NEW MODELS OF PUBLIC HEALTH RESEARCH: OPTIMIZING ETHICS IN RESEARCH USING PUBLIC HEALTH DATA IN RESOURCE LIMITED COUNTRIES

INAUGURALDISSERTATION

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Dekan

When being ethical is most challenging, it could be most rewarding

Own quote for the 2016 International Association of Bioethics (IAB) Conference

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Brief Summary

Progress in public health retains the greatest potential to advance global health and innovation through research. The research arena has revolutionized through many methodological changes: changing research environments require changes to ethical practices. This is especially crucial in contexts where ethical growths are developmental. The health and demographic surveillance system (HDSS) is a public health model in the Global South which provides critical data for evidence generation. The model is common in countries where data availability for public health and for research is otherwise limited because of inadequate resources. Resource limitations and the general dwindling of global funding internationally require strategic alignment of health goals with cost effective research methodologies like research using public health data (RUPD). RUPD has therefore become a key tool in developing countries' research progress towards meeting global health goals like the Sustainable Development Goals (SDGs). Africa is poised to meet the SDGs with RUPD as an efficient option for increasing scientific productivity without tallying up cost. The role of RUPD in the continent's public health agenda is established. Like every new endeavor however, RUPD raises its own set of features, changes, and challenges for which there exists a comparatively narrower frame of opportunities for ethical practice than in traditional research. The goal of this project was primarily to evaluate whether and how to optimize or make the most possible good of traditional research ethics principles in RUPD. Optimization of ethical principles would offer the best protection of the interests and wellbeing of RUPD populations. This empirical study adopts a critical applied ethics approach, comprising a quantitative survey and qualitative interviews involving practitioners knowledgeable about RUPD in Ethiopia, Ghana, and Tanzania. The main findings are that the HDSS model offers a fertile environment for optimizing ethics in RUPD beyond the commonly required practice of research ethics review and protection of confidentiality. Optimizing the longstanding ethical principles that have brought major successes to the biomedical research arena is desirable for RUPD populations, science, and for the general development of ethics in the South. This study shows that doing so is possible without necessarily sacrificing values of comparable worth. Using critical applied ethics also permitted consideration to emerging global issues of important implications for the future of RUPD. Therefore, this thesis secondarily presents empirical views encapsulating both the affirmation and skepticism about public health data sharing from Africa. Such views are largely absent in ongoing data sharing deliberations and in the literature. They highlight issues affecting the under-resourced data-producing scientist and the new challenges in data sharing. Of additional interest to this study was the arrival of the new CIOMS Guidelines this past month in December 2016. It is better suited to RUPD than previous versions, but still leaves room for more to be done towards ethics in RUPD.

Thesis Outline

Chapter One gives an overview of RUPD and briefly analyzes ethical developments. This background information is situated within the literature on HDSSs in the Global South, and Africa in particular, to explain the knowledge and contextual base of RUPD and to identify the ethical gaps that justify the aim and objectives of this project. This chapter also outlines the peer-reviewed articles and manuscripts that form the basis of this thesis as well as details concerning contributions to them.

Chapter Two provides a detailed overall description of the study methods for this PhD project. It comprises the methodological approach to the project and my experiences during the different research processes I went through. I explain the design of the study tools, pre-testing and data collection (fieldwork) phases of the study, data entry, analysis, and interpretation of the results.

Chapter Three involves the results from the quantitative survey discussing the application of ethical principles to RUPD. It enhances the limited empirical data regarding ethics for RUPD while coming to grips with the differences in the application of traditional norms that are set for research ethics principles and their implementation in RUPD practice. It posits what could be ideal to advance and safeguard the collective interests of populations based on the study findings.

Chapter Four focuses on findings from qualitative interviews, highlighting the ethical issues surrounding the growing international requirements for public health data sharing and how they influence and are influenced by some under-studied issues pertaining to professionals and processes, commitments, investments, careers, and ethical-legal governance structures. The findings explain ways of optimizing the benefits of data sharing especially to data producing regions of the South.

Chapter Five offers a theoretical analysis infused by empirical findings on acknowledging global inequalities and how to promote fairness in RUPD data sharing in an unfair world.

Chapter Six provides an empirical probe to the views of key stakeholders on what they think is the "missing link" in the gamut of factors which account for their knowledge about and practice of ethics in RUPD.[1] The chapter also proposes how these gaps could be closed.

Chapter Seven draws on the key findings and discussions of the articles constituting the main results of the thesis to facilitate a general discussion of the entire study. A summary of the general limitations to the study are then given. The thesis ultimately culminates into conclusions, implications, and recommendations, including those for future research in Chapter Eight.

[1] Throughout this project, ethics in RUPD, ethics for RUPD, and the ethics of RUPD are used interchangeably.

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List of Abbreviations

CHESS	Comprehensive Health and Epidemiological Surveillance System
CIOMS	Council for International Organizations of Medical Sciences
DHS	Demographic Health Survey
GHS	Ghana Health Service
HDSS	Health and Demographic Surveillance System
H3Africa	Human Heredity and Health in Africa
IBMB	Institute for Biomedical Ethics, University of Basel
ICMJE	International Committee of Medical Journal Editors
IHI	Ifakara Health Institute
INDEPTH	International Network for the Demographic Evaluation of Populations and their Health
IRB	Institutional Review Board
MDGs	Millennium Development Goals
MRC	Medical Research Council
REC	Research Ethics Committee
RUPD	Research Using Public Health Data
SDGs	Sustainable Development Goals
Swiss TPH	Swiss Tropical and Public Health Institute
UNDP	United Nations Development Programme

1.0 General Introduction

1.1 Background

1.1.1 International data collection for public health

Progress in public health requires advances and innovation in knowledge through evidence generation from data (Public Health Ontario, 2012). In the current global technological and information age, public health data serves both as a critical resource for decision making in population health and as a research tool for the promotion of global health. At community levels, data enables the monitoring of the health of populations who supply it and ensure the quality of ongoing interventions. At national, sub-continental, and global levels, public health data assists in the planning of health programs on the basis of available resources and the levels of disease burdens borne by different regions (C.J. Murray, 2007, W.G. van Panhuis et al., 2014). Measuring progress in health and development as in the measurements of the erstwhile Millennium Development Goals (MDGs) and the current Sustainable Development Goals (SDGs) are rendered accurate from public health data. Identifying new issues of public health interests, disease burdens, containing threats to our global health and assessing what works and what does not all require public health data (C.J. Murray, 2007). Given such immeasurable importance of public health data, interests and activities for realizing public health data are often undertaken as a legal established function of governments (R. Bayer and A. Fairchild, 2004).

In the Global North comprising mostly developed countries, national level data for planning public health is generally available from routine government implemented vital registration systems. Projects like the SAPALDIA cohort of Switzerland (The SAPALDIA, 2015) and the health care co-operatives of Canada (Health Care Co-operatives Federation of Canada, 2016) are notable examples. These projects potentially serve as data sources for a wide range of health related activities including research and as auxiliary data resource to aid in measurements of the determinants of health.

In the Global South or the South, that is developing countries primarily in the southern hemisphere (United Nations Development Programme, 2016), national level public health data collection and availability is generally impeded by resource constraints. Rather,

pseudo-government models like the Demographic Health Survey program (DHS) and the health and demographic surveillance system (HDSS) exist. The former, ran by the USAID for instance undertakes smaller scale sub-national data collection across vast regions in Africa, Asia, Latin America, the Caribbean, and Europe (Demographic and Health Surveys Program, 2016). The latter HDSS, which is currently unified under the International Network for the Demographic Evaluation of Populations and their Health (INDEPTH Network) has a current membership of 49 field sites in 43 research centers across 19 countries in Africa, Asia, Oceania, and Central America.

The INDEPTH HDSS collectively observes an estimated 3.8 million people (INDEPTH, c2018, F. Levira et al., 2014, K. Herbst et al., 2015, INDEPTH, 2016a). It has developed to become a critical resource of evidence for informing public health in the South, particularly in sub-Saharan Africa. In addition to the primary uses of both the DHS and HDSS as general public health systems, the data they produce serve for important secondary uses in the conduct of health-related research. For the purposes of this project, such research enabled by pre-collected public health data, retrospective or prospective, without necessitation further human contact, in the conduct of health related research is referred to as research using public-health data (RUPD).

In this thesis, we use the HDSS as a relevant profile example of public health systems in the South which routinely collect population-level data and use same in the conduct or support of RUPD. We further present the INDEPTH-HDSS as representing some of the most widely collected data in the sub-region, some of the most underused data sources needed for the conduct of global health research, a source of contemporary interest in data sharing discourses, and one of the most important complements of RUPD in the sub region.

1.1.2 The health and demographic surveillance systems of Africa

Starting from the 1940s in South Africa and in the 1960s in Senegal, West Africa (Y. Yazoume et al., 2012), the HDSS has developed to become internationally identified public health systems that operate under domestic laws and regulatory institutional policies in their host countries. Contexts targeted in sub-Saharan Africa for building HDSSs usually have high disease burdens, inadequate health infrastructure, health inequalities, and poor availability of data to direct public health decisions (WHO, 2013, F. Levira et al., 2014, O.

Sankoh and P. Byass, 2012). The HDSS has been notable for its strategy of longitudinally documenting millions of person-years and vital statistics which are permanently related to individuals in specific communities which would otherwise remain less known (O. Sankoh and P. Byass, 2012). House to house visits are conducted on annual, biannual, or quarterly basis depending on resource availability to collect the HDSS data. The data generally covers various indicators including births, deaths, migration, marital status and or changes, health seeking behavior, lifestyle, social, and economic circumstances of the communities, at the population level (INDEPTH Network, 2013, INDEPTH, 2013, F. Levira et al., 2014). The system thereby provides an invaluable platform to accommodate varied public health needs and activities such as the assessment of health service effectiveness, interventions, mortality and morbidity surveillance (O. Sankoh, 2015). It also accommodates contemporary interventions such as population level pharmacovigilance of susceptible groups to clinical issues of global health interests (F. Kirakoya-Samadoulougou et al., 2016).

Another key advantage of the HDSS is its unified characteristic under the INDEPTH Network (INDEPTH Network, 2017). Headquartered in Accra, Ghana the Network has since its inception in 1998 worked to enable the standardization of data collection and management across member-HDSS sites. It provides the needed training, skillsets, and assistance in tackling the technical challenges associated with the complexity and dynamism of HDSS databases. (O. Sankoh and C. IJsselmuiden, 2011) INDEPTH has undertaken several innovative programs. Its latest concept called the Comprehensive Health and Epidemiological Surveillance System (CHESS) is under continuing integration to link traditional HDSS information on individuals to their health data which is held within the respective local health facilities, using unique electronic individual identification systems. The new phase of the HDSS under CHESS will introduce additional depth of data from clinical, laboratory, environmental, health systems, and other contextual data on their respective populations (F. Kirakoya-Samadoulougou et al., 2016, O. Sankoh, 2015). In other words, as the CHESS integration comes into full force, not only will it add to the already available HDSS data as well as the inclusion and provision of empirical unbiased data, but it would add to data reliability and comprehensiveness in use for public health and for research. For instance, mortality data captured within the system encapsulates both regular data from health facilities via medical certificates on cause of death as well as specially integrated verbal autopsies carried out in the community (O. Sankoh, 2015, O. Sankoh and C.

IJsselmuiden, 2011, F. Kirakoya-Samadoulougou et al., 2016). What is thus missed by hospitals in poor countries by way of unreported deaths would for instance be more easily picked up by the HDSS via CHESS.

1.1.3 RUPD and data sharing

Given the foregoing data opportunities, generating sufficient sample sizes for various population groups and for varied research questions is possible. Whether in crude, corrected, or predicted forms (C.J. Murray, 2007), the depth of HDSS data now empowers otherwise under-resourced institutions to mirror data repositories across the world as a useful source of analytical processing for public health activities and for RUPD (INDEPTH Network, 2013, INDEPTH, 2013, F. Levira et al., 2014). New rounds of data collection provide new chances for growing already existing data or introducing new modules of public health or research interests subject to national and regulatory approvals. Combined with the ongoing acceleration of technological and analytical advances, the possibilities for increasing scientific productivity using RUPD are immense. The HDSS therefore offers an effective alternative for testing new hypotheses through RUPD without the rigors of starting research from scratch or contacting research participants prospectively. Moreover, RUPD data can be shared to enable the conduct of multiple-site RUPD.

The advantages to sharing RUPD data for science in the South are similar to those espoused in the literature in relation to other health related data. They include the following: they enable reproducibility of research; maximize cost efficiency; prevent duplication of research, participant contact, and other redundancies; foster transparency; accelerate the production of new knowledge; and help save lives (C.J. Murray, 2007, W.G. van Panhuis et al., 2014). However, optimizing ethics in public health data sharing and use in research (RUPD) are not quite simple. They go beyond technical, economic, and scientific issues to encapsulate issues underlain by reciprocity, justice, trust, and confidence between those in need of or able to optimize data for science and those from whom such data is attainable.

1.1.4 Towards achieving global health goals with RUPD

Having failed to meet the MDGs, Africa is poised to meet the new SDGs in spite of the region's deep rooted systemic challenges. The INDEPTH HDSSs can help speed the realization of these goals as they target hard to reach communities as a means of addressing hard to preempt hurdles to these goals. They can also help by using and or sharing the data they collect to further research. RUPD's justification as a strategic tool for meeting the SDGs in the South and Africa in particular is also founded on utilitarian and deontological arguments. In this sense, practitioners' ability to fulfill their professional obligations (deontology) to global health efforts by making the most benefit out of available data for public health and research purposes would translate into improved health outcomes for populations at the community level and beyond (utilitarianism). Further, in regions like sub-Saharan Africa which largely depend on external investments for research, RUPD arguably offers the most cost effective strategy for increasing research productivity without additional costs. This is of particular importance given the general dwindling of funding for health endeavors including research (Rani and Buckley, 2012). It is my view therefore, that RUPD could be the best staple research strategy for sub-Saharan Africa and the South in general.

With the right balance of technical and ethical provisions, RUPD is capable of accelerating the chances of African countries to achieve the SDGs especially by improving health outcomes in communities to which the poorest national health indices could otherwise be attributed. Yet, RUPD depends largely on the corporate and individual commitments of scientists and institutions to use and share public health data. Various global actors and the scholarly literature have argued for the importance of data sharing in its general role of enabling research to increase scientific productivity (E. Pisani et al., 2018, E. Pisani et al., 2016, S. Bull et al., 2015). Despite the advantages, public health data sharing is challenging in real practice (W.G. van Panhuis et al., 2014, M. Brack and T. Castillo, 2015, S. Dallmeier-Tiessen et al., 2014). Although there has been scholarly contributions of varying relevance or scope of applications (S. Bull et al., 2015), there is yet to be a global systematic framework or guidelines on data sharing (S.G. Denny et al., 2015, W.G. van Panhuis et al., 2014).

Technical barriers to data sharing may be easy to theoretically address, but there are ethical issues to consider about relational, professional, and personal matters of importance

to scientists, regulators, and other stakeholders that have potential to sharpen possible tensions between international requirements and local adherence to data sharing. These factors have attracted limited attention in the literature, but need to feature as a priority area in the data sharing and RUPD development discourse. Therefore, this thesis ultimately argues that to make the most of RUPD for scientific or research productivity and more importantly for the promotion of global health towards the SDGs, optimizing the use of public health data must be met with commensurate attention to the issues that influence the stakeholders who make RUPD possible.

1.1.5 RUPD and ethics

Data emanating from core HDSS activities and also health research undertaken within HDSS systems are combined to undertake RUPD. Literature on policy, ethical and legal developments (Public Health Ontario, 2012, Council for International Organizations of Medical Sciences, 2002) support RUPD as a clear means of maximizing the public good beyond the narrower purposes for which public health data is originally collected. Yet in the context of contemporary research ethics, there is a growing debate as to what applicable ethical principles can be practiced in the interest of the people who provide RUPD data (research participants), the scientists who invest in collecting the data and holding same for future research (producing scientists), and scientists who may not have contributed to data collection, but could make the most optimal creation of new knowledge (user scientists). The traditional ethical model of research ethics principles generally focuses on the individual, the research participant. Translating these principles to apply to populations and worse scientists, is therefore less straightforward, more challenging and in terms of contemporary writing, seemingly impractical.

Research ethics principles however remain ideal in letter and in spirit for every research: the letter may be challenging, but the spirit will always remain invaluable and full of benefit to all stakeholders, but particularly to populations who are yet to benefit fully from scientific developments. Communities in the South are typical examples. For instance, informed consent is being heavily challenged in epidemiological and database studies (S.S. Cargill, 2016, J. Sim and A. Dawson, 2012 , Hawkins and Longstaff, 2015), but indeed the arguments put forward can rarely challenge the essence of fulfilling the elements of disclosure of information, its comprehension, recipient's voluntariness, capacity in decision-

making, and authorization before being involved in an endeavor which concerns them. It is therefore my firm belief that general arguments made that the longstanding research ethics principles that have evidently developed research in other fields to heights otherwise unachievable should be under-emphasized for RUPD and more generally for public health data sharing are not ideal. Various reasons bordering on cost and impracticality and supported by utilitarian principles are given for such stands (CIOMS, 2016a, U.S. NIH, c2016). And it is such arguments that have successfully led to worldwide decisions to mostly limit the ethics of RUPD to the sole step of protocol approval by a research ethics committee (REC).

It is also true that there are major challenges to research ethical practice in RUPD which are posed by the sheer numbers involved as well as the inseparable link of RUPD activities with public health activities (core HDSS activities). So, while REC approval alone may sound acceptable in the interest of speed and scientific productivity, such a narrow view of ethical requirements for RUPD and little to none for data sharing fails to recognize that science is a means to an end. Its progress rests in the health, interests, and well-being of key stakeholders other than the research participant who make data possible. If science must increase, it must increase along with its impact on research populations and all other stakeholders. Research ethics is a proven way of ensuring these ideals and more (CIOMS, 2016b, CIOMS, 2016a, IOM, 2015, Nuffield Council on Bioethics, 2002).

For contexts with developmental ethical and or legal systems such as is common in sub-Saharan Africa, RUPD Ethics can perhaps, be explained as an under-explored strategy. This is because of the existence of generally weaker ethical structures, stronger research naivety among research populations (R.L. Klitzman, 2012), and social justice concerns (S. Bull et al., 2015) that systemically posit *apriori* grounds for limiting the optimization of research ethics in favor of overall scientific productivity and health benefits. Any effort to promote the growth, awareness, and practice of research ethics and particularly in newer research dimensions like RUPD is necessary. Moreover, the expansive reach of HDSSs for data, research, and sharing provides an unparalleled fertile option for reaching institutions, scientists, and populations with formal ethics structures. Those reached can then effect changes towards stronger ethical safeguards and encourage the best possible practices for the best science and health outcomes in the sub-region and the South in general. I therefore entreat on utilitarian basis that there is need for a balance between increasing

scientific productivity and optimizing benefits to communities, scientists, and the millions of populations who make RUPD possible, as long as these benefits remain comparably higher in moral worth than any sacrifices that would be made in the process such as speed and ease of science (Singer, 2009).

1.1.5.1 Ethical considerations for RUPD populations

In December 2016, the Council for International Organizations of Medical Sciences (CIOMS) released its latest guidelines for health-related research involving humans. Before this, the vacuum of ethics for RUPD was much larger. The current CIOMS document has turned out to be the best available international ethics guidelines for RUPD. Its provisions under Guidelines 3, 7, 8, 12, and 24 are largely aligned with expectations of ethical practice in RUPD. For instance, Guideline 3 on "Equitable distribution of benefits and burdens in the selection of individuals and groups of participants in research" inherently addresses collective risks as detailed in manuscript 1 and 4 included in this thesis. Guideline 7, "Community engagement" calls for attention to the engagement of communities in sustained and meaningful participatory processes that involves them in research, and in the dissemination of results as espoused in this project (Manuscript 1) as well. Guideline 8 on "Collaborative partnership and capacity building for research and review" is discussed in the document as a crucial need for research and a responsibility to be spearheaded by governmental health-related institutions oversee research involving human participants. In respect of RUPD, the CIOMS provision engenders community trust for research as important for capacity-building for research and review. Both are clearly argued for RUPD in the survey results (Manuscript 1 and 4) of this project. RUPD is argued to thrive on this as collaborative partnership improves trust both on the part of communities or populations and on the part of scientists (Manuscript 3).

CIOMS' (2016) Guideline 12 on the "Collection, storage and use of data in health-related research" has arguably the greatest link to RUPD. It stipulates requirement for stored data and essential governance systems for acceptable authorization for future use in research. By way of application, RUPD researchers have a duty to ensure that their use, storage and further use of data for primary and secondary RUPD "do not adversely affect the rights and welfare of individuals from whom the data were collected" (CIOMS, 2016a). Last but not least, Guideline 24 on "Public accountability for health-related research" which links

the realization of social and scientific value (E.J. Emanuel et al., 2004) for health-related research is a critical pillar in RUPD ethics. As I discuss this primarily in Chapters 3 (Manuscript 1) and 6 (Manuscript 4), I entreat researchers, sponsors, RECs, funders, editors, and publishers on their joint quest to make data sharing obligatory to also recognize the challenges this would pose to the under-resourced sections of the scientific community in Chapters 4 (Manuscript 2) and 5 (Manuscript 3). This project further aligns its findings to the CIOMS' on sharing the results of data in a timely manner to improve RUPD benefits to populations and prevent fatigue or demotivation of communities in contributing data. The importance of the REC is as usual dominant through all the cited guidelines of the CIOMS document. It is similarly reported in this thesis.

Despite the importance these new ethical additions bring to bear on RUPD and its future, there still remain gaps. This is partly because the guidelines are rightly made to generally fit with the current examples of international database frameworks like databanks that hold biological data and repositories, but may not necessarily require routine longitudinal updates and other community level characteristics. The stakes are therefore different when these frameworks are compared to RUPD given the earlier explained features of routine HDSS contacts and ease of possibility to locate and individualize data. The virtuous RUPD practitioner, REC member, or stakeholder does not have a straightforward framework even in the newest version of CIOMS to guide their conduct in RUPD. Rather they have to still maneuver and use discretionary "good effort" extrapolations or deductive analysis to define what is ethical to do. The corollary is that, RUPD systems in sub-Saharan Africa with slow growths in ethics could suffer sub-optimal research ethics practices. The potential vacuum between what is expected and what could be achieved for populations given the ideals of the new CIOMS document (CIOMS, 2016a) and other guidelines which have proven successful and dependable in building the biomedical research arena is still worth new considerations.

1.1.5.2 Ethical considerations for RUPD scientists

Early on in 2016, a proposal to make data sharing a new norm following publications was made by the International Committee of Medical Journal Editors (ICMJE), an authoritative committee of thirteen general medical journals. The proposal has since attracted much interest and debate (D.B. Taichman et al., 2017, D.B. Taichman et al., 2016).

Several global funding actors had also issued directives obliging data sharing particularly in clinical trials prior to the ICMJE's. These developments have much potential influence on RUPD and to scientists involved in it. For sub-Saharan Africa, they raise additional issues associated with the continent's systemic inadequacies which are in turn rooted in its economic, technological, and structural limitations. These challenges in turn influence public health and RUPD in ways farther and more difficult to deal with than dealing with the incoming new risks of data sharing to scientists whose productivity are affected by Africa's systemic situations. I therefore further argue in this thesis that if RUPD can be increased in sustainable ways at the global level to match the needs of our fast and changing technological world, a new dynamic of ethics aimed at safeguarding the interests and protections of at risk scientists is necessary.

Under-resourced scientists, mostly in the Global South face many challenges in their quest to increase scientific productivity. While data sharing opportunities for enhanced and cheaper science grows worldwide, key ethical principles based broadly on fairness and reciprocity are needed to promote a balance between the rights and responsibilities of scientists and institutions who analyze and publish results using their data (CIOMS, 2016a, O. Sankoh and C. IJsselmuiden, 2011). The skepticism that thrives in spite of the many advantages and general positive attitudes to global data sharing benefits (E. Pisani et al., 2018, J.E. Sieber, 2015, E. Pisani et al., 2016, E. Pisani et al., 2010) are greater for under resourced contexts and thus must not be ignored. Moreover, the true extent of the implications of data sharing cannot be easily predicted yet (M. Brack and T. Castillo, 2015). Giving attention to how the data evolution is going to be shaped by the new calls for sharing relative to the scientific community's interest in data production, recognition for efforts in data collection and management, funding prospects subsequent to easy and cheaper access to data, and how these can be guided to avoid any negative impact on the South remain a significant ethical challenge and a critical research gap. Addressing this gap will require international dialogue among stakeholders from the different sections of the scientific community.

1.2 The Research Gap

From the foregoing, any notion equating RUPD to traditional database studies and limiting it to an ethic of REC review and confidentiality protection alone is flawed. Similarly,

the focus of today's science on increasing productivity without the requisite attention to professional risks to scientists, especially the under resourced members of the community is problematic. The gap in ethics for RUPD can therefore be seen from a dual perspective: ethical issues critical to traditional provisions to safeguard research populations' interests and wellbeing; and ethical issues surrounding the implications of international stipulations like data sharing on RUPD scientists.

A good approach to addressing this gap is via critical applied ethics. This approach requires basing enquiries on empirical findings to explain normative issues. In other words, empirical evidence from the lived experiences of RUPD practitioners that include both affirmations and skepticism about what is known and what is the norm for the respective situation is used to guide the ensuing discussion (A.M. Hedgecoe, 2004). Consequently, this thesis makes considerations of moral theory and research practice using both the theoretical literature and the empirical findings resulting from this project as means of contributing agreements and contrary views to the ongoing discourse and to the literature on the overall ethics of RUPD and data sharing.

1.2.1 Research justification, aims, and objectives

The primary goal of this project was to explore the differences between RUPD and traditional health research that encourage variations in its research ethics applications in order to make a case, if feasible, for change. A secondary aim was to explore and explain what data sharing means for scientists in the under-resourced sections of the global scientific community and in sub-Saharan Africa in particular to help unveil some under-studied issues that could impede data sharing. The overall goal was to suggest a guiding framework for a fuller realization of research ethics principles in RUPD in contrast to general suggestions for limiting RUPD ethics to REC review and anonymization processes. Motivation for this PhD study and for change lies in a utilitarian beneficence argument (Singer, 2009) which I argue out as follows: as long as benefits realizable from research ethics principles for populations and scientists involved in RUPD remain incomparable in moral worth to the costs of optimizing the principles, we ought to seek and implement them. This thesis is ultimately a modest attempt at contributing ideas that can help in closing ethical gaps in RUPD and also contributing to the limited empirical research on data sharing in public health research and by association, RUPD.

Against this backdrop, I set out primarily to question if and which research ethics principles are necessary for the ethics of RUPD and what matters to stakeholders in the South in general and sub-Saharan Africa in particular about data sharing. The thesis focuses on the following specific objectives:

1. To reveal the unique features of HDSSs and RUPD in order to understand the current knowledge and practice base for conceptualizing an ideal ethic for RUPD.
2. To explore challenges faced by scientists and stakeholders who operate in environments where the completion of data cycles from data production to knowledge production (publications) is generally slow in order to identify the real reasons surrounding hesitations to share data.
3. To document perceived and real gaps to ethical practice in RUPD from the perspective of practitioners and REC members whose work are related to RUPD.
4. To examine the values, norms, and assumptions found in the study in order to design a basic ethical framework for RUPD and data sharing.

1.3 Contributions and publications making up this thesis

The main work for this thesis was conceived, designed, and undertaken by me under the close supervision of my internal PhD advisors (Prof. Elger, Prof. Tanner, and Dr. Wangmo) as well as a field referee (Prof. Sankoh). I developed the data collection tools with their support. In the course of the project, I sought independent ethical review from seven research ethics committees in Switzerland, Ghana, Tanzania, and Uganda. The data collection was done solely by me as follows: (1) I conducted a pre-test of the study tools; (2) I completed the field work necessary for the quantitative survey in Ethiopia; (3) I undertook a survey and conducted 46 qualitative interviews in Ghana and Tanzania; (4) Subsequently, I carried out the data entry, transcriptions, analysis, and result interpretation leading to the writing of the articles in this thesis. Dr. Wangmo, my immediate supervisor offered me technical support in developing the appropriate data entry templates in the IBM SPSS Statistics Version 21 for the quantitative data entry and management. For the qualitative data, we worked together to develop a template using MaxQDA software Version 12. This software program is specially designed for computer-assisted qualitative and mixed methods data, text, and multimedia analysis. As part of the initial coding process and quality assurance in identifying essential concepts and ideas in the data for accurate interpretations,

my supervisor doubled up as a co-analyst in concurrently reading a selected sample of ten transcripts from the number completed. Doing this together improved accuracy and reliability in developing the coding frame. I solely completed the rest of the coding and analysis.

I drafted all first-authored articles and critically revised them, based on the critique of members of the supervisory team, who are also co-authors in the papers. Other articles I have co-authored (three) and have included as appendices form part of the broader original public health ethics project plan which I initiated with a colleague, Dr. Claire Leonie Ward towards an overall collaborative project. This collaboration ultimately encapsulates Dr. Ward's work on vaccine trials as an example of key activities undertaken by HDSSs, the profile example of new models for public health research in resource limited countries in this thesis. Dr. Ward also made intellectual input in the writing of my second Paper and is thus a co-author. The four manuscripts to which I am first author form the main basis of this thesis while the other three form the thesis of Dr. Ward's:

1. **Anane-Sarpong E,** Wangmo T, Sankoh O, Tanner M, & Elger B.S. (2018) Application of Ethical Principles to Research Using Public Health Data in the Global South: Perspectives from Africa. *Developing World Bioethics;* 18(2):98-108. doi: 10.1111/dewb.12138. Epub 2016 Dec 22.
2. **Anane-Sarpong E,** Wangmo T, Ward CL, Sankoh O, Tanner M, & Elger B.S. (2018) "You cannot collect data using your own resources and go and put it on open access": Perspectives from Africa about public health data sharing. *Developing World Bioethics*; 18(4):394-405. doi: 10.1111/dewb.12159. Epub 2017 Jul 25.
3. **Anane-Sarpong E,** Wangmo T, & Tanner M. (2019) Ethical principles for promoting health research data sharing with sub-Saharan Africa*. Developing World Bioethics* Accepted for publication.
4. **Anane-Sarpong E,** Wangmo T, Tanner M, Sankoh O, & Elger B.S. Probing and Addressing Missing Links in the Ethics of Research Using Public Health Data: A Qualitative African Study. *Journal of Public Health in Africa.* Under review.
5. Ward CL, Shaw D, **Anane-Sarpong E,** Sankoh O, Tanner M, Elger B.S. (2018) The ethics of health care delivery in a pediatric malaria vaccine trial (PMVT): The perspective of stakeholders from the malaria vaccine candidate trial RTS,S in Ghana

and Tanzania. *Journal of Empirical Research on Human Research Ethics;* 13(1):26-41. doi: 10.1177/1556264617742236. Epub 2017 Nov 28.

6. Ward CL, Shaw D, **Anane-Sarpong E,** Sankoh O, Tanner M, Elger B.S. (2018) Defining Health Research for Development (HRD): The Perspective of Stakeholders from an International Health Research Partnership in Ghana and Tanzania. *Developing World Bioethics*; 18(4):331-340. doi: 10.1111/dewb.12144. Epub 2017 May 3.
7. Ward CL, Shaw D, **Anane-Sarpong E,** Sankoh O, Tanner M, & Elger B. (2017) The Ethics of End of Trial Obligations in a Paediatric Malaria Vaccine Trial: The Perspectives of Stakeholders From Ghana And Tanzania. *Journal of Empirical Research on Human Research Ethics*; 13(3):258-269. doi: 10.1177/15562 64618771809. Epub 2018 May 13.

2.0 Methodology

2.1 Outline

This study was conceived to address gaps in ethical notions, practice, and guidance in RUPD as well as related issues of contemporary connections to RUPD, through reflections on shared real life experiences relative to the normative literature. The project forms part of a broad collaborative venture between the Institute for Biomedical Ethics and the Swiss Tropical and Public Health Institute, designed to enable a northern and southern scholar to conduct self-selected research in public health, including research, and ethics. The supervisory team comprised Prof. Bernice Simone Elger, Dr. Tenzin Wangmo, and Prof. Marcel Tanner all of the University of Basel and Prof. Osman Sankoh of the INDEPTH Network, Accra, Ghana. Some initial support was offered by Prof. Dr. Angus Dawson of the University of Sydney. The objective of the project was not to oppose international ideals set generally for research that share similar characteristics with RUPD, but to make a strong case for more ethical considerations to be given to RUPD using the many available opportunities made possible by the numerous activities undertaken by the mother HDSS. To the best of our knowledge, this is the first empirical project on the ethics of RUPD in HDSSs.

The project officially took off in February 2014 and was completed and defended in May 2017. The rest of this chapter describes the methodological approaches used in the entire study phases, from scoping visits and data collection to normative and empirical analysis of the data. More details are provided as part of each of the manuscripts included, hence the following paragraphs give a more general description of the methods.

2.1.1 Study design

The study design was cross sectional, involving multi-center participation from HDSS member sites (Figure 1), using a mixed methods approach (B. Dawson and R.G. Trapp, 2004, N Mays and C. Pope, 1995 , G. Guest et al., 2012). The empirical phases were preceded by a review of the theoretical literature which subsequently informed reflections on the ideal ethics for RUPD in Chapters 3, 4, and 6. A theoretical approach was used in writing Chapter 5 and for explaining concepts and principles in the examination of the literature for issues imputed by respondents in the empirical chapters.

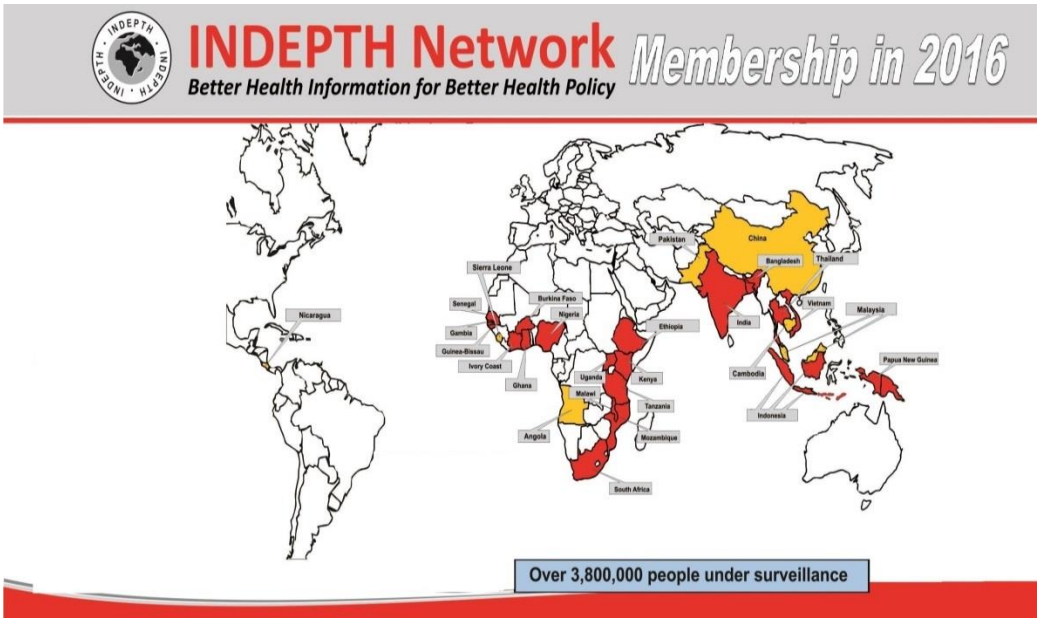
Three INDEPTH-member HDSS sites in Tanzania and two in Ghana, six RECs, and three institutions affiliated to ministerial agencies, academia, or legal institutions in each country were involved in the qualitative aspects of the project. The selection of Ghana and Tanzania was convenient: the PhD candidate who comes from Ghana is familiar with the national terrain, and could better assist her northern colleague on conducting her project on-site in her familiar home base. The Swiss TPH which sponsored the project has longstanding academic and research collaborations with Tanzania leading to its selection as the second study area. A third country, Ethiopia, was purposively added for the conduct of a survey (quantitative side of the project). Ethiopia's selection was as a result of INDEPTH's decision to use it as the venue for its Scientific Conference, following a cancelled earlier plan to hold the conference in Uganda. The project plans for Uganda, as evident in ethics approval from a Ugandan REC, was cancelled in the aftermath of the Ebola epidemic in three countries of the West African sub-region. Although institutional permissions had been sought, ethics review processes completed, and preparations to visit were well advanced, the site had to be excluded. This unexpected but cautious cancellation of the Uganda meeting affected the data collection schedule and delayed the finding of an alternative for thirteen months. In the interim, administering the survey online became a viable option. However, after much preparation, completion, notifications, and advertisements with the kind help of the Executive Director and staff of the INDEPTH Network in Accra, the online survey yielded a woefully inadequate participation. Following a two month extension, announcements in two consecutive newsletters of the INDEPTH Network, personal reminders via emails with links to the survey, and twelve respondents (including incomplete forms), the last alternative option of physical presence at the conference had to be necessarily waited for.

2.1.2 Study sampling

Sampling for the qualitative interviews was purposive (N. Mays and C. Pope, 1995, V. Braun and V. Clarke, 2006) to include predefined persons who were knowledgeable of the research question and willing to consent to participation. Members of RECs with oversight responsibility over the HDSSs work were approached through their chairpersons and administrators. Participants from HDSSs were approached mainly through institutional directors and unit heads.

A snowball approach was used: heads of institutions generally recommended potential participants or directly asked others if they could participate and they in turn recommended others to contact. A large number of the interviewees were enrolled by this approach. It was also useful for identifying the participants independent of the HDSSs, that is the experts and policy makers working in ministerial and other agencies of public health, national and international who are involved in public health research and decision-making in Africa. Special effort was made to include independent experts with training in the Law given the discipline's close proximity to deliberations in ethics and the role it plays in ethical developments in the region. One participant each in Ghana and Tanzania were from European affiliated institutions and based in Africa.

Figure 1: World Map showing countries where INDEPTH member-HDSSs are located



Source: http://indepth-network.org/about-us

Combined, the multi-center participants of both the quantitative survey which yielded participation from 18 countries viz. comprising thirteen Southern countries (Ghana, Nigeria, Burkina Faso, Mali, Senegal, the Gambia, Kenya, Uganda, Ethiopia, Tanzania, South Africa, Malawi, Mozambique and Bangladesh) and four Northern countries with a critical stake in HDSSs (Sweden, Switzerland, the Netherlands, and the United States) and the qualitative interviews from the two countries, Ghana and Tanzania constituted a reasonable representation of HDSSs to inform this project's reflection and the achievement of the study objectives.

2.2 Development of study tools, field work, and data collection

2.2.1 Qualitative interviews

A thematic review of existing literature was conducted to inform decision making on the best approaches to use. In-depth data that could not be obtained using questionnaires was collected via interviews. Once the decision for conducting both a quantitative survey and qualitative interviews was made, scoping visits to Ghana and Tanzania were carried out to discuss the acceptability or otherwise of the project, feasibility of the proposed methods, and local regulatory and procedural requirements.

An interview guide was finalized after the scoping visits. The interview questions were semi-structured to allow for openness to useful emerging concepts and allow participants the opportunities to probe responses (See Appendix 4). Interviews were audio-taped, continued until theoretical saturation was attained and thereafter, continued to clarify grey areas and unclear responses earlier received from other interviewees. Side notes of relevant comments were also taken with permission from interviewees to be used to support data analysis, where necessary.

The key-informant face-to-face interviews were conducted with an effective sample of 46 participants from November 2014 to February 2015. The HDSS affiliated participants were as follows: five HDSS directors or ex directors, thirteen unit heads including field supervisors, and eight scientists. From RECs, participants were made up of eight members including two chairpersons and six REC administrators. Four participants were from the national ministries of health and two from the country offices of the WHO, speaking on their personal professional experiences rather than positing views on behalf of the international body.

The substantive and procedural steps to obtain institutional permissions for inclusion and individual informed consent were undertaken for each participant. Efforts to assure confidentiality were made throughout the project by delinking consent documents from interview records and transcripts. Participants were given token souvenirs of Basel-embossed pens, travel tags, or post cards for their participation, time, and inconvenience. Debriefing sessions were held on-site with center leaders before departure from each institution with plans of final dissemination to the rest of staff before the project ends.

2.2.2 Quantitative survey

A detailed literature search involving the keywords and terms similar in experiential application to RUPD was undertaken using search engines including PubMed, MedLine, Hinari, CINAHL, Web of Science, and Google Scholar. While these searched were largely targeted at the theoretical aspects of the project, it was useful for identifying content, methodological approaches, challenges, and gaps in their application to RUPD to inform the questionnaire development. The literature search was also very relevant to the critical applied ethics approach I adopted to help explain normative issues surrounding RUPD and the sub-discussion on data-sharing using empirical findings from various lived experiences of RUPD practitioners (A.M. Hedgecoe, 2004).

No validated study tool was found suited to our population and research questions. Hence, a provisional collection of questions was made during the literature review to inform a first attempt at conceptualizing the outputs of this project. This review also informed the construction of the survey vignette to mimic real-life RUPD scenarios based on HDSS-RUPD contexts, the study objectives, and expected outcomes. This choice of using vignettes in the quantitative survey yielded the following advantages: (1) Ability to orient respondents to the issues of interest given the use of a common scenario; (2) Assurance of face validity; (B. Dawson and R.G. Trapp, 2004) (3) Better elicitation of answers relevant to the project; (4) Enabling participants' agreements and dissenting opinions to be narrowed to a common scenario for ease of comparison; and (4) It ensured the practicality of questions without making participants feel personal about it or incriminated if their practices were not aligned with ethical ideals featured in some sections of the questionnaire. Moreover, the decision to use a vignette with a common scenario proved very useful given the reality that often there is more than one way to behave ethically because ethical principles can be prioritized differently (T.L. Beauchamp and J.F. Childress, 2001). Both closed and open-ended questions were used (See Appendix 2).

Despite the initial disruptions to the quantitative data collection due to program cancellations from October 2014 to November 2015, the replacement conference in Addis Ababa was worth the wait. It offered a sizeable number of participants to enable analysis, although the number was still below expectation. By this time however, the survey completion had to be left to participants' benevolence, interest in capturing knowledgeable

participants' experiences, and a confidence that representativeness or the lack of it took little away from the importance of the shared views on RUPD (K.J. Rothman et al., 2013). Effective participation was from eighteen countries in Africa, Asia, Europe and the North America with a response rate of 40.6% (N=350). An inclusion criterion of completion of at least two of the three sections of the questionnaire finally led to an inclusion of 130 questionnaires in the analysis.

2.2.3 Enhancing the quality of the study tools

An assessment of the content validity of both the survey tool (B. Dawson and R.G. Trapp, 2004) and interview guide was undertaken by the student under guidance of the supervisory team. Yet, the survey tools were only approved in Tanzania on condition of being fielded in both English and Swahili, the national language. Because the student researcher did not speak or write Swahili, all documents had to be translated by independent translators. The final version of both questionnaires and interview guides in English were first translated to Swahili and back translated to English by different translators. Both translators were given a brief summary of the project to help them contextualize their translations. The back translator (Swahili to English) however, had no access to the original English document. A final comparison of the original English version and the new back translated one was made to seek corrections and amendments for differences. It was a lengthy iterative process among the student researcher, English to Swahili translator, and Swahili to English back translator, sometimes involving complaints of each other (translators) being wrong in their translation. The student researcher was unable to tell who was wrong. Hence, the views of a third translator (a member of an REC) was sought to clarify the paragraphs for which finding agreement between the two translators was impossible. The latter translators also helped to correct technical terms in research ethics that defied the general translations given by the other translators. The final versions of the Swahili translation was pre-tested for clarity with a colleague at the Ifakara Office, Mikocheni before the interviews were started in Tanzania. Ultimately however, all participants agreed to be interviewed in English in apprehension of the depth of confusion that translation of full transcripts could bring to the student.

2.3 Data Analysis

The quantitative analysis was conducted using IBM SPSS Statistics Version 21. Closed-ended questions were analyzed via descriptive statistics while open-ended responses were entered initially as string variables and subsequently collated into relevant themes using content analysis (V. Braun and V. Clarke, 2006). Numerical data was checked for errors and then analyzed using frequencies and proportions.

Audio-recorded interview data and written field notes were transcribed verbatim using the MaxQDA software Version 12 (MaxQDA, 2013). Detailed processes from transcriptions to codification into themes and sub-themes are provided in Chapters 3 to 6. Support for data analysis was given by my immediate supervisor to help improve reliability (N. Mays and C. Pope, 1995, V. Braun and V. Clarke, 2006). A thematic analysis was used.

2.4 Ethical considerations

This study was undertaken with consideration to a critical understanding of research ethics principles in application to all human research as well as the subsequent use of the data emanating from same. Procedures undertaken for data were virtues-based to include honesty and transparency with prospective participating institutions and participants. The processes followed are aligned to international research ethics requirements including REC review and institutional permissions. Independent ethical review of the project were given by the following seven RECs and one national regulating commission: (1) Ethics Commission of North Western and Central Switzerland, which oversees human research participation in projects of the University of Basel; (2) Ghana Health Service Ethical Review Committee; (3) Dodowa Health Research Center Institutional Review Board (IRB), Ghana; (4) Navrongo Health Research Center IRB, Ghana; (5) National Institute for Medical Research Ethics Committee, Tanzania; (6) Ifakara Health Institute IRB, Tanzania; (6) the Commission for Science and Technology, Tanzania; (7) The ethics committee of the Uganda Virus Research Institute, operated under the National Health Research Organization; and (8) The Commission of Science and Technology of Tanzania. The REC approval from Uganda was however, rendered less relevant since data collection in Uganda had to be cancelled as earlier discussed.

Permissions were also sought from various executive and or scientific committees or heads of study institutions prior to the REC applications. Individual study participants received information leaflets and consent documents (see appendices) to read, agree and sign or otherwise, and return them without names to the researcher during or before interviews. In the case of the quantitative survey completed by participants from several countries, most participants returned both the consent document and answered questionnaires. These were however, received and compiled by the student in ways that did not foster their linkage. All study procedures were conducted as approved by the respective RECs.

3.0 Application of Ethical Principles to Research Using Public Health Data in the Global South: Perspectives from Africa

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Application of Ethical Principles to Research Using Public Health Data in the Global South: Perspectives from Africa

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3.1 Abstract

Existing ethics guidelines, influential literature and policies on ethical research generally focus on real-time data collection from humans. They enforce individual rights and liberties, thereby lowering need for aggregate protections. Although dependable, emerging public health research paradigms like research using public health data (RUPD) raise new challenges to their application. Unlike traditional research, RUPD is population-based, aligned to public health activities, and often reliant on pre-collected longitudinal data. These characteristics, when considered in relation to the generally lower protective ethical and legal frameworks of the Global South, including Africa, highlight ethical gaps. Health and demographic surveillance systems are examples of public health programs that accommodate RUPD in these contexts. We set out to explore the perspectives of professionals with a working knowledge of these systems to determine practical ways of appropriating the foundational principles of health research to advance the ever growing opportunities in RUPD. We present their perspectives and in relation to the literature and our ethical analysis, make context relevant recommendations. We further argue for the development of a framework founded on the discussions and recommendations as a minimum base for achieving optimal ethics for optimal RUPD in the Global South.

Key words: The Global South; Public health research; Research ethics; Public health ethics; Health and demographic surveillance systems

3.2 Introduction

Global health thrives on large scale population health information and research which have changed considerably in volume and nature (Largent, 2016, O. Sankoh, 2015). In the Global North, national health data is generally available from government implemented vital registration systems (R. Bayer and A. Fairchild, 2004). In the Global South or South, that is developing countries which are located primarily in the southern hemisphere (United Nations Development Programme, 2016) and particularly in Africa, conducting such surveys is often constrained by inadequate resources(Demographic and Health Surveys Program, 2016, O. Sankoh and P. Byass, 2012, INDEPTH, 2016a). Instead, smaller scale household surveys are used to report nationally representative data for public health (Demographic and Health Surveys Program, 2016). The health and demographic surveillance system (HDSS) is

one such framework for collecting, storing, and managing otherwise difficult to obtain public health data. HDSS data is longitudinal and permanently connected to its population. This enables population-based retrospective investigations or the nesting of prospective research into ongoing data collection (O. Sankoh, 2015, F. Levira et al., 2014). In this paper, such systematic investigations designed to develop or contribute to generalizable knowledge (South African Medical Research Council, 2007, US Department of Health and Human Services, 2009) and incorporated into the HDSS or extracted from its pre-collected database are referred to as research using public health data (RUPD).

Research ethics has largely been shaped by principles, four of which are espoused in the framework of Principlism (T.L. Beauchamp and J.F. Childress, 2001, M. A. Rothstein, 2015): respect for persons (study participants and communities), beneficence, non-maleficence, and justice. These principles are contained in a range of international codes, national legislation, and regulations that have effectively guided research for decades (M. A. Rothstein, 2015, Largent, 2016). Unlike traditional health research, RUPD's public health dimension, sheer numbers involved due to its population based characteristic, and its database methodology make pursuit of these principles less straight-forward. Scholars and ethicists have argued for waivers on the basis of "impracticality" (J. Sim and A. Dawson, 2012 , CIOMS, 2016a, B.S. Elger, 2010) while some have suggested reliance on ethics review and opt-out options (where feasible) as adequate ethical safeguards (CIOMS, 2016a, B.S. Elger, 2010, S. Bull et al., 2015). There is ongoing debate on whether these proposals are the best mechanisms for similar research (M. A. Rothstein, 2015, Largent, 2016). The debate is particularly important for the South and Africa in particular, where protective frameworks and levels of individual awareness about rights and abilities to exercise them are generally at developmental stages (S. Bull et al., 2015, E.J. Emanuel et al., 2004). Hence, arguments for abandoning proven principles that have safeguarded populations in the name of optimizing science may hold less tightly in this context. We conducted a survey involving professionals with a working knowledge of the HDSS and RUPD, mostly in Africa to (a) explore their perceptions, attitudes, and practices towards the implementation of basic ethical principles; (b) determine practical ways of optimizing the implementation of the principles; and (c) consider the results in relation to the literature to make context relevant recommendations.

3.2.1 Household surveys in the Global South

Household surveys are commonly carried out in place of national level registries to support public health activities and research. Two of the most notable organizations that undertake such surveys are the USAID which is responsible for the Demographic and Health Survey program (Demographic and Health Surveys Program, 2016) and the INDEPTH (INDEPTH, 2016a), involved with the HDSS framework. This paper focuses on the latter as an example of a public health program that accommodates RUPD in the South.

3.2.2 The HDSS and INDEPTH

The HDSS concept started in the 1940s and 1960s in South Africa and Senegal respectively (Y. Yazoume et al., 2012). The system involves house-to-house data collection from whole communities on annual, biannual, or quarterly basis. Apart from the core data on births, deaths, migration, marital status changes, social, and economic indicators (F. Levira et al., 2014), they may conduct assessment of health service effectiveness, mortality, and morbidity surveillance (O. Sankoh, 2015). The data are thus used to analyze the population's health, inform public health decisions, and support the conduct of research (F. Levira et al., 2014, Y. Yazoume et al., 2012). HDSSs generally operate under domestic law (R. Bayer and A. Fairchild, 2004, Public Health Ontario, 2012) and regulatory institutions like the research ethics committee (REC).

INDEPTH was established in 1998 to develop a network of HDSSs, unify them, help them tackle the technical challenges associated with the complexity and dynamic nature of their databases (O. Sankoh and C. IJsselmuiden, 2011), and conduct research using their data (O. Sankoh, 2015, F. Levira et al., 2014). With a current number of 43 members, the Network collectively observes an estimated 3.5 million people in 20 countries across Africa, Asia, and Oceania (INDEPTH, 2016a, INDEPTH, 2015b). New technological and analytical advances have opened immense possibilities for HDSSs to generate unbiased empirical data that is essential for developing and assessing interventions (O. Sankoh, 2015) while contributing to scientific productivity (O. Sankoh and C. IJsselmuiden, 2011) like RUPD. INDEPTH has several innovative programs. Its latest concept, the Comprehensive Health and Epidemiological Surveillance System, is for instance planned to integrate population and health facility data systems that will link demographic, epidemiological, mortality, morbidity,

clinical, and household data among others with a unique electronic individual identification system (O. Sankoh, 2015) in the future. The HDSS thus offers an effective alternative for testing new hypotheses through RUPD without the rigors of starting research from scratch. Although RUPD can be smoothly incorporated into HDSS activities and be recognized for its role in the promotion of public health, it remains research. There is therefore a need to optimize the implementation of ethics in the interest of participants and communities.

3.2.3 Contextual issues surrounding RUPD and public health ethics

For many communities in the South, the protection and awareness of individual rights and liberties that support international research ethics implementation may be limited, unknown or undesired (T. Metz, 2010). This is due to differing perceptions and interpretations of essential values that form the basis of international ethical deliberation, as well as cultural practices which are more communal (T. Metz, 2010, H3Africa Working Group on Ethics and Regulatory Issues, 2013). Ethical frameworks in these contexts are generally not fully developed and regulatory authorities including RECs are limited in numbers (T. Mduluza (eds), 2007, M. Kruger et al., 2014). General protections instituted through national constitutions and awareness creation about human rights and individual liberties (A.M. Capron et al., 2009) that spur ethical developments are also generally low.

Concerning design, the connectedness of RUPD to core HDSS activities which have direct public health ends makes it difficult to balance research ethics and public health ethics principles. Applying the former privileges individuals over the public (E. Vayena et al., 2015) and the latter does the opposite (Public Health Ontario, 2012). One can either safeguard the implementation of protections at the broader population level or for the individual. For an appropriate balance, scholars have suggested to focus on principles or issues of confidentiality and privacy, data ownership, data sharing and integrity (S. Bull et al., 2015, European Commission, 2013b, I. Jao et al., 2015), transparency, trust, accountability, openness, and global justice (European Commission, 2013b, E. Vayena et al., 2015). Issues surrounding the underexploited value of databases are also gaining attention (J. Manyika et al., 2011). Challenges such as the impracticalities of obtaining consent and providing benefits to the population have been documented (J. Sim and A. Dawson, 2012 , H3Africa Working Group on Ethics and Regulatory Issues, 2013). The discussions have favored a focus on the 'public' that understates the interests of the individual (CIOMS, 2016a, B.S. Elger,

2010, Public Health Ontario, 2012) mainly because of challenges to implementation. The debates however, miss two important issues that are unique to RUPD in the South: (1) opportunity availed through the routine re-contact with residents during the HDSS activity; and (2) the huge populations that could have their welfare, interests, and protections better safeguarded when research ethics principles are upheld for the individual, especially in light of otherwise less protected environments.

3.3 Methods

A questionnaire based survey was conducted in Ghana from October to December 2014 and during an INDEPTH Scientific Conference held in Addis Ababa, Ethiopia in November 2015. In Ghana, the questionnaires were administered to personnel at the Dodowa and Navrongo HDSSs. The INDEPTH Conference was organized for HDSS-member and partner institutions worldwide. It offered a unique opportunity to reach stakeholders with a working knowledge of RUPD (INDEPTH, 2015a). We did not aim for representativeness of the population, but rather sought knowledgeable participant availability, willingness to participate, and a quest to ensure that relevant issues were discussed to arrive at a useful view of how the ethics of RUPD could be cast in the South (K.J. Rothman et al., 2013, B. Dawson and R.G. Trapp, 2004). Of the 350 questionnaires administered, 142 were returned, representing a response rate of 40.6%. Completed questionnaires from eleven Ghanaian respondents at the conference who had earlier been administered questionnaires in Ghana were matched for hand-writing and socio demographic characteristics to enable exclusion based on possible double participation: six questionnaires were excluded. An inclusion criterion of completing at least two of the three sections of the questionnaire was implemented. In total, 130 surveys were included in the analysis.

3.3.1 The Survey Tool

A questionnaire was formulated, approved by all authors, and put through an internal review session by ethicists working at the Institute for Biomedical Ethics, University of Basel. It was pilot-tested using five HDSS practitioners who did not participate in the main survey. Questions were based on a vignette (Appendix 2) informed by features of RUPD and relevant literature to assure face validity. The questionnaire was examined by the

supervisory team of experts to assure content validity (B. Dawson and R.G. Trapp, 2004). The vignette gave a short scenario of a retrospective RUPD, but questions relevant to prospective RUPD were also surveyed. We posed closed-ended questions on familiarity with RUPD and specific expectations of what respondents deemed ethically acceptable practices linked to research ethics principles. The closed-ended questions were either dichotomous (yes or no) or five point Likert-type questions (strongly agree, agree, neutral, disagree or strongly disagree). Blank spaces were provided to enable respondents to add information if they chose to. Although not exhaustive, the information given in the vignette was adequate to offer respondents an equal understanding of the research topic.

3.3.2 Data Analysis

Using IBM SPSS Statistics Version 21, closed-ended questions were analyzed via descriptive statistics. We examined issues documented as problematic in other population and database research including informed consent and benefit provision (J. Sim and A. Dawson, 2012). Open-ended responses were collated into relevant themes. We characterized the HDSS as 'custodian' in line with literature that support organized systems' data creation and holding status. By implication, we assumed that while HDSS communities may not own their data in practical terms, they have a stake in its ownership (A.M. Capron et al., 2009).

3.3.3 Ethical Considerations

Ethical approval for the project was sought from the Ethics Commission of North Western and Central Switzerland and six other committees in Ghana and Tanzania where separate in-depth interviews were planned. In Ethiopia, where conference delegates completed the questionnaires, ethics review was not required. Questionnaires and consent documents were self-administered, anonymous, and returned to the researcher on site in Ghana, during the conference, or by email.

3.4 Results

The socio-demographic characteristics of the 130 respondents are shown in Table 1. Most respondents (84.6%) were based in Africa and were less than 50 years old. On average, participants had spent 8.7 years (range 1 - 33 years) at their current roles. More

than two-thirds of respondents (66.7%) had undergone some levels of training in research ethics: around half (n=66) had a month or less of training, six undertook fellowship programs, and eight had degrees in various fields of bioethics.

3.4.1 General issues

The majority of respondents (N=130; 93.1%) indicated that they had seen publications emanating from RUPD. Around half (N =130; 54.3%) thought RUPD occurred 'often', with a third (N =130; 31.5%) having personally undertaken it. A quarter of respondents (N =130; 25.4%) disagreed that use of pre-collected HDSS data could be considered as research and more than two-thirds (N=124, 71.3%) supported it as a valid alternative methodology.

3.4.2 Independent review and ethical governance of RUPD

About three-quarters of respondents (N=111; 76.2%) thought RUPD should undergo REC review, but a minority either disagreed (9.2%) or declined to answer (14.6%). Nineteen respondents (N=126; 15.1%) opted for RUPD without any ethical requirement while 7.5% (N=120) would start RUPD without REC review until they had a publishable manuscript. Most respondents (N=115, 83.5%) were not aware of any written rule, policy or regulation governing RUPD. When asked if there was a need for specific RUPD guidelines, 85.6% (N=125) agreed with 73.8% of them choosing 'strongly agree'.

Table 1: Socio-demographic characteristics of survey participants (N=130)

Variable	Category	Frequency	Percentage (%)
Regions	West Africa	65	(50.0)
	East Africa	41	(31.5)
	Southern Africa	4	(3.1)
	*Asia, Europe, & North America	5	(3.8)
	Unspecified	15	(11.5)
Age (years)	<30	16	(12.3)
	31-50	92	(70.8)
	>50	15	(11.5)
	Unspecified	7	(5.4)
Primary training	Public Health (including Medicine)	48	(36.9)
	Epidemiology	16	(12.3)
	Statistics & Information Systems	16	(12.3)
	Law and other fields	12	(9.2)
	Demography & Social Sciences	7	(5.4)
	Economics	5	(3.8)
	Bioethics	2	(1.5)
	Unspecified	24	(18.5)
Institution of work	Research Institution	75	(57.7)
	Ministry of Health	33	(25.4)
	International Organization	6	(4.6)
	Academic	3	(2.3)
	Other	4	(3.1)
	Unspecified	9	(6.9)
Professional role	Researcher	59	(45.4)
	REC Member or Administrator	18	(13.8)
	Public Health Officer or Clinician	18	(13.8)
	Data Management	8	(6.2)
	Research Center Administrator	5	(3.8)
	Policy Making	4	(3.1)
	Other	9	(6.9)
	Unspecified	9	(6.9)
Ethics training	Yes	88	(67.7)
	No	31	(23.8)
	Unspecified	11	(8.5)

* Due to small numbers, non-African respondents with a stake in HDSSs from Bangladesh, The Netherlands, Sweden, Switzerland, and the Unites States are pooled.

3.4.3 Respect for study participants and communities

Respondents' views on preferred stages for seeking permission and prior processes for conducting RUPD were sought (Table 2). Majority (N=120, 95%) of them agreed to seeking prior permissions. Of six possibilities given, obtaining permission from the custodian and REC approval was the most preferred (41.7%). Six respondents would 'use only personal and professional discretion'.

Table 2: Preferred stages for seeking permissions to conduct RUPD (N=120)

Step 1	Step 2	Step 3	N (%)
Custodian	REC	-	50 (41.7)
Custodian	REC	Regional or national health authorities	48 (40.0)
Custodian	Analyze data. If publishable take Step 3	REC	9 (7.5)
Use only personal and professional discretion	-	-	6 (5)
Custodian	-	-	5 (4.2)
Custodian	Regional/national health authorities	-	2 (1.7)

3.4.4 Informed consent

Using Likert-scale responses, we assessed perceptions about practices associated with the principle of respect for persons. Obtaining individual consent was rejected by most respondents (70.1%), but when RUPD involving genetic data was made a possibility, the rate of rejection was only 14%. Table 3 presents the distribution of responses to practices that are argued against in the literature.

Table 3: Perspectives on informed consent

Practice	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Seek individual consent for every study (N=127)	13 (10.2%)	9 (7.1%)	16 (12.6%)	25 (19.7%)	64 (50.4%)
Prohibit RUPD involving genetic records, if individual consent is not sought (N=93)	60 (64.5%)	14 (15.1%)	6 (6.5%)	6 (6.5%)	7 (7.5%)
Seek one-time consent for future publications (N=125)	36 (28.8%)	16 (12.8%)	21 (16.8%)	26 (20.8%)	26 (20.8%)
Grant individual rights to withdraw their own data from RUPD (N=127)	46 (36.2%)	17 (13.4%)	21 (16.5%)	19 (15%)	24 (18.9%)
Individual interests and consent could slow down RUPD (N=126)	40 (31.7%)	29 (23%)	20 (15.9%)	15 (11.9%)	22 (17.5%)

In the "comment" section, six respondents stated that individual consent should be sought only at researchers' discretion. One respondent remarked that there was no question about participants' rights to individual consent in any research, but the problem with RUPD was one of feasibility.

3.4.5 Communities' autonomy

The majority of respondents (N=126; 65.9%) supported prior disclosure about RUPD to community leaders (N=120; 62.5%), but 23% disagreed. Three respondents added that community advisory boards should be established; eight suggested local representation in RUPD discussions within the community; and three added that selected community representatives should inform themselves about RUPD and serve as REC members.

Asked about concerns communities might have about RUPD, respondents mentioned the following:

- conducting scientifically interesting but socially-undesirable studies
- insensitive publications

- discontent about data use
- doubts about RUPD findings and legal battles
- exploitation and deception
- absence of compensation for time and effort

3.4.6 Providing benefits

Only a quarter of respondents (N=124; 24.9%) agreed to the notion of providing benefits to RUPD participants. More than half (55.7%) were against it and a fifth undecided (19.4%). To a proposal for result dissemination to communities before publications, 69% agreed, 14% disagreed, and 17% were undecided.

We sought examples of realistic benefits to provide in RUPD. Respondents suggested building custodians' data managing capacities to improve funding and employment (n=15); using RUPD to support policy legislation (n=7); prioritizing research that is of local interest (n=5); access to interventions (n=5); sustaining systems in which RUPD knowledge can be applied to improve health (n=4); focusing on on-site data analyses to promote local leadership in RUPD, address local questions and speed result translation to relevant policies (n=2); and providing policy briefs (n=1). Six respondents suggested that HDSS communities should proactively state what benefits they expect from RUPD for researchers to comply.

3.4.7 Risks in RUPD and procedures for minimizing them

Table 4 documents respondents' opinions about risks that are suggested in the literature as well as risks they identified in their practice. Compromise of personal and family data following release to researchers was the most (59.5%) endorsed, but under a quarter of respondents (23%) thought that HDSS residents faced risks to confidentiality from RUPD publications.

Table 4: Perceptions about identified risks

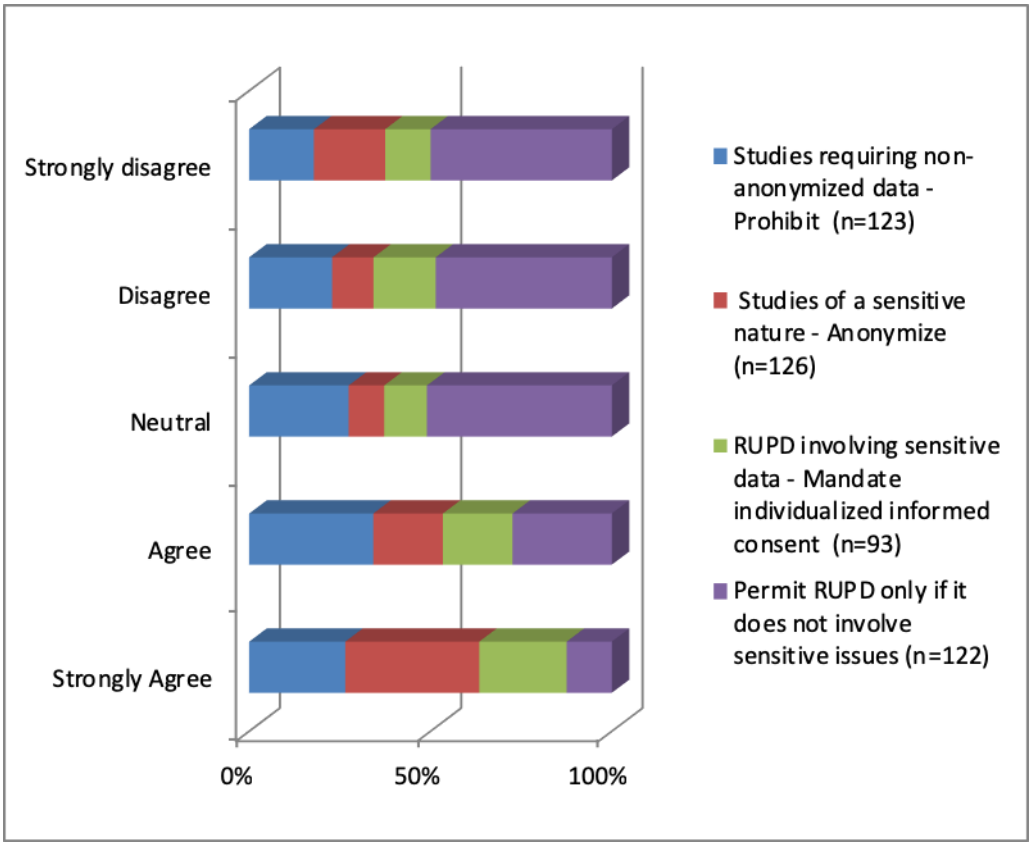
Risks	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Risk to confidentiality in publications (N=126)	14 (11.1%)	15 (11.9%)	32 (25.4%)	31 (24.6%)	34 (27%)
Rights to control use of personal and family data may be compromised (N=121)	53 (43.8%)	19 (15.7%)	13 (10.7%)	20 (16.5%)	16 (13.2%)
Stigma and stereotyping, if results are negative (N=126)	28 (22.2%)	26 (20.6%)	19 (15.1%)	22 (17.5%)	31 (24.6%)
Communal rights of control on data storage, use and publication (N=121)	36 (29.8%)	29 (24%)	18 (14.9%)	19 (15.7%)	19 (15.7%)
Feelings of being over researched (N=126)	13 (10.3%)	12 (9.5%)	25 (19.8%)	29 (23%)	47 (37.3%)
Loss of trust in custodian for allowing RUPD (N=120)	17 (14.2%)	21 (17.5%)	27 (22.5%)	30 (25%)	25 (20.8%)

Additional risks identified by respondents

- Disregard for community dignity
- Social embarrassment
- Communal fear of being under international scrutiny
- Unresolved issues after long years of research could cause local rage
- Misuse of data
- Data access by parties unknown to the community
- Lack of opt-out opportunities
- Mismatch between research goals and local interests
- Non awareness of RUPD by community

Figure 2 below shows respondents' attitudes to risk minimization procedures. Seventy four percent of respondents supported anonymizing data before release to researchers. The least preferred option for risk minimization was limiting RUPD to non-sensitive studies.

Figure 2: Attitudes to risk minimization procedures



3.4.8 Fairness in assigning communities to RUPD

Respondents did not consider community perceptions of being over-researched or burdened relevant in RUPD (Table 4). The three most important conditions for RUPD to be considered acceptable were REC approval, potential to result in change in health policy, and local leaders' agreement (Table 5).

3.4.9 Respondents' general recommendations

Respondents recommended the following for RUPD ethics: (A) custodians should collaborate and create awareness about RUPD to enable residents know what their data is or should be used for, its importance to science, and what benefit communities stand to gain from being participants; (B) promote a working link between the community via its representative team and the respective REC; (C) develop institutional regulations and ensure

adherence to them; (D) build capacity in use of analytical tools to improve funding and employment; (E) prioritize research that is of local interest; (F) negotiate access to health interventions; (G) sustain systems in which RUPD knowledge gained can be applied to improve health; (H) publish in ways that are culturally and socially appropriate; and (I) maintain community dialogue.

Table 5: Perceived conditions for fairness

Condition of RUPD	**Strongly Agree**	**Agree**	**Undecided**	**Disagree**	**Strongly Disagree**
Receives local REC permission (N=120)	79 (65.8%)	24 (20%)	8 (6.7%)	2 (1.7%)	7 (5.8%)
Can result in change of health policy (N=117)	59 (50.4%)	31 (26.5%)	13 (11.1%)	7 (6%)	7 (6%)
Has the agreement of the community leadership (N=120)	41 (34.2%)	34 (28.3%)	18 (15.0%)	17 (14.2%)	10 (8.3%)
Is in line with local or national health priorities (N=117)	41 (35.0%)	32 (27.4%)	23 (19.7%)	11 (9.4%)	10 (8.5%)
Conforms to the custodian's mission (N=118)	40 (33.9%)	30 (25.4%)	22 (18.6%)	15 (12.7%)	11 (9.3%)
Receives permission from head of the custodian (N=118)	38 (32.2%)	25 (21.2%)	22 (18.6%)	20 (16.9%)	13 (11%)
Does not involve sensitive questions (N=117)	32 (27.4%)	19 (16.2%)	18 (15.4%)	28 (23.9)	20 (17.1)
Proposing team was involved in HDSS data collection (N=119)	10 (8.4%)	11 (9.2%)	22 (18.5%)	29 (24.4%)	47 (39.5%)

3.5 Discussion

This survey assessed perspectives of stakeholders experienced or knowledgeable about RUPD in relation to research ethics principles. Each question attracted a high (>70%) response rate which is suggestive of practitioners' acknowledgement of the relevance of the selected issues and their own awareness about the implied principles. RUPD practitioners

support the literature which recommends data use beyond the narrower purposes for which they are collected (CIOMS, 2016a, S. Bull et al., 2015, Public Health Ontario, 2012), but differ in perspectives on what, how, and when research ethics principles and governing regulations are needed. The issues discussed are common to health research, but have dimensions peculiar to HDSSs. To our knowledge, available empirical literature (A.M. Capron et al., 2009) on the closest methodologies to RUPD, such as biobanks (A.M. Capron et al., 2009, B.S. Elger, 2010) and epidemiological research (J. Sim and A. Dawson, 2012 , CIOMS, 2016a) have structural and paradigmatic differences. These differences do not enable effective comparisons with this survey. Indeed, the evolution of health research renders available ethical provisions inadequate (Largent, 2016). Ongoing updates to guidelines as relevant and authoritative as the 'Common Rule' (US Department of Health and Human Services, 2009) and the CIOMS Guideline s(CIOMS, 2016a) attest to this fact and justify this survey for RUPD.

3.5.1 Independent review and ethical governance of RUPD

The international requirement for the ethical review of health research (South African Medical Research Council, 2007, CIOMS, 2016a, World Medical Association, 2013, Nuffield Council on Bioethics, 2002, Nuffield Council on Bioethics, 2013) is clearly supported for RUPD. However, the perception that RUPD is not 'research' is substantial and can reduce practitioners' adherence with seeking prior REC review. To date, developments in ethical research have been largely based on compliance with guidelines, policies on best practices, and frameworks (S. Bull et al., 2015, E.J. Emanuel et al., 2004, Kass, 2001, G. Marckmann et al., 2015). Low levels of awareness of the relevant provisions for RUPD and the high endorsement of the need for a RUPD-specific framework are suggestive of a gap in ethical RUPD. Calls for the development of institutional regulations and adherence to them are justified and urgent. We recommend that because scientists may rarely pay attention to the philosophical reasons for which ethical RUPD conduct should be or is the way it is prescribed (J. Sim and A. Dawson, 2012), including REC review, providing a specific ethical guidance framework for RUPD will improve ethical conduct.

3.5.2 Respect for study participants and communities

Consistent with relevant literature (CIOMS, 2016a, B.S. Elger, 2010, A.M. Capron et al., 2009, J. Sim and A. Dawson, 2012 , H3Africa Working Group on Ethics and Regulatory Issues, 2013), individualized informed consent was not supported for RUPD. Cost and impracticality (US Department of Health and Human Services, 2009, CIOMS, 2016a, J. Sim and A. Dawson, 2012), communal cultures of the collective against individualistic views (T. Metz, 2010) and the fact that relevant guidelines support general public health data use or research without informed consent (CIOMS, 2016a, Public Health Ontario, 2012, H3Africa Working Group on Ethics and Regulatory Issues, 2013) may account for this. Nonetheless, individualized consent becomes necessary when research questions are sensitive. Researcher discretion is important.

The importance of 'community' values was dominant in the survey findings. Support for actively involving community leaders in RUPD exceeded the traditionally acclaimed importance of requiring institutional permission from custodians for similar methodologies (S. Bull et al., 2015, B.S. Elger, 2010, H3Africa, 2016). These findings are suggestive of preferences for decision making that involve local leaders' permission (group autonomy) (A.M. Capron et al., 2009). Our endorsement mirrors attitudes in many cultures of the South, particularly Africa where seeking elders' permissions for important activities are common (H3Africa Working Group on Ethics and Regulatory Issues, 2013, T. Metz, 2010). We recommend the following: responsibility towards RUPD should be entrusted to a recognized community team (I. Jao et al., 2015, Jao et al., 2015, Tindana et al., 2015); a working link among the community team, custodian, and REC would enable effective engagement of the community team to lead in creating local awareness about RUPD, its governance, conduct, and implications of RUPD results to promote ethics. The community representative team becomes the practical unit for decision making and communal determination in RUPD.

Another important dimension of the principle of respect for persons in RUPD, at least for traditional setups in Africa where humaneness and rightness are generally constituted by positive relation to others (T. Metz, 2010), is that what is right is defined in its harmonious relation to and contribution to one's community. Opt-out options which influential literature support as safeguards of voluntariness in database studies (Largent, 2016, CIOMS,

2016a, B.S. Elger, 2010, S. Bull et al., 2015, H3Africa Working Group on Ethics and Regulatory Issues, 2013) may thus not be considered practical in these communal systems. Since one-time consent (CIOMS, 2016a, B.S. Elger, 2010) was also not a decisive option in the survey, the search for an ideal solution should consider alternatives to opt-out options. We suggest optimizing the unique feature of re-contact with residents via the HDSS rounds. The following mix of procedural processes will also be helpful.

First, essential information about RUPD should be shared with the custodian and community representative team for prior permissions. REC review and approval should then be sought. Second, brief information about RUPD should be provided orally or as an addendum to the routine HDSS document used during the house-to-house visits preceding or following the start of RUPD. Tick boxes may be provided for options to the following issues: (1) Sunset agreements (B.S. Elger, 2010) stating how often and how long residents may wish to be re-consented, for instance 5 years, 10 years or a lifetime; (2) what should happen with data upon death or emigration; and (3) broad topics a resident might wish to be informed about before RUPD or have their data excluded from. Where societal pressures against opt-out are strong for communal reasons (T. Metz, 2010), dialogue and researchers' assurance of the worth of individual rights both to consent or dissent to participation should be prioritized. If paper-based activities may render these recommendations unbearably costly, documentation may be substituted with oral consent, but the remaining elements of informed consent expressed in disclosure, comprehension, voluntariness, and self-determination (T.L. Beauchamp and J.F. Childress, 2001) can be upheld.

3.5.3 Providing value and benefits

The obligation for researchers to provide value and benefit (T.L. Beauchamp and J.F. Childress, 2001, E.J. Emanuel et al., 2004) often necessitates providing concrete gains on the basis of reciprocity and justice (Kass, 2001, G. Marckmann et al., 2015, E. Vayena et al., 2015). The principle itself is not questionable, but simply challenging to apply in RUPD given the general large numbers of individuals involved. Practitioners' several attempts to suggest realistic alternatives to individual benefit highlights their agreement in principle as well as their challenge, based on cost. In line with the literature (CIOMS, 2016a, S. Bull et al., 2015, E.J. Emanuel et al., 2004, Kass, 2001), they settled on knowledge dissemination as the most practical benefit for RUPD. However, there are problems even with this possibility,

especially in Africa. With only 16% of internet access in Africa and 90% of households not connected to the internet (International Telecommunication Union, 2013), assuring even this minimal benefit is a challenge. Further, many cultures have vernacular languages that are spoken and often not read (H3Africa Working Group on Ethics and Regulatory Issues, 2013). This necessitates oral forms of communicating results. With 89% of people in these regions using mobile phones (International Telecommunication Union, 2013) exploring mobile technological knowledge sharing opportunities would better assure that benefit is possible in RUPD. As some practitioners suggested, dialogue with community teams will also uncover other culturally and socially appropriate avenues including durbars and local radio stations for reaching the most inaccessible groups with RUPD knowledge. Lastly, the opportunity of re-contact through the routine house-to-house visits should be utilized to share RUPD results.

At the custodian and regulatory levels, practitioners' suggestions for capacity building to improve funding and employment; use of RUPD to contribute to health policy developments (A.M. Capron et al., 2009), and legislation of policies; prioritizing research that is of local interest; negotiating access to health interventions; and sustaining public health systems in which new RUPD knowledge can be applied to improve health ought to be considered. Additionally, HDSS communities are a good source of knowing and aiming for relevant benefits in RUPD.

3.5.4 Risks and procedures to minimize them

Much of the emphasis in the literature has been on issues of confidentiality and privacy (CIOMS, 2016a, A.M. Capron et al., 2009, B.S. Elger, 2010, S. Bull et al., 2015), but our study reveals significant ambivalence about these issues in RUPD. The practitioners' attitudes may be linked to characteristics unique to INDEPTH HDSSs. We suspect that knowledge about ongoing processes of anonymization that are being introduced by INDEPTH's *iShare2* Program (INDEPTH, 2016b) and the solidarity of member HDSSs may have influenced respondents to think that anonymization is already a norm for HDSS data and RUPD. The communal nature of the contexts may also explain part of this. Practitioners were more clearly concerned about negative reporting of studies that contribute to stigmatization, discrimination, and stereotyping of communities (T. Mduluza (eds), 2007). Recognition of the commonality of HDSS communities in collectively facing risks led to much emphasis

being placed on publishing in culturally and socially sensitive ways. Aligning RUPD's goals to issues that are relevant to host communities also helps balance risks. A helpful list of data protection and security measures is available internationally (CIOMS, 2016a, European Commission, 2013b, European Commission, 2016). It is also expected that the upcoming updated CIOMS guidelines will, like its preceding ones, be a useful resource to RUPD and Africa.

3.5.5 Fairness in the assignment of communities to RUPD

Apart from selecting RUPD populations to ensure scientific validity and reduce risks, enabling community teams to contribute to RUPD decision making is an important approach to justice. The survey revealed that careful assignment of communities' data to different RUPD is important: communities with poor indices need not disproportionately be assigned to studies which stigmatize them for scientific benefit. The values of trust, transparency, and accountability (E. Vayena et al., 2015) in these assignments are supported by practitioners and need to be integral to sustain the long term commitments, gains, and scientific growth that RUPD promises.

It is distinctive to note that contrary to the literature (Y. Yazoume et al., 2012), practitioners thought that communities would not feel 'over-researched' over time. Only HDSS communities could confirm or challenge this view. In line with the literature (T. Mduluza (eds), 2007) nonetheless, practitioners' concerns about stigma, discrimination, and discontent make it prudent to recommend that community inclusion in RUPD be driven both by scientific and socio-cultural considerations. The level of engagement needed to exercise self-determination may sometimes be questioned because of low literacy rates and knowledge gaps. However, collaborative efforts from custodians, community teams, and RECs via workshops, training, and education will help overcome these challenges for the benefit of science and the people.

3.6 Limitations

Information provided in the vignette may have influenced some responses or discouraged respondents' own reasoning based on their experiences. The choice of distributing the survey at the conference limited access of participation largely to delegates. Because participants who returned the questionnaires were mainly based in African HDSSs,

we missed cultural differences and operational diversities from the Asian and Oceanian regions of the South. The study does not claim to be representative. To the best of our knowledge however, this is the first survey of practitioners about the ethics of RUPD which can contribute to its future prospects. Empirical research involving HDSS residents' perspectives on the subject would further advance the understanding and reflections we have started.

3.7 Concluding thoughts

This survey has revealed some differing attitudes to the literature and current guidelines that are indicative of a need for education and re-examination of the extant ethical provisions that are relevant for RUPD. For RUPD ethics to be robust, the following will be important: empowering communities to proactively contribute to planning, review, conduct, and dissemination of findings from RUPD; seeking appropriate permission from custodians; and undergoing REC review. Where knowledge dissemination is the only realistic potential benefit, researchers' obligations to provide it should be raised to assume the status that medical ethics, for instance places on doctors towards their patients. Collective risks need to be considered seriously. Although practitioners' interests in completing most questions is suggestive of receptiveness to the idealistic possibilities of implementing research ethics principles in RUPD, RUPD ethics need not be left to individual or even institutional changes alone. It needs a higher motivation which, from historical evidence and the progress made in health research, rests in raising standards through the development of a specific RUPD guidance framework. The new CIOMS Guidelines are expected to be particularly useful to the South, but the presence of a specific framework for RUPD, gleaned from it and adapted to the South will be ideal.

3.8 Declarations

3.8.1 Conflict of interest

The authors declare no conflict of interest.

3.8.2 Acknowledgement

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4.0 "You Cannot Collect Data Using Your Own Resources and put it on Open Access": Perspectives from Africa about Public Health Data Sharing

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"You Cannot Collect Data Using Your Own Resources and put it on Open Access": Perspectives from Africa about Public Health Data Sharing

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4.1 Abstract

Data sharing is a desired default in the field of public health and a source of much ethical deliberation. Sharing data potentially contributes the largest, most efficient source of scientific data, but is fraught with contextual challenges which make stakeholders, particularly those in under-resourced contexts hesitant or slow to share. Relatively little empirical research has engaged stakeholders in discussing the issue. This study sought to explore relevant experiences, contextual, and subjective explanations around the topic to provide a rich and detailed presentation of what it means to different stakeholders and contexts to share data and how that can guide practice and ethical guidance. A qualitative design involving interviews was undertaken with professionals working in public health institutions endowed with data (HDSS), ethics committees, and advisory agencies which help shape health research in Africa. A descriptive form of thematic analysis was used to summarize results into six key themes: (1) The role of HDSSs in research using public health data and data sharing; (2) Ownership and funding are critical factors influencing data sharing; (3) Other factors discourage data sharing; (4) Promoting and sustaining data sharing; (5) Ethical guidance structures; and (6) Establishing effective guidance. The themes reveal factors regarding the willingness or not to share and an intricate ethical system that current discourse could reflect. Many of the concerns resonate with the literature, but a whole other gamut of people and process issues; commitments, investments, careers, and the right ethical guidance are needed to realize a sustainable goal of reaching 'share' as a default.

Key words: Data sharing; Public health; Health and demographic surveillance systems; Research involving public health data; Research ethics; Africa

4.2 Introduction

Datasets, databanks, and data repositories are rapidly multiplying and expanding opportunities for data sharing in order to advance global health (E. Pisani et al., 2016, Wellcome, 2016, E. Pisani et al., 2010, U.S. NIH, c2016). Even in the Global South or the South, that is developing countries located primarily in the southern hemisphere (United Nations Development Programme, 2016, Demographic and Health Surveys Program, 2016, M. Brack and T. Castillo, 2015), many data repositories are being established. Two of the

most notable public health database programs that feed into repositories in the South are the USAID's Demographic and Health Survey program (Demographic and Health Surveys Program, 2016, INDEPTH, 2016a) and the International Network for the Demographic Evaluation of Populations and their Health's (INDEPTH) health and demographic surveillance system (HDSS). In 2015 for instance, HDSS data on cause specific mortality in low-to-middle-income countries was the largest to have been ever published (K. Herbst et al., 2015). Africa constitutes 88% of HDSSs globally, with the rest in Asia, Oceania, and Central America (INDEPTH, 2016a). In this article, we use the HDSS as a profile example of public health systems that produce critical volumes of data for secondary research and for which data sharing is a critical resource. We also refer to research based on the pre-collected routine public health data held by institutions like the HDSS as research using public-health data (RUPD).

Data sharing is a non-negotiable source of HDSS activities and RUPD advances. It increases data volumes, velocity, and variety to solve complex research problems (M. Brack and T. Castillo, 2015). It helps tackle the problems of irreproducibility in science, opens up methodological alternatives to otherwise costly research involving primary data (Wellcome, 2016, E. Pisani et al., 2010, E. Pisani and C. AbouZahr, 2010), and enables scientists to fulfill their moral obligations to improve global health. However, collecting data, storing data, owning data, collaborating on data, sharing data or not, transferring data, and publishing on data involves a complex mix of concerns. Data is not a simple issue anymore: it is no longer based for instance on physical and specific storage on recognizable drives for controlled sharing. Rapid duplication, storage in multiple places at any one time, and concurrent use for multiple research are easy and cheap. This is perhaps one of the reasons why public health data sharing has been slow globally (W.G. van Panhuis et al., 2014). As more data repositories develop, data requests increase (E. Pisani et al., 2016), advocacy for data sharing gets propelled (E. Pisani et al., 2016, S. Bull et al., 2015), and the pressure to share data mounts from scientists, regulatory authorities, sponsors, and scientific journals (E. Pisani et al., 2016, Wellcome, 2016, D.B. Taichman et al., 2016), considering what all these mean to both the scientifically productive and less productive sections of the scientific community is critical. Moreover, regions like Africa which have high burdens and risks of diseases may produce rich data, but it may not necessarily advantage them in scientific productivity. Reasons for such failure include resource constraints which in turn motivate the ethical

considerations of contemporary data sharing (M. Brack and T. Castillo, 2015, S. Bull et al., 2015).

4.2.1 Public health data sharing and ethical guidance in Africa

The HDSS model involves the collection, storage, and management of longitudinal population level data to help inform public health activities and facilitate RUPD. The data undergoes annual, biannual, or quarterly updates that ensure their permanent connection to respective populations. Data from ongoing research projects are also added to grow the database. Although the HDSS is ideally planned like all public health institutions to operate under domestic law (R. Bayer and A. Fairchild, 2004), legal and ethical provisions are generally insufficient in many African contexts (S. Bull et al., 2015, E. Anane-Sarpong et al., 2018a). The authority and responsibility to share data may be mandated at institutional or national levels and governed legally, ethically or both depending on available governing structures. A code of conduct on public health data sharing may be initiated locally, built on international provisions (E. Anane-Sarpong et al., 2018a, Wellcome, 2016) or simply assumed. There is yet to be an ethical guideline, endorsed reporting, or evaluative framework specific to public health data sharing even in comparatively advanced systems like South Africa (W.G. van Panhuis et al., 2014). Legislative landscapes in the North serve as useful guides, but they are sometimes poorly understood even in the North (M. Brack and T. Castillo, 2015). Moreover, research contexts in the North differ from those of the South. Reliance on the research ethics committee (REC) and guidelines from international ethical organizations including the Council for International Organizations of Medical Sciences – CIOMS (CIOMS, 2016a); the US Department of Health and Human Services (US Department of Health and Human Services, 2009); Wellcome Trust (Wellcome Trust, 2010); and the H3Africa Working Group (H3Africa, 2016) is common and helpful. They are however unmatched with the novelty, quick technological advances, and implications for data producers and production processes in ways which had not been present before or as complex as they have become.

4.2.2 Concerns about data sharing

Reported obstacles to data sharing in Africa include the following: loss of control once data is shared; sub-optimal gains to those who create and manage data; undue

advantages to more technologically resourced contexts because of technological imbalances and skillsets in their favor; and technical issues including data quality, interoperability, and risks of misinterpretation due to unfamiliarity with data-originating contexts (E. Pisani et al., 2016, E. Pisani et al., 2010, M. Brack and T. Castillo, 2015, D.B. Taichman et al., 2016). Many of the technical obstacles are understood to be largely resolved (M. Brack and T. Castillo, 2015). What remains less reported are issues pertaining to fears, risks, and uncertainties on the part of data-producers in under-resourced contexts like Africa, who may be unable to maximize the benefits of data sharing to match their burdens of data production. That these contexts are also generally characterized by weak ethical developments (S. Bull et al., 2015) adds to the challenge. Evidence-based views from Africa are limited, but it is by stepping into their context, experiences, and concerns that ongoing data sharing discussions can be brought in touch with practical standpoints that could inform data sharing calls more comprehensively.

We undertook this study to explore relevant experiences, contextual, and subjective meanings, as well as values that public health stakeholders in Africa attach to the scientific, socio-professional, and ethical dynamics of data sharing. The project is directed towards understanding the forms of skepticism that characterize data-producing scientists' interests and willingness to share public health data. We sought to explore and provide a rich and detailed collection of the informed perspectives of the selected stakeholders. The importance we attach to the views expressed by the participants is based on their practical engagement and direct experiences with data production and sharing. The reported themes in this article are therefore descriptively derived from the data gathered, rather than advanced from the study team.

4.3 Methods

We employed a qualitative design in our exploration of the perspectives of stakeholders experienced or knowledgeable about the HDSS, public health, and RUPD. Our choice of participants was based on their involvement in the relevant administration, conduct, and or scientific and ethical oversight of issues related to data sharing. We also sought the views of independent experts who play advisory roles to international agencies involved in helping shape health research in Africa. Our elaboration of the study results are based on the subjective, interpretative, and context based accounts of the participants.

4.3.1 Collaborators and study area

This international study was undertaken as part of a PhD project in Switzerland in collaboration with INDEPTH-member HDSSs in Ghana and Tanzania (INDEPTH, 2016a). INDEPTH is the unifier-organization of HDSSs across Africa, Asia, Oceania, and Central America and has been particularly involved in promoting the sharing of HDSS data (Wellcome, 2016, O. Sankoh and C. IJsselmuiden, 2011). Four institutional and two national RECs which oversee HDSS activities were included in the study. Practitioners from the ministries of health, international agencies, and the country offices of the WHO also participated in the study. With seven HDSSs between them, both Ghana in the West and Tanzania in Eastern Africa have seen repository (HDSS) operations for over 20 years.

4.3.2 Participants

We purposively sampled 50 respondents via recommendations by HDSS leaders and REC administrators. Further snowballing was done based on referrals. The characteristics collectively shared by our sample in relation to the science, ethics, and regulation of RUPD provided diverse, rich, and relevant answers concerning the willingness, capacity, and enthusiasm to share data. The directors, REC administrators, and several other participants had earlier met and interacted with the interviewer during scoping visits. With three experts unavailable at different appointed times and one participant's withdrawal of his recording because he thought his responses may not have been good enough, our analysis eventually included 46 interviews.

The mean age of participants was 44 years (range: 29-59). Participants had spent six years (range: 1-15) on average at their current roles with all except two having participated in research ethics training. Additional participant characteristics are shown in Table 6.

4.3.3 Study procedure

Ethical approval for the project was first sought from the Ethics Commission of North Western and Central Switzerland which oversees research at the University of Basel. In Ghana, the Ghana Health Service, Dodowa Health Research Center, and Navrongo Health Research Center RECs granted review and approval. In Tanzania, approvals were obtained

from the National Institute for Medical Research and Ifakara Health Institute RECs as well as the regulatory Commission for Science and Technology. Participant information leaflets and consent documents were sent to all prospective interviewees. The documents were returned signed to the researcher during or before interview dates. We undertook all procedures in accordance with the ethical standards of the respective RECs.

A semi-structured interview guide comprising open-ended questions was developed by the research team. The questions were broadly related to the HDSS-RUPD context, experiences around data sharing, descriptions of ethical structures, data sharing initiatives, perceived risks and benefits, and expectations about data sharing. The guide made space for soliciting additional specific views relating to data sharing. It was pilot-tested with colleagues at the Institute for Biomedical Ethics (IBMB), University of Basel, three HDSS student-practitioners studying in Basel, and two REC members in Ghana. Authors 1 and 3, PhD students and research assistants at the IBMB organized and undertook the scoping and data collection visits. They however, focused on interviews for different research questions. All interviews for this article were conducted by Author 1 in English, lasted 19 to 69 minutes (mean of 38), and took place at a venue of the interviewee's choice. Twelve participants asked to see and were availed the interview guide prior to the interview dates. Of the 46 interviews, 21 were conducted in Ghana between November 2014 and January 2015 and 25 in Tanzania from January to February 2015. The point of saturation was reached by the fifteenth interview in both countries (G. Guest et al., 2012), but to confirm saturation, delve into grey areas and clarify issues, already scheduled interviews were continued to completion.

Except for two pairs of field-supervisors who asked for joint interviews, all interviews were individually conducted face-to-face, on site, and tape recorded with no one else present at the venue. Notes were taken with participants' permission if they had additional contributions before or after the interview.

Table 6: Characteristics of interviewed participants (N=46)

Variable	Category	Ghana (n=21)	Tanzania (n=25)
Sex	Male	13	18
	Female	8	7
HDSS Role (n=26)	Director or ex Director	3	2
	Chief Scientist	1	3
	Head of Unit/ Field Supervisor	3	8
	Site Manager	0	2
	Scientist	2	2
REC Role (n=14)	Chairperson	1	0
	Committee Member	3	4
	Committee Administrator	3	3
Independent (n=6)	Policy Making Agency or Ministry of Health	2	0
	Law	1	1
	International Research Organization	2	0
Primary Training	Social Sciences	4	9
	Medicine	8	4
	Health and Allied Sciences	4	3
	Epidemiology	4	2
	Physical Sciences	1	4
	Other	0	3
Years of Experience	1-3	1	6
	4-6	3	4
	7-9	2	3
	10-12	6	3
	13-15	4	1
	16-18	0	1
	>18	2	6
	Unspecified	3	1

4.3.4 Data Analysis

Author 1 transcribed the recorded data into a WORD document and subsequently checked a sample of the transcripts with the tapes to confirm accuracy. The processes from transcription to coding assignments were as follows: (1) The transcriptions and initial checks allowed Author 1 some degree of immersion into the data; (2) Authors 1 and 2 carefully read

ten randomly selected transcripts to identify various concepts, ideas, and explanations given. During this process, relevant texts including concepts, information, and reasons for them were assigned codes that captured their descriptive elements. We grouped the codes into ideas that complemented participants' arguments and reasoning to result in themes and sub-themes. Doing the initial coding together improved the accuracy of characterizing responses and served to control for reviewer biases (B. Dawson and R.G. Trapp, 2004). It resulted in an agreed basic coding framework; and (3) The rest of the coding was independently done by Author 1 using MaxQDA 12.

The initial interpretation of the findings were compiled and sent to two authors who presented their critique of the results, organization, and interpretation of the themes. This iterative process continued until three authors agreed on the themes, sub-themes, and their meanings. The thematic analysis was guided using Guest et al (G. Guest et al., 2012) and Braun & Clarke (V. Braun and V. Clarke, 2006).

Because we used a qualitative thematic approach for data analysis, participants' opinions were taken at face value and interpreted as depicting their true views, regardless of whether they were in line with the literature. These opinions guided us in developing themes in line with our research questions and the relevant literature. Six key themes were identified**:** (1) The role of the HDSS in RUPD and data sharing; (2) Ownership and funding are critical factors influencing data sharing; (3) Other factors discourage data sharing; (4) Promoting and sustaining data sharing; (5) Ethical guidance structures; and (6) Establishing effective guidance.

In our presentation of the findings we avoid exact frequency counts, but use the following terms when a sizeable number of interviewees dwell on a theme or meaning: "most", when more than twenty-three participants report a meaning; "frequently", "many" or "often" for ten or more participants; and "some" or "other" for less than ten. We corrected non-significant grammatical mistakes in the quotes to aid readability and comprehension. For anonymity, we classified interviewees using participants' sex (M or F), interview number, institution of affiliation, role, and background training. Where descriptors were inadequate to protect anonymity, we dropped background training. For instance, Interviewee Number 15, a female REC administrator with training in Sociology is denoted as F15_REC/Administrator/Sociology or only F15_REC/Administrator if identification is possible. Independent experts are denoted by "IE". Combined descriptors

denote dual affiliation. Once a participant is introduced in full, their subsequent quotes are identified by sex and number only.

4.4 Results

4.4.1 The role of the HDSS in RUPD and data sharing

For most participants, the HDSS-RUPD and data sharing relationship revolved around the growing resourcefulness of accumulated HDSS data. The data serves as a sampling frame for RUPD. For instance, **M1**_HDSS-IE/Medicine-Epidemiology pointed out the following:

> The HDSS is community based. There is a certain need for the population to serve as a platform for looking into the future as far as health problems are concerned. The data provides a sampling frame. To that extent, there is a relation between the data and what is needed for research.

Although we tried to explicitly delineate RUPD from core HDSS public health activities, responses frequently echoed a conflation of the two. There were differing opinions on whether RUPD constituted research and whether it and data sharing required ethical considerations. **M8**_HDSS/Medicine-Epidemiology for instance argued that "[They are] all for the general good and require no ethical interference". In contrast, most participants acknowledged a need for ethical considerations e.g., "Research is becoming more complex. Data is becoming the currency with which you can do a lot. It is important that we take [ethics] seriously" (**F16**_REC-HDSS/Scientist).

Many participants mentioned the growth and inevitability of data sharing and urged adequate preparedness e.g., "Science is evolving; technology is evolving. With my cellphone, I can transfer data anywhere" (**M32**_REC, IE/Medicine-Public health). Another added the following statement:

> The world has become like a single village: information can move across very quickly. People have to be prepared or else they will collect lots of information only to find it out there in a span of one or two months. (**M33**_HDSS/Medicine-Epidemiology)

4.4.2 Ownership and funding are critical factors influencing data sharing

One critical issue influencing the willingness to share data was the question of "who owns data?" There were differing views ranging from institutional assumption of complete ownership to their role as custodians holding data in which other stakeholders have important stakes. Many respondents cited investments in data production as reasons for claims to ownership and hesitation to share:

> We (institution) own the data and it costs us so much not only in terms of finance, but also in terms of our time, managing it, and participants who we visit over and over. It's not really value for investment to just give out the data to a third party. **F36**_HDSS/Epidemiology

Others believed that HDSS data was a public good that should naturally be shared:

> There is a public good here. There is some ceding of individual and community liberties towards this good [when communities supply data]. The liberty given to researchers is in the name of the public good. If [HDSS] lacks integrity with the public good, it has no business being in existence. **M1**

Some participants saw HDSSs as custodians who could not be the sole arbiters in decisions to share data:

> [HDSS] doesn't own data. They can advise that "ok we don't have the right permission from the community. . . ." That is why they (HDSS) also need to have guidelines in terms of releasing data to others. **F16**

Funding was another critical factor in data sharing e.g., "once the data is funded by us [HDSS], nobody influences how it should be used. But sponsors and funders have a say" (**M14**_HDSS/Epidemiology). A clarification was made:

> The HDSS is not like the DHS which is funded by government to gather information and make them publicly available. We have multiple people funding it and you cannot just say yes to anybody who needs the data. **F17**_HDSS, REC/Epidemiology

4.4.3 Other factors discourage data sharing

Support for data sharing was deemed good at national and institutional levels, but difficult to implement at individual levels e.g., "the willingness [to share] is there at least at the management level, but it's hard to get individuals to actually do it" (**F23**_HDSS/Unit-Leader/Epidemiology).

Reasons underlying low motivations to share data were mostly underpinned by distributive justice concerns (fairness), reciprocity, and inclusiveness. **F17** for instance argued that they "look at what that person can also contribute to the system, because over the years somebody else has built the system". Another stated that "we have issues with sharing data. These days the thing that has come up all over the world is 'open access'. You cannot collect data using your own resources and put it on open access (**M8**)! The need for the principle of reciprocity was emphasized in the following two quotes:

> I collected your data, what position are you going to give me in authorship? Are you just going to acknowledge me or make me second author? Do I sell the data? Without me collecting data, there won't be secondary analysis. **F42**_REC/Scientist/Bioethics

> You are not a primary source of the information: you earn a PhD or become an expert and those who are the source of the information have nothing? **M4**_IE/Medicine-Law

Others bemoaned concerns with transparency e.g., "Data is used out of the country without the original collectors only to later hear of a new publication. It's not fair (**M43**_REC/Theology)! Another stated that "it's all been taken for granted. . . . If somebody at the country level does not raise eye brows, [data] just goes" (**F17**).

Some participants were discouraged by the inadequacies of local resources and oversight:

> The complexity comes from investments in technology. We in Africa and poorly resourced countries do not have the capacity to make sure that we safeguard or monitor anything. This is a very big challenge. No matter how many laws or regulations there are, they cannot do anything. We have the DTA [Data Transfer Agreement], but with these developments DTA cannot help. **M32**

Trust was a major concern. Participants noted risks to the HDSS-community relationship as noted in the following two quotes:

> When we go to collect data, they give it to us as an institution; people that they know and have worked with for decades. They have a relationship with us, but might not have a relationship with [secondary user]. **F16**
>
> People ask for analysis to be done left, right, and center without consideration for ethical standards. Scientists might overlook these things, but we forget that they can have a huge impact on our relationship with communities. **M33**

Some participants pointed to gaps in international guidelines e.g., "some journals are even requiring [data sharing], but the guidelines around it are very loose" (**F12**_REC/Medicine-Public health).

Issues of professional ethics were also raised e.g., "I foresee stealing of other people's data and issues of authorship" (**F42**).

4.4.4 Promoting and sustaining data sharing

Measures to promote and sustain data sharing were suggested. Within descriptions especially by participants at management levels, it was observed that institutional policies were being developed to encourage data sharing while guarding data use and transfers. **F23** explained that her institution "allows two years of use by [data producers], another two years of open access to staff and after these four years, openly avail the data to the world". Other managers described different institutional arrangements:

> We have elements of data that you can freely download [institutional website], some that require institutional permissions and REC review, and others that you cannot download. The latter have restrictions: obtain REC approval and we will analyze the data for you. **M24**

> We study our own data, state purposes of collection per dataset, and consider how the data could be used or not. **M33**

Financial contributions were deemed important for sustenance in data sharing e.g., "because data is maintained at a cost, there should be a fee for use. You have to contribute to make sure we keep it going" (**M41**).

For some participants, the principles of inclusiveness, collaboration, and capacity building were needed to promote and sustain data sharing e.g., "We want to see the involvement of local scientists. We have limited capacity. Hence, a PI who wants to share data must help add capacity" (**M41**). Another requested that they should "be notified about data requests to enable them to plan collaborations and agreements" (**F21**/REC/Bioethics). To **M11** (IE/Law) local scientists simply "want to finish their publications first. When they are satisfied with what they can, they shall make data available". Equity and benefit sharing could not be over-emphasized e.g., "a researcher who is tapping into the data of another should give credit where credit is due" (**F13**_IE/Medicine-Public health). "Transactions should be mutual for everybody to be happy. That's the bottom line" (**F42**). Another concluded that "issues of intellectual property, patenting, and ownership" **(M4)** were also critical.

4.4.5 Ethical guidance structures

This part of the results relates to the role that ethical structures were expected to play. Although national and international guidelines, institutional policies, and REC oversight were predominantly mentioned, most participants expressed uncertainty about their existence or how their provisions informed data sharing.

Regarding international guidelines, **F17** stated this: "I'm yet to see any guideline that talks about [data sharing]". **M24** insisted that "It's clear! As far as I know [guidelines] do not exist. If somebody comes up and pulls one, it will be very useful". In contrast, REC members exhibited awareness about international guidelines on data sharing. Some preferences were stated e.g., "the WHO guidelines seem ok, but CIOMS is quite appealing" (**F16**). Another observed that "CIOMS gives you flexibility. It's too broad, but it makes it possible to adjust and to think of what suits particular issues" (**F15**_REC-HDSS/Administrator-Scientist). No specific provision on data sharing was mentioned.

National guidelines and institutional policies were seen as intertwined in their guidance relationship, relevance, and authority over data sharing. A quote by **M11** succinctly captured several views by other participants:

> Regulatory institutions' policies are useful because nations appreciate that they cannot make laws to regulate some situations (like data sharing). Policies must fall within the law and become part of administrative processes. If [HDSS] has a policy, you must follow it. You cannot substitute it with an international policy: you'll fall into conflict. Precisely because we (Africans) have not found relevant national laws in some countries, let's ask for acceptable terms and allow HDSSs to negotiate them within the country's law.

Reliance on institutional policies was however deemed to have a major flaw: "institutional policies, as regulatory procedures, are binding on individuals who subscribe to it. If an HDSS has a policy, it is their policy in-house" (**M32**). By this assertion, scientists external to an HDSS were not necessarily bound by their institutional data sharing policies.

The role of RECs in data sharing was largely recognized as necessary and protective, but developmental e.g., "until recently we [REC] were not reviewing HDSS activities and data issues" (**F16**). A few participants opposed the involvement of RECs in HDSS data sharing issues e.g., "I don't think National Births and Deaths or Statistical Service undergoes [REC review]. They don't obtain any REC approval" (**M8**). Nonetheless, some participants insisted that anyone wishing to share or use HDSS data secondarily should either "obtain REC review or go back to the community [for permission]" (**M19**_ HDSS/Epidemiology).

4.4.6 Establishing effective guidance

Given the perceived inadequacies of guidance structures explained above, participants justified a need for new provisions suited to their circumstances. **M5** (REC-HDSS/Medicine-Public health) for instance argued for a new framework because he thought that "[data sharing] is an evolving area. I'm sure the crafters of the original [guidelines] hadn't envisaged that this is the way things will grow". Others had had practical challenges with what exists: "[Named REC] once reviewed a protocol. All members had different opinions. If we have a framework, it will be good" (**M27**_REC/Biostatistics).

Given the foregoing, some participants argued that "we need a new framework" (**M26**_REC/Theology) while others thought that "further expansions to the available guidelines would help" (**M5**). Other ideas were suggested: "Perhaps we should get one document that picks the strengths of the individual guidelines and put them together into one [guideline]" (**F12**). To be effective, this process would "require an engagement with stakeholders to examine local norms, values, and assumptions" (**M4**) for inclusion in the framework.

4.5 Discussion

We have analyzed views expressed in an empirical qualitative study involving public health professionals from Ghana and Tanzania involved in the planning and ethical oversight of HDSSs. Other participants were independent experts who play advisory roles for HDSS institutions. Our goal was to explore and understand perceptions, experiences, practices, and attitudes influencing data sharing decisions. We focused the study on contexts where the translation from data production to scientific productivity may be generally slow. These contexts hold great prospects for producing quality useable data for useful data sharing because of the high burdens of public health issues (United Nations, 2015), the perpetual growth of the data, the routine updates the data undergoes, and the under-utilized data they often hold, even at the stage of the publication of an analysis. Data sharing is highly justified for such settings. We sought to explore and understand challenges and reasons that constrain their data sharing potential, in spite of the prospects. The study uncovers distinctive characteristics of under-resourced scientists and institutions relative to their resources including skillsets that may restrict their full realization of data sharing benefits and hence deter sharing.

To the best of our knowledge, the extent of the risks and implications of data sharing remains unknown (M. Brack and T. Castillo, 2015). They are also beyond the scope of a qualitative study. What this study contributes are therefore simple but practical considerations and recommendations that could increase data sharing from contexts which may otherwise have reasons not to share. What is unique about the findings lies in the nuanced explanations regarding perceived and real risks behind the current low levels of public health data sharing (W.G. van Panhuis et al., 2014, S.G. Denny et al., 2015). Despite

Africa and HDSSs' great potential to share quality useable data, their voices have been largely unheard in the ongoing data sharing discourse. There is no empirical data on their perspectives. Some articles from the South share general perspectives on public health data sharing (W.G. van Panhuis et al., 2014, K. Hate et al., 2015), but they are dominated by issues pertaining to research data or individual level data. The data in this article is not only informative for Africa, but for other contexts in the South which operate HDSSs and have comparable characteristics.

The findings are suggestive of views that both align and conflict with the global interests and expectations in data sharing. The community-related issues uncovered in the study were deemed largely dealt with in the literature (M. Brack and T. Castillo, 2015, I. Jao et al., 2015). Hence we limited this discussion to issues concerning the scientist and the data-repository.

The view that accelerated data growth makes data sharing a scientific and ethical imperative (CIOMS, 2016a, G. Aellah et al., 2016, K. Herbst et al., 2015, E. Pisani et al., 2016, E. Pisani et al., 2010, S. Bull et al., 2015) to increase new knowledge production, promote health, and save lives (E. Pisani et al., 2016, Wellcome, 2016, O. Sankoh and C. IJsselmuiden, 2011) is largely supported by the study. The results however, speak to questions of fairness, reciprocity, equity, transparency, inclusiveness, protection, trust, and capacity building in reaching the data sharing imperative. The results unearth duties and responsibilities which could exemplify a system of best practices and guidance for data-producing and user scientists. Data sharing is expected to go hand in hand with minimizing risks and losses and assuring equity in benefit-sharing between the sharer and user.

The general concerns of the participants—scientists, managers, administrators, consultants, REC chairpersons, and administrators—are not entirely new (E. Pisani et al., 2016, M. Brack and T. Castillo, 2015). The specific intuitions, meanings, and experiences expressed in them are rather clearer for aiding a better understanding of how data sharing is perceived, feared, and managed. They also help conceptualize practices and expectations that could be motivated by these characteristics.

First, the results indicate that data sharing is critically thought of in relation to ownership and funding, contrary to global interests and expectations (E. Pisani et al., 2016,

E. Pisani et al., 2010, Wellcome, 2016, Asia Pacific Association of Medical Journal Editors, 2015). Some of the reasons underlying this persistence are underpinned by Africa's systemic resource constraints (G. Aellah et al., 2016) and an urge to maximize the value of data at the local level. They reinforce the overarching call for equitable rather than free data sharing (O. Sankoh and C. IJsselmuiden, 2011) to at least promote positive burden-benefit ratios in data sharing decisions. While we agree with the general critique of data-ownership entitlements as detrimental to data sharing for the public good, we also acknowledge that investments in data production fuel feelings about rights to ownership that cannot be ignored. Persons who believe in ownership rights generally lay claim to their investments in producing the data. Disrupting ownership rights to open up benefits would require sharing in the burden of investments. Thus, where feelings of entitlements are difficult to curb, cost sharing would help by first normalizing situations in which all contributors to the burden of data production become positioned as co-owners. This will continue until such a time that ownership and perceptions of decisional-authority are too widespread to claim at individual or institutional levels. We therefore argue for collaborative partnerships (E.J. Emanuel et al., 2004) that share investment burdens as better arguments against "data ownership" than simple critique. Ongoing developments like the Research Fairness Initiative (Council on Health Research for Development (COHRED)) could also be drawn on to complement quality data sharing partnerships, remove "ownership" hurdles, and introduce the needed balance to enhance accountability and responsibility in data sharing (European Commission, 2013b, European Commission, 2016).

There is some indication that data sharing is ongoing at local and regional levels as evidenced by the increasing numbers of inter-HDSS publications (INDEPTH, 2015a) as well as specified provisions in institutional policies that are fashioned to enable local scientists maximize data utility before international data sharing. This is suggestive of challenges to sharing that may be peculiar to international data sharing.

The most extreme and feared form of international data sharing is deemed to be "open access" requirements (A. Ault, 2013). Such data are generally stripped of both identity (participant/communities) and source (scientist/repository/community). While this process reduces risks to participants and communities, it paradoxically reduces opportunities of benefit to the producing scientists and institutions. This is because data is delinked from them as the original sources. The situation evokes concerns about reciprocal justice and is

partly responsible for the reported sub-optimal gains in data sharing (E. Pisani et al., 2010, M. Brack and T. Castillo, 2015). Many are therefore unwilling to accept open access data sharing in particular, approach it hesitantly, or insist on conditional sharing (K. Herbst et al., 2015). Likely conditions might include making only basic data available and leaving out data essential for fuller engagement and analysis. The initiatives reported in this article to grant exclusive periods to data-producers to help maximize utility before sharing are good steps to safeguard producing scientists' interests (E. Pisani et al., 2010, E. Pisani and C. AbouZahr, 2010, M. Brack and T. Castillo, 2015, H3Africa, 2016). They may slow down international data sharing, but help increase local scientific productivity in research that is aligned to local needs without crippling global needs.

Dimensions revealed in our data about authorship and capacity development issues highlight a discourse on secondary-user duties: a duty to credit those who make data possible, invest (E. Pisani et al., 2016) in sustaining data production, and share tangible rewards like authorship opportunities. Although data is acknowledged as a public good for the public good, the practice and recommendations of merely acknowledging data-producers (E. Pisani et al., 2010, Wellcome, 2016) in publications is generally deemed inadequate. Since collaboration may also not be desired by secondary-users at all times, good-faith negotiations that contain equitably tangible incentives for both data producing scientists and users should be promoted(E. Pisani and C. AbouZahr, 2010). This would necessarily require proactive efforts by secondary data users to involve producing scientists in their secondary analysis and production of new knowledge. The onus lies on the secondary user to take the necessary steps to invite and include intellectual input from data producing scientists to enable them access the ultimate benefits of their data production for science. That ultimate is publications and its associated recognition in the scientific community. Maximizing co-authorship opportunities in secondary research for the data producer would require their prior notification and invitation to contribute to manuscripts. Therefore, conducting secondary analysis and scientific writing independent of data-producing scientists must be progressively directed to become exceptions rather than the norm in ethical data sharing. Persons who have produced data that is good enough for secondary analysis that result in publications have certainly made prior intellectual input in decision-making on what data to collect. Adding more to lead their data to its most effective ends of publications deserve optimal opportunity. We therefore argue that authorship

involving data producers should be a matter of order ranking in authorship lists than a question of inclusion to promote inclusiveness in science.

Data commodification via fee-for-use arrangements is considered a possible solution to funding shortfalls in under-resourced contexts. It is however, unsustainable for our increasingly complex data world and the multiple parties involved in public health data production. Questions about who to bear data-production costs for continuity in data sharing are legitimate, but they still find answers in the many organizations which are willing to fund public health and research for health. The changing dynamics of governmental interests in research funding can also avert some of the funding concerns (M. Brack and T. Castillo, 2015).

Regarding guidance structures, our findings highlight inadequate awareness, skepticism, and the absence of one go-to ethical framework for data sharing as limiting to data sharing prospects. There is yet to be a unified international guideline that focusses on the totality of the data sharing issues raised. There is no reporting or evaluative framework either (M. Brack and T. Castillo, 2015). The virtuous researcher has to find relevant bits and pieces of different guidelines to consider in using secondary data produced by other scientists. This practice is overly onerous for busy scientists and risks encouraging "cherry picking" of ethical considerations: provisions which are favorable and obvious to detect may be implemented while more demanding requirements like seeking and inviting intellectual input from those from whom data emanated may be ignored. In line with the findings about challenges surrounding the authority of local guidelines and institutional policies in international data sharing, limitations in their application to scientists who are external to an issuing region or institution, and possible inter-institutional conflicts (M. Brack and T. Castillo, 2015), we support the study participants' advocacy for developing a new framework. One selected international document, preferably the CIOMS guidelines, given its reported advantages for developing settings (Largent, 2016) as well as its "flexibility" could be adapted to accommodate regional policies like the INDEPTH's (INDEPTH Network, 2012). With effective consultation, such a document would be more universal in implementation and adherence. Situating the foregoing indications with the calls for a new data sharing framework strongly supports the case for a new data sharing framework. Its development should also benefit from relevant excerpts from other guidelines, note the identified gaps pertaining to the interests of producing-scientists as well stakeholder views about what

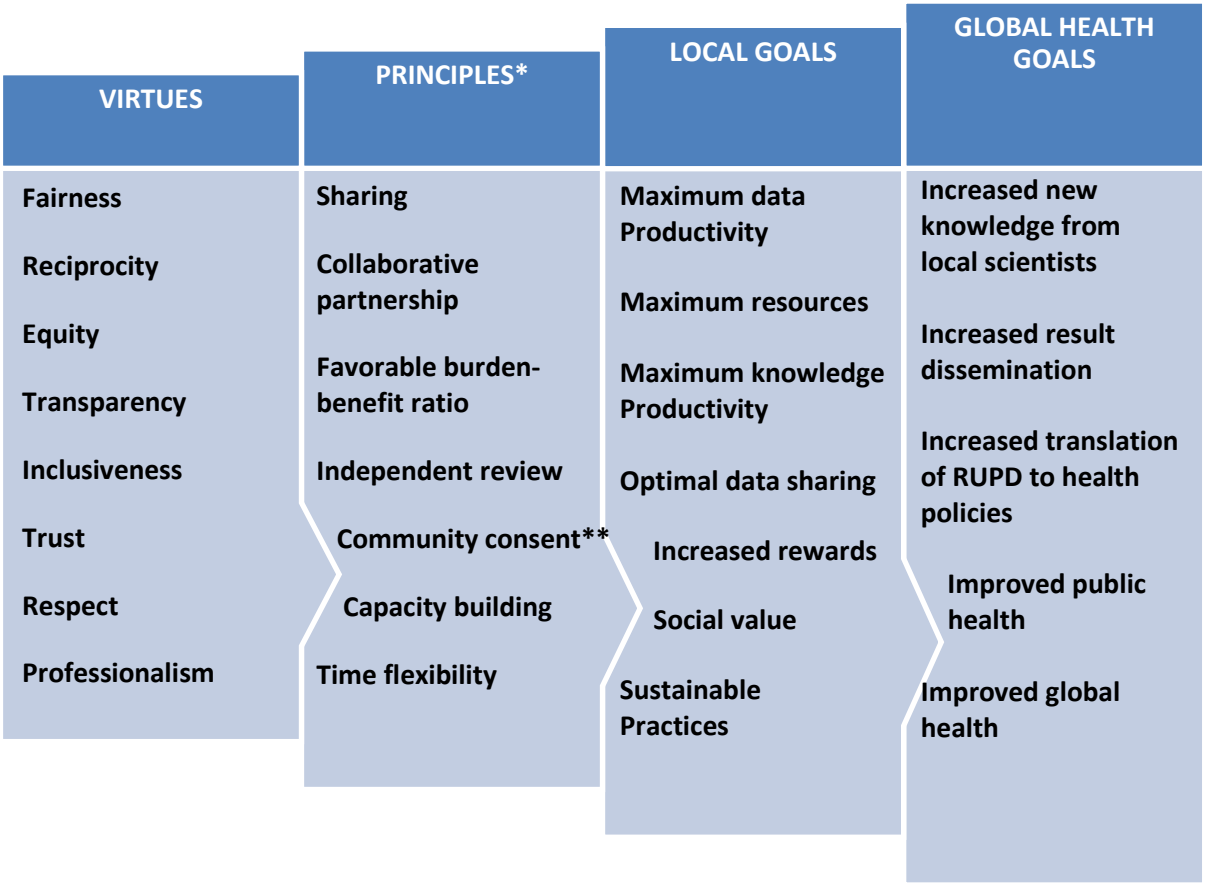
might additionally count as ethical in data sharing. Figure 3 below conceptualizes the basic principles that could form part of this framework-development endeavor.

Because national ethical and legal frameworks are generally at developmental stages in Africa (S. Bull et al., 2015), developing strong institutional policies will remain necessary. Institutional policies have the advantage of context, administrative, professional, and practice suitability when tailored to specific endeavors like data sharing. Another key advantage they have is their preclusion of countries with weak national ethical systems from being completely orphaned in ethical safeguards.

Regarding RECs, their acceptance seemed challenged and sometimes misunderstood. Their involvement in data sharing considerations is not always supported. Even for pro-REC participants, the normal conflation of the HDSS, public health, and RUPD, backed by assumptions that public health activities do not require ethical considerations fuel apathy towards ethical review. The inability of RECs to monitor secondary data use because of financial and infrastructural constraints also reduces researcher confidence in their oversight roles. In spite of these challenges, we believe that they remain the best suited ethical authority to help control data sharing risks and institute requirements that could help data-producers to maximize benefits. It may be efficient for countries to invest their limited available resources in RECs to help them undertake effective monitoring of data sharing risks since they are fewer than research institutions and can concurrently serve many institutions and scientists. Modern technological infrastructure like digital data finger-printing (N. Paskin, 2010) which enable tracing, monitoring, and informing of stakeholders about data-shared could enhance REC oversight. The literature has also theorized expedited reviews and training as helpful solutions to delays and other poor researcher-REC experiences that reduce researcher confidence (World Health Organization, 2011). Finally, RECs could collaborate with local data repositories to define and document context appropriate ethical direction in data sharing for the future.

The foregoing discussion provides an empirical frame of ethical dimensions that could be situated into key ethical principles and virtues for accelerating global data sharing goals with under resourced contexts. Figure 3 diagrammatically presents essential principles underlying the study findings to re-conceptualize critical factors to reflect on when considering what data sharing could mean to under-resourced stakeholders and regions.

Figure 3: Relevant virtues and principles for designing an ethical framework for reaching data sharing goals



* The proposed principles align with the Emanuel Framework (E.J. Emanuel, D. Wendler, J. Killen & C. Grady. What makes clinical research in developing countries ethical? The benchmarks of ethical research. *J Infect Dis* 2004*;* 189(5): 930-937)

**The study findings about community consent are not reported in this paper since, like other findings concerning community issues, they are largely dealt with and supported in the scholarly literature.

The overall findings do beg for concerned authorities to consider the following:

- Lead in defining and standardizing data sharing plans that stipulate adequate periods for local data optimization before wider sharing (E. Pisani et al., 2010);
- Create an enabling environment for the growth and sustenance of the needed virtues and principles for promoting data sharing;
- Institute guidelines and agreement templates that could guide equitable data sharing negotiations;

- Need-based data sharing should be considered as an alternative to open access sharing which is deemed most risky (A. Ault, 2013), at least in the initial steps towards creating a new culture of sharing;
- Collaborations can leverage technology and capacity building to increase Africa's scientific productivity and align RUPD to local needs to spur improvements in public and global health. They will also enhance skillsets, resources, and idea-sharing. Data sharing should be made an avenue for collaboration;
- Secondary-users should be mandated to attest in their publications that their use of data is in accordance with prior agreements (D.B. Taichman et al., 2016, K. Herbst et al., 2015). This will encourage ethical adherence and inclusiveness;
- RECs need to be resourced to monitor reports and publications involving data shared. Increased confidence in their ability to reduce data sharing risks will help encourage the practice;
- Incentivization of quality data-production and sharing is long overdue (E. Pisani and C. AbouZahr, 2010). Efforts must be made to include quality data production in the global recognition framework. Assessment of scientists' suitability for research career progressions must for instance recognize quality, useable data production as a step to sustain data-production for increased data sharing.

Africa remains the bearer of the highest burden of diseases globally and is behind in reaching the SDGs (United Nations, 2015). Local scientists have moral obligations to increase scientific productivity for the populations' and global health. The region also remains largely challenged by resource constraints. RUPD via data sharing is an efficient option for resource constrained scientists, but their confidence in fair data sharing will go a long way to validate their obligations to increase new knowledge for health. Much attention to the new data sharing culture is focused on data. It should however, shift to consider issues underlying people and processes that make data possible. We risk sacrificing diversity of ideas for speed in data-utility in creating new knowledge (publications) if the under producing sections of the scientific community are not helped to catch up on productivity rather than competing too early for data they produce and share. There are inconveniences in being ethical in every endeavor, but they are not comparable to the ultimate benefits. As

this study has shown, there is room for making data sharing more ethical with a little ingenuity.

4.6 Limitations

The varied contributions across levels of staff, fields of experience, and institutions allowed us to explore diverse perspectives. Regardless, lead professionals and those who were recommended to be invited for participation could likely have had perspectives different from those who were not. Generally, qualitative studies cannot claim representativeness (N. Mays and C. Pope, 1995). Although the findings are suggestive of hesitations about data sharing, we should be wary of assuming that Africa may necessarily be vulnerable in data sharing.

4.7 Conclusions

We have explored and unpacked the perspectives of public health professionals who operate in under-resourced regions and discussed their implications for international data sharing. We considered their expertise and roles to enable us bring together practical and diverse views underlying general hesitations to share data in spite of the indisputable global gains attached to it. There are institutional, administrative, financial, ethical, legal, scientific, and relational views about why this is so. The following issues are highlighted as the major impediments to international data sharing prospects:

- risks faced by under-resourced scientists and institutions which are slower in translating data produced into new knowledge;
- the absence of a harmonized guideline and structures to help address the risks and institute fairness in data sharing rewards;
- inadequate confidence in available protective safeguards including guidelines and RECs.

Scientists and institutions which produce great volumes of rich data (problem-wise) may not be able to direct their data cycles into knowledge production at the speeds ideal for reaching global health goals. The differences in data production and knowledge production strengths across different sections of the global resource divide must motivate collaboration

to maximize both data and scientific productivity. It is important to note that although scientists are generally not a population which requires ethical safeguards, this study's findings indicate need for a new dynamic of ethics which could protect the interests of under-resourced scientists in the new data sharing era. Meanwhile, data sharing deliberations need to shift from the focus on access to data to considering the whole gamut of people and processes that make data possible. The ongoing data sharing discussions should therefore be placed within a broader context of safeguarding science, data production, and human systems.

We finally recommend that because the true extent of data sharing risks is yet to be measured and beyond the scope of qualitative research, a comparative quantitative study that involves under-resourced settings which are advantaged by the proposals advanced in this article and in the literature versus settings without would help quantify the level of threat to data sharing. Such a study would help validate our recommendations and attract the needed global responses to them.

4.8 Declarations

4.8.1 Conflict of interest

The authors declare no conflict of interest

4.8.2 Acknowledgement

This paper is written as part of an academic project on "New models of public health research: Optimizing Ethics in Research Using Public Health Data in Resource Limited Countries". The project is undertaken under the kind auspices of the Institute for Biomedical Ethics (IBMB) and the Swiss Tropical and Public Health Institute of the University of Basel. Partial funding for the project also came from the Basel-Stadt Commission for Scholarships for Young Professionals from Developing Countries. We are grateful to the INDEPTH Network for its support throughout the project. We also benefitted a great deal from assistance to the overall project by Dr. Charles Mayombana of the Ifakara Health Institute. We are indebted to all participants for taking time from their busy schedules to grant us interviews.

5.0 Ethical principles for promoting health research data sharing with sub-Saharan Africa

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Ethical principles for promoting health research data sharing with sub-Saharan Africa

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5.1 Abstract

A powerful feature of global health research is data sharing with regions which bear the heaviest burden of disease. It offers novel opportunities for aggregating data to address critical global health challenges in ways higher than relying on individual studies. Yet there exist important stratifiers of the capacity to share data, particularly across the Global North-South divide. Systemic challenges that characterize the Global South, including sub-Saharan Africa and disadvantage the region's scientific productivity threaten the burgeoning data sharing culture too. Like all endeavors requiring equal commitments under unequal circumstances, a strong ethical impetus is needed to help reduce inequities and imbalances to encourage adherence. This article discusses mandatory data sharing in relation to peculiar challenges faced by sub-Saharan African scientists to suggest ethical principles for rethinking and reframing solutions. We propose six principles which mirror guidelines from the Institute of Medicine and encapsulate principles from the Emanuel Framework, Nairobi Data Sharing Principles, and the COHRED guidelines.

Keywords:

Data sharing; Mandatory sharing; Systemic challenges; Inequities; Fairness; sub-Saharan Africa; Global South

5.2 Introduction

The dominant paradigm of health research that necessarily involves primary data collection is decisively shifting to incorporate secondary data. Advances in technological and analytical tools help scientists to source different health research datasets to help in the creation of new knowledge, insights, and innovation for improving and saving lives (E. Pisani et al., 2016, L. Merson et al., 2016, Wellcome Trust, c2016). Combined datasets, used alone or in addition to primary data, yield research solutions often superior to results from individual studies (E. Pisani et al., 2018a, M. Gottesman, 2015). Other advantages make data sharing desirable as follows:

- Reduced duplication of research data collection;

- Access to data that cannot be readily replicated;
- Rapid reuse of shared data to generate new insights;
- Maximized scientific knowledge returns and value on research investments as new analysts bring novel ideas and perspectives to the data;
- Validation of research to promote reliability of results and improved methodology for strengthening findings;
- Re-purposed analyses to address issues left unexplored in original studies;
- Enhanced statistical significance (e.g., rare diseases through merging of datasets and combined analysis/methods otherwise difficult to realize within small samples;
- Respect for and recognition of research participants' altruism; and
- Acceleration of knowledge translation into health products and procedures (Pisani et al., 2018a, D.B. Taichman et al., 2017, L. Merson et al., 2016, U.K. MRC, 2016. D.B. Taichman et al., 2016, Pisani et al., 2016).

Data sharing is in itself thought to promote trust, integrity, and completeness in science (L. Ferguson, 2014, T. Lang, 2011, S. Dallmeier-Tiessen et al., 2014). It is increasingly becoming a new marker of scientists' responsibility and openness (E. Pisani et al., 2018a, Brack M and T. Castillo, 2015, E. Pisani et al., 2016; T. Lang, 2011; M. Parker and S.J. Bull, 2009). To these ends, there are increasing global efforts to make all possible data findable, rapidly available, ethical, equitable, eternal, accessible, interoperable and reliable (E. Pisani et al., 2018b).

Particularly, for the Global South (or South) which comprises developing countries primarily in the southern hemisphere, including sub-Saharan Africa (UNDP, 2016), sharing health research data provides an effective avenue for increasing research. The costly processes of contact with research participants, data collection, and management are reduced in studies that can rely on shared research data (E. Pisani et al., 2018a, E. Pisani et al., 2010). Consequently, there is a growing body of literature and global actors pushing for mandatory early and complete data sharing (U.S. NIH, c2016, U.K. MRC, 2016; Royal Society, 2013). In 2008, a draft international code on public health data sharing was discussed in Mali (E. Pisani et al., 2010). Earlier, and for over a decade starting 2005, the WHO began encouraging transparency in research through data sharing. Other global actors have joined in codifying rules and guidelines to promote health data sharing. Notable funding

organizations including the National institutes of Health and the Bill and Melinda Gates Foundation have made data sharing a condition for sponsorship (U.S. NIH, c2016*,* U.K. MRC, c2016, E. Pisani et al., 2018a). Several influential Journals and publishers have also instituted data sharing as a condition for publication (D.B. Taichman et al., 2017, L. Ferguson, 2011*)*.

To date, genomic research and clinical trials seem to attract the most advanced obligatory thresholds for data sharing (E. Pisani et al., 2018b). Requirements have generally been for scientists to commit part or complete research data to publicly accessible databases following stipulated periods after publication (E. Pisani et al., 2018). The data to be shared are largely embedded as supplementary material in published articles, on institutional or project webpages, or deposited in repositories (E. Pisani et al., 2018b, L. Ferguson, 2014).

The reach of influence of the burgeoning new culture of data sharing, the compelling advantages outlined above, and others put forward in the literature (L. Bezuidenhout, 2019, E. Pisani et al., 2018a, D.B. Taichman et al., 2017, CIOMS, 2016, E. Pisani et al., 2016, U.S. NIH, c2016; L. Merson et al., 2016, U.K. MRC,2016) make it reasonable to expect that the scientific community will adopt obligatory data sharing across all health disciplines and perhaps beyond (L. Merson et al., 2016).

Yet there are risks in data sharing which are less deliberated (L. Bezuidenhout, 2018, S. Bull., 2016, Wellcome Trust, 2016, L. Merson et al., 2016, G. Aellah et al., 2016, E. Pisani et al., 2016), especially when considered in relation to the inherent equality assumed between data-producing scientists and user scientists. Some of the risks stem from lack of confidence in data sharing; doubts concerning utility and quality of data; unwillingness to invest additional resources to make data sharable; and a general disconnect between data-originators and data-users (E. Pisani et al., 2018b). These risks are thought to be aggravated in research environments like sub-Saharan Africa which bears the greatest burden of global health problems and yet has the least dedicated resources for research (CIOMS, 2016, M. Rani and B. Buckley, 2012, G. Aellah et al., 2016).

This article is written to align our experiences in working in sub-Saharan Africa with relevant literature to explore the most typical risks facing science and scientists in the region. We contend that the risks we outline pose critical ethical hurdles that give moral grounds for giving obligatory data sharing a second look. It also gives a strong basis for treating the South unequally under the emerging culture. The issues are however, neither

peculiar to sub-Saharan Africa nor solely pertaining to the Global North-South divide. They are also of interest and relevance to all collaborations that are characterized by substantial differences in expertise, financial, and technological capacities among scientists/researchers (L. Bezuidenhout, 2019). For sub-Saharan Africa, the issues are generally underlain by systemic factors that are embedded in historically and politically rooted structural issues beyond solving by the scientific community. We raise them nonetheless because there exist well-established ethical principles that could help address or reduce their potential to perpetuate data sharing risks in the region. We recommend six principles, three of which mirror the principles espoused by the Institute of Medicine (IOM) for sharing patients' data (IOM, c2015, E. Pisani et al., 2018), and more broadly encapsulate the Nairobi Data Sharing Principles (Committee on Data for Science and Technology, 2014). For clarity, the views expressed exclude data sharing issues relating to data solicited for challenging results, exposing errors, or verifying manuscripts; data sharing inhibitions related to research participants' welfare; and data sharing related to commercial potential and intellectual property rights.

5.2.1 Producing quality health data in sub-Saharan Africa

Large scale collection of health research data is limited in sub-Saharan Africa largely because of resource constraints (E. Pisani et al., 2018, M. Rani and B. Buckley, 2012). Rather, models like the health and demographic surveillance system (HDSS) with global presence across Africa, Asia, Oceania, and Central America collect and aggregate data through small scale household surveys (INDEPTH Network, c2018, K. Herbst et al., 2015). The aggregated data is used to report nationally representative data, support population health analysis, and inform national and international health decisions and policy. The introduction of projects like INDEPTH iSHARE and Data Documentation Initiative and have encouraged data sharing among sites and across the North-South divide to facilitate research (E. Pisani et al., 2018a, INDEPTH Network, c2016, Y. Yazoume et al., 2012). With 88% of HDSSs in Africa, the successes of the model and its global data sharing ratings point to advantages that sub-Saharan Africa can realize from promoting data sharing (E. Pisani et al., 2016, K. Herbst et al., 2015). Yet, even among HDSS scientists, many are unconvinced and hesitant to share data (E. Anane-Sarpong et al., 2018b). Globally, some 54% of all authors do not share their data (L. Ferguson, 2014) while some 65% of those who publish peer reviewed articles also desist

from sharing data or providing information that allows readers to discover or access data underlying their articles. Even for data storage in repositories, only 20% of authors deposit their own data while less than 9% of all authors share links to their data (Pisani et al., 2018b).

5.2.2 To share or not to share data: the paradox of being production-rich and reward-poor

Because of sub-Saharan Africa's high burden of disease and other conditions of global health interest (Global Forum for Health Research, 2008), the region plays host to essential data that are unavailable in other regions. Scientists are keenly aware that this ironically presents comparative advantages since many of the issues are less likely to threaten the North. The situation therefore presents international and scholarly interests for local scientists to collect data, access resources, produce scientific papers, and build research skills (E. Pisani et al., 2018b). The region's poor health indices also mean that given the right research, it has the greatest potential to make an impact on global health and the Sustainable Development Goals - SDGs (United Nations, c2015, UNDP, 2016, T. Lang, 2011*)*. Yet, limited essential skillsets in scientific productivity, scarcity of technological resources, and emigration of trained and experienced staff among other limitations stifle the region's capacity to create new knowledge and innovations for health (E. Pisani et al., 2018b, G. Aellah et al., 2016). Analyzing large datasets is sometimes too cumbersome for locally available analytical tools (D. Serwadda et al., 2018, D. Boyd and K. Crawford, 2012) while resources for searching and accessing data, linking and comparing, cross-referencing, aggregating, and merging datasets to identify patterns for generating insights are in limited availability (D. Serwadda et al., 2018, G. Aellah, 2016). Health institutions and scientists may therefore have rich data in terms of the critical nature of health issues still confronting the region, for which there are no existing solutions (CIOMS, 2016). Yet, rich data production may neither necessarily advantage local scientists in increasing publications, attaining professional reward systems which are heavily allied to publications (S. Dallmeier-Tiessen et al., 2014, S. Hodson, 2013), or helping the region bail itself out of its problems. The paradox of being production-rich and reward-poor is that producing rich data becomes both a reason to share data and also for discouraging present data sharing in the hope of potential future rewards. This paradox represents a complex issue underlain by inequalities and imbalances

which posit a unified risk to data sharing by the South that may be bigger than the sum and implications of data sharing disadvantages espoused in the scholarly literature (L. Bezuidenhout and E. Chakauya, 2018, E. Pisani et al., 2016, D. Boyd and K. Crawford, 2012, S. Dallmeier-Tiessen et al., 2014, E. Pisani and C. Abouzahr, 2010).

5.2.3 Burden-benefit discrepancies

In producing and sharing data for health research, those who contribute data (burdens) must be given credit of benefits. The fundamental principle of producing interoperable, reliable quality health data (Committee on Data for Science and Technology, 2014) using basic technological tools goes beyond regular research processes which are often possible for one person to do within a short time. Yet they are critical because potential user-scientists have limited ways of checking the quality of those data (E. Pisani et al., 2018a). The burdens of running lengthy simulations, studying complex trends, designing and creating appropriate databases for data collection, and narrowing data to suit different research questions are demanding and expensive when resources are limited (S. Hodson, 2013). Yet, these investments are needed to increase the likelihood of utilizing data for new findings (E. Pisani et al., 2018a). Moreover, the long manual processes benefit greatly from producing-scientists' aspirations, ideas, and intellectual goals which we deem substantial enough to compare in value with post-publication secondary analysis leading to new publications (E. Pisani, 2018b , D. Boyd and K. Crawford, 2012). Meanwhile, scientific rigor is as central to data production as for the ultimate knowledge production (D. Boyd and K. Crawford, 2012). However, prominence in recognition and rewards in science remain largely, if not solely, on publications (S. Dallmeier-Tiessen et al., 2014, S. Hodson, 2013, E. Pisani and C. Abouzahr, 2010). Data production is rarely rewarded (E. Pisani et al., 2018, E. Pisani et al., 2016), creating a burden-benefit discrepancy against scientists whose competitive advantages lie in data production (D. Serwadda et al., 2018, E. Pisani et al., 2016), but who for one reason or the other may fail to complete the continuum from data to knowledge production. The discrepancy discourages data sharing from the South.

5.3 The "values-adherence gap"

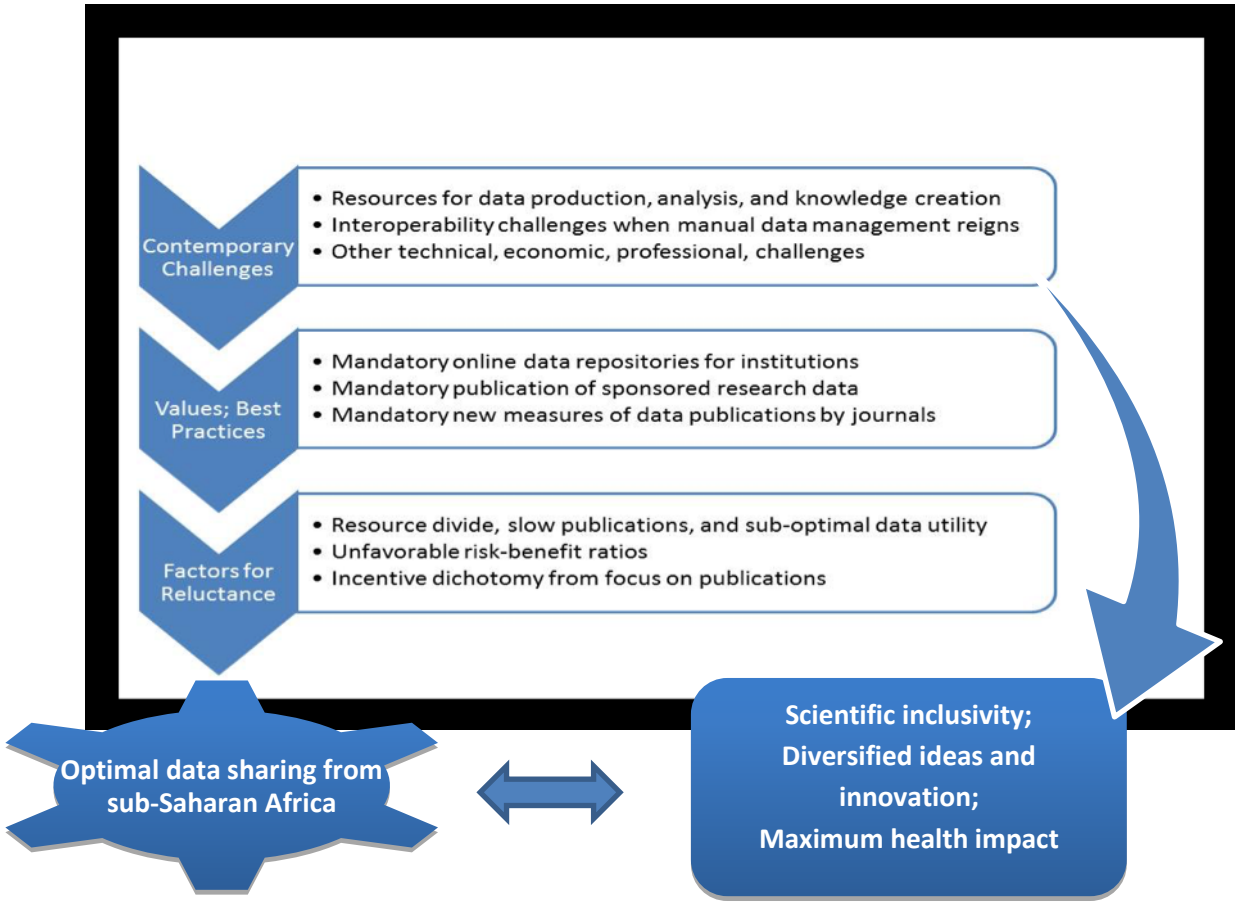
It is reported in sub-Saharan Africa that the ethical values of data sharing are generally embraced at institutional levels, but not as much at individual levels (L.

Bezuidenhout, 2019, E. Pisani et al., 2018a, E. Pisani et al., 2018b, E. Anane-Sarpong et al., 2018b). Apart from hints of underlining security and actuarial concerns, the reluctance stems from scientists' hopes of waiting to make the most of their data before sharing. Broader utilitarian losses arise. Figure 4 pictorially depicts a conceptualized phenomenon which we name the "values-adherence gap". It shows good faith in data sharing and a reluctance to adhere as a fear of it.

First, the values-adherence gap in data sharing is fuelled by reluctance to share data in spite of good faith and trust in the benefits of doing so. The factors for reluctance which we sum in the model point to inequities in the environment, privileges, burdens, incentives, opportunities, and rewards.

Sub-Saharan Africa has the least gross domestic product globally and the least support for scientific infrastructure (UNDP, 2016, G. Aellah et al., 2016, United Nations, 2015). With 85% of households not connected to the internet (International Telecommunication Union, c2017), the region arguably has the least access to scientific journals and publications, much less Open Access Journals (L. Bezuidenhout, 2019). Post graduate student earnings in the North are often three to four times higher than young PhD graduate professional earnings in the South. Young lecturers earn monthly salaries equivalent to about USD1200.00 immediately following PhD studies, a figure two to three times less than what they earned as PhD students in Europe (Personal communication with two returnee-lecturers from Tanzania and Ghana, 2018; see http://www.snf.ch/SiteCollectionDocuments/Annex_XII_Ausfuehrungsreglement_Beitragsreglement_E.pdf).

Figure 4: The values-adherence gap



Computers and basic analytical tools and reference software such as EndNote which are easily available in Northern institutions at no cost to scientists must be bought by individual producer-scientists, out-of-pocket in the South (L. Bezuidenhout, 2019). The implications of these challenges include slow speeds to write and publish as well as limited potential to access and share other scientists' data. Besides, scientists who invest personal incomes in research (limited though they might be) face raised magnitudes of the perils of losing data if mandatory sharing periods elapse before they can maximize publications. For them, concerns about override normative motivations towards taking the practice up as the right action (L. Bezuidenhout, 2019). Under-resourced scientific environments thus impede adherence to data sharing in spite of scientists' faith in it.

Second, data which is under-utilized at first publication due to manual processes or use of sub-standard analytical tools holds the greatest potential for further analysis and new manuscript preparations because of their untapped knowledge-potential. Under-resourced scientists are the most likely to contribute such data because of the reasons earlier explained. When mandatory sharing times prove inadequate, producing scientists may get

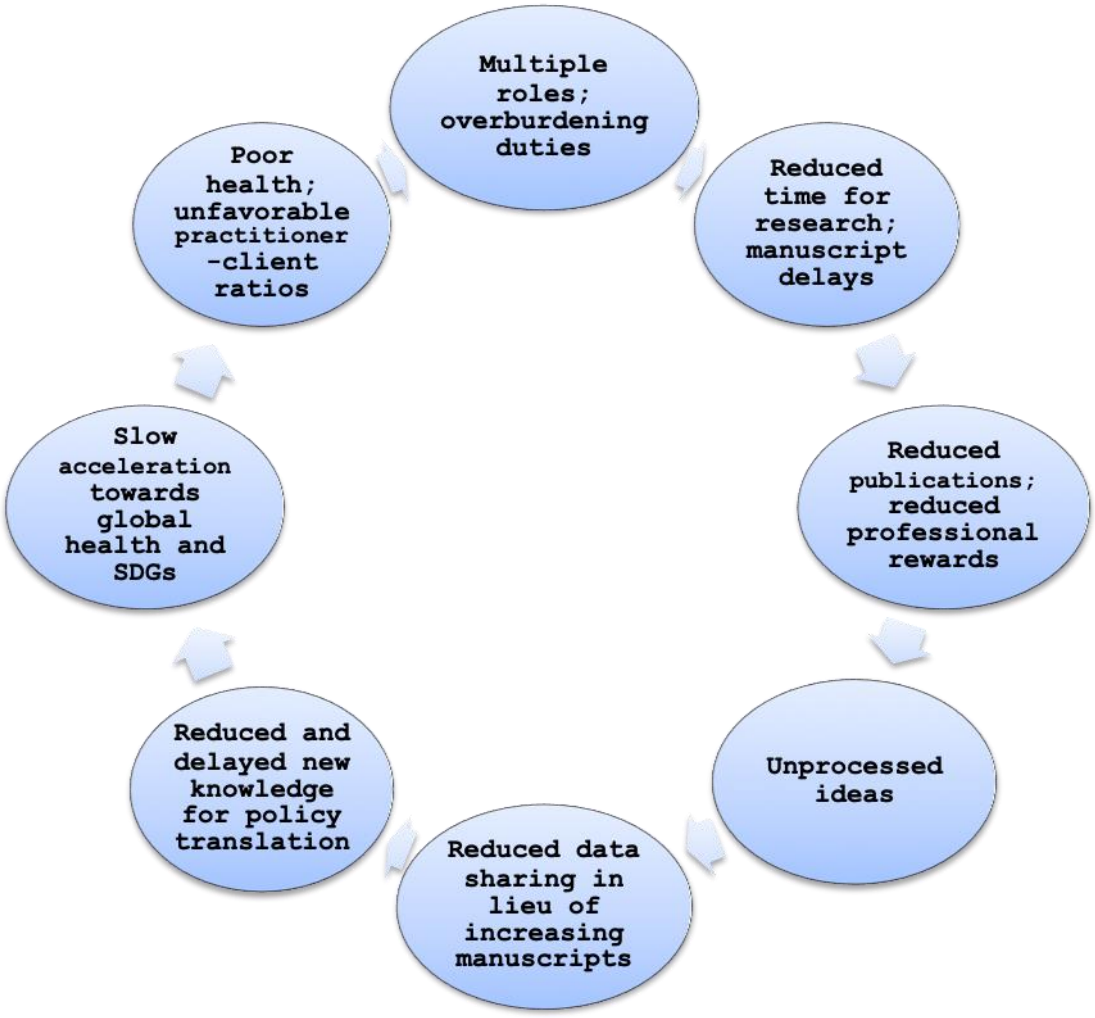
catapulted to a field of stiff competition for use of their data with better resourced competitors, without rights or privileges (S. Dallmeier-Tiessen et al., 2014, S. Hodson, 2013). The fear of ideas being overtaken by more resourced competitors in the subconsciously imposed and growing global professional race of "publish or perish" takes effect (L. Bezuidenhout, 2019, E. Pisani et al., 2018a, L. Ferguson, 2011, E. Pisani and C. Abouzahr, 2010). The corollary may include rushed thought processes and premature manuscript submissions as a means of reducing risks, perceived or real in adhering to data sharing requirements. This values-adherence gap requires instituting protections such as data priority and exclusive user rights for producing-scientists.

Third, preserving data in ways that make for effective aggregation and third party analysis without the participation of producing scientists requires interoperability provisions which are generally beyond the competencies of under-resourced individuals. Additional expertise like biostatisticians may be sought at an extra intellectual and financial cost. This fuels the values-adherence gap: the involvement of additional expertise does not preclude need for the remaining work to benefit from the producing-scientists' efforts; leadership, aspirations, and ideas. They must also remain linked to the initial intellectual goals of the project, demanding continuing attention from originating-scientists (L. Merson et al., 2016, D. Boyd and K. Crawford, 2012, E. Pisani and C. AbouZahr, 2010). Ignoring such onerous data sharing efforts may encourage the sharing of technically unusable data. Therefore, scientists who go the extra mile to shoulder future scientists' data needs by making data interoperable and accessible must be duly recompensed during secondary use. The scientific community could help bridge this adherence gap in two ways: institute data sharing rewards that have comparative professional weights to the current ultimate of authorship; or make quality data production a sufficient criterion for it. The "publish [paper] or perish" paradigm must shift to encapsulate "publish [data] or perish" (E. Pisani et al., 2018a, L. Merson et al., 2016, S. Hodson,2013, E. Pisani and C. AbouZahr, 2010), if the virtue of health research data can remain in its knowledge generation ability.

Fourth, because of the relatively lower availability of trained health expertise, sub-Saharan Africa like other poor regions is characterized by scientists who perform multiple roles and work under extreme pressures in congested health and or teaching facilities. There is fear that relatively better resourced researchers who are not simultaneously under similar conditions can quickly analyze and publish data before data-originators. A vicious

cycle ensues (Figure 2). An intuitive response to this cycle may include the following: (a) holding on to data with plans of fuller use in manuscript writing; (b) delaying the submission of ready manuscripts until the highest number of manuscripts is ready for concurrent submission to retain control of data for as long as one is engaged in other roles; and (c) avoiding the publication of novel complex new ideas requiring release of copious data and perhaps metadata. Not only can quality, depth, urgency, and novelty in finding critical solutions be sacrificed in this cycle, but there may be reduced capacity for training and imparting scientific writing skills to upcoming scientists who get caught in the cycle (U.S. NIH, c2016, U.K. MRC, c.2016, G. Aellah et al., 2016*)*. This reluctance-factor against publishing novel findings would perpetuate the already low scientific productivity from the region, reduce aggregated data availability for new knowledge, and slow down the region's reach of the SDGs (United Nations, 2015).

Figure 5: The vicious cycle of multiple roles and their effect on scientific productivity



5.3.1 Closing the values-adherence gap through principles-based solutions

It is clear that the global health vision of optimizing health research data sharing for the common good is not by itself sufficient for promoting data sharing from under-resourced sections of the scientific community. Attention to the potential safeties and perils for data-producing scientists need consideration (E. Pisani, et al., 2018b, E. Pisani, et al., 2016). It is in the very nature of knowledge to be a public good, but data is not necessarily a public good, except when needed for health emergencies (E. Pisani, et al., 2018). Mandatory sharing of what is not necessarily a public good attracts diverse individual valuing options. Calls for obligatory data sharing should therefore be considered within a broader context beyond promoting science. It must necessarily target areas of intervention that focus on the individual: Attention is necessary to promote the interests of scientists who make both the science and data for making this science possible (L. Merson et al., 2015).

Although there may be much good will in data sharing, many scientists do not wish to simply share data. They wish to benefit from other scientists' data, the journals publishing them, and to contribute constructively to matters arising (U. Schuklenk, 2018, L. Merson et al., 2015). They thus want their scientific interests protected and to make positive net gains. The data sharing aspirations will develop lopsidedly until and unless the scientific community formally acknowledges this.

A key strategy for addressing the issues raised and promoting data sharing with sub-Saharan Africa is through a framework of ethical principles, rules that are universal, desirable, and feasible for general implementation. The relevant actors include scientists, research institutions, funders, *open-science advocates,* regulatory bodies, and journals/publishers. We propose six principles to help reflect on how the burgeoning new culture could be grown differently. The principles are (1) Justice; (2) Respect for scientists whose data are shared; (3) Minimizing risks; (4) Maximizing benefits; (5) Collaborative partnership; and (6) Transparency.

5.3.2 Justice

Synonymous with fairness and equity (T.L. Beauchamp and J.F. Childress, 2001), this principle could be expressed in the new data sharing culture via respect and reciprocity among scientists. Applying the principle requires the general benchmark of treating

unequals unequally. Scientists receive different levels of support in the research environment that they work in. Until such support becomes comparable, scientists will remain unequal as far as data sharing governance is concerned. Research environments characterized by limited sponsorship necessitate support to reduce personal individual-level research investments. Personal investments encourage perceptions of data as "owned property", a concept that is far from data sharing ideals (Anane-Sarpong et al., 2018, M. Brack and T. Castillo, 2015, L. Ferguson, 2014, A.M. Capron et al., 2009). Yet, ownership claims constitute genuine *entitlements that should not be ignored from the data sharing discourse either. This is because when* a scientist finances, resources, generates, and preserves data in formats useable by others, they are entitled to some basic rights to "ownership". So then, *how much tolerance can be given to such entitlements, especially when perpetuated by global inequalities and most impacting on individual scientists? What role can the different actors play in addressing it?* We can borrow protocols from the pharmaceutical arena that direct that well-meaning ethical science should not encourage free-riding or disproportionate benefiting off the investments of others (L. Diependaele, 2017, S. Hodson, 2013, E. Pisani et al., 2010). Under-resourced scientists risk losing their "investments" or utility of their data too soon. Their data may also be under-utilized because of technological limitations to data analysis and usability (E. Pisani et al., 2016). They need protections (L. Bezuidenhout, 2019).

We propose that the principle, Justice be actualized via formal attempts by journals/publishers, regulatory bodies and where applicable, funders to vary the periods required for mandatory sharing (E. Pisani et al., 2018a) and incorporate negotiable levels of privileges including data exclusivity. Protected periods will grant temporary exclusive user rights to data-originators as is used to protect drug originators against unfair commercial use (L. Diependaele, 2017).

As regards the systemic challenge of limited access to journals and articles "published out of reach" for many under-resourced scientists, we take cognizance of the efforts of some publishers and the WHO to increase accessibility and affordability for scientists from the South (U. Schuklenk, 2018). However, the imbalances that remain are enough to still render the sharing culture unfair. In light of this, a sub-principle of Justice, Reciprocal Justice is implicated in requiring actions that make appropriate return on gains made (A.M. Capron et

al., 2009, T.L. Beauchamp and J.F. Childress, 2001). It can be applied in data sharing if requests for data are made to proceed on case-by-case or solicited-basis rather than uncontrolled, unrestricted, open, and free access (Committee on Data for Science and Technology, 2014). This gives opportunity to prospective users to negotiate data sharing with data-originators. The involvement of the latter will likely increase obligations to reciprocate efforts. This will promote inclusivity in knowledge creation (G. Aellah et al, 2016).

The foregoing proposals do not preclude other forms of compensation outlined below to compensate for secondary use of other scientists' data. This is particularly warranted if users require datasets in whole to address new research questions.

Another application of the principle of Justice is for the public and funders to extend sponsorship to all quality research thereby reducing demands on individuals to fund research out-of-pocket. This is because compliance with data sharing is significantly dependent on available financial and technical resources (L. Merson et al., 2015). Justice must also support the protection of young and or busy (slow) scientists in the critical post-first-publication period when perceived and real risks of losing data are greatest. Even where this risk is barely perceived, its interpretation could be informed by traditions and concerns which nonetheless influence actions and reactions to mandatory data sharing (L. Bezuidenhout, 2019). Justice will increase the generation of new ideas from otherwise under-producing scientists, assure equity in the new culture, and show empathetic recognition of effort and the stumbling blocks that handicap scientists' own exploitation of data.

5.3.3 Respect for scientists whose data are shared

The principle of respect is generally underlain by values of dignity and considerations for the welfare of the "other" (T. Metz, 2010). In relation to data sharing, it relates best to a conscious recognition of the efforts of all who share data and considerations that benefit them. At the point of first publication when health data is intellectually prepared, analyzed, and ready for secondary use, user-scientists have much effort and cost taken off their work. The now smaller (not necessarily inclusive of metadata) datasets require minimal processing and fewer resources to translate into new knowledge. By this principle therefore, we

advocate for recognition and subtle rights of producing scientists to benefit from all potential arising from the data they share.

Many cite acknowledgements and citations for such effort, but other forms of recognition are more commensurate. In agreement with Pisani and colleagues (E. Pisani et al., 2018a, Pisani et al., 2016*)* that prioritizing the recognition of publications need not preclude other deserving efforts in science, we appeal for international backing from the global academic/scientific community, including institutions to the inclusion of quality data production in the assessment of scientists' suitability for research career progression. Other professional incentives can be created and given international recognition. Respect for scientists who share data should therefore revolve around recognition, incentivization, and motivation (E. Pisani et al., 2018a, L Merson et al, 2015). to ensure continuity of quality data production, especially from the most unreached sections of the research community.

5.3.4 Minimizing risks to scientists who share data

It is our view that some of the risks outlined stem from sheer unfamiliarity with the data sharing concept and its potential benefits. For these, training and resourcing may be adequate (L. Bezuidenhout, 2019, L. Merson et al., 2015). Participation would help change perceptions and the fear factor too. Our focus is however, on risks revolving around unfair competition. Ethical sharing necessitates the removal of anything unfair that is preventable and in this case outweighs potential benefits (E.J. Emanuel et al., 2004). Scientists are generally not a population who needs protection. The literature rarely discusses risks they face and where mentioned are downplayed in order not to sound patronizing of the noble profession. Mandatory data sharing in spite of systemic and professional inequalities is a recipe for vulnerabilities in research and sharing relationships. Yet, even apart from major research funders in the region that are overt with their sanctions (E. Pisani et al., 2018b), mandatory data sharing is inherently punitive when compliance is non-negotiable. As the under-resourced regroup, rethink, and re-plan additional manuscripts, they would require protections including periods longer than the proposed six months after publication (E. Pisani et al., 2018a, D.B. Tiachman et al., 2017). Institutions, publishers, and data repositories may further grant priority access and exclusive use during these periods. In the absence of such considerations, losses on data use to more resourced user-scientists are unjustifiable. The pressures and genuine strain on producing scientists should compel

flexibilities in mandatory data sharing periods. This recommendation is especially relevant in minimizing risks following a project's first publication.

Other ways of relaxing the risk of "use or lose" include requirements for data-originators to be notified about other scientists' intentions to use their data. At systems' levels, funders could also consider adding substantial investments into building analytical capacities and infrastructure across academic institutions to ease researchers' efforts and support those for whom analyzing data is problematic (L. Bezuidenhout, 2019, E. Pisani et al., 2018a) Incentives could also be made available for private researchers whose data are consciously and consistently made usable. As perceived and real risks are reduced, hesitations to share will decrease (L. Bezuidenhout, 2019).

5.3.5 Maximizing benefits to scientists who share data

For an endeavor to be ethical, its benefit to risk or cost evaluations must necessarily be positive (E.J. Emanuel et al., 2004). Benefits necessarily form the flip side of risks or costs. The value of data sharing is therefore justified by its benefits.

We earlier explained data sharing hesitations that stem from dissatisfaction with having producing and using scientists on two sides of an incentive-dichotomy that disproportionately benefits the latter. We also suggested support for rewards and recognition to be equitably spread across data production through to knowledge creation, regardless of whether the research process is a continuum or separated by different actors. We have also made the case that quality data production already has intellectual properties from contributing scientists that deserve high valuing. These arguments point to the persuasion that sharing data must be accompanied by reward. Need for a benefit model is thus a matter of both Justice and Beneficence -moral obligation to act for the benefit of others- (D.J. Hurst, 2016, T.L. Beauchamp and J.F. Childress, 2001). We therefore suggest the following beneficent options as critical for promoting quality data production: co-authoring opportunities, global recognition, professional promotions, partnering for mutual exchanges of data, cost-sharing, training, and skills strengthening. We wish to emphasize that closing the research-output gap can be helped if quality data that solely supports successful peer-reviewed secondary publications can be considered as containing adequate intellectual content to justify originating-scientists' authorship status (Anane-Sarpong et al., 2018). Additional contributions may be warranted in accordance with the ICMJE's

authorship requirements (ICMJE, c2017), but the discussion should at that point be left to a matter of author ranking than possibility. Ethics committees and research institutions should give this recommendation their backing to make data sharing more attractive for the South.

5.3.6 Collaborative Partnership

The complexities of contemporary health issues, the uncertainties surrounding data from unfamiliar contexts, and the need for diversity of ideas necessitate collaboration (S. Bull., 2016). When scientific teams of diverse backgrounds collaborate on research, the quality, quantity, and rigor improves. Team effort, networking, and large scale analysis help build critical pillars for future research. The principle of Collaborative Partnership, especially across the North-South divide is important for data sharing in the following ways: (1) it is effective for diversifying, respecting, and encouraging different types of knowledge and processes of their creation; (2) minimizing "data ownership" claims for smoother and early sharing of data; (3) encouraging the formation of formal and informal sharing networks in which mutual analysis of one another's data can increase scientific productivity (e.g., closed consortia, trust-based networks, and small-scale internally-funded institutional repositories); (4) improving the responsiveness of new analysis to the health needs of communities from whom data originated; and (5) strengthening attachments, impact, and commitment to translate findings into policy and tangible health products. These advantages in-turn strengthen collaboration within and across the sub-region's institutions and scientists as seen in the INDEPTH experience, the Global Health Network which shares research data across many low and middle income countries (INDEPTH, 2013, E. Pisani et al., 2018a, E. Anane-Sarpong et al., 2018a, E. Anane-Sarpong et al., 2018b) and several other research facilities for instance in Kenya and South Africa (L. Bezuidenhout, 2019).

Emanuel and colleagues (2004) outline several benchmarks of Collaborative Partnership relevant in application to data sharing with sub-Saharan Africa. Key among them is the determination of research value, responsibilities, equality in partnership, respect, and benefit sharing. *The Council on Health Research for Development's* Research Fairness Index (COHRED, c2017) also provides guidelines, tools, checklists, and agreement templates that can complement the implementation of the principle. What remains is for

the international regulatory organs to reflect on adapting the relevant provisions into a globally accepted principles-based data sharing framework. Collaboration in data sharing will however, not always be possible or practical. Prospective producer-scientists could be controversial or in disagreement with new research plans (D.B. Taichman et al., 2017). Therefore, while the principle remains largely desirable (D.B. Taichman et al., 2017, S. Dallmeier-Tiessen et al., 2014), producing-scientists should be left to make good faith efforts to work effectively with user-scientists who express interest in their data. Much however, depends on user-scientists to notify and make opportunities for collaboration available and discoverable. Collaborative partnership is also strengthened through Reciprocal Justice. This requires setting obligations for reciprocation on the part of user-scientists corresponding to whether data is required to be released or shared in partial or complete forms. In anticipation of unequal intellectual contributions, written agreements are helpful. We strongly recommend that except where the aim of secondary analysis and new manuscript writing from shared data is to challenge original results or where major conflicts of interest exist, Collaborative Partnership should be promoted or subtly mandated by Journals and data repositories.

5.3.7 Transparency

For shared data to be Findable, Accessible, Interoperable, Reusable (FAIR), Equitable, Ethical, and Efficient as advocated by public health research funders in 2010 (E. Pisani et al., 2018a, E. Pisani et al., 2018b), the principle of Transparency is necessary. Transparency encapsulates trust and accountability (E. Pisani et al., 2018, E. Pisani et al., 2018b, L. Merson et al., 2015) in an intricately woven fashion. Transparency enhances trust in assuring fairness; trust motivates accountability by assuring that data sharers and users take cognizance of each other's risks and benefits; and the process altogether enhances trust and motivates further transparency towards accountability. If data shared can be trusted, scientists who share them must be trustworthy; trustworthy scientists are likely transparent and accountable. A virtuous cycle ensues. Yet, Transparency will likely not come naturally to the culture of freely available data after first publication, especially among unequal scientists. Experiences reported in the literature of researchers' low commitment to research participants following completion of research (E. Anane-Sarpong et al, 2018b, R. Purvis et al., 2017, D.J. Hurst, 2016) are suggestive that commitments to originating-

scientists will generally wane once data is available. Commitment generally wanes when the object of attraction is reduced or moved; if data can be gotten without its originator, any commitments to the latter will reduce or vanish. The situation worsens with distance, non-familiarity, and the absence of guidelines (S. Molyneux et al., 2016). Only international regulation can elicit the kind and scope of adherence needed to remove this challenge.

Overall, in noting that mandatory data sharing requirements presuppose a certain level of equality towards compliance, transitioning to the new culture should necessarily be guided by further reflections around inequalities, opportunities, privileges, benefits, and incentives. Voices from relevant authorities' in sub-Saharan Africa are critical because of successes and challenges in the region that may not be familiar to the North, where most global scientific actors are based (E. Pisani et al., 2018a, E. Pisani et al., 2016). Besides, there has been a marked absence of empirical engagement with scientists from the region on data sharing (L. Bezuidenhout, 2019). Any planned international guidelines will thus benefit from the early involvement of research ethics committees and scientists in the South before the data sharing rules get established.

5.4 Conclusion

Mandatory data sharing signifies the future standard for best ethical science and is critical for the growing technological dispensation and the generation of new knowledge. It offers hope for new opportunities, innovations, relationships, and products that can improve health and save lives at minimum costs and optimum speed. Yet, it is clear that the strong global health vision of optimizing data sharing for the common good alone is not sufficient for good faith adherence. Particularly for sub-Saharan Africa where several generative issues impede the realization of favorable risk-benefit ratios in data sharing, the culture may not as yet be favorable relative to their expected outcomes. It is our view that the absence of established guidance to correct existing imbalances also makes acceptance, adherence, and promotion difficult. Motivating appetite for data sharing under unequal circumstances will therefore not come naturally; the change must be spurred by technology, new beliefs and norms, and incentives. It requires transformative steps that are persuasive of increasing scientific productivity from the South, maximizing benefits and minimizing risks, respecting stakeholders, reciprocating effort, encouraging collaboration, and exhibiting transparency.

The six ethical principles proposed will help address these by providing protections for the under-resourced scientists in the South, improving the realization of various scientific aspirations, access to technological infrastructure, helping close the global research-output gap and accelerating the South's reach of the SDGs through research. On our part, conducting a future empirical study on the application of the principles would provide additional insights into the discussion to complement this paper.

5.5 Declarations

5.5.1 Conflict of interest

The authors declare no conflict of interest.

5.5.2 Acknowledgement

This paper was written as part of an academic project made possible with support from the Institute for Biomedical Ethics (IBMB) and the Swiss Tropical and Public Health Institute of the University of Basel. Partial funding for the project came from the Basel-Stadt Commission for Scholarships for Young Professionals from Developing Countries. We are grateful. We wish to also thank the anonymous reviewers of this journal for their critique and comments on the earlier version of the article which has made the final product better.

6.0 Improving public health in sub-Saharan Africa through optimal ethics in database research: perspectives from Ghana and Tanzania

This manuscript is under the review by the Journal of Public Health in Africa (JPHiA).

Improving public health in sub-Saharan Africa through optimal ethics in database research: perspective from Ghana and Tanzania

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6.1 Summary of the submitted paper under review

Sub-Saharan Africa has an urgent need to increase scientific productivity to promote public health and global health. The region is however bedeviled with limited research resources and worse, is largely dependent on external and dwindling support. The situation calls for innovative solutions that can survive the region's systemic challenges which are beyond solving in the short term. In terms of research in public health, many possibilities exist for combining archived clinical and public health databases from designated communities in place of the more costly collection of large scale data for such research. To this end, longstanding public health institutions such as HDSSs which have since the 1940s (Y. Yazoume et al., 2012) been collecting such data hold a key to the future of public health research in the region. This is because these systems incorporate routine and scheduled longitudinal data collection from designated local hospitals and communities, resulting in large volumes of longitudinal databases that are traceable to their respective populations (K. Herbst et al., 2015, O. Sankoh, 2015). HDSSs already undertake research using both the public health data they have accumulated, processed, aggregated, and sometimes curated and sometimes, in addition to prospective data. This article, as in the remaining articles in this thesis, refers to such research as research using public health data (RUPD).

What is critical to note however, is that in spite of the prospects of RUPD for the sub-region, its genre of research is yet to be made whole, formalized, and excellent. Its processes are yet to attract the fullness of ethical resources and deliberations at the international level. Therefore, as expected of contexts with less well established, less effective, and developing legal and ethical infrastructure, the scientific community risks sub-optimal ethical benefits from the furtherance of RUPD, particularly in the Global South and sub-Saharan Africa where ethical development is generally young.

We conducted face-to-face interviews in Ghana and Tanzania with 46 key informants who were varied by fields of expertise, ranks, roles, and institutions to improve diversity. The study attracted a response rate of 92% of all invitations sent out. The enthusiastic response from busy scientists is quite suggestive of an acknowledgement of the relevance of the issue to them. Indeed, the high interest on the part of practitioners and research stakeholders to reconsider ethical practices in relation to RUPD is particularly significant because it is these

researchers who specialize in the methodology, understand what ethical processes do to research processes, and hence must bear the privilege and responsibility of finding the right ethical standard for its quality and rigor. The interview data was thematically analyzed.

Our findings in this article also pointed to the substantial consensus that the practice of RUPD in sub-Saharan Africa introduces nuanced ethical dimensions for which current international guidance is, at best, narrow. Participants also noted that international provisions for ethical review of the methodology are still generally unclear and inadequate. More interestingly though, there was acknowledgment that following 70 years of the *UN Declaration of Human Rights, a* key foundation of research ethics, old pledges such as "health for all" (United nations, 2015, WHO c2017) must invoke thoughts like "bioethics for all". Hence, in reference to HDSSs, public health activities, and RUPD, that extrinsic need for something ethical, new, and appropriate remained justified. Contributions by participants reflected fresh insights into the following questions pertaining to research ethics in RUPD, the generic nature of ethical guidelines for it, and optimal bio- and public health ethics in general:

- What ethical obligations are appropriate to make of RUPD researchers?
- How might RUPD optimize social value/beneficence to communities?
    - How can researchers be encouraged to optimize data cycles to increase social value?
- Which technology-based risks are important to consider in RUPD ethics?
    - What considerations are acceptable for assessing risk-benefit ratios when benefits could be generally "far-fetched"?
- What considerations are necessary to ensure fairness to communities who supply data?
- How can less elaborate forms of informed consent like group consent be implemented to achieve the greatest good in RUPD?
    - What standards can be used to assess the effectiveness of group consent in communal and non-communal systems?

The article synthesizes the study findings from the various answers received to the above questions for further reflections. Our initial deliberation on the matter first led us to align the ideas and views on the way forward to the principles of the Emanuel Framework (EF).

Further reflections resulted in an evaluation of our decision and a subsequent conclusion that the EF was less exacting for RUPD largely as a result of it being designed for clinical research. We therefore propose modest adaptations. We also make a strong recommendation for the international scientific community to engage with what we have begun as a modest starting point for further reflections.

The main proposal we make in the paper encapsulates six ethical principles proposed by our key informants to assure the quality and rigor RUPD needs. The principles are described in the following order of importance, based on participant's views and the emphasis they placed on discussions surrounding each principles: (1) Scientific and ethical review of RUPD; (2) Social value; (3) Risk reduction; (4) Scientific integrity; (5) Collaborative partnership; and (6) Respect for study populations. For ease of implementation, ethics committees would need, upon further deliberation, to re-frame new guidance via standard operating procedures at the local levels for RUPD. They would also need to re-orient scientists about the new framework and practice in the overall quest to optimize ethics in RUPD as part of achieving optimal benefits in public health and research in sub-Saharan Africa.

Our strongest opposing argument to scholarly opinions in the article centers on general proposals for narrowing ethical application in database studies (S.S. Cargill, 2016, J. Sim and A. Dawson, 2012). The article submits that while such suggestions may apply to RUPD in sub-Saharan Africa and could be scientifically healthy, they fall short of helping achieve universality in the *optimal realization of bioethics and its benefits first for the methodology and most especially for the "naive" research populations (in terms of research ethics development and application) in these contexts.*

We finally disclaim in the article that as it is with all qualitative studies, the interview data contained subjective notions for which the analytical processes may sometimes have seemed multifarious and vague (J. Ives at al., c2017). Determining objectivity was thus sometimes elusive. However, we assure readers that we did our utmost best to reduce biases through reflective and iterative processes which we explain in detail under the materials and methods section of the article. Some quotes were also of answers that seemed indirect or deviating from the substantive questions asked. These quotes were still used and supported based on emerging writing innovations that may be challenging for those not familiar with qualitative research (J. Ives at al., c2017). We fully acknowledge that

although the respondents were varied by fields of expertise, ranks, roles, and institutions to improve diversity, the results and conclusions may not necessarily be transferrable to all contexts in sub-Saharan Africa. These limitations regardless, the findings espoused in this article when published, will inspire more ideas about optimal alternatives for promoting ethics in RUPD.

6.2 Future research proposed in the article

We noted our firm belief and continuing advocacy that there is good cause to promote optimal ethical practices in all kinds of research, regardless of methodology. Concerns to the contrary may be several in the literature, but are mostly theoretical. More empirical quantitative evidence is needed to ascertain whether those arguments that research ethics principles pose obstacles to non-traditional research or our proposals form the overall project reflected in this article and the overall thesis could indeed promote equity in public health and global health through research ethics. Our study findings therefore set a good platform for more empirical enquiries, particularly from different contexts in the Global South towards these ends.

6.3 Declarations

6.3.1 Conflict of interest

The authors declared no conflict of interest in this paper.

6.3.2 Acknowledgement

The paper was written under the kind auspices of the Institute for Biomedical Ethics (IBMB) and the Swiss Tropical and Public Health Institute of the University of Basel. Partial funding for the project also came from the Basel-Stadt Commission for Scholarships for Young Professionals from Developing Countries. We benefitted a great deal from assistance to the overall project by Dr Charles Mayombana of the Ifakara Health Institute, Tanzania. Very importantly, we are grateful to all participants for making the time to grant us interviews. We also thank the anonymous reviewers in anticipation of comments that will further enhance the article for future publication.

7.0 Discussion

7.1 Outline

This chapter provides a composite explanation of the perspectives collated from both the quantitative survey and the qualitative interviews in order to bring the primary and secondary aims of this project to a coherent whole. First, the discussion focusses on how RUPD aligns with and how it evades existing research ethics guidance and traditional ethical practices such that the resultant vacuum created can be filled. The discussion then shifts to an examination of issues related to data sharing in RUPD with a focus on data-producing scientists of the Global South, represented by HDSS practitioners in sub-Saharan Africa. The latter discussion delineates the risks of the new technological data environment for these scientists relative to the ongoing data sharing deliberations spearheaded largely by stakeholders including *open-science advocates,* regulatory bodies, and journals and publishers (U.S. NIH, c2016, OECD, 2013, H3Africa, 2016, European Commission, 2016). The overall goal to this part of the discussion is to examine whether ethical safeguards are necessary to protect the interests of scientists and ultimately RUPD.

This thesis is focused on perspectives shared mostly by African stakeholders. The qualitative data was largely collected from stakeholders in Ghana on the west coast of Africa and Tanzania in the east. Data forming the quantitative part was collected in Ethiopia, but with the participation of delegates from 16 countries apart from Ghana and Tanzania. The three core participating countries, Ethiopia, Ghana, and Tanzania, serve appropriately as under-resourced contexts in the South with several HDSS-RUPD among them. They are also characterized generally with ethical structures that are at developmental levels as well as populations that are relatively naive to research ethics. Participating practitioners were selected on the basis of their knowledge, interest, and or involvement in public health and its related disciplines associated with RUPD; membership with RECs which have oversight responsibilities in HDSS-RUPD; and independent experts knowledgeable about the current practice base of RUPD as well as general developments in research involving HDSS data. On the basis of the findings from these scientists and key stakeholders, I argue that the fast developing technological world that supports RUPD fails to offer both an adequate frame of ethical applications in RUPD and a fair field of competition in the scientific community for

under-resourced data producing scientists. I therefore make a case for what is needed to build ethics for RUPD and also for data sharing.

7.2 RUPD and research ethics application: Conceptualizing new ideals for safeguarding research populations' interests and wellbeing

Findings from the quantitative survey analysis involved 130 effective respondents from countries represented at the 2015 INDEPTH Scientific Conference in Addis Ababa, Ethiopia. They also include in-depth insight from the interviews with the 46 key stakeholders. They indicate general support for making more out of public health data beyond the narrower purposes for which they are collected (CIOMS, 2016a, S. Bull et al., 2015, Public Health Ontario, 2012) by using such data for research and other purposes. RUPD is thus established and acknowledged as public health research. What remains less established is knowledge and practice in respect of the ethics of this research (RUPD). Its methodological and contextual differences from both traditional and database research and the limited availability of international ethical provisions and scholarly input for them posit perceptions of low thresholds in the ethics of RUPD.

The closest and arguably best known comparable research to RUPD is database research. They have similar methodology, but scholarly literature on the ethics of database research is better known and advanced. It generally limits ethical practice to REC review and to a lesser extent, permissions of custodian-institutions and protection of confidentiality and privacy (CIOMS, 2016a, U.S. NIH, c2016, A.M. Capron et al., 2009, H3Africa, 2016). In the absence of any other alternative guidance, RUPD ethics is presumed to follow the same lines of database research ethics. This thesis has sought to make a contrary argument to this presumption and practice. In line with this and to solidify my ultimate argument in justifying the need for this thesis, it is important to bring back to mind the huge successes that research ethics has brought to traditional research over the past six decades. Further, we should consider the impact of such successes on the welfare of research participants (Grodin, 1992, World Medical Association, 2013, CIOMS, 2016a). It is equally important to note that since implementing research ethics principles is still not challenge-free even in the older paradigms and genres of research which characterize the biomedical field (CIOMS, 2016b), there should be no discouraging of optimal ethics in RUPD on the basis of challenges. The goal as has and will continue to always be for the scientific community is to

aim for the best possible practices by setting ideals which stakeholders can use to evaluate their conduct and those of others in the quest to optimally reach global health goals.

7.2.1 Structural differences between RUPD and other research methodologies matter

Participants in this study explained the unique features of the HDSS that warrant ethical possibilities beyond what is commonly known and accepted for database research. An important difference unearthed in the course of discussion lies in the characteristic routine house to house visits and the sustained re-contact with the people to collect data on quarterly, biannually, or annual basis. The empirical views discussed in Chapters 3 and 6 on how this feature changes the dynamics of RUPD ethics relative to database research ethics reinforce the theoretical arguments I make in this thesis for optimizing ethics for RUPD.

Per participants' observations, the differences between practicing research ethics in RUPD and what is generally known for other health research involving humans in real time pertains largely to what, how, and when the research ethics principles are needed as well as pragmatic ways to deal with the challenges of impracticalities (S.S. Cargill, 2016, J. Sim and A. Dawson, 2012). None of the participants objected to any of the ethical principles per se. As explained below, independent review which is mostly the purview of RECs; beneficence and social value for the common good; non-maleficence as expressed in collective risk assessments; fair assignment of the data of different communities to address RUPD questions; and informed consent representing respect for persons and community engagement (E.J. Emanuel et al., 2004, T.L. Beauchamp and J.F. Childress, 2001) were the most notably perceived as necessary for RUPD ethics. Challenges they posed in practice were not uniquely different from the known ones in other health research and thus possible to overcome with a little ingenuity.

The challenges observed centered on the sheer number of subjects or participants involved in RUPD due to its population based characteristic; the inseparable link between the public health activity (HDSS) that provides RUPD data and RUPD; the longitudinal nature of the HDSS; and RUPD's database methodology which is deemed straight-forward and free of human (research participant) involvement at the point of conduct. These same characteristics underline the arguments in the literature that support the waiving of core

research ethics principles in many epidemiological studies, database research, and public health in general (S.S. Cargill, 2016, J. Sim and A. Dawson, 2012 , R. Bayer and A. Fairchild, 2004). However, even the closest specific public health methodologies to RUPD such as biobanks (of the genre of database research) and cluster-randomized research have major structural and paradigmatic differences from RUPD that do not enable effective comparison and a simple translation of their ethical provisions to each other (S.S. Cargill, 2016, J. Sim and A. Dawson, 2012). My work has provided empirical evidence of these differences to facilitate the argument for ethics in RUPD to be allowed to thrive beyond reservations about impracticalities theorized in the literature. It has further shown that the HDSS has a larger structural, contextual, and methodological frame within which research ethics principles can be rendered practical for RUPD.

7.3 Conceptualizing ethical principles for RUPD

7.3.1 Independent Review

Independent review which is generally normalized through REC review was deemed the least debated and most feasible research ethics principle for RUPD. It was also deemed the most relevant for RUPD. As evidenced in Chapter three however, perceptions that RUPD does not constitute "research" are substantial among practitioners. The corollary is that decision-making around seeking REC review for RUPD is influenced by whether a researcher deems it research or a part of their routine public health practice. Perhaps this perception that RUPD is not research is one of convenience to avoid the hurdles of seeking REC review, but even the majority who said they would apply for REC review for RUPD also had reservations. They largely complained about inadequacies in known ethical provisions (international and national guidelines) for it as well as challenging REC processes. They explained the latter challenge as that REC processes for RUPD were not standardized or worse, too cumbersome for research "as simple as RUPD". Therefore, in the absence of a specific international ethical guidance framework for RUPD, the virtuous scientist is left to locate relevant portions of different guidelines and use discretion on what is ethical to observe. Even then, they found these relevant provisions in international guidelines unclear and thus inadequate as an ethical guide. Consequently, scientists would look for the least burdensome ethical approaches, if any to consider relevant for RUPD. Such decisions often

favor utilitarian choices, that is, seeking to make the most output, gains, happiness or other goals perceived as "good" while making the least of or avoiding losses, risks, and burdens which are collectively deemed "bad" (T.L. Beauchamp and J.F. Childress, 2001). These kind of decisions concerning consequentialist ethical approaches speed science, but I ague that they also relegate ethical issues of comparable worth like the "good" of the research participant or the community to the background.

REC member-participants in this study also reported their challenges in the review of RUPD. They were sometimes similar to the challenges associated with RUPD conduct, that is, issues flowing from the distinctions between RUPD and routine health research and the non-specificity of ethical guidelines for the nuances between them. More critically expressed however, was the effect of poor technological resources available to RECs to enable effective monitoring after RUPD is approved. To them, the characteristic digital nature of contemporary datasets which can be rapidly duplicated, stored in many places across the globe at any one time, and be used and shared simultaneously for multiple RUPD requires a level of review and monitoring that the South and sub-Saharan Africa in particular is not ready for. Further, if REC review is the main research ethics requirement of RUPD but informed consent is assumed impractical, then RECs must assume a stronger responsibility to safeguard the interest of the participants and communities as a core part of RUPD ethics. To do this, a specific framework for review is needed either separately or as a part of their standard operating procedures.

7.3.2 Beneficence and social value for the common good

Beneficence (T.L. Beauchamp and J.F. Childress, 2001) and social value (E.J. Emanuel et al., 2004) are linked in research ethics by their common end of "value in research" (CIOMS, 2016a). In respect of either principle, beneficence or social value which may be used synonymously in many public health research contexts in their ultimate aim at the common good, there is an imputed obligation to provide value and benefit to RUPD participants. This obligation is also underlined by a broad reference to the values of reciprocity and justice (Kass, 2001, G. Marckmann et al., 2015, E. Vayena et al., 2015). Both principles are acknowledged by the study participants as relevant to RUPD in that populations who supply data to enable RUPD must in turn be benefitted in kind. Implementing benefits can however, be addressed more realistically at the community rather than individual levels

(common good). Four main challenges were emphasized: (1) the general "abstract" nature of potential RUPD benefits to participants; (2) under-utilization of data in generating new knowledge to benefit local populations; (3) sub-optimal realization of result translation into policies and health outcomes; and (4) poor dissemination practices that minimize the impact of research on the populations' health. These issues are also indicative of an increasing view that increased scientific productivity or publications do not necessarily benefit populations, unless they serve as a means of promoting public health and global health. Ultimately, they must aim at the more macro goals of SDGs. Dissemination of RUPD findings to communities and to local authorities involved with health policies (A.M. Capron et al., 2009) was therefore supported as a critical and realistic RUPD benefit. It can be practically implemented in RUPD by using the routine house to house visits and the re-contact with participants that HDSS visits allow. Dissemination of RUPD findings must therefore be included in minimal ethical requirements for RUPD.

I strongly urge that as the region with the biggest gap in attaining global health goals in spite of being home to high volumes of research, it is incumbent for sub-Saharan Africa to mandate RUPD scientists and institutions to balance interests in publications in peer reviewed journals with local dissemination of results to participants. This would not only satisfy beneficence and social value, but social justice and reciprocity (T.L. Beauchamp and J.F. Childress, 2001). These would in turn uphold the principle of respecting the populations who contribute data to sustain HDSSs and RUPD (T.L. Beauchamp and J.F. Childress, 2001, E.J. Emanuel et al., 2004, G. Marckmann et al., 2015). It can therefore be argued as I have that at a minimum, beneficence is imputed in RUPD for its consequential values in global health. Therefore, the obligation to disseminate new RUPD knowledge to communities should be raised to the status of clinicians' duties to informing their patients. Similarly, the rights of communities to know the results of RUPD can be equated to those of patients in the doctor-patient relationship.

7.3.3 Non-maleficence as practiced via collective risk assessments

Findings related to risks in RUPD were generally communal and centered on negative reporting of studies that could lead to stigma, discrimination, and stereotyping of communities. Although the probability of such risks may be low in RUPD, participants explained that the magnitude of impact when they happened could be high because of the

commonality of facing risks collectively as communities in public health systems. RUPD researchers should therefore be sensitive in their presentation of results, particularly to audiences who might be able to ascertain the identification of the communities. Analysis of data by scientists who are unfamiliar and not connected to research populations are likely to remove connections to the data as well as commitment to minimize risks to the community. Besides, RUPD which is conducted away from its populations has reduced chances of being disseminated locally. Therefore, important risks lie in the perceived failure of institutions, RECs, and regulatory bodies to adequately monitor RUPD oversight. This has been hinted on under independent review above, yet in relation to risks, it requires solutions in coordinated risk management because of Africa's general challenges with technology and resources. I therefore propose for instance, that the burden of responsibility for technological monitoring could be shifted to a selected REC rather than all RECs. This way, the expensive technologies required could be made available to fewer institutions who can then be assigned responsibility for overall monitoring of issues thus related. In other words, resourcing one REC per country for instance with the advanced technological digital software for data finger-printing, which is otherwise unavailable to critical research institutions, would enable the tracing and monitoring of data use elsewhere (N. Paskin, 2010, T. Lang, 2011) on behalf of the country and its research community.

Related to the issue of data sharing, this proposal would ensure that scientists are better informed about the secondary use of data they publish to enable users contact and involve them in the analysis and report of new publications. Such involvement would also assure the RUPD population of scientists they are familiar with who they can look to for information and new knowledge from RUPD.

7.3.4 Fair assignment of communities to RUPD

Ensuring fair assignment of communities to RUPD is yet another principle. It has close links with risk minimization and scientific validity (E.J. Emanuel et al., 2004) because it directs the selection of datasets on more justifiable or fair basis like scientific reasons rather than the ease of access or mere availability of data for use. Implemented, it ensures for instance that datasets that may be of scientific interest, but is of concern to some groups which may be at risk of being found out, discriminated against or stigmatized are adequately protected. Social justice is implied (T.L. Beauchamp and J.F. Childress, 2001).

Anonymization, the generally proven risk minimization method for database studies (S. Bull et al., 2015, CIOMS, 2016a, World Medical Association, 2013, Hawkins and Longstaff, 2015), becomes necessary. More so for RUPD because of its advantages of permanent connection to the populations through the routine HDSS contacts and the soon to be rolled out model of the INDEPTH CHESS (F. Kirakoya-Samadoulougou et al., 2016, O. Sankoh, 2015, K. Herbst et al., 2015). This system will boost RUPD data by connecting the routine public health data to the clinical data of members of the HDSS. This would render RUPD data even more personalized warranting more ethical responsibility towards protection.

7.3.5 Informed consent via community engagement

The substantive processes of informed consent were downplayed for RUPD both the quantitative and qualitative aspects of this project. This is in large agreement with the literature (CIOMS, 2016a, B.S. Elger, 2010, A.M. Capron et al., 2009, J. Sim and A. Dawson, 2012 , H3Africa Working Group on Ethics and Regulatory Issues, 2013, S.S. Cargill, 2016). Participants however, maintained interest in its procedural forms. They acknowledged that although effective individual consent that fulfills the elements of full disclosure of information, comprehension, voluntariness, capacity in decision-making, and authorization at the individual level is not practical for RUPD ethics (T.L. Beauchamp and J.F. Childress, 2001) may be impractical, other forms of consenting are available for RUPD. Group autonomy which highlights preferences for allowing decision-making by local leaders or representatives on behalf of the people whose data are sought was largely supported. This is in line with the literature on genetic databases and biobanks (A.M. Capron et al., 2009, T. Metz, 2010). Such consent processes do not adequately cover individual rights and freedoms to accept or refuse RUPD, yet they optimize what is possible to gain from the key elements of consent including disclosure, comprehension, voluntariness, and authorization which are universally acclaimed ((T.L. Beauchamp and J.F. Childress, 2001). Implementation is therefore justified and possible through the routine HDSS data collection visits. At the macro level, community gatherings at which public health issues are usually announced can serve for obtaining group consent. An important implication for this level of consent relates to the role of the REC in RUPD. Effective group consent would require a more heightened oversight role by the REC as they double up their responsibilities to compensate for what would traditionally have been given and borne by research participants.

From the foregoing and the structural insights gained about the HDSS-RUPD, I propose that a regional team, preferably operational under the INDEPTH Network, as the mother organization of HDSSs, should in consultation with selected national ethics committees of HDSSs, undertake a process of developing an ethical framework for RUPD. My observations in the field showed that INDEPTH or the more experienced HDSS member institutions of the network are best suited to lead in the consolidation process for an ethical framework to improve acceptability when completed. The framework would also benefit greatly from the relatively new CIOMS guidelines (2016) and should additionally select provisions in other existing guidance documents that have relevance for RUPD (CIOMS, 2016a, World Medical Association, 2013, Nuffield Council on Bioethics, 2002, US Department of Health and Human Services, 2009). The selected provisions could then be consolidated in line with selected member-countries' national laws and ethical guidelines, HDSS institutional policies, and the scholarly literature. The principles outlined in Figure 6 for working with and ensuring data integrity (European Commission, 2016, OECD, 2013, H3Africa, 2016) would help in reflections. A concurrent dialogue with key international collaborators would be crucial to this process. The advantage of holding such inclusive deliberations would be in the diversity, comprehensiveness, and contextual relevance which will together make the framework useful, practical, locally accepted, and universally acknowledged.

7.4 RUPD ethics and data sharing: Conceptualizing ethical ideals involving under-resourced scientists

The second main question of this project concerned the inevitability of data sharing as a need and goal of RUPD and the emerging ethical issues to anticipate particularly from under-resourced environments and scientists involved in the evolution. Data sharing has important implications for RUPD. This study's critical applied ethics approach therefore warranted analyzing parts of the empirical data within the main RUPD data that is of relevance to the data sharing discourse. This approach to applied ethical deliberations is supported in the literature (A.M. Hedgecoe, 2004). This part of the discussion is therefore directed towards understanding the level of skepticism about data sharing which is under-reported in the literature. The focus is on the under-resourced RUPD scientist of sub-Saharan Africa or the South in general who has rich data (problem-wise) and has strengths in

data production, but weaknesses in directing their data cycles to their complete ends of knowledge production.

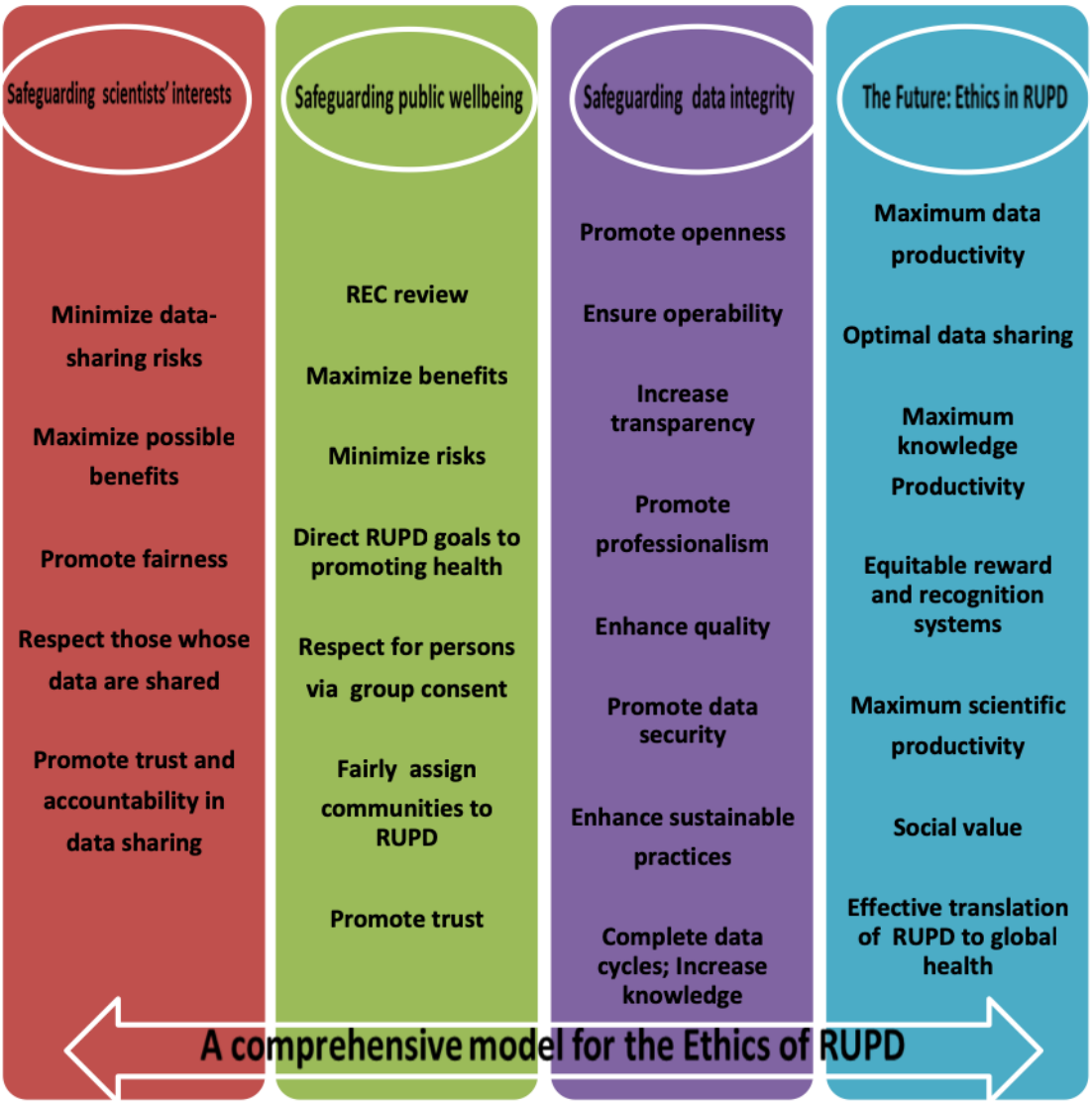
Discussions on data sharing are largely focused on the advantages of increasing data availability for research including RUPD. The overall goal is to promote data availability and access to scientists to achieve the most possible number of new ideas and additions of new knowledge about health to save lives (D.B. Taichman et al., 2016, WHO, 2015, CIOMS, 2016a, W.G. van Panhuis et al., 2014). Much of the discussions have been hinged on theoretical arguments in favor of data sharing (E. Pisani et al., 2016, D.Carr and Katherine Littler, 2015, M Walport, 2011). Many influential organizations have moved a step further to propose or oblige data sharing in endeavors they are affiliated to (Wellcome, 2016, U.S. NIH, c2016, OECD, 2013, European Commission, 2016).

Less common in the deliberations however, are skeptic arguments about data sharing including those that question the valuation of the downsides of sharing. Some have argued that despite the importance that data sharing holds, there is yet to be a measurement of its full effects on matters of indirect bearing on science and consequently RUPD (M. Brack and T. Castillo, 2015, E. Pisani et al., 2010). There are institutional, professional, relational, and personal factors that influence and are influenced by data sharing, but there is limited discussion on the issue. Of the literature available on public health data sharing in particular, only a limited number share perspectives from the South and much less of those is based on empirical data (K. Hate et al., 2015). The literature is also dominated by issues pertaining to individual level data (S. Bull et al., 2015, S.G. Denny et al., 2015, I. Jao et al., 2015) with a few on public health data sharing (W.G. van Panhuis et al., 2014, K. Hate et al., 2015). The empirical data available from this research is therefore useful for informing an ethical reflection on data sharing as pertains to models like the HDSS which hold significant influence in public health database capacity in the South. The motivation for this discussion is to examine how RUPD data sharing can be promoted in line with increasing scientific productivity and in ways that support favorable risk-benefit assessments and justice particularly for under-resourced scientists. The issues outlined are from the in-depth interviews in Ghana and Tanzania alone.

Data sharing in public health has been slow at the global level (W.G. van Panhuis et al., 2014) with sharing outputs from the South comparatively acknowledged as positive (E.

Pisani et al., 2016). In the case of HDSSs, accelerated data growths from routine public health data collection and the additions of data from various research undertaken on the HDSS platform generally support data sharing as a scientific and ethical imperative (K. Herbst et al., 2015, E. Pisani et al., 2016). Findings of this study however, show that data sharing is challenging to normalize, at least in sub-Saharan Africa.

Figure 6: Designing an inclusive ethical framework of principles for RUPD in resource limited contexts



The study findings aligned with the literature on the following as factors mitigating against data- sharing: (1) risks of loss of control once data is shared; (2) sub-optimal gains to data-producing scientists including poor recognition for their roles in data-origination; (3)

lack of technological resources to enhance maximum utility in analysis and publications before sharing; (4) limited capacity to enable fairness in sharing, that is the capacity of the under-resourced scientist to access and use other scientists' data just as other scientists use the under-resourced scientists' data; and (5) limited international guiding principles on data sharing (E. Pisani et al., 2016, M. Brack and T. Castillo, 2015, E. Pisani et al., 2010, W.G. van Panhuis et al., 2014).

What is quite unique about the findings of this project, as described in detail in Chapters 4 and 5, lies in the nuances underlying the explanations found behind the scientists and other key stakeholders' views on why these factors must be put at the center of the data sharing discourse. The views pertain largely to justice issues on processes, commitments, investments, and careers in public health. The issues are further complicated by historically rooted structural issues bordering on socio-economic factors that face the region (G. Aellah et al., 2016) and which are beyond the remit of the scientific community alone. Nonetheless, the issues form formidable stumbling blocks to data sharing, RUPD productivity, increasing new knowledge (publications) about problems especially those experienced in the region and understood better by local scientists, and promoting public health in general.

The intrinsic challenges outlined in relation to hesitations to share data in time, in fullness and in usability evoke considerations to broad ethical dimensions of fairness, reciprocity, equity, and solidarity to help safeguard the interest of the under resourced but data rich scientist. Since these ethical concepts fit within the wider frameworks of the ethical principles of justice and inequality, I argue that if the envisaged environment of data sharing is such that both resourced and under-resourced scientists producing data with varying capacities and under differing circumstances have to be equally obliged to share, then there is need guidance on assuring fairness and reciprocity principles (E.J. Emanuel et al., 2004, G. Marckmann et al., 2015, E. Pisani et al., 2010, G. Aellah et al., 2016). A serious consideration of the recommendations in Chapters 4 and 5 of this thesis is warranted for the ongoing data sharing deliberations. Indeed, any upcoming or revised data sharing rules as well as global actions have potential to lessen the impact of risks faced by the under-resourced members of the scientific community. Safeguarding their interests is a sure way

of increasing RUPD productivity and indirectly helping accelerate sub-Saharan Africa's progress towards meeting the SDGs.

Below is a brief principles-based discussion that helps engage with the intuitions, meanings, and experiences gathered about why stakeholders in this study may resist data sharing or fail to share their data, unless perhaps mandated; a situation that is not ideal for the professional growth of the scientific community.

7.4.1 Favorable burden-benefit ratio

There has been some effort to discourage the concept of "data ownership" in order to enhance research (E. Pisani et al., 2016). It however, remains a large determinant of the extent and willingness to share. Removing this hurdle requires a balanced act between the burdens that motivate claims to ownership and the benefits that arise from ownership. Producing scientists' investments of effort, skillsets, finances, and careers leads to increased connection with the data they collect and hold for different public health uses. This explains the commonly reported hesitation to share on the basis of fears of losing control of data after it is shared (S. Bull et al., 2015, D.Carr and Katherine Littler, 2015, E. Pisani et al., 2016). For this reason, I argue that optimal data sharing in RUPD can best be conducted on need-based negotiated sharing (A. Ault, 2013). This would allow collaboration with data producers and reciprocate their investments by sharing the rewards of further uses of their data. Rewards like sharing of skillsets, resources and ideas would in turn increase co-authorship opportunities in publications. This raises benefits to the producing scientists to offset or balance the weight of costs (burdens) in data production. Controlling "ownership" claims also be addressed by an awareness creation about the reality that the populations and communities who provide data for the public good, funding agencies, and governmental institution have important stakes in the data held by scientists and institutions. Therefore, data holding must be considered more as a matter of custodianship than ownership (A.M. Capron et al., 2009).

7.4.2 Sustainability

The South and sub-Saharan Africa in particular remains heavily reliant on external funding for public health activities including data collection and research (Largent, 2016, Rani and Buckley, 2012). The paradox of data sharing is that while it increases access to data

and make data availability free or cheap, it generally decreases the motivation to fund data collection. Easier and cheaper global access to data without the burden of investment reduces the necessity of investment, or at least the motivation to invest. As long as external funding remains critical to the region, "sustainability" for data collection and subsequent sharing will suffer. This risk must be considered within the equally challenging issue of rarely increasing local funding commitments to global health and research. Southern scientists and institutions must therefore strategize on how to sustain RUPD by optimizing the utility of data in quicker speeds while they enjoy minimal priority rights between data sharing times and deadlines for release. One opportunity lies in southern scientists re-directing some scientific efforts away from data production to knowledge production to complete data cycles and help make the most use of their data in publications before sharing. This would require more local networking such as south-south and HDSS-HDSS partnerships that harnesses the strengths of the collective to increase scientific productivity and make data more fully exploited before sharing (D.Carr and Katherine Littler, 2015). That way, as the scientists complete data cycles and optimize data use via increased publications, the benefits would outweigh the costs of data collection and motivate continuity and sustainability in data collection. Fears of sharing would be reduced as data-producers would have been satisfied with the optimal use of their data.

7.4.3 Upholding deontological principles

A key ethical dimension of the findings concerning data sharing relate to deontological approaches to RUPD ethics: the duty to credit those who make beneficial contributions to other people's ends (T.L. Beauchamp and J.F. Childress, 2001). Using shared data without the notification or involvement of data producers is akin to violating the categorical maxim against using people as a means to an end. The consequential benefit of an endeavor must be shared with the effectual burden of input. For this reason, I argue that conducting and benefiting from secondary analysis independent of data producing scientists must be an exception rather than a rule in ethical RUPD and ethical data sharing. Scientists and institutions specialized in knowledge production or benefitting from secondary data must assume a duty towards data production. Thus, in relation to the principle of sustainability above, user-scientists who intend to use data without collaboration must be duty bound to invest in sustaining data production (Wellcome, 2016, E. Pisani et al., 2010).

The resulting reciprocal investment can be aligned to the weight of expected benefits to producer scientists. The findings from this project were also indicative that the practice of merely acknowledging data-originators for instance in publications that solely use their data is deemed woefully inadequate and ethically unacceptable (E. Pisani and C. AbouZahr, 2010). User-scientists must make optimal effort to invite the intellectual input of producing scientists if their data is good enough to be re-used for further analysis leading to new knowledge. I support arguments that data production involves intellectual processes which require urgent recognition and agree that such recognition must be professionally aligned to the recognition given to publications (M. Brack and T. Castillo, 2015, E. Pisani and C. AbouZahr, 2010). Good-faith negotiations between data producers of the South and secondary-users require data sharing agreements that contain equitably tangible incentives for both sharers and users and oblige the necessary duties.

7.4.4 Collaborative partnership

Different institutions have differing advantages. Those rich in data deemed critical for addressing global health issues may not have the analytical advantages to translate the wealth of data into relevant knowledge. Institutions highly resourced in technological and analytical infrastructure may not have data that matches the most important needs of global health at any given time. This makes collaborative partnership a critical ethical principle in RUPD ethics (E.J. Emanuel et al., 2004, M. Parker and S.J. Bull, 2009). The importance of funding, skillsets, and technological infrastructure, and diversity of ideas towards accelerating the achievement of global goals cannot be over-emphasized. Participants in the study emphasized how limited access to technological and analytical resources slowed down their use of the data they produced and use of data shared by others. It is also well known that even differing writing styles and thought processes could account for differences in the success rates of translating data cycles into scientific publications. The low infrastructural advances of internet and information technology access in the South and sub-Saharan Africa in particular (International Telecommunication Union, 2013) escalates situations where scientists are themselves denied access to new knowledge emanating from data they produced. These are matters that do not adequately feature in the literature but account for low contributions of new health information from the South. They pose worse risks; slow finding of solutions to problems affecting the respective regions of slow scientific growth

impedes their reach of overall global health goals. As limited resources push under-resourced scientists to share data which is least exploited and hold the most potential for re-use by others or the capacity to compete for further use once shared with more resourced scientists become limited by resources (E. Pisani et al., 2016, S.G. Denny et al., 2015), the challenged lose the opportunity to crawl get out of their challenges. This is why I argue for collaborative partnership as a key strategy for data sharing with the South. Apart from capacity building and sharing of ideas towards increased scientific productivity, it would more importantly ensure that RUPD is collective, inclusive, and of most relevance in addressing the respective health problems of the communities who produced and understand their challenges best.

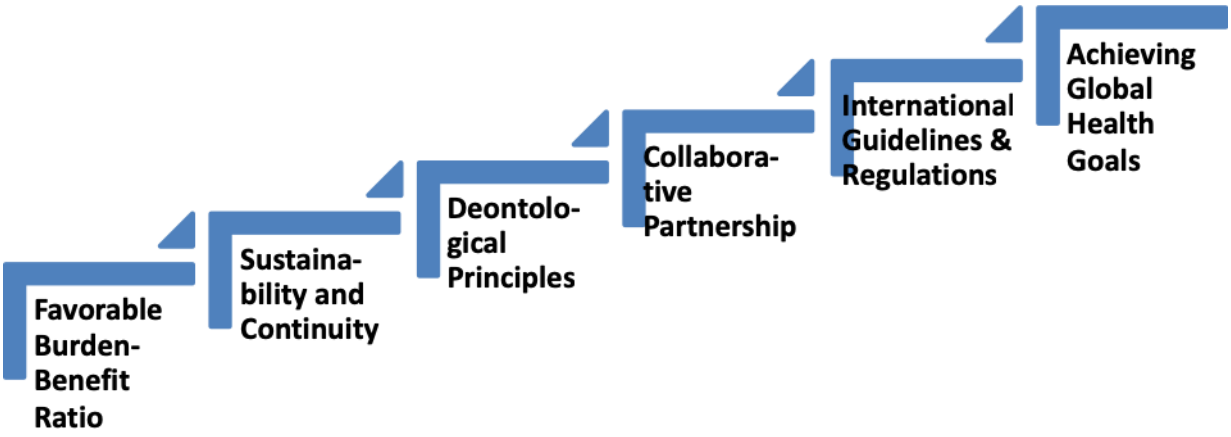
7.5 Developing new ethical guidelines

There is yet to be a unified international data sharing guideline that considers the relational, professional, and personal issues at the center of this study's findings (W.G. van Panhuis et al., 2014, M. Brack and T. Castillo, 2015). At least none among those best cited by the study participants, CIOMS (CIOMS, 2016a), Helsinki declaration (World Medical Association, 2013), and the Code of Federal regulations (US Department of Health and Human Services, 2009) has guidance on data sharing. Awareness about national guidelines and relevant data sharing provisions in the scholarly literature was also low among study participants. Many participants therefore believed that such guidelines are needed before current data sharing proposals are concretized into rules for RUPD. Considering that even the more-resourced countries of the South like South Africa do not have national guidelines relevant to the data sharing concerns raised (W.G. van Panhuis et al., 2014), I propose that the INDEPTH network, the mother organization of HDSSs in the South should lead in developing a RUPD-specific guideline on data sharing that gives particular attention to the issues raised by its scientists in this study. The Network has a known reputation for anticipating and addressing HDSS and its allied issues (O. Sankoh and C. IJsselmuiden, 2011, E. Pisani et al., 2016) and is in the best position to bring together the right stakeholders to dialogue for inputs into such a guideline. In the interim, southern institutions would benefit by developing institutional level policies on data sharing given the general limitedness of national ethical and legal structures in the South (M. Kruger et al., 2014). Institutional policies must however, be viewed in their limited scope of influence since, as gathered from

the project's legal practitioner-participants, institutional policies are helpful, but nor adequate as instruments of international data sharing. This is because scientists and institutions external to a policy instituting institutions are not necessarily bound by its policy requirements. Therefore, when data use is planned to be done away from data producing institutions, data-users may choose to or not to comply with the policies of the producing institution. Conflicts may also arise between an incoming data user's home legislations abroad and the data producing institution's policies (M. Brack and T. Castillo, 2015) to force relegation of the latter's rules. Specific international guidelines on data sharing are therefore required and they must necessarily consider the relational issues to do with the scientist and the institution. Concurrently, education and advocacy on what already exists cannot be over-emphasized.

Finally, I urge that the steps towards reaching the SDGs and other global health goals may have obstacles at different stages, but Figure 7 helps re-conceptualize ethical principles that would optimize the value of data sharing and enhance the scientific productivity.

Figure 7: Ethical principles for promoting data sharing towards global health goals



As Figure 7 diagrammatically presents the essential principles imputed by the study findings, it posits them as necessary to optimize ethics in RUPD and also data sharing. As for the systemic challenges of the South, they may not be redeemable by the most optimal ethics alone, but there is a much that can be done to help reduce the full and continual effects of their impact and those are seen in Figure 6. The overall, experiences, opinions, fears, doubts, and concerns shared by the participants in this project, key stakeholders in the

endeavors of both RUPD and data sharing are worth considering. Left uncontrolled, the corollary would be a vicious cycle of low data production, low scientific productivity, reduced funding, reduced investments in technological and analytical resources, reduced analytical capacity, reduced scientific productivity, low capacity building, reduced diversity in the creation of relevant ideas for solving critical problems, and an overall reduction in the capacity of RUPD to impact on global health. Therefore, on the basis of utilitarian beneficence (Singer, 2009), the crux of my argument in this thesis remains that it is within the power of the scientific and ethical community to enhance ethical practices in RUPD to maximize potential benefits to RUPD populations and to scientists in the South without sacrificing any benefits of comparable worth. Hence, the scientific and ethical community ought to exercise that power by adopting a fuller and more comprehensive ethical framework for RUPD and for data sharing.

7.6 General limitations

Like every study, this work has limitations which have been explained in the various chapters. This section describes the limitations more broadly. First directing the study on the two broad terrains of traditional ethical issues in RUPD as pertain to RUPD participants and encapsulating the seemingly extrinsic issues pertaining to data sharing may seem to show a disconnect which is actually only on the superficial level. The idea is not to look at the two issues differently, but to consider their origins in the same study, methodology of qualitative interviews, and key informants who form a holistic endeavor for which each part of the discussion has a crucial vacuum to fill. The whole, RUPD ethical development is bigger than the sum of all other issues at the levels of scientists, RECs, and other interests including data sharing. The focus should therefore be on the broader goal of reaching global health goals using what research is most feasible to the under-resourced (RUPD) and how that can be optimized with the critical human resource to reach the most benefits.

As expected the second limitation concerns representativeness (B. Dawson and R.G. Trapp, 2004) in the survey and transferability of results from the qualitative methods (V. Braun and V. Clarke, 2006). However, ethical arguments and reflections are not be hinged on numbers (CIOMS, 2016a). The diversity and in-depth nature of the perspectives shared were enough to inform normative reflections on addressing the two main questions. Obtaining data physically in three countries and getting an additional input from

representatives of fifteen more is good enough diversity that should outweigh absolute numbers.

A final limitation borders on the familiarity of the research student to participants, particularly those encountered in the interview sessions in Ghana and Tanzania. Her known involvement in earlier clinical trials involving some of the study centers made her a familiar face at all sites. This may have introduced some social desirability biases via participants giving answers thought to be more acceptable to the interviewer.

Despite these limitations, the words of an anonymous reviewer of Article 1 sum up the overall positivity of this thesis. He or she wrote that even if the project could "not change the world, it is very informative. The ethical discussion of this specific kind of research might benefit from more insight from stakeholders".

8.0 Conclusions and implications for action

A re-conceptualization of the ethics of RUPD is a developing area for the future of technology enhanced research with large population-level public health datasets. The initial ethical infrastructure has revolved around ethics review and anonymization of data to protect confidentiality. Yet, the results from the empirical findings from this doctoral research inform a normative analysis that suggests a wider frame of opportunity for ethical considerations in RUPD. The traditional research ethics principles are practical for RUPD albeit to differing extents. The means of optimizing the principles are more akin to the principles and benchmarks framework proposed by Emanuel and colleagues (E.J. Emanuel et al., 2004) for the conduct of ethical clinical research in developing countries. The ease of fit demonstrates a level of universality in research ethics practice and support the case for the requirement of more ethics for RUPD. What remains critical is to ensure that the suggestions made in the thesis both on ethical regulations for RUPD and data sharing are carefully reconsidered in order for them to be sufficiently sensitive to the gaps in RUPD and data sharing without needlessly being restrictive to scientific progress.

The release of the new CIOMS document in 2016 when this thesis was being finalized is a timely ethical intervention and complement. The CIOMS' focus on issues that affect the South help lay a stronger foundation for the RUPD ethics framework being sought by scientists and REC members alike in this study. Complemented by the existing scholarly literature (S. Bull et al., 2015, E. Pisani et al., 2016), there is enough to develop a new comprehensive ethical framework for RUPD in the South. At a more decentralized level, local RECs and HDSSs may henceforth revise their standard operating procedures and policies respectively to extract and inculcate the relevant portions of the following: (1) RUPD-suited provisions in Guidelines 3, 7, 8, 12, and 24 of the new CIOMS document; (2) Available guidelines concerning open access which is considered the most extreme form of data sharing (European Commission, 2016, A. Ault, 2013). This would signal attention to the most important risks in the data holding and sharing endeavor and point to ethical provisions to minimize them; and (3) Relevant provisions from the H3Africa project (H3Africa, 2016) which is deliberating issues in genomic and database research which have relevance to RUPD. When these are done, further dialogue for instance at the level of the INDEPTH network will

impart additional intuitions on what might count as ideal and what is pragmatic for the future of RUPD and sharing.

Although scientists are generally not a population that require ethical safeguards, findings in relation to data sharing in this thesis are suggestive that under-resourced scientists may require safeguards in the future. Obligations have inherent punitive measures. Therefore, as the global calls for data sharing crystalize into rules, they will soon be non-negotiable regardless of risks to scientists who for various reasons cannot optimize their data in the required speeds before sharing. These vulnerabilities on the part of scientists will have implications for research and global health. Solutions can be found in collaborations, flexible time-allowances that permit maximum data utility before sharing, equity in reward systems, and above all, showing solidarity by sacrificing part of the speed expected in science for diversity of ideas. For long term purposes and sustainable data-production, global actors must assume the responsibility to re-instate quality data production in the global recognition framework. Assessments of scientists' suitability for research career progressions that consider data production is for instance a step to protect RUPD sustenance through continued production of quality data production, regardless of whether originators translate data into knowledge (S. Hodson, 2013, G. Aellah et al., 2016). This satisfies justice. The indirect fashioning of scientists to "publish or perish" is beneficial to science, but lack much applause in its impact on population's health in the South partly because of the ambivalence to whether or not southern scientists contribute to scientific productivity. Just commitments to fulfil ethical obligations generally wane with distance, non-familiarity, and absence of guidelines, as does commitments to disseminate new knowledge where it can make the most global health impact. As global scientific actors push for data sharing, there needs to be ethical actors of comparable authority to inject each scientific step with an optimal amount of ethical reflections. Data sharing deliberations and the ethics of RUPD must go beyond focus on quick analysis and maximum publications. There is a whole gamut of people and processes for which realizing this culture must reflect. Because journals, organizations, and funders advocating data sharing are mostly northern based and challenges to sharing are largely southern, Africa's voice must be heard in highlighting concerns peculiar to the systemic challenges they face. These discussions must be placed within a broader context of safeguarding science, data, and the human systems that make the whole endeavor possible.

Finally to the under-resourced scientist, mandatory data sharing will soon signify that data sharing is a determinant of the ethical status of RUPD and a standard for best ethical practice. The onus lies on all scientists to prepare themselves better for the burgeoning new sharing culture. There will be inconveniences in being ethical and sharing data speedily for science, but the inconveniences are not comparable to the benefits that stand to be lost to populations whose data may yield new knowledge, ethical developments in the growing data world, scientific breakthroughs, and the ultimate attainment of global health and the SDGs. If it must, research ethics must be re-instated in its fullest practicable limit in RUPD and data sharing and as this thesis has shown, both are possible with a little ingenuity.

8.1 Future research

This study has charted a course in empirical research and critical applied ethics for RUPD and data sharing with the South. The arrival of the CIOMS document during the latter part of the project's implementation opens a unique opportunity to examine the principles espoused in the thesis in relation to the RUPD-relevant aspects of the document namely Guidelines 1, 2, 3, 7, 8, 12, and 24. Conducting additional empirical studies using other settings in the South would enable a critical examination of how the proposals in the thesis can be adapted into one go-to guideline for RUPD ethics. I cite the CIOMS document in particular because it is best-suited among other guidelines for the South in general (Largent, 2016). Moreover, its current status attracted extensive dialogue, making it comprehensive and abreast with the technology-enhanced and epidemiological features of RUPD.

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APPENDICES

Appendix 1

Information Leaflet and Declaration of Consent (Respondents) - Survey

Project Title: New Models of Public Health Research: Optimizing Ethics in Research Using Public Health Data in Resource Limited Countries"

Dear Sir/Madam,

I am a PhD student at the Institute for Biomedical Ethics (IBMB), University of Basel, Switzerland. As part of the requirements for my doctoral degree in Public Health Ethics, I am undertaking this project funded by the Swiss Tropical and Public Health Institute in collaboration with the IBMB.

The project aims at exploring characteristics of research involving use of pre-collected surveillance data (RUPD) as well as documenting challenges researchers and ethics committees face in applying existing ethics guidelines to RUPD. The ultimate goal of my project is to develop a practical and context appropriate guidance document to support future ethical conduct and review of RUPD.

I am, through this letter, requesting your kind participation in the study by responding to the study questionnaire. Questions will center on your expert experiences and opinions about RUPD, as well as your recommendations for its ethical conduct. Your responses, together with that of other colleagues will be synthesized with existing literature on public health ethics, surveillance ethics and research ethics to, if feasible, develop a RUPD-specific ethics framework.

Participants will be from Ethiopia, Ghana, and Tanzania, and representatives of Health and Demographic Surveillance Sites who will be present at the October 2014 meeting of the International Network for the Demographic Evaluation of Populations and their Health in Addis Ababa, Ethiopia.

Please be assured that you are free to choose not to participate in this study, even if your name was suggested or recommended by someone else. You may also decline to answer a specific question without any consequence or prejudice to you. Be informed that because consent documents are de-linked from questionnaires and the process is anonymized, there will be no attempt to link answers to you as an individual or your institution.

I thank you in advance for your time and support.

Sincerely yours,

Ms. Evelyn Anane-Sarpong
Institute for Biomedical Ethics and The Swiss TPH
University of Basel, Bernoullistrasse 28,
4056 Basel, Switzerland
Email: evelyn.anane-sarpong@unibas.ch

<u>This leaflet summarizes key points necessary to allow you to reach a decision to or not to participate.</u>

1. **Who is participating in the study?** - You have been approached to participate in this study because you are a/an:
    - key stakeholder who provides professional services for the activities of Health and Demographic Surveillance Systems (HDSS) centers;
    - head of an HDSS;
    - ethics committee administrator and or member in Ethiopia, Ghana, and Tanzania;
    - independent (non-HDSS) public health professional with expertise in health systems surveillance and research activities in Ethiopia, Ghana, and Tanzania;
    - senior personnel of the national health ministerial agency in Ethiopia, Ghana, and Tanzania;
    - public health expert working with a locally based international health agency such as the WHO.
2. **Study procedures you will be involved in** - You will be asked to spend 20 - 40 minutes of your time to respond to a self-administered questionnaire on the project topic (please see Page 1). Both open and closed ended questions will be used to document your opinions about a short vignette (scenario).
3. **Risks and Benefits -** Except for your time to answer the questionnaire or to be later interviewed, if you agree, there is no foreseen risk associated with taking part in this study. Upon study completion, only anonymized data will be presented in reports and publications resulting from the data. The results of this project will contribute to the development of a framework for RUPD, or at a minimum, increased knowledge on ethical issues surrounding RUPD. This will help improve advancements that HDSSs are making in research and scientific publications. As a token of appreciation for your time, a small souvenir (Basel embossed pen) will be presented to you. At the close of this project, access links to all published pieces will be communicated to you or your institution.
4. **Confidentiality** - Be assured that because the process is anonymized, there will be no attempt to link answers to you as an individual or your institution. Signed consent

documents will not at any point be linked to completed questionnaires or interview records. I will personally pick up completed questionnaires to ensure that responses you give will be confidential, and they will not be shared with anyone other than members of the PhD project team.

5. **Participation and Withdrawal from the study** - You are free to choose not to participate in this study, even if your name was suggested or recommended by someone else. You may also decline to answer a specific question without any consequence or prejudice to you.
6. **Ethical Approval** - This proposal has been ethically reviewed by the Ethics Commission of North Western and Central Switzerland that oversees ethics review at the University of Basel, and ethics committees in all participating sites in Ethiopia, Ghana, and Tanzania.
7. **Contacts** - If you have any question concerning this study, during and/or after data collection, please contact evelyn.anane-sarpong@unibas.ch. You may also use the following phone contacts: +233 (0)20 820 00 23 (Ghana), +255 (0)<<Tanzanian number to be stated>> and <<Ethiopian number to be inserted>> until January 31, 2015, and subsequently, +41 61 2671788.

If you have any complaint, you may communicate to me at the address above, or to the Administrator of the [name of IRB], [name of administrator] at [administrator's email address], if appropriate.

Declaration of Consent

I understand that:

- this is an academic project, the content of which has been explained to me
- my participation is given of my own free will without any consequence or prejudice
- all correspondence, including completed questionnaires and audio recordings will be kept confidential
- no identifying information will be used in discussions and publications from this study
- if I feel unable or unwilling to answer any question, for any reason, I may move on to the next or discontinue with the questionnaire or interview, without providing any reason.

I have been given the opportunity to ask questions which were answered to my satisfaction.

I agree to participate in this study.

…… ……..

Signature of Participant Place, Date

Thank you very much.

Appendix 2

Study Questionnaire: Research Using Public Health Data (RUPD)

Please read the following scenario to answer the questions below

Proposal to re-use previously collected health and demographic surveillance data

The Tanghu Center (a fictitious health research center) was established in 2000. It has a population of 99000 under its surveillance. It has received local community support and significant funding to invest in modern facilities for health and demographic data collection, and storage. Researchers at the center now suggest that this surveillance data should be explored and analyzed for scientific publications. Many topics are immediately proposed. Dr. Ghutan for instance wishes to use the data gathered between 2005 and 2012 to compare issues between old and new residents after tuberculosis infection. It is agreed by many members present that such a coordinated effort to re-use existing data for such publications could increase scientific capacity, enable young and new researchers to gain analytical skills and ensure the fullest use of the hard earned data. Others note that the evidence from such publications will impact health policy, and result in new ideas and research questions. Some members however, think that there could be ethical issues to consider.

SECTION A: GENERAL QUESTIONS

1. **Have you ever seen a publication involving use of previously collected demographic surveillance data?**
   ☐ Yes ☐ No
2. **Have you ever used Dr. Ghutan's approach to publish?**
   ☐ Yes ☐ No
3. **How often do you see use of demographic surveillance data for publications occur?**
   ☐ Very often ☐ Often ☐ Sometimes ☐ Rare ☐ Not at All
4. **Do you consider the use of only previously collected data for publications as research?**
   ☐ Yes ☐ No
5. **Should use of previously collected surveillance data for publications require research ethics review?** ☐ Yes ☐ No

SECTION B: QUESTIONS ABOUT ETHICS IN PUBLIC HEALTH AND RESEARCH

1. Please indicate what you think about the following statements: (*Please circle only one response per statement*)	**Strongly Agree**				**Strongly Disagree**
a. The Tanghu community, via its leaders, should be told about Dr. Ghutan's proposal to re-use their data before any publication	1	2	3	4	5
b. Individual Informed consent of Tanghu community members should be sought for every publication involving their data	1	2	3	4	5
c. Tanghu residents should have rights to withdraw their data from being analyzed for publications	1	2	3	4	5
d. Tanghu residents face risks to confidentiality of data with such publications	1	2	3	4	5
e. The Tanghu community will face stigma and stereotyping if negative results are published	1	2	3	4	5
Please indicate what you think about the following statements: (*Please circle only one response per statement*)	**Strongly Agree**				**Strongly Disagree**
f. The Tanghu community faces risks of being over-researched with continued publications involving their data	1	2	3	4	5
g. If publications like Dr. Ghutan continue, it will Tanghu residents from providing surveillance data in the discourage future	1	2	3	4	5
h. Each time a proposal like Dr. Ghutan's is made, every should have a right to disagree with the re-use of their resident data for publication (i.e. opt-out options for community members)	1	2	3	4	5

Your own suggestions are most welcome.

2. In relation to Dr. Ghutan and his colleagues' proposals, please indicate your agreement or disagreement with the following: (*Please circle only one response per statement*)	**Strongly Agree**				**Strongly Disagree**
a. Ethics committee review should always be sought before using existing surveillance data for new research	1	2	3	4	5
b. Specific ethical guidelines need to be developed to govern re- use of existing surveillance data for publications	1	2	3	4	5
c. The use of surveillance data for purposes that help improve the community or public health should not be slowed down by individual residents' interests such as informed consent	1	2	3	4	5
d. Residents whose data meet the inclusion criteria should be given some benefit when publications arise from re-use of their data	1	2	3	4	5
e. Surveillance data should be permanently open to use without restrictions by ethics committees	1	2	3	4	5
f. Surveillance data involving sensitive issues (e.g. genetics)should be released to researchers only after names of residents have been removed from the data	1	2	3	4	5
g. One consent at the beginning of surveillance data collection is enough for use and for all future publications	1	2	3	4	5
h. Whenever data analysis for a publication cannot be effectively done without first removing names from the datasets, re-use should not be permitted	1	2	3	4	5

i. Research approaches like Dr. Ghutan's should be encouraged 1 2 3 4 5

Comments

3. Using the scenario, please explain any <u>general concerns</u> (e.g. social, legal, economic, cultural etc.) that might affect the following:

Individuals residing in Tanghu:

The Tanghu Community as a whole:

4. Using the scenario, please explain any <u>ethical issues</u> that might affect the following:

Individuals residing in Tanghu:

The Tanghu community as a whole:

5. Considering the scenario, what would be your advice to the Tanghu Team. Re-use of surveillance data for publications should be permitted only if … (*circle only one response per statement*)	**Strongly Agree**				**Strongly Disagree**
a. it conforms to Tanghu Center's objectives or mission	1	2	3	4	5
b. the head of the Center grants permission	1	2	3	4	5
c. Tanghu community leadership consents to it	1	2	3	4	5
d. it is in line with local or national health priorities	1	2	3	4	5
e. it can result in change of health policy relevant to the community	1	2	3	4	5
f. investigators asking to re-use the data for publications were themselves involved in the original data collection	1	2	3	4	5
g. the expected publications do not include sensitive issues like genetics	1	2	3	4	5
h. the local ethics committee reviews the proposal and grants permission	1	2	3	4	5

Please suggest other desirable conditions below

6. The following ethical issues should be considered by Dr. Ghutan if he goes ahead to analyze the data for publications (*Please circle only one response per statement*)	**Strongly Agree**				**Strongly Disagree**
a. Personal and family confidential data may be compromised	1	2	3	4	5
b. Tanghu community members' rights to control how their personal and family data is stored, used and publicized may be violated	1	2	3	4	5
c. It is alright for Dr. Ghutan's request to be permitted without informed consent from community members	1	2	3	4	5
d. Research proposals involving genetic records should not be	1	2	3	4	5

permitted without informed consent					
e. Tanghu community may lose trust in the Tanghu Centre for allowing Dr. Ghutan to use their existing surveillance data for new publications	1	2	3	4	5
f. Results of the analysis should be first disseminated to Tanghu community before publication	1	2	3	4	5

Your own suggestions are most welcome.

7. In your opinion, what should Dr. Ghutan do before using the data? (*Please select* only *one answer for 7a)*

☐ Seek official permission from the Tanghu Centre only

☐ Seek official permission from the Tanghu Centre, as well as ethics committee review

☐ Seek official permission from the Tanghu Centre, and proceed to use the data. If the analysis leads to a publishable manuscript, then ethical clearance to publish should be sought

☐ Seek official permission from the Tanghu Centre, and notify the regional/national health authorities

☐ Seek official permission from the Tanghu Centre and the ethics committee, and then notify the regional/national health authorities

☐ Use personal and professional discretion about how to use the data in an ethical manner

(b) Dr. Ghutan may also undertake the following processes. (*Please recommend*)

_____

_____

8. Do you know of any written rule, policy or regulation governing the use of existing surveillance data for publication purposes? ☐ Yes ☐ No
(*If yes, please assist by stating the name of this document and what it says in brief*)

_____

_____

9. **What role, if any, should the following stakeholders play regarding re-use of existing surveillance data for publications?**

Tanghu Center:

National Health Authority/Agency:

Tanghu Community:

Tanghu Leadership:

Local Ethics Committees:

The Government:

Other Stakeholders: (*please name and explain)*

SECTION C: BACKGROUND INFORMATION

In which age category are you? ☐21-30 ☐31-40 ☐ 41-50 ☐ 51-60 ☐61-70 ☐>70 years

Sex: ☐ Male ☐ Female

In which country do you work? _____

Please describe your primary training. (*please state e.g. BSc. Population Studies, PhD. Statistics)*

_____

What type of institution do you work for? *(please select as many as apply)*

☐ Research ☐ Health ☐ Academic ☐ Ministry/Agency of Health

☐ International Organization ☐Other (*please state*)

What is your role in your institution? *(please select all that apply)* ☐ Researcher

☐ Administrator ☐ Ethics Administrator ☐ Ethics Committee Member

☐ Public Health Professional ☐ Policy Maker ☐ International/Non-National Public Health

☐ Expert ☐ Clinician ☐ Other (*please state*) _____

How long have you performed this role? *(please state in years)*_____

Have you ever attended a workshop or training in research ethics? ☐ Yes ☐ No

(*please select period of training*) ☐ <1 week ☐ 1 week ☐ 2 weeks ☐ 1 month

☐ fellowship program ☐ degree

Thank you very much for your time, attention and responses. If you have questions or further thoughts, please feel free to send me an email to evelyn.anane-sarpong@unibas.ch. Again, thank you.

Appendix 3

Letter of Invitation, Information Leaflet, and Consent Declaration for Interview

Project title

New models of public health research: Optimizing Ethics in Research Using Public Health Data in Resource Limited Countries

Dear Sir or Madam,

I am a PhD student at the Institute for Biomedical Ethics (IBMB), University of Basel, Switzerland. As part of the requirements for my doctoral degree in Public Health Ethics, I am undertaking this project funded by the Swiss Tropical and Public Health Institute in collaboration with the IBMB.

The overall project aims at exploring and documenting characteristics of research involving use of pre-collected public health data (RUPD): the experiences and challenges that researchers and ethics committees face in their practice and in applying ethics guidance. The ultimate goal of the project is to develop a practical and context appropriate guidance document to support future ethical conduct and review of RUPD.

I am, through this letter, requesting your kind participation in the study by giving me an opportunity to hold an interview with you. Questions will center on your expert experiences and opinions about RUPD, as well as your recommendations for its ethical conduct. Your responses, together with that of other colleagues, will be synthesized with existing literature on public health ethics, surveillance ethics and research ethics to, if feasible, develop a RUPD-specific ethics framework.

Participants will be from Ghana and Tanzania.

Please be assured that you are free to choose not to participate in this study, even if your name was suggested or recommended by someone else. You may also decline to answer a specific question without any consequence or prejudice to you. Be assured that because the process is anonymized, there will be no attempt to link answers to you as an individual or your institution.

I thank you in advance for your time and support.

Sincerely yours,

Ms. Evelyn Anane-Sarpong
Institute for Biomedical Ethics, and Swiss TPH
University of Basel, Bernoullistrasse 28,
4056 Basel, Switzerland
Email: evelyn.anane-sarpong@unibas.ch.

This leaflet summarizes key points necessary to allow you to reach a decision to or not to participate.

1. **Who is participating in the study**? - You have been approached to participate in this study because you are a/an
    a) key stakeholder who provides professional services for the activities of the Health and Demographic Surveillance System (HDSS);
    b) head of an HDSS;
    c) ethics committee administrator and or member in Ghana and or Tanzania;
    d) independent (non-HDSS) public health professional with expertise in HDSS and public health research activities in Ghana and or Tanzania;
    e) senior personnel of the national health ministerial agency in Ghana or Tanzania;
    f) public health expert working with a locally based international health agency such as the WHO.
2. **Study procedures you will be involved in** - You will be asked to participate in an interview lasting no more than 1 hour. A semi-structured interview guide will be used to lead the discussion. If you permit it, the interview will be audio recorded.
3. **Risks and Benefits** - Except for your time to be interviewed, there is no foreseen risk associated with taking part in this study. Upon study completion, only anonymized data will be presented in reports and publications resulting from the data. The results of this project will contribute to the development of a framework for RUPD, or at a minimum, increased knowledge on ethical issues surrounding RUPD. This will help improve advancements that HDSSs are making in research and scientific publications. As a token of appreciation for your time, a small souvenir (Basel embossed pen) will be presented to you. At the close of this project, access links to all published pieces will be communicated to you or your institution.
4. **Confidentiality** - Be assured that because the process is anonymized, there will be no attempt to link answers to you as an individual or your institution. Signed consent documents will not at any point be linked to completed interview records, which will not be shared with anyone other than members of the PhD project team.
5. **Participation and Withdrawal from the study** - You are free to choose not to participate in this study, even if your name was suggested or recommended by

someone else. You may also decline to answer a specific question without any consequence or prejudice to you. You may stop the interview at any time.

6. **Ethical Approval** - This proposal has been ethically reviewed by the Ethics Commission of North Western and Central Switzerland that oversees ethics review at the University of Basel, and ethics committees in all participating sites in Ghana and Tanzania.
7. **Contacts** - If you have any question concerning this stud, during and or after data collection, please contact Evelyn at evelyn.anane-sarpong@unibas.ch. You may also use the following phone contacts: +233 (0)20 --- (Ghana) or +255 (0)--- (Tanzania) until February 28, 2015, and subsequently, +41 61 ---.

If you have any complaint, you may communicate to me at the address above, or to the Administrator of the --- IRB, Ms.---, if appropriate.

Declaration of Consent

I understand that

- this is an academic project, the content of which has been explained to me
- my participation is given of my own free will without any consequence or prejudice
- all correspondence, including audio recordings will be kept confidential
- no identifying information will be used in discussions and in publications
- if I feel unable or unwilling to answer any question, for any reason, I may move on to the next or discontinue with the interview without providing any reasons.

I have been given the opportunity to ask questions which were answered to my satisfaction.

I agree to participate in this study.

…… ……..

Signature of Participant Place, Date

Consent for Audio Recording

I agree to the audio recording of the interview to facilitate data collection. I understand that due to possible risks to confidentiality of audio data (albeit minimal), transcripts made will be anonymized for both me and my research center. If I inadvertently mention mine or my center's name, they will be deleted during transcription. The tape will not be linked to this consent document. The non-identifiable tapes will be kept safely until completion of the project when they will be destroyed. Following their destruction, only anonymized paper transcripts or reports of the recordings will be kept.

…… ……..

Signature of Participant Place, Date

Thank you very much.

Appendix 4

New Models of Public Health Research: Optimizing Ethics in Research Using Public Health Data in Resource Limited Countries

To explore conceptual and practical issues of RUPD and its critical features (data-use, re-use, sharing etc.) as well as the application of existing research ethics governance structures to it. Responses obtained will enable us make recommendations for the future of public health research based on data

THE INTERVIEW GUIDE

Dear Sir or Madam,

My name is _____. As we discussed during the consent process, I am a student of the University of Basel, Switzerland. As a recap of the information I gave you earlier, we are conducting this survey involving experts with experience in the workings of the health and demographic surveillance system (HDSS), public health activities, research, and ethics. The study specifically concerns research or publications undertaken by using pre-collected HDSS data. The main purpose of this interview is to seek your expert opinions on RUPD, its characteristics, and challenges that arise in the application of existing ethics guidance to them. The ultimate goal is to synthesize your opinions with those of other participants, existing literature, and if feasible, develop an ethics framework to guide the future conduct of RUPD. *(Do you have any question up to this point?)*

So, we are meeting today to explore your own experiences as an expert involved either in public health research and or HDSS activities including research conduct, management, and oversight. I will be posing questions concerning the use of pre-collected HDSS data for new research analysis and publications and would like to hear your personal opinions about them.

Main questions in Bold, follow-on questions in Ordinary Font **and Prompts in** *italics*

1. **Could you please describe your experience with the health and demographic surveillance system (HDSS) in this country?** (*How have you been involved with them)?*
    a. **What kinds of research do they undertake?**
    b. **Do you think HDSS surveillance differs from research** (How so?)
    c. **What is the relationship between the data collected and research or publications by the center?**
    d. **Do you think that HDSS activities should be distinguished from research, for ethical regulation purposes?**
2. **Could you share any ethical issues you have experienced or which you anticipate from the secondary use of HDSS data for publications?**
3. **In your opinion, how should institutions like the HDSS that have large datasets proceed with conducting research or publications using [or sharing] the data?**
    a. What processes should be required, if any, before access and use of such data? (*e.g., seek official permission from HDSS, apply for ethics review etc.*)
    b. What conditions, if any, should a scientist or researcher satisfy in order to use or access the data? (*e.g., s/he should have participated in the data collection; s/he should be locally based)*
    c. What factors should be relevant to determine access and use of the data?
    d. Should there be limits to the scope of further use of HDSS data for research or publications?
    e. What have been your experiences?
4. **What experiences with using, sharing or re-using HDSS data for RUPD *(in your own application or anticipation)* have you found difficult to address?** *(You may consider issues like data integrity, benefits etc.)*
    a. Why is it that difficult?
    b. How can they be solved?

5. **What role, if any, does or should the following play in connection with the issues you have raised?**
    a. HDSS institution (What are your expectations here? [*Repeat for b - e*)
    b. Ethics committee
    c. National bodies you know to be linked to the HDSS
    d. International guidance
    e. Others (*please explain*)
6. **Which international research ethics guiding documents would you recommend for guidance in these matters of our discussion?**
    a. Does your selected ethics guideline properly tackle RUPD? *(E.g., the problems you mentioned earlier such as benefits, fairness?)*
    b. What gaps or weaknesses exist in relying on this document for RUPD?
    c. What could be added to make it more appropriate?
    d. What could be deducted to make it more appropriate for RUPD?
    e. Which other guidelines have you found helpful in your work?
7. **From your experience so far, do you think that developing a separate ethics guide document (e.g., a framework) is necessary?**
    a. What among issues, ethical principles etc. would you recommend to be given priority consideration in such a document?
    b. What among your own concerns would you recommend to be given priority consideration?

I would like to close our discussion by gaining some information about you, if that is alright:

1. **If you don't mind, could you please tell me how old you are** *(if s/he hesitates - in what age category are you)***?**
2. **Please describe your primary training?** (*e.g., BA. History)*
3. **What type of institution do you work for?**
4. **What is your role in your institution?**
5. **Have you ever attended a workshop or training in research ethics before?**
6. **Is there anything else that you would like to add concerning our topic of discussion?**

Thank you very much for your time and responses. Please feel free to send me an email at evelyn.anane-sarpong@unibas.ch, if you have questions or further thoughts.

Again, thank you.

CURRICULUM VITAE
EVELYN ANANE-SARPONG

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Phone: +41 78 832 49
evelyn.anane- sarpong@unibas.ch
Date of Birth: 4 January, 1976

Education and training

2014-2017: **PhD Candidate of Public Health Ethics -** Institute for Biomedical Ethics and Swiss Tropical and Public Health Institute,
University of Basel, Switzerland.
Supervisors: PD. Dr Tenzin Wangmo
Prof. Bernice Simone Elger
Prof. Marcel Tanner

09/2016: **Summer School Bioethics** - Predelut, Romania

06/2016: **Summer Academy Population-level Bioethics** - **Brocher Foundation, Hermance,** Geneva, Switzerland

08/2014: **Summer School Public Health Policy, Economics & Management** - Università della Svizzera Italiana, Lugano, Switzerland

09/2014: **Intensive Course Contemporary Ethical Issues regarding Choices in Health Care**, Katholieke Universiteit Leuven, Belgium

2007-2009: **MPH Health Research Ethics** - School of Health Systems and Public Health, University of Pretoria and University of KwaZulu Natal, South Africa.

06-07/2007: **Summer Institute on Ethical Issues in Human Subjects Research in Developing Countries -** The Johns Hopkins University Bloomberg School of Public Health, USA.

06/2007: **Intensive Bioethics Course** - Georgetown University, USA.

2003-2005: **MSc Health Services Planning and Management** - School of Medical Sciences, Kwame Nkrumah University of Science and Technology (KNUST), Kumasi, Ghana.

1996-1999: **BA (Hons.) Social Sciences** - Faculty of Social Sciences, KNUST.

Awards

Academic

2007: Best Masters Student, South African Research Ethics Training Initiative (SARETI); Joint Program by the Universities of Pretoria and KwaZulu Natal, South Africa

1992: Best Student in Biology, English, English Literature, and Economics. General Certificate of Examinations (Ordinary Level), Our Lady of Apostles (OLA) Girls' Senior High School, Kenyasi, Ghana

1991: One of two best students selected to represent OLA Girls' Senior High School at the National Science, Technology, and Mathematics Education Clinic for selected high school girls, University of Ghana, Accra, Ghana

Grant awards

2014: Recipient, Basel-Stadt Scholarship, Young professionals from developing countries

2013: Recipient, PhD academic and research scholarship, Swiss TPH

2007: Recipient, SARETI/Fogarty International Centre and the US National Institutes of Health Scholarship (Grant Number 2 R25 TW01599-03)

Professional awards

2011: **Project Ambassador**, Mapping African Ethics Review and Drug Regulatory Capacity Project (MARC), a Council on Health Research for Development (COHRED)-University of KwaZulu Natal, South African Initiative

2005-2012: **Honorary Member**, Board of Governors, OLA Girls' Senior High School

2002: **Dean's Award**, Best Worker (per department), SMS, KNUST

Professional and research Experience

02/2014 to 02/2017: **PhD training and Research Assistance** in Public Health Ethics; under a collaborative project between the Institute for Biomedical Ethics (IBMB) and the Swiss Tropical and Public Health Institute.

- Taught one seminar on public health ethics (Contemporary Debates) in Fall 2015
- Co-organized block course on public health ethics, Spring 2015
- Undertook a quantitative survey in Ethiopia in Fall 2015
- Conducted 46 qualitative interviews in Ghana and Tanzania in Spring 2015

2011 to date: **Assistant Lecturer of Bioethics,** School of Medical Sciences (SMS), University of Cape Coast (UCC), Cape Coast, Ghana

2008–2013: **Research Ethics Training Facilitator and Local Advisor** on Ethical Issues in Clinical Trials (the RTS,S Malaria Vaccine Trial Team, Agogo)

2008–2013: **Research Ethics Training Facilitator** for local institutions (please see workshops)

2008-2011: **Research Ethics Committee Administrator,** Committee on Human Research, Publication and Ethics, SMS, KNUST

2005-2006: **Program Manager,** Bill and Melinda Gates-SMS, KNUST Linkage Program

2001 - 2006: **Administrator, Advisor on Ethical Issues, Financial Manager and Data Entry Personnel** for the following Clinical Trials:

- Severe Malaria in African Children Network - SMAC

- Randomized controlled study on Safety and Efficacy of Rectal Artesunate in Pediatric Patients (Malaria) in KATH
- Human Genetic Variants Influencing Susceptibility and Resistance to Severe and Complicated Malaria
- Malaria/Genetics Study
- SMAC's Ocular Fundus in Cerebral Malaria

2000: **Assistant Budget Analyst**, Ashanti Regional Directorate of the Ministry of Finance, Kumasi, Ghana

Conferences and seminars organized (with international sponsorship)

11/2010: Organizer and presenter, 2nd Health Research Ethics Seminar of the SMS, KNUST, held in Feyiase, Ghana.

05/2009: Organizer and presenter, 1st Health Research Ethics Seminar of the SMS, KNUST, held in Feyiase

Training in operation and functioning of international research ethics committees

07/2007: The Johns Hopkins University Institutional Review Board, Baltimore

01-05/2007: University of Pretoria Research Ethics Committee, Pretoria, S. Africa

Courses undertaken during PhD Training

Summary of credits attained: **30 ECTs; 22 ECMECs; and 2 MDCCs**

University of Basel

Code	Course Title	Credits
37799	Public health ethics	**2 ECTs**
41621	Contemporary Debates in Bioethics: Public health ethics	**2 ECTs**
43202	Advanced Research Methods in Bioethics – Data Analysis	**1 ECT**
43203	Research Methods in Bioethics – Data Analysis	**1 ECT**
39429	Contemporary Debates in Bioethics: Insights into prisons	**2 ECTs**
39425	Advanced Research Methods in Bioethics – Data Analysis	**2 ECTs**
39426	Research Methods in Bioethics – Data Analysis	**1 ECT**
36270	Advanced Research Methods in Bioethics – Specialized topics	**2 ECTs**
36272	Research Methods in Bioethics – Specialized topics	**1 ECT**
36000	Roundtable Review of Research and Reflection	**2 ECTs**
36271	Contemporary Debates in Bioethics – Pediatric ethics	**2 ECTs**

University of Zürich

OMFS14IP	Introduction to Philosophy	**2 ECTs**
OMFS14CE	Clinical Ethics Cases Seminars	**2 ECTs**
OMFS14SU	Bioethics Research Methods	**3 ECTs**

Credits attained from additional courses

09/2016:	Summer School in Bioethics, Predelut, Romania.	**2 ECTS**
08/2014:	Summer School in Public Health Policy, Economics and Management, Università della Svizzera Italiana, Lugano	**1 ECT**
09/2015	Transferrable Skills – Presentation Training	**1 ECT**
03/2015	Conducting Qualitative Research in Health	**1 ECT**
09/2015	European Congress on Tropical Medicine and International Health (ECMEC: European Continuing Medical Education Credits)	**22 ECMEC**
12/2014	Continuing Professional Development Workshop on Ethics in Healthcare Delivery (MDCC: Ghana Medical and Dental Council Credits)	**2 MDCC**

Non-scoring training and webinars attended

09/2015	Writing to be Published (postgraduate program)	-
09/2015	The messenger is the message	-
12/2015	Global Health Ethics Seminar: Ebola and Ethics - The Unfinished Agenda (WHO, Geneva)	-
06/2015	Maximizing Benefits to Research with Human Subjects through Data Sharing (PRIM&R, USA)	-
09/2014	Ethics and Ebola Challenges for Care Givers & for Public Health (Johns Hopkins Berman Inst. of Bioethics, USA)	-
04/2014	Research Ethics Case Study (Johns Hopkins Berman Inst. of Bioethics)	-

Safety and security courses for field work

12/13	United Nations Department of Safety and Security Basic Security Courses I and II	**Passed**

Publications

- **Anane-Sarpong E,** Wangmo T, Sankoh O, Tanner M, & Elger B.S. (2018) Application of Ethical Principles to Research Using Public Health Data in the Global South: Perspectives from Africa. *Developing World Bioethics;* 18(2):98-108. doi: 10.1111/dewb.12138. Epub 2016 Dec 22.
- **Anane-Sarpong E,** Wangmo T, Ward CL, Sankoh O, Tanner M, & Elger B.S. (2018) "You cannot collect data using your own resources and go and put it on open access": Perspectives from Africa about public health data sharing. *Developing World Bioethics*; 18(4):394-405. doi: 10.1111/dewb.12159. Epub 2017 Jul 25.
- **Anane-Sarpong E,** Wangmo T, & Tanner M. (2019) Ethical principles for promoting health research data sharing with sub-Saharan Africa*. Developing World Bioethics* Accepted for publication.
- Ward CL, Shaw D, **Anane-Sarpong E,** Sankoh O, Tanner M, Elger B.S. (2018) Defining Health Research for Development (HRD): The Perspective of Stakeholders from an

International Health Research Partnership in Ghana and Tanzania. *Developing World Bioethics*; 18(4):331-340. doi: 10.1111/dewb.12144. Epub 2017 May 3.

- Ward CL, Shaw D, **Anane-Sarpong E,** Sankoh O, Tanner M, Elger B.S. (2018) The ethics of health care delivery in a pediatric malaria vaccine trial (PMVT): The perspective of stakeholders from the malaria vaccine candidate trial RTS,S in Ghana and Tanzania. *J Empir Res Hum Res Ethics;* 13(1):26-41. doi: 10.1177/1556264617742236. Epub 2017 Nov 28.
- Ward CL, Shaw D, **Anane-Sarpong E,** Sankoh O, Tanner M, & Elger B. (2017) The Ethics of End of Trial Obligations in a Paediatric Malaria Vaccine Trial: The Perspectives of Stakeholders From Ghana And Tanzania. *J Empir Res Hum Res Ethics*; 13(3):258-269. doi: 10.1177/1556264618771809. Epub 2018 May 13.
- **Anane-Sarpong E,** Wangmo T, Tanner M, Sankoh O, & Elger B.S. (2017) Probing and Addressing Missing Links in the Ethics of Research Using Public Health Data: A Qualitative African Study. *Journal of Public Health in Africa.* Under review.
- Wangmo T, Hauri S, Gennet E, **Anane-Sarpong E**, Elger B.S. (2018) A systematic analysis of empirical research in bioethics journals: Is bioethics continuing its empirical trend? *BMC Medical Ethics*; 19(1):6. doi: 10.1186/s12910-018-0246-9
- Olola CHO, Missinou MA, Issifou S, **Anane-Sarpong E,** Abubakar I, Gandi JN, Chagomerana M, Pinder M, Agbenyega T, Kremsner PG, Newton CRJC, Wypij D, Taylor TE, on behalf of the SMAC Network. (2006) Standardized data collection for multi-center clinical studies of severe malaria in African children: Establishing the SMAC network. Trans R Soc Trop Med Hyg.
- **Anane-Sarpong E**. Stakeholder perceptions of the ethics of qualitative health research in Ghana [MPH Thesis]. Pretoria (Gauteng): University of Pretoria; 2009
- **Anane-Sarpong E**. Designing a Management System for the Coordination of Research Projects at the School of Medical Sciences, KNUST [MSc Thesis]. Kumasi (Ashanti): Kwame Nkrumah University of Science and Technology; 2005

International conference presentations until thesis defence in May, 2017

Oral presentations

- **Anane-Sarpong E,** Wangmo T, Sankoh O, Tanner M, & Elger B.S. (2016) Ethical guidance challenges in research involving pre-collected, active public health data in resource-limited countries. *World Congress of the International Association of Bioethics Conference,* Edingburgh, Scotland
- **Anane-Sarpong E,** Wangmo T, Sankoh O, Tanner M, & Elger B.S. (2015) Vexation of ethical guidance: Walking the tight rope of research involving pre-collected public health data, *Oxford Global Health and Bioethics International Conference*, Oxford, UK
- **Anane-Sarpong E,** & Elger B.S. (2014) Containing an outbreak involving frail systems and vulnerable populations: The Ebola Experience. *EACME Conference on Frailty,*

Vulnerability and Social participation: Ethical, social and political challenges for an inclusive society, Lille, France

- **Anane-Sarpong E** and Wassenaar D.R. (2010) Stakeholder perceptions of the ethics of qualitative health research in Ghana. *UNESCO Chair in Bioethics International Conference on Bioethics Education: Contents, Methods, Trends.* Zefat, Israel (Sponsorship for this conference constituted my award for being the best student of the SARETI Class of 2007)
- **Anane-Sarpong E** and Wassenaar D.R. (2010) *2nd African Health Research Ethics Symposium*, Durban, South Africa

Poster presentations

- **Anane-Sarpong E,** Wangmo T, Sankoh O, Tanner M, & Elger B.S. (2015) Justifying re-use of public health data for research in low-to-middle income countries and ethical issues. *UNESCO Chair in Bioethics Conference on Bioethics, Medical Ethics and Health Law,* Naples, Italy
- **Anane-Sarpong E,** Wangmo T, Elger B.S., Tanner M, & Sankoh O. (2015) Vexation of ethical guidance: Walking the tight rope of research involving pre-collected public health data. *INDEPTH Scientific Conference*, Addis Ababa, Ethiopia
- **Anane-Sarpong E,** Wangmo T, Sankoh O, Tanner M, Dawson A, & Elger B.S. (2015) New Models of Public Health Research: Developing an Ethical Framework for Research using Surveillance Data in Resource Limited Countries. *UNESCO Conference on Bioethics, Medical Ethics and Health Law,* Jerusalem, Israel

Invited presentations

12/2014: Invited speaker - Ethics of First-in-Human Use of Experimental Agents in Healthcare Delivery: Issues surrounding the 2014 Ebola Virus Disease Outbreak, SMS, University of Cape Coast, Ghana

05/2013: Invited speaker - Good Clinical Practice and Ethics in Research Workshop, Agogo, Ghana

05/2013: Invited speaker - Ethics in Research Seminar, Coconut Grove Hotel, Accra

03/2013: Invited speaker - Grant and Proposal Writing Workshop, African Royal Beach Hotel, Accra

04/2012: Invited speaker - Good Clinical Practice and Ethics in Research Workshop, Agogo

08/2008: Invited speaker - Orientation into Ethical Issues surrounding Health and Demographic Surveillance Systems at the INDEPTH Network's Annual General Meeting, Dar es Salaam, Tanzania

07/2009: Invited speaker - Ghana-Michigan Collaborative Alliance's workshop on Health Research Ethics for lecturers from public universities in Ghana and staff of the Ghana Health Service, Kumasi, Ghana

Additional conference attendance (participation only)

11/2016: SCOPES Workshop on Teaching Bioethics, Basel

10/2016: International Conference on Dignity in Mental Health, Cape Coast

06/2016: International Network on Feminist Approaches to Bioethics' World Congress, Edinburgh

05/2016: FEAM Spring Conference on Precision Medicine, Berne

04/2016: Harvard Annual Bioethics Conference, Harvard Medical School, Boston

04/2016: Building a Biomedical Information Commons: Ethical and Policy Issues, Harvard, Boston

04/2016: Global Health and Innovation Conference, New Haven, Connecticut USA

03/2016: Virtues in the Ethics of Life, Pontifical Academy for Life Workshop, Rome, Italy

01/2016: European Conference on Prison Health, Basel

06/2015: SCOPUS Introductory Workshop, Basel

06/2015: Global Ethics - Responsible Leadership in Action: The Value of Values. Geneva

06/2015: **E**thical Universities (symposium), University of Basel

05/2015 Medical Anthropology Symposium, University of Basel

11/2014: Ebola Basics Seminar, Kumasi Centre for Collaborative Research, KNUST

09/2014: Ethics of Health Systems Research in Low and Middle Income Countries, Brocher Foundation, Hermance, Switzerland

04/2014: Is "'Value for Money' the Best Approach for Improving Weak Health Systems? (Seminar) Basel

09/2013: Research Within Bounds - Protecting Human Participants in Modern Medicine and the Declaration of Helsinki, **Brocher Foundation, Hermance, Switzerland**

04/2012: Global Forum for Health Research by the Council on Health Research for Development, Cape Town, South Africa

12/2011: American Society for Tropical Medicine and Hygiene's 60th Annual Meeting on Global Health, Philadelphia, USA

09/2011: African Research Ethics Committee Administrators' Conference, Kasane, Botswana

06/2010: 1st Continent-wide meeting to harmonize Standard Operating Procedures for ECs in Africa, Zanzibar, Tanzania

11/2008: Science with Africa Experts Meeting to Develop Guidelines for Health Research in Africa (organized by the United Nations Economic Commission for Africa), Ethiopia

08/2008: Strategic Management of Health Research Sites, Maputo, Mozambique

09/2007: Consultation on Ethical-Legal Complexities in Adolescent HIV Vaccine and Microbicide Trials, Durban, South Africa

07/2008: Advanced Health Research Ethics for Investigators in Africa, Dar-es-Salaam, Tanzania

10/2006: Good Clinical Practice Training Course for Investigators, Kilifi, Kenya

09/2006: Basic Health Research Ethics Training Course, University of Dar-es-Salaam, Tanzania

Additional Information

Professional Membership

Since 2015: Member, International Forum of Teachers, UNESCO Chair in Bioethics

Since 2014: Member, Public Responsibility in Medicine and Research (PRIMR)

Since 2011: Member, University Teachers Association of Ghana

Committees

2011- 2013: Member, Problem Based Learning Committee, SMS, UCC

2011 - 2013: Member, Student Electives Committee, SMS, UCC

2012 - 2013: Member, Medical Students' Hostel Committee, SMS, UCC

2012 - 2013: Student Counsellor, Level 100 students, SMS, UCC

2011 - 2012: Student Counsellor, Level 200 students, SMS, UCC

Since 2005: Annual Mentoring Program for students of the OLA Girls' Senior High School

Computer skills

MS Excel: Excellent working knowledge

MaxQDA: Good working knowledge

SPSS: Basic knowledge

Stata: Basic knowledge