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Debate

International variation in ethics committee requirements: comparisons across five Westernised nations

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Abstract

Background: Ethics committees typically apply the common principles of autonomy, nonmaleficence, beneficence and justice to research proposals but with variable weighting and interpretation. This paper reports a comparison of ethical requirements in an international cross-cultural study and discusses their implications.

Discussion: The study was run concurrently in New Zealand, UK, Israel, Canada and USA and involved testing hypotheses about believability of testimonies regarding alleged child sexual abuse. Ethics committee requirements to conduct this study ranged from nil in Israel to considerable amendments designed to minimise participant harm in New Zealand. Assessment of minimal risk is a complex and unreliable estimation further compounded by insufficient information on probabilities of particular individuals suffering harm. Estimating potential benefits/ risks ratio and protecting participants' autonomy similarly are not straightforward exercises.

Summary: Safeguarding moral/humane principles should be balanced with promotion of ethical research which does not impede research posing minimal risk to participants. In ensuring that ethical standards are met and research has scientific merit, ethics committees have obligations to participants (to meet their rights and protect them from harm); to society (to ensure good quality research is conducted); and to researchers (to treat their proposals with just consideration and respect). To facilitate meeting all these obligations, the preferable focus should be promotion of ethical research, rather than the prevention of unethical research, which inevitably results in the impediment of researchers from doing their work. How the ethical principles should be applied and balanced requires further consideration.

Background

It is widely understood that in evaluating the ethical aspects of medical and psychological research, ethics committees typically apply a common set of secular principles

to all project proposals.[1] The four clusters of principles are respect for autonomy, nonmaleficence, beneficence and justice. Autonomy (derived from the Greek *autos* 'self' and *nomos* 'rule') relates to the freedom of people to make intentional decisions independent from controlling influences. Nonmaleficence is the obligation to do no harm, whereas beneficence relates to helping others and promoting good. Justice is the impartial, equitable and appropriate treatment of all – the fair distribution of benefits, risks and costs.

These principles are not necessarily complimentary and may be conflicting or at times even mutually exclusive. This may require balancing of one principle against another. There is a *prima facie* obligation to fulfil a principle unless a stronger obligation overrides this on a particular occasion. The safety of, and benefit to, the individual is usually considered to take precedence. For example, should an individual participant be at any risk of harm then the potential good to society or future individuals with relevant needs must heavily outweigh the potential risk.[2]

A primary function of an ethics committee therefore is to protect study participants.[3] Where research involves human participants, one of the roles of an ethics committee is to ensure that the privacy, safety, social sensitivities and welfare of such participants are protected.[4] Researchers should make every attempt to minimise any potential physical, psychological, social or cultural risks to participants. Possible risks include pain, illness, stress, emotional distress, fatigue, embarrassment, cultural dissonance and exploitation.

In addition, ethics committees scrutinise research proposals to ensure that they are scientifically valid with rigorous methodology. Poorly designed projects do not justify the commitment made to them by participants and hence can be considered unethical.[2] However, it is noted that ethics committees often require considerable changes to research design and methodology and in the view of some, have been overstepping their bounds into the domain of the researcher.[5] Part of the reason for this might be that ethics committee members are drawn from a variety of experience and qualifications, and not all have a background in scientific thinking. Some of the changes required by these committee members may in fact weaken the scientific validity of the proposed research.

For example, research ethics committees frequently insist that researchers provide potential participants with comprehensive (usually written) details of the proposed research. The abundance of information that participants are requested to peruse and understand in order to give informed consent may discourage participation in research, causing the true preference or willingness of some people to participate to be unexpressed and response rates to be reduced. By weakening the quality of quantitative research, small response rates can make research unethical.

Even when there is a consensus within an ethics committee on what requires approval, there can be huge diversity between committees in the interpretation of such requirements. Multi-centre studies that span several regions or districts, or are national in coverage, may require separate applications to the individual committees that serve each location. There are numerous studies evaluating the specific requirements and outcomes of these applications and overwhelmingly, these report a huge variation, both in the information that the committees want supplied and their responses.

For example, in a British multi-centre study that required twenty-four separate applications, fourteen were approved without modification and three were rejected.[6] The remaining seven committees requested various methodological changes that substantially changed the design and potentially the outcome of the study. Diverse application criteria and responses of regional ethics committees similarly have been documented in many other one nation, multi-location studies. [7–12]

Given the considerable variation between ethics committee requirements within a country, it would be expected that similar difficulties exist for researchers wishing to conduct international studies. The aim of this paper is to report a comparison of ethical requirements in a cross-cultural study spanning five countries and to discuss the implications of the varying ethical requirements we encountered in conducting this international research.

Discussion

Cross-cultural comparison

The authors of this paper are researchers participating in an international collaborative study addressing comparisons of the credibility of statements heard in cases involving child sexual abuse (CSA). The purpose of the study was to test the hypotheses that testimony balance and imbalance (particularly in relation to expert testimony) affect believability, and that prior knowledge about the recovered memory therapy – false memory syndrome debate affects participants' believability judgement of the accusing daughter and accused father's testimonies regarding alleged CSA.

This study was run concurrently in five different countries (New Zealand, UK, Israel, Canada and USA) with participants who presumably had been differentially exposed to that debate, and whose prior knowledge was assessed using a specifically designed questionnaire. The sample

from each country was proposed to consist of 120 introductory psychology students attending the researchers' respective universities. Participants were exposed to one of the four following experimental conditions related to expert testimony: accusing daughter and accused father's testimonies regarding alleged CSA plus (1) two expert testimonies, one each for the daughter and the father; (2) an expert testimony for the daughter; (3) an expert testimony for the father; or (4) no expert testimony. In each group, participants judged the daughter's and the father's believability. This data collection took place over about 30 minutes during a lecture to introductory-level psychology students. All responses were completely anonymous and collated in a standardised database before being forwarded to Israel for cross-cultural comparison.

In the course of the study, it became apparent that ethical requirements differed markedly between the various countries. Following consultation between investigators in the five involved countries, full details of Ethics Committee or Institutional Review Board (IRB) requirements and applications for approval were forwarded to the first author for comparison and analysis.

At Bar-Ilan University in Israel there was no requirement at all to obtain ethics committee approval for this study. Israeli ethics committees are active mainly in the field of medical research. Giving questionnaires to psychology students is not perceived as an hazardous activity that needs special screening and approval and in general, academic university staff are free to carry out such research without seeking approval. First year psychology students at Bar-Ilan University are required to contribute a few hours of their spare time by participating as participants in scientific experiments.

In the United Kingdom at the University of Leicester all staff carrying out experiments must submit an outline description of the study and confirm that it concurs with British Psychological Society prescribed ethical guidelines. Researchers complete an ethics monitoring form which is used for both human and animal research. If there are no areas of concern, then the Chair of the ethical committee is empowered to sign the application and the researchers may proceed immediately with their study. Controversial items which require explanatory notes and ethics committee review include specific participant populations (persons aged under sixteen years; with special needs; with mental disorders; disadvantaged in any way or detained); the practice of serious deception in the study; lack of confidentiality of research records or research involving invasive procedures.

The believability study did not raise any of these ethical issues and researchers at the University of Leicester were therefore able to conduct the study on the approval of the ethics committee Chair.

At the University of Victoria in British Columbia, Canada, the researchers were required to provide an outline description of the study and make an application for ethical review of human research to the University's Office of the Vice President Research. The study was defined as 'minimal risk research' as the potential participants could reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered in everyday life. While the study dealt with the topic of CSA, the description of the alleged abuse was stereotypical for cases of childhood sexual assault and such description is well within the realm of ordinary experience gained through the various news and entertainment media in North America today. Further, the description provided no detail of the actions included within the assault, only the allegation of a type of assault.

It was also noted by the Canadian researchers that this study closely resembles numerous "mock juror" studies that have been conducted over the past decade in which research participants have been asked to assign credibility to those who have provided testimony; in no published studies have reports of harm to research participants been noted and the researchers saw no reason to expect any such harm. The Canadian students participating in the study gain bonus points towards their grades as an encouragement to participate in and understand research activities in psychology. Because participants' data are unsigned and anonymous, their responses can not be linked in any way to their course grade.

The ethical review application was approved with the additional requirement that in the remote possibility that participants' reading of the materials caused some emotional distress (because the vague description of sexual abuse provided in the material served to remind them of experiences had by themselves or had by others known to them), the testing session would be terminated and the person referred to the university counselling centre. Given that the consent form students sign prior to participating in the study describes the nature of the material to be read, students for whom sexual abuse is an emotional topic are likely to decline.

In the United States, at the University of Wisconsin-Whitewater, an application was required for ethical approval from the IRB. The chair of the Board can determine that an expedited rather than a full review is required. An expedited review is indicated when the risk of harm anticipated in the research is not greater than those ordinarily encountered in daily life or during the performance of

routine physical or psychological examinations or tests. This is equivalent to the Canadian 'minimal risk research' category. In an expedited review the chair makes an executive decision to approve the study on behalf of the committee.

The researcher (and subsequently the majority of the IRB members) were of the opinion that the study involved minimal risk and that participants were adequately warned of the potential risks before agreeing to participate. The researcher followed the board's guidelines for addressing the potential for unanticipated harm in the consent procedures. The researcher presented all possible arguments for a finding of minimal risk. However the Chair of the board still perceived a potential for harm and did not feel that their own prescribed steps for addressing the harm were adequate.

Because of the perception that the project involved some risk of psychological and/or emotional harm to certain participants, the chair did not sign off for expedited review and the proposal was required to go through full board review. The board addressed this concern by removing the statement 'there are no known risks to the study' from the consent form.

As in Canada, extra course credits for participating in the study are awarded to US students, which they are entitled to keep should they choose to withdraw from the study after its onset.

In Auckland, New Zealand a full and comprehensive application was required by the University of Auckland Human Subjects Ethics Committee. Information regarding the study's background, methodology and data analysis was required in greater detail than that called for by the Canadian and US review boards.

While Auckland students are not required to sign a consent form for anonymous questionnaires, they are issued with a Participant Information Sheet (PIS) prior to participation. This outlines the nature of the study and emphasises that participation is voluntary – students may choose not to participate with no negative repercussions.

The Auckland committee were of the opinion that participation in this study could place some students at risk of psychological harm. They were concerned that because the subject matter was CSA participation could be very distressing for some students. As well as requiring the full contact details of the Student Counselling Service to be included, they required the PIS to be amended to include the additional instructions that students could ask their lecturer to help them make an appointment for counselling should they feel they were not capable of doing this on their own.

The study was to be conducted during the second half of a regular first year psychology lecture. In a similar fashion to the Canadian and US consent forms, the PIS specified that the study was about child abuse, and that students could choose not to participate. They could either absent themselves from the lecture-room while the other students filled in their questionnaires, or they could engage in alternative activities provided by the lecturer. However the committee was concerned that students who found a study dealing with the topic of CSA distressing might be reluctant to absent themselves from the class. It was therefore required that the study be outlined and the PIS be distributed during a preceding class, to allow particularly sensitive students to avoid the lecture completely (full lecture notes were available).

Students in Auckland are not offered the extra course credits available in North American universities as an incentive to participate in studies. Recruitment of students to participate in the study was lower than anticipated, and did not meet the 120 threshold achieved in all other participating countries. Certainly the number of enrolled students might have been less in New Zealand than the other nations, with a smaller pool of potential participants. However the suggestion that students who chose not to participate in the study did not need to attend the subsequent lecture, with course material made available and no penalty for non-attendance, may well have resulted in students with no negative issues regarding CSA deciding to stay home that day, and may thus have contributed to the poor recruitment rate.

It can therefore be seen that the ethics committee requirements to conduct this study across five different countries ranged from nil to detailed instructions on how to conduct the research and considerable amendments designed to minimise harm to the participants. The changes in procedure that the New Zealand researchers were required to undertake may have resulted in a reduction in possible participation rate and may have compromised the scientific validity of the study. While the argument could be made that these more stringent recruitment procedures should have been followed by all the involved countries, the various structural and organisational features of the different institutions rendered such an option impossible to achieve.

Estimate of minimal risk

In line with the ethical principle of nonmaleficence (do no harm), risks of the study should be considered. On the one hand, it is possible that the lack of ethics committee approval required in Israel might have exposed some stu-

dents to potential harm; on the other hand, perhaps the ethics committees in the USA and New Zealand were over-cautious and over-reacting to what are generally regarded as negligible risks in this instance. It could be contended that the forcefulness of the warnings researchers were obliged to make about remote possible risks might have actually scared away potential participants.

A minimal risk could be considered to be one that does not exceed in magnitude or probability the risks we encounter in our daily lives.[13] The disparity in ethic committee requirements was based on their variable evaluation of what constitutes minimal risk research. The dimensions of risk include the likelihood, nature and magnitude of potential harm.[14] Four categories of potential risk to research participants have been identified: physical, psychological, social and economic.[15] In the current situation only psychological risk was relevant, whereby the research affects the participant's perception of self, causes emotional suffering such as anxiety or shame, or induces aberrations of thought or behaviour.[14] The determination of potential risk is neither obvious nor intuitive, and is open to interpretation by ethics committees according to their assessment of the context of each case in question. In our example, the concept of minimal risk was clearly applied quite variously.

In the study discussed above, the participants were presented with a brief case study of woman reporting that she had been sexually abused by her father on a number of occasions when she was eight to nine years of age. The daughter alleged that she suffered such emotional trauma from this abuse that she repressed all memory of it and only recovered her memories for those events when she was in psychological therapy at age 29 years.

It may be argued that the description of CSA did not contain graphic detail of any kind and certainly contained considerably less description than is likely to be found in written media about sexual abuse (such as newspaper and popular magazine articles), or that which may be viewed on television or at movies. It may be counter-argued that in everyday life people can choose to avoid disturbing material in the media – they can turn off the television or radio, or select what they read. While the material presented above is unlikely to cause any psychological damage to the majority of people exposed to it, it may have the potential to cause anxiety or distress to someone who believes themself to be a victim of CSA, especially under similar conditions to the scenario.

The rate of enrolled NZ students participating in the study was significantly less than in other centres. It could be argued that when informed about the study, students elected not to attend the lecture in question nor participate in the research project because f the nature of the material involved. However, it could equally be argued that the reduced participation was due to avoidance of unnecessary effort. The students were told at the preceding lecture that they need not attend the following session at which the study was to take place and that they would receive no penalty for non-attendance. They had already been provided with copies of the full lecture notes. It would seem likely that this, plus the fact that the lectures were presented at a satellite campus geographically distant from the main campus and from most students' residences and thus somewhat inconvenient to get to, could contribute significantly to the small numbers choosing to attend the session in person.

The study of psychology, by its very nature, is likely to present students with material that might be found distressing to a small minority of students. The extent to which course material should be monitored and restricted on the basis of this concern could be a matter for academic debate. Whether student exposure to material for research purposes should follow similar or more restrictive guidelines than that applying to course content is also open to question. If students are likely to encounter such material in the course of their studies, it could be reasoned that it is acceptable for them to have similar exposure when participating in a research project. Conversely the non-essential aspect of research participation could dictate that more stringent criteria should apply to the latter.

Furthermore, minimal risk refers to interventions or experiences routinely encountered by us in daily life and hence common to us all.[14] It does not refer to any risk encountered by any person and therefore does not include possible but unlikely risks posed to particular individuals by virtue of their personal attributes or past experiences. For this reason, ethics committees need to assess the probability of a risk as well as its possible nature and magnitude.

In our study, the Israeli university considered that the research project posed no risk to the students. The UK and Canadian institutions considered that the risk was minimal. The US IRB members were divided in their opinion that the study posed no or only minimal risk. The Auckland ethics committee, however, had concerns that the research might cause significant psychological harm to some students. This variability in consideration of what constitutes minimal risk had implications with respect to the comparability of data across these countries.

Potential benefits

The potential benefits to participating in a study also should be considered. Benefits may be direct (arising from receiving the intervention being studied), collateral (aris-

ing from being a participant) or aspirational (benefits to society arising from the results of the study).[16]

Because this study did not involve an intervention, there were no direct benefits to students from their participation. However students might have derived collateral benefit from their participation in our study in several ways. An appreciation of research methodology might have contributed to their understanding of psychology. In some instances this may be a course requirement. As a form of experiential learning, active participation in psychological research may enhance students' understanding and knowledge of research principles. The awarding of extra course credits for participating in research in US and Canadian universities is in recognition of this. Further collateral benefit may be obtained by students from personal gratification of altruism – the satisfaction that they are contributing to knowledge in that field, which may benefit society.

The results of this study may add to general knowledge. Therefore aspirational benefit might be derived from the contribution made to scientific understanding and hence to society in general in a number of ways.

A realistic assessment of the risks versus gains ratio is required. Reviewers need to assess both the risks to participants and also the potential benefits of the research. For research to be ethical, benefits and risks must be shown to be in a favourable ratio.[14] Ethic committees must estimate the nature, magnitude and likelihood of any potential benefit and weigh this against any possible harm.

Autonomy

The principle of autonomy emphasises suitably informed and voluntary participation in research as well as satisfying conditions of confidentiality and privacy.[17] Expedited ethics committee (or IRB) review is recommended provided study methods are considered valid; participation poses no more than minimal risk; and does not involve a vulnerable population.[14] The Auckland committee were anxious to put safe-guards in place to protect students who might suffer psychological harm from reading the summary information contained in the study. On the one hand, this could be considered a responsible action to prevent any students becoming distressed. On the other hand, an undergraduate population of young adults generally is not considered to be a vulnerable population (a term usually applied to groups such as children, prisoners or the mentally infirm). Offering this degree of protection to students could be considered not respecting their autonomy, their ability to assess information and make informed adult decisions.

The study of psychology is likely to include topics dealing with aspects of human behaviour which are potentially distressing to some people – mental illness, maltreatment of certain populations (such as racial or religious persecution or child abuse and neglect) interpersonal violence, sexual assault or abortion. It is unlikely that course readings and other resources undergo the same degree of scrutiny to ensure that students are not exposed to case material pertaining to any such sensitive issue. It could therefore be argued that it is acceptable for research-based scenarios to be similar in content to course-based scenarios. Should there be genuine concerns that studying such topics may pose more than minimal risk, then an argument could be made for students undergoing a pre-course assessment to exclude vulnerable individuals from enrolling in such courses.

Balance of ethical principles

As outlined in our introduction, ethics committees typically apply the four principles of respect for autonomy, nonmaleficence, beneficence and justice when considering research proposals.

It could be argued that in many countries ethics committees have increasingly focused on the principles of autonomy and nonmaleficence. In their intention to ensure that research participants are freely choosing to participate and are not harmed by their experience, the principle of beneficence might be under-valued.

While it was initially intended that the four moral principles would have equal moral weight and would be applied differently according to specific situations,[1] in practice autonomy has become the main principle guiding decision-making by many ethics committees.[18] This dominance of autonomy has occurred in a climate of increasing consideration of patient rights and issues of individual choice, informed consent, privacy and confidentiality. In many westernised countries, autonomy therefore has tended to over-ride and devalue the other principles, particularly justice and the needs of the community.[19]

However the ascendancy of the principle of autonomy may be inappropriate in non-western countries with differing religious or social norms. Examples include Pacific Island and Asian nations and this may also apply to Israel. The latter exemplifies an attempt to reconcile the universal demands of social justice with the particularistic demands of its nation. Autonomy is not the primary concern because the community cannot permit the individual to founder. Historically, as a communitarian state, Israel has operated under a form of social paternalism whereby the community protects the welfare of each individual, who is expected to "subordinate rank egoism and selfinterest for

the good of all".[20] Through advice and, if necessary, gentle coercion, the community (represented for example by an ethics committee) seeks to alter the individual's preferences to reflect the collective assessment of what is in his or her best interests. In Israel the concept of patients' rights is subordinate to the national commitment to the provision of universal health care and the curtailing of informed refusal of treatment.[20] As the country becomes more westernised, increasing consideration is being given to patients' rights for autonomy, privacy and due process of informed consent.

There is a danger that the ethical review process is becoming increasingly adversarial, with researchers being seen as the source of the ethical problem and reviewers as the protectors and police. The issue of who is liable should harm occur in the course of the research needs to be addressed. It is our understanding that in general ethics committees are not legally accountable if a study participant is harmed by research that they have sanctioned,[21,22] although a small number of UK health authorities and universities do offer no-fault indemnity.[23]

However, reviewers may be under threat of public censure should they approve a research project that results in a scandal, whereas they suffer no penalty should they reject a project that should have been approved. If the goal is to minimise the incidence of unethical research, then the simplest way to achieve this is of course to prevent any research from occurring. Clearly the alternative goal is for the ethics committee to facilitate and support ethically informed research.[17]

Research which poses minimal risk to its participants should not be obstructed by excessive review requirements. Evidence indicates that many researchers believe that ethics committees' actions unnecessarily impede research.[5] Reducing the work load of reviewers could improve the quality of ethical review.[5] This could be assisted by the identification of categories of research which might not require full ethics committee review. The international variability of review requirements in our study begs the question: what degree of review is necessary for such research? In our study, involving the anonymous completion of questionnaires by university students, the risk to participants is overwhelmingly less than in medical research carried out on patients. In the latter a much more vulnerable population may be exposed to an experimental clinical intervention with significant potential for harm and a greater degree of review should therefore be required. Generally, anonymous retrospective audit findings of clinical practice have been exempt from the remit of ethics committees, whose brief is to assess research proposals.[2,24] More recently it has been suggested that all published audit findings should have prospective ethics committee approval.[3,25,26] Ironically, such a requirement could result in a many-fold increase in review applications and therefore ethics committee workload.[27]

Summary

This paper proffers more questions than answers. The four ethical principles of autonomy, nonmaleficence, beneficence and justice may govern research ethics committees internationally, but these are not uniformly applied. The protective function of an ethics committee or IRB is to ensure that study participation presents a favourable balance of potential benefits and risks and that the rights of participants are treated with respect. In practice, assessment of minimal risk is a complex and unreliable estimation further compounded by insufficient information on the probability of a particular individual suffering any harm. Estimating the potential benefits / risks ratio and safeguarding the autonomy of participants similarly are not straightforward exercises. The resultant possible diversity of response is clearly demonstrated by our example of the range of ethic committee requirements encountered for a psychology study conducted simultaneously in five different countries.

At one extreme it could be argued that, considering that our study posed minimal risk, permitted its execution in Israel without consideration of the ethical questions involved. Conversely the New Zealand response could be viewed as an over-cautious reaction to a negligible risk which may have compromised the integrity of the cross-cultural comparison.

Ethics committees need to balance the safeguard of moral and humane principles with the promotion of ethical research without impeding research that poses minimal risk to participants. In ensuring that ethical standards are met and research has scientific merit, ethics committees have obligations to all players. They have an obligation to ensure that participants' rights are met and that they are protected from harm; they have an obligation to society which provides the resources for research and will ultimately be affected by the results to ensure that good quality research is conducted; and lastly they have an obligation to the researchers, to treat their proposals with just consideration and respect. To facilitate meeting all of these obligations, the preferable focus should be the promotion of ethical research, but not the prevention of unethical research, which inevitably results in researchers being impeded from doing their work. How the balance is to be achieved requires further consideration.

Competing interests

None declared.

Author's contributions

Author 1 FG participated in the design of the cross-cultural study; was involved in data collection for this study in NZ; collected and collated the ethics committee requirements from each participating country; drafted this manuscript on comparison of ethical committee requirements.

Author 2 BL was involved in data collection for this study in NZ; contributed to this manuscript on comparison of ethical committee requirements.

Author 3 GD participated in the design of the cross-cultural study; was involved in data collection for this study in the UK; contributed to this manuscript on comparison of ethical committee requirements.

Author 4 IN conceived of the cross-cultural study; participated in its design; was involved in data collection for this study in Israel and performed the statistical analysis; contributed to this manuscript on comparison of ethical committee requirements.

Author 5 SS was involved in data collection for this study in the USA, contributed to this manuscript on comparison of ethical committee requirements.

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