruited at the mother and child clinic immediately after receiving their second EPI dose, with the first SP prophylaxis being immediately given after the consent was granted. However, because the intervention was spread over several months, a chance to withdraw was then later possible. Indeed 14 parents did withdraw their consent and left the study. Regarding the consent element, written informed consent was said to have been obtained from either the parents or guardian. Positive is that the aspirational goal of controlling understanding was pursued, with action being taken to check that the understanding of the potential participants was assessed. On conclusion, there are indications of a good level of

⁶³⁵ See IPTi Consortium website: URL <http://www.ipti-malaria.org>.

compliance with the core elements, but more information would be needed to fully judge by looking at the protocols and conducting interviews.

Looking beyond compliance with existing guidelines, was the approach taken to consent optimal? Although no issues are raised in the publication of the results of this study, insights are obtained by considering an article published that reports on research conducted on the community response to IPTi in Mozambique.⁶³⁶ This study found that IPTi delivered together with EPI was generally accepted but only after initial rejection. During the early stages of the IPTi trial, there was serious community resistance to participation, including rumours about blood stealing and poisoned refreshment (that were connected with political, historical events and background). These doubts were stimulated by the weight put on providing information to the community, and the focus in individual consent processes on the risks of SP for infants – what, it was asked, is the true purpose of IPTi; why is this effort being taken as the adults had been taking SP for some time without this being an issue, and without being asked to give consent? Why were the risks suddenly being emphasized in the context of the trial? Why did the mothers have to go through a detailed consent procedure, and sign forms in order for their child to receive IPTi, whereas they had never had to sign forms to take SP or to receive immunization in the past?⁶³⁷ The list given above of the risks and uncertainties of IPTi in its trial phase shows that: a) it was reasonable in view of the risk profile that the locals were concerned, and b) precisely this risk profile necessitated making efforts to fully inform the potential participants. Although transferring these experiences in Mozambique directly to Tanzania is questionable, the case shows that acting in the best intentions (and following guidelines) in explaining risks, providing information, and seeking consent can have repercussions that can endanger the successful recruitment for a research project. There are of course situations in which it is appropriate that a project is not completed for scientific or ethical reasons; there can be important and good reasons why consent is rejected – one function of individual community consent and assent is to give individuals and communities the opportunity to turn down an intervention, with most guidelines explicitly stating that they are not required to justify their decision – their opinion is simply to be respected. However,

⁶³⁶ R. Pool et al., “Community response to intermittent preventive treatment delivered to infants (IPTi) through the EPI system in Manhic, Mozambique.” *Tropical Medicine and International Health* (2006): 670-678.

⁶³⁷ Ibid.

being forced to breaking-off a trial due to recruitment problems based on fallacious misunderstanding of the nature of the project may lead to important knowledge not being acquired. The conclusion must be that especially when complex and potentially contentious interventions are planned that have more than minimum risk, a full information and involvement strategy of individuals and communities is the way forward, with resources being available to pick up on issues and fears that arise, and to deal honestly with them.

c) On the subject of respecting community rights, interests and traditions, the individual, invasive nature of the intervention meant that in line with the current guidelines, the main focus was on seeking parental consent on behalf of the infants. The IPTi intervention does not have the 'herd' ethics aspects that a bednet campaign has – individual participation or abstention does not have epidemiological impacts. However, the Mozambique example indicates that a solid level of community involvement and communication is always advisable in this kind of complex trial.

d) Finally, would obtaining a waiver have been conceivable; was unnecessary energy expended on conducting informed consent processes, or are there any indications that not enough attention was given? The risk level was too high to make waiver a conceivable option. There are no indications that insufficient attention was given to consent and assent issues at the individual level, nor was too much attention given. On the contrary, in the intervening years since the research was conducted (1991-2000), issues surrounding placebo trails have become more, rather than less complex. Giving more time to the community level could have been advantageous, but before firing-up any judgement, this intervention must be evaluated as being a part of the whole IPTi project.

9.12 The IPTi Acceptability Study

The article "The acceptability of intermittent preventive treatment of malaria in infants (IPTi) delivered through the expanded programme of immunization in southern Tanzania"⁶³⁸ reports on one of the acceptability studies carried out from February 2005 to April 2007 that examined the IPTi programme. It was part of the IPTi Consortium's programme aimed at evaluating if the WHO should include IPTi in their recommended policy for malaria control.

⁶³⁸ Robert Pool et al., "The acceptability of intermittent preventive treatment of malaria in infants (IPTi) delivered through the expanded programme of immunization in southern Tanzania," *Malaria Journal* 2008, 7: 213.

Although at the time of the study sound safety and efficacy data has been accumulated (as produced by the trial outlined above), there were various open issues that needed resolution before scaling-up an IPTi programme. The questions that the acceptability study considered included looking at the reception of IPTi and the various contextual factors that influenced this reception.⁶³⁹ For example, it was essential to ensure that IPTi was acceptable to the community, and would not adversely affect attitudes to immunization or existing health seeking behaviour.

Regarding ethics approvals, the publication stated that the acceptability study was a part of an IPTi project that received ethical approval from the local and national institutional review boards of Ifakara Health Research and Development Centre, Tanzania, the National Tanzania Medical Research Co-coordinating Committee, the Tanzania Commission for Science and Technology, the London School of Hygiene and Tropical Medicine and the Swiss Tropical Institute.

Verbal informed consent was reported as being sought from all participants, and recorded at the time of interviews or focus group discussions, with all digital recordings and transcripts being stored on secure computers to which only project staff had access, and with participants being identified through identification numbers.

The study design was to collect data through conducting in-depth interviews, focus group discussions and participant observation, using a central team of two trained interviewers and a social scientist that regularly visited and spent time in all the research sites. Data were also collected through a network of eight local resident interviewers who are reported as being well integrated in their communities, with community leaders and members being supportive of their role in the project.⁶⁴⁰ These community based assistants were paid approximately US\$25 per month, and were visited, debriefed and interviewed quarterly by members of the central social science team. Their role was also to mobilize members of the community for

⁶³⁹ Ibid.

⁶⁴⁰ Ibid.

focus group discussions and in-depth interviews that were carried out. An ethnographic study involving participant observation in health centres and communities was also undertaken.⁶⁴¹

Validating the IPTi Acceptability Study

The IPTi acceptability study that used in-depth interviews, focus group discussions and participant observation to collect data will now be assessed.

a) Regarding the ethics approvals obtained, the publication states that the acceptability study was part of the main IPTi project conducted within the framework of the IPTi Consortium that received the appropriate clearance. More information than that available in the public domain is needed to judge the adequacy of the multi-intervention approvals obtained. This obtaining of a blanket approval may be open to debate although in the absence of clear international indications for waiver or inclusion of consent for social science research, this is an understandable approach.

b) An individual informed consent process was undertaken. Regarding the core set of obligatory (minimal) steps, there is no reason to doubt the competence and voluntariness of those who took part in the study. Regarding the adequacy of information provided, more research and access to documentation not in the public domain would be necessary to judge this. Regarding conducting a culturally appropriate consent process, and documenting consent in a culturally appropriate way: verbal, not written consent was sought from all participants and recorded at the time of interviews or focus group discussions. The CIOMS epidemiology guidelines state that consent may be indicated in a number of ways; an ethical review committee may waive the requirement of a signed consent form if the research carries no more than minimal risk, and if the intervention would not usually require a signed consent form if performed outside the research context. When consent has been obtained orally, investigators are responsible for providing documentation or proof of consent;⁶⁴² the publication states that the consents were recorded. The Tanzania Guidelines on Ethics for Health Research, 2001 Chapter 3 “Consent” (see Annex III) read that the types of consent include oral or written, with consent given in writing not being superior to verbal.

⁶⁴¹ Ibid.

⁶⁴² CIOMS, *International Ethical Guidelines for Epidemiological Studies*, 2009: 40-44.

It seems reasonable to classify the intervention as carrying no more than minimal risk, although the CIOMS Guidelines comment that epidemiology studies including “observational” studies such as administering a questionnaire or conducting an interview were in the past regarded as not raising any significant ethical issues, and were commonly carried out without approval of an ethical review committee. However, recent years have brought increased attention to the ethical conduct of research generally, greater awareness of the potential harms to research subjects including non-physical harm.⁶⁴³ One problem with this IPTi acceptance study is the “participant observation” that is said to have taken place. It may not be feasible to seek prior consent for this kind of research. Therefore conducting some form of community proxy and community consultation prior to the intervention would have been appropriate, but is not referenced in the publication.

c) Concerning the question if the principle of respect for community and sensitivity to local cultural traditions were observed, and how the relationship informed consent and community assent were handled: the engagement of local people who were well integrated in their communities, the mobilizing of members of the community suggests that the local context was respected as being an important factor.

d) Was unnecessary energy expended on conducting informed consent processes – would obtaining a waiver have been conceivable? Or are there any indications that not enough attention was given to consent and assent issues? Bearing in mind that the intervention was based on a one-to-one interaction, dispensing with any kind of consent was not an option. However, the non-invasive nature of the interactions suggests that it was justified to seek oral, not written consent.

Section 5.4 above (see also Annex I) outlined the requirement for informed consent in the social sciences. Both the UNESCO Code of conduct social science research, and the Association of Social Anthropologists of the UK and Commonwealth Ethical Guidelines for Good Research Practice clearly require informed consent, although the Social Anthropologist Guidelines refer to “negotiating informed consent,” reading that, “the principle of informed consent expresses the belief in the need for truthful and respectful exchanges between social researchers and the people whom they study.”⁶⁴⁴ There is a complex and contentious

⁶⁴³ CIOMS, *International Ethical Guidelines for Epidemiological Studies*, 2009, Introduction: 14-16.

⁶⁴⁴ See the Association of Social Anthropologists of the UK and Commonwealth URL http://www.theasa.org/ethics/Ethical_guidelines.pdf.

debate regarding whether ‘informed consent’ as developed in medical fields should be expanded into social science research, an assertion that has met with considerable opposition.⁶⁴⁵ Surely social science research might sometimes be different from health research in ways that justify a different approach to ‘consent’ being taken?⁶⁴⁶ The social sciences seek data on life as experienced, not data on something that can be measured using the methods of the natural sciences. The data is not generated but gathered; access to the data requires a different kind of relationship between researcher and participants compared to taking a blood sample.

On the other hand, there are also arguments that support the need for formalized research ethics in the social sciences, with a few voices supporting reflection on the meaning and role of informed consent in the social sciences. One such argument is that “it is probably good to have bureaucratic recognition of the need to negotiate research participation as a countervailing pressure on researchers, funders and publishers.”⁶⁴⁷ Also the fact that a research project is challenged or even made impossible by ethical requirements, does not conclusively demonstrate the unreasonableness of the ethics requirements – it may be that the intervention contains serious flaws that an ethics review has drawn attention.⁶⁴⁸

9.13 Case Study Conclusions

The limitations of this kind of case study analysis in validating the normative, guideline-driven status quo of consent and assent processes have become clear. The work of this section should be seen as a ‘warming-up’ exercise that is of particular value in identifying new areas that need reflection. It is in this spirit that the following conclusions are offered. Regarding obtaining appropriate REC approvals, the apparent use of blanket approvals needs to be considered, although in the absence of clear international indications for waiver or inclusion of consent for public health, social science research, this is an understandable

⁶⁴⁵ Michael M. Burgess, “Proposing modesty for informed consent,” *Social Science & Medicine*,” 65 (2007) :2284-2295, 2286.

⁶⁴⁶ Ibid.

⁶⁴⁷ Ibid.

⁶⁴⁸ Ibid.

approach. There are open questions on the standards that RECs should apply to consent and assent in public health interventions (and that the interventions should then follow in the field), especially when social science methodologies such as ethnology and anthropology are being applied, and regarding social marketing interventions. More work is needed to consider when and what aspects of informed consent can be varied; when consent processes are required, and when they can be waived.

KINET illustrates the questions that arise when complying with standard requirements such as obtaining informed consent is not being feasible. A major issue is not to under- or overestimate the risk or uncertainty of an intervention, and avoiding a) unnecessary complexity, or b) underestimating the need for consent or assent processes.

Both IPTi and KINET illustrate that more work is needed to explicate the role of community assent qua community interests, and the role of community surrogate assent (as proxy for individuals) in public health. The Mozambique case also showed a more pragmatic side to community involvement in order to address legitimate concerns and diffuse misconceptions. It is interesting to review KINET in the light of the hypothesis that an individual consent process should be evaluated not only as a stand-alone process, but also in the context of its being embedded in a particular intervention. Can the absence of individual consent be argued as being compensated in KINET by the various activities that involved the community (although they may not have been designed and coordinated with this goal in mind, but rather to ensure pragmatically the cooperation of the stakeholders)? If this is the case, this motivation to involve communities should be carefully planned as part of the consent and assent process (and be submitted to and approved by RECs).

The only identifiable instance of weak compliance with guidelines is that the CIOMS recommendation that the agreement of a representative of a community or group should be sought in the event that individual consent is not possible was not explicitly followed in KINET. Such problems may come from the inappropriate nature of the contents of the guidelines for some types of public health interventions, or lack of knowledge of these recommendations. The role, however, of local codes should not be forgotten when planning an intervention.

In general, work is needed to develop an ethics of social marketing, and to clarify its relation to public health ethics. Fundamental questions arise with social marketing interventions that use psychological pressure to change behaviour: is there a point at which respect for persons or communities is infringed? Can on the other hand, the kinds of community consultations and collaboration that took place in KINET be argued as counteracting the problems of a social marketing approach? Is social marketing a valid method for research projects?

Regarding social science research ethics in public health, it is proposed that the debate in the social sciences of the applicability of informed consent is fruitful for the work of a) developing an ethics of public health, and b) for issues surrounding informed consent and community assent. Accepting that informed consent is not an end in itself, but is one way of showing respect for an individual and their dignity, some of the approaches to consent coming from the social sciences that are less-procedural, judicial and ritualised might be valuable, such as the concept of an on-going negotiation of consent.⁶⁴⁹ The argument that the medicine-based formal doctrine may not be an adequate or reasonable approach to achieving the respectful research relationship that is the basis of social sciences work in order to produce knowledge does have value.⁶⁵⁰

Finally, is the validation criterion that the actions in the field should operationalize the principles that underlie informed consent and community assent so that the process upholds the principles (i.e. that persons or diversity is respected) duly satisfied? The Mozambique IPTi intervention raises questions that need more research: complex processes may indeed confuse rather than inform participants; informed consent can rather than respecting persons, be negatively perceived as being disrespectful. Nevertheless, it is vital to provide information on complex interventions that contain various risks. The importance of the role of local ethics review committees in designing processes that address these questions is once again highlighted.

⁶⁴⁹ Lynoe Hoeyer, "An organizational perspective on ethics as a form of regulation," *Med Health Care and Philos* 12 (2009): 385-392.

⁶⁵⁰ Michael M. Burgess, "Proposing modesty for informed consent," *Social Science & Medicine*, 65 (2007): 2284-2295, 2286.

In conclusion, the case studies suggest that there is a need for further investigation if all aspects of the informed consent and assent processes as prescribed, and as implemented in the field, can be 'validated.'

CHAPTER 10

ILLUSTRATIVE EXPLORATORY EMPIRICAL RESEARCH

The second part of the inductive, descriptive ethics tranche of the dissertation now commences, that covers the exploratory exemplary expert interviews that have been conducted as part of this dissertation.

10.1 Research Approach

The preparations made for the research followed the FAM model that structures the research process as having three elements: F, A and M.⁶⁴⁹ 'F' is the foundational framework necessary for conducting research formed by the epistemological position taken, and includes issues such as the generation and justification of knowledge; the role of evidence, and considering the various forms of 'research' that are relevant to a particular discipline. The position taken in this dissertation was outlined in Chapter 1, being that empirical research and the resulting evidence are inputs necessary for sound ethical reasoning. This role was expanded in the Deductive – Inductive Feedback Structure (Figure 2) that describes the relationship between the ethical normative and the descriptive work in ethics as being one of a two way feedback, with neither a "top-down" (principles, theories) nor a 'bottom-up' approach (cases, individual judgments) being alone sufficient for ethical decision making.

The next step in the FAM model is to build on 'F' and clarify 'A': the area of concern (the subject matter of the research), which is here informed consent and assent in public health in international contexts.

'A' needs then to be operationalized in the selection of the *methodology*, 'M.' The methodology and method of data-gathering is suggested and shaped by: 'F'; the contents of A; the nature of the discipline within which the research is being conducted, and the resources (time, financial, manpower) that are available.^{650, 651} After making a review of the methodologies that would be

⁶⁴⁹ Peter Checkland, Sue Holwell, *Information, systems and information systems: making sense of the field* (Chichester, UK: Wiley, 1998).

⁶⁵⁰ Juliet Corbin, Anselm Strauss, *Basics of qualitative research: Grounded theory procedures and techniques*, 3rd edition (Sage Publications, 2000): 12.

⁶⁵¹ Kathy Charmaz, "Grounded Theory: Objectivist and Constructivist Methods," in *Handbook of Qualitative Research*, Second Edition, ed. Norman K. Denzin, Yvonna S. Lincoln (Thousand Oaks, CA: Sage): 509-536.

suitable and practical, the qualitative, inductive grounded theory methodology was selected.⁶⁵² The reasons for this choice include that the suitability of grounded theory for intercultural research has long been advocated.⁶⁵³ Also when bearing in mind the limited resources, it is clear that this research can only be exploratory and exemplary, making no claim to being representative. The iterative, constant comparison method of grounded theory allows for the hope that hypothesis can be developed that are of value to the subject matter of consent and assent in public health.

The qualitative grounded theory (“grounded theory”) research method was developed by the sociologists Barney Glaser and Anselm Strauss.⁶⁵⁴ The motivation behind its development was to question the view that only a positivist, quantitative, deductive methodology such as developed by Merton is capable of producing knowledge and theories. According to this positivist point of view, qualitative research is unsatisfactory, unsystematic and biased, and cannot (inductively) generate theory, a position that Glaser and Strauss challenged with their approach. Grounded theory supports inductive methods of generating knowledge, with the issues emerging from the data and the general goal being to construct theories in order to understand a given phenomenon.⁶⁵⁵ The researcher analyses the data by a method of constant comparison of the transcribed data, with the comparisons being translated into codes and categories that will be compared with the next set of data etc. The grounded theory methodology allows the flexibility to follow leads that emerge during data collection. Thus grounded theory does not commence with a theory that is then tested by empirical methods, but adopts an open, exploratory, interpretive, process-oriented approach. This iterative, constant comparison method analysis should result in the theories being grounded in the participants’

⁶⁵² The Grounded Theory Institute, *The official site of Dr. Barney Glaser and Classic Grounded Theory*, URL: <http://www.groundedtheory.com>.

⁶⁵³ Vera Sheridan, Storch, Katharina, "Linking the Intercultural and Grounded Theory: Methodological Issues in Migration Research," *Forum Qualitative Sozialforschung Forum: Qualitative Social Research* [Online], Vol. 10, Nr 1, 2009.

⁶⁵⁴ Barney Glaser, Anselm L. Strauss, *The discovery of grounded theory: strategies for qualitative research*, (Chicago: Aldine 1967).

⁶⁵⁵ Brian D. Haig, *Grounded Theory as Scientific Method*.

experiences. The theories (or hypothesis) generated will be grounded in the data, not in a theory.⁶⁵⁶

Having selected the theoretical, methodological approach to the research, the form of data collection needed to be decided. Recalling that the methodology determines the appropriate ways to gather data,⁶⁵⁷ of the various methods that are appropriate to grounded theory, the choice was made to conduct semi-(minimally) structured, exemplary expert interviews.^{658, 659} The main reason for this choice is that expert interviews are particularly constructive in the exploratory phase of a research project, as they offer fast access to a field through the special knowledge that experts will have.⁶⁶⁰

10.2 Sampling: Expert Selection Criteria

The primary expert selection criterion was their status as expert regarding the phenomena under examination: consent and assent in public health as practised in the field.⁶⁶¹ To locate this knowledge, experts were sought who had practical experience in conducting public health preventive research and practice interventions in Africa, as exemplified by the work in malaria control and prevention; experts having such experience, are likely to have been exposed to informed consent and assent questions. The next step was to select the experts by looking at who was frequently named in publications; considering then the feasibility of securing (geographically) an interview with them, followed by using a 'snowballing' technique (with one expert recommending another). In spite of resource limitations, experts were chosen not from the same institution, but taken from two different globally active academic institutions based in

⁶⁵⁶ Juliet Corbin, Anselm Strauss, *Basics of qualitative research: Grounded theory procedures and techniques*, 3rd edition (Sage Publications, 2000): 12.

⁶⁵⁷ Kathy Charmaz, *Constructing Grounded Theory: A Practical Guide Through Qualitative Analysis*, (Sage Publications Thousand Oaks, 2006): 16.

⁶⁵⁸ Juliet Corbin, A Strauss, *Basics of qualitative research: Grounded theory procedures and techniques*, 3rd edition (Sage Publications, 2000): 12.

⁶⁵⁹ Kathy Charmaz, *Constructing Grounded Theory: A Practical Guide Through Qualitative Analysis*, (Sage Publications Thousand Oaks, 2006): 13.

⁶⁶⁰ See Website <http://www.ies.be/>, Leo Van Audenhove.

⁶⁶¹ ILMES - Internet-Lexikon der Methoden der empirischen Sozialforschung
URL: <http://www.lrz-muenchen.de/>.

two different European countries. Some variations in professional and cultural backgrounds were strived for, as the aim of the explorative interviews was to access a wide range of viewpoints. This process resulted in four experts being successfully recruited. Their backgrounds were as follows: a European professor of epidemiology with a background of biology and epidemiology; a European professor of epidemiology with background in clinical science and medicine; an African epidemiologist primarily educated at an African University, and a European anthropologist. Interviews were held in both countries over a period of 2 months in line with the iterative nature of grounded theory.

10.3 Obtaining Research Ethics Committee Approvals

Although no discipline specific guidelines exist covering what approvals are needed for the particular forms of research that practical ethics would typically conduct, the position is taken that the same principles should be applied to these interviews in the field of ethics as would be applied to research in any other discipline that involves human participation. There is, however, disagreement as to when and if expert interviews need to obtain approvals. As it is reasonable to expect from ethicists that they give special attention and vigilance to obtaining review board approvals,⁶⁶² the assumption was made that a protocol for expert interviews should be submitted for approval. Therefore the draft information sheets, informed consent documents, and project outline were submitted to the appropriate authorities in the two countries where the interviews were to take place. One of the review bodies was a regional Ethics Research Review Commission; the other was an Institutional Review Board. There were considerable differences in the approaches and complexity of the two sets of required documents. The regional Commission issued a notice of non-objection (whilst commenting that they did not consider that such interviews required approval, nor was it necessary to have informed consent forms), with the Institutional Review Board accepting the documentation and issuing an approval letter.

⁶⁶² Marcus Düwell, „Wofür braucht die Medizinethik empirische Methoden? Eine normativ-ethische Untersuchung,“ *Ethik in der Medizin*, Vol. 21. Nr. 3, 2009: 201-211, 208.

10.4 Preparing and Structuring the Interviews

An expert interview that applies grounded theory should take a conversational form, whilst still following the etiquette of questioning, reflecting, probing and clarification.⁶⁶³ It should be an open or semi-structured dialog, in which the interviewer actively participates.⁶⁶⁴ Questions should explore the interviewer's topic and 'phenomena' (in this case issues surrounding consent and assent), but focus on the participant's experience.⁶⁶⁵

The preparations for the first interview started by reading the expert's major publications. A few broad, open ended questions were prepared, plus some more focused questions to follow-up in more detail (for use, however, only as necessary if the interview became 'stuck'). Immediately after the interview, the transcription was made and analysed. For the next interview, the broad and follow-up questions were revised and expanded after analysing the previous interview transcription in line with the iterative nature of grounded theory, and taking into account the knowledge and experience of the next expert. This process was then repeated for the subsequent interviews.

10.5 Conducting Expert Interviews: The Theory

The relationship between interviewer and expert involves complex, mutual role expectations and questions of power that influence the interview dynamics, having effects that are then part of the data produced.^{666, 667} Various roles (that then define the relationship and type of interaction between expert and interviewer), can be played or assigned within an interview. The interviewer can deliberately assume a role as a strategic choice, or be assigned a role as a result of the interview dynamics. The various interviewer roles include: the interviewer being a

⁶⁶³ Kathy Charmaz, *Constructing Grounded Theory: A Practical Guide Through Qualitative Analysis*, (Sage Publications Thousand Oaks, 2006): 26.

⁶⁶⁴ Leo Van Audenhove, Methodological Research Colloquium Expert Interviews and Interview Techniques for Policy Analysis.

⁶⁶⁵ Kathy Charmaz, *Constructing Grounded Theory: A Practical Guide Through Qualitative Analysis*, (Sage Publications Thousand Oaks, 2006): 29.

⁶⁶⁶ Bogner Menz et al., *Das theoriegenerierende Experteninterview, Theorie, Methode, Anwendung* (VS Verlag für Sozialwissenschaften, Wiesbaden 2005. 2nd edition).

⁶⁶⁷ Ibid.

co-expert in the same field; being a co-expert in another discipline; having the position of lay person; assuming the role of critic of the expert, or being a co-conspirator to the expert. Each type of relationship brings different benefits and problems for data content and quality.⁶⁶⁸

Interviewers conducting expert interviews need not remain completely neutral, but can share knowledge, thoughts and insights with the experts, especially if acting in some kind of co-expert role.

Regarding interviews between different disciplines, the reputation of the interviewer's discipline can influence the dynamics. For instance, the subject of ethics is seen in some circles as creating obstacles for science.⁶⁶⁹ Therefore, an ethicist may implicitly be ascribed the role of critic, and be forced in the interview into the difficult role of disproving this supposition. Interviews between disciplines can also bring the problem of interdisciplinarity caused by epistemic differences.⁶⁷⁰

10.6 Transcription Approach

The act of transcribing interview material is a pivotal aspect of qualitative inquiry.⁶⁷¹ There are two directions that transcription can take: denaturalized or naturalized.⁶⁷² In 'naturalized transcription', the interview tapes will be transcribed in as much detail as possible. The analysis will include textual symbols and layouts (similar to a score in music) that notate time gaps, speed of speech, overlapping dialogs, etc. The other direction is denaturalized transcription that focuses on the informational content of the interview transcribing only the words said.

⁶⁶⁸ Ibid. 49-61.

⁶⁶⁹ Jeantine E Lunshof, "Desperate times call for desperate measures." *Nature Reviews Genetics* 7, 162, (2006).

⁶⁷⁰ Bogner Menz et al., *Das theoriegenerierende Experteninterview, Theorie, Methode, Anwendung* (VS Verlag für Sozialwissenschaften Wiesbaden 2005. 2nd edition): 18.

⁶⁷¹ Daniel G. Oliver et al., "Constraints and Opportunities with Interview Transcription: Towards Reflection in Qualitative Research," *Soc Forces*, 2005 December; 84(2): 1273-1289.

⁶⁷² Mary Bucholtz, "The politics of transcription," *Journal of Pragmatics* Volume 32, Issue 10, September 2000: 1439-1465.

Denaturalized transcription is held to be suitable to grounded theory, and was the approach used.⁶⁷³

10.7 The Treatment of Sensitive Interview Data

It was noted that as an interview progressed, a relationship of trust was built up between an expert and the interviewer, with the experts becoming more generous in their preparedness to share their experiences and opinions. Often speaking with passion and conviction, opinions and information were shared that: a) are of a sensitive nature, and b) can rather be described as being provocative. It is accordingly necessary to address the question of how (with reference to research ethics) such statements should be handled, and what position should be taken regarding their presentation. The informed consent and information sheets stated that although the information gained from the interview data would be integrated into the dissertation, no citation from the transcription would be attributed personally to any expert. However, the small sample number means that special care was needed to uphold the anonymity of the experts. After consulting ethics of research normative documents to locate the principles that are of relevance,^{674, 675} the position that has been developed is that sensitive statements that are central to the research question will not be quoted verbatim, but the gist of the data will be extracted and included in the results. Provocative comments will be neither directly nor indirectly referenced especially, considering the exploratory nature of the research, although the inputs can stimulate future research projects.

10.8 Exemplary Expert Interview Results

The transcriptions of the exploratory expert interviews have been analysed to identify, name, categorize and describe phenomena found in the text in line with the methodology of grounded

⁶⁷³ Kathy Charmaz, *Constructing Grounded Theory: A Practical Guide Through Qualitative Analysis*, (Sage Publications Thousand Oaks, 2006): 27-30.

⁶⁷⁴ Programme RESPECT, "Guidelines for Conducting Ethical Socio-Economic Research European Commission's Information Society Technologies, 2004."

⁶⁷⁵ UNESCO, Paul de Guchteneire, *Code of conduct social science research code social science (undated)*.

theory.⁶⁷⁶ The following are the main issues and observations that have arisen from this work. Firstly is the observation generated by the data regarding which dimension of health is prioritized by the researchers, and placed by them at the centre of their work. The value that the epidemiologists reported as motivating them was to do good science in the service of improving physical health. However, it was also critically observed that projects are selective in their focus on this one “mechanical” (medical scientific ‘Western’) aspect, whereas it is also necessary to look at the social and cultural aspects of health, and at how the local culture defines health. Concern was expressed that in focusing only on physical health, and not looking at the wider social context such as questions of justice and political background, the necessary systemic fundamental changes necessary to secure health on the long term will not be achieved. The point was also raised that only through political and social changes, can consent be ultimately informed and free.

The experts strongly criticised the REC approval process, and the informed consent rules and processes that REC’s require to be followed in the field. The excessive bureaucracy and formalities associated with ethics reviews, particularly reviews made in developed countries, were overly burdensome. The example was cited that a change to a protocol in a phase III trial of a malaria vaccine must be approved by 40 or 50 review boards, with the bureaucracy and formalities being counter-productive. Criticisms were expressed that the rules that RECs apply appear to be neither consistent nor coherent. Also RECs were thought to impose standards for an intervention in a developed country that are not required by the local ethics committee in the country itself. All-in-all, obtaining approval and complying with REC requirements were described as being a “minefield”, that is of doubtful service to anyone, with the situation being a ‘war’ that risks killing research and therefore science, with the seriousness of this situation being that Africa needs “operational research.”

Nevertheless, completely abandoning the practice of ethics review was not suggested. It was acknowledged that some kind of REC is required as scientists have ‘behaved badly’ in the past. Rules and sanctions are needed, but this is not seen as justifying the status quo of bureaucracy and inconsistency. Scientists, not politicians, should be involved in setting the rules. Paradoxically, however, one expert did say that if one was involved in an intervention that had

⁶⁷⁶ Kathy Charmaz, “Grounded Theory: Objectivist and Constructivist Methods,” in *Handbook of Qualitative Research*, Second Edition, ed. Norman K. Denzin, Yvonna S. Lincoln (Thousand Oaks, CA: Sage): 509-536.

ethically controversial aspects, the fact that an ethics approval had been received was welcomed as a security against any challenge made against the intervention.

The experts did not, however, have a clear idea of what the role of RECs should be, nor of the ideals and principles that underlie consent. The experts did not make any comments that developing countries RECs suffer from resource constraints and inadequate training (as is often mentioned in the literature⁶⁷⁷), nor to a need for capacity-strengthening.

Regarding the informed consent processes to be followed in the field, although intending to show respect, the informed consent process has become so “heavy handed and cumbersome” that it is perceived as being disrespectful. An opinion shared was that the individual informed consent processes that they felt obliged to follow is inappropriate for use in developing countries. For instance, in a culture with an oral tradition in which giving a verbal agreement to do something is binding, asking individuals for a signature is offensive and seen as a sign of mistrust. Furthermore being asked to provide a signature or thumbprint is associated with police actions or people wanting to take land or impose taxes. Requesting in general that formalities be complied with invokes a suspicion that what is proposed to be done is somehow ‘wrong.’ On a more conceptual level, one interviewee echoed the point often found in the literature as to whether a genuine *informed* consent is possible in view of the complexity of many interventions and the length, form and contents of the information sheets required in order to comply with guidelines. Also are people in developing countries truly able to decide to consent or not, as they often do not any have real choices open to them; giving consent is thus rather a reflection of the constraints that poor people suffer (the only chance for therapy is by taking part in a project) regarding their lack of access to health care?

Although the interviewer did not ask any direct questions on compliancy with guidelines or the terms of REC approvals, on the subject of compliance with informed consent requirements, one interviewee reported that the researchers working for many western institutions do not in reality comply with the strict informed consent requirements when working in the field.

In response to the interviewer asking about their understanding of the term “community assent,” the epidemiologist’s responses showed an understanding of the term as meaning the need to

⁶⁷⁷ A Nyika et al., “Composition, training needs and independence of ethics review committees across Africa: are the gate-keepers rising to the emerging challenges?” *J Med Ethics* 2009 35: 189-193.

obtain official permission or approvals from state, local government, institutional officials, administrative leaders, politicians or religious leaders. The reasons given for involving the appropriate officials was pragmatic rather than moral or ethical. No opinions were expressed that it was the right thing to do, or it being necessary to respect community rights or respect diversity. It was seen as being an essential part of a project in order to smooth the path for the project, avoid problems, and provide credibility for the intervention. One interviewee admitted, however, to sometimes doubting if the officials being asked were authorized to make a decision, although the power structure found in a context were generally accepted and complied with.

Regarding the relationship between official 'community' approval and individual informed consent, there was no understanding shown of the status quo as outlined in Chapter 6, that if customs require that permission from a community leader be obtained before entering a community and seeking individual consent, these customs should be respected (although such permissions are not a substitute for individual informed consent).⁶⁷⁸ On the contrary, the opinion was expressed from one expert that if assent is obtained from the local authorities, this can replace individual informed consent. However, the same expert suggested that a condition for waiving individual consent was that the degree of invasiveness of the intervention must be minimal.

One research project that was quoted by an expert (without any prompting from the interviewer) as being an example of a situation where an official approval was seen as being adequate, with individual consent not being needed, was the IPTi research and practice program (see IPTi placebo trial case study above). The reasoning offered was that a standard malaria medicine was being delivered to healthy or asymptomatic infants, alongside standard childhood vaccination packages; it was not necessary to undertake an informed consent process as the malaria medications had received marketing authorization. However, although a formal individual consent was not considered necessary, the expert commented that in the event that a mother refused the intervention for her child, this decision was to be respected.

The interviewer enquired whether the experts had ever reflected on the subject of consent and assent in a social marketing intervention when individual consent was not possible. The opinions offered were that no consent or assent is needed for social marketing campaign such as the KINET campaign. The question was answered in the negative if representatives of a

⁶⁷⁸ CIOMS, *International Ethical Guidelines for Epidemiological Studies*, Guideline 4.

potential target market should be asked to approve a planned social marketing campaign such as KINET. The argument used was that as residents of Switzerland are not asked before a poster is hung in their public space, why should a foreign researcher seek permission in a developing country before undertaking the same kind of action? However, it was felt to be pragmatically important to obtain local input to make sure that the social marketing promotional materials actually communicate the message that is intended in an appropriate way. Pragmatically, if people are offended “you are not going to get your message across.”

Only one expert expressed concerns that applying a social marketing approach in another culture is problematic because social marketing relies on the external party obtaining knowledge by appearing to have a real interest in the culture, but then using this knowledge in an instrumental way. In general, being ‘culturally sensitive’ has primarily the instrumental value of finding out who to talk to, and whose permission or cooperation should be sought to gain acceptance of the intervention. This pragmatic approach of using knowledge of a culture only to the extent necessary to achieve the scientific goals was questioned; is such an attitude really showing respect?

Another attitude towards local context and culture was encapsulated in the statement that the concept of consent has “gone too far”: entering a village and asking a mother for consent to undertake an intervention on her child will often simply bemuse the woman, because in her context the norm is that teachers abuse the girls; females are generally not consulted; mothers are “yelled at” in health clinics, and asked for bribes. When people then come from outside the community, and ask the mothers for their informed consent, they are treating the women in a way that is completely at odds with how they will otherwise be treated.

In response to asking whether the experts have any opinions on the ethics of development work (for instance, the prominence given to participation and capability building), only one expert had any opinion, making reference to literature that criticises the ‘participatory approach’. The basis for the criticism is that participatory approaches often do not reflect the local culture, but are upheld as a matter of political correctness. Taking a participative attitude and involving the locals by calling meetings and workshops serves the needs, and follows the values of the external partners, rather than the communities where the interventions are performed. Indeed, participatory approaches could be seen by the locals as lacking in sincerity and being hollow gestures that are disrespectful.

Regarding the position found in the development ethics literature that respect should be shown for local knowledge, with use then being made of the knowledge, one of the experts reported that there is no real interest to do this. The reason is that experience has shown that even if advice was obtained from the local community, if it was then followed, it was usually found to be ineffective in achieving the intervention goals.

10.9 Discussion

The experts had a strong need to communicate and verbalise problems with research ethics review committees (RECs). The criticism that consent and patient information forms are too long, complex and sometimes inappropriate is reported in the literature, and such concerns have been raised in the deductive tranche above when discussing current interpretations of informed consent. The counter argument is that the ethics review complexity is needed to assure quality and to protect individuals and communities, and that if a REC rejected a project, this was in the best interests of the potential participants. It would seem that the researchers (and possibly the RECs) are not fully aware of the possibilities that are foreseen in the guidelines to allow the simplification on a consent process, and that these possibilities are not fully utilized.

One response to the standards, being seen as being inappropriate, is a lack of motivation or interest to comply with the guidelines. This is a serious issue that requires further investigation. Is non-compliance due to: a) truly inappropriate guideline content, b) to how they are explained (lack of appreciation of the ethical principles they try to uphold), or c) to systemic problems that hinder the application of the norms – or a mixture of all these possible reasons?

Any public health intervention consent documentation submitted to the local RECs that is culturally inappropriate should be refused by local ethics committees (assuming their competence to judge), and indeed reports exist of disagreements between host and sponsoring country RECs regarding if an intervention should be rejected, and what consent processes should be vetoed or varied.^{679, 680} There may then need to be a dialogue with sponsoring country

⁶⁷⁹ N Kass et al., "The structure and function of research ethics committees in Africa: A case study." *PLoS Med* 4(1): e3. (2007): 191.

⁶⁸⁰ Irene Kuepfer, Christian Burri, "Reflections on clinical research in sub-Saharan Africa." *International Journal for Parasitology* 39 (2009): 947-954.

RECs in order to develop a consensus. In this respect, this vetoing role or even vetoing *responsibility* of local review committees is an important function; their capabilities and empowerment to perform this role based on balanced appropriate criteria must be (in an ideal world) strengthened.

Regarding the supposed impacts of RECs that include their delaying or halting the research agenda in an unacceptable way, these concerns are expressed elsewhere.^{681, 682} As was mentioned when discussing the concept of validating informed consent, some research has been undertaken into such impacts. A study has been conducted with developing country researchers published in 2004 that explored the experiences and attitudes of these researchers regarding the role of institutional review boards (with 29% of the responses coming from African researchers). Researchers were asked if they ever had to abandon a research project because it was impossible to get developed country approval despite modifications. Whilst 17% said that they had to abandon the research project, a rather low number – only 6% – reported having to abandon their project because it was impossible to obtain approval.⁶⁸³ More research is clearly necessary on what is being rejected, and why.

That different REC arrive at different decisions and apply different rules has been acknowledged in the literature. If the different opinions are justifiable, this is not necessarily negative if sufficient coordination and resources exists to exchange and learn from the different points of view, and may even add to the overall protection of science and subjects. Work must continue on looking at possibilities for streamlining approvals, and upholding and improving the standards of ethical judgements made by RECs. Two approaches are possible in international work: either to develop a centralized, multicentre international, approval system, without diluting the vital inputs of local knowledge and local point of view, or to keep the various approval processes, but to try to constructively harmonize the activities. Whatever route is taken in the future, work needs to be done on investigating the reasoning and principles applied by

⁶⁸¹ A Nyika et al., "Composition, training needs and independence of ethics review committees across Africa: are the gate-keepers rising to the emerging challenges?" *J Med Ethics* 2009 35: 189.

⁶⁸² Michael M. Burgess, "Proposing modesty for informed consent." *Social Science & Medicine* 65 (2007): 2284-2295, 2289.

⁶⁸³ A A Hyder et al., Ethical review of health research: a perspective from developing country researchers *J Med Ethics* 2004;30: 68-72, 69-70.

committees,⁶⁸⁴ and supporting the increasing interest being shown in undertaking research on the quality of ethics reviews conducted.⁶⁸⁵

The opinion expressed that informed consent would not have been necessary in the IPTi randomised, placebo controlled trials suggests that collaborative work is needed between researchers, regulators, ethicists and RECs on what public health interventions require a consent process, and when it can be waived. Practice-oriented clear guidelines are needed. Regarding the attitude shown by the experts towards host contexts and cultures, discussions between researchers, intercultural experts, and representatives from different cultures might be a constructive part of researcher education programmes, and an important topic in the expert literature. Interdisciplinary discussion is also needed to avoid sound participatory measures and approaches slipping into being mere formalities of “political correctness,” rather than being of positive value and relevance for the community and the intervention. Community engagement needs to move beyond the tokenistic involvement, and towards more power sharing relationships.⁶⁸⁶

The same conclusions pertain to the interviews as found in the case studies: more work is needed on consent and assent in social marketing, especially in situations where seeking individual informed consent is not possible (that will include most social marketing and many public health interventions). Researchers and RECs must have sound practical guidelines available.

On the question of whether the underlying principles of consent and assent are operationalized and applied in the field so that they really achieve what they aim to achieve, i.e. respect for individuals, communities, and diversity, the epidemiologists did not engage with their research subjects at this level of reflection; getting the science done was for them the paramount aim.

⁶⁸⁴ Andrew Vallely et al., “How informed is consent in vulnerable populations? Experience using a continuous consent process during the MDP301 vaginal microbicide trial in Mwanza, Tanzania,” *BMC Medical Ethics* 2010, 11:10: 4.

⁶⁸⁵ John Tripp, “Defining quality in the ethics review process,” *The Quality Assurance Journal* December 1997 Volume 2, Issue 4: 157-196.

⁶⁸⁶ N W Mamotte et al., “Convergent ethical issues in HIV/AIDS, tuberculosis and malaria vaccine trials in Africa: Report from the WHO/UNAIDS African AIDS Vaccine Programme’s Ethics, Law and Human Rights Collaborating Centre consultation, 10-11 February 2009, Durban,” *South Africa BMC Medical Ethics* 2010, 11:3: 2-3.

Regarding the subject of 'community', a pragmatic approach towards involving community leaders or representatives is standard practice. There was confusion shown on the relationship between community assent and individual consent, with (contrary to all current guidelines), it being considered possible to substitute a community assent for individual consent. The reason for all this deserves attention. Is the problem of perceived inappropriate contents of the guidelines, one of weak communication of the guidelines, or differences in opinions on the role and importance of consent and assent? Work is needed to answer this question.

10.10 Key Conclusions of the Empirical Tranche

The main aim of this tranche was to test or validate the informed consent and assent as prescribed in the guidelines by looking at processes in public health transcultural interventions to see how they are implemented, how they perform in the field, as well as considering in the light of the empirical work if the processes can be internally validated: if they achieve what they aim to achieve (according to the underlying ethical principles stated in the guidelines).

The empirical work has confirmed both the importance of RECs, and the problems that are encountered: the adequacy of the guidance for researchers and RECs regarding their work in public health interventions has been questioned by the case studies and expert interviews. Just as the question was located in the deductive tranche as to what principles should underlie consent and assent in public health, considering this issue from the empirical side of the Deductive – Inductive Feedback Structure has raised the analogous question: what standards should RECs and researchers apply to consent and assent in public health interventions? More work is needed to consider when and what aspects of informed consent can be varied; when consent processes are required, and when they can be waived in public health interventions. KINET illustrates the questions that arise when trying to comply with standard requirements such as obtaining individual informed consent when this is - due to the nature of the intervention – simply not feasible (as will often be the case in public health interventions). Work is in particular needed to develop an ethics of social marketing, and to clarify its relation to public health ethics; also regarding social science research ethics in public health.

Some instances of non-compliance with the guidelines were located. One of the most serious issues raised was that informed consent requirements are often knowingly disregarded.

Is non-compliance due to inappropriate guideline contents; to how they are explained (lack of appreciation of the ethical principles they try to uphold), or to systemic problems that hinder the application of the norms – or a mixture of all these possible reasons? To what extent are problems arising from either the wrong, or rather an incomplete set of principles being applied and interpreted in regulating the consent and assent processes necessary in public health – see in this respect, the conclusions of Chapter 8 on the ethics of public health, and the hypothesis that the core principles on which consent and assent should be based needs to be widened.

What can be concluded from the case studies and expert interviews, bearing in mind their exploratory, non-representational nature? The exploratory, hypothetical findings do not have sufficient strength to firmly assert that informed consent and assent must be completely revised, but certainly support revisiting the guidance that is needed to support public health interventions and protect the rights and interests of all stakeholders, particularly those of the individuals and communities involved. The exploratory expert interviews agree with the tentative comments made on the case studies that the findings fail to ‘validate’ the informed consent process as prescribed in guidelines such as CIOMS; the guidance is not entirely satisfactory for use in public health interventions in various contexts, particularly in transcultural interventions.

Suggestions of disparities have been identified between the guidelines and what is practised. Problems have been located regarding implementation and how the consent processes ‘perform’ in the field; it is doubted if informed consent and assent as prescribed in the guidelines achieve (according the underlying ethical principles) what they aim to achieve. The question remains, however, whether the aims set are the appropriate aims; if the principles they seek to apply are the only appropriate principles.

Taking a teleological, consequentialist standpoint, a major issue is to neither underestimate nor overestimate the risk (physical and social) or uncertainty of a public health intervention; to avoid unnecessary complexity in consent and assent processes, but also to avoid underestimating the need for a consent or assent process. Taking a deontic, duty-based approach, the issue for ethicists, regulators, RECs, and researchers, to be aware that designing actions that actually put principles into practice (that are felt by the recipients as showing respect for individuals, communities, for diversity, and for future generations) needs on-going reflection and research (particularly conducting impact assessments), to avoid both unnecessary complexity and

unwise oversimplification. Taking a human rights impact assessment approach could be a constructive tool in this work.

In this connection, the relevance of the hypothesis that an individual consent process should be evaluated not only as a stand-alone process, but also in the context of its being embedded in a particular intervention – including the role of community and community assent and involvement - has been strengthened by the empirical work. Both the IPTi and KINET case studies and the expert interviews illustrate that more work is needed to explicate the complex interplay of individual consent, and community assent and involvement on practical and ethical levels in public health. The ethical analysis must integrate an understanding of pragmatic aspects of community permission and involvement.

PART IV: SYNTHESIS

CHAPTER 11

ADDRESSING THE RESEARCH QUESTIONS AND RESEARCH AIMS

11.1 Consolidating the Theoretical and Empirical Tranche Findings

The first task of the synthesis is to draw together the system, driving force and target force knowledge generated in the deductive and inductive and empirical tranches in preparation for applying these findings to the research question.

11.2 Systems Knowledge

As mentioned in Chapter 1, systems knowledge is knowledge of the status quo. It comprises current thinking on the theoretical background of informed consent; normative descriptive knowledge of existing guidelines; the status quo of what is done in real life, e.g. the results of the explorative empirical research, as well as knowledge of the current understanding of a phenomena, disease, discipline or methodology.

11.2.1 System Knowledge Generated in the Deductive Tranche

The system knowledge identified in the deductive tranche will now be recapitulated.

- a) Chapter 3 produced system knowledge on the theoretical background and status quo of informed consent in a medical context, and community assent in epidemiology, with time-lines being developed. The central deontological principle underlying and shaping the informed consent process is the principle of respect for persons, although various criticisms of this understanding of informed consent were identified. One ethical consideration flowing from this principle is respect for autonomy; one way of giving voice to this principle is conducting an informed consent process. This principle should be applied to all competent individuals, irrespective of the repercussions of how or if this autonomy is used.
- b) The descriptive normative systems knowledge of consent and assent found in existing laws, guidelines, codes and commentaries was outlined in Chapter 5, and analysed in Chapter 6. The status quo found is of the primacy of deontological – duty based – principles that protect and respect the individual person, and a widespread acceptance of the default position of the obligation to obtain an individual's prior informed consent.
- c) Chapter 7 developed exploratory models as basic guides for public health practitioners, based on the status quo systems knowledge outlined in the Texts.

d) Chapter 8 reviewed a selection of articles regarding public health ethics (“the Literature”), which displayed a pluralist theoretical approach from which the Public Health Ethics Array of Cluster of Principles and Approaches Framework (“the Cluster Framework”) was then distilled and developed.

In conclusion, the systems knowledge generated in the deductive tranche indicates that there is no clarity on the appropriate ethical standards that should be applied to consent and community level assent in public health in developing countries.

11.2.2 System Knowledge Generated in the Inductive Tranche

The system knowledge identified in the inductive, empirical tranche will now be sketched:

- a) The work done in preparing for the interviews on the subjects of malaria; understanding the science of malaria interventions; understanding social marketing in public health, and in developing ethical reflections on public health formed an important system knowledge resource on which the case study and interview analysis could be built;
- b) The description of the case studies in Chapter 9 provided important insights into how consent and assent are handled in transcultural interventions;
- c) The report of the findings of the expert interviews in Chapter 10 provided information on the status quo of consent and assent as practised through the eyes of the experts, especially the various problems they encounter.

11.3 The Driving Forces

Driving Forces knowledge is knowledge about the forces that exert pressure, drive forward a change process, and challenge the status quo of a phenomenon (in this case informed consent and community assent). Driving force knowledge can come from analysing the status quo, and identifying what is ineffective and what brings negative impacts; it can come from theoretical analysis and reflection, or from empirical research that identifies problems and concerns.

11.3.1. Driving Force Knowledge: Deductive Tranche

The main driving forces coming from the deductive tranche are now summarized:

- a) The standards derived from the Texts were found to be unsatisfactory for public health, resulting in the open question: what should the theoretical foundation of informed consent and community assent be in public health interventions conducted in developing countries;
- b) The existing Texts focus on developed countries, paying little attention to other contexts. This is a problem as it is held that factors such as culture, the economy, and the political situation are ethically relevant when considering consent and assent questions;
- c) A disconnect was revealed between the theoretical, descriptive normative basis found in the Texts that is primarily deontological, and the pluralist general principles, theories and approaches located in the public health ethics articles;
- d) There is no internationally accepted ethics of public health that can provide a framework of principles. The concern is that the individual informed consent process developed for medical, individual contexts is not wholly satisfactory for transcultural public health interventions;
- e) Different roles and functions of 'community' in consent and assent in transcultural contexts have been identified, with there being no clarity on which role and function community should play in the multi-faceted consent and assent processes that arise in public health interventions in developing country contexts;
- f) The role of history (such as economic, political, military, social and scientific factors and forces), is asserted as being a major driving force in forming informed consent, with the hypothesis being developed that an awareness of past and on-going historical influences on theory development and application should be a part of the work in developing standards for consent and assent.

11.3.2 Driving Force Knowledge: Inductive Tranche

The driving forces arising from the case studies and expert interviews include the following:

- a) The tentative conclusion was reached that an informed consent process as prescribed in CIOMS guidelines could not be validated regarding public health for various reasons, including the information from the expert interviews of non-compliance with the current guidelines, and opinions that the review process and informed consent requirements have the negative impact of delaying or even halting the research agenda;

- b) The analysis of the cases studies and the findings of the expert interviews support revisiting the guidance that is needed to protect the rights and interests of the individual and communities involved;
- c) Concerns are raised whether: i) guidelines prepared with developed countries in mind can be transferred into developing countries, and ii) if Texts developed for medical research and practice can be simply transferred onto public health interventions;
- d) Doubts also arose if guidelines prepared for epidemiology should be widely applied in public health fields outside epidemiology.

To conclude, although the exploratory, hypothetical findings do not have sufficient statistical power to firmly assert that informed consent and assent must be revised, they support the need for revisiting the guidance that is required to support public health interventions, and protect the rights and interests of all stakeholders, particularly the individual and communities involved.

11.4 Deductive and Inductive Tranches Explorative Target Knowledge

Having reviewed the systems knowledge and located the driving forces, the question that arises is: what should be done with these driving forces for change; what responses are appropriate? Target knowledge is the knowledge that should address these questions; target knowledge is prescriptive knowledge concerning the aims or targets that are right, appropriate, and also practical. The need to identify or generate target knowledge results from the pressure coming from driving forces that justifiably stimulate and demand change.

This dissertation has produced some exploratory, hypothetical target knowledge that can be divided into knowledge of a more theoretical nature, and that with a more practical slant. However, target knowledge production must be an interdisciplinary exercise. Therefore, what now follows is just one aspect of the reflections that are necessary. The theoretical target knowledge includes the following:

- a) The proposal that the application of ethics theory in analysing informed consent and community assent in public health needs to take place on three levels;
- b) The hypothesis that historical events (such as economic, political, military, social and scientific factors and forces), have had an impact on public health ethics, therefore public

health ethics should be open to revision in the light of inter alia critically considering these influences on its past and on-going development;

c) A revised approach to assent and consent in public health is proposed of taking a neutral stance when applying the Cluster Framework, without assuming any default position;

d) The decision-making framework for public health interventions that was developed;

e) The hypothesis that an individual consent and community assent process for a public health intervention should not be designed and evaluated as if it were a self-contained activity, but when considering how the process is embedded in the structure and context of a particular intervention. The reason for this hypothesis is to acknowledge the limitation of a consent and assent process to perform functions such as upholding principles of protecting and respecting the rights and interest of individuals and communities; the hypothesis does not deny the validity of the principles, but voices doubts as to the capacity of current consent and assent processes to carry these principles alone.

The practical-focused target knowledge includes the following:

a) The notion of validating a consent process;

b) The identification of the various roles and functions of 'community' that might need to be integrated into the design of an informed consent and assent process in a public health transcultural intervention;

c) The community assent and individual consent models developed for public health, transcultural interventions;

d) The following bundle of target knowledge that has been generated at various points in the dissertation on the important but problematic role of research ethics committees:

i) The proposal that the ethics of public health (including aspects related to consent and assent) needs to be revisited, implying that the basis on which RECs currently make their decision also needs revision;

ii) Based on the fact that RECs in developing and developed countries are often limited in their ability to meet the expectations made of them, such shortcomings should be openly acknowledged, and the consequences reflected in the design of quality assurance aspects of an intervention;

iii) If the central duty of RECs in medical research is to act as a guardian of the rights and dignity of research subjects, the question arises who is acting as advocate for the public when evaluating public health interventions? Is some kind of representation required to

act on the collective's behalf, or can the same REC handle medical and public health interventions?

iv) The vetoing role, or even vetoing responsibility of local review committees in adjudicating appropriate consent and assent is very important; their capabilities and empowerment to perform this role based on balanced and informed criteria must be strengthened.

11.5 Addressing the Research Question and Research Objectives

The question at the centre of this dissertation is now addressed:

- Have the inductive and deductive tranches resulted in knowledge being produced that answers the research question: what should the role and place of individual informed consent and community assent be in international public health interventions in order to support an intervention, whilst satisfying the appropriate ethical standards?
- *This is not the case; a satisfactory answer to the question has not been found.*

There are two main reasons for this failure. One reason is that the ethics of public health is at an early stage of development, especially when compared to the rapid developments in the fields of medical and clinical ethics; therefore no 'appropriate ethical standards' are yet available. The 'standard' that is applied is derived from the descriptive normative guidelines. This has been found not to be wholly satisfactory for public health interventions in transcultural contexts, from both a theoretical, public health ethics point of view, and in the light of explorative results from the empirical tranche. An exploratory approach has been devised by looking at public health ethics in Chapter 8, but this can only be seen as being part of the on-going project of developing an international framework for public health ethics, and is not ripe for providing an answer to the research question. The second reason is that there is no clarity in the Literature, the Texts, or in the minds of public health experts on what the relationships between informed consent, community assent, and community participation should be in transcultural, public health interventions.

An element of the research question has also proven to be questionable: the research question makes an implicit assumption that the appropriate ethical standards will support an intervention. However, the exploratory results of the empirical tranche suggest that implementing the status quo understanding of the 'appropriate' consent processes (in the

limited class of public health interventions covered by this dissertation), can be a hindrance rather than a support for an intervention. Research is needed to ascertain if, and how often unreasonable and unjustifiable hindrances occur. The assumption however should not be completely overturned that following sound ethical standards can bring practical benefits as “in addition to the ethical imperative of achieving informed consent, researchers are finding that failure to do so can have negative consequences in regard to study accrual, retention, and scientific validity.”⁶⁸⁷

A further issue that has arisen with the research questions is that as the complexity of the question has become evident, the use of the formulation “appropriate standards” seems unrealistically simple, and should be amended to read that the aim is to produce a public health ethics framework within which the appropriate standards can be derived for a particular intervention.

However, although the research question is not able to be answered, paradoxically the *objectives* of the dissertation: to offer a support from the field of ethics for international, especially transcultural public health interventions in developing countries, and add to the emerging ethics of public health in developing countries with respect to questions concerning community assent, *have been tentatively achieved*. It is hoped that the conclusions of the deductive tranche make a contribution to the emerging ethics of public health in developing countries with respect to questions concerning community assent and informed consent. Regarding offering support from the field of ethics for transcultural public health interventions in developing countries, the hypothesis that the underlying principles, requirements, and details of the consent and assent processes in public health need to be revisited, reviewed and possibly revised, is hoped to meet this ambitious aim. Therefore, the work of both tranches has succeeded in providing insights that will be applied in the following penultimate section. This will consider how to further pursue the work started in this dissertation of the establishment of a framework within which the appropriate standards for consent and assent can be selected for a particular intervention.

⁶⁸⁷ Cynthia Woodsong, Karim Abdool, “A model designed to enhance informed consent.” *American journal of Public Health* Vol. 95, No. 3 (2005): 412-419, 412.

11.6 The Way Forward: Developing an ‘Appropriate Ethical Standards’ Framework

“In recent years, there has been growing attention to ethics from a public health perspective ... the moral obligation to protect population health holds important implications for identifying appropriate ethical norms to guide research ethics.”⁶⁸⁸

An admittedly idealistic action plan is now proposed for moving forward the development of a framework. However, motivation for entering into any such process may only exist if evidence has shown that practical, scientific or health-related unintended negative impacts occur that are caused by applying the status quo understanding of informed consent and community assent processes. ‘Negative’ is here understood as meaning that the application of the status quo consent norms have resulted in delays and hindrances, with there being no justification for this occurring. The structure of the plan is built on what has been learnt in this dissertation by following the ‘Deductive – Inductive Feedback Structure,’ and the application of the ‘System – Driving Force – Target – Transformation Knowledge’ analytical framework. The steps (some of which have been commenced in this dissertation) are shown below.

Step 1 Ascertain the status quo of consent and assent by:

- Examining the contents of the descriptive normative guidelines;
- Locating the theoretical basis underlying the guidelines;
- Locating any other theoretical lines of argument that exist;
- Conducting research on the status quo of what is done regarding consent and assent in the field;
- Investigating what consent and assent processes do RECs approve and reject?

Step 2 The step should be taken of entering into a discourse between: researchers, regulators, REC members, sponsors/funding institutions and ethicists coming from developed, developing, and transition countries. The aim is to establish the practical problems with consent and assent as seen from all these perspectives.

⁶⁸⁸ David Buchanan et al., “Assuring Adequate Protections in International Health Research: A Principled Justification and Practical Recommendations for the Role of Community Oversight.” *Public Health Ethics* Vol. 1, No. 3 (2008): 246-257, 247.

Step 3 The causal chains that have resulted in the aspects of the informed consent and community assent in public health that are problematic should be identified by undertaking the following analysis:

- Identifying the historical events that acted as driving forces for changes in consent and assent;
- Locating – unravelling –the responses to the forces that led to the status quo (see Figure 21).

The value and aim of this step is based on the assumption that understanding the genesis of a problem is a constructive approach to finding a resolution that addresses the issues that are at the root of the perceived problem.

Step 4 This Step analyses why the responses were chosen; what were the motives and arguments; what were the practical, political and social considerations; what principles were applied in deciding how to respond to a driving force (with the response leading eventually to today's status quo).

Step 5 An interdisciplinary discourse should commence that seeks agreement on the target knowledge, i.e. what the stakeholder think (normatively and practically) the roles and functions of informed consent and assent should be, and should not be. The results of the 'unravelling' of Step 3 should then be movers forward by thinking what should now be built (public health ethics has an important role to play in this stage).

The Step 2 REC members should be drawn from projects such as European and Developing Countries Clinical Trials Partnership EDCPT, UNESCO ABC project – Assisting Bioethics Committees; the African Malaria Network Trust (AMANET), FERCAP, and the South African Research Ethics Training Initiative (SARETI).

An exemplary attempt to apply Step 3 is shown in Figure 21. Starting at the left hand side, the first column contains the year of an event; the driving force is named in the second column; the year and the response are then noted. In addition to the driving forces that are generally mentioned as influencing informed consent such as World War II, and research ethics scandals such as the Tuskegee studies, more subtle driving forces that interface especially with public health are included.

Figure 21: Genesis of Informed Consent: Driving Force – Response

Year of Event	Event (Driving Force)	Year of Response	Responses	Status Quo
1932	U.S. Public Health Service initiated Tuskegee Studies		-	Status Quo (with its benefits, human rights impacts, possible negative impacts)
1939-45	Research atrocities in Germany and Asia	1946 1947 1948 1964	WHO Constitution; Nuremberg Code; UN Declaration Human Rights; WMA Helsinki Declaration	
1966	H. K Beecher, NEJM article: Ethics and clinical research. ⁶⁸⁹	1975	Helsinki Revision requirement independent REC review of protocols Belmont Report Ethical Principles and The Texts(USA)	
1972	Details of Tuskegee studies published	1979		
1994	ACTG Study HIV maternal-infant transmission published ⁶⁹⁰	1996 1997 1998 2000	Helsinki Fourth revision; Angell M Article in NEJM; Gambian Government response in the Lancet; UNESCO activities	
1995	Further Trials in Africa mother to child HIV transmission with placebo arm			
1996	Pfizer Nigeria TROVAN® trial	2000 -on-going	Legal cases against Pfizer	
2004 -	Poverty, political instability, emerging global zoonotic diseases, e.g. avian flu ⁶⁹¹	?	?	

⁶⁸⁹ H.K. Beecher, "Ethics and Clinical Research," *New England Journal of Medicine* (274)24, 1966: 1354-1360.

⁶⁹⁰ E. M Connor et al., Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment." *New England Journal of Medicine* Vol. 331 (1994): 1173-1180.

⁶⁹¹ E.g. Highly Pathogenic Avian Influenza A virus subtype H5N1 (H5N1 HPAI).

These include the controversy surrounding the standard of care (SOC) debate that flared-up by the 1997 publication of a paper by Lurie and Wolfe, and an editorial by Angell,^{692, 693} and the TROVAN[®] trial. More forward-looking is the inclusion of the exemplary public health problem of emerging global zoonotic diseases. More details of these driving forces are included in Annex VIII. More general states such as poverty and political instability are included as they have a considerable impact on public health on a local and global scale.

The responses listed in Figure 21 represent a selection only; a more elaborate table could be constructed by referring back to the contents of the timelines developed in Chapter 3. The 'Responses' column is followed by a vertical longitudinal column indicating 'soft' responses that take the form of reflections and analysis coming from various disciplines: philosophy, ethics, law, anthropology, sociology, human development, that contribute to the informed consent and assent status quo in developed and developing countries in subtle ways. To these should be added advances in medicine, science in general and epidemiology that can influence the situation. Finally at the far right is the status quo that is the result of the preceding columns. This includes hopefully benefits and gains, as well as unintentional negative impacts of the change process. Figure 21 should thus represent a 'map' that identifies the historical events that acted as driving forces, matching them with the responses made, and therefore adding to the understanding of the status quo.

It is interesting to note that there can be a considerable time delay between a driving force and a formal response, and that the responses that drive an issue forward can take various forms: codes, guidelines, legal cases, laws, as well as stimulating inter alia ethical reflection and analysis.

Interesting is also that the location driving forces seem to be shifting from being centred in developed, to being located in developing countries. There are no doubt driving forces and responses coming from transitional regions such as India, China, and former communist

⁶⁹² P Lurie, S M Wolfe, "Unethical trials of interventions to reduce perinatal transmission of the human immunodeficiency virus in developing countries," *New England Journal of Medicine*, 1997, 337(12): 853-6.

⁶⁹³ M. Angell Editorial, "The ethics of clinical research in the third world," *New England Journal of Medicine*, 1997, 337(12): 847-9.

countries, a question that is, however, outside the scope of this dissertation. Figure 21 does therefore have a bias favouring one type of driving force and response.

Regarding Step 4, one approach to analysing why a particular response was made to a particular driving force (that led then to the status quo) is based on the position that various roles and functions have been integrated over time into the basic idea of 'consent' in response to historical events and processes. The tentative hypothesis is that informed consent has become overloaded with roles and functions, some of which are necessary, and some of which can, and some of which should be delegated or abandoned in some situations. It is also hypothesized that community assent (in its many guises) has been under-loaded or underused.

A reason suggested for the overload is that a 'preventive ethics' approach has been applied to the development and implementation of informed consent and community assent. Preventive ethics is primarily concerned with identifying potential ethical problem areas or driving forces, and designing actions, i.e. an informed consent process, that should prevent the problem occurring.^{694, 695} Policies of informed consent have widely been applied to many situations based on the assumed power of informed consent to prevent various harms to the individual. Whilst this view of informed consent does have merit, it is suggested that it has been too extensively applied, and is too narrow for public health. An explanation for an over-emphasis on informed consent could be that consent is a manageable vehicle to counter or avoid problems, and has, therefore, been applied to solve a number of problems irrespective of whether it is the appropriate vehicle or not.⁶⁹⁶ One example of overloading is the expansion of informed consent away from being the expression of substantive principles, towards a main role being to fulfil formalistic legal requirements. This risks (as seen in the IPTi case study in Mozambique) that the process becomes counter-productive.

Another perspective on this 'overloading' hypothesis is that a strict application of a deontological, principled approach can spill-over into a rigid practice of informed consent that

⁶⁹⁴ G. Lindegger, L.M. Richter, HIV vaccine trials: critical issues in informed consent, *South African Journal of Science* 96, June 2000.

⁶⁹⁵ June Levine-Ariff, "Preventive ethics: the development of policies to guide decision-making," *ACN Clin Issues Crit Care Nurse* May; 1(1); (1990): 169-177.

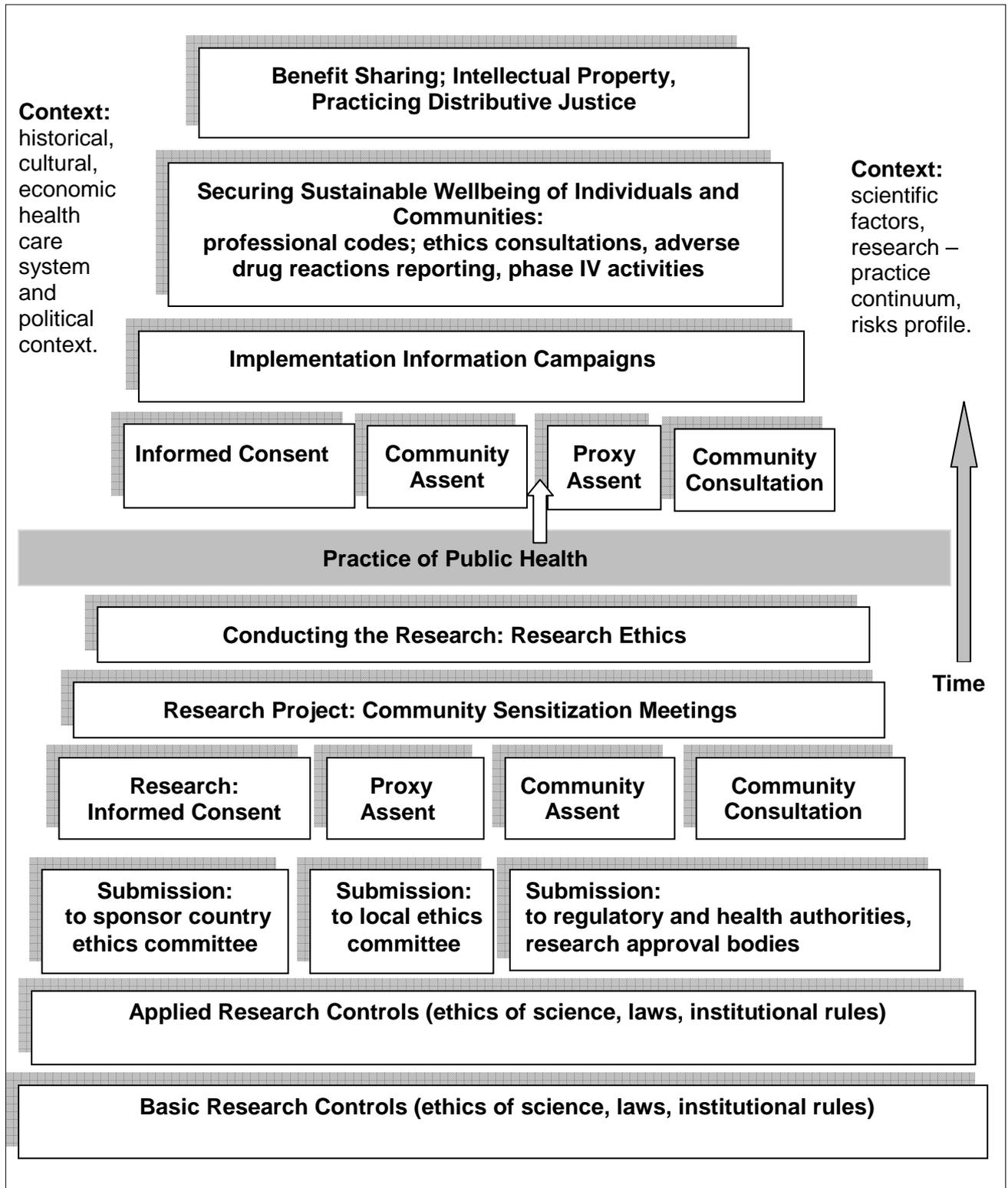
⁶⁹⁶ Ibid.

is no longer justified by the underlying principles (see the reference in Section 8.6.3 to threshold deontology).

An interdisciplinary discourse should in Step 5 seek agreement on the target knowledge, with one approach being to unravel the functions that have been given to or taken away from informed consent (and look for any functions and roles given to community level assent and involvement). The discourse should then locate the functions that are inappropriate, redundant, and not justified by public health principles, if any should be added, and consider where a function can, or should be delegated or abandoned in some public health situation (see the discussion of the waiver of consent in Chapter 6).

It is proposed to structure this ‘unravelling–re–allocation’ work by using the hypothesis suggested in Section 7.6 that reads that *an individual consent and community assent process for a public health intervention should be designed and evaluated not as if it were a self-contained event, but by considering how the process is embedded in the structure and context of a particular intervention*. This hypothesis views informed consent and community assent in public health as being elements in cascade of measures that take place at various stages of an intervention. Informed consent and assent is one part of quality assurance, respecting and protecting measures that take place through all stages of the life cycle of research, development, and practice in individual and population health care interventions. Before judging what can be expected or not of a particular consent and assent process, one needs to look upstream and downstream, at preceding and succeeding events, to see what indispensable functions and responsibilities can or should be distributed to other quality assurance instances. Figure 22: “Upstream and Downstream Scaffold for Embedding Consent and Assent Processes” provides a draft ‘scaffold’ that assists considering what functions can or should belong where, by outlining the steps in the research, development and application process within which a particular consent/assent process is embedded. An example of applying this scaffold is to look at the hypothesis that RECs are often limited in their ability to meet the expectations made of them, and that the consequences of this should be reflected in the design of quality assurance aspects of an intervention. The hypothesis acknowledges the limits of a consent and assent process to perform the many legal, ethical and practical roles and functions that are expected. It acknowledges that: “Adopting a public health perspective thus entails the moral obligation of researchers to consider the interests of the community as a whole as well as the individual research participants; a public health

Figure 22: Upstream And Downstream Scaffold for Embedding Consent And Assent Processes



perspective on research ethics is based on due recognition of the inherently social purpose of health research.”⁶⁹⁷ Looking at the upstream downstream scaffold would encourage accepting the REC limitations, and stimulate considering possible new activities to protect rights and interests of individual and communities, such as involving patient organisation (thinking also back to the various forms of ‘community’ illustrated in Figure 7).

Thus the ‘doctrine of Informed consent’ often referred to in the medical context, is transformed in public health into a maxim of transparent planning, and an approach of being open to combining informed consent, community assent, and community multi- level engagement, all in pursuit of protecting individual and communities whilst supporting international public health research and practice.

11.7 The Way Forward: Further Research Activities

The priority areas in which further research is needed are now summarized. A high priority is to conduct impact assessments to identify, or discount suggestions of the negative impacts of REC requirements, and implementing informed consent in public health interventions. A human right impact assessment should be part of the research. A part of this work should be to examine if research ethics committees' guidance to researchers is actually followed, and to look more into the status quo of what is done regarding consent and assent in the field in public health interventions. Research is needed on the forms of consent and assent processes that RECs approve for public health, international interventions. How do research ethics committees interpret and apply national and international guidelines on informed consent?⁶⁹⁸ Vital is also to find what kind of projects are rejected by RECs in developed, developing and transitional countries. The work already done should be noted and continued

⁶⁹⁷ David Buchanan et al., “Assuring Adequate Protections in International Health Research: A Principled Justification and Practical Recommendations for the Role of Community Oversight.” *Public Health Ethics* Vol. 1, No. 3 (2008): 246-257, 247.

⁶⁹⁸ Andrew Vallely et al., “How informed is consent in vulnerable populations? Experience using a continuous consent process during the MDP301 vaginal microbicide trial in Mwanza, Tanzania.” *BMC Medical Ethics*, 2009,10: 17.

in conducting outcome assessment, auditing and accreditation of ethics review committees.⁶⁹⁹

The theoretical interdisciplinary discourse on public health ethics must be continued, but with more focus on developing and transitional countries. Work on developing public health ethics and its interface with social marketing ethics is required, as is continuing the interdisciplinary work with the social sciences regarding research ethic in public health work. Practical ethics positions need to be formulated regarding informed consent, community assent and other kinds of community interaction.

Finally, work is needed to ensure that ethicists fully understand what approvals, permissions, courtesy-call or gate-opening activities are commonly practised for pragmatic reasons and to respect local customs; ethicists need to interact with practitioners working in the field.

⁶⁹⁹ C.H. Coleman, M.C. Bouesseau, "How do we know that research ethics committees are really working? The neglected role of outcomes assessment in research ethics review." *BMC Medical Ethics* Vol. 9, No. 6 (2008).

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ANNEX I

STATUS QUO OF INFORMED CONSENT GUIDELINES, CODES AND COMMENTARIES EXEMPLARY EXTRACTS

Council Of Europe Convention On Human Rights And Biomedicine, Oviedo Convention, 1997 (Extracts)

Chapter II – Consent

Article 5 – General rule

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time.

UNESCO Universal Declaration On Bioethics And Human Rights, 2005 (Extracts)

Article 6 – Consent

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.

2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.

3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

Article 27 – Limitations on the application of the principles

If the application of the principles of this Declaration is to be limited, it should be by law, including

laws in the interests of public safety, for the investigation, detection and prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others. Any such law needs to be consistent with international human rights law

Nuremberg Code, 1949

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

Declaration Of Helsinki: Comparison Of Versions 1964 - 2008

1964	1975 /1983	1989 /1996	2000	2008
<p>II. Clinical Research Combined with Prof. Care</p> <p>1. If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation. In case of legal incapacity consent should also be procured from the legal guardian; in case of physical incapacity the permission of the legal guardian replaces that of the patient.</p> <p>III. Non-therapeutic Clinical Research</p> <p>3a. Clinical research</p>	<p>3. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.</p> <p>9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be</p>	<p>3. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.</p> <p>9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it</p>	<p>8 .Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.</p> <p>15. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.</p> <p>20. The subjects must be volunteers and informed participants in the research project.</p>	<p>14. In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well</p>

<p>on a human being cannot be undertaken without his free consent, after he has been fully informed; if he is legally incompetent the consent of the legal guardian should be procured.</p> <p>3b. The subject of clinical research should be in such a mental, physical, and legal State as to be able to exercise fully his power of choice.</p>	<p>informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The doctor should then obtain the subject's freely given informed consent, preferably in writing.</p>	<p>may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.</p>	<p>21. The right of research subjects to safeguard their integrity must always be respected.</p> <p>s, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent .</p>	<p>as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.</p>
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CIOMS
International Ethical Guidelines For Biomedical Research Involving
Human Subjects 2002 (Extracts)

Guideline 4: Individual informed consent

For all biomedical research involving humans the investigator must obtain the voluntary informed consent of the prospective subject

Commentary on Guideline 4

General considerations.

Informed consent is a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation. Informed consent is based on the principle that competent individuals are entitled to choose freely whether to participate in research. Informed consent protects the individual's freedom of choice and respects the individual's autonomy. As an additional safeguard, it must always be complemented by independent ethical review of research proposals. This safeguard of independent review is particularly important as many individuals are limited in their capacity to give adequate informed consent;

Process.

Obtaining informed consent is a process that is begun when initial contact is made with a prospective subject and continues throughout the course of the study. By informing the prospective subjects, by repetition and explanation, by answering their questions as they arise, and by ensuring that each individual understands each procedure, investigators elicit their informed consent and in so doing manifest respect for their dignity and autonomy. Each individual must be given as much time as is needed to reach a decision, including time for consultation with family members or others. Adequate time and resources should be set aside for informed-consent procedures.

ICH Guidelines Good Clinical Practice, Version 1996 (Extracts)

1.28 Informed Consent

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

2.9 Freely given informed consent should be obtained from every subject prior to clinical trial participation.

2.11 The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).

4.8.1 In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki. Prior to the beginning of the trial, the investigator should have the IRB/IEC's written approval/favourable opinion of the written informed consent form and any other written information to be provided to subjects.

4.8.2 The written informed consent form and any other written information to be provided to subjects should be revised whenever important new information becomes available that may be relevant to the subject's consent.

4.8.3 Neither the investigator, nor the trial staff, should coerce or unduly influence a subject to participate or to continue to participate in a trial.

4.8.4 None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the subject or the subject's legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence.

4.8.5 The investigator, or a person designated by the investigator, should fully inform the subject or, if the subject is unable to provide informed consent, the subject's legally acceptable representative, of all pertinent aspects of the trial including the written information and the approval/ favourable opinion by the IRB/IEC.

4.8.6 The language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the subject or the subject's legally acceptable representative and the impartial witness, where applicable.

4.8.7 Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject or the subject's legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject's legally acceptable representative.

4.8.8 Prior to a subject's participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion.

4.8.10 Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following: *[there follows a list of 20 items for disclosure]*

Ugandan National Guidelines For Research Involving Humans As Research Participants 2007 (Extracts)

5.6 Informed consent process

The purpose of informed consent is to ensure that individuals control whether or not they wish to enrol in the study and participate only when the research project is consistent with their values, interests and preferences. To provide informed consent, individuals must be accurately informed of the purpose, methods, risks, benefits and alternatives to research; understand this information and its bearing on their own situation, and make a voluntary and uncoerced decision whether or not to participate.

6.1 Introduction

Respect for persons requires that research participants be given the opportunity to make choices about what should be done to them. Consent is not just a form or a signature/mark but a process of information exchange between the researcher and research participants on the whole research process. Information provided should be adequate, clearly understood by the research participant with decision making capacity and the research participant should voluntarily decide to participate.

6.2 General Requirements for the Informed Consent Process

Except as provided elsewhere in these guidelines, no investigator shall involve an individual person as a research participant unless the investigator has obtained informed consent of the individual or the individual's authorized representative. As an example, a community leader may not consent for the participation of community members in research without the individual research participants' informed consent. An investigator shall seek such consent only after ascertaining that the prospective research participant has adequate understanding of the relevant facts and of the consequences of participation. For certain types of research, the IRC may require the investigator to administer a comprehension test (or test of understanding) to ensure that prospective research participants have acquired adequate understanding of the relevant facts and of the consequences of participation. Seeking consent shall be carried out under circumstances that provide the prospective research participant or the representative, sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the research participant or the representative, whether it is conveyed orally, in writing or other delivery mechanism, shall be in a language and form understandable to the participant or the representative. No informed consent, whether oral or written, shall include any exculpatory language through which the research

participant or representative is: (1) made to waive or appear to waive any of the research participant's rights, or (2) appears to release the investigator, the sponsor, the institution, or its agents from liability.

The investigator shall ensure that there is initial monitoring at the start of the study and continued adequacy of the informed consent process and renewal of informed consent if there are significant changes in the conditions or procedures of the research project or if new information becomes available that could affect the research participant's willingness to continue in the research project.

6.4 Documentation of Informed Consent

The research participant may imply consent by voluntary actions, express consent orally, or sign a consent form. Except as provided in section 6.5 below, informed consent shall be documented by the use of a written informed consent form approved by an IRC and signed by the research participant or the research participant's representative and the person obtaining the consent. A copy shall be offered to the research participant or the research participant's representative signing the form.

The consent form shall contain all of the elements listed in section 6.3 above. This form may be read to the research participant or the research participant's representative. The research participant or the research participant's representative must be given sufficient time to read the consent form before the research participant or the research participant's representative signs the form or places his or her thumbprint on the form indicating that he or she has read and understood and agrees to participate in the study. IRCs shall determine whether the investigator's proposal to obtain verbal informed consent is appropriate or not.

Tanzania Guidelines On Ethics For Health Research, 2001 NHREC (Tanzanian) National Health Research Ethics Committee (Extracts)

6.2 Consent of the community

There are circumstances where it may not be feasible to obtain informed consent from individual subjects recruited for epidemiological studies. In such situations:

6.2.1. An agreement of the community representation may have to be sought from the community where the planned study is to take place;

6.2.2. Selection of the representative should be carried in a manner that conforms with the traditions and culture of the community;

6.2.3 Approval provided for by the community has to be assessed and to conform with ethical norms; and

6.2.4. there may be need to establish the authenticity of the community approval

**American Medical Association
CEJA, PDA E-8.08 1981(application of principles) Informed Consent (Extracts)**

The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The patient should make his or her own determination on treatment. The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice.

Informed consent is more than simply getting a patient to sign a written consent form. It is a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention. In the communications process, you, as the physician providing or performing the treatment and/or procedure (not a delegated representative), should disclose and discuss with your patient:

- The patient's diagnosis, if known;
- The nature and purpose of a proposed treatment or procedure;
- The risks and benefits of a proposed treatment or procedure;
- Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);
- The risks and benefits of the alternative treatment or procedure; and
- The risks and benefits of not receiving or undergoing a treatment or procedure.

In turn, your patient should have an opportunity to ask questions to elicit a better understanding of the treatment or procedure, so that he or she can make an informed decision to proceed or to refuse a particular course of medical intervention.

This communications process, or a variation thereof, is both an ethical obligation and a legal requirement spelled out in statutes and case law in all 50 states. Providing the patient relevant information has long been a physician's ethical obligation, but the legal concept of informed consent itself is recent.

(...)To protect yourself in litigation, in addition to carrying adequate liability insurance, it is important that the communications process itself be documented.

The Pakistan Medical And Dental Council Code Of Ethics For Medical And Dental Practitioners 2001 (Extracts)

18.0 Consent

Consent is the “autonomous authorization of a medical intervention by individual patients.” Patients are entitled to make decisions about their medical care and have the right to be given all available information relevant to such decisions. Patients have the right to refuse treatment and to be given all available information relevant to the refusal.

Consent may be explicit or implied. Explicit consent can be given orally or in writing. Consent is implied when the patient indicates a willingness to undergo a certain procedure or treatment by his or her behaviour. For example, consent for venipuncture is implied by the action of rolling up one’s sleeve and presenting one’s arm. For treatments that entail risk or involve more than mild discomfort, it is expected that the physician will obtain explicit rather than implied consent. Signed consent forms document but cannot replace the consent process. There are no fixed rules as to when a signed consent form is required. Some hospitals require that a consent form be signed by the patient for surgical procedures but not for certain equally risky interventions. If a signed consent form is not required, and the treatment carries risk, clinicians should seriously consider writing a note in the patient’s chart to document that the consent process has occurred.

When taking consent the physician should consider issues of adequate disclosure, the patients capacity, and the degree of voluntariness.

In the context of patient consent, “disclosure” refers to the provision of relevant information by the clinician and its comprehension by the patient. Disclosure should inform the patient adequately about the treatment and its expected effects, relevant alternative options and their benefits and risks, and the consequences of declining or delaying treatment and how the proposed treatment (and other options) might affect the patient’s employment, finances, family life and other personal concerns.

Good Epidemiological Practice IEA Guidelines For Proper Conduct Of Epidemiological (Extracts) Informed Consent

Respect for individuals in research entails accepting an individual’s right to refuse to participate; to be informed about the research subject; and to be properly equipped to make a decision based on the best possible information. The principle of informed consent rests on the principle of autonomy and respect for those who take part in research. Written informed consent should be obtained when the research involves risks – the purpose should be to inform the study participants, not to protect the researcher against possible claims for compensation if something goes wrong.

Formal written consent is unnecessary if the research is carried out in settings that pose no threat to the potential participants, when it is stated that taking part is voluntary and it is obvious that no benefits are at risk of being lost if potential participants refuse to take part. Such situations often arise in studies based on self administered questionnaires or telephone interviews where providing the data involves giving de facto consent. There may also be

instances where informed consent is impossible, difficult, or even unethical to obtain. There may even be circumstances where requiring specific information poses a threat to the participants and to the validity of research - for example, in the use of already existing data. The early guidelines of the Council for International Organisations of Medical Sciences (CIOMS) state that:

Informed consent is a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation.

CIOMS

International Ethical Guidelines For Epidemiological Studies 2009 (Extracts)

Guideline 4 Individual informed consent

For all epidemiological research involving humans the investigator must obtain the voluntary informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the permission of a legally authorized representative in accordance with applicable law. Waiver of informed consent is to be regarded as exceptional, and must in all cases be approved by an ethical review committee unless otherwise permitted under national legislation that conforms to the ethical principles in these Guidelines.

Commentary on Guideline 4

General considerations. Informed consent is a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation. Informed consent is based on the principle that competent individuals are entitled to choose freely whether to participate in research. Informed consent embodies the individual's freedom of choice and respects the individual's autonomy. As an additional safeguard, it must always be complemented by independent ethical review of research proposals. This safeguard of independent review is particularly important as many individuals are limited in their capacity to give adequate informed consent; they include young children, adults with severe mental or behavioural disorders, and persons who are unfamiliar with medical concepts and technology

Process. Obtaining informed consent is a process that is begun when initial contact is made with a prospective subject and continues throughout the course of the study. By informing the prospective subjects, by repetition and explanation, by answering their questions as they arise, and by ensuring that each individual understands each procedure, investigators elicit their informed consent and in so doing manifest respect for their dignity and autonomy. Each individual must be given as much time as is needed to reach a decision, including time for

consultation with family members or others. Adequate time and resources should be set aside for informed-consent procedures.

Language. Informing the individual subject must not be simply a ritual recitation of the contents of a written document. Rather, the investigator must convey the information, whether orally or in writing, in language that suits the individual's level of understanding. The investigator must bear in mind that the prospective subject's ability to understand the information necessary to give informed consent depends on that individual's maturity, intelligence, education and belief system. It depends also on the investigator's ability and willingness to communicate with patience and sensitivity.

Comprehension. The investigator must then ensure that the prospective subject has adequately understood the information. The investigator should give each one full opportunity to ask questions and should answer them honestly, promptly and completely. In some instances the investigator may administer an oral or a written test or otherwise determine whether the information has been adequately understood.

Documentation of consent. Consent may be indicated in a number of ways. The subject may imply consent by voluntary actions, express consent orally, or sign a consent form. As a general rule, the subject should sign a consent form, or, in the case of incompetence, a legal guardian or other duly authorized representative should do so. The ethical review committee may approve waiver of the requirement of a signed consent form if the research carries no more than minimal risk—that is, risk that is no more likely and not greater than that attached to routine medical or psychological examination—and if the procedures to be used are only those for which 799 signed consent forms are not customarily required outside the research context. Such waivers may also be approved when existence of a signed consent form would be an unjustified threat to the subject's confidentiality. Particularly when the information is complicated, it is usually advisable to give subjects information sheets to retain; these may resemble consent forms in all respects except that subjects are not required to sign them. Their wording should be cleared by the ethical review committee.

Guideline 5 details “Obtaining informed consent— Essential information for prospective research subjects”

Before requesting an individual's consent to participate in research, the investigator must provide the following information, in language or another form of communication that the individual can understand [*there follows a list of 26 items for disclosure*]

The points specified in this Guideline are generally relevant when obtaining informed consent for interventional research (especially population studies of drugs and devices) but are not all required in most observational studies.

Guideline 6 Obtaining informed consent—Obligations of sponsors and investigators

Sponsors and investigators have a duty to:

- refrain from unjustified deception, undue influence, or intimidation;
- seek consent only after ascertaining that the prospective subject has adequate understanding of the relevant facts and of the consequences of participation and has had sufficient opportunity to consider whether to participate;
- when individual consent is required, obtain from each prospective subject a signed form as evidence of informed consent
- investigators should justify any exceptions to this general rule and obtain the approval of the ethical review committee
- renew the informed consent of each subject if there are significant changes in the conditions or procedures of the research or if new information becomes available that could affect the willingness of subjects to continue to participate; and,
- renew the informed consent of each subject in long-term studies at pre-determined intervals, even if there are no changes in the design or objectives of the research.

Nuffield Bioethics Council
Report “Public Health – Ethical Issues” 2007 (Extracts)

2.24 The concept of consent is rightly at the centre of clinical medicine. Although some of the issues addressed in the sphere of public health concern medical interventions, such as vaccinations, many others, such as the provision of health-conducive environments, occupational health and safety regulations or measures aimed at preventing excessive consumption of tobacco and alcohol, do not. The question is therefore to what extent consent is morally relevant in these areas. Public health interventions may interfere to different degrees with people’s choices or liberties. For example, in the case of quarantine and isolation the degree of intrusion is considerable, but restricting the movement of people suspected of having a severe infectious disease, whether or not they agree with it, can be justified on the basis of the classical harm principle. Many other interventions do not concern this degree of intrusion, and it is important to recognise the difference between consent requirements that are relevant in the context of clinical medicine and research, and those for infringements of people’s choices or liberties in the non-clinical context of public health. Often, requiring each person to consent individually to nonintrusive public health measures is almost impossible and certainly impractical. More importantly, the possible harms and restriction of liberties that are entailed by a range of public health measures may not be severe. The essential point is that a greater, more explicit justification is needed for the state to interfere in a situation where individual consent would otherwise be required due to the considerable health or other risks involved. In contrast, such justification may not be needed where an interference merely limits certain choices.

2.25 Therefore, although in the case of potentially harmful medical interventions individual consent is required to authorise the implementation of the procedure, a ‘procedural justice’ approach that uses conventional democratic decision-making processes may be sufficient to authorise measures where there are no substantial health risks. Key elements of such an approach, which has also been described under the concept of ‘accountability for

reasonableness', are: transparency of decision-making processes (in terms of the evidence, reasons and rationales cited in favour of an intervention that reduces some choice of individuals or otherwise inconveniences them); a focus on rationales that those affected recognise as being helpful in meeting health needs fairly; and involvement of individuals and stakeholder groups in decision-making processes, with opportunities to challenge interventions in preparation and in practice.

Nuffield Council On Bioethics 2002
The Ethics Of Research Related To Healthcare In Developing Countries (Extracts)

6.1 Respect for persons is a fundamental moral duty. In research relating to healthcare, this duty requires that we do not act against a person's wishes. His or her consent to participate in research must thus be obtained. The duty upon those conducting research ordinarily to obtain consent is widely recognised in national and international guidance and in legislation.

6.1.1 The three elements of consent reflected in ethics, national legislation and human rights law are that it must be informed, given voluntarily, and given by a person competent to do so. In this chapter we will focus on two elements of consent which are particularly relevant to externally-sponsored research conducted in developing countries: the provision of information to participants in research; and the requirement that consent to research be given voluntarily. Appropriate means of documenting consent to take part in research will then be considered.

6.2 When externally-sponsored research is conducted in developing countries, a range of issues arise in seeking consent to take part in research. With regard to informing potential participants, concepts that are common in research, such as the idea of randomisation, or of using placebos, may be unfamiliar to the culture in which the research is being conducted. As regards the voluntariness of consent, in some communities it is common for a spouse or senior member of a family to assent to healthcare (and by extension, to research) on behalf of a woman or adult children (see paragraph 3.18). In addition, access to better healthcare and other benefits which may accrue from taking part in research may act as powerful inducements, casting doubt on the true voluntariness of a participant's consent.

6.3 In research, in addition to their responsibilities to individual participants, researchers are seeking to conduct scientifically sound research that will provide generalised information that can improve health care. When medical care is combined with research, researchers may make different choices about clinical measures than they would if the participants' best interests were their only concern. For example, during research, healthcare workers may administer placebos or take blood samples for tests that will not benefit participants directly, in order to obtain information. The potential conflict between the dual roles of healthcare providers in such circumstances means that the process for obtaining consent to research must be rigorous and that participants must be made aware of the dual purpose of research before being asked to consent to it. Conversely, when research does not contain any therapeutic component, this fact must also be made clear to prospective participants.

6.4 A prospective participant in research must be provided with information about the proposed research before any consent to participate can be considered to be valid. The ethically significant requirement is that consent to research be genuine. Ensuring that consent is genuine requires care in detecting a lack of consent. The apparent genuineness of consent can be defeated by a number of circumstances, including coercion, deception, manipulation, deliberate misdescription of what is proposed, lack of disclosure of material facts, or conflicts of interest.

6.5 To obtain genuine consent, health professionals must do their best to communicate information accurately and in an understandable and appropriate way. The information provided to participants must be relevant, accurate and sufficient to enable a genuine choice to be made. It must include such matters as the nature and purpose of the research, the procedures involved, and the potential risks and benefits. National and international guidance sets out the factors which prospective participants must be informed of (see Box 6.1).

6.6 Requirements of particular relevance to externally-sponsored research conducted in developing countries include the need to ensure that participants be provided with information about the study in a language that they can understand, and at their level of comprehension. The importance of allowing potential participants the time to ask questions, obtain answers and to reflect and give due consideration to their participation is also emphasised.

6.7 An awareness of the social and cultural context in which the research is to be conducted is required, so that communities and individuals can be informed of any aspects of the research that may cause them particular concern. These may include such matters as the amount of blood to be taken, or whether participants will be physically examined by researchers of the opposite sex. The process of informing participants about research must also provide opportunities for individual participants to ask about such matters as whether the research may affect their ability to carry out their livelihood. Consent may sometimes need to be sought in the presence of another person, or group, so that the individual feels supported, and more able to ask questions or voice concerns. In other circumstances, privacy may be essential; for example if the prospective participant wants to discuss confidential issues, such as HIV status, with the researcher.

6.8 Healthcare professionals should respect the limits of individuals' understanding and capacity to deal with difficult information and allow time for them to reflect and ask questions. For example, participants may have little understanding of the biological processes that take place in their bodies, or have different beliefs about the causes of disease, which make it more difficult to comprehend the information given. If all reasonable care is exercised, genuine consent may be given.

ANNEX II

GENERAL REFERENCES TO COMMUNITY

CIOMS

International Ethical Guidelines For Biomedical Research Involving Human Subjects, 2002 (Extracts)

Guideline 10: Research in populations and communities with limited resources

Before undertaking research in a population or community with limited resources, the sponsor and the investigator must make every effort to ensure that the research is responsive to the health needs and the priorities of the population or community in which it is to be carried out; and any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community.

When an investigational intervention has important potential for health care in the host country, the negotiation that the sponsor should undertake to determine the practical implications of responsiveness, as well as reasonable availability, should include representatives of stakeholders in the host country; these include the national government, the health ministry, local health authorities, and concerned scientific and ethics groups, as well as representatives of the communities from which subjects are drawn and non-governmental organizations such as health advocacy groups. The negotiation should cover the health-care infrastructure required for safe and rational use of the intervention, the likelihood of authorization for distribution, and decisions regarding payments, royalties, subsidies, technology and intellectual property, as well as distribution costs, when this economic information is not proprietary.

CIOMS

International Ethical Guidelines For Epidemiological Studies 2009 (Extracts)

Commentary (Guideline 2 Ethical review committees)

Ethical review committees membership should include lay persons qualified to represent the cultural and moral values of the community and to ensure that the rights of the research subjects will be respected. Lack of formal education should not disqualify community members from joining in constructive discussion.

Commentary (Guideline 3 Ethical review of externally sponsored research)

Committees responsible for reviewing and approving proposals for externally sponsored research should have among their members or consultants persons who are thoroughly familiar

with the customs and traditions of the population or community concerned and sensitive to issues of human dignity.

The ability to judge the ethical acceptability of various aspects of a research proposal requires a thorough understanding of a community's customs and traditions. The ethical review committee in the host country, therefore, must have as either members or consultants persons with such understanding; it will then be in a favourable position to determine the acceptability of the proposed means of obtaining informed consent and otherwise respecting the rights of prospective subjects as well as of the means proposed to protect the welfare of the research subjects.

**Commentary (Guideline 4 Individual informed consent):
Consultation with community members.**

Even when individualized consent is not feasible, investigators may be asked by the ethical review committee to ascertain the views of representative members of the relevant community on the proposed research. Consultation with the community, as well as feeding the information back to the investigator, is not a one-time activity but should be sustained throughout the period of the study; eliciting community concerns may require study staff to mobilize the community and provide means for members to express their opinions. The opinions of persons in a position equivalent to those whose biological samples or records will be used in a study offer a relevant point for determining whether such a study would offend community norms of privacy and autonomy.

Such efforts are not the same as obtaining permission from community leaders to undertake a study; rather they are aimed at obtaining the views of people who are in effect proxies for the potential subjects—for example, unions or other workers' organizations for studies involving occupational records, associations that represent population at high risk for disease (such as sex workers' group, in the case of HIV infection), and patient organizations for studies involving records or pathology specimens stored at a hospital.

Commentary Guideline 5; Community review of, and permission for, studies.

Investigators carrying out epidemiological research sometimes include a process of review by representatives of the community in which it is proposed to conduct the study, particularly when the research originates outside that community or even outside the country in which the community is located. Such review can take the form of a "dialogue" with the community about the proposed study and its potential implications, or a more structured consultation that would document the concerns of a socially identifiable group. In some cases, formal approval may be legally required; for example, under US law, a Native American tribal council must formally approve any research conducted within tribal jurisdiction. In industry-based occupational epidemiology, the agreement and cooperation of employers and employees is a necessary requisite to the conduct of studies. Epidemiologists should usually follow the same approach when developing field investigations, especially when research findings may be presented or interpreted in ways that directly relate to a community or other identifiable group of people or in

which the collectivity itself is the unit of analysis. Those consulted should be in a position to speak on behalf of the community or to reflect its views; researchers should have adequate time and resources to discern how the study population is organized socially and politically and which groups can best speak with authority for the population. Care should, of course, be taken to ensure that those consulted include all relevant groups and do not exclude, for instance, women or members of minority groups. As previously noted, plans for community review should be specified in the protocol, to allow their evaluation by the ethical review committee.

Guideline 10: Research in populations and communities with limited resources

Before undertaking research in a population or community with limited resources, the sponsor and the investigator must make every effort to ensure that:

- the research is responsive to the health needs and the priorities of the population or community in which it is to be carried out and
- any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community.

National Guidelines For Research Involving Humans As Research Participants, Uganda National Council For Science And Technology 2007 (Extracts)

3.5.3 Community Advisory Boards

3.5.3.1 Establishment

Community Advisory Boards (CABs) are established by the study investigators. They are important forums for facilitating dialogue between community members, study volunteers and researchers. CAB members shall be largely identified from communities where research is to be undertaken through a stake holder consultative process.

Ethical Considerations in the Review of Research Protocol

5.4 Community involvement

Where appropriate, there should be a provision for involvement of the community in the research process right from the inception to the post research period. The community in this context may be geographical or study population specific. Community involvement includes participation in planning and implementation of the research project and dissemination of research findings. Community involvement shall not override the rights of individuals to provide voluntary consent for participation in the research project.

Ethical Considerations in HIV Preventative Vaccine Research 2000

(<http://data.unaids.org/>) (Extracts)

Guidance Point 5 : Community participation

To ensure the ethical and scientific quality of proposed research, its relevance to the affected community, and its acceptance by the affected community, community representatives should be involved in an early and sustained manner in the design, development, implementation, and distribution of results of HIV vaccine research.

Commentary

Involvement of community representatives should not be seen as a single encounter, nor as one-directional. The orientation of community involvement should be one of partnership - towards mutual education and consensus-building regarding all aspects of the vaccine development programme. There should be established a continuing forum for communication and problem-solving on all aspects of the vaccine development programme from phase I through phase III and beyond, to the distribution of a safe, effective, licensed vaccine. All participating parties should define the nature of this ongoing relationship. It should include appropriate representation of the community on committees charged with the review, approval, and monitoring of the HIV vaccine research. Like investigators and sponsors, communities should assume appropriate responsibility for assuring the successful completion of the trial and of the programme. Appropriate community representatives should be determined through a process of broad consultation. Members of the community who may contribute to a vaccine development process include representatives of the research population eligible to serve as research participants, other members of the community who would be among the intended beneficiaries of the developed vaccine, relevant nongovernmental organizations, persons living with HIV/AIDS, community leaders, public health officials, and those who provide health care and other services to people living with and affected by HIV.

Participation of the community in the planning and implementation of a vaccine development strategy can provide the following benefits: information regarding the health beliefs and understanding of the study population input into the design of the protocol input into an appropriate informed consent process, insight into the design of risk reduction interventions effective methods for disseminating information about the trial and its outcomes information to the community-at-large on the proposed research trust between the community and researchers, equity in choice of participants, equity in decisions regarding level of standard of care and treatment and its duration, and equity in plans for applying results and vaccine distribution.

Commentary to Guidance 12

A process of consultation between community representatives, researchers, sponsor(s) and regulatory bodies should be used to design an effective informed consent strategy and process. Issues such as illiteracy, language and cultural barriers, and diminished personal autonomy

should be addressed in this consultative process. In some communities, special efforts may be required to achieve adequate understanding of 'cause and effect', 'contagion', 'placebo', 'double blind', and other concepts involved in the scientific design of the research. HIV preventive vaccine trials require informed consent at a number of stages. The first stage consists of screening candidates for eligibility for participation in the trial, which will involve, among other things, an assessment of the individual's risk-taking behaviour and a test for HIV status. Informed consent should be obtained during this screening process after the candidate has received all material information regarding the screening procedures, as well as an outline of the vaccine trial in which he will be

invited to enrol, if found eligible. Fully informed consent should also be given for the test for HIV status, which should also be accompanied by pre-and post-test counselling, and referral to clinical and social support services, if found positive. The second stage at which informed consent is required occurs once a person is judged eligible for enrolment. That individual should then be given full information concerning the nature and length of participation in the trial, including the risks and benefits posed by participation, so that s/he is able to give informed consent to participate. Once enrolled, efforts should then be made throughout the trial to obtain assurance that the participation continues to be on a basis of free consent and understanding of what is happening. Informed consent, with pre- and post-test counselling, should also be given for any repeated tests for HIV status. Throughout all stages of the trial and consent process, there should be assurance by the investigator that the information is understood before consent is given.

NBAC National Bioethics Advisory Commission
Ethical And Policy Issues In International Research: Clinical Trials In Developing
Countries, (Extracts)

Scope and Structure of the Oversight System

Recommendation 2.3: Researchers and sponsors should involve representatives of the community of potential participants throughout the design and implementation of research projects.

Researchers should describe in their proposed protocol how this will be done, and ethics review committees should review the appropriateness of this process. When community representatives will not be involved, the protocol presented to the ethics committee should justify why such involvement was not possible or relevant.

**National Guidelines For Research Involving Humans As Research Participants,
Uganda National Council For Science And Technology 2007 (Extracts)**

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Ethical Considerations in the Review of Research Protocol

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Where appropriate, there should be a provision for involvement of the community in the research process right from the inception to the post research period. The community in this context may be geographical or study population specific. Community involvement includes participation in planning and implementation of the research project and dissemination of research findings. Community involvement shall not override the rights of individuals to provide voluntary consent for participation in the research project.

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Involvement of community representatives should not be seen as a single encounter, nor as one-directional. The orientation of community involvement should be one of partnership - towards mutual education and consensus-building regarding all aspects of the vaccine development programme. There should be established a continuing forum for communication and problem-solving on all aspects of the vaccine development programme from phase I through phase III and beyond, to the distribution of a safe, effective, licensed vaccine. All participating parties should define the nature of this ongoing relationship. It should include appropriate representation of the community on committees charged with the review, approval, and monitoring of the HIV vaccine research. Like investigators and sponsors, communities should assume appropriate responsibility for assuring the successful completion of the trial and

of the programme. Appropriate community representatives should be determined through a process of broad consultation. Members of the community who may contribute to a vaccine development process include representatives of the research population eligible to serve as research participants, other members of the community who would be among the intended beneficiaries of the developed vaccine, relevant nongovernmental organizations, persons living with HIV/AIDS, community leaders, public health officials, and those who provide health care and other services to people living with and affected by HIV.

Participation of the community in the planning and implementation of a vaccine development strategy can provide the following benefits: information regarding the health beliefs and understanding of the study population input into the design of the protocol input into an appropriate informed consent process, insight into the design of risk reduction interventions effective methods for disseminating information about the trial and its outcomes information to the community-at-large on the proposed research trust between the community and researchers, equity in choice of participants, equity in decisions regarding level of standard of care and treatment and its duration, and equity in plans for applying results and vaccine distribution.

Commentary to Guidance 12 : A process of consultation between community representatives, researchers, sponsor(s) and regulatory bodies should be used to design an effective informed consent strategy and process. Issues such as illiteracy, language and cultural barriers, and diminished personal autonomy should be addressed in this consultative process. In some communities, special efforts may be required to achieve adequate understanding of 'cause and effect', 'contagion', 'placebo', 'double blind', and other concepts involved in the scientific design of the research. HIV preventive vaccine trials require informed consent at a number of stages. The first stage consists of screening candidates for eligibility for participation in the trial, which will involve, among other things, an assessment of the individual's risk-taking behaviour and a test for HIV status. Informed consent should be obtained during this screening process after the candidate has received all material information regarding the screening procedures, as well as an outline of the vaccine trial in which he will be invited to enrol, if found eligible. Fully informed consent should also be given for the test for HIV status, which should also be accompanied by pre- and post-test counselling, and referral to clinical and social support services, if found positive. The second stage at which informed consent is required occurs once a person is judged eligible for enrolment. That individual should then be given full information concerning the nature and length of participation in the trial, including the risks and benefits posed by participation, so that s/he is able to give informed consent to participate. Once enrolled, efforts should then be made throughout the trial to obtain assurance that the participation continues to be on a basis of free consent and understanding of what is happening. Informed consent, with pre- and post-test counselling, should also be given for any repeated tests for HIV status. Throughout all stages of the trial and consent process, there should be assurance by the investigator that the information is understood before consent is given.

**UNAIDS Good Participatory Practice:
Guidelines For Biomedical HIV Prevention Trials 2007
10 Core Principles (Extracts)**

Towards shared responsibility

Researchers, trial funders, research site staff, local authorities (including health authorities), and the community of people affected by a trial (including trial participants, family members, community leaders, and related advocacy groups) should work jointly to develop and conduct ethical biomedical HIV prevention trials whose goals, risks, and benefits are clearly understood and supported by all stakeholders. Shared responsibility commits all stakeholders to work in partnership towards the achievement of study goals and to honour the commitments that they have made to one another throughout the research lifecycle, from initial outreach to dissemination of research results.

ANNEX III

REFERENCES TO COMMUNITY CONSENT, ASSENT, PERMISSION

UNESCO Universal Declaration on Bioethics And Human Rights, 2005 (Extracts)

Article 5 – Autonomy and individual responsibility.

In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought.

Article 12 – Respect for cultural diversity and pluralism

The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.

Article 15 – Sharing of benefits: Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries.

Declaration Of Helsinki, Version 2008 (Extracts)

7. Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.

8. Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.

CIOMS

International Ethical Guidelines For Biomedical Research Involving Human Subjects 2002 (Extracts)

Guideline 4: Individual informed consent

Cultural considerations. In some cultures an investigator may enter a community to conduct research or approach prospective subjects for their individual consent only after obtaining permission from a community leader, a council of elders, or another designated authority. Such

customs must be respected. In no case, however, may the permission of a community leader or other authority substitute for individual informed consent.

CIOMS

International Ethical Guidelines For Epidemiological Studies 2009 (Extracts) Guideline 4 Individual informed consent, Commentary

Cultural considerations. In some cultures an investigator may enter a community to conduct research or approach prospective subjects for their individual consent only after obtaining permission from a community leader, a council of elders, or another designated authority. Such customs must be respected. In no case, however, may the permission of a community leader or other authority substitute for individual informed consent.

(To avoid a misunderstanding, the person from whom permission is sought should be informed in advance that consent will be still sought from individuals enrolling in research, lest this practice be seen as unanticipated disrespect for his or her authority.

Consultation with Community Members

Even when individualized consent is not feasible, investigators may be asked by the ethical review committee to ascertain the views of representative members of the relevant community on the proposed research. Consultation with the community should be sustained throughout the period of the study; eliciting community concerns may require study staff to mobilize the community and provide means for members to express their opinions. The opinions of persons in a position equivalent to those whose biological samples or records will be used in a study offer a relevant point for determining whether such a study would offend community norms of privacy and autonomy. Such efforts are not the same as obtaining permission from community leaders to undertake a study; rather they are aimed at obtaining the views of people who are in effect proxies for the potential subjects

Community review of, and permission for, studies. Investigators carrying out epidemiological research sometimes include a process of review by representatives of the community in which it is proposed to conduct the study, particularly when the research originates outside that community or even outside the country in which the community is located. Such review can take the form of a "dialogue" with the community about the proposed study and its potential implications, or a more structured consultation that would document the concerns of a socially identifiable group. In some cases, formal approval may be legally required; for example, under US law, a Native American tribal council must formally approve any research conducted within tribal jurisdiction.

**Ethical Considerations In HIV Preventive Vaccine Research
UNAIDS Guidance Document 2000 (Extracts)**

Guidance Point 5 : Community participation

To ensure the ethical and scientific quality of proposed research, its relevance to the affected community, and its acceptance by the affected community, community representatives should be involved in an early and sustained manner in the design, development, implementation, and distribution of results of HIV vaccine research.

**Ethical Considerations In Biomedical HIV Prevention Trials UNAIDS/WHO 2007
(Extracts)**

Guidance Point 2: Community Participation

To ensure the ethical and scientific quality and outcome of proposed research, its relevance to the affected community, and its acceptance by the affected community, researchers and trial sponsors should consult communities through a transparent and meaningful participatory process which involves them in an early and sustained manner in the design, development, implementation, monitoring, and distribution of results of biomedical HIV prevention trials.

Ethical Considerations In Hiv Preventative Vaccine Research 2000
<http://data.unaids.org/> (Extracts)

In some communities, it is customary to require the authorization of a third party, such as a community elder, in order for investigators to enter the community to invite individual members to participate in research. Other situations which make individual informed consent difficult include those in which an individual requires approval of another person or group in order to make decisions, where there is coercion, and where there is a cultural tradition of sharing risks and responsibilities, e.g. in some cultures where men hold the prerogative in marital relationships, where there is parental control of women, and/or where there are strong influences by community and/or religion or hierarchy (see Guidance Point 13). Such authorization or influence must not be used as a substitute for individual informed consent. Nor should trials be conducted where truly individual and free consent cannot be obtained. Authorization by a third party in place of individual informed consent is permissible only in the case of some minors who have not attained the legal age of consent to participate in a trial. In cases where it is proposed that minors will be enrolled as research participants, specific and full justification for their enrolment must be given, and their own consent must be obtained in light of their evolving capacities (see Guidance Point 18). In addition to the standard content of informed consent, prior to participation in an HIV vaccine trial, each prospective participant must be informed, using appropriate language and technique, of the following specific details:

EGE European Group On Ethics In Science
Opinion Nr 17 Clinical Research In Developing Countries, 2003 (Extracts)

Para 2.7 Free and Informed Consent

Consent of family or community leader may be required in addition to individual consent:

‘The involvement of people with knowledge of the local conditions and traditions and able to defend the interest of those affected by the project is necessary to guarantee the most appropriate procedures of informing of the potential participants in a clinical trial. According to the local situation, it may be appropriate to seek agreement on the implementation of a research project from persons representative of or invested with a certain authority within the community, or the family.’

Tanzania Guidelines On Ethics For Health Research, 2001 (Extracts)

Chapter 3, Consent

3.1 Introduction

Care must also be observed in obtaining consent in societies where elders and community leaders have final say in matters related to family, clan or tribe. It is not uncommon for women to rely on their husbands for consent. Researchers must ensure that in such circumstances, consent is given in the best interest of the participating subject.

6.2 Consent of the community

There are circumstances where it may not be feasible to obtain informed consent from individual subjects recruited for epidemiological studies. In such situations:

6.2.1. An agreement of the community representation may have to be sought from the community where the planned study is to take place;

6.2.2. Selection of the representative should be carried in a manner that conforms with the traditions and culture of the community;

6.2.3 Approval provided for by the community has to be assessed and to conform with ethical norms; and

6.2.4. there may be need to establish the authenticity of the community approval.

**National Guidelines For Research Involving Humans As Research Participants
Uganda National Council For Science And Technology 2007 (Extracts)**

3.5.3 Community Advisory Boards

3.5.3.1 Establishment

Community Advisory Boards (CABs) are established by the study investigators. They are important forums for facilitating dialogue between community members, study volunteers and researchers. CAB members shall be largely identified from communities where research is to be undertaken through a stake holder consultative process.

Ethical Considerations in the Review of Research Protocol

5.4 Community involvement

Where appropriate, there should be a provision for involvement of the community in the research process right from the inception to the post research period. The community in this context may be geographical or study population specific. Community involvement includes participation in planning and implementation of the research project and dissemination of research findings.

American College Of Epidemiology Ethics Guidelines, 2000 (Extracts)

2.8.2 Involving community representatives in research

To the extent possible and whenever appropriate, epidemiologists should also involve community representatives in the planning and conduct of the research such as through community advisory boards.

2.11. Obligations to Communities

Epidemiologists should meet their obligations to communities by undertaking public health research and practice activities that address health problems including questions concerning the utilization of health care resources, and by reporting results in an appropriate fashion.

2.11.3 Respecting cultural diversity

Epidemiologists should respect cultural diversity in carrying out research and practice activities and in communicating with community members.

3.11. Obligations to Communities

Obligations to communities are central to any account of the professional role of epidemiologists. Epidemiologists meet their obligations to communities by undertaking public health research and practice activities that address causes of morbidity and mortality or utilization of health care

resources, and by reporting results in a timely fashion so that the widest possible community stands to benefit. These measures help to build and maintain public trust (Section 3.8). Providing community service (for example, providing scientific expertise to community-based organizations) is an epidemiologic virtue. Epidemiologists have an obligation to communicate with communities directly or through community representatives to explain what they are doing and why, to transmit the results of their studies, to explain their significance, and to suggest appropriate action, such as the provision of health care. This suggests the need for formal communications training for epidemiologists so that they can better communicate research findings.

Epidemiologists should respect cultural diversity in carrying out research and practice activities and in communicating with community members. To do this effectively, epidemiologists should be well-informed about the history, circumstances, and perspectives of groups within the community. They should form relationships with formal or informal leaders in the community and consider the relevance of the epidemiologic research agenda to perceived community needs.

**APHA American Public Health Association
Principles Of The Ethical Practice Of Public Health (Extracts)**

The Principles

2. Public health should achieve community health in a way that respects the rights of individuals in the community.
3. Public health policies, programs, and priorities should be developed and evaluated through processes that ensure an opportunity for input from community members.
4. Public health should advocate and work for the empowerment of disenfranchised community members, aiming to ensure that the basic resources and conditions necessary for health are accessible to all.
6. Public health institutions should provide communities with the information they have that is needed for decisions on policies or programs and should obtain the community's consent for their implementation.

Values and Beliefs Underlying the 12 Principles of the Ethical Practice of Public Health.

Community: Humans are inherently social and interdependent. Humans look to each other for companionship in friendships, families, and community; and rely upon one another for safety and survival. Positive relationships among individuals and positive collaborations among institutions are signs of a healthy community. The rightful concern for the physical individuality of humans and one's right to make decisions for oneself must be balanced against the fact that each person's actions affect other people.

Each person in a community should have an opportunity to contribute to public discourse.

Public health institutions should provide communities with the information they have that is needed for decisions on policies or programs and should obtain the community's consent for their implementation

Nuffield Council On Bioethics 2002
The Ethics Of Research Related To Healthcare In Developing Countries
Executive Summary (Extracts)

Consent

The Working Party concludes that in some cultural contexts it may be appropriate to obtain agreement from the particular community or assent from a senior family member, before any prospective participant in research is approached. However, genuine consent to participate in research must also always be obtained from each participant.

1.9 If research on healthcare is to be ethically acceptable, participants should be given the relevant information in a comprehensible manner, and must freely consent to take part. This is particularly important in developing countries where many participants consent to research because they believe it is their only means of receiving healthcare or other benefits. The procedures for consent that are used in developed countries may be ineffective or inappropriate in some developing countries because of differences in social and cultural environments. For example, participants in research may feel much more able to discuss research and ask questions within a meeting of the local community than on a one-to-one basis with researchers. In some regions, individuals may feel unable to refuse to participate in research that their elders, family members or community have assented to.

3.16 In many developing countries, concepts of respect for the family and community are equally as important as, or more important than, concepts of individual autonomy and rights. The belief that there may be mutual effects on each other by members of a kinship or other group is found in many non-Western societies. For example, in parts of Africa, if one person commits an offence, such as the violation of a sexual prohibition, the whole village or family may have to undergo a cleansing ritual in order to rid themselves of the harmful effects of that person's act. This is a quite different understanding of individual autonomy from that found in many developed countries. In such circumstances, to seek individual consent.

3.19 Attitudes have changed dramatically in much of Africa, where many women, especially in non-Muslim societies, have now cultivated a more assertive position with regard to healthcare, often aided by mission hospitals, clinics and health focused non-governmental organisations (NGOs) The rapid and increasing emergence of households headed by women in parts of Africa as a result of AIDS may have accelerated these changes in attitude. As cultures are not fixed, researchers may need to find means of fostering discussion about what is required by cultural

norms in a particular context. For example, research in South Africa has shown that even within a culture with strong beliefs about the importance of the community, many women favour the approach of requiring individual consent to research.

Sensitivity to cultural differences

4.13 An important characteristic of externally-sponsored research carried out in developing countries is that there are often cultural differences between those organising or funding the research and the research workers and participants in the host country. The moral significance of these differences requires special attention.

4.14 Individuals live within particular societies, the cultural assumptions and practices of which shape their understanding of themselves and others. The ways in which different peoples define themselves in terms of gender, family, kinship, status and nation, and go on to organise relationships involving matters of authority and questions of sickness and health, are endlessly varied. Even when they are in revolt against their cultural upbringing, individuals often tend to think of themselves in the light of the concepts and understandings they have acquired in their society, including their understanding of sickness and health.

4.15 As a result, the general duty of respect implies a duty to be sensitive to other cultures. Thus one potential misuse of power is to be insensitive to the cultural perspectives that individuals bring to questions of health and healthcare. Indeed, the variety of beliefs and practices that exist may challenge the notions of overarching ethical principles. This in turn prompts an analysis of the relationship between the requirement of sensitivity to cultural differences and the concept of moral relativism, the view that different moral codes cannot be critically compared and evaluated.

4.16 In our view, recognition of the existence of diverse cultures and communities with different moral codes does not lead to moral relativism. The relativist position mistakenly suggests that because a particular set of moral norms is embedded in the culture, it must be accepted uncritically. This is to confuse two distinct questions: (i) What does the local culture prescribe?(ii) What is the right thing to do bearing in mind the local culture? Ethical judgments are of this second type. Thus, sensitivity to the values inherent in local practices does not require uncritical acceptance of them.

4.17 What then are the demands placed on us by the requirement of sensitivity to cultural differences? Plainly, one demand is the willingness to explore such differences without prejudice and to seek as far as possible to understand them informed by knowledge of local traditions and material circumstances. Equally, once this understanding has been achieved, those organising research related to healthcare should as far as possible take account of the local culture, taking the trouble to find ways that respect local practices even where, on the face of it, they complicate the research. But, it does not require those involved to compromise fundamental values. In particular, since sensitivity to cultural differences is an implication of the fundamental principle of

respect for persons, if local cultures transgress values inherent in this principle, researchers will need to follow different procedures from those prescribed in the local culture.

4.18 This analysis is particularly relevant when we consider the need for consent by participants in clinical trials. One of the distinguishing characteristics of cultures in developing societies is that they are often less individualistic than those in Western Europe and North America. In such cultures, consent may not be seen to be a purely individual matter. It may be associated with wider obligations to family, village or clan. Our approach in this chapter suggests that when we come to consider the requirements for consent in Chapter 6, we need to be sensitive both to local cultural traditions and to the general requirement of respect for persons implied by our common humanity.

6.18 As discussed above, for consent to be genuine, it must be freely given. In some societies in developing countries, it is considered inappropriate for an individual to be asked to consent to participate in research without the community, or leader(s) of the community, having been consulted first. In other groups, a family or leader(s) of the community may be expected to make decisions about participating in research on behalf of women and older children, who would make their own decisions in other societies.

6.19 In some societies it would be considered culturally inappropriate for researchers to ask individuals to participate in research without consulting the community or permission from community leaders. Three such situations can be distinguished: consultation is required with the community before individuals are approached about research; permission from a leader(s) of the community is required before any research is discussed with the community or individuals; the leader of the community is considered to have the authority to enrol participants in research.

6.20 In each of these circumstances, to seek consent from an individual without seeking assent from leader(s) of the community, or creating public acceptance of research, may be considered disrespectful and may harm relationships within that community and between a community and researchers. The role of the community in the process of obtaining consent is specifically recognised in some countries' guidance on research.

6.21 The third of the situations set out in paragraph 6.19, where the leader(s) of the community or a senior family member customarily has the authority to make decisions on behalf of others, including whether they will participate in research, is the most problematic... the notion of consent on behalf of others is more widespread and ingrained within some cultures in developing countries.

**Human Genome Diversity Project
Model Ethical Protocol for Collecting DNA Samples
North American Regional Committee (Extracts)**

Along with permission of the relevant governments, researchers must obtain both the informed consent of the population and the informed consent of the individuals who give samples. RE DNA Although this requirement goes beyond the strictures of existing law and ethical commentary, we believe it flows necessarily from the nature of the research, which is, by definition, research aimed at understanding human populations and not individuals.

In addition to individual informed consent, the North American Regional Committee believes that a further consent process is required. The Project intends to study populations, not individuals. As a result, we believe that the populations, as well as the individuals, must give their free consent to participate. This is particularly true because the effort to include samples from throughout the human species means that many of the populations sampled will not be part of the industrialized world, where genetic studies to date have concentrated. Many of the populations that might participate in the Project are politically or economically marginal in their countries.

ANNEX IV

COMPARATIVE ANALYSIS OF INTERNATIONAL DOCUMENTS GUIDELINES COMMENTARIES ADDRESSING WAIVERS

U.S. Department Of Health & Human Services Office For Protection From Research Risks Summary Of Basic Protections For Human Subjects 1997(Extracts)

US regulations covering research state that an Institutional Review Board may approve a waiver or alteration of informed consent requirements where it finds that (all of the following conditions are met):

- (1) the research involves no more than minimal risk to subjects;
- (2) the waiver or alteration will not adversely affect the rights and welfare of subjects;
- (3) the research could not practicably be carried out without the waiver or alteration; and
- (4) where appropriate, the subjects will be provided with additional pertinent information after participation.

Ethical And Policy Issues In Research Involving Human Participants Report And Recommendations Of The National Bioethics Advisory Commission (NBAC) 2001 (Extracts)

Recommendation 5.2

Federal policy should permit Institutional Review Boards in certain, limited situations (e.g., some studies using existing identifiable data or some observational studies) to waive informed consent requirements if all of the following criteria are met:

- a) all components of the study involve minimal risk *or* any component involving *more* than minimal risk must also offer the prospect of direct benefit to participants;
- b) the waiver is not otherwise prohibited by state, federal, or international law;
- c) there is an adequate plan to protect the confidentiality of the data;
- d) there is an adequate plan for contacting participants with information derived from the research, should the need arise;
- e) in analyzing risks and potential benefits, the Institutional Review Board specifically determines that the benefits from the knowledge to be gained from the research study outweigh any dignitary harm associated with not seeking informed consent.

CIOMS International Ethical Guidelines For Biomedical Research Involving Human Subjects 2002 (Extracts)

Guideline 4: Individual informed consent

For all biomedical research involving humans the investigator must obtain the voluntary informed consent of the prospective subject... Waiver of informed consent is to be regarded as uncommon and exceptional, and must in all cases be approved by an ethical review committee.

Commentary on Guideline 4

Waiver of the consent requirement. Investigators should never initiate research involving human subjects without obtaining each subject's informed consent, unless they have received explicit approval to do so from an ethical review committee. However, when the research design involves no more than minimal risk and a requirement of individual informed consent would make the conduct of the research impracticable (for example, where the research involves only excerpting data from subjects' records), the ethical review committee may waive some or all of the elements of informed consent.

Australian National Statement On Ethical Conduct In Research Involving Humans, 2007 (Extracts)

Waiver

2.3.5 Only an HREC may grant waiver of consent for research using personal information in medical research, or personal health information. Other review bodies may grant waiver of consent for other research.

2.3.6 Before deciding to waive the requirement for consent (other than in the case of research aiming to expose illegal activity), an HREC or other review body must be satisfied that:

- a. involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 20) to participants;
- b. the benefits from the research justify any risks of harm associated with not seeking consent;
- c. it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records);
- d. there is no known or likely reason for thinking that participants would not have consented if they had been asked;
- e. there is sufficient protection of their privacy;
- f. there is an adequate plan to protect the confidentiality of data;

- g. in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media);
- h. the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled;
- i. the waiver is not prohibited by State, federal, or international law.

2.3.7 Before deciding to waive the requirement for consent in the case of research aiming to expose illegal activity, an HREC must be satisfied that:

- a. the value of exposing the illegal activity justifies the adverse effects on the people exposed;
- b. there is sufficient protection of their privacy;
- c. there is sufficient protection of the confidentiality of data; and
- d. the waiver is not otherwise prohibited by State, federal, or international law.

2.3.8 Given the importance of maintaining public confidence in the research process, it is the responsibility of each institution to make publicly accessible (for example in annual reports) summary descriptions of all its research projects for which consent has been waived under paragraphs 2.3.6 and 2.3.7. Waiver decisions under paragraph 2.3.7 should not be made publicly accessible until the research has been completed.¹

American College of Epidemiology Ethics Guidelines 2000 (Extracts)

2.6.3 Conditions under which informed consent requirements may be waived

Requirements to obtain the informed consent of research participants may be waived in certain circumstances, such as when it is not feasible to obtain the informed consent of research participants, in some studies involving the linkage of large databases routinely collected for other purposes, and in studies involving only minimal risks. In such circumstances, research participants generally need protection in other ways, such as through confidentiality safeguards and appropriate review by an independent research ethics committee. Informed consent requirements may also be waived when epidemiologists investigate disease outbreaks, evaluate programs, and conduct routine disease surveillance as part of public health practice activities.

¹ http://www.nhmrc.gov.au/publications/ethics/2007_humans/section2.3.htm

CIOMS
International Ethical Guidelines For Epidemiological Studies 2009 (Extracts)

Individual informed consent

For all epidemiological research involving humans the investigator must obtain the voluntary informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the permission of a legally authorized representative in accordance with applicable law. Waiver of individual informed consent is to be regarded as exceptional, and must in all cases be approved by an ethical review committee unless otherwise permitted under national legislation that conforms to the ethical principles in these Guidelines

Waiver of consent requirements in epidemiological studies.

Investigators should not initiate epidemiological research involving human subjects without first obtaining each subject's informed consent, unless they have received explicit approval to do so from an ethical review committee or the research activity is authorized by legislation or competent authorities in accord with the ethical principles in these Guidelines.

Categories of epidemiological research for which consent may be waived include:

- a. the use of personally non-identifiable materials;
- b. the use of personally identifiable materials with special justification;
- c. studies performed within the scope of regulatory authority;
- d. studies using health-related registries that are authorized under national regulations; and
- e. cluster-randomized trials.

a. When personally non-identifiable materials are used.

As noted under Guideline, some epidemiological studies, for example those using publicly available data, may be exempt from ethical review and, a fortiori, from individual informed consent. In other cases, review may be appropriate but individual consent may not be relevant or required. For example, the individual consent requirement does not arise when the materials used in the research are not personally identifiable (meaning that, by definition, the individuals concerned would be unknown to the researcher and hence could not be contacted to obtain consent).

b. When personally identifiable materials are used.

Even when a study involves data or material that carry a person's name or that are linked by a code to a person, an ethical review committee may approve observational research using such data or material without requiring individual consent prior to the research. The committee may do so if it is convinced by the protocol that

- (a) subjects would be exposed to no more than minimal risk, and
- (b) either the study involves only publicly available data or the requirement of individual informed consent would make the conduct of the research impracticable.

An investigator who proposes not to seek informed consent for a non-interventional study that uses personally identifiable information which is not publicly available (including data derived from biological samples and medical records) must justify to an ethical review committee not obtaining consent; the committee should ensure that access to such information is strictly limited in time and extent for the specific research purposes, that allowing the investigator to use it will not compromise the interests or welfare of any persons identified by the data, that any risk of harm will be minimized, that the use accords with locally applicable legal requirements, and that there is no known objection of the individual to such use.

The most common justification for using records or samples collected in the past without consent is that it would be impracticable or prohibitively expensive to locate the persons whose samples or records are to be examined; this may happen when, for instance, the study involves reviewing hospital records or performing new tests on blood samples collected at a time when consent to future research uses of such samples was not usually sought (a point further elaborated under Guideline). On the other hand, the reluctance of individuals to agree to participate would not constitute impracticability; data from individuals who have specifically rejected such uses in the past may be used only with proper, official authorization in public health emergencies... Implicit in the argument for use of personally identifiable material without consent is the claim that the value of the research and the unfeasibility of obtaining consent justify violating a person's interest in becoming a subject of research only with his or her knowledge and agreement. Thus, the task of the ethical review committee in each case is to evaluate the merits of this claim when set forth by an investigator: how important is the research and could the desired information be produced by another method, what would be the costs and burdens of contacting the persons whose data would be used in the study, how difficult would it be to meet those costs and burdens, and is the imposition of this difficulty justified by the nature of the interests that would be infringed or the potential harm created by allowing the investigator to proceed without consent? The committee should also consider whether any mitigation—such as anonymizing the data—can be undertaken without seriously compromising the scientific merits of the proposed study. When research using personally identifiable data from records or samples collected in the past without an appropriate consent procedure is permitted without consent, the committee should ensure that the investigator (and sponsor) will strictly safeguard the confidentiality of subjects. For this purpose, up-to-date technical means of data encryption may be valuable for safeguarding the confidentiality of records.

c. When studies are performed within the scope of regulatory authority.

Consent may also not be required for studies that involve data not publicly available but which are carried out under legislative or regulatory authority for public health, such as disease surveillance. The extent and limits of such permission are a matter of local law but epidemiologists must still consider whether, in a given case, it is ethical to use their public authority to access personal data for research purposes. When their use of such data does not clearly constitute a public health activity (e.g., when adverse reaction monitoring produces findings which raise a research issue the study of which would go beyond routine surveillance), the epidemiologists should seek individual consent for the use of the data or demonstrate that the research meets one of the other conditions for waiving informed consent, as explained in this

Commentary. Even when individual consent is not required, the usual expectations of risk minimization, protection of confidentiality, and compliance with all other legal requirements still apply.

d. Studies using health-related registries.

The creation and maintenance of health-related registries (e.g., cancer registries, databanks of genetic and other anomalies in newborn babies, etc.) provide a major resource for many public health activities, from disease prevention to resource allocation. Several considerations support the common practice of requiring that all practitioners submit relevant data to such registries: the importance of having comprehensive information to provide accurate information about an entire population; the scientific need to include all cases in order to avoid undetectable selection bias; and the general ethical principle that burdens and benefits should be distributed equitably across the population. Hence, registries that are established or officially recognized by governmental authorities usually involve mandatory rather than voluntary collection of data.

Studies using data from such registries (as well as studies that link data from several registries or that combine registry-data with information from publicly available sources) thus involve the use of data that have been compiled without the informed consent of the individuals involved.

Such studies should be submitted to an

ethical review committee and permission should also be sought from the competent authority that is legally responsible for the maintenance and use of the registry. When an investigator plans to contact persons based on their inclusion in the registry (e.g., to obtain from them additional information for research purposes beyond the data supplied by the registry), the investigator should bear in mind that these persons may be unaware that their data were submitted to the registry or unfamiliar with the process by which investigators obtain access to the data. Investigators are cautioned to ensure that their access to the registry information is appropriately explained to the potential research subjects by the people who run the registry or other public authorities, preferably before the investigators approach the subjects.

Consultation with community members.

Even when individualized consent is not feasible, investigators may be asked by the ethical review committee to ascertain the views of representative members of the relevant community on the proposed research. ... Such efforts are not the same as obtaining permission from community leaders to undertake a study; rather they are aimed at obtaining the views of people who are in effect proxies for the potential subjects..The process of community consultation, and the justification for using it, should be specified in the protocol so that the ethical review committee can evaluate what is proposed.

**American College Of Epidemiology
Ethics Guidelines 2000 (Extracts)**

2.6.3 Conditions under which informed consent requirements may be waived

Requirements to obtain the informed consent of research participants may be waived in certain circumstances, such as when it is not feasible to obtain the informed consent of research participants, in some studies involving the linkage of large databases routinely collected for other purposes, and in studies involving only minimal risks. In such circumstances, research participants generally need protection in other ways, such as through confidentiality safeguards and appropriate review by an independent research ethics committee. Informed consent requirements may also be waived when epidemiologists investigate disease outbreaks, evaluate programs, and conduct routine disease surveillance as part of public health practice activities.

**Nuffield Bioethics Council Report
Public Health – Ethical Issues 2007 (Extracts)**

2.24 The concept of consent is rightly at the centre of clinical medicine. Although some of the issues addressed in the sphere of public health concern medical interventions, such as vaccinations, many others, such as the provision of health-conducive environments, occupational health and safety regulations or measures aimed at preventing excessive consumption of tobacco and alcohol, do not. The question is therefore to what extent consent is morally relevant in these areas. Public health interventions may interfere to different degrees with people's choices or liberties. For example, in the case of quarantine and isolation the degree of intrusion is considerable, but restricting the movement of people suspected of having a severe infectious disease, whether or not they agree with it, can be justified on the basis of the classical harm principle. Many other interventions do not concern this degree of intrusion, and it is important to recognise the difference between consent requirements that are relevant in the context of clinical medicine and research, and those for infringements of people's choices or liberties in the non-clinical context of public health. Often, requiring each person to consent individually to nonintrusive public health measures is almost impossible and certainly impractical. More importantly, the possible harms and restriction of liberties that are entailed by a range of public health measures may not be severe. The essential point is that a greater, more explicit justification is needed for the state to interfere in a situation where individual consent would otherwise be required due to the considerable health or other risks involved. In contrast, such justification may not be needed where an interference merely limits certain choices.

2.25 Therefore, although in the case of potentially harmful medical interventions individual consent is required to authorise the implementation of the procedure, a 'procedural justice' approach that uses conventional democratic decision-making processes may be sufficient to authorise measures where there are no substantial health risks. Key elements of such an approach, which has also been described under the concept of 'accountability for reasonableness', are: transparency of decision-making processes (in terms of the evidence,

reasons and rationales cited in favour of an intervention that reduces some choice of individuals or otherwise inconveniences them); a focus on rationales that those affected recognise as being helpful in meeting health needs fairly; and involvement of individuals and stakeholder groups in decision-making processes, with opportunities to challenge interventions in preparation and in practice.

ANNEX V

INFORMATION TO BE PROVIDED AS PART OF CONSENT PROCESS

CIOMS

International Ethical Guidelines For Epidemiological Studies 2009 (Extracts)

Before requesting an individual's consent to participate in research, the investigator must provide the following information, in language or another form of communication that the individual can understand:

- 1) that the individual is invited to participate in research, the reasons for considering the individual suitable for the research, and that participation is voluntary;
- 2) that the individual is free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled;
- 3) the purpose of the research, the procedures to be carried out by the investigator and the subject, and an explanation of how the research differs from routine medical care;
- 4) for controlled trials, an explanation of features of the research design (e.g., randomization, double-blinding), and that the subject will not be told of the assigned treatment until the study has been completed and the blind has been broken;
- 5) the expected duration of the individual's participation (including number and duration of visits to the research centre and the total time involved) and the possibility of early termination of the trial or of the individual's participation in it;
- 6) whether money or other forms of material goods will be provided in return for the individual's participation and, if so, the kind and amount;
- 7) that, after the completion of the study, subjects will be informed of the findings of the research in general, and individual subjects will be informed of any finding that relates to their particular health status;
- 8) that subjects have the right of access to their data on demand, even if these data lack immediate clinical utility (unless the ethical review committee has approved temporary or permanent non-disclosure of data, in which case the subject should be informed of, and given, the reasons for such non-disclosure);
- 9) any foreseeable risks, pain or discomfort, or inconvenience to the individual (or others) associated with participation in the research, including risks to the health or well-being of a subject's spouse or partner;

- 10) the direct benefits, if any, expected to result to subjects from participating in the research;
- 11) the expected benefits of the research to the community or to society at large, or contributions to scientific knowledge;
- 12) whether, when and how any products or interventions proven by the research to be safe and effective will be made available to subjects after they have completed their participation in the research, and whether they will be expected to pay for them;
- 13) any currently available alternative interventions or courses of treatment;
- 14) the provisions that will be made to ensure respect for the privacy of subjects and for the confidentiality of records in which subjects are identified;
- 15) the limits, legal or other, to the investigators' ability to safeguard confidentiality, and the possible consequences of breaches of confidentiality;
- 16) policy with regard to the use of results of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of the results of a subject's genetic tests to immediate family relatives or to others (e.g., insurance companies or employers) without the consent of the subject;
- 17) the sponsors of the research, the institutional affiliation of the investigators, and the nature and sources of funding for the research;
- 18) the possible research uses, direct or secondary, of the subject's medical records and of biological specimens taken in the course of clinical care (See also Guidelines 4 and 18 Commentaries);
- 19) whether it is planned that biological specimens collected in the research will be destroyed at its conclusion, and, if not, details about their storage (where, how, for how long, and final disposition) and possible future use, and that subjects have the right to decide about such future use, to refuse storage, and to have the material destroyed;
- 20) whether commercial products may be developed from biological specimens, and whether the participant will receive monetary or other benefits from the development of such products;
- 21) whether the investigator is serving only as an investigator or as both investigator and the subject's physician;
- 22) the extent of the investigator's responsibility to provide medical services to the participant;
- 23) that treatment will be provided free of charge for specified types of research-related injury or

for complications associated with the research, the nature and duration of such care, the name of the organization or individual that will provide the treatment, and whether there is any uncertainty regarding funding of such treatment;

24) in what way, and by what organization, the subject or the subject's family or dependants will be compensated for disability or death resulting from such injury (or, when indicated, that there are no plans to provide such compensation);

25) whether or not, in the country in which the prospective subject is invited to participate in research, the right to compensation is legally guaranteed;

26) that an ethical review committee has approved or cleared the research protocol.

ANNEX VI

CONSENT IN SOCIAL SCIENCES Paul de Guchteneire, UNESCO

Preamble

UNESCO attaches the highest priority to the maintenance of high standards of integrity, responsibility and accountability in the research it supports. This applies to all aspects of that research from collection, recording, citing and reporting to the retention of scientific material.

As UNESCO fosters international, interdisciplinary, comparative and policy- relevant social science research, network and research activities will take place in many parts of the world, and within a variety of economic, cultural, legal and political settings. Researchers may therefore inevitably face ethical, sometimes legal, dilemmas from competing obligations and conflicts of interest.

For the most part, researchers will be aware of the potential difficulties arising from their work. However, UNESCO is concerned to draw the attention of all researchers to certain areas in which conflicts between ethical principles and aims of the research might arise, and to stress the need for their resolution.

Therefore, a set of Ethical Guidelines has been developed to provide a framework to guide research practice. They are intended to act as signposts rather than detailed prescriptions or regulations. They are not intended to be a substitute for the scientific and professional judgement of the individual researcher.

UNESCO encourages the participating institutions and networks to develop policies and promote information sessions for awareness-raising concerning ethical issues in social research.

Code of Conduct and Ethical Guidelines

Researchers should be fully aware of the ethical issues involved in their work and adhere to the following basic principles:

1 Responsibility for all procedures and ethical issues related to the project rests with the principal investigators.

2 Research should be conducted in such a way that the integrity of the research enterprise is maintained, and negative after-effects which might diminish the potential for future research should be avoided.

3 The choice of research issues should be based on the best scientific judgement and on an assessment of the potential benefit to the participants and society in relation to the risk to be borne by the participants. Studies should relate to an important intellectual issue.

4 The researcher should consider the effects of his/her work, including the consequences or misuse, both for the individuals and groups among whom they do their fieldwork, and for their colleagues and for the wider society.

5 The researcher should be aware of any potential harmful effects; in such circumstances, the chosen method should be used only if no alternative methods can be found after consultation with colleagues and other experts. Full justification for the method chosen should be given.

6 The research should be conducted in a competent fashion, as an objective scientific project and without bias. All research personnel should be qualified to use all of the procedures employed by them.

7 The research should be carried out in full compliance with, and awareness of, local customs, standards, laws and regulations.

8 All researchers should be familiar with, and respect, the host culture. Researchers undertaking research on cultures, countries and ethnic groups other than their own should make their research objectives particularly clear and remain aware of the concerns and welfare of the individuals or communities to be studied.

9 The principal investigators' own ethical principles should be made clear to all those involved in the research to allow informed collaboration with other researchers. Potential conflicts should be resolved before the research begins.

10 The research should avoid undue intrusion into the lives of the individuals or communities they study. The welfare of the informants should have the highest priority; their dignity, privacy and interests should be protected at all times.

11 Freely given informed consent should be obtained from all human subjects. Potential participants should be informed, in a manner and in language they can understand, of the context, purpose, nature, methods, procedures, and sponsors of the research. Research teams should be identified and contactable during and after the research activity.

12 There should be no coercion. Participants should be fully informed of their right to refuse, and to withdraw at any time during the research.

13 Potential participants should be protected against any and all potentially harmful effects and should be informed of any potential consequences of their participation.

14 Full confidentiality of all information and the anonymity of participants should be maintained. Participants should be informed of any potential limitations to the confidentiality of any information supplied. Procedures should be put in place to protect the confidentiality of information and the anonymity of the participants in all research materials.

15 Participants should be offered access to research results, presented in a manner and language they can understand.

16 All research should be reported widely, with objectivity and integrity.

17 Researchers should provide adequate information in all publications and to colleagues to permit their methods and findings to be properly assessed. Limits of reliability and applicability should be made clear.

18 Researchers are responsible for properly acknowledging the unpublished as well as published work of other scholars.

19 All research materials should be preserved in a manner that respects the agreements made with participants.

ANNEX VII

MARKETING ETHICS CODES

AMA The American Marketing Association Ethical Norms And Values For Marketers (Extracts)

Ethical Norms:

- Do not harm
- Foster trust in the marketing system.
- Embrace ethical values. This means building relationships and enhancing consumer confidence in the integrity of marketing by affirming these core values: honesty, responsibility, fairness, respect, transparency and citizenship.

Ethical Values

Honesty – to be forthright in dealings with customers and stakeholders. To this end, we will:

- Strive to be truthful in all situations and at all times.
- Offer products of value that do what we claim in our communications.
- Stand behind our products if they fail to deliver their claimed benefits.
- Honor our explicit and implicit commitments and promises.

Responsibility – to accept the consequences of our marketing decisions and strategies. To this end, we will:

- Strive to serve the needs of customers.
- Avoid using coercion with all stakeholders.
- Acknowledge the social obligations to stakeholders that come with increased marketing and economic power.
- Recognize our special commitments to vulnerable market segments such as children, seniors, the economically impoverished, market illiterates and others who may be substantially disadvantaged.
- Consider environmental stewardship in our decision-making.

Fairness – to balance justly the needs of the buyer with the interests of the seller. To this end, we will:

- Represent products in a clear way in selling, advertising and other forms of communication; this includes the avoidance of false, misleading and deceptive promotion.

- Reject manipulations and sales tactics that harm customer trust. Refuse to engage in price fixing, predatory pricing, price gouging or “bait-and-switch” tactics.
- Avoid knowing participation in conflicts of interest. Seek to protect the private information of customers, employees and partners.

Respect – to acknowledge the basic human dignity of all stakeholders. To this end, we will:

- Value individual differences and avoid stereotyping customers or depicting demographic groups (e.g., gender, race, sexual orientation) in a negative or dehumanizing way.
- Listen to the needs of customers and make all reasonable efforts to monitor and improve their satisfaction on an ongoing basis.
- Make every effort to understand and respectfully treat buyers, suppliers, intermediaries and distributors from all cultures.
- Acknowledge the contributions of others, such as consultants, employees and coworkers, to marketing endeavors.
- Treat everyone, including our competitors, as we would wish to be treated.

Transparency – to create a spirit of openness in marketing operations. To this end, we will:

- Strive to communicate clearly with all constituencies.
- Accept constructive criticism from customers and other stakeholders.
- Explain and take appropriate action regarding significant product or service risks, component substitutions or other foreseeable eventualities that could affect customers or their perception of the purchase decision.
- Disclose list prices and terms of financing as well as available price deals and adjustments.

Citizenship – to fulfill the economic, legal, philanthropic and societal responsibilities that serve stakeholders. To this end, we will:

- Strive to protect the ecological environment in the execution of marketing campaigns.
- Give back to the community through volunteerism and charitable donations. Contribute to the overall betterment of marketing and its reputation.
- Urge supply chain members to ensure that trade is fair for all participants, including producers in developing countries.

Code Of Ethics And Standards Of Practice The Canadian Marketing Association (Extracts)

Overarching Ethical Principles

Personal Information Practices Marketers must promote responsible and transparent personal information management practices

Truthfulness Marketing communications must be clear and truthful. Marketers must not knowingly make a representation to a consumer or business that is false or misleading.

Campaign Limitations

Marketers must not participate in any campaign involving the disparagement or exploitation of any person or group on the grounds of race, colour, ethnicity, religion, national origin, gender, sexual orientation, marital status or age. Marketers must not participate in the dissemination of unsolicited material that is sexually explicit, vulgar or indecent in nature

Marketers must not participate in the dissemination of any material that unduly, gratuitously and without merit exploits sex, horror, mutilation, torture, cruelty, violence or hate

Marketers must not knowingly exploit the credulity, lack of knowledge or inexperience of any consumer, taking particular care when dealing with vulnerable consumers. The term “vulnerable consumer” includes, but is not limited to children, teenagers, people with disabilities, the elderly and those for whom English or French is not their first language.

Universal Marketing Practices

These practices apply regardless of industry sector, sub-discipline or marketing medium employed.

Accuracy of Representation

Marketers must not misrepresent a product, service or marketing program and must not mislead by statement or manner of demonstration or comparison.

Photography, artwork, type size, colour, contrast, style, placement, verbal description and audio-visual portrayal must accurately and fairly describe the product or service offered.

Marketers must ensure that the general impression of the communication does not deceive by omission or commission.

Clarity

Marketing communications must be executed in a manner that is simple and easy to understand.

Disguise

Marketers must not engage in marketing communications in the guise of one purpose when the intent is a different purpose.

Protection Of Personal Privacy

Privacy Principles:

1. Accountability
2. Identifying Purposes
3. Consent

4. Limiting Collection
5. Limiting Uses, Disclosure And Retention
6. Accuracy
7. Safeguards
8. Openness
9. Individual Access

Special Considerations In Marketing To Children

Responsibility

Marketing to children imposes a special responsibility on marketers. Marketers must recognize that children are not adults and that not all marketing techniques are appropriate for children.

Consent

When marketing to persons between 13 years and the age of majority, marketers are strongly cautioned that children may be exposed to these communications and, in such cases, these interactions with children are governed by the following guidelines concerning consent.

Special Considerations In Marketing To Teenagers

Responsibility

Marketing to teenagers imposes special responsibilities on marketers. Marketers will use discretion and sensitivity in marketing to teenagers, to address the age, knowledge, sophistication and maturity of teenagers. Marketers should exercise caution that they do not take advantage of or exploit teenagers. Marketers must not portray sexual behaviour or violence that is inconsistent with community or industry standards. Marketers must respect the parent/guardian-teenager relationship and must not encourage the teenager to exclude parents or guardians from a purchase decision. Marketers must not solicit, collect or knowingly use personal information from teenagers as a means of acquiring further household information.

Consent

This section enables marketers to establish communication with teenagers in defined stages, according to the sensitivity or type of information, the teenager's age and the nature of the consent to be provided. Marketers must obtain the opt-in consent from a teenager under the age of 16 for the collection and use of their contact information. Marketers must obtain the opt-in consent of the parent or guardian prior to the disclosure of a teenager's contact information to a third party. Marketers must obtain the opt-in consent of the parent or guardian for the collection, use or disclosure of personal information of a teenager under the age of 16. Marketers must obtain the opt-in consent from the teenager for the collection, use and disclosure of their personal information. Where the teenager, parent or guardian withdraws or declines the permission required to collect, use or disclose a teenager's information, marketers must immediately delete all such information from their database.

Annex VIII

DRIVING FORCES

Standard of Care Debate

The standard of care (SOC) debate was (or is still) the criticism of placebo-controlled trials in which short-course zidovudine treatments were given to HIV-infected pregnant women in a resource limited context.² It was argued by Angell that the trial design was unacceptable (even though it had been approved by the local ethics committee) based on the argument that it is not justifiable to give a control group a placebo when a known effective treatment – a longer course of zidovudine – had been proven. The use of a placebo arm cannot be justified by arguments related to the local context such as that in real life no treatment would be available; a universal standard of care must be applied in clinical trials irrespective of the context. There were many responses disputing this Angell et al position, with many counterarguments taking a consequentialist position, arguing that a strict implementation of a universal standard of care would have the profound negative of hindering research relevant to the needs in developing countries.³ An important input came from the Gambian Ethical Committee who disagreed with the ethical acceptability of an intervention depending on a comparison being made with the best therapy available in affluent countries as this nullifies the main objective of many research projects that target an economically weak population, which is precisely to test interventions that are relevant for that local resource poor situation.⁴ They commented that it should not come as a surprise that people in developing countries prefer to do research that addresses their own needs rather than seek solutions relevant only to affluent countries.⁵ There is a parallel between the question central to the SOC debate and the subject matter of this dissertation: is there a universal standard of care, and is there a universal ‘standard-of-informed-consent’ that must be applied independently of context? The SOC controversy also raises a question relevant to consent and assent of the role that local ethics review committee should play. Should local opinions be overridden by external review committee judgements, or should they be held as being the instance best equipped to decide for instance what consent and assent is appropriate?

² See P Lurie , SM Wolfe, “Unethical trials of interventions to reduce perinatal transmission of the human immunodeficiency virus in developing countries,” *New England Journal of Medicine*, 1997, 337(12): 853-6. See also: M. Angell Editorial, “The ethics of clinical research in the third world,” *New England Journal of Medicine*, 1997, 337(12): 847-9.

³ Peter Aaby et al., “Ethics of HIV trials.” *The Lancet*, Vol 350, November 22, 1997: 1546.

⁴ Gambia Government / Medical Research Council Joint Ethical Committee, “Ethical Issues facing medical research in developing countries,” *The Lancet* 1998; 351: 286–87.

⁵ Ibid.

The Gambia government commented that if commentators from affluent societies dismiss the decisions of these local committees as unethical, the developing world will make the justifiable charge of ethical imperialism. Ethics cannot be owned by affluent countries alone; committees coming from countries such as Gambia are just as capable of acknowledging and operating under proper standards of research ethics and contributing to the international debate about ethical issues that affect those who depend on us as their advocates.⁶

TROVAN Case

In 1996 Pfizer conducted clinical trials testing an unapproved drug TROVAN® on children with brain infections during a major meningitis epidemic in Nigeria that led, according to the prosecution (the Nigerian government) of the death of circa 200 children. A United States court determined in 2009 that conducting medical experiments on human subjects without their consent violates customary international law (a fact that Pfizer had denied).⁷ The TROVAN® case provides an opportunity to revisit some basic principles surrounding consent, and to test the international status of informed consent when seen as a legal 'doctrine'.

Emerging Zoonotic Diseases

The problem of emerging zoonotic diseases as illustrated by the Highly Pathogenic Avian Influenza A virus subtype H5N1 (H5N1 HPAI) became an issue in early 2004 mainly in Southeast Asia, but also in Europe and Africa. Dealing with this class of public health issue will need to have an awareness of the multidimensional linkages between wild animals, livestock production and global public health.⁸ Leaving extreme situations of emergency to one side, how are international issues of public health activities in response to such threats to be handled? At what level, and using what mechanisms is any kind of community assent, involvement or consultation to be organized or should full competences be delegated to some political body – and which one? What responses are adequate to such issues?

⁶ Gambia Government / Medical Research Council Joint Ethical Committee, "Ethical Issues facing medical research in developing countries," *The Lancet* 1998; 351: 286–87.

⁷ See the website <http://www.aslme.org/>.

⁸ FAO AIDE news Situation Update 68, August 2010 Emerging zoonotic diseases in a changing world

Curriculum Vitae

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