RESEARCH ETHICS

Obtaining informed consent and other ethical dilemmas

Ruth Macklin *is a well-known bioethicist and member of IJME's international editorial advisory board. She was in Mumbai in January 2008 and spent a morning with researchers from the Centre for Enquiry into Health and Allied Themes. Also participating was* ***Diana Guerrero-Cohen****, a clinical psychologist who works with inmates in a federal prison in the US.*

In the extracts from the discussion presented below, Prof Macklin (RM) and Dr Guerrero-Cohen (DG-C) respond to researchers' queries. Some of the dilemmas that the researchers describe were faced in their own work. Others, based on questions raised by the institutional ethics committee of the Anusandhan Trust, were summarised from the IEC's report.

Unforeseen problems or inadequate preparation?

Researcher: When doing a state-wide study on abortion incidence, researchers found that in some areas the participants spoke neither of the languages into which the questionnaire had been translated, nor one that the researchers were familiar with. Arguing that not interviewing the women in question would exclude information on abortion incidence in that area, they conducted interviews using local translators. But when analysing the results, they realised that they could not be sure that informed consent was taken, or even whether the translations were accurate.

RM: *Should this problem really have been unforeseen given the number of languages spoken in India? Could this have been anticipated and arrangements made? Some problems may be unforeseen because they are not given enough thought. The languages that researchers will have to know can largely be determined in advance. And if they are not confident of interviewing in all the local languages, they must establish exclusion criteria. Of course, this has its own ethical problems: it may exclude people or groups who might benefit from being in the study.*

Researcher: I'd like to propose another scenario: Survivors of domestic violence were interviewed as part of a study on the impact of counselling in a crisis centre. The interview was conducted in Hindi and Marathi. During one of the interviews, the participant switched to Tamil, knowing that one of the researchers also spoke that language, and indicated that she was distressed. The researcher continued the discussion in Tamil, translating for her colleague. Now the researchers are concerned about the accuracy of the translation.

RM: *Again, it sounds like there was not adequate preparation. When the researcher switched to Tamil, she stopped research and started counselling. The interviewers should have been trained to stop the interview when the woman expressed her distress and refer her to a counsellor.*

As an aside, it's not enough to know the language; you also need to know the lingo. For example, when you're talking to adolescents about sex, you can't ask them about "intercourse". You need to use the language that they use. Your language has to be adolescent friendly.

Competence or decisional capacity

Researcher: In one study researchers found that some potential participants had been labelled mentally ill and incompetent by their family members. What is the definition of competence to give informed consent for participation in a study? How can competence be assessed?

RM: *Family members cannot make this assessment. It can be prejudiced. Or they may confuse mental illness with traits such as stubbornness. Or the person may be different in other settings.... Researchers must always presume that the individual has the capacity to participate in research unless there is good reason or evidence to believe otherwise.*

But what if you are unsure? How do you decide?

First, the word competence in the US is a legal term. We want to talk about "decision-making capacity". Competence requires a judicial determination, a judge, expert witnesses, an evaluation by psychologists.... So let's look at the elements of capacity. What is the definition of capacity? If you sit down with a person who seems to fall into this category, what would you do?

Introduce yourself: your name, why you are there, and so on.

That's a good idea. What next?

Ask questions. I would start by seeing if the person is oriented to reality. So I might ask if the person knows why she is here.

The term "orientation to reality" is vague. It may have nothing to do with informed consent. In the US doctors use what is called the mental status exam. They ask you the date. Does that tell you anything? You may be okay, but not know the date. Or they may ask who the president of the US is. Well, if I am asked I'd rather not say. Or they ask you to count backwards from 100 subtracting seven. Why does that show a person's mental state? A person may know his name, but not why he is in the hospital. Can such tests tell you about capacity to give consent for research?

The first thing is to ascertain that she knows that this is research. If you are asking the question in a hospital, your questions may be the same as those asked during a medical examination. For example, in Latin America, where abortion is illegal, a woman may come for medical treatment of the consequences of an unsafe abortion. The doctors treating her can be punitive. If the doctor

asks whether the woman knows why she is in the hospital, she will not respond because she is worried that the doctors may abuse her. Now, a social science researcher on abortion will ask the same questions that the doctor will ask. You need to separate research and clinical care. This would also hold for something like research on domestic violence. The doctor will ask questions about broken bones, and then the researcher will ask the same questions.

Going back to capacity, once the potential participant is clear that this is research not service delivery, and understands the goal of research, the rest is like any informed consent procedure. The researcher must be sure that they understand the risks, benefits, goals, what participation will entail, etc. And the job is the same, to ensure that the potential participant understands the questions.

Therefore, while seeking consent from individuals to participate in a research study, the purpose must be explained clearly. They can be asked to paraphrase what is said to ensure that they have understood what has been told to them. They must understand the goal of the study and the benefits, risks and consequences of being part of the study. If this is clear, the individual is capable of giving consent.

Now, let me pose another scenario, related to consent not for research but for medical treatment. Treatment for depression can consist of electro-convulsive therapy. In this case a psychologist seeking the patient's informed consent tells her that there is a one in 3,000 chance of dying from the procedure. The woman responds, "I hope I am the one." What does that say about her capacity to give consent?

She has an intention to die, so she has the capacity to give consent.

That's right. She took the risk to be the benefit. But that doesn't disqualify her. Her understanding is clear, but her values are different. Cognition is different from values. She has an affective disorder, but feelings are not cognition. On the other hand, for people with severe forms of schizophrenic illness there may be questions about their orientation towards reality.

In fact that's what the team did when deciding on a participant's mental capacity. They used their own judgement.

Signed consent

Researcher: In a study that we are conducting interviews with hospital staff trained as counsellors for a domestic violence crisis centre to find out why they were dropping out. They may be worried that written consent would put them at risk of punishment from their seniors. Their experiences may be known and identified and they are worried that others will find out that they have complained. Should we insist on signed consent?

RM: *There are many situations in which people may agree to participate, but refuse to give their signatures. For example, participants in a study on HIV, or on domestic violence, can face stigma or violence if they are identified through a signed document. In such circumstances you can go to the IEC and ask for a waiver. As long as the research is of minimal physical risk, such as social science research, and you give justification, you can make a case for verbal consent. Signatures could be replaced by attestations from researchers that individuals have agreed. Not signing should not become a barrier to participating in a study.*

But the decision not to seek signed informed consent should be applied uniformly in the study.

Also, remember that you can't promise complete confidentiality; it doesn't exist. For example, if the laptop containing all the data for a project is stolen...

The right to refuse

Researcher: What if a participant has made a comment not for the record? Can it be used if it gives critical information that will make a difference to the study?

RM: *It is hard to give a general answer. In some instances it's clear, in others one has to go on a case by case example. We don't know how that insight would help; you need to spell it out. We all think our own research is so important, that it will get published and lead to health policy change, etc. There is a big gap between doing research, arriving at conclusions and what follows.*

Also, a promise is a promise. In a way it's no difference from a woman who gives an entire interview and then says "don't use it". You have to respect her request. She has the right to withdraw from the research at any time. Sometimes it is useful for researchers to know why people have refused. But once they have refused, asking them for their reasons is actually continuing the research.

And what if you publish the research and by some chance the woman reads it and recognises her comment that you promised not to use? That violation will violate people's trust in all research.

Consent and the mystery client

RM: *Now, let me introduce a problem often faced in social science research. It often uses the "mystery client": someone who works with the research team, but deceptively enters a situation to find out about it. For example, a mystery client may pose as a patient to find out whether doctors treat their patients with respect. Can participants give informed consent in this situation?*

Early in the HIV epidemic our ethics committee received a proposal on dentists' attitudes towards people with HIV. Actors were to phone dentists' offices; in half the cases they would identify themselves as HIV-positive and in the other half of cases they would identify themselves as gay. The idea was to see if dentists refuse gay patients fearing that they were HIV-positive. Our committee said, "No way, there is no consent here. The study was then redesigned and used gay men rather than actors as mystery clients. The committee held that the dentist would be put at risk of legal action from the "patients" as there is a law against discrimination. The solution was to have dentists contacted in advance and told that fake clients would come to them but they wouldn't know who they were. Would they consent to participating in this study? Then the question is what do you disclose as the purpose of the study? If you give the real reasons then no one will consent. So the committee said give "general purposes". In social

science research if the purpose is given that can bias the study. The rule is that researchers are obliged at the end of the study to inform participants of the real purpose.

Researcher: I'd like to mention that in India an advocacy campaign on abortion by an NGO involved the use of decoys -- pregnant women asking doctors for sex selection. Revealing the true purpose of the campaign would hinder its effectiveness. But since it was an advocacy campaign, it was cleared by the ethics committee.

RM: *This is again an issue for ethics committees: should ethical standards of advocacy campaigns be any different from those for research?*

Consent, the individual and the family

Researcher: In the field, before starting research, we hold meetings in the community, distribute pamphlets about the organisation, what, why, etc. There is a possibility that the community might refuse. Sometimes the community agrees, but the family refuses to let the individual participate. If that happens, I try to persuade the family. But if after trying they refuse, what can I do? What if woman is a victim of domestic violence? Surely I want to contact her...

RM: *Some hold that informed consent is different in India; that it's not just the individual but also the family.... People have a mistaken belief that in the US it's all about individuals and their autonomy. The requirement is only that individual participants give informed consent. Not that they can't consult.*

The question is whether the family should be given the power to veto the individual's decision. What happens if the family interferes with a person's decision to give consent? Should the family have veto power regarding participation?

You want to reach her, but not at home. This is true in any case. In proposals that we see, if the place of interview is not described in the proposal we ask interviewers how they plan to ensure privacy if the interview is in the house. There is a lot of door-to-door sampling, all kinds of family dynamics, even for recruitment. You have to give a general explanation, something like: "We are studying family relations."

Obtaining consent through a service delivery programme

Researcher: In a community-based study researchers got access to participants through a collaborating agency that also provided subsidised health care in the area. The ethics committee asked if the community would confuse researchers and providers. If so, would this confusion compromise people's consent to participate?

RM: *This is not a conflict between service provision and research. Researchers would not have access to this information if the service was not being provided. In any case, the institution must be introduced as an outsider. About getting consent, the thinking has changed over time. Earlier the institution would get consent, but this is extra work, impractical. The consent form should include the statement that refusal to participate in the research study will not affect future health care in any manner, so as to assure them of their right to refuse.*

Researcher: Is it possible that if clients are asked for consent by their health care provider they will fear being denied treatment?

RM: *This would really depend on the way the information is imparted and consent sought. For example, biomedical research is a big enterprise and most participants are patients who were asked by their doctors to participate. You don't get any biomedical research done without this. You can demand that a person unrelated to the research take consent. But that person can't answer all the questions for the research team.*

DG-C*: This also depends on the topic of research. In biomedical research, the relationship between the doctor/researcher and the participant is more "objective" in the sense that the patient is mainly sharing factual information about medical history, physical symptoms, etc. Therefore, the relationship is not as personal and the participant may feel less threatened if he/she refuses to participate. It is different when a victim of domestic violence is asked to participate in research by the same mental health provider with whom the patient has already shared a personal history of abuse. This personal history may be perceived by the patient as intimate, shameful, or embarrassing, and the patient may feel more vulnerable and less able to refuse.*

Confidentiality and research in prisons

Researcher: We were going to interview prisoners on HIV/AIDS in prisons and we were told that policeman would be present during the interviews. We knew that if prisoners revealed their HIV status they would be harassed.

RM: *That's wrong, wrong, wrong. That can't be done.*

DG-C*: Even though I am an official employee of the a US prison, I face a similar situation when providing clinical care to inmates while maintaining an adequate level of patient privacy and confidentiality. For any research, the warden would have to give permission, first of all. The researcher could explain that he/she is obliged by professional ethics to keep all discussions with the inmates confidential and request the prison authorities to provide space for adequate privacy to keep the information out of earshot of the prison guards and other inmates.*

Researcher: The prison officials said they were doing this for our security.

DG-C*: Since you are conducting HIV/AIDS research, you must describe the study to the prison authorities and explain that because of the sensitive nature of the study, it is absolutely necessary that interviews be kept confidential. While confidentiality in research is always important, there is a special concern for HIV positive inmates. If other inmates learn about their medical status, they can be treated as outcasts, harassed, intimidated, or even assaulted.*

Prison authorities always bring up the question of "security" which

is primary to their mission. As researchers, we have to find ways to meet their security and safety concerns while still practise what we are trained and educated to do. I conduct my clinical interviews of inmates in private rooms with doors with large glass windows. This allows the correctional officer to keep visual surveillance of the inmate and me. I might request that the inmate be handcuffed if he/she is agitated or likely to become violent. If the officers insist on staying inside the room, I tell them I won't be able to conduct the interview unless they step outside.

RM: *There is another issue about research in prisons. In the US, federal regulations had many restrictions on research in prisons. There is a history to this restriction: in the past researchers have injected diseases into prisoners and observed them, they have got prisoners to participate in such research in exchange for money or by offering to commute the term of imprisonment.... Then last year, a new committee was set up to ask if the research was too restrictive. It concluded that research could be conducted on prisoners under certain circumstances. First, the topic had to be related to incarceration and prison conditions: for example, a case can be made for HIV-related research related to MSM or IDU. Second, a prisoner advocate had to be involved in some way in the research. This person's role was not defined but it could not be the warden. That advocate has to be credible.*

Researcher: Another issue we faced was about the use of focus group discussions with women prisoners about their health. The issue is of confidentiality.

RM: *This is always a danger in focus group discussions. When obtaining informed consent the researcher should make it clear that participants should not talk about themselves, and they should not reveal the content of FGDs to others. But whatever they say, people may talk about themselves anyway; they may reveal the discussion to others. So this is a concern.*

Consent for access to medical records

Researcher: In one study we wanted access to information in clinic records of the collaborating organisation. Would using this information for research violate the confidentiality between patient and provider? Or should the researchers go back to the participants for consent to use the records?

In another study of counselling services for survivors of domestic violence, we needed to analyse the case papers of the clinic's clients. Did we need to take the clients' (now participants') consent? Should we have sought consent for research in advance? Or should we collect this information anew during the research process? We were instructed not to ask for the history from the women since it was already recorded and doing so would make the women relive the trauma of abuse.

RM: *Patient confidentiality is much talked about but so many people see medical records: the billing department, insurance, etc. Today, partly because of the pressure of researchers in epidemiology, public health, you don't need consent for using medical records as long as no identifying information is used. But if the records are from a small clinic, it might be difficult as unique information is gathered: birthdays, ethnic background, language, residence, education...*

But if the same researchers wish to use the records to identify persons eligible for the study and to interview them, someone from the clinic should approach the persons and introduce the researchers. The participants must be clearly informed that the clinic has nothing to do with the research and that the researchers are outsiders.

Quality research vs privacy

Researcher: A 12-month study was conducted on seasonal illnesses, health seeking behaviour, access to health care, availability of food and work, and the impact on people's health. During data collection, researchers became uncomfortable that they were subjecting people to repeated interviews and asking for detailed, personal information. However, these repeated interviews and detailed information were necessary for the study.

RM: *You should do the best you can to ensure high-quality research while also respecting participants. Ensure that you give complete information while taking consent on how many interviews, how long each will be, and so on. And take their consent at each encounter. Also ensure that there is a mechanism for contacting people that respects their privacy. If participants wish to withdraw from the study at any point, they have the right to do so.*

Researcher: In this context I'd like to mention one of our experiences as students. When we were training in social work, students were placed in various institutions where they would interact with vulnerable women such as unwed teenage mothers. We were told to do case studies and ask the girls for their history. That's when we found out from one of the girls that every year social work students ask her the same questions. Is it right to subject the girl to having to repeat their life story every year to students?

RM: *Interesting. That's a comment on the training process.*

Tensions between methodological and ethical gold standards

Researcher: We were studying the impact of a government-organised resettlement of a slum community to compare conditions before and after resettlement. As the researchers started interviews, they realised that unauthorised occupants made up 10 per cent of the new settlement and were hostile to questions identifying them as unauthorised. Based on the ethics committee's recommendations, the interview schedule was modified to exclude questions on the pre-relocation period.

But the study's intention was to look at the impact of resettlement by comparing the two situations. Researchers also pointed out the undocumented occupants may not be all that vulnerable: they had obtained their accommodation because they had political clout.

And when analysing the results, the researchers realised that clubbing the responses of unauthorised and authorised occupants in a study on the effects of an organised resettlement process could distort the results. On the other hand, analysing and presenting the results separately might invite government action. Was their inclusion in the study justified? Should their responses be included? Should their responses be analysed and presented separately?

RM: *This raises the question of the ethics of publishing results. In the US there is a huge issue of undocumented immigrants -- there is immense prejudice towards this section of the population in the USA. A researcher planned a study to see whether TB was more common among undocumented immigrants. Preliminary reports had indicated that it was, and this might be because undocumented migrants are reluctant to approach health care facilities, fearing that they would be deported. The researchers wanted to find out if this was true and make a case for ensuring people health care regardless of their legal status. Now, publishing the study would make the point that migrants were being denied health care. But it could also be used to reinforce stigma and discrimination towards undocumented immigrants because they may be spreading a highly infectious disease.*

Participants at the discussion were Ruth Macklin, Diana Guerrero-Cohen, Padma Deosthali, Sangeeta Rege, Mahasweta Satpati, Shabana Ansari, Tabassum Mulani, Chandrima Chatterjee, Reena George, Rashmi Thacker, Aarthi Chandrashekhar and Sandhya Srinivasan. The discussion was documented by Aarthi Chandrashekhar and Sandhya Srinivasan.