CHAPTER 13

IMPROVING THE ETHICS REVIEW OF QUALITATIVE HEALTH RESEARCH THROUGH INCREASED COLLABORATION BETWEEN RESEARCH ETHICS COMMITTEES, RESEARCHERS AND RESEARCH PARTICIPANTS

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ABSTRACT

Most qualitative health research is subject to ethics review and approval by a research ethics committee (REC). Numerous studies, though, have identified shortcomings with current ethics review practices and the challenges these present to qualitative health research. Now, researchers are increasingly calling for research to focus on possibilities for improving current ethics review practices. Practical suggestions or guidelines are needed for specific challenging methodological designs in qualitative research. The discussion here is based on

Reframing Qualitative Research Ethics
Advances in Research Ethics and Integrity, Volume 12, 217–233

ISSN: 2398-6018/doi:10.1108/S2398-601820250000012013

our reflections on, and experiences with, ethics review and our research experiences with people with dementia or psychiatric diagnoses and their families. We explore how to ensure that research participants are protected from harm but enabled to access participation in research. The inclusion of people with cognitive impairments or psychiatric diagnoses in research requires attentive consideration because they might be at a higher risk of being in a vulnerable situation. We suggest that to appropriately assess competence to consent and risks of harm, consideration must be given to the specific research design, the research participants' lifeworlds and their situational well-being. Recognising the need for increased collaboration between RECs, researchers and research participants is, we propose, one solution to better addressing ethical challenges and the shortcomings of current ethics review practices. We suggest that such collaboration would enable making research ethically 'safe' for participants and researchers by jointly developing appropriate protective safeguards.

Keywords: Dyadic interviews; confidentiality; capacity to consent; research ethics review; mental health; dementia research; ongoing consent; Germany

INTRODUCTION

The history of biomedical research has clearly demonstrated how important it is to protect research participants from harm. This applies in particular to the abuse and exploitation of people with psychiatric diagnoses, cognitive impairments and mental disability in research. Examples of this abuse include the hepatitis studies at the Willowbrook State School for Children (Staten Island, NY, USA), in which developmentally disabled children were deliberately infected with hepatitis A and B viruses, and the harmful research on people with psychiatric disorders at the Allen Memorial Institute in Montreal, Canada, without their informed consent (Bracken-Roche et al., 2016). In response, however, participants considered to be vulnerable due to a psychiatric diagnosis, cognitive impairments or mental disabilities have often been completely excluded from research for reasons of protectionism. In these cases, it was generally assumed that vulnerability is inherent in the diagnosis and that this would particularly impair free and informed decision-making (Bell et al., 2014). The strong protectionist stance of many RECs has led to limited inclusion of under-researched populations in research, meaning that there is insufficient health data relating to such populations, which is problematic (Friesen et al., 2023).[1] However, knowledge from the perspective of people with experience of mental illness and cognitive impairment is essential to tailor health and social care services to their needs. Research therefore requires involving people with severe mental illness and cognitive impairment, as they can best inform the study (Graor & Knapik, 2013; Reitinger et al., 2018). In recent years, there have been increasing efforts to redress this imbalance between necessary protection and benefit in accordance with the principle of justice.

The exclusion of population groups considered to be vulnerable has often been applied not only to high-risk biomedical research but also to quantitative and qualitative health research more generally. The exclusion of people deemed vulnerable from research has frequently been justified by an assumption that such participants have diminished decision-making capacity in relation to giving free and informed consent, especially for people with a psychiatric diagnosis. However, several scholars have highlighted that assuming limited or lacking decision-making capacity due to a person's psychiatric diagnosis is highly problematic and stigmatising (Allbutt & Masters, 2010; Bell et al., 2014; Bracken-Roche et al., 2016; Holland, 2007). Accordingly, a person's psychiatric diagnosis should not be interpreted as a sign of a lack of capacity to consent, but, rather, a presumption of 'capacity to consent' should prevail (Grisso & Appelbaum, 1998; Kim, 2010; Scholten et al., 2021). At the same time, conditions such as signs of acute psychosis or mania, impaired memory or spatial disorientations are risk factors for impaired consent capacity and must be considered by researchers (Kim, 2010).

In this chapter, we look at how RECs weigh up the potential future risks and benefits of qualitative health studies. Ethical challenges in qualitative research may result from the generally close relationship between researchers and research participants and from the deep insights that may be generated into the participants' lifeworlds (Peter & Friedmann, 2017). Ethnographic observation may raise concerns about privacy and consent, and in-depth interviews may implicate issues around potential identifiability and confidentiality (Peter, 2015; Tolich & Tumilty, 2020). Moreover, risks of harm can arise from methods of access and recruitment, data storage methods and the conclusions drawn from qualitative research (Tolich & Tumilty, 2020; Ummel & Aichille, 2016; Witham et al., 2015).

In the following discussion, we first problematise the concept of vulnerability, which is often used in the practice of research ethics review. Second, we explain the research ethics governance structure in Germany, where we conducted our research and gained our experience with research ethics review. We then draw on two cases from our own research to explore the ethical complexities and ambiguities that can arise and how we as researchers and the respective RECs dealt with these issues. These cases involved research with people with dementia and users of mental health services who had diagnoses of psychotic disorder, affective disorder, substance dependence and/or personality disorder – and their families. Based on our reflections on these two studies, we conclude by developing ideas for improving the management of potential future risks, versus benefits for research participants, within qualitative health research.

ASSESSING VULNERABILITY

Article 19 of the Declaration of Helsinki states that vulnerable groups and individuals 'may have an increased likelihood of being wronged or of incurring additional harm' and should therefore 'receive specifically considered protection' (World Medical Association, 2013). The guidelines of the Council for International Organizations of Medical Sciences (CIOMS) mention the following

special protective measures: inclusion of individuals considered to be vulnerable only in studies that pose no more than minimal risks, supplementing the consent of the individual with that of their legal representative and the use of other tailored safeguards to minimise risk (CIOMS, 2016). Although the CIOMS (2016) guidelines recognise that 'vulnerability involves […] also aspects of the ongoing participation in research studies' (p. 57), RECs generally require that the vulnerability of potential research participants be defined and determined prior to the beginning of a study (Allbutt & Masters, 2010; Friesen et al., 2023; Holland, 2007; Peter & Friedland, 2017). As individual research participants are not known at the stage of an anticipatory ethics review, RECs are likely to assess the vulnerability of potential research participants based on group characteristics (Bell et al., 2014; Potthoff et al., 2023). Several authors have pointed out that identifying vulnerability based on group characteristics can lead to enhancing the stigmatisation of, amongst others, people with a psychiatric diagnosis and those with cognitive impairments (Bell et al., 2014; Bracken-Roche et al., 2016; Carlsson et al., 2017; Øye et al., 2016; Schrems, 2014; Witham et al., 2015).

This discrimination should be avoided, and recent approaches to research ethics have accordingly argued that the term 'vulnerability' would benefit from a broader understanding rather than being used as a rigid, fixed label (Bell et al., 2014; Bracken-Roche et al., 2016; Racine & Bracken-Roche, 2019). Thus, Bell et al. (2014) and Bracken-Roche et al. (2016) argued for a relational understanding of vulnerability: according to them, relational sources of vulnerability include the educational level and health literacy of participants, as well as, from the research side, suboptimal study designs, dependencies and asymmetrical power relations between researchers and participants and lack of support for participants.

RESEARCH ETHICS GOVERNANCE STRUCTURE IN GERMANY

Whether a prior ethics review of a planned qualitative study including humans is mandatory, and which type of REC is responsible, depends on national regulations and their respective ethics governance infrastructure. There are different types of RECs in Germany, namely medical RECs, which are institutionalised nationwide, and non-medical RECs, which are affiliated with academic or professional associations. The latter can be further differentiated according to disciplines such as psychology and social sciences, although social science specialised RECs are relatively rare (RatSWD, 2017; Strobel et al., 2022; von Unger et al., 2016). Research involving humans is subject to approval by a medical REC located at a medical faculty or a medical professional organisation if one of the following conditions apply: the research is (1) conducted by a physician, (2) conducted at a medical faculty or hospital or (3) the participants are patients. Independent ethics review is not mandatory for qualitative health research involving humans that does not meet any of these criteria, although, in fact, this is relatively rare in practice (Dilger, 2017; Potthoff et al., 2024; von Unger et al., 2016). For social scientists working at a social science faculty, there is no nationwide

legal or professional obligation to obtain approval from an independent REC for research involving human subjects (Strobel et al., 2022; von Unger et al., 2016).

Medical RECs are institutionally embedded in the medical faculties of universities, the German regional medical associations (*Landesärztekammern*) or the regional state office (*Kommissionen der Länder*). They are organised in The German Association of Medical Ethics Committees (*Arbeitskreis medizinischer Ethikkommissionen*), comprising 51 of the 54 medical RECs established under regional state law in Germany. While the general procedures for medical RECs are standardised, this is only partly the case for the composition of their membership: medical RECs are composed of physicians from different specialties and must by law also include at least one member with legal training (Gauckler, 2021). Typically, a REC's makeup also includes one member with expertise in ethics, and another with expertise in biometrics (Pigeot et al., 2019). Individual REC statutes also stipulate the membership of at least one layperson or patient representative. However, there are currently no statutes that require the membership of a person with expertise in qualitative research methods (Buchner et al., 2019; Gauckler, 2021). Individual REC statutes also regulate the responsibilities and working methods of the committee, such as the basis on which external experts can be called in to advise them. Involvement of the researchers submitting the application to explain the research and its methodology is not generally envisaged: on the contrary, if an applicant is a member of the REC, they are, according to the statutes, usually excluded from the committee's deliberations on this application. All the RECs are committed to the Declaration of Helsinki (World Medical Association, 2013). The members of the REC are usually listed on the university clinic's website.

For the two research cases that we present from our respective viewpoints and discuss below, obtaining an ethics review from a medical REC was mandatory. We are both social scientists and, therefore, not subject to the professional obligation to obtain an ethics review in Germany, but the research was conducted at medical faculties and some of the participants were patients.

CASE 1: IN-DEPTH INTERVIEWS WITH MENTAL HEALTH SERVICE USERS AND FAMILY MEMBERS

The present case is based on the first author's experience with ethics review by a medical REC during the design and implementation of a grounded theory study on informal coercion and psychological pressure in psychiatry (Potthoff et al., 2022). The first author designed and conducted the study together with colleagues in Germany between 2019 and 2020. The study aim was to explore mental health service users' and their relatives' experiences of psychological pressure in their social environment and in psychiatry. Psychological pressure encompasses communicative strategies used by professionals and relatives to influence service users' decision-making to increase their adherence to recommended treatment or social rules (Hempeler et al., 2024; Potthoff et al., 2022). Persuasion, interpersonal leverage, inducements and threats have all been described in the

literature as examples of treatment pressures (Szmukler & Appelbaum, 2008). In-depth problem-centred interviews with service users and relatives of service users were planned for the data collection. Our inclusion criteria for service users were a self-reported psychiatric diagnosis and previous experience with formal coercion in mental health care. To avoid undue pressure to participate in the study, we excluded service users who were involuntarily detained at the time of the interview and included only service users who were undergoing voluntary inpatient or outpatient treatment or who were not undergoing treatment. The service users included in the study had self-reported diagnoses such as psychotic disorder, affective disorder, substance dependence and personality disorder. We generally assumed a 'capacity to consent' in order to avoid discrimination and stigmatisation based on psychiatric diagnoses (Grisso & Appelbaum, 1998; Kim, 2010; Scholten et al., 2021). Nevertheless, we were aware that conditions of acute psychosis or mania may impair a person's decision-making capacity and therefore carried out a structured capacity assessment if prospective research participants displayed symptoms of such conditions.

The ethics review of this project by the responsible medical REC resulted in a requirement that we must inform and obtain informed consent from service users before undertaking any interviews with their relatives. In the following, we will review the ethical considerations and challenges of our research project in light of this requirement. A distinction should be made between two options, which the REC did not do explicitly: (a) the inclusion of dyads consisting of a service user and their family member, and (b) the inclusion of service users and family members of other service users who did not know each other.

To understand the phenomenon of psychological pressure in mental health settings and the social environment of service users and relatives in depth, we had proposed the inclusion of dyads of service users with one of their personal relatives, so as to conduct a dyadic analysis (Eisikovits & Koren, 2010). We understand dyads to be 'individuals who have shared an intimate, common experience' (Ummel & Achille, 2016, p. 807). A dyadic analysis enables comparison of common experiences and situations narrated from the perspective of a service user and their relative. For each dyad, we had proposed to conduct two separate interviews (one with the service user, one with their relative) but not to do any joint interviews with the dyad members. This was because our main interest was in the experiences and perspectives of both parties on common situations and not their interaction in the interview situation (Voltelen et al., 2018; Zarhin, 2018). We saw a potential risk of negatively influencing the relationship of the dyads through participation, which could have caused emotional distress or mistrust. After the research ethics review, we chose to involve only service users and relatives of *other* service users who had also experienced coercion and had self-reported psychiatric diagnoses but who did not know each other. Zarhin (2018) calls this strategy involving 'social partners' (p. 851), that is, people who share similar experiences but are not connected as personal dyads. Responding to the constraints imposed by the REC, we decided to change our methodology: we were then unable to gain insight into shared experiences and perspectives of dyads on common situations and to compare them in the sense of a dyadic analysis. However, we were still

able to understand psychological pressures from the perspective of service users and of service users' relatives while, according to Zarhin (2018), minimising the risk of harm to participants. Ultimately, the REC approved an amended study protocol involving option (b) as described above (Potthoff et al., 2023). With this adapted study design, we were not obliged to implement the requirement for double consent, because the situation of interviewing service users and their relatives did not arise. We reasoned that the purpose of interviewing relatives was to understand *their own* experiences and perspectives, which would likely also include some experiences they had shared with others. In our view, such narratives of relatives must be distinguished from the collection of personal data about service users from relatives, for which informed consent would have been required.

Afterwards, reflecting on the original requirement to seek consent from service users to interview their relatives, we considered that this kind of restriction could lead in an absurd direction: if narrating experiences which relate to other people already required their informed consent, interviewees would never be allowed to talk about their experiences relating to other people without first obtaining their informed consent. Therefore, we felt that the REC's requirement for us to obtain informed consent from service users if their relatives wished to participate was not justified – at least if conducting interviews with relatives only. This is not to say that conducting interviews with dyads does not raise ethical issues, but we did not see these as being addressed by a requirement for informed consent from the service users. We even envisaged some ethical issues that would have arisen if implementing such a requirement, as we would have had to collect names and contact details from service users to obtain their informed consent to our interviews with others, even if they themselves did not participate in the study. Furthermore, we would have had to contact the service user even if the relative had considered the relationship to be very problematic. Thus, in such a case, we could have exacerbated the situation and caused harm to the participants.

Nonetheless, qualitative research involving personal dyads of patient-relative, patient-caregiver or patient-healthcare professional is widespread (Collaço et al., 2021; Gumede et al., 2019), although the literature on ethical considerations for this research is still limited (Forbat & Henderson, 2003; Ummel & Achille, 2016). Accordingly, we turn now to discussing what appropriate safeguards could be put in place to ensure safe participation when involving dyads of family members in qualitative health research. Our suggestions result from ethical considerations based on a reflection of the recruitment practices and interviews conducted as part of the presented study. We will not address methodological questions and study results here.

Ethical Considerations – Internal Confidentiality

As Ummel and Achille (2016) pointed out, research in healthcare is likely to include individuals who are in crisis or whose time is limited and precious. In these often distressing circumstances, there is a fairly high risk of causing emotional harm to participants if they receive information about each other that is

not intended to be shared. This is described as *internal* as distinct from *external confidentiality* (Tolich, 2004; Tolich & Tumilty, 2020). Internal confidentiality can be breached by interviewers if they intentionally or unintentionally disclose information from one interview to another and if study participants are able to identify each other when research results are disseminated. The risk of a breach of internal confidentiality is not limited to dyads but is higher in this model. It is almost impossible, though, to determine in advance what relatives will (or will not) share with each other, what secrets might be kept and which specific events or experiences lead to emotional distress (Gumede et al., 2019). However, pursuing our strategy of involving social partners instead of personal dyads also raised new ethical concerns. In one case, both a relative (the parent) and their adult child (the service user) wanted to take part in the study. We had to exclude one of them due to the limitations of study protocol as approved by the REC, even though this exclusion resulted in emotional distress for the dyad. The parent initially contacted me by phone and expressed her interest in taking part in the study. After speaking with the parent and confirming the interview and making an appointment, she called me again and asked if her child could also participate in an interview. Her child was very enthusiastic about the study and also wanted to express her point of view. The mother explained that they lived in the same household and that she supported her child's wish to take part in an interview. She believed that it would be good for both if they had the opportunity to contribute something from their perspective to the study.

This example shows the importance of going beyond *procedural ethics* to also take account of researchers' identification and treatment of ethical issues during the research process, which Guillemin and Gillam (2004) refer to as *ethics in practice*. In our view, this requires continuous reflection by researchers and a high level of ethical sensitivity together with a dialogue between researchers and REC that improves the basis for ethical decisions during research. In addition, to better prevent possible conflicts and emotional distress to participants, we recommend involving (potential) participants in certain decision-making processes. The present case concerns (1) the participation or non-participation of dyads and, if so, (2) the disclosure or blocking of personal information to the dyad partner. We develop these suggestions based on our reflections of our recruitment practices and interviews conducted with social partners of service users and relatives.

In one case, a service user wanted his partner, who was also a service user, to be present during the interview. He requested this before the appointment, explaining that it would make him feel more comfortable. In another case, I conducted individual interviews with two service users who were a couple living in the same household. During the first interview, the partner was in another room. However, the content of the interview did not appear to be confidential to the partner as the doors were open. At the end of this interview, the interviewee went to inform their partner (who had been resting) that it was their turn now to be interviewed. Then, she came into the room and spoke to her partner and me before I started the interview with her. The first interviewee then went into the kitchen and came back with coffee for us. During these moments when both participants were in the room with me, the atmosphere did not change; both seemed to know each

other's stories. In contrast, in two further cases, relatives who had agreed to take part in an interview and shared their household with their partner (the service user) specifically wanted to conduct the interview without their relative knowing. Accordingly, they suggested a location outside of their home for the interview. For other participants, both service users and relatives, the question of confidentiality of the interview did not arise so directly as they did not live in the same household. This was particularly the case with parents and adult children. In some cases, parents explicitly stated that they would not share what they were saying in the presence of their children (including the service user and siblings). In other cases, service users explicitly stated that they no longer had contact with their family due to negative experiences. In one case, a service user who was an inpatient at that time spoke critically about his relationship with his wife. When informing him about the study, I pointed out the confidentiality of the interview, especially towards other patients and professionals in the clinic and also when disseminating the results, and he gave his informed consent to being interviewed. Nevertheless, the treating physician informed us the next day that this patient had major worries about his participation in the interview and the statements he had made. He felt uncomfortable and was restless. A team member then contacted the participant and explained to him (as I had already when informing about the study) that he had the option of withdrawing consent. This would mean that we would delete all of his data. This conversation assisted the participant's decision to withdraw. Afterwards he felt relieved. The last example shows that participants' well-being can be harmed not only by breaches of confidentiality but also by content shared with the interviewer when confidentiality is guaranteed.

In our view, the wide range of different relationship types and degrees of openness or privacy between people in close relationships shows that strict exclusion of personal dyads before the start of a study with the aim of causing no harm is not always proportionate. What is needed instead is a situational and relational assessment of the respective relationships and the wishes of potential study participants in combination with the development of protective safeguards.

The following are possible protective safeguards that can be put in place to ensure safe participation of dyads of service users and relatives (personal or social partners):

- Comprehensive advance, and ongoing, information from the researchers on internal confidentiality and possible breaches.
- Joint preliminary discussion by researchers and (potential) participants on their needs regarding internal confidentiality and possible negative consequences of breaches of confidentiality for the respective participant.
- Joint discussion on how to prevent a breach of internal confidentiality, e.g. the interviewee could explicitly flag up a potential concern during the interview or in the preliminary discussion.
- Researchers must maintain integrity and not use the knowledge gained in an interview for other purposes in contact with the other dyad partner.
- Ongoing joint reflection on informed consent and the possibility of withdrawing consent.

- If data analysis raises sensitive topics not previously known to a dyad, the results can be disseminated either at a general level to preserve internal confidentiality or not disseminated at all. The information from the preliminary separate discussion with the two dyad partners on how to deal with internal confidentiality must be considered and is a guide for the researchers' decision.
- If distress or conflicts arise from a dyad's participation in the study, counselling from a trained counsellor/therapist outside of the research team should be offered.

CASE 2: QUALITATIVE INTERVIEW STUDY WITH PEOPLE WITH DEMENTIA

The second author's PhD research in 2013 involved an evaluation study on integrative validation therapy (IVA) (Erdmann & Schnepp, 2016), an appreciative form of communication with people with dementia. In IVA, various communicative techniques are used to recognise the subjective reality of the person with dementia and not to correct them as would be the case with reality orientation training. For example, the emotions or motivations shown by a person with dementia verbally or nonverbally are validated with short sentences such as 'You are very worried' or 'You know your duties'. Emotions and motivations are also validated by mirroring the body language of the person or by using proverbs, wise sayings, songs or biblical sayings if these sayings are well known by the person. An important goal of IVA is to give the person with dementia the feeling that their situation and emotions are understood and that their identity is recognised (Erdmann & Schnepp, 2016).

In this study, we worked methodically with Fourth Generation Evaluation according to Guba and Lincoln's methodology (1989), which involves interviews with various stakeholders of the evaluation object. In the case of the IVA evaluation, relevant stakeholders were people with dementia, their relatives and experts on dementia. We therefore planned to involve people with early-stage dementia in the study. We wanted to show them conversational situations from an educational film in which IVA was being used and then ask them a few questions about what they thought and felt about these situations. The film showed conversational situations in which people with severe dementia were shown doing something that made sense to them but was nonsensical for healthy people. For example, one scene depicted a former shopkeeper who was physically re-arranging laundry that had been hung on a laundry rack to dry. Mentally, this person was organising goods in the shop where they had worked. A geriatric nurse positively recognised the (for others) nonsensical action – and thus demonstrated IVA (Erdmann & Schnepp, 2013). Interviewing people with dementia about how the nurse behaved in this situation and therefore including them in our research appeared to also be ethically appropriate, as some authors have been extremely critical of the systematic exclusion of people with dementia in research projects (Hellström et al., 2007; Wilkinson, 2007).

Despite several arguments in favour of involving people with dementia, the REC which reviewed the proposal recommended that this research project should preferably include relatives of people with early-stage dementia rather than those individuals themselves. The basis for this decision was a concern that when showing an excerpt from an educational film on IVA, people with dementia 'face the problem of possible uncertainty or provocation of emotional breakthroughs' (Erdmann & Schnepp, 2013). Although the REC did not specify what kind of emotions can occur, it can be assumed that unwanted emotions were meant, such as sadness, fear, worry or anger. The committee also proposed, as an alternative, an 'assessment of the individual risk situation by a familiar and gerontopsychiatrically experienced physician' (Erdmann & Schnepp, 2013) before any inclusion of a person with early-stage dementia. However, as people with early-stage dementia usually still live at home and are treated by various doctors who would have had to check the risk situation, this approach would have resulted in considerable additional work not only for the researchers but also for the people with dementia and the various doctors. Based on these considerations, we decided to exclude people with dementia and to interview relatives instead, despite knowing that those affected by dementia and their relatives do not necessarily always have the same interests (Erdmann & Schnepp, 2013).

The REC's recommendation in effect excluded people with early-stage dementia from participating, as the risk assessment by a physician with expertise in geriatric psychiatry appeared to be difficult to carry out in practice. The question is whether the ethics committee could have recommended other, more practical alternatives. In this context, the constitution of the REC is also interesting: the members of the committee were a clinical pharmacologist, a dentist, an ethicist (pastor), a lawyer/physician, a human geneticist, a radiologist and a mathematician. It is quite possible, then, that none of the members had any in-depth or specialised professional experience either with people with dementia or with qualitative research, and it is therefore questionable whether this committee had sufficient expertise to recommend other alternatives. But what alternative courses of action would have been possible and ethical? We make some suggestions below:

Ongoing Consent Instead of an One-off Consent and the Assessment of the Emotional Well-being

The recommendation of the REC in our example above suggests that its members assume that people with mild dementia cannot weigh up the risk (of an emotional breakthrough) posed by the research against the benefits themselves, but that only a doctor trained in geriatric psychiatry can do so. However, as dementia develops slowly, people with a dementia diagnosis are not immediately incapable of giving consent; rather, the ability to give consent depends on the progression of the disease and can vary depending on the time of day, concentration, motivation and general well-being (Gove et al., 2019). Considering that emotional breakthroughs can also occur in interview situations with participants suffering from other debilitating illnesses such as terminal cancer or motor neurone disease, it is inconceivable that people with dementia who are able to consent should be

deprived of the opportunity to contribute to research. The questions that need to be answered are: in which cases, in which phase of the research process, and how, can the capacity to consent be determined, and who is responsible for this. We cannot assume that a person with a dementia diagnosis automatically has a limited capacity to consent, yet testing all such patients to assess their capacity, regardless of their clinical symptoms, may unintentionally stigmatise them and undermine their dignity. However, if researchers, the family or caregivers recognise clinical symptoms such as impaired memory, spatial disorientations, functional disability, poor concentration or communication, behavioural problems, fluctuation in mental performance or emotional dysfunction (Blossom & Brayne, 2014), then a structured evaluation of the capacity to consent may be appropriate. In addition, we should keep in mind that other reasons can cause a lack of capacity to consent, such as alcohol, medication, insomnia, etc. If we also cannot assume that the capacity to consent and the emotional resilience of people with dementia are not always equally good, they should not only be evaluated once prior to the start of the research but also during the research itself, for example, during the interview. However, this can only be done by the researcher themselves, unless an additional competent person is present at the same time. For this purpose, Dewing (2008) developed the 'process consent method', which entails as a first step generating biographical knowledge about how the person with dementia behaves when in a state of well-being. Taking this approach, a person's usual level of well-being should be recognised, and a description of their typical facial expressions for different levels of well-being should ideally be established to assess the person's emotional state. With this knowledge, a person's emotional state can be assessed at any time during the interview by the researcher themselves. Alternatively, a proxy who knows the person well could perform the role of tracking their well-being during the interview (Dewing, 2008). Should a person's well-being deteriorate significantly during their interview, the proxy could also act supportively.

Assessment of Capacity for Informed Consent

Assessing capacity to grant informed consent can be carried out with structured procedures. The most well-known and best validated questionnaire is the MacArthur Competence Tool for Clinical Research (MacCAT-CR) (Gilbert et al., 2017). This tool measures the capacity for informed consent on four dimensions: 1. understanding of the research project and procedures; 2. appreciation of the effects of research participation on the person themself; 3. reasoning about taking part in research; and 4. capacity to formulate a choice. Kim et al. (2001) tested the capacity for informed consent in a clinical trial with 37 people who had mild to severe Alzheimer's disease (AD) compared to 15 healthy elderly people who did not have AD. The proportion of people with AD who were unable to give informed consent depended on where the cut-off point was set. With a normative definition of the cut-off point (two standard deviations from the average of the comparison group), the incapacity on at least one dimension of the tool was 84% in the AD group. When the cut-off point was set by the judgement of

three experts, however, the proportion of people with AD who were deemed not to have capacity in this context was only 62%. Conversely, this means that some people, despite their dementia, were competent in all four dimensions of capacity to consent (Kim et al., 2001). It would therefore be entirely possible to conduct studies with these people ethically, if the ability to give consent is checked with the MacCAT-CR when clinical symptoms are obvious and is continuously checked as part of ongoing consent. However, when obtaining informed consent, dementia-friendly methods should be used according to cognitive capacity. The information can also be communicated in plain language and possibly supplemented with pictures, objects or short videos (Dewing, 2008). Educational interventions for people with dementia could possibly improve their decisional capacity: Carpenter et al. (2000) used an abbreviated form of the MacCAT-CR to evaluate an educational intervention in patients with schizophrenia to improve their decisional impairment. During two 30-minute sessions, the study protocol was reviewed, information was provided, patients could ask questions and examples were given to illustrate the educational material. The authors tested the hypothesis that a reduced capacity for informed consent can be improved by the educational intervention. Indeed, the results showed a significant improvement in the understanding scores of patients participating in the educational sessions (Carpenter et al., 2000). This example shows that careful education can improve the informed consent process with people who are cognitively impaired.

CONCLUSION

Rather than excluding people with psychiatric and dementia diagnoses or intellectual disabilities from health research as a precautionary measure for their own protection, we strongly recommend enabling their access to research that is relevant to them. In any case, exclusion should never be based on diagnosis, as this would constitute discrimination (Bell et al., 2014; Carlsson et al., 2017; Øye et al., 2016; Schrems, 2014). However, enabling access to safe participation in research requires careful consideration. As our reflection on these cases shows, for a more appropriate assessment of the capacity to consent and the risks of harm, all three of the following dimensions should be considered: the specific research design (e.g. dyadic or non-dyadic interviews, participant-friendly study information, ongoing consent), the lifeworlds (e.g. dynamics in close relationships, dependencies, institutional settings) and the situational well-being of the research participants.

One way to achieve this, from our point of view, is to recognise and address the need for increased collaboration between RECs and researchers before, during and after research ethics review. Ethics review should not be one-sided, but a deliberative process between researchers and RECs, as this will allow for the development of a deeper understanding of the ethical challenges that research might raise. A deliberative process requires a spirit of collaboration and respect for each other's expertise (Brown et al., 2020; Carniel et al., 2023; Hickey et al., 2022). Prerequisites for developing respect for each other's expertise are that at

least one member of the ethics committee has expertise in the field of research being reviewed, that the researchers perceive the ethics review as an opportunity for improvement and that both sides listen and communicate respectfully (Guillemin et al., 2012; Potthoff et al., 2024).

To enable consideration of knowledge about the respective lifeworlds of study participants, we propose two strategies. First, specific patient representatives should be included in REC meetings, where applicable, during the review process to sensitise committee members to the possible experiences of prospective participants, in our case of people with a psychiatric or dementia diagnosis. Second, the discussion should be extended to include (potential) study participants, as they know best about their personal situation including their personal relationships and situational well-being. Participant involvement in decisions that affect them should be continuously sought throughout the research process. In addition, researchers and, where appropriate, participants could be provided with specific guidelines containing information on particular research methods or participant groups. For example, the guideline 'Overcoming Ethical Challenges Affecting the Involvement of People with Dementia in Research: Recognising Diversity and Promoting Inclusive Research' (Gove et al., 2019) offers useful ideas for managing ethical challenges in the participation of people with dementia in research. Furthermore, when involving personal dyads of family members in health research, ethical considerations could be guided by the principle of preserving the 'pre-existing relationship between participants and their continuing relationship after the interview' (Voltelen et al., 2018, p. 9) in order to facilitate the best possible conditions for the future without causing distress to participants and endangering their well-being. A useful tool would be a joint preliminary reflection by researchers and (potential) participants on their needs regarding internal confidentiality. For example, interviewees could explicitly point out sensitive topics during the interview or in the preliminary discussion, which would assist researchers conducting the research.

Overall, we believe that our recommendations are also relevant to qualitative health research more widely, beyond the examples of individuals considered to be vulnerable that have been elaborated above, as health research often involves people who are in crisis, in a distressing situation or whose time is limited and precious.

NOTE

1. RECs are also known as institutional review boards (IRBs) and research ethics boards (REBs).

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