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Article

## Enhancing patients' autonomy by involving them in research ethics committees

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### Abstract

**Objective:** Although clinical trial participants are the most affected by research ethics committee's decisions, they are not formally represented on Swiss committees. We aimed to find out what patients think about the idea of being members of such committees.

**Design:** Latent thematic analysis was used to analyse the interviews.

**Setting:** Patients were recruited in a Swiss university hospital.

**Participants:** The study involved 26 patients suffering from diabetes or gout.

**Interventions:** We conducted semi-structured interviews.

**Main Outcome Measures:** We explored what patients think of being established members of research ethics committees.

**Results:** We identified three different attitudes among our participants regarding participation in research ethics committees: (i) positive attitude regarding the idea of being members of such committees, (ii) ambivalent attitude and (iii) negative attitude. Patients belonging to the first group (i) often mentioned that they wanted their health condition to be more visible. Patients from the second group (ii) mentioned positive as well as negative aspects. Patients from the third group (iii) said that patients in general did not have enough background knowledge to be able to gain an overview of a whole clinical trial.

**Conclusions:** Our study adds important knowledge about the idea of patients becoming research ethics committee members by exploring their perceptions of being members. Stable patients tended to be interested in the idea of participation and some specific recommendations could be derived (patients could have an advisory instead of a decision-making role on committees). However, further studies with more patients and further quantitative research are needed.

**Key words:** research ethics committee, autonomy, stable patients

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### Introduction

According to the Declaration of Helsinki, every trial involving human beings must be approved by a research ethics committee (REC) in advance. Each committee member must be independent of the researcher and sponsor and must operate free of any other inappropriate influence [1]. RECs are constituted by members of different specialities (e.g. physicians, statisticians and ethicists). In the

UK, RECs need to include so-called 'lay members' who are independent of health services. Half of them are required to never have worked in the healthcare sector. Some RECs also include patient representatives [2]. Swiss RECs are similar as they include experts from different scientific disciplines, but they are not required to include lay members [2, 3]. Nevertheless, each state (canton) of the federalist Swiss Confederation can decide whether its REC needs to

include lay persons, defined as any person who is not a physician. However, the lay person is not necessarily a representative of patients [4]. While three cantonal RECs (Zurich, St. Gallen, Vaud) employ patient representatives, only 1.6% of Swiss REC members are patient representatives [4]. In contrast, 41.5% are physicians [4]. This means that although clinical trial (CT) participants are the group most affected by the REC's decisions, they are not formally represented on Swiss RECs [3]. Including patient representatives on RECs, however, is not necessarily enough to support patient interests. The question is whether patient representatives are able to speak for patients who suffer from other diseases. Therefore, it might be helpful to include patients rather than patient representatives or lay members in RECs and decision-making regarding CTs to ensure that patients' voices are heard [2].

A possible disadvantage of having patients as REC members could be the whole process of recruiting appropriate patients (e.g. stable patients), which could be very costly and time consuming [2]. CTs involving novel technologies (e.g. synthetic biology) and stable patients (i.e. not terminally ill), are more likely to be rejected because RECs consider it highly risky to enrol stable patients in first-in-human (FIH) trials. In these cases, the potential damage to health outweighs the potential benefit for volunteering participants [2]. Terminally ill cancer patients are a common target group for CTs, given the absence of alternative treatment options. However, decisions of patients who have a life-threatening illness may be strongly affected by the lack of treatment alternatives [5]. Indeed, patients with a high degree of psychological strain might be more likely to accept possibly high risks and be victims of the therapeutic misconception (i.e. lacking awareness of the difference between clinical research and therapeutic treatment) [6]. Moreover, the informed consent process itself can be exhausting for severely ill patients and be considered as too harmful [7]. Enrolling stable patients in FIH trials (e.g. diabetes patients) could be a way to avoid these ethical issues. Stable patients have more treatment options than near-death cancer patients. Hence, they are more likely to make free choices [5] and less likely to fall victim to the therapeutic misconception [6]. Additionally, they might benefit from the medications developed through CTs since despite limited quality of life, life expectancy is only slightly decreased [8, 9]. Therefore, RECs' tendency to reject high-risk studies involving stable patients could be criticized as unjustified paternalism [10, 11]. It has been argued that stable patients are capable of giving reflective 'independent' answers [5] and should be allowed to decide whether to take trial related risks. McKinstry [12] concludes that paternalism, especially with respect to competent patients, is rarely justified. Respect for patient autonomy is one of the four principles of modern biomedical ethics [13]. Two prerequisites for a person to be autonomous are identified: liberty and agency. This means that a person can decide independently, free from others' influence and has the capacity to act in an intentional manner [13]. Autonomy has acquired increased importance in medicine [7]. Failing to consider patients' willingness to accept risks, i.e. the paternalistic attitude of RECs [2, 11], seems to create an anachronistic situation regarding autonomy. This situation could lead to the patient's right to make autonomous decisions regarding participation in clinical research being restricted. Therefore, shifting from paternalistic decision-making to a patient-centred and shared decision-making by putting patients on RECs increases patients' ability to engage in autonomous decision-making [14]. Thus, patients should have the opportunity to participate in decision-making regarding CTs.

## Aim of the study

Given the identified advantages and disadvantages of a system where RECs include patients as members [2], we aimed to find out what stable patients think about being members of RECs. Therefore, we explored this issue using qualitative interviews from a broader study on FIH trials with stable patients.

## Methods

We employed an empirical research design with the overall goal of exploring stable patients' attitudes towards participation in RECs as established members. The data were gathered as a part of a larger interview study where patients were asked about their attitudes towards synthetic biology and related CTs [15]. A pilot study was carried out in order to ensure patients' understanding. We used the 32-item checklist from consolidated criteria for reporting qualitative research (COREQ) [16]. We obtained ethical approval from the local REC.

## Sampling and data collection

The interview study involved a purposive sample of patients suffering from diabetes or gout. Inclusion criteria for this study were that patients were (i) >18 years, (ii) stable and (iii) suffered either from diabetes or gout. The recruitment was carried out in the hospital during a time period of six months in 2014/2015 while patients were there for a routine check-up. Our recruiting physicians approached suitable patients and asked if they would be interested in participating in an interview study. Subsequently, a research assistant (trained in qualitative research) went to the hospital and asked patients if they agreed to participate. In case of agreement, patients received a participant information sheet, and an informed consent form and were given time to consider whether to consent. Afterwards, the research assistant approached the patients via phone or email and made an appointment. The interview took place at the patient's home, our research institute, or in the hospital. During the interview only the interviewer and the interviewee were present in the room. All interviews were conducted by the same research assistant. Written informed consent was obtained from all participants. On average, the interviews lasted for 44 min (range: 16–102 min). All interviews were conducted in Swiss German, transcribed verbatim and fully anonymized.

## Interview guide

After a literature search for research on cutting edge biotechnology, we developed an interview guide. Based on the previous literature research, we selected topics which should be included in our interview guide (e.g. examples of CTs and patients' current health status). The semi-structured interview guide provided a short explanation of our study and of RECs, followed by two questions regarding patients' opinion on RECs (Table 1). These two questions were specifically analysed in this paper.

## Analysis

Of the 36 patients, 26 answered the question about the topic of patient representation in RECs. Overall, 10 patients responded that due to not knowing the concept of RECs they could not give an appropriate answer. Here, we present and analyse the responses of the remaining 26 patients. We used latent thematic analysis as it is independent of a particular theory or epistemology. Therefore, it can be applied across different approaches [17]. The project did not intend to develop a

**Table 1** Questions about research ethics committees

Before a new type of treatment (e.g. gout or diabetes capsules) can be tested on patients within clinical trials, a committee of experts decides whether this trial may take place at all. This committee assesses the possible risks and benefits related to this trial, and weigh them up against each other. In Switzerland there are many different ideas about who should be represented in such a committee.

1. What do you think about this? Who should be represented in such a committee and why?
2. How do you see the participation of patients in such committees?

**Table 2** Descriptive statistics of our study population ( $n = 26$ )

Gender (male)	88.5%
Age (M*; SD*) (1 missing)	64.9 (16.599)
Education (1 missing)	
• University	19.2%
• Apprenticeship	76.9%
Household (1 missing)	
• ≤ Two person	88.5%
• > Three person	7.7%
Disease	
• Diabetes mellitus I	23.1%
• Diabetes mellitus II	38.5%
• Gout	38.5%

\*M = mean; SD = standard deviation.

theory or understand the experiences of the patients, but to study their opinions on participation on RECs. First, all authors read the interview-transcripts in order to inductively obtain preliminary themes that are not a priori defined based on a theory [17]. The authors discussed the preliminary themes. Afterwards, we agreed on themes and coded the transcripts according to the agreed themes. Member check was done by the co-authors. During the analysis for the questions analysed for this article, data saturation was reached according to Guest et al. [18]. The final themes are presented in Results.

### Study population

In total 88% ( $n = 23$ ) of the patients were males; age ranged from 26 to 91 years. Other demographic information is presented in Table 2.

### Results

We identified three different attitudes regarding participation on RECs: (i) exclusively mentioning positive aspects, (ii) ambivalence about the idea and (iii) exclusively mentioning negative aspects.

#### Positive aspects of being members of RECs

The majority were very positive about patient participation in RECs. Participants often mentioned their own benefit as a reason to participate as members. More precisely, patients saw a chance of a long-term benefit on their own health condition from participating in RECs and perhaps allowing more CTs. Another frequent reason was that patients wanted their situation to be visible. Patients also said that they have experience with the disease and therefore they can tell what it is like to live with it. For this reason, they should be able to integrate their opinions on whether a CT should be performed within an REC. Another reason for patient participation in RECS was that they possibly add different perspectives on a certain aspect of the disease (Table 3).

**Table 3** Positive aspects of being members of RECs

Patient 8: This would be good. [Good] in the sense that they [patients] talk from experience, they know what happens in the body [e.g.] of a diabetes patient. In my opinion there should be both types of diabetes patients in there [committees]. This would mirror the reality very well (...), because they [diabetes patients] know what they are talking about and you can rely on their opinion. This would be the main goal that these kinds of people [patients] are represented in such committees (...), people who know the problem (diabetes diagnosis 10 years ago).

Patient 1: To be able to see the patients' situation. He/she can, only he/she can, say how hard the disability is, caused by the disease. He/she can estimate the agony caused by the disease. A physician is not able nor is a psychologist, right. That is something only the patient can (...) and I think that [patients] should be heard and incorporated [in RECS] (gout diagnosis one year ago).

Patient 7: Because they [patients] are interested that science gets on (...), because there are a lot of things that do not work 100% yet. This could be a reason that they [patients] are interested in being part of such committees and maybe they can positively influence the whole thing (gout diagnosis <1 year ago).

Patient 16: Because he/she [patient] can maybe add some things, which might get forgotten by more educated people (diabetes diagnosis 3 years ago).

**Table 4** Ambivalent aspects of being members of RECs

Patient 25: There are pros and cons (...) which speak for and against it, right. Patients have some experiences as well. (...) if there are more [patients], there is an exchange of ideas and they could talk together and accordingly influence something in a positive or negative way (diabetes diagnosis 15 years ago).

Patient 36: I think that is delicate, because the 'ego-thinking' comes up again, yes that could bring something or it [drug, treatment] could help a little bit. I do not think so (gout diagnosis 12 years ago).

Patient 23: For this [patient participation in RECs] that they can see what is being done. Against it [patient participation in RECs] that there will be maybe a pushing [due to own profit] in order to get it [drug] developed.

#### Ambivalent aspects of being members of RECs

A smaller second group of patients was ambivalent. Participants mentioned both positive (e.g. to see what is happening; patients experience) and negative aspects (e.g. patients may not have enough knowledge; they only see their own benefit) of being on RECs. Some patients said that it does not necessarily have to be patients but independent people who are on the committee (Table 4).

#### Negative aspects of being members of RECs

Finally, a few patients did not see any positive aspects of making patients members of RECs. The main reason cited regarding why patients should not be part of RECs was that they do not have enough expertise to be able to gain an overview of the whole study. In addition, participants mentioned that they did not understand the purpose of having ordinary people on a REC (Table 5).

In summary, our analysis showed that most participants were positive about the idea of being members of RECs. Interviewees illustrated their experience and their comprehension of the disease, but also their interest in propelling research. Many patients think that present RECs do not pay enough attention to their health condition, and that only patients are able to assess it.

**Table 5** Negative aspects of being members of RECs

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Patient 13: He/She [patient] does not have the overview of the whole thing [study], of what was and what might come (...). The patient cannot determine this (diabetes diagnosis 40 years ago).

Patient 24: They [patients] cannot decide, because they [patients] have no knowledge. They [patients] only can say if this [treatment, drug] would be something for me, but if it [treatment, drug] is really good, that is something they cannot decide (...) (diabetes diagnosis 41 years ago).

Patient 28: Because I think that we as ordinary mortals do not really have an idea what really goes on [diabetes diagnosis 12 years ago].

Pat 29: (...) I need to leave this [decision] to the experts (gout diagnosis 1 year ago).

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## Discussion

To our knowledge, this is the first empirical study to specifically explore stable patients' perceptions of being REC members. The most commonly mentioned advantageous aspects were: (i) potential benefit for affected patients and (ii) the disease burden of the patients, which enables them to add new perspectives on certain aspects of the disease.

Surprisingly, although the interviewees were informed that participation in CTs does not lead to any personal benefit in terms of changes in therapy, they still anticipated personal benefit as one of the main incentives for the involvement of patients in RECs. This might be seen as a biasing factor affecting proponents of this idea, because the hope of long-term benefit for oneself might make one overlook the risks of participating. Considering this as an indicator for a persistent therapeutic misconception disqualifies this as an argument for involving patients in RECs.

However, this biasing factor does not seem to operate on a broader scale. This presumption is supported by the data of a large cross-sectional survey exploring community understanding of medical RECs [19]. According to this study the majority of the respondents were aware of the role of RECs.

The second most-mentioned motivation was disease-related knowledge, particularly regarding the accompanying psychological and physical strains, which could allow RECs to obtain additional insight into a specific medical condition. Generally, patients believed themselves to be most familiar with their specific medical issue and this specific aspect has not yet been addressed by RECs.

Interestingly, our cohort, with a relatively high average age of almost 65 years, had similar views to participants in a study investigating young participants' views on composition of RECs (mean: 16 years). Overall, participants expressed the need for a broader view provided by lay people [20].

Amongst the negative aspects mentioned in our cohort were patients' lack of knowledge compared to experts, and potential difficulties in assessing the consequences of decisions made in the context of complex studies. Similarly, professional expertise was considered important among young people [20].

Nevertheless, the argument that lack of medical knowledge could count against patients' inclusion in decision-making is not tenable. As stated by Edwards *et al.* [10], it is not the task of RECs to judge the competence of patients. As in the shared decision-making model, participating patients would have to be properly provided with all relevant information (e.g. risks and potential benefits) before engaging in REC decisions.

Overall, stable patients seem to be particularly appropriate decision-makers as they suffer from a chronic disease with a significant burden [21–24]. Due to the relatively slow progression and associated

mortality of, e.g. diabetes compared to acute diseases, stable patients are more likely to benefit from future research [23, 25]. Therefore, REC decisions on CTs might affect them indirectly over the medium-term, and the problem of 'therapeutic misconception' could have a less prominent role [6]. The most important ethical consideration favouring the inclusion of stable patients is the need to respect patient autonomy. In order to meet this requirement, affected patients should have the opportunity to participate in decision-making in RECs through their representatives. It has been claimed before that qualified individuals are in the best position to decide which risks are acceptable for them [10]. From this point of view, the exclusion of competent patients from RECs can be seen as a form of paternalism, contradicting the concept of shared decision-making. Shared decision-making—in a clinical setting—means that neither the physician ('paternalism') nor the patient ('informed choice') on his own decide what is going to be done (e.g. what kind of treatment). Instead, the decision is made together [26]. This requires the ability of an individual to make his or her own, independent choices and respecting patients' perspectives as being just as valuable as experts' perspectives [26, 27]. The impression of RECs as a paternalistic characterized decision-making body [10, 28] could be countered by enhancing patients' autonomy through involving them in decision-making.

## Limitations

The limitations of this current study relate to its qualitative design and relatively low number of participants: the subjectivity of data analysis and the limited generalizability of the results that we obtained from German-speaking patients. Furthermore, 10 out of 36 persons could not say anything about the idea of patients as members of RECs because they were lacking respective knowledge. Since our investigation only focused on stable patients, generalizable statements about other patient groups are limited. Another possible limitation could be the overrepresentation of male patients (88.5%). However, an epidemiological study showed that 80% of gout patients were male [29]. Also, a review showed a male excess in diabetes mellitus I, whereas diabetes mellitus II seemed to be fairly distributed among both sexes [30]. Generally, it cannot be ruled out that supposedly healthy lay members suffer from a chronic disease themselves, in which case their decision-making may also be affected.

## Conclusion

From the previous considerations we conclude that stable patients appear to be suitable as REC members in the field of clinical research. This is particularly true for CTs in which novel treatment technologies will be evaluated in affected but stable patients. The reasons for this are various: First, it can be argued that respect for patients' autonomy as one of the four fundamental principles of medical ethics requires the involvement of patients instead of healthy third parties (e.g. physicians, ethicists and lay members). Furthermore, the interviews revealed a tendency towards the idea of involvement of stable patients. The primary stated motivation for this was the improvement of therapeutic options in the future. This seems to be supported by the fact that chronic diseases such as diabetes commonly have a slowly progressive clinical course over several years and do not pose an acute threat to life compared to, e.g. advanced stages of cancer. In addition to this idea of being able to influence new therapeutic options in the future, there are presumably further reasons why it could be appealing for stable patients to be part of RECs. Taking part in decision-making regarding CTs could create a feeling of inclusion and respect for patient

perspectives. In this way, early integration of persons affected could influence the general acceptance of research in a positive manner. In contrast to terminally ill patients, stable patients are more likely to be able to fulfil the demanding work of a REC member because of their better health condition. Relatively slow disease progression with possible stable phases under therapy, comparatively good life expectancy and diverse treatment options especially in early stages may prevent stable patients from experimental treatment approaches.

The improvement in quality of life in the long-term instead of a short-term prolongation of life expectancy appears to be the primary objective for many of the stable patients. Therefore, the possible objection that stable patients could generally have a bias towards approving research on novel treatment technologies is not applicable. Patients could play an important role when it comes to the benefit-risk assessment of future therapeutic interventions. The main additional benefit of this patient group, compared to healthy REC members, is the disease-burden that these patients are aware of and the direct insight into patients' perspectives that they could provide.

For practical purposes it could generally make sense to reach out to stable patients that match the inclusion criteria of the planned study. The patients included in RECs should not take part in the study themselves in order to avoid biased opinions. Another important point is that patients would have to be properly informed about their role in the REC as affected patient representatives. By excluding patients from taking part in the trial and by providing detailed information the influence of therapeutic misconception should be reduced. A point of concern in this context could be that patients who take part in decision-making but do not participate in the study themselves, may overlook potential risks to participants of the trial by attaching greater weight to potential long-term benefits. To counter this, patients could have an advisory instead of a decision-making role on RECs.

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## Ethical approval

Ethikkommission der Zentral- und Nordwestschweiz (EKNZ); No. EK 193/12.

## References

- World Medical Association (WMA). WMA, *Declaration of Helsinki 2008*. <http://www.wma.net/en/30publications/10policies/b3/> (07 September 2016, date last accessed).
- Shaw D, Elger B. Putting patients on research ethics committees. *J R Soc Med* 2014;**107**:304–7.
- The Swiss Federal Council. *Organisationsverordnung zum Humanforschungsgesetz 2014*. <https://www.admin.ch/opc/de/classified-compilation/20121179/index.html> (31 August 2016, date last accessed).
- The Swiss Federal Office of Public Health. *Tätigkeiten der Ethikkommissionen für die Forschung 2014*. [http://kofam.ch/filemanager/downloads/gutachten\\_und\\_berichte/BAG\\_Zusammenfassung\\_Ethik\\_A4\\_D\\_low.pdf](http://kofam.ch/filemanager/downloads/gutachten_und_berichte/BAG_Zusammenfassung_Ethik_A4_D_low.pdf) (05 September 2016, date last accessed).
- Dresser R. First-in-human trial participants: not a vulnerable population, but vulnerable nonetheless. *J Law Med Ethics* 2009;**37**:38–50.
- Henderson GE, Churchill LR, Davis AM et al. Clinical trials and medical care: defining the therapeutic misconception. *PLoS Med* 2007;**4**:e324.
- O'Neill O. *Autonomy and Trust in Bioethics*. Cambridge: Cambridge University Press, 2002.
- Chen JH, Lan JL, Cheng CF et al. Effect of urate-lowering therapy on the risk of cardiovascular disease and all-cause mortality in patients with gout: a case-matched cohort study. *J Rheumatol* 2015;**42**:1694–701.
- Franco OH, Steyerberg EW, Hu FB et al. Associations of diabetes mellitus with total life expectancy and life expectancy with and without cardiovascular disease. *Arch Intern Med* 2007;**167**:1145–51.
- Edwards SJL. Research ethics committees and paternalism. *J Med Ethics* 2004;**30**:88–91.
- Shaw D. The right to participate in high-risk research. *Lancet* 2014;**383**:1009–11.
- McKinstry B. Paternalism and the doctor-patient relationship in general practice. *Br J Gen Pract* 1992;**42**:340–2.
- Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*, 7th edn. New York: Oxford University Press, 2009.
- Charles C, Gafni A, Whelan T. Decision-making in the physician-patient encounter: revisiting the shared treatment decision-making model. *Soc Sci Med* 1999;**49**:651–61.
- Rakic M, Wienand I, Shaw D et al. Autonomy and fear of synthetic biology: how can patients' autonomy be enhanced in the field of synthetic biology? A qualitative study with stable patients. *Sci Eng Ethics* 2017;**3**:375–88.
- Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care* 2007;**19**:349–57.
- Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;**3**:77–101.
- Guest G, Bunce A, Johnson L. How many interviews are enough? *Field Methods* 2006;**18**:59–82.
- Fritschi L, Kelsall HL, Loff B et al. A cross-sectional survey to investigate community understanding of medical research ethics committees. *J Med Ethics* 2015;**41**:545–8.
- Audrey S, Brown L, Campbell R et al. Young people's views about the purpose and composition of research ethics committees: findings from the PEARL qualitative study. *BMC Med Ethics* 2016;**17**:53.
- Stolar M. Glycemic control and complications in type 2 diabetes mellitus. *Am J Med* 2010;**123**:S3–11.
- Fowler MJ. Microvascular and macrovascular complications of diabetes. *Clin Diabetes* 2008;**26**:77–82.
- Morgan CL, Currie CJ, Peters JR. Relationship between diabetes and mortality: a population study using record linkage. *Diabetes Care* 2000;**23**:1103–7.
- Nathan DM. Long-term complications of diabetes mellitus. *N Engl J Med* 1993;**328**:1676–85.
- Collins TC, Petersen NJ, Menke TJ et al. Short-term, intermediate-term, and long-term mortality in patients hospitalized for stroke. *J Clin Epidemiol* 2003;**56**:81–7.
- Makoul G, Clayman ML. An integrative model of shared decision making in medical encounters. *Patient Educ Couns* 2006;**60**:301–12.
- Elwyn G, Frosch D, Thomson R et al. Shared decision making: a model for clinical practice. *J Gen Int Med* 2012;**27**:1361–7.
- Garrard E, Dawson A. What is the role of the research ethics committee? Paternalism, inducements, and harm in research ethics. *J Med Ethics* 2005;**31**:419–23.
- Mikuls TR, Farrar JT, Bilker WB et al. Gout epidemiology: results from the UK General Practice Research Database, 1990–1999. *Ann Rheum Dis* 2005;**64**:267–72.
- Gale EA, Gillespie KM. Diabetes and gender. *Diabetologia* 2001;**44**:3–15.