

Chapter 6

Producing evidence ethically

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Introduction

Even established researchers can sometimes forget that their research proposal contains issues for the participants and/or the researcher themselves that have wider implications for the health, safety and dignity not only of the participants and researcher but also of society at large. In the drive to have that proposal accepted for funding and/or for academic recognition, researchers sometimes fail to think through the implications of their research, especially those implications that impact directly on the well-being of their participants.

This chapter examines research from an ethical perspective. It will identify ethical issues inherent within the research process from the research participant's perspective. It also looks at the process of ethical review and helps locate within professional perspectives how the research participant is protected by examining the ethical issues found within the various research methods discussed earlier in this book.

1 Development of ethics within research

Concern about the potential harm to participants inherent within research designs is not a purely twentieth century phenomenon. During the late nineteenth century, after an era of medical experimentation conducted under the 'ethos of science and medical progress' (Vollmann and Winau, 1996, p. 1445), concern was expressed about the lack of consent obtained in experimental research. In 1898, Albert Neisser, who discovered the bacterium *Gonococcus*, was fined by the Royal Disciplinary Court for failing to obtain consent from participants in his clinical trials on serum therapy for syphilis prevention at the University of Breslau (now the University of Wrocław, Poland). Neisser injected cell-free serum from patients with syphilis into patients admitted with other medical conditions, who were never told about the experiment or asked for their consent. When these women contracted syphilis, Neisser concluded that his vaccine had not worked and, as the women were mainly prostitutes, he claimed they had contracted syphilis from their work as prostitutes (Vollmann and Winau, 1996).

During the German Third Reich (1933-1945), medical experimentation brought a new dimension to ethical dilemmas in medical research, which has had a lasting effect on human biomedical research today. After the Nuremberg Trials, a code of practice was drawn up, based on the Articles of the Nuremberg Tribunal in 1947, known as the Nuremberg Code (Eby, 1995).

Following World War Two and the Nuremberg Trials, concern was publicly voiced about the protection of participants involved in research. Yet, despite the outcomes of these trials and the development of the Nuremberg Code, research continued often regardless of its outcome on participants. Some 20 years after the Nuremberg Code, the World Medical Association in 1964 adopted the Declaration of Helsinki, revised in 1996 (South Africa), and currently under review (Nicholson, 1999).

The Declaration cites 12 basic principles, which are somewhat similar to the Nuremberg Code's principles with one major exception. The Nuremberg Code gives primacy to the research participant's voluntary, informed consent, while the Declaration of Helsinki states, 'if the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee' (Medical Research Council, 1998, p. 32).

The Declaration of Helsinki does provide for the independent ethical review of biomedical research. It is apparent, however, that the concept of informed consent has been modified from the Nuremberg Code. Under the Declaration of Helsinki, Nuremberg's rigid requirement for respect for persons is softened, and the requirement for informed consent differentiates between therapeutic and non-therapeutic clinical research. Grodin *et al.* (1993, cited in Seidelman, 1996, p. 1465) believe that the Declaration of Helsinki 'undermined the primacy of subject consent in the Nuremberg Code and replaced it with the paternalistic values of the traditional doctor-patient relationship.'

Despite the development of both the Nuremberg Code, published in 1947, and the Declaration of Helsinki nearly 20 years later, research was still being done without regard to the health and well-being of its participants. The literature cites many examples (Krugman *et al.*, 1978; Campbell *et al.*, 1992; LoBiondo-Wood and Haber, 1994; Lock, 1995; Dowd and Wilson, 1995; Nicholson, 1997; Homan, 1998) but two studies stand out as illustrative of the lack of concern and respect for the individuals involved. The Tuskegee syphilis study (1932-1972), characteristic of medical research of its time and in its treatment of informed consent, is described in Box 1 (overleaf).

Fundamental problems with this longitudinal study were the lack of information given to the participants, the lack of adequate treatment, especially after the discovery of penicillin, and the lack of voluntary consent. Even though in some cases consent was nominally obtained, it was based on misinformation and/or failure to inform the participant of the real risks of the research study.

Box 1 The Tuskegee experiment (1932-1972) in Macon County, Alabama used two groups of black male farm workers to examine the long-term effects of syphilis. One group consisted of individuals who had the disease while the other group was judged to be free of the disease. Over the years, and despite the advent of penicillin which in the 1950s was accepted as the gold standard treatment for syphilis, no treatment was made available to the group with syphilis. In fact, some commentators suggest that efforts were made to keep the group from learning about or even receiving penicillin. The study ended in 1972 after a Congressional investigation, which led to the enactment of legislation establishing institutional review boards or local research ethics committees.

(Source: based on Kampmeier, 1972; Cobb, 1973; Benedek, 1978; LoBiondo-Wood and Haber, 1994; Brawley, 1998)

The second example, which also illustrates this lack of concern and respect for the research participants involved, is Stanley Milgram's *Behavioural Study of Obedience* (1963), described in Box 2.

Box 2: Experimental design - behavioural study of obedience (1963)
Stanley Milgram (1933-1984), investigating the destructiveness of obedience, designed an experiment in which informed subjects - 40 men - administered increasingly higher voltages of electricity to a victim - a white Anglo-Irish male - within a teaching-learning situation; that is, when the victim either gave the wrong response or was unwilling or refused to answer a question, ever-increasing electrical shocks were administered. In reality, the electrical generator was a fake, and the victim, a confederate of the experimenter, was acting out the moans, cries and screams in response to allegedly receiving electrical shocks. At the end of the experiment, 26 subjects obeyed the commands of the experimenter and administered the highest shock - 450 volts - on the generator even when there was no response from the victim; while 14 subjects broke off the experiment between 300 and 375 volts, after the victim protested and refused to provide further answers. Milgram was surprised by the high number of individuals who were willing to administer what was supposedly a lethal electrical shock, but he did not expect the extreme levels of anxiety exhibited by some of the subjects.
(Source: based on Milgram, 1963)

Milgram goes on in his paper to describe a 'de-hoaxing' session in which he ensured the subjects met the victim so they could see that the victim was not hurt or even dead. Baumrind (1964, cited in Gross, 1996) criticises Milgram for not taking adequate measures to protect his research participants from psychological harm. Whether Milgram's one de-hoaxing session went far enough is difficult to know as there appears to be no follow-up of these participants. Milgram stressed that anxiety and emotional distress was never an intended outcome of his research, stating:

Understanding grows because we examine situations in which the end is unknown. An investigator unwilling to accept this degree of risk must give up the idea of scientific inquiry.

(Milgram, 1974, cited in Gross, 1996, p. 854)

Or, as Richard Gross (1996, p. 854) concludes, 'you cannot know your results in advance!'

The question to ask is would these studies be conducted today? Most academic disciplines have adopted guidelines or codes for research involving humans and animals. These codes and guidelines are based on fundamental ethical principles that attempt to protect the research participant from harm. However, as Michael Hornsby-Smith (1993, p. 63) concludes, '... in the last analysis, it is the individual researcher who must take responsibility for the methods he or she uses ... '.

2 The ethical review of research

The process of ethical review is in some instances very formalised, as in the case of biomedical research with local health authorities setting up and relying on the advice from local research ethics committees. They may also rely on the more recently convened multicentred ethics committees that are responsible to the Secretary of State for the ethical review of biomedical research within NHS Executive regions of the UK (McHale *et al.*, 1997; Parker, 1994; Tierney, 1995). These ethics committees include the perspectives of ordinary individuals as they contain members of the public who are not in professional practice.

Social services departments have also centralised ethical review through the Association of Directors of Social Services Research Group whose 'aims [are] to encourage social services departments to use empirical evidence when they are developing policy and practice' (ADSS Research Group, 1996, p. 1). Some university academic departments also have research ethical review boards. However, research is still done today without ethical review: for example, public opinion polls, market research, and even some government-funded research.

Approaches to ethical reviews

There are many different approaches to thinking about ethics. Richard Rowson, a philosopher and teacher of medical ethics, defines ethics as 'thinking and reasoning about morality' (Rowson, 1990, p. 3, cited in Brechin *et al.*, 2000, p. 121) while morals are 'the actual standards of behaviour or conduct held by individuals or groups' (Eby, 1994, p. 22, cited in Brechin *et al.*, 2000, p. 120). Ethics can be thought about in terms of virtues or qualities of worth and value such as wisdom, courage, truthfulness and honesty. The researcher is seen as a virtuous individual, one who knows what the right course of action is and takes it. The virtuous researcher would not harm or deceive the research participant.

The duties approach to ethics is important to researchers as well because it stresses the principle of doing good or beneficence. The Nuremberg Code places on researchers the duty not to harm the research participants, requiring that the risk involved does not outweigh the importance of the research problem under investigation. Incumbent in most guidelines, standards, principles and codes of research conduct is the implied responsibility of the researcher towards the research participant, which is cast in the language of a 'duty to care'.

The consequences approach, especially utilitarianism, is used by researchers to justify using research participants as a means to an end, especially if that end brings health to many more individuals. This is the essence of utilitarianism - that the good of one person may be sacrificed for the good of many.

The feminist approach, on the other hand, focuses on the emotions, beliefs and values of the researcher and how these may influence the research agenda. Unravelling the power relationships within the research process and exposing exploitative relationships have led to changes in how research is done (Grbich, 1999).

Despite the influences these ethical approaches have had on the research process, the ethical review of research stems from two fundamental approaches - the principle-based and the human rights approach. Most guidelines, standards, principles and codes of conduct are based on one of them. The UK mainly uses the principle-based approach in its ethical reviews of biomedical research; in the USA and Europe the human rights approach prevails.

Principle-based approach

The principle-based approach focuses on the four fundamental principles of biomedical ethics: namely, beneficence or the principle of doing good; non-maleficence or the principle of doing no harm; respect for autonomy and truthfulness; and justice or fairness (see Box 3). These four principles form the basis for many of the stipulations upon

Box 3: Fundamental ethical principles*The principle of respect for persons*

The duty to respect the rights, autonomy and dignity of other people.

The duty to promote their well-being and autonomy.

The duty of truth-full-ness, *honesty* and sincerity (honour = respect), for deceit is *dishonourable*.

(The concept of a person (i.e. a bearer of rights and duties) is the constitutive principle for both law and ethics (and politics).)

The principle of justice

The duty of universal fairness or equity.

The duty to treat people as ends, never simply as means to an end.

The duty to avoid discrimination, abuse or exploitation of people on grounds of race, age, sex, class, gender, or religion.

(The principle of justice requires of us that any personal rule of action we use, should, in principle, be capable of being universalised for all people. For this reason it is sometimes described as the principle of universalisability.)

The principle of beneficence (or non-maleficence)

The duty to do good and avoid doing harm to others

The duty of care, to protect the weak and vulnerable.

The duty of advocacy: defending the rights of the weak and vulnerable, or incompetent.

(Like the golden rule (do unto others as you would have them do unto you), this principle is sometimes referred to as the principle of reciprocity.)

(Source: Thompson et al., 1994, p. 59)

which various health care professional organisations' guidelines and codes are based.

Thinking of these principles when reviewing a research protocol within the health and social care field might raise questions that hitherto had not been apparent. For example, would the researchers in the Tuskegee study still not have treated the research participants with penicillin if they had considered the principles of justice and non-maleficence? Or, based on the principle of respect for autonomy and truthfulness, would the researchers have disclosed to the participants the true nature of their participation in this research study?

Human rights approach

Human rights are claims and demands of individuals or groups that are justified in the eyes of society. Essentially there are five basic human rights as shown in Table 1 (opposite), which also gives examples of when these rights are violated. An ethical review should ensure that the research participants' basic human rights are not violated, which essentially was the basic principle underpinning the Nuremberg Code (1947). Interestingly though, the right to fair treatment and the right to anonymity and confidentiality are not mentioned in the Nuremberg Code - or in the Declaration of Helsinki for that matter.

Using these five basic rights as the framework for an ethical review might raise questions that had not previously been considered. For example, in Milgram's study, the participants' right to self-determination was violated through the deception of the experimental design. The rather impressive electrical generator was an elaborate fake - it could not deliver an electric shock at all. Consequently, the victim had to feign his responses, leading the research participants to believe he was actually being injured to the point that his silence was construed by them as his death.

Questions to ask in an ethical review

The ethical review of research, whether through formal institutional review or by the individual, rests upon a reflective and deliberative interrogation of the researcher's research design and methods based on fundamental ethical principles and approaches. Within health care, the local research ethics committees (LRECs) or the centralised multicentred research ethics committees (MRECs) have a proforma framework that essentially addresses the questions in Box 4.

Box 4: Ethical review of research

Validity of the research (consequence-based)

How important is the research question?

Can the research answer the question being asked?

Welfare of the research subject (duty-based)

What will participating in the research involve?

Are any risks necessary and acceptable?

Dignity of the research subject (rights-based)

Will consent be sought?

Will confidentiality be respected?

(Source: based on Department of Health, 1997, p. 11)

Table 1 Protection of human rights

<i>Basic human right</i>	<i>Definition</i>	<i>Examples of violation</i>
Right to self-determination	Based on the ethical principle of respect for persons; people should be treated as autonomous agents who have the freedom to choose without external controls. An autonomous agent is one who is informed about a proposed study and is allowed to choose to participate or not to participate; and research participants have the right to withdraw from a study without penalty Research participants with diminished autonomy are entitled to protection. They are more vulnerable because of age, legal or mental incompetence, terminal illness, or confinement to an institution Justification for use of vulnerable subjects must be provided	A research participant's right to self-determination is violated through the use of coercion, covert data collection and deception Coercion is when an overt threat of harm or excessive reward is presented to ensure compliance Covert data collection is when people become participants and exposed to research treatments without knowing it Deception is when subjects are actually misinformed about the purpose of the research Potential for violation of the rights to self-determination is great for research participants with diminished autonomy; they have decreased ability to give informed consent and are vulnerable
Right to privacy and dignity	Based on the principle of respect. Privacy is the freedom of a person to determine the time, extent and circumstances under which private information is shared or withheld from others	Invasion of privacy occurs most frequently during data collection when invasive questions are asked that might result in loss of job friendships or dignity, or might create embarrassment and mental distress. It also may occur when subjects are unaware that information is being shared with others
Right to anonymity and confidentiality	Based on the principle of respect. Anonymity exists when the subject's identity cannot be linked even by the researcher with his or her individual responses Confidential means that individual identities of research participants will not be linked to the information they provide and will not be publicly divulged	Anonymity is violated when the research participant's responses can be linked with their identity Confidentiality is breached when a researcher, by accident or by direct action, allows an unauthorised person to gain access to study data that contain information about the research participant's identity or responses that create a potentially harmful situation for that participant
Right to fair treatment	Based on the ethical principle of justice, people should be treated fairly and should receive what they are due or owed Fair treatment is equitable selection of research participants and their treatment during the research study. This includes selection of research participants for reasons directly related to the problem studied versus convenience, compromised position, or vulnerability. It also includes fair treatment of research participants during the study including fair distribution of risks and benefits regardless of age, race or socio-economic status	There have been injustices in selecting research participants as a result of social, cultural, racial and gender biases in society Historically, research participants are often from groups of people who were regarded as having less 'social value', poor people, prisoners, slaves, mentally incompetent and dying people. Often research participants were treated carelessly without consideration of physical or psychological harm
Right to protection from discomfort and harm	Based on the ethical principle of beneficence, people must take an active role in promoting good and preventing harm Discomfort and harm can be physical, psychological, social or economic in nature. Levels of harm range from no anticipated effects to temporary discomfort to unusual levels of temporary discomfort to risk of permanent damage to, finally, certainty of permanent damage	A research participant's right to be protected is violated when researchers know in advance that harm, death or disabling injury will occur and thus the benefits do not outweigh the risk

(Source: adapted from LoBiondo-Wood and Haber, 1994, pp. 32)

These six questions form an ethical framework based on a consequences, a duties and a rights-based approach to ethics. The questions can be used to examine research designs, methods and their effects on research participants. Some people feel this type of proforma framework does not go far enough in ensuring the protection of the research subject (Eby, 1995; Ashcroft, 1998; Smith, 1999; Sprumont, 1999). For example, will the research participant be protected from both physical and emotional harm? Allowing the researcher to calculate the risk may not always be in the best interest of the research participant. These questions also fail to identify the hidden social and political pressures underpinning the researcher's epistemological and ideological basis. Fernando (1989, pp. 250-51, cited in Patel, 1999, p. 9), drawing upon research into the area of mental health, suggests:

... that the prevailing political context must be taken into account in examining the effects of mental health research published in scientific journals it is naive to assume that research on issues involving 'race' is value free when conducted in a racist society, within a discipline, such as psychiatry, with a powerful racist tradition.

3 Ethical issues within research design

Both the principles and human rights approaches to the ethical review of research are discussed in this section, which focuses on specific ethical issues emerging out of the research designs discussed in earlier chapters. A series of research vignettes will be the focus of discussion. Although aimed at being representative, they cannot of course cover the complete range of research methods available. However, the aim of this section is to highlight some of the major ethical issues found within these representative examples.

Vignette 1 (opposite) illustrates a pharmaceutical randomised control trial (RCT), which will provide the evidence needed by a drug company for establishing a safe and effective dosage range required for drug licensing. Three crucial aspects of the RCT raise ethical concerns: the process of randomisation; the intervention itself; and the use of a control group. Ethical concerns for the process of randomisation relate to the research participant's consent to enter the trial based on that individual's understanding of what the trial was about.

Research by Kate Featherstone and Jenny Donovan (1998, cited in Joule, 1998, p. 23) showed that, even though patients could indicate an understanding of the concept of randomisation, they nevertheless thought that the doctor had assigned them to a group based on their own symptoms and medical history. This, as Featherstone indicates, has 'implications for informed consent. Perhaps patients need to be given the opportunity to explore these issues more fully before consenting to participation in a trial' (Featherstone, 1998, cited in Joule, 1998, p. 24).

Vignette 1: Randomised controlled trial - protocol for a dose-finding study of G1234 (a new drug) in patients with uncomplicated essential hypertension

This is a single-centre, randomised, double-blind, placebo-controlled trial to evaluate a new drug, G1234, which lowers blood pressure. Animal studies have shown that G1234 is well tolerated to 50 mg/kg/day. Phase I studies of single doses up to 100 mg of G1234 in 12 volunteers showed rapid oral absorption to peak levels in one to two hours and only one volunteer exhibiting a significant drop in blood pressure but without fainting. This proposed study will last nine weeks and is in three stages: Stage 1 - a four-week wash-out period without medications to establish a baseline of the subject's hypertension; Stage 2 - a four-week treatment period consisting of a double-blind placebo-controlled randomised parallel comparison of three different dosages (12.5 mg, 25 mg, 50 mg) and a placebo; and Stage 3 - a one-week wash-out follow-up period without drugs.

Subjects, to be recruited from out-patient clinics, will be aged 18 to 70, with a diagnosis of essential hypertension and with a diastolic blood pressure between 95 and 125 mm Hg at each of the last two visits before the start of Stage 1. After obtaining consent and detailed screening investigations to rule out exclusion criteria, eligible subjects will be withdrawn from their current anti-hypertensive medication and switched to a placebo medication for the wash-out period. After this, subjects will be randomly allocated to 12.5 mg, 25 mg or 50 mg of the drug or to the placebo in Stage 2. Subjects will be assessed at each study visit and if, during the active treatment period, the blood pressure remains uncontrolled, the subject can be withdrawn from the study at the discretion of the investigator.

(Source: based on Department of Health, 1997, pp. 38-39)

In the case of pharmaceutical drug trials, consent to participate from competent adults is required by UK, European and international regulations. In the UK, the Department of Health's *Guidelines to Local Research Ethics Committees* (1991, reprinted in McHale *et al.*, 1997, p. 573) advises that consent be obtained in writing and, in the case of therapeutic research as in Vignette 1, consent should be recorded in the patient's medical record.

Currently, the *ICH Harmonised Tripartite Guidelines for Good Clinical Practice* (ICH, 1996) specify required elements that need to be included in the patient information sheets used to recruit individuals into pharmaceutical drug trials. In line with ICH*, the Scottish Office has produced a set of guidelines for researchers preparing patient information sheets and

* International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

consent forms. These guidelines will now become integrated into the MRECs' and Scottish LRECs' process of ethical review of research (Scottish Office, 1999, p. 8). Having reliable and valid information is a corner-stone of autonomy and self-determination but it relies on the principle of truth telling and honesty. However, information is only one aspect of consent. Comprehension of the information is crucial to obtaining consent as is the notion of voluntariness, that is, consent obtained free of coercion and undue influence.

Ethical issues arising from the actual intervention under investigation in an RCT relate to the assessment of risk with regards to the potential benefits to be derived from the actual treatment or drug under study. In Vignette 1, individuals are being asked to consider trying out a new drug that will control their blood pressure presumably as well as, if not better than, their current medication. But, if one of this new drug's side-effects is a 25% increase in the risk of stroke, while uncontrolled high blood pressure has only a 15-20% risk of stroke, the risks of this drug outweigh any possible benefits. Will the researchers be truthful and inform the prospective research participants that these risks exist? Under current guidelines they now must and, clearly, this is one aspect of ethical review that is closely scrutinised.

But this is not quite so clear-cut as it seems for it depends on whether the intervention is therapeutic or non-therapeutic, which relates to the acceptable degree of risk an individual should be allowed to face. For non-therapeutic research, it is generally felt that research participants be exposed to only minimal risk, which is defined as 'a risk of injury or death that is no more than that encountered in daily life' (Smith, 1999, p. 90).

This leads on to one of the most highly contentious aspects of RCTs - the use of a control group receiving a placebo rather than the active treatment or intervention being tested. The basis for the use of placebos is that patients who think they are trying out a new treatment tend to expect and then find an improvement in their condition - this is known as the placebo effect (Elander, 1991; Smith, 1999). In Vignette 1, a research participant could be randomised into the control group and for nine weeks be deprived of any real medication for their high blood pressure. Is that acceptable? This use of a non-treatment or placebo group raised issues of deception in the past since research participants were often not told that randomisation into such a group was possible. Given current guidelines that should no longer happen. The use of a blind study also ameliorates the issue of lying since the doctor does not know whether the research participant is having the active or the placebo treatment.

But even with these current changes, the problems of equity and justice still persist. Should not all research participants have equal access to new and potentially beneficial treatment? On the other hand, the safety and efficacy of new treatments can only be established by testing. Treating any participants carries a risk but it may be justified as part of a trial.

Vignette 2 describes another RCT and, like Vignette 1, there is the issue of consent, randomisation and a control group. But, unlike Vignette 1, the

control group is not receiving a placebo or no intervention but rather will remain on the same level of service that currently would be available. The issue for this RCT relates to consent from vulnerable groups, that is, homeless and/or with long-term severe mental illness.

Vignette 2: Randomised controlled trial - social services case management

This study's aim was to evaluate the effectiveness of social services case management for individuals with long-term mental illnesses within the community. Participants were referred from hostels for the homeless, night shelters, GP clinics for homeless people, a city council homelessness unit and local voluntary group homes if, in the opinion of the referrer, the person had a severe, persistent, psychiatric disorder, was homeless or about to become homeless, was not coping, was experiencing social isolation or causing disturbances, and was not already within a case management service. Of the 103 individuals referred, 80 agreed to be randomised after initial assessment. Participants were randomised into the case management group or the control group. The case management group was offered an assessment of need with interventions provided. The control group continued to receive the same level of support as before the study.

(Source: based on Marshall *et al.*, 1995)

There are no references in the published article of this research to issues of consent. However, obtaining consent from such a vulnerable group does require careful thought for the issue is not just about an individual's mental capacity to comprehend the information given but, more importantly, it is about the very form and nature of the explanation given. Arguably, all individuals have the right to self-determination and, as the Department of Health guidelines state, 'the presence of mental disorder does not by itself imply incapacity, nor does detention under the Mental Health Act 1983' (Department of Health, 1991, reprinted in McHale *et al.*, 1997, p. 587). However, balancing this right to self-determination and autonomy is the duty on the researcher not to expose the research participant to harm, either physical or psychological.

Guidelines within health care stress the value of allowing people who cannot consent to participate in research (Royal College of Psychiatrists, 1990; Medical Research Council, 1991; Department of Health, 1991) but with the following safeguards in place (Medical Research Council, 1991, p.22):

- the research protocol is approved by the LREC
- the individual concerned has not expressed any objections either verbally or through action
- in the case of therapeutic research, participation in the research would be in that individual's best interest

- in the case of non-therapeutic research, participation in the research would be of negligible risk to health and not against the individual's best interest.

But do these safeguards deal with the issue of power and control? There may be covert pressure to participate in the research either to please the researcher, who happens also to be that individual's treating doctor, or because the researcher is in a position to influence outcomes for the individual, that is, obtain further treatment or secure housing or additional benefits (Royal College of Psychiatrists, 1990; Mount *et al.*, 1995, cited in Devereux, 1998). This certainly seems to strengthen the paternalistic position of the researcher, one that inhibits the research participant's self-determination and autonomy. As Devereux continues, 'in my experience patients often consider it their duty to participate in a study or see it as some sort of repayment. They may feel obliged to participate because they think that they are indebted to the caring professions as a result of their illness' (Devereux, 1998, p. 58).

Interviewing shares with RCTs similar concerns about consent, although in Vignette 3 the issues of power and control are made more acute by the fact that the researcher interviewed the women in their own homes. This raises issues of privacy, which it can be argued has been invaded, and betrays a sense of hidden coercion since the mothers would undoubtedly feel indebted to the midwives for the safe delivery of their babies. Again it can be argued that the mothers were also a vulnerable population.

Vignette 3: Interviewing - promoting successful breast feeding among women with low incomes

The aim of this study was to identify factors that promoted or discouraged successful breast feeding in a sample of women with low incomes who delivered at a district general hospital. The community midwives were asked to identify postnatal women who had breast-fed their latest baby at least once and who at booking were identified as receiving state benefits or were aged 16-17 and unemployed. In addition, the researcher scanned all postnatal notes returned to the clinic for filing to ensure no eligible woman was overlooked. Of the 20 eligible women only 15 agreed to participate in the study. The women were interviewed in their homes between 21 and 28 days post-delivery using a semi-structured interview format, which lasted from 2 to 3 hours. These interviews were tape-recorded and then transcribed verbatim by the interviewer. The authors' discussion with colleagues concluded that this research was an audit and thus ethical approval was not needed.

(Source: based on Whelan and Lupton, 1998)

Crucial to this research method is the basic human right to confidentiality and anonymity, which is based on the principles of respect and trust, as well as the right to dignity and privacy, which is based on the principles of beneficence and non-maleficence. Interviewing as a research method depends on the ability of the interviewer to probe and search for the hidden voice within the research respondent before the respondent realises what has been said. As Fontana and Frey (1994, p. 373) state, 'the techniques and tactics of interviewing are really ways of manipulating respondents while treating them as objects or numbers rather than individual human beings.' But interviewing can also leave the researcher in a dilemma especially if during the interview the respondent reveals disturbing or painful information or information about illegal behaviour. Does the researcher break confidentiality to reveal this information?

Confidentiality is a principle found in all professional codes and guidelines related to research. Essentially, disclosure of confidential information requires the consent of the individual unless 'disclosure is required by law or by order of the court' or when disclosure is considered 'necessary in the public interest' (UKCC, 1996, p. 27). However, the British Association of Social Workers' *Code of Ethics for Social Work* (1996, p. 5) states that 'information clearly entrusted for one purpose should not be used for another purpose without sanction.'

The Department of Health's *The Protection and Use of Patient Information* (DoH, 1996) states that sometimes it is defensible to disclose confidential information in the public interest without consent or statutory authority. However, there are no clear guidelines on what exactly constitutes 'in the public interest'. The Public Interest Disclosure Act 1998, para. 43B (HMSO, 1998), which came into force on 2 July 1999, defines a protected disclosure as one made in good faith which the employee reasonably believes relates to one of the following situations.

- A criminal offence has been committed, is being committed or is likely to be committed.
- A person has failed, is failing or is likely to fail to comply with any legal obligation to which he or she is subject.
- A miscarriage of justice has occurred, is occurring or is likely to occur.
- The health or safety of any individual has been, is being or is likely to be endangered.
- The environment has been, is being or is likely to be damaged.
- Information tending to show any matter falling within anyone of the preceding paragraphs has been, is being or is likely to be deliberately concealed.

The Protection and Use of Patient Information continues:

Each case must be considered on its merits, the main criterion being whether the release of information to protect the public should prevail over the duty of confidence to the patient. The possible therapeutic consequences for the patient must be considered whatever the outcome.

Decisions will sometimes be finely balanced and may concern matters on which NHS staff find it difficult to make a judgement. Therefore it may be necessary to seek legal or other specialist advice or to wait or seek a court order. It is important not to equate 'the public interest' with what may be 'of interest' to the public.

(Department of Health, 1996, p. 18)

Anonymity or the removal of identifying information also reinforces dignity and respect for people, although often this is a neglected area within research design. In the published article for Vignette 3, the authors include short paragraphs taken from the transcriptions of the audio-tapes. There is no mention in the published article of whether they allowed the respondents to look over or verify the transcriptions of their own interviews. Allowing respondents access to the transcribed interviews enhances dignity and reinforces their autonomy.

These short paragraphs, although not attributed by name, are identified by a number and whether the mother was breast feeding or bottle feeding. In that sense, the authors have maintained anonymity. However, the individual respondents reading through the article could recognise themselves by what they had said. Not knowing that what they said in confidence was going to be published may well have quite an impact on trust. Seeking permission from research participants to include short extracts of what they said in the interview in publications further enhances the trust between researcher and participant.

Vignette 3 also describes the dilemma researchers face between audit and research and whether an ethical review is needed. Audit is about monitoring the services offered to patients and clients. 'Audit seeks to improve practice and treatment and to reduce risk by the systematic review of the process and outcomes of care and treatment and by the evaluation of records and other data' (UKCC, 1996, p. 36) or, as the British Medical Association states, 'Research is concerned with discovering the right thing to do; audit with ensuring that it is done right' (BMA, 1996, p. 5).

The BMA (1996) and the UKCC (1996) have recommended that audit projects do not need to be submitted for ethical review by a research ethics committee but rather that audit committees set up to co-ordinate audit projects should consider the ethical issues that arise from audit such as confidentiality, anonymity, consent to use patient/client's records, and the scientific validity of the proposed audit methodology. AVOIDING ethical review by LRECs does not remove the researcher's obligation to ensure that the research participants are not exposed to unacceptable risks and do derive some benefits from co-operating in the research.

Action research 'is simply a form of self-reflective enquiry undertaken by participants in social situations in order to improve the rationality and justice of their own practices, their understanding of these practices, and the situations in which the practices are carried out' (Carr and Kemrnis, 1986, p. 162; see also Chapter 5 of this book). Action research in Vignette 4 aims to empower the participants, which appears to have been the goal of

the day care centre for people with learning difficulties. In this action research, the researcher and participants became partners, although whether they are equal partners is questionable. In this case, the participants involved individuals with learning difficulties, a vulnerable group. This raises the issue of consent - first, to whom are the participants giving their consent and, second, to what have the participants consented (Williams, 1995)?

Vignette 4: Action research - day care on the move

This project focused on a day' care centre for adults with learning difficulties and aimed to change the culture of the centre from care management and principled contracting to one of user involvement and choice through participative action research. Individuals with learning difficulties and the day care centre staff, using the Scottish Human Services package *Changeover*, became co-researchers to create shared and usable knowledge that aimed to transform the culture of the day centre. The techniques used to facilitate the change were group discussion, brainstorming, SWOT analyses, and reflective discussion. The outcomes of these activities were the development of network groups and a self-*advocacy* group, which has created a new discourse that challenges traditional disablist discourse.

(Source: based on Baldwin, 1997)

Were these participants giving consent to the researcher - the individual charged with implementing the changeover from case management to user choice - or were they consenting to the organisation itself - the day care centre - to act as volunteers in this change over process? And what exactly were they consenting to? Was it to continue to participate in the day care centre? Or were they actually consenting to the change itself, that is, instead of case management, the participants were consenting to the changeover to user involvement and choice?

As Williams (1995, p. 52) suggests, 'action researchers normally try to facilitate change in *others*. In "helping", "facilitating" and "emancipating", one runs the risk of being labelled patronising.' Change itself also brings the element of fear of the unknown. In this case, fear of the day care centre closing could well have prompted the participants to consent. Given the complexities found within consent in action research, the scope for deception in these circumstances raises many questions regarding power and control.

Confidentiality also becomes an issue if the participants are co-researchers and partners. Who, then, makes decisions about what is revealed or not and to whom it is revealed? As Williams (1995, p. 55) points out:

... ideas about democracy and egalitarianism in some ways sit uneasily with ideas about the responsibility of researchers to protect and

maintain the integrity of research participants. If the so called 'co-researchers' had equal control over the research, then confidentiality would be a matter of a collective agreement on the part of all co-researchers (including 'the researcher') to respect the sensitivities of all.

Vignette 5 raises three kinds of issues. The first concerns the open-ended nature of qualitative research, which is often started without the researcher knowing exactly what will be found. This makes it very difficult for researchers to seek ethical approval from ethics committees in advance of the research being done. Similarly, it is difficult for research participants to be forewarned about what the researcher is exactly looking for, which makes informed consent an impossible task. Usually, it is not until researchers are well into analysing the data after leaving the research location that they know what the data are saying. Some researchers tackle this problem by offering the research participants the opportunity to read and comment on the draft research publication. But should the researcher allow those studied to rewrite the research findings? Vignette 5 poses this problem in its most extreme form. If Bowler had warned the staff of her growing interest in racist stereotypes and discriminatory practices then presumably the staff would have modified and changed their expressed views and practices. If she had offered editorial control over the published results then it is unlikely this study would have been published.

Vignette 5: Evaluation - ethnographic research in an obstetrics unit

Isobel Bowler spent three months observing activities in a maternity hospital and recording what she saw and heard. She also held in-depth interviews with midwives, obstetricians and mothers. Her particular interest was in how South Asian mothers were thought about, spoken about and treated by staff. Her findings present a picture of white staff holding racist stereotypes about South Asian women and of poor midwifery and obstetrics practice for South Asian mothers in comparison with white mothers. It is not clear how Bowler explained the purpose of her research to the staff or to the mothers. But, given the results, it seems reasonable to assume she did not forewarn the staff she was particularly interested in their racism. The hospital concerned was made anonymous in the published research, but there must have been many people who knew where Bowler had done her research, including the people who are quoted extensively in the published article.

(Source: based on Bowler, 1993)

The second issue raised by Bowler's study is about striking a balance between the rights of those studied to confidentiality, privacy and honesty versus the benefits to be derived from being reticent about the purpose of the research and then breaching privacy by publishing the results in order to draw attention to institutional racism within obstetric care.

The third issue concerns the most effective means to combat racism. Would it have been more effective to have abandoned the research to draw attention to institutional racism within the hospital concerned; perhaps to have the issue successfully dealt with locally? Or was it more effective to do as Bowler actually did, which was to collude with racist practice for the duration of the research in order to produce evidence that might be used to confront racism in midwifery more generally?

It should be obvious that too enthusiastic an adherence to the values of privacy, confidentiality and non-deceptive research would make abuse, malpractice and discrimination 'no-go areas for researchers. Much the same might be said for the value of doing no harm to the people studied, if they engage in racial or sexual discrimination, or unlawful or unprofessional activities. Looking again at the deception practised by Milgram (Section I), it is perhaps worth suggesting that, although his research would not be passed by a research ethics committee today, the study has been enormously valuable in demonstrating the power of obedience. Among other things, it is frequently cited in discussions of research ethics to illustrate how easy it is for researchers to persuade people to consent to research in which they really do not want to be involved.

Conclusion

This chapter focused on the process of producing evidence ethically. Whether as a user of research, a research participant, a reader of research for work or professional development, or a researcher designing and carrying out research, ethical review is a fundamental part of the research process. Considering how the evidence was obtained is an important step in its evaluation. Without ethical guidelines, informed by explicit ethical principles, there would be no shared basis on which to judge the appropriateness of the research strategy. The desire to construct a tight research design and produce clear findings that will be of future value to other service-users may often be in conflict with individuals' rights to respect and dignity. A very respectful piece of research may be ethically sound and a positive experience for participants, but it may nevertheless fail to provide any useful contributions to knowledge. Ultimately, the issues are value-based. The challenge, for researchers and practitioners alike, is to judge research in terms of how well it keeps its balance - between rigour and respect. In other words, how far it succeeds in producing evidence ethically.

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