Guest editorial

Research ethics guidelines and occupational therapy:
Can we risk thinking they do not apply to us (or the populations we study)?

Matty van Niekerk B.Proc (UFS) B.Arb (UP), Dip Voc Rehab (UP)
Lecturer in Adult Psychiatry, Dept of Occupational Therapy, School of Therapeutic Sciences, University of the Witwatersrand
(Currently completing MSc Med (Bioethics & Health Law) at the University of the Witwatersrand)

Research is not only necessary for the development of every health profession, but also to establish the efficacy of existing assessment and treatment procedures. This, more often than not, requires using humans as research subjects/participants[a].

Research involving human participants has a notorious history. In the early days of human research, researchers abused the power they exercised over the research subjects, amongst others by misinforming the subjects or not informing them at all of the aims of the research and the possible outcomes and harms that might befall them for participating in the research project. In addition, research subjects' human rights and human dignity were not recognised or honoured. The most notorious example of the abuse of research subjects is probably the experimentation that was done on holocaust victims during the Second World War.

The Nazi regime in Germany under Adolf Hitler arguably brought about the darkest days in research involving humans – despite ethics guidelines that existed at the time. One set of guidelines was formulated in 1900 by the Prussian Minister of Religious, Educational and Medical Affairs and another by the German Minister of the Interior in 1931. Both sets of guidelines required consent from the participants in human research[1]. The experiments performed on humans in the concentration camps were in contravention of these guidelines since none of the subjects consented to participate in these experiments (and consequently to lose their lives). When the West defeated Germany and its allies, the experiments of the Nazi physicians and scientists came to light and consequently these scientists were tried for war crimes and crimes against humanity in Nuremberg.

The Nuremberg judgement must be considered the turning point in human research. In this judgement the first international code of research ethics, the Nuremberg Code was formulated, consisting of ten principles[2]. In a nutshell, the ten principles of the Nuremberg Code prescribe three requirements for research involving human participants:

- People should consent voluntarily before they participate in human research,
- They should be permitted to withdraw from the research at any stage, without any dire consequences to themselves, and
- There ought to be possible advantage to them from participating in the research and minimal harm[3].

Although the preamble to the Nuremberg Code makes it clear that it attempts to formulate basic principles applicable to all instances of research on humans[4], including prospective international research, researchers and healthcare workers erroneously believed that the Nuremberg Code only applied to the accused found guilty at the Nuremberg trial. Because of the egregiousness of the experiments conducted by the Nazi physicians, the Nuremberg Code was rejected by most Western physicians[1, 4] and researchers viewed it as a code "for Barbarians … not civilised researchers"[5]. However, the very same researchers who may have viewed the Nuremberg Code as applicable only to barbaric researchers conducted their own research that also egregiously violated the human rights of the research subjects, such as in the case of the Tuskegee Syphilis Study on which the film, Ms Evers' Boys, was based.

The 'Tuskegee Study of Syphilis in the Negro Male' studied a cohort of impoverished African-American men infected with syphilis between 1932 and 1972. Their syphilis was left untreated, although by the 1940s it was confirmed that penicillin was an effective cure for the disease. The subjects were neither informed that they had syphilis, nor that a cure, penicillin, was found to be successful at treating the condition. This omission by the researchers and the nurse assisting them necessarily resulted in the secondary infection of the subjects' wives and children (who were born with congenital syphilis). Many physicians and scientists questioned the morality of this study from its inception, however, it continued for thirty years[1]!

As a result of the Tuskegee syphilis study, the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research was established in the United States of America[2]. It formulated ethical principles for research, published in their Belmont Report[2]. In order to ensure that research on humans was conducted ethically, the Commission relied heavily on Institutional Review Boards to protect human research subjects. Many other examples can be cited of unethical research studies and how they influenced international research ethics guidelines.

It cannot be disputed that research ethics developed as a result of unethical practices by healthcare professionals and researchers other than occupational therapists. Do the international and local guidelines then apply in their entirety to occupational therapists, or should we really only be concerned with aspects thereof, e.g. informed consent? In order to best answer this question, it is necessary to focus on the ethical principles underlying international and local research ethics guidelines as well as South African legislative provisions related to research ethics.

Three ethical principles have developed since the original formulation of the Nuremberg Code, i.e. respect for persons, beneficence and justice[6]. These principles underlie all research ethics guidelines, both international research ethics guidelines and local research ethics guidelines.

1. Respect for persons

The principle of respect for persons entails at least two human rights or ethical values, that of autonomy and the right to self-determination.

Autonomy refers to concepts such as 'self-governance … individual choice, freedom of the will ... and being one's own person[7]. Thus, researchers should respect the research participants' right to exercise their own will independently. This means that participants must consent individually and independently to research. They can only exercise their own will if they understand the aim and methods of the proposed research study[6, 8], otherwise they cannot be said to have exercised their autonomy. Another component of autonomy relates to research participants' withdrawal from a study at any

[a]It is preferred to refer to humans who participate in research as research participants, since it implies that they provided informed consent and that their human rights are honoured by the researchers. In this paper, the term research subject will be used in reference to examples of research where the humans who were being studied either did not consent to participating in the research or their consent was based on inaccurate or inadequate information.

point without any possibility of impending harm to them as a result of their withdrawal[6, 8].

Beauchamp and Childress differentiate between **actual governance and capacity for governance**[7]. When people with the capacity for self-governance fail to exercise this right amongst others due to ignorance or coercion by 'conditions that restrict options' they have not acted autonomously, e.g. when a person who is capable and qualified to act, signs a consent form without reading it or without fully understanding the conditions contained in the form (or the form itself). Thus it may occur that persons with the capacity for self-governance do not actually govern themselves[6]. However, the choice to act autonomously may never be removed from a person by a third party.

In the South African (and larger African) context many conditions exist which restrict participants' ability to exercise their autonomy, including cultural and linguistic factors[3]. A chieftain, for example, may have consented to a whole village's participation in a study, thus limiting the ability of the individual residents of the village to exercise their own will. Similarly a person's ability to exercise his own will independently will be limited should he not understand the language in which information is provided or the concepts used to convey the information. Because of the extremes in the health, education and income of South Africans, the underprivileged in society may be at risk of exploitation by researchers[3].

Populations who are unable to exercise their own will independently are regarded as vulnerable[8]. This may be because of the power the researcher has in relation to them (e.g. in the case of orphans, prisoners or soldiers), their mental (or physical) incapacity, age (e.g. minors), and their health status (i.e. seriously ill persons)[6]. Research ethics guidelines, which are onerous with regards to the protection of vulnerable populations, protect them from being exposed to potentially dangerous research.

One group of vulnerable persons that bears further discussion is children, since they form an important focal point of both occupational therapy services and research. National and International guidelines are clear about the caution with which research on children should be approached. Research on children may only be conducted using children if the research cannot be done at all, or equally informatively with adults[6, 9, 10] and the research concerns the health needs of children specifically[6, 8, 11]. Research Ethics Committees may only approve such research if the research involves minimal risk to the child[11, 9]. Should the risks be greater than minimal, the benefits of the research should outweigh the risks[11, 9]. It should be noted that risks do not only relate to the physical harm to the child, but also to an infringement of their privacy and confidentiality[6].

Research may only be conducted on children with the necessary consent from the parent or guardian of the child and, where possible, assent from the child[6, 9, 11]. This means that after the parent or guardian has consented to the research, the child must also agree to participate. Similarly, the child has the right to withdraw from continued participation or to dissent from participating in the research [9] and then should not be included in the research project.

The right to self-determination allows persons the right to make decisions about their own bodies. It is found in research ethics guidelines and South African legislation, e.g. the Constitution of South Africa 108 of 1996 (hereafter referred to as the Constitution) and the National Health Act 61 of 2003 (hereafter referred to as the NHA). Section 71 of the NHA governs human research and requires informed consent from possible participants[12].

In terms of the Constitution[13], the following rights pertaining to autonomy and self-determination in a healthcare context are enshrined in the Bill of Rights (making the protection of human research participants' autonomy more onerous in the South African context):

- The right to inherent dignity and the right to the protection and respect of their dignity.[b]
- The right to freedom and security of the person, including the rights to be free from any form of violence from either public or private sources[c] and not to undergo any form of torture.[d]
- The right to bodily and psychological integrity, which means *inter alia* that people should have control over their own bodies[e] and not be subject to medical or other experimentation without their informed consent.[f]
- The right to privacy.[g]
- The right to access[h] healthcare services and reproductive healthcare.[i]

2. Beneficence (including non-maleficence)[j]

The principle of beneficence means that benefits should be maximised and harms minimised[6] so as to ensure the well-being of persons participating in research. In this regard the Declaration of Helsinki holds that the well-being of the research participant must outweigh any other concern. For this reason, research designs such as clinical trials must be approached with great care. Studies employing control groups who either receive no treatment or placebo treatment do not appear to consider the benefits to the research participants and thus are unethical. In these cases the therapy (or medication) being studied should be compared with the "established effective intervention"[14]. In the occupational therapy context this would mean that we cannot deny clients access to physiotherapy or biokinetic services so as to establish the efficacy of occupational therapy for certain conditions or related to participants' selected occupations (e.g. work). Similarly, we cannot deny research participants access to educational psychology or remedial education to establish the efficacy of occupational therapy in treating children with learning difficulties.

The question arises whether we may choose as a control group a population of participants who do not have access to occupational therapy services. This would only be permissible if the research participants will have access to such treatment intervention that was identified in the study as beneficial after the study is concluded[8]. Thus we would be obliged to provide some service to them after the conclusion of the study, which would be in line with the principles of beneficence and justice (see discussion below). If not, we are exploiting one population to the benefit of another, which is unethical and thus not permissible.

Beneficence also entails that the risks of research should be reasonable in comparison with the expected benefits thereof. The Declaration of Helsinki has formulated two paragraphs that explain this principle. Paragraph 20 holds that before research is conducted, the risks involved therein must be "adequately assessed" and should be "satisfactorily managed"[15]. Healthcare researchers should stop a study immediately when the risks outweigh the possible benefits to the participating individual, (or when there is convincing evidence of a positive outcome)[8].

Paragraph 21 holds that medical research should only be conducted on human participants if the importance of the research objective outweighs the risks inherent to the study[8]. Deliberate harm to participants is prohibited[6].

3. Justice

Justice requires that the research participants are treated according to that which is right and proper and that the participants are protected from harm[6]. It usually refers to distributive justice, which entails the fair distribution of the benefits and liabilities (burdens) of participating in the research[6].

Because of their profound inability to protect their own interests, vulnerable persons require special provisions to protect their rights, interests and welfare[6], whilst at the same time they are not excluded from the potential benefits of either participating in research, or the advances made in healthcare (very often because

[b] Section 10 of the Constitution.
[c] Section 12(1)(c) of the Constitution.
[d] Section 12(1)(d) of the Constitution.
[e] Section 12(2)(b) of the Constitution.
[f] Section 12(2)(d) of the Constitution.
[g] Section 14 of the Constitution.
[h] This right relates to adults, as children have the right to basic healthcare services (s28(1)(c) of the Constitution)
[i] Section 27(1)(a) of the Constitution.
[j] It should be noted that Beauchamp and Childress describe non-maleficence as a fourth ethical principle.

of their participation). Similarly, some populations cannot carry all the burdens of research participation whilst other populations have all the benefits of the same research without ever participating in research[6, 8].

The principle of justice further demands responsiveness to the health needs of the vulnerable, however, the least vulnerable populations possible should participate in the research to achieve the research objectives[6].

In the occupational therapy context this may have far reaching implications. Whilst convenient sampling may be an accepted method of finding a sample population, does this correlate well with the notion that research should be responsive to the health needs of vulnerable populations? Most research is done within relative close proximity to academic centres. This necessarily means that vulnerable populations in remote areas are excluded from participating in research, which is an obvious breach of the principle of justice.

If vulnerable populations from remote areas do participate in research, they may not have access to continued occupational therapy after the conclusion of the research study, contrary to what the principle of justice would demand. Does it suffice to make intermittent occupational therapy services provided by inexperienced (community service) practitioners available to these populations in an attempt to satisfy compliance to this principle? Whilst it could be argued that it may suffice, this question would require an interrogation of the issue of "procedural" and "substantive" compliance (to borrow terms from the legal fraternity) to the requirement of justice. Procedural compliance may be a more superficial compliance, whereas substantive compliance would relate to a deeper value-based concern with the populations involved and placing their health needs above any other concerns.

Because non-adherence to these three principles (or "bending" the principles to suit the researcher's needs) is likely to result in research participants being treated unethically and without dignity, occupational therapists should acquaint themselves with local and international research ethics guidelines. The ethical considerations should be well described in papers, as journals ought not to publish unethical research[3,16].

Unfortunately the mere existence of research ethics guidelines and codes do not guarantee that all research will be conducted ethically[2], but do at least provide standards for measurement:

The mere formulation of ethical guidelines for biomedical research involving human subjects will hardly resolve all the moral doubts that can arise in association with much research, but the Guidelines can at least draw the attention of sponsors, investigators and ethical review committees to the need to consider carefully the ethical implications of research protocols and the conduct of research, and thus conduce to high scientific and ethical standards of biomedical research[6:13].

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