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Are research ethics guidelines culturally competent?

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Abstract

Research ethics guidelines grew out of several infamous episodes where research subjects were exploited. There is significant international synchronization of guidelines. However,

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indigenous groups in New Zealand, Canada and Australia have criticized these guidelines as being inadequate for research involving indigenous people and have developed guidelines from their own cultural perspectives. Whilst traditional research ethics guidelines place a lot of emphasis on informed consent, these indigenous guidelines put much greater emphasis on interdependence and trust. This article argues that traditional guidelines are premised on relationships of equal power, and that often the researcher has more power that is not fully equalized by providing information. Where there is a relationship of unequal power, then focusing on interdependence and trust is more likely to achieve ethical safety. We illustrate this thesis by describing the detail of a research project looking at the use of interpreters, where we video-recorded live consultations and then interviewed the patient, interpreter and doctor. We conclude by suggesting that mainstream research ethics guidelines should pay more attention to the development of a trustworthy relationship between subject and researcher, and that, following the lead from clinical medicine, we should develop a culturally competent ethical framework for research on human subjects.

Keywords
culturally competent ethics, interpreted medical consultation, relationship, research ethics guidelines, trust

Introduction

Research ethics guidelines were developed internationally, published by the Council for International Organizations of Medical Sciences (CIOMS), with the aim of avoiding the exploitation of research subjects by researchers, and introduced a range of requirements including: that the methodology of the study has to be able to answer the question asked, that informed consent be required from research subjects, and that particular care should be taken with vulnerable populations (Council for International Organizations of Medical Sciences and World Health Organisation, 2002). Several infamous episodes are frequently cited to justify the need for such guidelines. These include: Nazi experiments in concentration camps (United States Holocaust Memorial Museum, 2012); the Tuskegee Syphilis experiment in the US (where African Americans were enrolled in a study lasting 30 years looking at the natural course of syphilis, without being aware that research was being done, and being denied effective treatment when it became available) (Reverby, 2009); and US research exposing people to radiation (Faden et al., 1996). However, the current international guidelines were written from a mainstream social and cultural perspective and as a result have been widely criticized as being inadequate for doing research involving indigenous minorities. This has led to the development of alternative research guidelines for research involving indigenous peoples. Examples include *Te Ara Tika: Guidelines for Māori research ethics* in New Zealand (Hudson, 2010), *Guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research* in Australia (Australian

National Health and Medical Research Council, 2003) and *the Tri-Council Policy Statement: Ethical conduct for research involving humans, Chapter 9: Research involving the First Nations, Inuit and Métis Peoples of Canada* in Canada (Canadian Institutes of Health Research et al., 2010). These alternative guidelines challenge the universalist assumptions built into the international guidelines: in particular, all share a greater emphasis on the development of a trusting relationship between researcher and subject.

The argument put forward in this article is that aspects of these indigenous ethical frameworks could usefully be incorporated into mainstream research in New Zealand and elsewhere. Using examples from the New Zealand context, this article will examine the premise that a trustworthy relationship between subject and researcher is central to ethical research, and that the absence of a trustworthy relationship increases the likelihood of harm to the subject.

We first provide a brief overview of the New Zealand context, including the research guidelines developed by Māori researchers for research involving Māori subjects Te Ara Tika (Māori are the indigenous people of New Zealand with recognized rights under the Treaty of Waitangi, the founding document of the country, which constitutionally mandates a bicultural partnership approach to governance). We then put forward a proposed theoretical framework for understanding and applying research ethics more generally, drawing on the concepts of relationship and trust as outlined in Te Ara Tika. We illustrate this framework by applying it to a case study of a research project on the use of interpreters in New Zealand general practice consultations.

The New Zealand context

In New Zealand a major change in the management of research ethics resulted from a research study at the National Women's Hospital (Bunkle and Coney, 1987), where an experiment by Professor Green observed the progression of cervical cancer without treatment, and without the women's knowledge or consent. This led to a parliamentary inquiry (Cartwright, 1988) (The Cartwright Inquiry). Paul succinctly summarized the way in which the findings of the inquiry affected both healthcare and health research:

> The revelations of the inquiry have damaged this trust and good faith not only in the National Women's Hospital but also elsewhere in New Zealand … The trust that existed has been shown not only to have been misplaced but to have been dangerous to the women concerned.
>
> Inevitably, new consent procedures will be recommended, especially for patients concerned in research and teaching. In the past the principal safeguard for the patient has been the integrity and good faith of the doctor. When that good faith is brought into question at the highest levels in the hospital there must be recourse to other mechanisms to protect the patient. Patients will

> welcome more information and a greater chance to make informed decisions about their treatments, but I suspect that both doctors and patients will continue to worry about the lack of trust. People who are ill need to be able to trust their medical advisers, but that trust is not bestowed with a higher degree; if it has been abused, it will need to be earned again. (Paul, 1988: 538)

The report made recommendations for far-reaching changes to laws and regulations around patient rights and research ethics. These included the establishment of a National Ethics Advisory Committee (NEAC), which developed guidelines (National Ethics Advisory Committee, 2012a; National Ethics Advisory Committee, 2012b) for research into human subjects, along with an operational standard on how to use the guidelines (Ministry of Health New Zealand, 2006).

In addition, the bicultural (Māori and Non-Māori) (Hayward, 2013) approach to governance in New Zealand developed progressively over the last 40 years and now pervades and exerts influence on most aspects of life in New Zealand, including research. The Health Research Council commissioned a group of Māori researchers to provide guidance on research with Māori subjects: Te Ara Tika (literally the correct path) (Auckland University of Technology [no date]; Hudson, 2010).

Te Ara Tika bases its process around good relationships between researcher and research participant, and particularly as the sensitivity of the research increases, the development of trust. Rather than the researcher presenting a project for consent (or no consent) there is an expectation (particularly for projects with high significance for Māori) that there is a substantial dialogue. Te Ara Tika describes an ideal of Māori taking a governance role, being involved in planning and development and the dissemination of results within the project, all with a view to ensuring that tangible outcomes are realized for Māori communities (Hudson, 2010: 7). All of the main principles covered in the CIOMS guidelines are addressed in Te Ara Tika, but with different emphasis. Informed consent is less central if the research participants have been intimately involved with choosing and developing the research project. Reciprocity is a principle not mentioned explicitly in the CIOMS guidelines (although partly covered by justice). This principle highlights that the benefits to researchers need to be balanced by benefits to the research subjects (Hudson, 2010: 17–18).

Relationship and power

The researcher–research-participant relationship is nearly always one of unequal power – power of knowledge, the power to act and the power to allocate resources – which is why there is a focus in research ethics guidelines on protecting vulnerable people. Six of the 21 CIOMS guidelines (Council for International Organizations of Medical Sciences and World Health Organisation, 2002: 49–74)

address issues around vulnerable persons/populations. However, vulnerability does not exist in a vacuum. We would argue that it is the product of a relationship of unequal power where the more powerful participant has the power to exploit the less powerful. The main power that the participant has is to refuse consent. In the absence of fully understanding the research proposal, or feeling unable to refuse to participate, or not having control over what happens to the research findings, patients make decisions based on whether they trust the researcher. Faden studied 1900 research subjects to find out how they decided to participate and commented:

> Many participants expressed that their decision to participate had been made before they had been given the consent form to sign. They knew they wanted to participate, they trusted that it was right and the details described in the form were not particularly relevant. (Faden, 1995: no page numbers)

The moral philosopher Annette Baier described trust: 'trust is appropriately placed in those who for whatever motives, welcome the equalisation of power, who assist the less powerful and renounce eminence of power' (Baier, 1995: 180). This definition is usefully applied to research ethics where a trustworthy researcher can renounce the eminence of power by providing information (knowledge), by seeking informed consent (for actions) and engaging in collaboration with research participants, seeking participants' input on what is researched, how it is researched and how the findings are disseminated (resource allocation).

Baier noted that much of Western philosophy is built around a presumption of equality of power, exemplified by the emphasis on autonomy. She points out that this philosophy has limited value when applied to relationships of unequal power, for example the dependent wife, who in the era of the great philosophers had little autonomy. She argues that if power is equal, then contractualism works well and an emphasis on choice, autonomy and independence is entirely appropriate. She then argues that this does not work well for relationships of unequal power, which are better understood by looking at issues of trust and the nature of the interdependence. Research guidelines that focus on informed consent aim to equalize power by the provision of information and consent, but fail to address the possibility that the power imbalance in the relationship cannot be equalized, in which case attention needs to be paid to processes that enhance trust and interrelatedness.

Understanding trust

Paul's commentary on the Cartwright Inquiry also focuses on the importance of trust. In this case the women misplaced their trust in Professor Green, and trust needed to be rebuilt following the findings of the Inquiry. So what do we mean by trust?

Rousseau defined trust as:

> a psychological state comprising the intention to accept vulnerability based upon positive expectations of the intentions or behaviour of another. Trust is not a behaviour (e.g., cooperation), or a choice (e.g., taking a risk), but an underlying psychological condition that can cause or result from such actions. (Rousseau et al., 1998: 395)

Lewis and Weigert (1985) divided trust into three elements: cognitive, emotional and behavioural, although they noted that in practice all three are inevitably interlinked. Cognitive trust is trust gained from knowledge, and is at the heart of the concept of informed consent. Informed consent as a process, however, is founded on emotional trust; do you trust this person to be telling you the truth? Emotional trust depends on a relationship. Trusting a complete stranger entails risk. For example, New Zealand is exceptional: it is the second least corrupt country in the world after Denmark (Transparency International, 2014). We are likely to place significant trust on the veracity of some facts, relying just on cognitive trust ('New Zealanders are trustworthy'). Thus it is likely to be seen as much safer to send money to a New Zealand web-based business, even if we have no existing relationship with that business, than to a web-based business based in the most corrupt country. Similarly, if a person purports to have a medical degree and to work for a reputable university in New Zealand, we can safely assume that this is highly likely to be true, and will thus be more willing to trust them to do research involving us.

In most circumstances we rely on both cognitive and emotional trust. Behavioural trust comes with experience: thus, the more times something is successfully purchased from a particular web-based business, the more likely they can be trusted. In addition, Rousseau added the concept of institution-based trust (Rousseau et al., 1998), which Paul alludes to when she talks of 'Trust in National Women's hospital'. Trust in an institution (a hospital or a profession) can also be divided into cognitive, emotional or behavioural. It is not uncommon for some minority cultural groups to lack trust in the hospital because of past experience of family members having died in hospital. Hospitals function on the premise that patients trust the institution. Care is provided by so many different individuals that it would be very difficult for a patient to develop an emotionally trusting relationship with all the individuals they encounter.

The NZMA Code of Ethics (New Zealand Medical Association, 2014: 2) assumes that people trust doctors: 'In return for the trust patients and the community place in doctors, ethical codes are produced to guide the profession and protect patients.' Consequently there is no focus on how trust might be developed or maintained.

Cultural differences with trust

How we reach a decision to trust another person varies a great deal between individuals and between cultural groups. Some would build their trust around their

religious faith and find it easy to trust a person who shared their faith and much harder to trust a person from another religious tradition. Others are rationalists; they make their decision predominantly on the information available. Another important distinction is the difference between more individualistic societies, as defined by Hofstede (Hofstede et al., 2010), and more collectivist societies such as, for example, New Zealand Māori. This is nicely illustrated by Māori tradition.

Māori have deeply held traditions around how 'hui' (meetings) should be conducted. Whilst this is most clearly expressed on the 'marae' (Māori traditional meeting house and grounds), for Māori the way of living implicit in these traditions flows over into all walks of life. In his book looking at the dynamics of Māori health, Durie devoted a full chapter based around these traditions to try to elucidate Māori psychology:

> Seldom however is there full appreciation of the potential of marae encounters for shaping thinking and behaviour and providing guidelines for codes of living.
>
> The Marae atea (courtyard) is used as a stage for clarifying the terms under which parties agree to come together. Formal debate (whaikorero) a hallmark of encounters on the marae atea is essentially about the negotiation of relationships. (Durie, 2001: 70)

Lacey et al. (2011) have responded to Durie's view that marae encounters can provide guidelines for codes of living by developing the 'Hui Process' as a framework for clinical encounters with Māori patients. One of the four elements of this process following the initial greeting is 'Whakawhanaungatanga' ('**noun:** *process of establishing relationships, relating well to others*') (Auckland University of Technology [no date]). Literally, it is the process of becoming family. The detail that Lacey et al. (2011) provide makes it clear that this maps very closely to establishing emotional trust. Only after this has been achieved can you proceed to 'Kaupapa' (the business of the encounter). This focus on relationship has also been applied to research ethics in the Māori Research Guidelines Te Ara Tika (Hudson, 2010), indigenous research in Canada (Canadian Institutes of Health Research et al., 2010: 105), and research on Aboriginal and Torres Strait Islanders in Australia (Australian National Health and Medical Research Council, 2003).

Trust and research ethics guidelines

Despite Paul's observations on the importance of trust, the NEAC guidelines (National Ethics Advisory Committee, 2012a, 2012b) that came out of the Inquiry's findings make no explicit mention of a trusting relationship, although it is implicit in concepts like integrity.

As a generalization, the NEAC process is one of ensuring that the research proposal has been developed properly, considering important ethical principles such

as informed consent and privacy of information. A lot of weight is put upon the research participant being able to make autonomous decisions. Relationship between the researcher and research participant is discouraged for fear of conflict of interest, and there is little discussion of how trust might be established.

The NEAC guidelines do include special clauses that relate to working with Māori that are clearly developed from Te Ara Tika:

> (4.7) …
>
> - partnership: working together with iwi, hapū, whānau and Māori communities to ensure Māori individual and collective rights are respected and protected in order to achieve health gain
>
> - participation: involving Māori in the design, governance, management, implementation and analysis of research, particularly research involving Māori
>
> - protection: actively protecting Māori individual and collective rights, and Māori data, cultural concepts, norms, practices and language in the research process.
>
> 4.8 There should be due recognition of Māori as the tāngata whenua and indigenous people of Aotearoa New Zealand.
>
> 4.9 Any potential cultural and ethical issues pertaining to Māori must be addressed through appropriate engagement with Māori, which may include discussions with appropriate representatives of specific whānau, hapū and iwi as determined by the scope and method of the study.
>
> 4.10 Comprehensive, high-quality Māori health research and information can inform both the Government and iwi on the matter of health priorities, and can assist whānau, hapū and iwi to be involved in meeting these priorities. (National Ethics Advisory Committee, 2012a: 9)

These standards applying to Māori have been developed because of the commitment to biculturalism.

The NEAC guidelines are heavily reliant on cognitive trust: informed consent and good processes. They almost completely ignore emotional trust and discourage relationship for fear of conflict of interest. They provide no expectation (except for Māori) that the research participant will have any power over decisions about what research is conducted, how the research is conducted or how the results will be disseminated.

By contrast, Te Ara Tika is explicitly based on the establishment of trusting relationships with rights and obligations. As already noted, there is an expectation, particularly for more sensitive research, that the research participants will be involved in the design of research and dissemination of results. Issues pertaining to cognitive trust are all covered but with less emphasis. This illustrates an ethical framework for research that is culturally appropriate for Māori. However, we

would argue that many of the same features are equally applicable to and of value for research with other groups, especially those typically framed as vulnerable populations.

We will now consider how this framework might apply to a particular research project involving such a population.

Case study of research on a 'vulnerable population'

Observing communication in interpreted health encounters: Processes and perceptions

Our study team (drawn from the Applied Research on Communication in Health Group[1]) brought two strands of work together in this project. The first strand was from multiple studies over the preceding 10 years based on studying the interaction in video-recorded medical consultations to understand how communication in the consultation works as it unfolds turn by turn (Dew et al., 2008; Dowell et al., 2007; Gardner et al., 2011; Stubbe et al., 2016). Ethical issues with this approach have been worked through and ethical approval has been given for the studies using this methodology. The second strand was looking at the care of patients with limited English proficiency (LEP) and the use of interpreters, both professional and ad hoc (Gray et al., 2011a, 2011b, 2012). We wanted to find out what works and why in an interpreted consultation. Owing to a lack of language concordance, LEP patients would be seen as vulnerable participants in a research project, and this increased the potential ethical problems. There are significant gaps in existing knowledge in the area of healthcare interpreting. Most previous research has focused on the perception of clinicians, patients and/or interpreters about interpreted communication using questionnaires, focus groups and/or interviews, and so is theoretically rather than empirically based. There is limited empirical evidence on (a) exactly how interpreted consultations are actually carried out (with both trained and untrained interpreters), and (b) the effectiveness of the various options for interpreting from the point of view of all participants (i.e. patient, clinician and interpreter). Even where actual interactions have been studied, existing research often only investigates one or two participant perspectives or only one category of interpreter (Gray et al., 2012).

The study looked at actual consultations between patients and GPs when interpreters were used. We made video recordings of the consultations and interviewed the patient, the doctor and the interpreter afterwards to ask them about the consultation. We wanted to include consultations that used trained interpreters as well as those where family or friends were used as interpreters.

The aim was to see how these consultations were conducted and to find out what made them satisfactory or challenging for each of the participants. By comparing what was actually said in the consultation with comments from the doctors,

interpreters and patients, we aimed to provide information that will help make these kinds of consultations more effective.

Who was involved

Primary health care services (health services)

The majority of patients were recruited via the doctors at the participating health services. These services all had policies to ensure the use of interpreters when needed, and were not-for-profit services with patient involvement in governance. They provided regular general practice services.

University Primary Health Care and General Practice Department (researchers)

The study was being run from the University Primary Health Care and General Practice (PHCGP) Department, which is across the road from the practices.

Interpreting services (interpreters)

Face-to-face and telephone interpreting services were used. The face-to-face service is a local not-for-profit organization that employs interpreters from the local communities, many of whom are leaders in their communities. The telephone service (Language Line) is a government-run service that provides on-demand telephone interpreting services to government agencies and health providers. Many patients will have used Language Line when visiting other agencies such as for income replacement benefits, or at the hospital. One interpreter in the study was employed by one of the health services. Other interpreters in the study were a bilingual nurse and six family members.

Patients

Patients in the study were all adults who had arranged their appointments in advance and were known to the doctor. Children and people arriving at the medical centre for urgent or unplanned appointments were excluded. Eight different languages are represented in the study.

Conducting the study ethically

The NEAC guidelines provided little guidance in addressing the many potential ethical problems we identified in carrying out this study. They do not even address the use of interpreters if the research participant is not fluent in English. Gaining

informed consent was a complicated issue. The first problem was that all three participants in the study needed to give separate informed consent. One of the participants (the patient) would not speak fluent English, and another (the interpreter) may speak English as a second language. Secondly, there were potential ethical problems of coercion if either the doctor (through the interpreter who was also involved as a participant) or the interpreter themselves carried out the patient recruitment. Our experience is that video recording is necessary for research on communication, to ensure identification of the person speaking and to pick up on all the other communication that occurs outside of speech. However, video recording is more intrusive than audio recordings, being more identifiable. For the interpreter (especially if the interpreter is a professional) and the doctor, there is the potential reputational risk of having their practice recorded, depending on who has access to the recordings. For patients who come from refugee backgrounds, there may have been significant risk of persecution in their home country and so significant wariness about speaking out in any way. Because of this, some patients can be particularly sensitive to being filmed. In addition, these are medical consultations with the possibility of personal and sensitive issues being discussed.

The participants potentially most open to exploitation by the researchers in this study were the patients. If we had relied on autonomous informed consent as the main mechanism for creating ethical safety, we might have distributed information about the study to potential participants who were going to be seeing their doctor soon, looking for volunteers. We would then hope that if a patient volunteered that the interpreter and the doctor would also participate. We did not try this strategy as we believed that it would not have worked. It would also have involved translating information into many different languages, and we had no knowledge in any case of how literate the patients might be in their own languages and thus whether they could read any notice we provided. Importantly for this particular project, no amount of information could adequately assure participants that we would keep the video recordings safely and use the information respectfully. That requires emotional trust and relationship – a conclusion also reached from a review of the literature on video recording as a research methodology by Wiles:

> Literature on the management of these issues in visual research … note the importance of developing relationships of mutual trust with study participants. (Wiles et al., 2012: 2)

The process we used was as follows. We first gained consent from the doctors. They then initially contacted the patients, who were known to them, through the interpreter if needed, to see if in principle they would be interested in participating in the study. If so, the interpreter was contacted and invited to participate. Just prior to the consultation a researcher met with the patient, and with the help of the interpreter explained the detail of the project. If they were happy with this, the patient signed the consent form and recording of the consultation proceeded. This

was followed by an interview with all parties, using a different interpreter to interview the patient.

Where the patient brought a family member to interpret or as a support person, consent for both the patient and the family member/lay interpreter was gained just prior to the consultation. Our ethics committee granted ethical approval.

Achieving ethical safety

This study had no indigenous Māori participants, but the traditional processes of ensuring ethical safety, like relying on informed consent, were unhelpful in much the same way as described for Māori in Te Ara Tika. We felt there were several important elements described in Te Ara Tika that enhanced the ethical safety of our study: a shared research goal, participation in research design, and focusing on relationships and thinking about how trust was established, developed and maintained at both an institutional and individual level.

Shared goal of research

The project was developed from University of Otago, Wellington. One of the study team (BG) had come to understand the issues around interpreting by working with LEP patients and their interpreters and with medical students, who are often asked to act as informal interpreters (Yang and Gray, 2008). Other members of the team had worked over many years in the field of English as a second language preparing migrants and refugees for study and work placements and in the training of interpreters and health professionals (MS, JH), and as clinicians in general practice and community settings (TD, LM). The ARCH Group as a whole has an extensive background in researching communication in a wide variety of health settings. Our initial consultation with potential stakeholders (clinicians, interpreters and community representatives) showed that understanding how well interpreted consultations worked was a shared goal, and our feedback after completion of the study about the effectiveness of the various interpreting options was of real practical relevance (as well as being of interest to other researchers and educators). The excerpt below from a post-consultation interview highlights the fact that patients also explicitly valued the research (PT = patient; RS = researcher):

PT: okay no I don't – it's just that I I'm I'm I'm happy that – I'm sure that this is going to be useful.
I mean you can see my my my the child is on my lap but I'm tired and when you put me through this if you don't know or if you wouldn't know that it's very useful.

RS: no thank you thank you very much um we really appreciate your time and our purpose is to um share the findings.
We are recording about twenty consultations with people in er like yourself in [city] who use an interpreter and we will share the results with interpreters and doctors to help them to do a a better job and to give people the kind of service that they would like to have.

PT: okay I I'm very happy and I I I would always love to be of service just like … they are just like they are helping me I would love to help too.

Shared research design

We discussed the design of the study with the doctors and interpreters as we developed it. As a result one element of design was significantly improved. For adequate analysis of the consultations it is necessary to have a transcript of the consultation. This is easily done if the consultation is in English, usually by members of the research team or by professional transcribers. We had no one in the team who could transcribe the foreign languages in the recordings. In one previous interaction study where we had recorded an interpreted consultation, this transcription was done by another interpreter. For this study where the focus was explicitly on communication in interpreted consultations, we were concerned about possible reputational issues, as the interpreter community is not large and asking a second interpreter to 'reinterpret' the consultation created a risk that they might view the original interpreting as being inadequate. We discussed this issue with the trainer at the interpreting service, who pointed out a fact that was not apparent to the researchers: that the interpreting community (who deal with the spoken word) are a different community from the translating community (who deal with the written word). The skill sets are different, with interpreters needing to be able to remember chunks of conversation in real time and interpret them on the spot, whereas translators have as much time as they need to work on a piece to ensure accuracy, usually though not exclusively based on a written text of some kind. Interpreters have a high need for interpersonal skills in two languages, whereas translators often work in isolation. In general you would expect the accuracy of translated language to be greater than the accuracy of interpreted speech. As a result of this discussion we amended the research design to send a de-identified audio file of the consultation to a translator and asked them to translate the foreign language part of the tape. Interpreting New Zealand believed that this virtually removed the reputational risk for the interpreters. Unfortunately, for some languages we could not find a suitable translator and we used independent interpreters, but only after significant consultation and discussion to try to minimize the reputational risk of those conducting the consultation.

Interrelationships enhancing trust

All the participants in this research project have existing relationships of trust: the patients with the doctors and the interpreters; the doctors with their patients and the interpreters; and the researchers with the doctors and interpreters.

The health services in this study have close relationships with the interpreting services because they have a high number of LEP patients and frequently employ interpreters. The interpreting services and the researchers have developed a mutually supportive relationship, with both services being interested in research on the use of interpreters. The staff at the health services have a close relationship with the researchers as many of them work part-time in the PHCGP department. The institutions also have a long history of collaboration on several research projects, training of students both undergraduate and postgraduate, and many shared goals around the provision of good care to underserved populations.

The patients all had an existing relationship with the doctor, and often with the interpreter. Most of the patients would not have had a relationship with the University, but because of proximity and the fact that students were trained in the practice they may have been aware of it. As a generalization, the idea of a university is understood by many people as being a place of higher learning and thus having more institutional trust than, for example, if the study had been proposed by an unknown interpreting company. Some patients may have known that their doctor also worked at the University.

There was likely to have been significant trust between patient and doctor – a combination of cognitive, emotional and behavioural. In order to maintain a good therapeutic relationship in the future, the doctor had an incentive not to coerce the patient for fear that they would regret the choice at a later time and that this would reduce their trust in the doctor. In addition, BG worked at one of the services and had a pre-existing professional relationship with all the doctors and with several of the interpreters.

At a formal level, the process of getting informed consent for this study could be framed as the process of attaining sufficient trust to proceed. The ethics approval process provided the collegial oversight to decide whether we as a research team had devised a trustworthy project. Information sheets and consent forms were tailored to each type of participant and explained respectfully by trained researchers. By being introduced to the patient by a trusted person the researcher had a base of trust to work from, but they still needed to work on enhancing emotional trust by observing cultural norms of greeting, paying attention to body language and eye contact where appropriate, and establishing an open and warm manner. This is not sufficient, though, and attention also had to be paid to cognitive trust: ensuring that the participants understood the project and were happy with the safeguards we provided to ensure confidentiality of their information. One of the investigators observed that sometimes asking people to sign the form created a slight feeling of

distrust in people who typically rely on oral communication. A lot of emphasis is placed by the formal ethics process on having signed informed consent, but the benefit of the form being signed is in fact almost all with the researcher. In the event of there being any dispute about whether the research was properly conducted the fact of the signature would carry significant weight.

With one patient we were able to demonstrate that she had a good understanding of the study and her choices within it, because she felt able to request that the camera be turned off for part of the consultation to allow her to talk about a sensitive matter that she did not want recorded. When that was dealt with, the camera was turned back on again. Another example of the trust-based nature of the process was with a patient who at first refused because of a previous bad experience with a video of herself being distributed without her consent or knowledge. This was worked through by bringing in the nurse (who was known, trusted and of the same ethnicity) to assist in the consent process and explain the project in more detail. A compromise solution was reached.

Accountability and conflict of interest

As is the case for most studies, our information sheets for participants provided contact details for all the researchers in case there were any questions, and also for the Health and Disability Advocacy Service if participants had any concerns they could not bring to the researchers. However, it seems likely that the pattern of complaints about researchers is not dissimilar to the pattern of complaints about health services. Bismark (Bismark et al., 2006) documented in her New Zealand study that among serious preventable adverse events only 4 per cent (2/48) resulted in complaints to the Health and Disability Commissioner. Reliance on complaints is thus not an effective way of identifying clinicians who are involved in serious preventable adverse events, and it is similarly likely that reliance on complaints is not an effective way of identifying researchers who are involved in harmful research.

To sum up, as noted above all the participants in this research project had existing relationships of trust. If that trust was undermined at all, it could have significant impacts: patients may no longer be willing to see the doctor or use a particular interpreter; and the researchers may not be welcome to do any further research projects at the practice or within the patients' communities. The nature of this project was such that there was significant potential for exploitation of the non-English-speaking patients. The best safeguard against such exploitation was by developing transparent trusting relationships with all those involved, and for it to be seen as a shared project to meet the needs of all participants. It is these relationships that diminish the likelihood of the researchers abusing that trust by behaving in a way that is unacceptable to the participants. By these means there is a

significantly greater level of accountability to the participants than merely providing access to Health and Disability advocates.

Discussion

New Zealand's NEAC guidelines are based on a premise that the research participant is autonomous, with little relationship with the researcher, and that risks of exploitation will be adequately managed by the use of informed consent. This works well for those people from the dominant culture who know and trust the institutions involved (the ethics committee process and the university employing the researcher). It fails to address the needs of people who have a greater reliance on emotional trust, which can only be established by sufficiently knowing the researcher. By contrast, Te Ara Tika, whilst including all the elements of cognitive trust, places the focus on trusting relationships between researcher and participant, and pays attention to reciprocity of outcomes. This case study of research into interpreted consultations illustrates how focusing explicitly on trusting relationships, in addition to the conventional attention to informed consent, provides a superior process for establishing and conducting the research, and offers some prospect of ethical safety to a population who could be vulnerable to exploitation by researchers.

Greater reliance on cognitive trust is a characteristic of the dominant European New Zealand community, and this is reflected in the existing NEAC guidelines. That said, there is some acknowledgement in the dominant discourse that emotional trust is important, for example in Paul's comments on how this was missing in the Cartwright Enquiry into Professor Green, and in Faden's finding in the USA that, in practice, emotional trust is often used in place of informed consent. It is our view that even the conventional processes rely at least implicitly on emotional trust. Researchers know full well that they need to pay attention to gaining a participant's trust whenever they invite someone to participate in a study, and all have had the experience of participants declining to read information sheets having decided they wish to proceed without the information. Māori researchers have provided an example via Te Ara Tika of how guidelines could be applied that better meet the needs of their community. They argue that the mainstream documents are culture-bound to the dominant culture, and thus not able to deliver culturally competent research.

Although this study was done in New Zealand and the discussion has focused on New Zealand research ethics guidelines, we believe that our findings have relevance further afield. New Zealand is very much part of the western ethics community, with a similar structure of guidelines and review boards to other western countries. The similarity between the Māori research ethics document and comparable documents from Canada and Australia suggests that this difference in approach may be common to research participants from other non-dominant cultural groups.

We have applied the approach outlined by Māori researchers to a non-Maori setting and found it to be a useful framework. Focusing on relationships with all parties was an effective strategy for developing and carrying out a research project on an ethnically diverse population. We suggest that it is time for research ethics guidelines to be looked at through cultural competence lenses tailored to local contexts. The comparison between indigenous guidelines and mainstream guidelines illustrates the way in which mainstream guidelines are significantly culture-bound to the dominant culture (although often referencing the needs of minority groups). New Zealand mainstream research guidelines include an expectation that Māori be involved in the design, governance, management, implementation and analysis of research, with the goal of protecting their rights and providing comprehensive high-quality information that can inform on health priorities. However, as Tolich and Smith (2015) note, merely including statements in guidelines does not necessarily lead to significant change. We suggest other communities might like to explore and share their own research ethics paradigms, and there may be other issues in addition to trust and reciprocity that might enhance research guidelines.

It is our contention that mainstream research ethics guidelines should pay more attention to the development of a trustworthy relationship between subject and researcher and give the concept of reciprocity more prominence. In the same way that clinical medicine has acknowledged that clinical care is significantly affected by culture and acknowledged the importance of culturally competent clinical care (Cross et al., 1989; Reitmanova, 2011; Taylor, 2003), it is timely to develop a culturally competent ethical framework for research on human subjects.

Notes

1. Applied Research on Communication in Health Group http://www.otago.ac.nz/wellington/research/arch/ (accessed 12 May 2016).

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References

Auckland University of Technology (no date) *Maori Dictionary OnLine*. Available at: http://www.maoridictionary.co.nz/index.cfm (accessed 8 May 2016).

Australian National Health and Medical Research Council (2003) *Values and ethics: Guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research*. Australia: Australian Government.

Baier A (1995) *Moral Prejudices: Essays on Ethics*. Cambridge, MA: Harvard University Press.

Bismark MM, Brennan TA, Paterson RJ, et al. (2006) Relationship between complaints and quality of care in New Zealand: A descriptive analysis of complainants and non-complainants following adverse events. *Quality & Safety in Health Care* 15: 17–22.

Bunkle P and Coney S (1987) An unfortunate experiment at National Women's Hospital. *Metro* 7(72): 47–65.

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada (2010) *Tri-Council Policy Statement: Ethical conduct for research involving humans*, December. Ottawa, Canada.

Cartwright S (1988) *Report of the committee of inquiry into allegations concerning the treatment of cervical cancer at National Women's Hospital and into other related matters*. Available at: http://www.moh.govt.nz/notebook/nbbooks.nsf/0/64D0EE19BA628E4FCC256E450001CC21?OpenDocument (accessed 8 May 2016).

Council for International Organizations of Medical Sciences and World Health Organisation (2002) *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. Available at: http://www.cioms.ch/publications/layout_guide2002.pdf (accessed 8 May 2016).

Cross TL, Bazron BJ, Dennis KW, et al. (1989) *Towards a culturally competent system of care: A monograph on effective services for minority children who are severely emotionally disturbed*. Washington, DC: CASSP Technical Assistance Center, Georgetown University Child Development Center.

Dew K, Dowell AC, Stubbe M, et al. (2008) Treating patients differently: A qualitative study of how clinical and social factors shape interactions between doctors and patients. *New Zealand Family Physician* 35: 382–386.

Dowell AC, Macdonald L, Stubbe M, et al. (2007) Clinicians at work: What can we learn from interactions in the consultation? *New Zealand Family Physician* 34: 345–350.

Durie M (2001) *Mauri Ora: The Dynamics of Māori Health*. Auckland, NZ: Oxford University Press.

Faden R (1995) *Report of the Advisory Committee on Human Radiation Experiments*. Available at: http://archive.org/stream/advisorycommitte00unit#page/n3/mode/2up (accessed 8 May 2016).

Faden RR, Lederer SE and Moreno JD (1996) US medical researchers, the Nuremberg Doctors Trial, and the Nuremberg Code: A review of findings of the Advisory Committee on Human Radiation Experiments. *JAMA* 276: 1667–1671.

Gardner J, Dew K, Stubbe M, et al. (2011) Patchwork diagnoses: The production of coherence, uncertainty, and manageable bodies. *Social Science & Medicine* 73: 843–850.

Gray B, Hilder J and Donaldson H (2011a) Why do we not use trained interpreters for all patients with limited English proficiency? Is there a place for using family members? *Australian Journal of Primary Health* 17: 240–249.

Gray B, Stanley J, Stubbe M and Hilder J (2011b) Communication difficulties with limited English proficiency patients: Clinician perceptions of clinical risk and patterns of use of interpreters. *The New Zealand Medical Journal* 124: 23–38.

Gray B, Hilder J and Stubbe M (2012) How to use interpreters in general practice: The development of a New Zealand toolkit. *Journal of Primary Health Care* 3: 18.

Hayward J (2013) *Biculturalism: From bicultural to monocultural, and back*. Available at: http://www.TeAra.govt.nz/en/biculturalism/ (accessed 8 May 2016).

Hofstede GH, Hofstede GJ and Minkov M (2010) *Cultures and Organizations: Software of the Mind: Intercultural Cooperation and its Importance for Survival*. New York: McGraw-Hill.

Hudson M (2010) *Te Ara Tika: Guidelines for Māori research ethics: A framework for researchers and ethics committee members*. Auckland, NZ: Health Research Council of New Zealand.

Lacey C, Huria T, Beckert L, et al. (2011) The Hui Process: A framework to enhance the doctor–patient relationship with Māori. *Journal of the New Zealand Medical Association* 124: 72–78.

Lewis JD and Weigert A (1985) Trust as a social reality. *Social Forces* 63: 967–985.

Ministry of Health New Zealand (2006) *Operational standards for ethics committees*. Wellington, NZ: Ministry of Health.

National Ethics Advisory Committee (2012a) *Ethical guidelines for intervention studies*. Wellington, NZ: Ministry of Health.

National Ethics Advisory Committee (2012b) *Ethical guidelines for observational studies*. Wellington, NZ: Ministry of Health.

New Zealand Medical Association (2014) *Code of Ethics for the New Zealand Medical Profession*. Available at: https://www.nzma.org.nz/__data/assets/pdf_file/0016/31435/NZMA-Code-of-Ethics-2014-A4.pdf (accessed 8 May 2016).

Paul C (1988) The New Zealand cervical cancer study: Could it happen again? *BMJ: British Medical Journal* 297(6647): 533–539.

Reitmanova S (2011) Cross-cultural undergraduate medical education in North America: Theoretical concepts and educational approaches. *Teaching and Learning in Medicine* 23: 197–203.

Reverby S (2009) *Examining Tuskegee: The Infamous Syphilis Study and its Legacy*. Chapel Hill, NC: University of North Carolina Press.

Rousseau DM, Sitkin SB, Burt RS, et al. (1998) Not so different after all: A cross-discipline view of trust. *Academy of Management Review* 23: 393–404.

Stubbe M, White S, Macdonald L, et al. (2016) Do surgeons want to operate? Negotiating the treatment plan in surgical consultations. In: White S and Cartmill J (eds) *Communication in Surgical Practice*. UK: Equinox.

Taylor JS (2003) Confronting "culture" in medicine's "culture of no culture". *Academic Medicine* 78: 555–559.

Tolich M and Smith B (2015) *The Politicisation of Ethics Review in New Zealand*. Auckland, NZ: Dunmore Publishing Ltd.

Transparency International (2014) *Corruption Perceptions Index*. Available at: http://www.transparency.org/cpi2014/results (accessed 8 May 2016).

United States Holocaust Memorial Museum (2012) *Nazi medical experiments*. Available at: http://www.ushmm.org/wlc/en/article.php?ModuleId=10005168 (accessed 8 May 2016).

Wiles R, Coffey A, Robison J, et al. (2012) Ethical regulation and visual methods: Making visual research impossible or developing good practice? *Sociological Research Online* 17: 8.

Yang C-F and Gray B (2008) Bilingual medical students as interpreters: What are the benefits and risks? *The New Zealand Medical Journal* 121(1282): 15–28.