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The Ethics of Care in Biomedical Research Committees

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Abstract

Principle based decision making is most commonly used by Research Ethics Committees. Whilst useful and encouraging the agreement of members from diverse disciplines, principles may be used without consideration of the specific situation under discussion.

It is argued that, were some members of the committee familiar with the concepts and application of the ethics of care, they could engage in debate when the universal principles are used without consideration of the specific nuances of the situation under discussion. An 'eclectic' theory is not advocated as, unless conversant with the intricacies of each of the theories amalgamated, one is apt to slur theories and arrive at a messy, relativistic hodgepodge which is able to be manipulated every which way. However, using more than one source on which to base ethical decisions ensures that the universal and objective approaches which currently dominate the realm of ethical decision making in medical research are modified.

The authors, both members of a university research ethics committee, argue the value of considering other approaches to enable ethics committees to adopt a more holistic and comprehensive view of the research situation, the people involved and the role of research in general.

Introduction

Health professionals of all disciplines emphasise the importance of rendering holistic and comprehensive care. However, when the issue of research ethics is considered, proposed research is submitted to an institutional Human Research Ethics Committee (REC) (in the United States of America this would be called an Institutional Review Board or IRB) for ethics approval. The proposal is usually evaluated using a process which relies mostly on principle based criteria: autonomy, beneficence (and non- maleficence) and justice and, to a large extent, eschews a more holistic assessment of the ethical correctness of the study. Blanche et al. [1] define the Ethics of Care as comprising a relatively new body of moral theories which focus on the character traits of the persons and the relationships in which they are involved. In this case, the relationships of the researchers and their participants in the pursuit of biomedical and social research studies (research which is not directly treatment related but looks at perceptions, policies, opinions, experiences and quality of life of participants) [1]. In view of the need for holistic and compassionate care, we propose that the ethics of care would provide a more comprehensive means of assessing the ethical compliance of proposed research.

We will briefly sketch a background describing the increasing need for research in all health care disciplines and the concomitant increase in the ethical monitoring of research by institutions. We will then discuss the profile of many people who are recruited as subjects for the research projects. In the African and developing world contexts, these may represent different groups of people from those envisaged by traditional Western ethical theorists.

The makeup of University Ethics Committees will be described and a very brief sketch given of the basis of their decision making. We will expand on the principle based approach, which is the approach most commonly used, as the REC members, coming from different cultures and disciplines, are more able to agree on principles rather than the details of more philosophical theories [2].

This is followed by a discussion of the ethics of care as related to medical and biological research ethics. A short critique of the ethics of care follows and then we will conclude with the assessment that, because the ethics of care is currently under-developed, it is insufficient to be used as a stand-alone approach but is important as an adjuvant approach to ethical decision making in research.

Background

In all areas and in different disciplines there is an urgent need for research and an increasing emphasis on practice based on empirical studies rather than tradition or theory. For example, leadership and management programmes are developed, structured and tested by research methods. In engineering, models and materials are tested in large studies prior to implementation in the field. The pharmaceutical industry invests millions of dollars internationally in the research and development of medicines. Patenting a drug ahead of rival companies can mean the difference between either an astonishing profit or a heavy loss. In academia, universities are graded on their research output; faculty members' academic tenure and progress are dependent upon research and publication output and research programmes are now mandatory in all professional and academic courses. Increasingly, the term "evidence based practice" is recognised in all facets of society and in all professional disciplines.

Concomitantly, the emphasis on human rights, ethical compliance in human research and a history of ethically questionable decisions, for example the infamous Tuskegee syphilis experiment in the United

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States of America [3,4] has meant that universities, hospitals and publication houses require evidence that the pharmaceutical, natural or social science proposed has been submitted to and sanctioned by a Research Ethics Committee. Moreover, the requirements for ethical research are constantly being refined and are being enforced more stringently at international, national, provincial and institutional levels in order to ensure that the research is trustworthy and the subjects enrolled are protected.

Research subjects

Health care is increasingly considered a commodity in developed countries. The sophistication of community members, danger of litigation should a serious adverse event result from a drug or trial procedure, the scrutiny of medical insurance and managed health care case managers has resulted in a scarcity of research subjects for enrolment in clinical trials. Consequently, students and the poor and indigent are frequently recruited in developed countries and paid for their participation [5].

Despite their willing participation in these studies, their increasing sophistication, consumer protection organisations and the presence of a free press generally prevent any overt negligent or maleficent practice on the part of the investigator. Notwithstanding this safety net, accidents do happen as evidenced by the recently publicised catastrophic adverse side effects experienced in the United Kingdom by trial participants [6].

In developing countries, less sophisticated people who may be inadequately protected by the law or unaware of their rights, may be enrolled in studies with greater ease and possibly less stringent requirements in place for their protection [7,8]. Different ethnic affiliations and language groups, differing levels of literacy and the use of medical and research terms may jeopardise the full comprehension of information documents provided for potential study participants.

The literature on cultural competence in research is growing rapidly [9], nevertheless, many researchers are unaware of the complexity of the subject. In developing countries, marginalised groups can be used for social, therapeutic and pharmaceutical research. They are frequently invited to participate when the focus of the study is related to issues which primarily affect poor or vulnerable populations, some examples are: HIV/AIDS and its opportunistic infections, information about health care delivery in a poor public health care system, social studies of domestic violence and abuse, studies about the nutritional status of children in poverty stricken communities. Corruption is rife in developing countries; Phase II and III trials to test the safety and efficacy of new formulations are likely to pass the ethical requirements set as, if the proposals are contested, a small fee is likely to facilitate ethics committee permission. Le Carre's novel "*The Constant Gardener*" presents a well researched, albeit fictional account of the use of poor, marginalised and illiterate people in developing countries as drug trial participants [10].

Women in health care studies

Women of childbearing age have not been included in several large scale prevention trials [11]. This has had some unintended and potentially serious consequences. For example, for many years the symptoms of myocardial infarct considered the norm were, in fact, those displayed by men. Women's symptoms were not recognised with potential and actual disastrous consequences. It is now recognised that women present with very different symptoms when experiencing a heart attack. In the United States, the National Institute of Health initially recognised symptoms of Acquired Immune Deficiency Syndrome (AIDS) which were demonstrated by men based on the results of several studies. Women in the final throes of the disease were unable to access social support grants because they didn't display the recognised symptoms [12].

However, to the contrary, in many instances women have been unfairly enrolled in trials as in some instances they present an easier option to research certain drugs (for example, those targeting urinary incontinence) or, and this is particularly noticeable in social and epidemiological research, they are more accessible because they can be found in their neighbourhoods, present themselves to clinical facilities more frequently when pregnant or bring their children for routine monitoring and interventions such as immunisation. HIV/AIDS epidemiological statistics in Southern Africa have primarily been generalised to the population from unlinked specimens obtained from women attending antenatal clinics. Despite the omission of women from clinical research trials, ninety percent of the global burden of disease is carried by developing countries and, within these countries; women bear an unequal burden of poverty, illiteracy and subordination [12].

Research Ethics Committees

In clinical and pharmaceutical research, many if not most proposals are processed through a University Research Ethics Committee (REC) because frequently the principal investigators are clinical specialists and joint university appointees. In addition, the links with universities add credibility and prestige to studies. In order to ensure as broad and fair an evaluation as possible, bioethical research committees are required to be constituted of representatives of different clinical disciplines, and should include people with a research background and those who are also qualified to offer racial/ethnic subgroup and gender-based perspectives, ethical, legal, community and religious counsel. Membership is voluntary and unpaid. Continuing education in research ethics is a prerequisite and this is supported by funding from the committee. In the case of research conducted outside of the auspices of a university, particularly when the research proposed is not funded by an international pharmaceutical company or when it is investigator driven, a small hospital or private hospital research ethics committee will scrutinise the proposal. All are required to conform to the Medical Research Council guidelines [13].

When one considers the composition of the University Ethics Committees, one is faced with the reality that they might well be flawed in their deliberations. There are many reasons for this, including varying motivations for membership (for example, prestige, compliance with university requirements that academics belong to various faculty and university committees); the dual or joint employment of the members as both clinicians and academic members of the provincial academic affiliated hospitals and the university; variable levels of expertise; varying levels of compliance (particularly when reviewing proposals from one's own department or research group or the reluctance to criticise a colleague or superior's practise); different approaches to decision making and also different paradigmatic perspectives on research methodologies and the adoption of a formulaic, rigid and conservative approach modelled on a Western theoretical vantage point [14]. There is also the problem of time, most university RECs are made up of clinicians and other busy people who have a limited amount of time to scrutinise and critique an increasing number of submitted protocols.

In the faculty in which the authors are based, between five to ten

pharmaceutical initiated clinical trials and between forty to eighty five university research proposals are reviewed every month by the thirty eight members of the committee. The number of small clinical studies presented for review has also increased as specialist training in all the medical, nursing and allied therapeutic disciplines requires a research project to be conducted to comply with higher education legislation. Proposals are submitted by undergraduate and post graduate students, joint clinical and university appointees, university staff members and any researchers wishing to conduct studies in the faculty or the university affiliated hospitals and clinics.

Each member is allocated a number of proposals to review in depth. Two members review each proposal and their findings are presented to the whole committee at the monthly meeting. In addition, the chairperson or deputy chairperson peruses each proposal. All members are in receipt of a detailed synopsis of the studies, the information and consent documents as well as the research instruments and letters of permission submitted to relevant authorities. Each proposal can then be accepted on the recommendation of the two assessors, discussed with recommendations for changes or rejected with or without conditions for re-acceptance for ethics assessment. Adopting a formulaic approach helps facilitate the process.

Ethical approaches

General normative ethics tries to formulate basic principles and virtues governing moral life [15]. Everyone grows up with a basic understanding of morality; lying, stealing, infringing on the rights of others, harming or killing others are recognised as wrong by almost all people in all societies. The term for this general understanding of moral norms is, according to Beauchamp and Childress (2001:24) the "common morality" [16]. Discipline specific approaches encompass the common morality and, in addition, consider norms, values and principles which impact upon the practice of the discipline.

Bioethics emerged from the disciplines of medical and nursing ethics in order to guide and regulate professional conduct in these fields. The concepts and norms are applied in clinical practice to maintain good practice standards, to guide decision making when ethical dilemmas have to be resolved or in attempting to ensure that research is conducted in a responsible and morally correct manner [17]. There are many ethical decision making approaches based on normative ethical theories as diverse as Deontological (Kantian and Rights Based approaches), Consequentialist theory (the best known of which is Utilitarian ethics), virtue or character ethics, situational, casuistry or case-based ethics, and feminist approaches [18,19].

Various principles are enshrined in these ethical theories and there is a consensus about primary principles in most of the major theories. Consequently, for reasons of utility and agreement, most western biomedical research ethics committees have adopted a principle based approach. This approach is valued for its impartiality, universality and detached stance and the emphasis it places on autonomy and justice.

A principle is a fundamental standard of conduct from which other standards and judgements draw support for their defence and standing [17]. The principle based approach is a generic approach which combines elements of liberal individualism, Kantian principles and utilitarian concern for the greatest good for the greatest number when relevant. The central principles held in medical ethics and foundational to most REC's functioning are those of Autonomy, Beneficence (and corresponding Non-Maleficence) and Justice.

The requirement is that the potential participant understands that participation is voluntary and may be terminated at any time, that the aim, procedures, risk and benefits and personal responsibilities should s/he be recruited as a participant are fully explained and that there is no coercion to enrol in the study. A consent form is signed indicating that the terms and conditions have been understood and that he or she willingly and voluntarily agrees to participate in the study.

Critique of principle based research ethics

The world is, to use an overworked phrase, a global village. The western philosophical and practice model is progressively being questioned as the multi cultural, multi-lingual and complex nature of society is being acknowledged, even (or one might say at times, especially) in bioethics [20-22]. Whilst research is urgently needed to plot epidemiological data, interrogate behaviours which impact on health, address the safety and efficacy of medication and evaluate the implementation of interventions, researchers are aware that religious, political, cultural, gender and socio-economic issues impact on all aspects of life and need to be considered and addressed with sensitivity to ensure that both parties benefit from the research relationship and harm is minimised.

Autonomy

There are a number of concerns with the concept of autonomy, these include: language, formal educational level, the power differentiation between researcher and subject, pressure or coercion which frequently isn't even perceived as such, gratitude for care in areas where there is little or no access to quality care, the potential participant's difficulty in distinguishing research from clinical treatment, the absence of community voices in the consent process and the fact that participants are often selected from a captive population.

Contrarily it can counter that the very idea of 'community consent' is problematic in communities where structural inequalities and gender disparities are built into the very fabric of 'culture'. In a liberal democracy, one could argue whether there should even be considerations about the collective and cultural. The very least one might expect is a provision for persons to 'opt out' of traditional customs and practices, should they so desire, as we see in South African marriage law which allows choice between polygamy and monogamy for persons whose culture accepts polygamy. It can be seen that the problem with the principle of respect for the autonomy of people, as is the case with all moral principles, is when its application must be interpreted for particular contexts and when it conflicts with other moral principles [17].

Where people are accorded a high degree of autonomy and individual choice, then the principle of respect for autonomy will obviously be of paramount importance. However, in many communities, autonomy is not valued to the same extent and the community is accorded greater significance. In much of the developing world and more traditional communities, society remains patriarchal in its organisation; ignoring the community hierarchical organisation is to display contempt for persons, not respect. Researchers need to be aware that challenging or ignoring the status quo is likely to cause repercussions for the research participants and not the research team. It should also be born in mind that most cultures are in a transitional situation; with increasing urbanisation and the emphasis on individual rights, many individuals within broad cultural groups are faced with conflicting norms and values.

Social research projects are often 'piggybacked' onto large studies as the subjects are accessible and form a captive pool. Frequently the

research is of little use but is performed as a requirement for a degree. For example: a young, male psychology student proposed to question women in an antiretroviral trial about their sexual behaviours. The questions were sensitive in the extreme. As the candidate came from a Francophone African country, he intended a fellow male student to accompany him and assist with the translation; neither the candidate nor the male supervisor or many of the ethics committee members found this objectionable; they were unable to see that the gender of the researcher might be problematic. Only the fact that two women assessors objected to this proposal prevented the study from being approved (Personal recollection, GL).

Many proposals are submitted to the university REC by novice researchers or students who are required to complete a research module for their degree. Some openly state that women subjects will be recruited. When questioned, they admit that women are accessible because they attend clinic appointments during the daylight hours and are more compliant and willing to give consent for participation. They are also more likely to be submissive in the presence of a person dressed in a white coat!

Whilst traditional gender roles need to be born in mind, much of the developing world is in a state of transition. Similarly, the western, 'developed' world is home to immigrants and their descendents from around the globe. Many of these people remain in traditional communities but often more western ideals have been adopted. The researcher cannot adopt a universal perspective but needs to take a tentative and sensitive stance and adapt the research process and ethical requirements to the situation at hand. This can only be evaluated in a relationship.

The legal requirement in the South African context is that the researcher personally must obtain consent from potential participants, not his or her agent or a translator [13]. Language itself is a problem; the belief that an interpreter is able to present all the nuanced information required to ensure valid consent is mistaken. In South Africa, nurses are frequently required to interpret for other health professionals as South Africa has eleven official languages and, in contrast to nurses, other health professionals are mostly drawn from groups who speak either English or Afrikaans as their home language. Many clinical trial information documents are, by necessity, detailed and complex. Nurses who are proficient in both English and the vernacular may have to read and translate ten to fifteen pages of detailed technical information extremely quickly to functionally illiterate patients, giving brief single word translations of obscure concepts and terms (which require careful reading by evaluators who are well versed in research and bio-medical language). They then request that the potential participant consider consenting to participate. How much more difficult to grasp the concepts if translated by a person who in turn is translating from a language which isn't their own!

Molyneux et al. [23] describe the confusion experienced by community members as to the aims, procedures and outcomes of clinical trials in Kenya [23]. The respondents in a study which sought to explore the understanding of trial subjects laughed and, as the title of the paper records, they stated: "even if they ask you to stand under a tree all day, you will have to do it…!" they had no idea as to what they were receiving in the form of drugs, what was to be done with the information requested or the specimens which were collected [23].

Justice

The term justice refers to fair and appropriation of benefits and burdens. However, Beauchamp and Childress (2001) point out that there is no single principle of justice; what is to be distributed depends very much on the perspective chosen [16]. Should the share be decided upon need, worth, individual effort, according to acquisition in a free market, societal contribution? In the application of bioethical theory in South Africa vast discrepancies exist in terms of access to quality specialist health care; for example, rationing of health care is mandated by policy in terms of finance and age to mention just two criteria [24,25].

Large clinical studies frequently include a clause requesting that extra tissue samples be given for 'genetic or DNA research'. No specific tests are mentioned and the request is apt not to raise any questions from the potential participants. Cell lines can be cultured from these samples and sold to research organisations involved in genetic or pharmaceutical studies for exorbitant amounts of money. The same practice is common in obtaining traditional medication (plants and herbs) from rural communities which are harvested using advanced technology and their use patented by the pharmaceutical or commercial institution. No profit or benefit accrues to the persons who willingly give their consent or to their communities. This leads us into the legal and ethical nightmare of intellectual copyright and patenting, one of the many areas where anti-globalization activists engage in battles over intellectual property [26].

The principle of justice is admirable when all involved are equal. While equality can be asserted by the researchers, a deep asymmetry in power exists between many potential subjects and researchers by virtue of education, gender norms, financial resources and social status. Moreover, asymmetries exist in members of the research team: principal investigators (PI's) are usually in possession of higher degrees and frequently are held in high regard by the research assistants, laboratory technicians and clinical trial administrators who are employed. Even if aware of ethically dubious practices, they are not likely to challenge the senior members of the team.

Beneficence

The primary goal of health care is the welfare of patients. Included in this is the dictum that one should first do no harm (non-maleficence). Harm often cannot be avoided, merely obtaining blood specimens as a prelude to treatment requires that the patient be harmed. The administration of toxic chemotherapeutic agents is required in oncology practice and surgical intervention is traumatic. However, in research, the harm inflicted must be weighed against the benefit likely to accrue. In the field of pharmaceutical research, whilst great care is taken, this frequently cannot be envisaged. In fact, in Phase I, II and III trials, designed test the toxicity, safe dosage and efficacy of medicines, adverse events are possible. In the urgency to test new products to gain an advantage over rivals, pharmaceutical companies may study insufficiently tested drugs and medical products.

Less than 50% of the world's population have access to even basic essential drugs and patients often are unaware of the difference between treatment and research [27]. When options or access to care is scarce, the offer of relatively sophisticated treatment can be construed by potential participants as benign and desirable. It is the health professional's duty to ensure that patients are fully informed but often this is not enough and beneficence requires that total autonomy be overridden by paternalism. Justice, autonomy and beneficence may clash and bias is required to ensure that the patient or research subject is protected, particularly when vulnerable. This requires that the practitioner relate to the patient as a person, aware of the patient's

strengths and vulnerabilities, needs and values; taking cognisance of the particular situation as well as the norms and values of the community which forms the context of the research. Children, the mentally ill and prisoners are considered vulnerable populations. In many countries women and the poor and illiterate are also vulnerable and need special protection. Beneficence here must over-ride justice.

Many ethicists, particularly communitarian ethicists reject the central tenets of liberalism found in the utilitarian, Kantian and rights-based theories which the principal based approach to bioethics espouses. That a universal, impartial and detached ethics is espoused is, for them, an anomaly as it ignores the particularity of situations, fails to appreciate the shared beliefs, values and obligations which exist in communities rather than among individuals or to acknowledge the historical and contextually constituted person who is embedded in communal life and social roles [28].

They are joined in their rejection of liberalism by feminist ethicists of differing viewpoints as universal approaches frequently fail to take into account the fact that women are not served by the ideals of a universal, justice-based ethics and, moreover, women may use different moral reasoning in considering moral questions. Feminist ethics approaches criticise the dominant discourse critiquing it from a modernist point of view, which holds that ethics expresses male subjectivity and is a product of a masculine experience of the world or from a post-modern perspective which posits that ethics itself is a construction and regulation of men as subjects.

One of these feminist approaches is the Ethics of Care. Caring refers to care for, an emotional commitment to, a responsibility and an advocacy for people with whom one is engaged within a personal, social or professional relationship. The qualities of trust, responsibility, faithfulness and sensitivity are emphasised.

Bioethics and the ethics of care

Patricia Benner (1984), a nurse and phenomenological theorist, maintained that nursing is situated in personal, embodied, contextual and caring interactions. In professional practice (as opposed to task and skills driven activities), nurses practise with compassion and respect [29]. Health care professionals are required to practise with compassion and respect for the inherent dignity and uniqueness of every individual, irrespective of considerations of social or economic status, personal attributes or lifestyle choices.

Professional practice is, according to the Virtue ethicist MacIntyre (1994:94), an "enacted narrative" which is conditioned by and, in turn, conditions relationships. Practice shapes lives and is shaped by individual and groups to direct future action [30]. Therefore, it is entirely congruent that an ethic of care be espoused by professionals in the medical and nursing disciplines as a moral theory to inform their practice, including the practice of ethical research. A relationship is required which can only function if participants can trust one another. The research relationship, in fact, requires a greater degree of trust and accountability as the possibilities for serious adverse consequences are so much more tragic. The ethic of care emphasises a different manner of ethical thinking. This is exemplified by the research of Carol Gilligan (1987) who argued for a feminine process of moral reasoning and critiqued Kohlberg's study on the stages of reasoning which contended that boys used logic, rules and principles to arrive at an answer to an ethical dilemma but adjudged girls as morally immature in their reasoning [31].

Grimshaw (1986) categorised Kohlberg's criteria for moral maturity as based on the tradition of deontological reasoning which ordered or structured knowledge and moral reasoning in absolute terms of good or bad, right or wrong (32:19-23). Consequently, she maintains, distinctions become value laden: perfect and flawed, superior and inferior and self and other [32].

By contrast, Gilligan maintained that women's moral development is not deficient but different to that of men. Female subjects in her studies viewed morality in terms of attachments to others and the maintenance and preservation of relationships. She contrasted this to the morality of rights and justice which was that commonly used by men, and, by extension, by most moral theorists.

Gilligan argued that men are influenced by the notion of freely accepted relationships, universal abstract principles and contractual agreements. Impartiality, dispassionate logic and rationality are valued. The thinking, Bowden (2002) maintains, in common with Grimshaw, is dualistic and oppositional – from the separation of man and nature to the division of emotions and intellect, body and mind [33].

Joan Chittester (1998) notes that the patriarchal view argues on one hand for universality, insisting that men and women are essentially alike and therefore universal ethical principles are appropriate and remarks that the same argument contends that women are different from men but dismisses the feminine and insists on applying masculine norms and standards [34].

Vacec (2001) maintains that women, on the other hand, view morality in terms of responsiveness in a complex interconnected network of prevention of harm, needs and care. Emotional connectedness rather than reason is valued as is consideration of others' needs and vulnerabilities [35]. This is not to say that the moral response is reduced to an emotional, knee-jerk reaction. The cognitive aspect of caring is acknowledged as insight and understanding of the other's circumstances, needs, beliefs, values and feelings is necessary. Beauchamp and Childress point out that Hume stressed that, while emotions inform of the other's character and motivate us, understanding directs the action chosen by the individual (24:91).

In contrast to utilitarian, rights based and Kantian theories which stress the obligations and rights of researchers and subjects, the ethics of care, in common with the practice of virtue ethics, stresses the character of the person acting and the relationship between the parties [19,36,37]. The ethics of care develops many of the themes in virtue ethics but also holds particularly important the character traits which enhance relationships: sympathy, compassion, love, friendship, fidelity.

Impartiality of judgement is not held paramount as bias is valued when considering the needs of the poor, the indigent, the dispossessed and the subjugated. The response of the researcher to the subject should be inter-subjective, partial and suited to the context rather than rational, objective, impartial and universal.

It must be stressed that, in speaking of the ethics of care or feminist ethics one is not advocating a universal feminine ethic. There are as many different types of women as there are women. But the idea that virtue is gendered has been central for many philosophers [32].

It is important that feminine virtues are not taken to support an idealised, romantic and subordinate role which has traditionally been accorded to women and has contributed to their being devalued as ethical persons and relegated to the private rather than the public sphere. The idea that women and men are totally unalike is essentialist and is in direct contradiction to the ethic of care. The practice of caring for others provides an ethical model for mutual benefit and self realisation

of all parties involved. Nor should one assume a 'split' between an ethics of care and an ethic of justice. If we see both care and justice as classical virtues, or at least what Reeder calls "clusters of virtues" (2001:19). He points out that though justice and care may carry varied connotations in patriarchal or liberal societies, neither of the virtues is limited to these settings. Nor indeed *ought* they to be incompatible or indeed limited to a (western) monoculture [38]. Moreover, where in much medical research, justice is reduced to *legality,* an ethics of care moves justice towards the principle of fairness that is central to the thinking of political philosophers like John Rawls (1973) and his disciples [39].

Critique of the ethics of care

Feminist theorists have registered concern about the possibility of celebrating the ethic of care as the basis of women's ethics but ignoring the oppressive conditions in which many women practice caring. Many women are dominated and exploited and, because of the patriarchal society or their dependent position, are unable to negotiate. Bowden (1997) warns that the caring virtues may reinforce the dependent and subordinate position which many women and professions endure (33:8).

The hierarchical, disciplined and still vocational nature of nursing emphasises the themes of duty, sacrifice, obligation and obedience and reinforces the gendered division of labour with all its inequities. If an ethics of care approach is to be adopted without attention to the nuanced and situated nature of relationships, it may well perpetuate the subordination of the ethic to a paternalistic, medically dominated; universal ethic as nursing has been subordinated to the dominant discourse of medicine. The ethics of care will be subordinated and considerations of practical justice (ever mindful of economic reality in an age of managed health care and shrinking budgets) will continue as the dominant ideology.

Bowden also points to the problem of 'naturalising' tendencies of the ethic; linking the ethic to mothering reinforces the stereotype of caring as a natural tendency of women as mothers and, therefore, determines women's roles as conceived primarily by white, western, middle class perspectives. She interrogates this conundrum by pointing out that a tension exists between acknowledging (and perhaps naturalising) the ethic of care and thus stereotyping them or ignoring this perspective altogether. She urges that anomalies within the ethic of care cannot be dealt with in a simplistic manner as ethicists attempt to further develop the theory [33]. It must be remembered that there is no such thing as the universal women. Gender essentialism is a dangerous myth [31,40]. Feminine practices are socially situated, affected by many factors such as class, race, age, education. These factors have divided women. The norms of motherhood have been interpreted and influenced by so called experts, the state structures and men to reflect and reinforce traditional gender, race and class divisions. They have also been corrupted by national governments to popularise national movements.

However, the strength of the ethics of care is it's tentative, flexible and context specific sensitivity. In this multicultural, multilingual and post-modern era of diverse values and norms, the tentative and sensitive nature of the ethic of care should be incorporated into the bioethical decision making process. The difficulty in setting precise boundaries and limits is significant. Relationships cannot be precisely defined and are at any time flexible and responsive.

It must also be conceded that the ethics of care are derived from a relatively under-developed theory and require further research and refinement both in social and medical research. There is no autonomous feminine ethic: women are as much part of the human race as are men. To draw too definite a distinction is to create the dichotomous thinking that traditional approaches have been accused of.

How might an ethic of care approach be integrated into Research Ethics Committees? We think there might be two possible approaches. One would be the promotion of the theory in short seminars, exchanges of articles and discussion within the Committee (subject of course, to time constraints). While this may seem an indulgence, it could also be construed as a contribution to the refinement of the work of Ethics Committees.

Another might be the construction of an instrument setting out Ethics of Care Criteria by which one assesses the ethics of research proposals. Such criteria might broadly include:

- To what degree does the proposed research promote gender equality?
- To what degree does the research benefit those who are marginalised (economically, socially, racially or by their gender or sexual orientation)
- To what degree does the research build community and human connectivity?

While such criteria may not necessarily be definitive or decisive in the approval of protocols, an endorsement that included a positive 'Care Quotient' might well be an incentive to encourage research that is practically useful as well as ethically sound.

Conclusion

We do not believe that principle based decision making in research should be dispensed with. Nor do we advocate for an 'eclectic' theory as, unless one is conversant with the intricacies of each of the theories amalgamated, one is apt to slur theories and arrive at a messy hodgepodge which is able to be manipulated every which way. This is to venture into the realm of relativism [41]. We do, however, urge that some members of Ethics Committees are acquainted with the concepts and application of the ethics of care in order to engage in debate when the universal principles are used without consideration of the specific nuances of the situation under discussion. The consideration of the ethics of care approach is important as it mitigates against the universal and objective approaches which dominate the realm of ethical decision making in medical research and, with consideration of other approaches such as Virtue ethics, enables ethics committees to adopt a more holistic and comprehensive view of the research situation, the people involved and the role of research in general.

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