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## EDITORIAL

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On 13 October 2005 the Centre for Human Bioethics celebrated its 25<sup>th</sup> anniversary. When Peter Singer and Helga Kuhse established the Centre in October 1980, they envisaged a research centre where philosophers would promote and advance public debate on the issues of the day. In its early years the Centre's research focused primarily on ethical issues concerning *in vitro* fertilisation and end-of-life decision-making. The ethical questions raised by subsequent developments in genetics and biotechnology lay on the distant horizon at that time, but they are now very much in the foreground of bioethics and are an important focus of the Centre's current research.

A prominent feature of the Centre's work over the years has been the application of ethical theory to practical questions in health care, reproduction, and genetics. Along with the empirical research carried out by the Centre's staff, many of the health professionals undertaking the Master of Bioethics course have been keen to use their developing understanding of ethical theories and principles to improve their professional practice.

One particularly impressive example of bioethics into action is the whistleblowing by ICU nurse and Master of Bioethics graduate Toni Hoffman on Bundaberg surgeon Dr Jayant Patel, earlier this year. Toni's concerted efforts to report the disastrous surgical outcomes at Bundaberg Base Hospital prompted the establishment of an extensive Queensland government Inquiry into the problems at Bundaberg.

Recent research in medical education suggests that medical graduates are often influenced by a 'hidden curriculum' in many hospital environments, where scant regard is paid to medical ethics by some of the senior medical staff towards whom graduates look as mentors. One of the disturbing aspects now emerging about Bundaberg is that this hidden curriculum may be reinforced by an economic imperative, whereby hospital administrators may be led to ignore staff concerns about patient safety in cases where a practitioner is helping the hospital to meet financial targets, by increasing patient throughput and reducing surgical waiting lists. Toni Hoffman is writing an article about her experiences at Bundaberg for the next issue of *Monash Bioethics Review*, and this should provide valuable insights into health care quality and safety and clinical governance in the current Australian health system.

This issue of *Monash Bioethics Review* contains an innovative ethnographic study of a research ethics committee, and a review article about a new book on the Nancy Olivieri drug trial revelations in Toronto, along with two articles discussing some current issues in research ethics. We are also delighted to present an article by Shyamala Nataraj, a recent nominee for a Nobel Peace Prize, on ethical issues raised by programs in India to prevent mother-to-child transmission of HIV.

**Justin Oakley**

**Co-editor**

***Monash Bioethics Review***

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## **NEWS IN BRIEF**

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### **UNESCO guidelines on bioethics and human rights under fire**

A recent UNESCO declaration on ethics and human rights in medical research has been criticised by an international group of specialists in the field, who believe that it has little value, and might even put research participants in developing countries at risk. The journal *Developing World Bioethics* devoted an issue to an analysis of the document. The criticisms include lack of clarity about key terms, a frame of reference limited to life sciences and their practical applications, and lack of consideration of cultural and religious differences.

*SciDev.Net*, 6/9/2005

### **HIV positive man denied a student visa**

A Zambian man who is HIV positive was recently denied a student visa. The ruling was upheld by the full bench of the Federal Court. The man was due to enrol in a PhD. He and his wife are both HIV positive, and have two children. They already reside in Australia. The court ruled that the health care costs that the government would incur while he was on a student visa were too great, although the man's doctor stated that the applicant would continue to pay for the cost of combination therapy. The man is in good health.

*The Age*, 30/9/2005

### **More evidence linking marijuana to psychosis**

More evidence has emerged that the use of so-called 'party drugs' like marijuana and amphetamines contribute to psychosis, and that users should be strongly advised to 'quit for life.' The use of these drugs is also thought to contribute to anxiety and depression. Australia leads the countries of the OECD in the use of amphetamines and was near the top in marijuana use. A recent report on the amphetamine market in Sydney found that the highly addictive drug 'ice' or crystal methamphetamine was readily available. Using this drug increases the danger of psychotic episode eleven fold.

*The Australian*, 3/10/2005

### **Doctors call for end to ban on RU486**

Doctors are calling on the federal government to lift its ban on mifepristone, a drug that induces abortion, claiming that it is a safe alternative to surgical abortion. The drug was approved in the US FDA in 2000, but was banned in Australia in 1996 at the request of Senator Brian Harradine. There is significant evidence that the drug is both safe and effective. The drug would be administered under medical supervision, but abortions carried out this way would not require anaesthesia.

*The Australian*, 3/10/2005

### **Australian state and federal governments attacked on mental health care**

A recent report has criticised the state of mental health care in Australia, suggesting that the reforms that commenced in 1992 have failed to deliver quality care. Many persons suffering from mental illness have difficulty accessing services, and are treated without dignity and respect when they do access them. It urges both state and federal governments to invest in mental health care. Ian Hickie, one of the report's authors, suggested that lack of care and treatment leads to further stigmatisation of the mentally ill. The report was based upon public consultation, community meetings, and meetings with professionals, non-government groups, and written submissions. *BMJ*, 29/10/2005.

### **Ten out of twenty-five EU countries restrict health care for asylum seekers to emergency care only**

A study of twenty-five countries has found that almost half of the members of the European Union restrict health care for asylum seekers to emergency care only. There are also discrepancies in health screening between countries. A survey reveals that in some countries, medical screening was offered to all new asylum seekers, but in others, including the UK, it was done only in reception centres. Asylum seekers who did not use this mechanism did not receive screening. Restriction to emergency care only for pregnant women was found in five countries, for children in seven countries, and for all adults in 10 countries.

*BMJ*, 29/10/2005

### **Public hospital errors rise forty per cent**

Victoria's public hospitals have reported a rise in errors of forty per cent this last financial year. These have included operations on the wrong patient, or the wrong body part, overdoses of medication, and surgical instruments being left inside patients. After reporting, hospitals are required to examine why mistakes happened, change systems where necessary and share lessons with other hospitals. This system of reporting is now in its fourth year. The health department would not reveal which hospitals posted the most errors, saying that to do so might give an inaccurate picture, and would discourage hospitals from reporting errors.

*The Age*, 31/10/2005

### **Disabled seek damages for 'wrongful life'**

Two young disabled Australians have appealed to the High Court over 'wrongful life'. Alexia Harriton is deaf, blind, and physically and mentally disabled. Her lawyers allege that her family doctor negligently failed to diagnose rubella infection early in her mother's pregnancy. They also claim that the doctor concerned assured her mother that her unborn child would not be affected. The issue of a 'wrongful life' is based upon the idea that the mother would have terminated the

pregnancy if she had been properly informed. Wrongful life cases have succeeded in the U.S., France and Holland, but in the U.K. legislation has been introduced to prevent them. At the same time the High Court will also hear a case involving Keeton Walker, a severely disabled four-year-old. If the cases are successful, they will provide a precedent for other actions.

*The Age*, 10/11/2005

### **South Korean scandal engenders concern for stem cell projects**

South Korean scientist Woo-suk Hwang, of Seoul University, recently resigned as the head of the World Stem Cell Hub, which he started in 2004. His team was the first to clone human embryonic stem cells, master cells from which specific kinds of tissue arise.

Hwang's team had become a world leader in stem cell research, having developed eleven more stem cell lines in the last year. His team also cloned a dog.

All was not well however. It became public that junior members of the research team were donating eggs for experimental purposes. Hwang resigned when it became clear that he had lied about the source of the eggs.

*USA Today*, 28/11/2005

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## AT THE CENTRE

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### **Ethics Officer position and Fellowship at WHO Human Genetics Programme**

The Centre has renewed its sponsorship of the Ethics Officer position at the World Health Organization Human Genetics Programme for 2006, following the successful inaugural stint by Angela Ballantyne earlier this year. The next incumbent in this position is recent Monash Master of Bioethics graduate Cathy Schapper. Cathy takes up this position in Geneva in January. The sponsorship was arranged through the Faculty of Arts and the Vice-Chancellor's office.

Also bound for Geneva in January is Adam Henschke, who has been awarded the next Monash-WHO Bioethics Fellowship. Adam will spend 3 months working as an intern at the WHO Human Genetics Programme. Adam and Cathy will be collaborating on several projects, including a report on ethical, legal, and social issues in pharmacogenomics.

### **Congratulations**

Congratulations to the following students who recently fulfilled the requirements for the Master of Bioethics degree. As part of the course the successful candidates wrote 10,000 word research papers on the following topics:

<b>Margaret Duncan</b>	Harvesting the living dead
<b>Victoria Dunne</b>	Ethical treatment of patients in public hospitals: identifying the features that allow medical scandals to flourish
<b>Dolores Ibarreta</b>	The ethics of selecting the embryos before they are transferred to the uterus after IVF using pre-implantation genetic diagnosis: drawing the line between health and disease in genetic terms
<b>Emma Livingston</b>	Is weak paternalism justifiable in exercise science research?
<b>Amanda Lyons</b>	Consent and universal newborn screening
<b>Joy Mendel</b>	Does evidence-based medicine compromise informed consent? Issues for mainstream and complementary medicine

- Katinka Morton** The moral position of doctors who violate boundaries with patients: their moral responsibility as agents, and blaming responses beyond blameworthiness
- Nat Neilson** What are the ethical obligations of Australia and Australians to help provide primary health care and treatment to AIDS-affected Sub-Saharan Africa?
- Eleanor Romney** Maintaining integrity: the conflicting obligations of the nurse as custodian of patient information
- Cathy Schapper** When, if ever, is it ethically acceptable to use preimplantation genetic diagnosis?
- Judith Schroeder** Enhanced parental autonomy in preparation for extreme premature birth
- Richard Stiles** Autonomy and heteronomy: moral bias and its bioethical implications – the case from obesity

Copies of these Master of Bioethics research papers are available for reading at the Centre's library, 9<sup>th</sup> floor, Menzies Building, Clayton Campus.

### **Special issue of *Monash Bioethics Review*, January 2006**

To commemorate 25 years of the Monash Centre for Human Bioethics, *Monash Bioethics Review* 25, no. 1, January 2006 will feature articles by past and present Centre staff, including Peter Singer and Helga Kuhse, Justin Oakley, and Deborah Zion, along with articles by other contributors, such as Bundaberg Hospital whistleblower Toni Hoffman.

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## ARTICLES

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### **The practical logic of reasonableness: an ethnographic reconnaissance of a research ethics committee**

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#### **Introduction: the circle of debate**

Lately, debates about research ethics committees (RECs) have focused on three main questions. What is the role of expert bioethicists<sup>1</sup>: do they have a place on these committees?<sup>2</sup> Should RECs be organized at a regional or local level?<sup>3</sup> Do RECs facilitate research or just hold it up with unnecessary delays?<sup>4</sup>

Within the literature, various authorities argue for various positions in relation to these three questions. More interesting than the positions they adopt is the typology of evidence that they bring to their arguments.

One group of authorities, bioethicists prominent among them, bring formal ethics to the debate. They typically substantiate the positions they adopt toward these questions with classical ethical principles; notably, *autonomy*, *beneficence*, and *justice*—the big three.<sup>5</sup> Their writing characterized by clarity and scholarship, they customarily deploy concepts formulated by those ancestral European men who are the founders and shapers of modern Western ethics (Jeremy Bentham, John Stuart Mill, Marmonides, Aristotle and others). Yet for their almost complete absence of original empirical research, they are too easily dismissed by their opponents as ‘armchair philosophizers’.

In contrast, there is a group of scholars that bring questionnaires,<sup>6</sup> statistical analysis,<sup>7</sup> and case studies<sup>8</sup> to the debate. Recognizable for their rigorous research design and methodically accumulated data sets, they appear to satisfy the need for empirical evidence. Yet, in their reliance on questionnaires and ideal typical cases, they tend to present data that are one step removed from the empirical life of an ethics committee. Their findings are usually based on people’s written responses to lists of questions about specific issues, with scant reference to how these issues are debated and resolved in the course of daily work on an ethics committee, or whether they even

arise at all.

Writing in a more subjective style is a group of people who have been involved in the business of research and its ethics for many years and who bring their personal perspectives to the debate.<sup>9</sup> Like diarists, their *forte* is experience, their mood is one of reminiscence. From the autobiographical tone of their articles, the reader can tell they were there. They themselves struggled with complex ethical issues, either as frustrated researchers or as thoughtful committee members.<sup>10</sup> Yet theirs is necessarily an individual vision, a partisan opinion without method.

The group who turns to formal ethics and the group who turns to questionnaire research have a common commitment to objectivity: one in the form of objective ethical principles, the other in the form of objective data. Those who reminisce are committed to their own subjectivity. These three find common ground in the 'case study', be it a hypothetical case, a celebrated case, or a personal experience: though each mines the case in a different way. Bioethicists use it to draw out principles and dilemmas, questionnaire researchers use it to elicit quantifiable responses from their research subjects, and those engaged in reminiscence use the case to tell us what actually happened to them and what they learned from it.

These three groups of authorities—bioethicists, questionnaire researchers, and personal diarists—effectively frame the debate. They define the questions at issue. They define the types of legitimate evidence that can be brought to the table—analytical introspection, data collection, personal reflection. Individual authors may move from one method to another, giving the literature variety and nuance. Yet their methods are constraining in four ways. First, they lack breadth and scope: they do not explore the theoretical and methodological possibilities of research in this area. Second, they lack depth: they unreflectively reproduce a superficial distinction between objective knowledge and subjective experience. Third, they fall short of the most minimal empirical requirements of any science, biological or social: they lack observationally grounded data on the complicated business of decision making in the complicated world of research ethics. Finally they lack dynamism: their hypothetical case studies are ideal typical constructs, and even their 'actual' case studies are static, retrospective accounts of events that already have a known outcome, often presented in a form that strips them of context, complexity and emotion.<sup>11</sup> Little wonder that the same questions resurface decade after decade. Little wonder that the debate goes round in circles.

### **Breaking out of the circle: ethnography**

In order to move the debate forward, it is necessary to introduce alternative types of evidence from outside the circle we have described. We suggest that one way to do this is to turn to ethnography, a research method that has long since reconciled the split between subjective and objective knowledge. Its principal technique of data gathering, 'participant observation', impels the researcher to generate objective data by subjective involvement in field work. The debate, we



argue, would be advanced by an ethnographic account of what members of a research ethics committee actually do in their minute-to-minute functioning, situated as they are in a particular social milieu that is characterized by the cross-cutting influences of individual personalities, hospital and academic institutions, economic forces—private and public—as well as ethical guidelines and government regulations. All of these influences would be observed in the interplay between formal committee deliberations and informal discussions, banter and ‘corridor conversations’.

Before we move along this ethnographic route, it is necessary first to glance back behind the debating circle to a previous era and to the pioneering work of Renée Fox. Published in 1959, *Experiment Perilous*<sup>12</sup> was ethnography’s signal contribution to medical research ethics. Although her fieldwork was carried out before institutional review boards or research ethics committees came into being, it remains a modern classic because it addresses issues that continue, to this day, to vex and perplex members of these bodies: issues that arise from the fundamental uncertainty of ‘medical experimentation with human subjects’ (p. 10). Fox explicated the potential contradiction in the position of the ‘clinical investigator’ which arose from the sometimes opposing roles of practising physician and ‘pure’ scientist. Clinical investigators, she wrote, were ‘not only obligated to protect and further the welfare of their patients, but they were also responsible for advancing general medical knowledge’, and their attempts to resolve this led to ‘a rather complicated moral titration process’ (p. 241). This contradiction has since been displaced onto research ethics committees and remains a source of tension and an ongoing matter of deliberation for them today.

Fox’s study focused on a group of young research physicians, the so-called Metabolic Group, and on their patients, who were admitted to Ward F-Second. Field work was undertaken at a turning point in the history of medical research, when the heady optimism of post-war science experienced its first doubts. The advent of the newly synthesized corticosteroid hormones had led to the treatment of certain diseases by means of adrenalectomy (the removal of the adrenal glands which produce much of the body’s steroids) followed by substitution therapy using manufactured steroid hormones. But during the course of her field work, doctors in the Metabolic Group were coming to the growing realization that the treatments they were pioneering had limited utility, and the replacement hormones they were prescribing had dangerous side-effects. It was this context that generated a tension between the scientist and the carer within each clinical investigator. Fox demonstrated how such tension gave rise to a culture of waggish, black humour that crystallized into a jocular game of chance. The clinical investigators, she observed, would make pretend bets on patients’ diagnoses, their investigation results, and their anticipated reaction to treatment (p. 82): so much so that the informal talk on the unit was largely couched in a sort of ‘gambling lingo’. Further, she identified an uncanny resonance between the physicians’ reactions to stress and that of their patients. With its human focus,

and its attention to the daily life of the unit, *Experiment Perilous* remains an exemplary piece of research that highlights the value of the ethnographic method to medical research ethics. Its principal finding—that clinical scientists navigated ethical dilemmas by a pattern of informal joking behaviour—was a major contribution to the literature.

It became a matter of consternation to us that our literature search - employing, amongst others, PubMed, Psychlit, Current Contents, Anthropology Plus, and Expanded Academic Index - revealed that there have been no substantial ethnographic contributions since this study was published. It was not as if the idea of ethnography was a foreign country in the field of medical research ethics—witness Barry Hoffmaster's call for an ethnographic contribution in *Social Science and Medicine* in 1992.<sup>13</sup> In the same vein, Fox and DeVries<sup>14</sup> have summarized a representative edited volume, published in 1998, on the intersection between social science and bioethics, but they are more caustic in their conclusions. These authors observe the repeated calls for ethnography by the contributors to the volume, and their repeated assertions of its value to bioethics as 'the method par excellence of conducting socially and culturally cognizant and sensitive bioethical research' (p. 273). Yet they lament that the closest approximations to rigorous ethnography take the form, firstly, of a watered-down version of the method, known to its originator by the neologism 'bioethnographic critique', secondly, a confusing conflation of sociology and bioethics, the originator of which coined the term 'social bioethics', and thirdly, a rather expansive variant called, idiosyncratically and somewhat airily, 'intellectual ethnography'.

It is difficult to determine why bioethics and ethnography went their separate ways. Perhaps bioethics shrank from the glare of the ethnographic gaze because its stock-in-trade was analytical concepts rather than lived experience. Perhaps ethnography lost interest in ethical dilemmas once the alarming excesses of unbridled medical research had been reigned in, constrained within the mundane minutiae of committee work. Whatever the reasons, *Experiment Perilous* spawned no offspring, and may therefore be described as a singular study but not a seminal study. If there is a criticism of Fox's work, it is that it was microscopic in focus. One comes away from the book with a rich sense of the daily life of medical doctors and patients caught up in their dilemmas, but with scarcely any sense of the place of the Metabolic Group in the wider structure of medical science and practice, and no sense of the place of Ward F-Second within the institutional structure of hospital care in post-war America. It foregrounds human agency, interaction and emotion, at the expense of an analysis of social structure. Like many ethnographic studies of its era, it examined institutions as if they were small, stable social entities walled off from the rest of society, and it sought only to demonstrate the mechanisms whereby members resolved their tensions to maintain balance and functionality—in this instance, through structured humour.

### **The need for a theory of practice**

We have outlined the reasons that ethnographic research is well positioned to address some of the major questions that arise in the contemporary bioethics literature. We further suggest that there is a requirement for such ethnography to be grounded in a theoretical approach that is consistent with our aims. Fox's functionalism was a social theory that suited the setting of her study, but with the subsequent formation of ethics review committees nested within hospital and academic institutions and coordinated at a national level, there is now a need for a theory that pays attention not only to the daily give and take of ethical decision making, but also to its location within these wider structures.

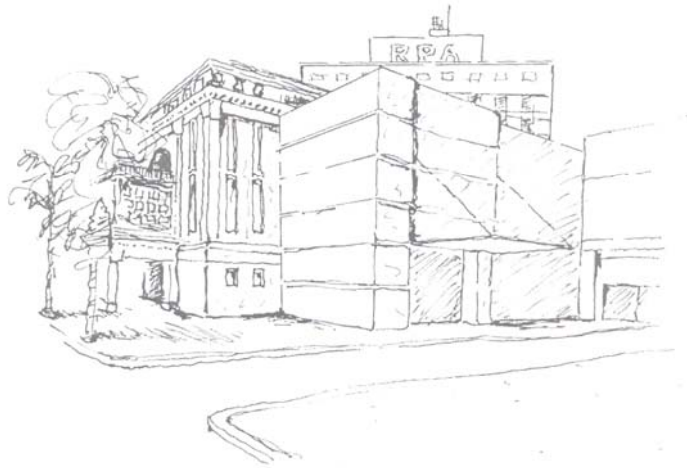
A body of social theory developed by Pierre Bourdieu is promising in this regard. Primarily a theory of practice,<sup>15</sup> this approach insists that we cannot understand interactions among groups of people, including their decision-making processes, without acknowledging the degree to which people are guided by supra-subjective structures such as rules, laws, and the historical trajectory of a person's life experience. This is not to downplay the extent to which these structures are moulded and transformed in creative ways by human agency. Bourdieu tacks and plies between an abstract, macro-societal structuralism characterized, say, by the work of Levi Strauss<sup>16</sup> and a more intimate and micro-interactional phenomenological approach to social life,<sup>17</sup> so much so that he collapses the distinction between structure and agency altogether.

This approach could not be more relevant to the study of research ethics committees, for Bourdieu also collapses the unproductive distinction between objective and subjective approaches that, as we suggested earlier, has frozen the literature on research ethics. Humans behave with a predictable regularity, claims Bourdieu. Yet if we account for this by resorting to models of action as if they were laws, we labour under what he calls the *objectivist* fallacy. Alternatively, if we focus just on human subjectivity, we have fallen under the spell of what he calls the *subjectivist* fallacy. Such an approach would be incapable of grasping the objective social conditions which produce this subjectivity.

Three landmarks of Bourdieu's theory are well known: *habitus*, *field*, and *capital*. *Habitus*: a structured set of dispositions and predispositions, acquired from infancy, which guide thought and action. These dispositions are not unconscious, in the sense that a person is wholly unaware of them, but nor are they fully open to manipulation by a person. *Field*: a network of objective relations between positions that social agents occupy<sup>18</sup> (for example, sport, the nuclear family, or the university). Humans operate within fields, guided by their habitus. *Capital*: the defining resources a person competitively accumulates when actualizing his or her habitus by operating in a specific field. (An academic field, for instance, is defined by intellectual capital rather than economic capital; intellectual capital, by the same token, has no caché in the field of sport).

That Bourdieu defines each conceptual salient in terms of the other two makes all but his earliest work irritating to read, to say the least; but he can be forgiven because, like all his Francophone compatriots in the realm of post-structural theory, he has cultivated this spiracular style of thinking and writing into an art form. On the other hand, he is to be admired for the way he does not try to escape the fact that all of us, French intellectuals or otherwise, characteristically define everything in terms of something else. More importantly, the serried homogeneity of his argument allows for no retreat into simplistic Cartesian splits.

### **Preliminary observations on a research ethics committee**



**Figure 1: The RPA**

With ethnography as our method, and Bourdieu's theory of practice as our guide, we report some preliminary ethnographic observations on a Research Ethics Committee (REC) located in what we have called the Royal Prince Andrew Hospital (RPA), a major teaching hospital in an Australian capital city (this and other names were chosen to disguise individual identities). Any ethnographic project worth a guernsey requires at least one year of participant observation in the field (Fox spent two years on the ward). This derives from the heyday of colonial anthropology when ethnography was exclusively carried out in foreign climes, where white-man-anthropologist imposed upon himself the burden of studying 'the natives' for at least one agricultural cycle. We therefore define this paper as an ethnographic reconnaissance rather than a mature study, because the data on which

it is based were gathered by observing just two meetings of the RPA REC, supplemented by five sessions, each of several hours duration, interviewing the Chair. We initially sought ethical permission to conduct this pilot study from the Chair, who we here refer to as John Clapham. Following deliberation with members of the Committee, permission was granted. The reflexive irony of seeking ethics permission from a committee in order to conduct a study of the processes whereby this committee granted ethics permission was not lost on any of us. Observations were recorded by means of hand-written field notes. We also gained permission to inspect examples of the considerable paper-work generated by this committee—submissions, protocols, the Chair's notes, records of meetings, and correspondence—and this was supplemented by a review of relevant local and national policy documents. Given that this was designed to be a pilot study, the ethnographic analysis narrowed down with perhaps unseemly haste on a limited number of themes which we now address.

### **Introducing the Royal Prince Andrew Research Ethics Committee**

The Royal Prince Andrew Research Ethics Committee (RPA REC) is constituted according to Australian National Health and Medical Research Council (NH&MRC) guidelines and it must report annually to that body in demonstration of its compliance with these guidelines.

The Committee operates within a framework of published guidelines handed down from regulatory authorities in the Australian Capital, Canberra, through the NH&MRC's Australian Health Ethics Committee (AHEC), whose structure and terms of reference are set out in a Federal Act of Parliament. The AHEC is composed of persons who have 'expertise in' law, philosophy, religion, research (medical, public health and social science), clinical practice (medical and nursing), health consumer issues, the regulation of the health-care professions, and disability. There must also be a Chairperson, whose area of expertise is not specified.<sup>19</sup> The AHEC assesses ethics committee literature, as well as policies and legislation from around the world, and it formulates 'guidelines for ethical conduct' in health research and clinical activity. It monitors institutional ethics committee compliance with its guidelines as set out in the *National Statement on Ethical Conduct in Research Involving Humans*.<sup>20</sup>

The RPA REC is also part of the public sector more broadly, including state and federal governments. It is answerable to the Board of Directors of the RPA and its existence is essential for the hospital to be eligible for NH&MRC research funding. No research can be conducted within the main hospital buildings or its network of suburban campuses without first being assessed and passed by the Committee.

Applications to the Committee are initiated by local investigators and funded by government, not-for-profit agencies, and the private sector, usually pharmaceutical or medical equipment companies. The

Committee, therefore, engages with the private sector at a local, national, and international level.

The RPA REC comprised 11 members. They included a laywoman, a layman, a clergyman, a nurse, a lawyer, four clinicians who were engaged in research, a clinical psychologist, and the Chair. Except for the two laypersons and the lawyer, the members of the Committee were employees of the RPA.

With regard to clinical trials of drugs, this REC was one of the busiest in the country. To process the heavy load of submissions, the REC had a formally constituted subcommittee, the Investigational Drugs Sub-Committee (IDSC), comprising the aforementioned Chair and seven other members with specialized knowledge of pharmacology, the structure of clinical drug trials, and the national regulatory system for drug approvals. The IDSC also met once per month, one week before the main REC meeting, to ensure an efficient flow of decisions.

Research protocols were submitted to the REC through an administrative assistant who was employed full-time to assist in the organization and maintenance of the Committee. Between meetings, the Chair read through each protocol and made a triage decision: it could be granted 'expedited approval', placed on the agenda of the next REC meeting, or referred first to the IDSC.

In giving a protocol 'expedited approval' or 'Chairman's approval', the Chair would decide that the protocol need not be examined by the whole Committee. Such protocols were approved between meetings and a letter of approval was sent by the Chair to the Chief Investigator. Delegated authority for expedited approval had written delimiters: the list of expedited approvals was tabled at the next Committee meeting for comment, and the Committee audited these approvals on a regular basis.

When a protocol went to the full Committee, it might be approved at the meeting or it might be considered approvable with amendments. On rare occasions, a protocol was rejected outright at its initial consideration. More commonly, where amendments were required, the Chair wrote a letter to the Chief Investigator setting out the required changes. These changes had to be incorporated into the protocol and resubmitted before final approval was granted.

In the case that a protocol was sent to the IDSC, this subcommittee made a recommendation which was tabled at the meeting of the REC one week later. The REC was guided by the IDSC's recommendation. In short, all protocols had to pass in some form through a meeting of the REC.

The written submission to the REC was the key document in the approval process. The submission had to include at least three components; namely, a research protocol, an information sheet for participants, and consent forms. The protocol had to specify the investigator's name, title, institutional affiliation, the purpose of the proposed study, including specific aims, the context of the study (for instance, previous studies, literature), how it was to be undertaken, how it was to be evaluated, and whether drugs or radiation were to be used. The information sheet had to state the voluntary nature of

participation for the research subject, the value of the study 'in plain language,' the rights of participants, and the potential benefits and risks of involvement in the study. It also had to contain contact details for the Chief Investigator and the Chair of the REC, who were available to hear complaints from participants. Additionally, the consent form had to state that participation was voluntary, that information collected would remain confidential, that the participant's privacy would be preserved, and that participation could be discontinued at any time.



**Figure 2: REC meeting in the RPA Boardroom**

The Committee met monthly in the Boardroom of the RPA during working hours for periods of two to three and a half hours, depending on the number of protocols submitted in the previous month. For each member, preparation for a meeting involved many hours of reading.

Before every meeting, sandwiches and orange juice were wheeled in on a hospital trolley by the administrative assistant. Prior to formal commencement of the meeting, members caught up on work and things in general as they ate, drank, and sorted through their paperwork. The Chair, John Clapham, sat at the head of the table. On his left sat the administrative assistant, Wendy Albright. On commencement of the meeting, John would inform the rest of the Committee of such things as business outstanding from the previous meeting, pertinent talk that was circulating around the hospital, and the work ahead. Once the first protocol was tabled, all heads were bent down in concentration, as individual members flicked back and forth to the relevant pages.

During the second meeting we attended, there was a brief but ethnographically illuminating ceremonial occasion. This was to mark Wendy's departure after fifteen years on the Committee. She was going on maternity leave. As the formal Committee proceedings were being wound up, John's wife, Jill, entered the Boardroom and sat well away from the table on a lounge chair, where she began to quietly read a

book. John then gave a speech, in which he said that Wendy had worked on the Committee before he had joined. Here he emphasized how much he had learned from her. He also commented on how over the years Wendy, Jill and he had become very good friends. At this part of the speech, Jill stood and came forward to the table to present Wendy with a gift. This was an emotional moment for the Committee. John later quipped that the only things that would make a member leave the Committee were moving interstate or, as in Wendy's case, having a baby. We were later told by two members of the RPA REC that the Committee was, for them, 'like a family.'

### ***Habitus, capital, and the RPA REC meeting***

There was a strong ethos of volunteerism which came with membership of the RPA REC. The laypersons were not remunerated for their service. Because meetings took place during office hours, members of the RPA staff fulfilled their REC commitments in the course of their daily work in the various hospital departments in which they were employed. It was accepted that the cost would be borne by those departmental budgets. Having said this, preparation for meetings was time-consuming and had to be done out of hours. They received no extra remuneration for this. They bore the cost themselves by voluntarily foregoing some of their leisure time. The administrative assistant was paid explicitly for Committee work, though she, too, served above and beyond the call of duty. Whatever the mix of paid and unpaid labour, all Committee members felt that their service on the committee was, to a greater or lesser extent, voluntary. This sense of volunteerism was compelling.

Following Bourdieu, we suggest that the capital accrued by membership of the RPA REC was primarily symbolic capital rather than economic capital. Symbolic capital in this case was a matter of professional standing and organizational status, because service on institutional committees was an important component of a professional's curriculum vitae. What made service on the RPA REC distinct from most other hospital committees was its identification with a quality of virtue that accrues with voluntary labour. This latter 'virtue capital' became crucial in the play of Committee deliberations, because it enabled them to occupy a moral space in their decision-making, a space of humane care, family values, decency and fairness. Given that the RPA REC decisions sometimes had significant financial consequences, it was imperative that Committee members operate outside this financial sphere. It was by situating themselves within such a moral space as volunteers, that they could distance themselves from even the perception of financial interest.

Just as there was a range of remuneration among Committee members, there was also a spectrum of expertise in medical research. It ranged from the archetypal 'intelligent layperson' (represented by the administrative assistant, the layman, the laywoman, the lawyer and the minister of religion) to the various clinicians, all of whom had considerable research experience, to John Clapham, whose primary role at the RPA was that of a medical scientist. Though the clinicians



were drawn from individual medical specialties, no attempt was made to have representatives from all these specialties. They were there to contribute their generic experience in medical research, not specialized expertise in a particular domain of research. The first reason for this was practical. There were so many areas of specialized medical research that to have them all represented would have made the Committee unwieldy. Secondly, there were ethical reasons. Committee members were frequently not allowed to comment on protocols that came from their own specialty because, as often as not, they themselves were involved in submitting the protocol, or they were close colleagues of the researchers who had made the submission. It was standard practice, under these circumstances, to absent oneself from the discussion lest there be a conflict of interest. Thus, although all the clinicians had extensive research experience, they were there as generalists, not specialists. Further, whatever the research background of the clinicians and of John, each also sat at the table as a layperson.

The non-medical people on the Committee brought different expertise to the table: the lawyer, legal expertise; the minister of religion, expertise in spiritual and moral matters; the administrative assistant, organizational expertise. Others such as the layman and the laywoman were there specifically because they were laypersons: they represented the general public.

What all members of the RPA REC had in common, be they clinicians, medical researchers, lawyers, ministers, or laypersons, was their 'layness'. All except for one had convened together for more than a decade. This long-term participation in a role is an important aspect of what Bourdieu identifies as the acquiring of a habitus—a set of structured dispositions that develop due to being positioned in a particular role. We argue that the distinctive common habitus of the RPA REC members was the habitus of a layperson. Whatever special expertise and experience various members contributed, it had to be expressed in a 'lay-ish' way, otherwise it lacked common currency. Medical specialists adopted the attitude and expressions of generalists, and even these traits were to a greater or lesser extent subsumed into their lay habitus.

### **Practical logic: from *agape* to reasonableness**

From the habitus we have described emerged a distinctive form of practical logic that was necessarily strategic: in part reflected upon; in part not reflected upon at all. Prior to this pilot study, John Clapham had determined, after many years' experience as Chair, and after much introspection, that the day-to-day decisions of the Committee were chiefly guided by a principle that he called *agape*. The Concise Oxford Dictionary defines *agape* as 'love, esp. as distinct from erotic love'.<sup>21</sup> It is significant that the term comes to English through Latin from a Greek word for brotherly love because, at least in its etymology, it invokes notions of kinship and ideas of affection between family members. Its provenance as a concept can be traced from Ancient Greek philosophy through to Judeo-Christian theology (the word was

associated with a feast of Christian love honouring the last supper). For John, *agape* carried the special meaning of love for the public.

We anticipated that the core ethical principles of autonomy, beneficence and justice, as enshrined in NH&MRC documents, would be articulated by Committee members as they proceeded through the decisions of the meeting. Yet John pointed out that members did not normally discuss the relative merits of applications with overt reference to these principles. This was corroborated by ethnographic observation. This is not to say, however, that these higher-order principles were ignored. In fact Committee decisions could always be shown, *post hoc*, to have conformed to them in various ratios, combinations, or balanced equations. But when the protocols were actually under scrutiny, autonomy, beneficence and justice were not deployed as working models for decision making.

This is why, in place of these three higher-order ethical principles, John had developed the notion of *agape* as a middle-order ethical principle that seemed to him more relevant to the work of the RPA REC. By middle order, we mean firstly that *agape* was abstract enough to encompass and distil the big-three ethical principles, as well as many more (confidentiality, integrity, dignity, and respect for persons, for example). Secondly, it was applicable enough to the day-to-day work of the Committee that it could serve as a useful working model for decision-making. In other words, it was rarely asked of a protocol, 'Is this in keeping with beneficence?', or 'Does this ensure the dignity of research participants?'. Instead, the characteristic test—a hypothetical question framed by the principle of *agape*—was, 'Would you let your daughter participate in this study?' By posing the question in this way, the imagined study participant was treated as classificatory kin; more specifically, as if he or she was a beloved family member. In this way, RPA REC decisions, through the principle of *agape*, were infused with the positive values that are associated in our culture with family and kinship.

*Agape*, we submit, served as a conceptual intermediary between abstract ethical principles and questions directly related to decision-making. It is important to note that it nevertheless functioned as an abstract principle. For example, John Clapham wrote and said of one proposal, 'Given the NH&MRC guidelines and the principle of *agape*, the study should be approved.' It is also important to note that *agape* was intentionally articulated, often reflected upon, and semi-theorized—Committee members were fully aware that it was a principle 'in use'.

In our observations, however, we noted that *agape* was mentioned only once. By contrast, the word that consistently cropped up in the talk of Committee was 'reasonable'.

When Committee members were talking in support of an application, they would preface their remarks with phrases such as, 'I think it's reasonable ...'. Critical comments would begin with, 'I just don't think that's reasonable ...'. Entire applications might be given an assessment in a single sentence beginning with, 'There doesn't seem much point to it ...'.

Struck by how often this word was repeated in discussion, we took our observation back to the Committee. John commented that he had not realized that the word 'reasonable' was so constantly in play, and added, on reflection, that the word *was* frequently used by everyone on the Committee, including himself. Unlike the principle of *agape*, 'reasonable' was not intentionally articulated, not reflected upon, and not theorized—Committee members were not even aware that it was so frequently used.

The term 'reasonable', from R. J. Lucas' classic exposition in 1963,<sup>22</sup> has been the subject of extensive debate in law,<sup>23</sup> political thought, and bioethics.<sup>24</sup> The 'reasonableness' that we identified bears a family resemblance to the traditional accounts found in these literatures. However, there are also decisive differences that arise from the fact that our method is ethnographic. The practical logic of reasonableness is unlike the legal concept of the reasonable person enshrined in case law and jurisprudence: it is not codified. Secondly, it is unlike the political concept of reasonableness espoused as an ideological tenet of liberal democracy: it is not a consciously articulated ideology. Thirdly, it is unlike the model of reasonableness in ethics which is defined and redefined in the abstract through the academic discourse of moral philosophy: it is not theorized.

Reasonableness was an expression of practical logic, the logic, *par excellence*, of the world of everyday life and the world of work.<sup>25</sup> Reasonableness provided a *modus operandi* for the committee member. Given their common lay habitus, it was shared by all. Reasonableness was taken for granted. In the words of Alfred Schutz, it was 'always that particular level of experience that is not in need of further analysis'.<sup>26</sup> There was no further explication from John or anyone else, about what 'reasonable' was. It was entirely self-evident. Reasonable was what was reasonable.

The scientific content of applications was evaluated in terms of reasonableness. We have explained above why the medical specialists on the Committee adopted the attitude and language of generalists, and subsumed this within their lay habitus. This generated a distinctive genre of commentary on the 'science' of applications wherein sophisticated scientific appraisals were expressed in informal lay-like language. Comments would characteristically be couched in a persuasive rhetoric of self-effacement, such as 'I'm not an expert in this area, but I wonder if ...', or 'I'm not sure if this is relevant, but ...'. Committee members would comment that one application was 'good science' while another looked like 'wobbly science'. Instead of making fine-grained criticisms of the research design, the number of subjects, the control groups or the statistical methodology, they would make ostensibly vaguely-couched yet obviously pointed comments such as, 'I'm not sure about the science,' and 'Wouldn't the study be more valid if ...?'. The most arcane scientific jargon we heard was, 'What's the point of taking blood again the next day?'. Though the Committee did not see its primary role as assessing scientific merit (this was normally the role of funding bodies), reasonableness had a direct bearing on scientific matters because in the end, 'bad science' or even 'wobbly

science', as they called it, was just not reasonable. It was not reasonable for participants to be involved in something that could never achieve the scientific findings it aimed for. This would be a waste of participants' time. At best it would inconvenience them; at worst it might put them at risk for nothing.

It is noteworthy that the one area where specialized scientific expertise was crucial to decision making concerned the assessment of drug trials, and this business was hived off to the IDSC. When IDSC recommendations came back to the RPA REC, the scientific critique had already been done, and thus the final approval could be negotiated in a lay idiom without the necessity of resorting to scientific jargon.

Reasonableness, as a form of practical logic, not only pervaded the Committee discussions but was also to be found in the notes that John Clapham made on each protocol in order to focus the discussion for the coming meeting. Here again, reasonableness was implied rather than explicit, and was usually expressed in the negative (what it was not rather than what it was). At the end of a summary of one study he wrote:

Since this study is with acutely ill patients, I don't think a 5<sup>th</sup> year medical student should be a contact person for NOK for this project.

Should an ICU physician be involved in the study and also be a contact person?

Here, John did not state outright that a fifth-year medical student could not answer telephone queries and provide information. Rather, he was implying that in serious matters like the well-being of a loved one, it was not reasonable that family members should have to speak with a person so junior. They should have the opportunity of being able to have their questions fielded by a more mature and qualified professional person, since this is what John himself would want in the same situation. Here, reasonableness, like *agape*, was an expression of the high value that Committee members placed on kin connections, and therefore, the necessity of kin having access to answers informed by a senior, clinically experienced doctor. Reasonableness was reasonable, in this instance, because it tacitly invoked core cultural family values.

The language of information sheets was another area for the exercise of reasonableness. John did not consider it reasonable to impose on participants either the jargon of medical science or the 'legalese' that emanated from pharmaceutical companies and their legal departments. Following the summary of another proposal, John wrote:

The information sheet is difficult to follow. The explanation of procedures is contained in a single paragraph which is one page in length. This should be 'broken up' into discrete sections to give participants an idea of the flow of events.

- On p.1, the brand name is used whereas on p.2, the generic name is used. Be consistent.
- On p.2, use 'alcohol' in place of 'ethanol'.
- On p.2, the statement 'At 9:15h you will be led to the Department of Nuclear Medicine to ...' seems rather sinister. Replace with, 'After arrival you will go to ...'.

- The information sheet refers to 'lower limbs' and 'dividing vessels'. Use 'legs' and 'cutting blood vessels'

Most research participants had no expertise in medical science or legal terminology. Some of the terminology John seized on (such as the brand names and generic names of drugs) was quite indecipherable, in which case, if such terms must be used, then at least they should be used consistently. On the other hand, some terminology was decipherable ('ethanol'), at least with the help of a dictionary. Notwithstanding this, it was not reasonable to put participants to the trouble of having to look it up. Yet other terms could be understood more easily ('lower limbs', 'dividing'). Even here, John wanted them changed into ordinary vernacular English ('legs' and 'cutting'), for this was the language of the lay person, the language that reasonable people used when they were being reasonable. Reasonableness therefore, we argue, had a linguistic dimension insofar as it was associated with a style of plain, clear communication that closely resembled oral discourse even when written.

Reasonableness tacitly invoked social norms of reciprocity that might best be summarized by the notion of a fair exchange, wherein scientific knowledge accruing to the researchers was exchanged for decent health care provided for the participants. John raised some issues in relation to one application: 'if study is terminated due to commercialization, drug supply must continue until it is available on a subsidy scheme'.

Here the Committee was requiring that if participants were offered free drug treatment as part of the study, it could not be ceased in such a way as to force the participants to pay the full price until federal government subsidies were introduced. To do so was not reasonable because it was not fair to give participants free treatment in exchange for scientific advancement and then after the study was over make them pay for it. When it focused on health care for participants, reasonableness was an expression of a moral position that lay outside the zone of commercial considerations. It tacitly invoked a sentiment, strong but not universal in Australia, of a person's basic right to enjoy subsidized health care.

The notion of reasonableness, then, was the principal means of putting protocols, their information sheets, their consent forms, and their science, to the RPA REC test. It was tacit: spoken but unheard; written but implied. Reasonableness was taken for granted: it needed no further justification. While it resonated with legal concepts of reasonableness, it was not codified. And while it resonated with ethical concepts of reasonableness, it was grounded in everyday action, not theory. Precisely because it was so ill-defined, it could be applied to a wide range of issues, and thus it pervaded the work of the Committee. We observed that it was rooted in cultural values concerned with family and kin, and embedded in social norms of exchange and reciprocity. It was articulated in a common or garden variety of language. It bound members of the committee together, whatever their differences, through the layperson habitus that all of them shared with each other.

### **The cultural field of research ethics**

As we indicated, the RPA REC was enmeshed in a wider cultural field. This field was covered by an extensive net of stakes and interests that were represented, for example, by the RPA itself, by nearby hospitals and universities with their own RECs, research funding bodies, local and national, the Federal Government including the NH&MRC, and transnational pharmaceutical companies. The practical logic of reasonableness guided the RPA REC in its interactions across this net, from its most intimate to its most peripheral strands. We provide only two examples here: the first, proximal, the second, distal.

Most of the Committee members worked in the RPA, the same institution as those who submitted applications. Personal knowledge<sup>27</sup> of the applicant and his or her research team was frequently mentioned in discussion. Committee members said that they 'knew' this or that applicant, or at least they 'had heard of her'. They matched their personal knowledge of the applicant with their appraisal of his or her application in such a way that applications by researchers known to Committee members to have a recognized track record of successful ethics approvals would be more likely to have a straightforward passage, providing they were seeking permission to do further research in the area for which they were so well known. John informed us that if such a researcher were to submit a proposal in a field that was an obvious departure from their usual research, this would be sufficient in itself to ring alarm bells, and the proposal would be subject to especially careful scrutiny that would extend to an assessment of adequacy of the resources of the research group to conduct the study. If consistency is a necessary (though scarcely sufficient) condition of reasonableness, then researchers were evaluated on this dimension. Consistency of character was matched against consistency of research track-record, and when these fitted together, it generated an overall sense of consistency—it hung together—an important aspect of any reasonable application.

Located at a distance from the RPA REC was the pharmaceutical industry which could be categorized loosely into two groupings, known colloquially as 'big pharma' and 'small biotech.' They interacted with the Committee when seeking ethics approval for phase one, two or three drug trials.

Phase one trials were the first studies of a new drug to involve human subjects. Looking only at safety in healthy volunteers, these trials used small numbers (tens or scores) of people. Therefore, they could be located at a single site, such as the RPA, and were the least expensive in the hierarchy of clinical trials. Phase two trials were the first studies of a drug that involved the target population for that drug; that is to say, patients. A dose-finding exercise, they were more expensive, involving large numbers (hundreds) of people. These numbers dictated that they must be multi-centre trials. Phase three comprised randomized controlled trials that looked at efficacy and safety. They were also multi-centre studies, and were massively expensive because they required very large numbers (sometimes

thousands) of patients.

Big pharma was represented by large scale pharmaceutical companies, all multinationals with headquarters overseas. They had a stability about them because they developed and marketed a wide stable of drugs: an entire range of products that were prescribed across many medical subspecialties. Through mergers and takeovers they had evolved into economic leviathans with sufficient financial power to influence national governments. Big pharma had the capital resources to come to the committee with proposals for phase two and three trials. Failure to gain ethical approval at the RPA was rarely a critical issue for them because they were simultaneously submitting multiple similar applications to other centres. The enormity of their cash flow gave them sufficient flexibility that a negative decision would rarely lead to adverse financial consequences—the expectation of a certain rate of refusal from RECs was most likely calculated into their business plan. A level of understanding had long since developed between the RPA REC and big pharma, which led to a certain consistency and predictability in dealing with these companies. Communication between the RPA REC and big pharma followed a liturgical order; question followed answer in a preordained sequence, like two choirs chanting an antiphonal psalm. When the REC pointed out problems with patient information sheets or research design, it was relatively easy to resolve differences and come to a reasonable compromise.

By contrast, small biotech firms were often national and listed on Australian stock exchanges, though some were international and listed overseas. In the pharmaceuticals landscape they tended to occupy that niche of innovative science which focuses on the development of a single entirely novel drug. These firms mainly came to the REC seeking approval for phase one trials located solely at the RPA; they did not have the financial reserves to go to phase two or three. When a trial was successful, they would usually license the drug to big pharma for them to further develop it through phase two and three, and ultimately market it. (Usually, the aim of small biotech was not to produce and market a drug, but to produce and sell a patent for a drug.) They generally had such a small cash flow that decisions made by the RPA REC could sometimes have significant and immediate implications for the financial survival of the firm. Thus a letter of approval or rejection was of sufficient importance to be reported to the stock exchange on the same day, and in fact it was mandatory that the stock market be notified of an event such as this because it would be expected to have an immediate impact on investors and affect the share price. A small biotech firm could rise or fall on an RPA REC decision. As a consequence of these fiscal pressures, interactions between the RPA REC and small biotech were less consistent, less predictable, and more pressured. This could lead to situations in which straightforward, practical concerns raised by the Committee could give rise to responses from company representatives that were not reasonable. These responses were driven by an imbalance in the acceptable ratio of commerce to science, commerce to ethics, and commerce to care. When commercial considerations outweighed the other three,

negotiations could become fraught—norms of reasonableness were breached.

We have sought to demonstrate that research ethics is a field pervaded—from the minutiae of decision-making to the high-stakes negotiations with transnational pharmaceutical companies—by the practical logic of reasonableness. We would further claim that reasonableness is the defining quality of research ethics as a field. For Bourdieu, a cultural field is, *ipso facto*, a field of power. A shortcoming of our analysis is that we have not given sufficient attention to the play of power in research ethics. However, based on our observations of the RPA REC interactions with big pharma and small biotech, we suggest that the expression of reasonableness is, in itself, an exercise of power. It is notable that the RPA REC could withstand the demands of small biotech: its defence was reasonableness. We tentatively advance the argument that the situation was reversed in the RPA REC interactions with big pharma. It is notable that the Committee tended to go along with big pharma, largely because big pharma tended to be so reasonable. That is to say, the persuasive force of big pharma, here, derived from its ability to co-opt the very habitus of REC members. Big pharma, we would contend, enveloped the RPA REC, and many others like it, in a gentle hegemony of reasonableness.

## Conclusion

In this paper, we have adopted an approach suggested by Bourdieu to examine preliminary ethnographic data gathered on a research ethics committee. This approach, we argue, has shed light on distinctive forms of symbolic capital accrued by Committee members which have to do with their professional standing, their organizational status, and that personal quality of virtue that so often accompanies volunteerism. We have argued that this effectively distanced them from any financial consequences of their decisions, conferring on them a mandate to make decisions that were moral determinations based on, for example, personal knowledge or the question of whether one would be happy to subject one's near and dear to an experiment. Bourdieu's approach has also enabled us to identify the layperson habitus that was shared by all Committee members, tempered especially in the clinicians by that of a medical scientist (though always that of a generalist, never a specialist). This habitus gave rise to a distinctive genre of Committee talk in which even complex scientific issues were artfully discussed in ordinary lay language. In the same way that recondite scientific matters were not discussed on the RPA REC, so the abstract ethical principles of autonomy, beneficence and justice, to which the work of the Committee conformed, were never articulated or brought to bear on a particular decision. Even the middle order principle of *agape* that guided the Committee was rarely mentioned.

Instead, we found the Committee conversation was permeated by the word 'reasonable,' and even when it was not heard, the tacit notion of 'reasonableness' was usually in play. This is the major substantive finding of this paper. Whereas Renée Fox found in her ethnography that ethical dilemmas were resolved through structured informal



humour, we found that reasonableness was the distinctive stock-in-trade of the RPA REC. We showed how it was not codified, not deliberately or consciously articulated, not theorized. Rather than a principle, concept or abstraction, it was a disposition, a stance, an attitude, a way of doing things, a way of approaching protocols, and a way of making decisions that was entirely consistent with the lay habitus we detected. It carried a persuasive force because it was taken for granted. So much was it beyond question that Committee members did not even think to question it. The practical logic of reasonableness also carried force because it tapped into and was reinforced by core cultural values concerned with fairness and care, as well as fundamental social norms of reciprocity and exchange.

Of all the values we observed, we were most impressed with the sense of family that pervaded the RPA REC. Members had a sense of belonging to the Committee as if it were a family, and it seemed fitting that Jill should be present at Wendy's farewell. The principle of *agape* itself was an expression of family love. The participants they never met were treated as if they were family members. Even the participants' family members were treated as if they were part of an extended family.

Furthermore, we showed how reasonableness not only drew members of the RPA REC together into a common family-like group with a common *modus operandi*, it extended outward from the committee into the cultural field that comprises research ethics. Whether dealing with applications from fellow colleagues in the RPA who were personally well known to Committee members, or dealing with the pharmaceutical industry in the form of big pharma or small biotech, reasonableness was the touchstone.

At the beginning of this paper, we identified three debates concerning research ethics committees: Do expert bioethicists have a role on RECs? Should RECs be regional or local? And do they facilitate or hinder research? We are unable to offer definitive contributions to these debates because our study is necessarily preliminary. Not only are our observations on the RPA REC limited, we also lack comparative ethnographic observations of the IDSC or of other RECs which might enable us to test our tentative findings. Based on our limited data, however, we would suggest that if bioethicists were to take a seat within a group such as the RPA REC, it would be necessary for them to come to the table as people with a lay habitus. They might be best advised to serve on the Committee in a voluntary capacity, to talk in plain language, and to leave Kant, Bentham and Mill outside the room, since the cut and thrust of decision-making follows the practical logic of reasonableness, not the theoretical logic of bioethics. With respect to the regional versus local debate, we would suggest that the decision-making that we observed relies on a balance between a broad grasp of the field and an intimate understanding of local context. A shift to regional level committees would strip RECs of half the knowledge base that they rely on to make sound ethical decisions. It would strip RECs of the personal knowledge that Michael Polanyi has identified as central to the progress of science. They would be forced into a form of distanced decision-making in the abstract, and

would lose the precision of practical logic. With respect to the third debate, we doubt very much, from our observations, that science is hampered by the practical logic of reasonableness. This logic, as we have emphasized, is underwritten by values of kinship, fairness, reciprocity, and plain talk. To challenge reasonableness, as we observed it in action on the RPA REC, is to challenge some of the core cultural values that underpin our society. This last debate, however, is probably a furphy. Protocols will always make it through the RPA REC—providing, of course, they are reasonable.

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### ENDNOTES

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# Ethical considerations in research on preventing mother-to-child HIV transmission

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## ABSTRACT

*Preventing mother to child transmission of HIV (PMTCT) is an issue that has come to the forefront in the global response to the HIV pandemic. This is particularly true for countries in sub-Saharan Africa and in Asia, which account for the largest proportion of people living with HIV. The relative success of PMTCT efforts to date have encouraged policy makers and donors alike to push for a rapid scaling up of the program in countries with a high prevalence of HIV. However, it is increasingly apparent that the relative success of the program has been at the expense of the rights and well-being of the mothers who are the primary recipients of the intervention. This article examines the nature and scope of the 'research enterprise' in PMTCT and shows how it has influenced intervention design and policy in India. It will also include the voices of 'target' women to convey the extent to which the research has impacted on their lives. Finally, this article indicates priorities for research that can help the situation of women as well as reduce MTCT of HIV.*

## Introduction

The prevention of mother to child transmission of HIV (PMTCT), has become one of the most prominent issues in the global effort to control the HIV pandemic. This is particularly true for countries in sub-Saharan Africa and Asia. 'About half of all adults living with HIV are women. There are about 2.5 million children living with the virus, 700,000 of whom were newly infected in 2003, mainly through mother to child transmission (MTCT)'.<sup>1</sup> Additionally, the relative simplicity and effectiveness of the intervention has contributed to the worldwide effort to combat PMTCT. The strategy consists of three stages. The first is the administration of antiretroviral prophylaxis to the HIV-positive pregnant woman during the pregnancy and/or during delivery. Second is the delivery of the child by 'elective' caesarian section. Finally, exclusive breast feeding by the HIV-positive mother for the first six months of the infant's life is promoted. Women in resource-limited settings are advised to give the infant nothing but breast milk for this period.

In the first two stages the HIV-positive pregnant woman is the passive recipient of an intervention designed solely to prevent HIV transmission to her child. The primary objective of the advice to exclusively breastfeed is also the prevention of MTCT. However, this

strategy ignores the consequences of the intervention for the mother additionally, it thrusts her back into the 'maternal and child health' framework from which the Cairo conference made such valiant attempts to rescue her.<sup>2</sup>

What are the circumstances which led to this situation? In this paper I will assess the nature and scope of the 'research enterprise' in PMTCT, and examine how it has influenced intervention design and policy in India. I will also include the voices of 'target' women to convey the effects of the research intervention on their lives. In doing so, I will also indicate priorities for research that will improve the outcomes for HIV-positive mothers as well as reduce mother to child transmission of HIV.

### **It all began when...**

In 1994, the results of studies conducted in France and the United States investigating the efficacy of zidovudine, were published by the AIDS Clinical Trial Groups (ACTG). The results indicated that zidovudine significantly reduced vertical transmission rates of HIV from mothers to infants: from 25.5% to 8.3% in these trials. The ACTG study regime soon became the standard therapy for preventing MTCT of HIV. However, a panel of experts subsequently convened by the WHO to consider strategies for reducing MTCT in developing countries, considered the ACTG regimen too expensive and recommended that a simpler regimen be evaluated. Soon after, 18 trials of antiretroviral drugs were initiated in different parts of the world, 15 of which used a placebo arm. In September 1997, the use of placebos in these trials became public and a prolonged and acrimonious debate on the ethical aspects of such trials followed.<sup>3</sup>

The use of ARV prophylaxis was established as the primary means of PMTCT of HIV. Predictably, the intervention was piloted in developing countries with great attention to the pharmacological details. Ethical considerations with reference to its impact on the women involved received little or no attention, except for a cursory acknowledgement of the principle of informed consent. Surprisingly, these studies attracted almost no criticism, either from HIV activists or from feminists in India. One plausible explanation is that the project employed the discourse of, 'babies as innocent victims', and the mothers themselves were only marginally included within this discourse. For a public made uncomfortable by the 'immoral behaviour' framework of HIV transmission that had dominated both the discourse and the response around the virus, this may have been a welcome relief. For policy makers too, here was a chance to wrest a semblance of control over an epidemic that constantly threatened to get out of hand. But what about the women involved?

### **The HIV positive pregnant woman as a subject of research**

Every pregnant woman is made vulnerable by the fact of her pregnancy. Not only is she undergoing changes in her body, uncomfortable changes over which she has no control, she is also acutely aware that she is primarily responsible for the well-being of another human being who is a fundamental yet distinct part of her.

In a country like India, this vulnerability is exacerbated by the premium put on being a mother, particularly the mother of a healthy male child. The expected child is all important, and for the space when she is bearing it, so is the woman. She is encouraged to do everything possible that will ensure the health of the child. In addition, not only is the pregnancy common knowledge, both within the family and in the immediate neighbourhood, the mother is the recipient of much attention and advice. A 'successful' pregnancy is therefore seen as a joint accomplishment and contributes a sense of fulfillment and joy to the lives of many people. This knowledge adds to the woman's anxiety to 'perform'.

Because the pregnancy is so public, so is any event associated with it. Visits by the nurse or to the hospital, the state of the woman's health and emotions, even her dreams, all are grist to the gossip mill. There is very little about the pregnancy that is confidential, especially if it is the woman's first child. So anything out of the ordinary, such as an additional visit to the hospital, a home visit by a nurse or social worker, or the request for a husband to visit the hospital, can all be interpreted as signs that something is going wrong with the pregnancy. Because the woman is the site of the pregnancy, this is invariably interpreted to mean something is wrong with her.

In India, HIV is primarily understood to be a consequence of 'immoral behaviour'. Therefore for anyone to be diagnosed as HIV positive is to invite shame and blame from the family and the community. For a woman, this can have disastrous emotional and social consequences. If she is pregnant and tests positive before her husband does, the discrimination is even more pronounced. Most often the woman is blamed for 'bringing the infection home', though in almost all cases she has acquired the infection from her husband. In addition, since the infection jeopardizes the child in the womb, she is doubly stigmatized. She may be subject to a number of actions - being taunted, cursed or avoided, not given adequate food, or sometimes, having to face physical violence.

### **PMTCT research in India**

Because current PMTCT interventions depend on knowledge of the woman's HIV positive status, pregnant women attending ante natal clinics at government hospitals are first tested and then 'enrolled' into related research studies. A report by the National AIDS Control Organisation (NACO) details a 2001 feasibility study assessing the administration of ARV prophylaxis to HIV-positive pregnant women.

In 11 hospital ante natal clinics across five states, all pregnant women attending the clinics were offered voluntary HIV testing after a

group education session on HIV/AIDS and pre-test counseling. The HIV test result was disclosed a few days later during a one-to-one counseling session. HIV-infected women were encouraged to bring their husbands/sexual partners for HIV testing. These women were also informed about AZT prophylaxis and its reported usefulness in preventing MTCT. The women were offered short duration oral AZT 300mg twice daily after 36 weeks of gestation. Informed consent was obtained from the women at all appropriate stages of the study.

Women who participated in the AZT trial were encouraged to deliver at the same institution so that AZT 300mg could be administered every three hours during delivery. In order to avoid stigma and discrimination against HIV-positive women who were to receive AZT, all HIV negative women with gestation beyond 12 weeks were offered identical looking oral Vitamin A as placebo.<sup>4</sup>

What the reports on this intervention do not reveal, and what has never been 'researched', is the actual processes employed during the research and their impact upon the women who participated in it.

### **Selvi says...**

Selvi is one of the women who was 'enrolled' in the study at a hospital in Tamil Nadu, and remembers the details vividly and with some bitterness:

When I was in my fourth month of pregnancy, I went to the government hospital at Namakkal, which is the town nearest my husband's village. It was the first time I had gone to such a big hospital. Though my neighbour was with me, I was nervous. They start the clinic in the morning at 8.00 itself, so we had to leave quite early ... I didn't eat anything because I was feeling nauseous and because I didn't want to miss the bus. It only comes every 40 minutes ... At the hospital I first had to wait in line to collect my OP chit (out patient registration forms) before waiting for my turn to see the doctor. There were about 20 or 25 other women ... we were all sitting on some benches. I remember that it was quite hot and I was sweating ... there were some pictures on the wall about AIDS, but I really wasn't looking or reading ... It was the first time I had ever been to such a big hospital, the place was so crowded, and with so much noise and smell ... I just wanted to finish seeing the doctor and to go home.

After we had been waiting for some time, a lady came in and said she was going to show us a film about AIDS. Nobody seemed very interested but she started the TV and we saw the film. Mainly it said how AIDS was spreading in Tamil Nadu because of going with many people, how even children in the womb could get it, and what we should do to not get it.

After the film, the lady told us that the hospital was offering a free test to see if any of us had AIDS. She said the hospital would give free treatment for women who were found to have AIDS so that their baby did not get it. She asked us if we were ready to be tested. Nobody said anything, so she asked us again. I didn't know what to say and nobody else said anything either. Actually I

was feeling somewhat uncomfortable about all the things in the TV about sex, and didn't want to talk about it in front of so many people. Maybe the others felt the same way. Then the lady said why don't you do the test anyway. Then even if by some chance you have it, we will give you free medicine to protect your baby. I didn't want to have the test but didn't know how to say no to the lady, especially when she was only trying to help us. The other women were also silent.

A little later, I was asked to go to a room where a man in a white coat took my blood. But he said I first had to sign my name on a piece of paper to say I was ready to do the test. I was feeling too nervous to read the paper so I simply signed where he pointed. I was wishing my husband was there with me, I would have felt better, maybe he would have asked some questions ...

### **Informed Consent anybody?**

Selvi's narrative highlights the fact that much of the testing, while not exactly coercive, hardly conforms to accepted standards of informed consent. Chief among these is the implications for Selvi of being the first one of the couple to test positive for HIV. Even if it had occurred to Selvi to raise the issue, we can see how her own tiredness, anxiety and discomfort in an alien environment and among a group of strangers, could have prevented her from doing so.

Did Selvi realize that she was part of a research study? 'No, I didn't know 'till the people from the hospital came home to ask why I hadn't gone back?' Would she have agreed to go through with the test had she known what the consequences were? 'I don't know, I'm very happy my child doesn't have HIV but I really went through a lot of pain and anguish because of the way the hospital people did everything. They could have talked to my husband as well before they did the test. They needn't have come home to find me because I hadn't gone back to the hospital to collect my test result. That's how everybody in the village started suspecting I had AIDS.' And why didn't she go back to collect the results? 'When I told my husband that day that I had a AIDS test, and they made me sign a paper, he got very angry and started shouting at me, saying I had no right to sign anything without his permission. I tried to explain that it was for our baby, but he just kept being angry with me. I was very hurt and confused and felt I had done something wrong. So when he said I should not go back to the hospital, I agreed. I felt that was the best thing to do.'

### **Follow-up**

The NACO research report on this intervention states that:

Women who participated in the AZT trial were encouraged to deliver at the same institution so that AZT 300mg could be administered every three hours during delivery. In order to avoid stigma and discrimination against HIV-positive women who were to receive AZT, all HIV negative women with gestation beyond 12 weeks were offered identical looking oral Vitamin A as placebo.<sup>5</sup>



### **What actually happened was...**

When Selvi did not return to the hospital for her scheduled appointment, the research team was instructed to visit her home and persuade her to come back to the hospital, so that she could be followed up. The first time the social worker went to her home, Selvi was out, but the social worker met her mother-in-law and left a message asking that Selvi attend the hospital as soon as possible. She recalls:

When my mother-in-law told me, I felt very scared and immediately knew it had something to do with the AIDS test. I didn't say anything even though she kept asking me if everything was alright. I was feeling trapped and wished I had never gone to the hospital. Other people in the lane had also noticed the social worker's visit ... it was the first time somebody from the hospital had come to somebody's home in the village, so they also knew something was wrong. As soon as my husband came home from work, my mother-in-law told him what had happened. He didn't say anything but that night he refused to speak to me or to come near me. I was crying all through the night, I couldn't sleep or eat. But I decided I would not go back.

A week later the social worker returned, this time when Selvi was home.

I told her to leave but she said she had something important to tell me. By this time, everybody in the neighbourhood was in the house, and so I said to her I would go with her to the hospital. My mother-in-law came with me. At the hospital, I met alone with the lady who had asked us to take the test, and she told me that I had AIDS and should come back to the hospital regularly for check-up so that they could give me the medicine to protect my baby. I was so shocked that I felt I didn't understand what she was saying. I kept having tears coming out of my eyes. The lady asked me to bring my husband for a test, and I didn't say anything. It was like all the words had been pulled out of me ... all I could think was what my husband would say and what his mother and all the other relatives would say when they found out ... I felt somehow guilty and ashamed, like I had done something wrong. Even then it did not occur to me that my husband may have been responsible.

Finally, I went out of the room and my mother-in-law kept saying, 'what's wrong, what did the doctor say?' and I said to her, 'She said I had AIDS', and then I couldn't keep from crying anymore. Maybe I hoped she would comfort me but she remained silent the whole trip home. As soon as we got home, she told my husband 'Your wife has AIDS. God knows what sort of a girl you married'. She wouldn't let me serve him the food and didn't ask me to eat either. I was crying but even my husband didn't look at me or talk to me ... it was the worst day of my life...If I could have killed myself at that time, I would have ...

A few weeks later Selvi returned to her mother's home, where she continues to live after the birth of her baby boy. Though her husband eventually confessed to having 'gone with a woman' before he married Selvi, he continued to be angry with her for having had the test without telling him. Her mother-in-law refused to speak with her except to accuse her of having brought the disease home and her two younger brothers-in-law began to avoid her. 'Everybody pretended everything was normal but even the neighbours began to avoid me. The worst thing was not being able to talk to anybody about it.' Selvi heard a few months ago that her husband was very ill but she refused to go back. 'They all blamed me, as if I was the one who had done something wrong. My baby is well, and I pray I stay well for a long time. Thank God, I am educated and have a job ... and thank God for my family ... my mother refused to allow anyone to say anything ... I know she will take care of me and my baby if something happens.'

### **So who did the study help?**

For Selvi, participating in the study destroyed her marriage, home and friendships, it all but destroyed her sense of worth and confidence in herself. But it can be argued that those might have been the consequences anyway even if she had discovered her and her husband's HIV status simultaneously, or learned her HIV status after her husband learned of his. It may also be argued that she was helped because her child was helped by the ARV therapy. However, there was no attempt to find a way of both protecting her child from HIV, and protecting her interests too. These important issues need to be addressed in the PMTCT endeavor. It is by talking to people like Selvi that we might find some answers.

A paper on health research ethics published from Pakistan highlights the specific issues in ethical research. Community participation is one of them.

Research needs to respond to community needs and national priorities ... the larger and more difficult challenge is to involve the communities themselves in the research' questions and to link the research to their own development. Such a participatory process with the community is a continuum that includes community consultation in protocol development, appropriate information of disclosure and informed consent, protection of confidentiality and right of dissent, and community involvement in the conduct of research<sup>6</sup>

### **ARV Prophylaxis and treatment for women**

In a belated attempt to rectify the instrumentalisation of women in the PMTCT program, WHO revised its recommendations for the use of ARV for PMTCT of HIV in February 2004. The first of these now says: 'Women who need ARV treatment for their own health should receive it.' Other recommendations talk about 'acceptable regimens' and include one that prescribes 'single-dose nevirapine to mother and to

infant<sup>1</sup>. This is the regimen currently being followed in India, as well as in several other developing countries. However recent research studies have shown that NVP has a long half-life and even a single dose may cause a high rate of resistance.<sup>7</sup> This leads to the inescapable and shocking consequence that women who require ARV treatment may no longer be able to access it if they have participated in a PMTCT program using NVP. Thus research in PMTCT, has the potential to harm, not only women's psychological and social well-being, but its application is also responsible for denying affected women access to life-saving treatment when they require it. This scenario is currently playing itself out in India, where despite policy and resources aimed at providing ARV treatment to HIV-positive women, a significant proportion of those requiring treatment are not considered eligible because of the high probability of NVP-induced resistance.

### **Current research in PMTCT**

A literature search of the field reveals that most of the research around PMTCT in the recent past continues to concentrate in three areas, namely:

- strategies to scale-up PMTCT programs
- effective drug regimens that can be administered to the HIV positive pregnant woman
- infant feeding options to reduce MTCT of HIV

### **Scaling up**

In a paper published in 2002 in the *Canadian Medical Association Journal*, Kathleen Steel O'Connor and Susan E. MacDonald argue for offering HIV tests as a routine part of pre-natal care in Canada.<sup>8</sup> Citing several studies the paper said:

In working towards the elimination of mother-to child transmission of HIV, 5 activities are critical in the prenatal and perinatal period. Pregnant women must present for prenatal care and must be offered and accept HIV testing. Women found to be HIV positive must accept and be able to complete a regimen of chemoprophylaxis.

Of the 12 references cited, 11 are from Canadian or US sources. Only one study was from a high prevalence area, and was on the '[c]ost effectiveness of single dose nevirapine regimen for mothers and babies to decrease vertical HIV-1 transmission in sub-Saharan Africa.'<sup>9</sup> However, there is no attempt to ask women what might be the best option for them, or to discuss potential risks to the woman engendered by such an approach.

The paper goes on to recommend an 'opt-out' policy for women towards prenatal HIV testing to 'achieve highest rates of screening and ARV prophylaxis.' An 'opt-out' policy treats HIV screening as a routine pre-natal screening test; a pregnant woman is informed that testing will be done, but consent is implied unless she specifically refuses. There is some mention of concern among women about side effects to herself and the infant, but this is casually brushed aside with the comment

that 'experience has shown that most pregnant women who know they are HIV positive accept therapy.'<sup>7</sup>

Even in a country like Canada, it is very likely that some pregnant women feel unable to refuse an HIV test simply because they are intimidated by the medical system that considers it routine, or are unable to immediately weigh up the consequences of having a positive result. In a culture that values the medical professional only slightly lower than the reigning monarch, it is not surprising that women were unable to assert themselves, especially when the well-being of their child was in the balance.

### **PMTCT and Elective Caesarean Section**

Research shows that there is a reduction in MTCT of HIV by about 50%-66% when babies are delivered by elective C-section.<sup>10</sup> However there is less mention of the risks to the women. Despite considerable evidence about the risks involved, it is unlikely that women participating in PMTCT research in India, or in other parts of the world, have been informed of the risks to themselves of delivery by CS. Meanwhile, CS is promoted as the best mode of delivery because of its effectiveness in reducing MTCT. Once again, the research has focused solely on clinical evaluation of 'percentages', 'odds ratio' and 'confidence intervals' around the mechanics of preventing transmission of HIV to the infant, rather on the health and well-being of both the baby and the mother. Where the discourse includes the mother it is often couched in the language of 'child survival' which advocates attention to the mother's health in order that the child may have a better life.

### **The Breast feeding debate**

This attitude is best exemplified in the research around infant feeding options. It has been known for some time that breastfeeding carries a substantial risk of transmission of HIV from mother to child. On the other hand, it is true that formula feeding in 'resource constrained settings' can compromise the health of the child for a variety of reasons. The only randomized controlled trial of formula versus breastfeeding showed a 16% increased risk of transmission of HIV in the breastfed group.<sup>11</sup> Quite apart from the findings, and subsequent policy development around breastfeeding, conducting a RCT after it has been known that breastfeeding increases risk of transmission is in itself ethically problematic. In addition to contravening the interests of both mother and child, it seems to negate the principle of informed consent and thereby the autonomy of the women involved. Even if we were to imagine that women were given all the information 'material' to consent, and the participants on the breastfeeding arm did give consent, it seems very unlikely that the women made an 'altruistic' decision in the interests of furthering scientific knowledge. One needs to examine the study processes in greater detail to comment more fully.

A prospective cohort study in South Africa<sup>12</sup> confirmed the earlier

finding, but went on to show that mixed feeding, which is most common, had a greater risk of transmission than exclusive breastfeeding. But equally, if not more importantly, the study reported that maternal mortality was higher among women who breastfed their infants. However, until recently, women participating in the PMTCT program were advised to breastfeed their infants and they were not informed of the risks that breastfeeding posed to their own health. Policy has recently shifted to give women the option to choose between exclusive breastfeeding and replacement feeding. However, they continue to remain uninformed about the fact that they may die sooner if they choose to breastfeed. What is particularly surprising, and ethically problematic is that this aspect is not even discussed by policy makers: including UNICEF, which is one of the leaders of the PMTCT campaign globally.

Despite being uninformed about the risks breastfeeding posed for her, Lakshmi, one of Selvi's friends who is also HIV positive, explains why she chose not to breastfeed her son:

Even though it is hard for me to afford it, I only give my child cow's milk. I don't want him to get HIV after all the problems I had to go through to see that he was safe at birth. Also, I don't think my health will permit me to give him only my breast and absolutely nothing else for six months. Even if I tried, somebody might accidentally give him something when I'm not around.

So why is it that the research is not looking at the real problems associated with exclusive breastfeeding, or affordable replacement feeding options? Why is there no research investigating the consequences of the PMTCT intervention for the women who underwent the intervention?

A Thai study that explored the quality of life of women after HIV diagnosis found that:

fewer women were living with their partners, most children were living with their mothers but only half the mothers were the primary caretakers, and fewer women had disclosed their status to others than to their partners, largely because of fear of disclosure. The women appeared to have high levels of depression and worry. Within two years after childbirth, substantial change within the families of HIV-infected women was evident. These were manifest by partner illness or death, reduced family income, shifting responsibilities for child care, and signs of depression and isolation. Providing family support is a major challenge in Thailand as the perinatal HIV epidemic progresses.<sup>13</sup>

While this attempts to look at the condition of the affected woman, it still does not ask the question, 'what is the intervention that will help women as well as prevent MTCT of HIV?'

### **New directions**

Fortunately, some advocates for women's health are looking at options that will maximize benefits to both the woman and her child. A

starting point is the development of interventions that do not depend entirely on the knowledge of the woman's HIV status<sup>14</sup> Recognising that test-dependent interventions can have adverse effects, Wendy Holmes and Tamara Kwarteng 'argue for a broad response to the problem raised by MTCT of HIV which includes: gathering information to inform the introduction of strategies that do not depend on HIV testing as well as continuing the test-dependent interventions; community education that reaches men as well as women; strengthening of reproductive health services; and mobilizing communities to care for infected women, their families, and orphans.'<sup>15</sup>

### **Conclusion**

The entire research enterprise around the Prevention of Mother to Child Transmission of HIV clearly instrumentalises the woman in order to ensure a HIV-free child. This is not to say that concern is solely for the child either. The primary motivation is to reduce costs associated with increasing the burden of care. Such pragmatism is understandable, perhaps even necessary. Yet, this particular exercise has not paid any attention to the benefits that may accrue to the HIV positive pregnant woman as a participant. Worse, it has paid even less attention to the many risks that the woman faces as a consequence of her participation.

These include mental trauma, stigma, breakdown of relationships including marriage, loss of status and damage to her self-esteem and identity. In addition, the projects have contributed to greater illness because of delivery through Caesarian Section. The list of losses continue into the future as women on NVP regimens during research face the prospect of drug resistance that will deny them access to ARV therapies when they need them. Of even greater concern is the manner in which the results of the research have influenced policy and practice of PMTCT in ways that continue to harm the women.

Clearly new directions are an urgent priority, and new studies must research ways that will benefit the HIV positive pregnant women in her own life in her family and in her community. Some new directions for research and policy around this issue need to be developed. These include research into strategies that do not depend on HIV testing, and research into the impact of the test-dependent interventions. Other important areas for research are: the practice of informed consent and the right of dissent, protection of confidentiality, , and community involvement in the conduct of research.

The focus of the research enterprise should be to find reasonable strategies that respond to the needs and concerns of pregnant women. This will not only be ethical research but successful research too, for the woman is the one with most at stake when the health and well-being of her child is threatened.

**ENDNOTES**

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## **NOTES**

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### **CONFERENCES AND MEETINGS**

#### **Dunedin, New Zealand, 10-12 February 2006**

New Zealand Bioethics Conference  
Making People Better  
University of Otago Bioethics Centre  
Website: [www.otago.ac.nz/nzbioethicsconference/](http://www.otago.ac.nz/nzbioethicsconference/)

#### **Dunedin, New Zealand, 13 February 2006**

UNESCO Ethics of Knowledge Production Conference  
For further information contact: [Sally.Boult@stonebow.otago.ac.nz](mailto:Sally.Boult@stonebow.otago.ac.nz)

#### **Beijing, China, 6-9 August 2006**

International Association of Bioethics  
8<sup>th</sup> World Congress of Bioethics  
Website: <http://www.chinamed.com.cn/IAB2006/>



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## **ETHICS COMMITTEE SUPPLEMENT**

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## JOTTINGS

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### **Many doctors who write practice guidelines have ties to the pharmaceutical industry**

A recent investigation in the journal *Nature* has found that a considerable number of researchers and physicians who develop guidelines on prescribing drugs have extensive financial interests and connections with the drug industry. The results of the survey suggest that drug companies are distorting decisions about how their products are being prescribed. An investigation of the panels that write clinical guidelines found that about 70% of these panels were directly affected by financial links. They are causing such concern because of their direct influence on medical practice.

*Nature*, 20/10/2005

### **Patients become guinea pigs in clinical trials in India**

Indian medical officials have recently expressed concerns about the vulnerability of Indian patients who volunteer to participate in clinical trials. The low cost of research and ease of recruiting large numbers of patients with different illnesses have made India a popular site for drug company recruitment. However, several unapproved and illegal clinical trials have taken place in different Indian cities in the last five years. Many of the drugs being tested are developed outside India. Nonetheless, studies have indicated that India is ill-equipped to handle the ethical issues that arise from such a volume of clinical research. Of 179 research ethics committees surveyed, only 40 had standards that met prescribed guidelines. Patients with heart disease and cancer have been among the victims of illegal trials.

*The Telegraph* (Calcutta), 24/10/2005

### **US alters test policy on psychiatric drugs**

The US government has backed down from a plan that to require long-term studies of new psychiatric drugs before allowing them on the market. The reversal was based upon the belief that delaying the release of new drugs might harm the interests of patients. The decision came after a barrage of complaints from industry executives, academic researchers and patient advocates. They suggested that drug companies might scale back drug development because of the potential increase in risk and cost. According to those who protested, many patients need to switch their drugs frequently, and conducting trials that focus on the long term effectiveness of medications will lead to focusing on a small subset of patients.

*The Washington Post*, 26/10/2005

### **Anti-HIV microbicide shows promise**

A triple-action gel could offer women greater protection from HIV infection than any other treatment currently being tested, say researchers. In a recent study in *Nature*, US-based scientists tested the microbicide on monkeys, then infected them with a mixture of HIV and a related virus that infects primates. The gel contained three components that block the virus in different ways. The combination's 100 per cent success rate — compared with 75 per cent when any single component was used — raises hopes that it could successfully protect women from becoming infected with HIV. Gels currently being tested on people need to be applied to the vagina just before sex. The combination gel, however, could be applied several hours before. There are currently no anti-HIV gels approved for human use. Five single-action gels are, however, undergoing clinical trials in Africa, which are due to end in 2007.

*SciDev.Net*, 31/10/2005

### **Jury finds for Merck in Vioxx case**

The pharmaceutical company Merck won a major victory in the battle over its Vioxx painkiller when a New Jersey state jury found that the company properly warned consumers about the risks of the medication. The finding means Merck will not be held liable for the 2001 heart attack suffered by a man taking Vioxx. After deliberating for less than eight hours over three days, the jury cleared Merck of allegations that it failed to warn consumers about the drug's risks, and that it engaged in 'unconscionable commercial practices' in marketing the drug to doctors and their patients.

The verdict is Merck's first win out of two Vioxx-related trials. In August, a Texas jury found the company liable in a Vioxx user's death. Damages there will be cut to about one-tenth of the jury's \$253 million award, due to that state's caps on punitive damages.

Much of the seven-week trial, eagerly watched by lawyers and plaintiffs from around the country, relied on the testimony of medical experts. Witnesses for Merck testified that the company believed Vioxx was safe for the heart before the drug was pulled from the market a year ago, after a study showed it doubled risk of heart attacks and strokes when taken for at least 18 months. The company faces more than 6,500 similar lawsuits. Merck has said it plans to fight the product liability suits one by one.

*AP*, 13/11/2005

### **Americans suspicious of participating in HIV preventative vaccine trials**

A telephone survey of 3,509 participants, which took place in 2002 and 2003 confirmed that there was general mistrust of medical research in HIV preventative vaccines. The researchers were particularly interested in the views of minority populations. Much of the mistrust was based upon knowledge of the famous Tuskegee study,

in which poor black men with syphilis went untreated so that the course of the disease could be observed. The new study on attitudes toward HIV vaccine trials also found that many people weren't aware that AIDS vaccines do not cause HIV infection. Seventy-eight percent of blacks thought that testing a vaccine could cause infection, 58 percent of Latinos believed this, as did 68 percent of gay and bisexual men.

*Health Day*, 21/11/2005

### **Brazil advised to break patents on AIDS drugs**

The Brazilian National Health Council has advised that Brazil is to be allowed to break the patents on three HIV/AIDS drugs, the costs of which could jeopardise Brazil's anti-HIV/AIDS efforts, and is to be allowed to make generic copies of the drugs at a much cheaper price. Brazil's strategy for combating HIV is considered to be the best in the developing world, and it instituted intellectual property law in 1996 allowing patents to be broken when companies used exploitative pricing practices.

*SciDev.Net*, 8/12/2005

### **Cheerleaders recruited by drug companies to increase sales**

U.S drug companies are hiring cheer leaders as sales representatives to promote drugs to doctors. Some industry critics view the use of cheerleaders as a variation on other inducements like holidays, dinners, and golf outings. However, representatives from the pharmaceutical industry suggest former cheerleaders for only a small proportion of drug representatives, and that all drug representatives are trained thoroughly.

*BMJ*, 10/12/2005

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## ARTICLE

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# Medical research and involuntary mental health patients: implications of proposed changes to legislation in Victoria

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### Introduction

In August 2005, the Victorian Departments of Justice and Human Services jointly releases a consultation paper entitled *Medical Research Procedures Involving Patients Under A Legal Incapacity*. In brief, the consultation paper puts forward the proposal that consent for medical research involving people who do not have the capacity to consent for themselves would no longer need to be given by the Victorian Civil and Administrative Tribunal (VCAT), but would be given in other ways. As the consultation paper points out, the requirement to seek consent from VCAT is quite recent; for people with long-term disabilities, it dates from 2000, and in 2003 the provision was extended to include people with short-term or indeterminate disabilities. So this is not a long-standing practice that has stood the test of time.

Submissions regarding the proposals in the consultation paper were invited, but the closing date was set as September the 2nd, 2005, giving less than 2 months for stakeholders and interested individuals to become aware of the proposals, canvass views and respond. Given that the proposals affect people in very vulnerable situations, it is unfortunate (to say the least), that a much longer and more extensive consultation process was not entered into. The consultation paper was circulated to HRECs, but the two month turnaround time was insufficient for some committee members to even receive it before the submission deadline, let alone have time to make a considered response.

We were prompted to write this article in part by a concern that the proposed changes should not pass into legislation without due attention from the research ethics community. In this paper, we address the implications for one specific group of people, namely involuntary mental health patients. As we will show, the implications are potentially very negative, but this would probably not be apparent

on a first reading of the consultation paper. It requires close examination of specific clauses, in conjunction with particular awareness of the realities of mental illness and the Victorian public mental health system. On the basis of the close scrutiny we have given to the proposals, we believe that the proposed changes will reduce the rights of, and protection given to, involuntary mental health patients who might be recruited into medical research, including clinical drug trials. The changes will make involuntary patients vulnerable to being included in research based on the decision of a person who has a vested interest in recruiting research subjects, without any independent scrutiny. We argue that this is ethically unacceptable.

We urge that those with expertise in other areas of health care, where incompetent patients might be involved in medical research, to consider carefully the implications for the patients affected by these proposals. The changes should not be made without an informed appreciation of what the impact on the ground will actually be for people who are already in vulnerable circumstances.

### **The implications for involuntary mental health patients**

Currently, involving an involuntary mental health patient (who may be unable to give consent to participate) in research, including drug trials, requires that consent must be obtained from VCAT. The *Chief Psychiatrist's Guideline Non-psychiatric Treatment and Special Procedures* specifically says that: 'The authorised psychiatrist cannot consent to the special procedure on behalf of the patient.'<sup>1</sup> We presume that the purpose of this is to ensure that an independent person can weigh up the pros and cons of any proposed procedure, from the perspective of the patient's best interests, without being influenced by other factors, such as the convenience of the treating hospital or the care providers. This guideline provides protection for patients who are in a particularly vulnerable position.

Under the new proposal for authority in medical research procedures, this will change. Specifically, the methods of obtaining consent proposed in the consultation paper are as follows. First, consent for the incompetent person could be given by the person legally appointed as having medical power of attorney (the medical agent), or the next of kin. Second, a mentally incompetent person could be included in research without consent, if a medical practitioner determines that there is a medical emergency and research intervention is needed to prevent damage to health. Finally, a patient could also be included in research without consent (or with 'procedural' consent only, to use the terminology of the consultation paper) if the next of kin or medical power of attorney cannot be found and it is not feasible to wait, and it is judged by a medical practitioner that this is not contrary to the patient's best interests.

Although none of the changes state directly or explicitly that the authorized psychiatrist will be able to consent on behalf of the patient, the nature and wording of the provisions mean that that the authorized

psychiatrist of an involuntary patient could very easily become the person to give consent for that patient to be involved in psychiatric or medical research.

This could readily happen in two ways, even assuming that an HREC has approved the research (as the proposed provisions require):

**If there is no next of kin or medical agent**

People with serious mental illness seldom appoint a medical agent. Additionally, up to 63.5% have no spouse or domestic partner and only 9.3% may have a primary carer.<sup>2</sup> If this is the case, under the proposed system, when the procedure is ‘time-critical’ (and all involuntary patients are already deemed to be in need of ‘immediate treatment’) ‘procedural authorisation’ is sufficient. Procedural authorisation requires that seven criteria be met; the person who decides whether the criteria have been met is the researcher. The researcher(s) in a clinical setting such as a public mental health service is likely to either have close working relationships with the authorised psychiatrists or themselves be the authorised psychiatrist.

The potential conflicts of interest for the clinician/researcher are well documented.<sup>3</sup> In psychiatric research the interests that compete with putting the patient’s interests first could include:

- a desire to get the best data from a trial by, for example, deliberately targeting excessively vulnerable first episode psychosis patients who physically are ‘drug naïve’ and so may appear to respond more positively than is generally the case.
- an interest in maintaining the involuntary status of a patient longer than is appropriate to ensure they remain in a drug trial.
- wanting to gain the maximum financial benefit and acclaim for their institution by recruiting as many patients for a trial as possible.

Involuntary psychiatric patients are particularly vulnerable in this situation because they have already lost any real autonomy, power or choice over their treatment: ‘Involuntary means against your will’.<sup>4</sup> Additionally there is a higher risk of harm compared to benefit for involuntary patients because being unable to give consent in the first place implies serious cognitive confusion and disability. This, for example, could negatively affect the patient’s capacity to articulate any of the side effects they experience from a medication provided in a drug trial.

**Medical emergency**

In a case such as this, it is decided that there is a medical emergency and that being in a clinical trial is necessary and urgent to prevent significant distress and that conventional treatment would not meet the patient’s urgent clinical needs. For example involuntary patients who are unable to consent to treatment and who are suffering from severe psychosis are regarded as being in a life-threatening

situation. The forms<sup>5</sup> used to confer involuntary status use descriptions denoting crisis or emergency – ‘your mental illness requires immediate treatment’ and ‘involuntary treatment is necessary for your health or safety (whether to prevent a deterioration in your physical or mental condition or otherwise) or for the protection of members of the public’. Under the new proposals, it is a registered practitioner who decides if there is a medical emergency but in practice this could be the authorized psychiatrist of an involuntary patient. On the basis of this decision alone, an involuntary patient could be included in a clinical trial of a new therapy with as yet unknown side-effects, especially in the long term.

The problems we have identified are not based on the assumption that individual psychiatrists will deliberately act against what they perceive to be the best interests of the patients. Rather, it is the context of involuntary treatment and the structural conflicts of interests built into the dual role of clinician and researcher that are of concern. In no other circumstances is it ethically acceptable for a researcher to give consent on behalf of research subjects, due to the inherent conflict of interest. We argue that in the situation of involuntary mental health patients, the stakes are even higher and there is even stronger ethical reason not to allow this to happen.

## **Conclusion**

In summary, we believe this new proposal of authority for medical research procedures offers insufficient protection to involuntary patients with mental disorders, and hence is ethically inadequate, at least in that regard. We hope that others with knowledge and experience in other specific areas of health care affected by these proposals will also consider the implications for patients and make representations to the government departments involved. The consultation period is officially closed but the proposals have not yet become legislation. It is of great ethical importance that as a society we get it right as regards the involvement in medical research of people who lack decisional capacity. It is important that good quality medical research is carried out, so that health care for people in this situation is improved however, it is vital that this is achieved while not exposing already vulnerable people to the risk of exploitation and additional ‘unconsented-to’ harm.

## **Acknowledgement**

We would like to thank Rose Nero for drawing the consultation paper to our attention in time for us to make a submission. That submission forms the basis of this paper.

## **ENDNOTES**

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  - 3 See either Bhandari M, Busse JW, Jackowshi D, Montori VM, Schunemann H, Sprague S, Mears D, Schemitsch EH, Heels-Ansdell D and Devereaux PJ, 'Association between industry funding and statistically significant pro-industry findings in medical and surgical randomized trials', *Canadian Medical Association Journal*, vol. 170, no. 4, 2004, pp. 477-480 or Lexchin J, Bero LA, Djulbegovic B and Clark O, 'Pharmaceutical industry sponsorship and research outcome and quality: systematic review', *British Medical Journal*, vol. 326, no. 7400, 2003, pp. 1167-1170.
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  - 5 See the *Mental Health Act*, 1986, Section 14, 'Community treatment order form' and *Mental Health Act*, 1986, section 9, *Mental Health Regulations 1998* Regulation 5(2), 'Recommendation for person to receive involuntary treatment from an approved mental health service form'.

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## REVIEW ARTICLE

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**Miriam Shuchman, *The Drug Trial. Nancy Olivieri and the Science Scandal that Rocked the Hospital for Sick Children*, Random House, Canada 2005, ISBN: 0-679-31084-3**

The Drug Trial follows the synthesis of deferiprone in England in the 1980s, and growing hopes that it might replace the then standard treatment for thalassemia, deferoxamine, which was effective but inconvenient and uncomfortable. Thalassemia is the commonest single gene disorder in the world. Prior to deferoxamine, it led to disfigurement, early deaths, and social stigma. One of the standard bearers of deferiprone was Nancy Olivieri, who in the late 1980s and early 1990s was working at the Hospital for Sick Children, and the University of Toronto. Once an enthusiast for deferiprone, Olivieri became aware that it did not seem to work as well as deferoxamine. At this point in its evolution, the main deferiprone trial was sponsored by a pharmaceutical company, Apotex. Apotex neither welcomed Olivieri's growing suspicions nor shared her belief that the patients in the trial should be informed of emerging doubts about the new drug. Rather than warn, the drug was removed from Toronto overnight. When patients turned up for their treatment, they found a bewildered hospital staff, who had neither a treatment nor an explanation to offer. The deferiprone study continued elsewhere.

Many of the reviewers of this book have conflicts of interests, but have not always made them fully clear. Miriam Shuchman gives no indication about any conflicts she might have, other than what might be inferred between the lines. I have a bunch of conflicts that cannot be ignored. First, I think Nancy Olivieri is fabulously attractive, charming and a force of nature, just as this book makes clear many of her patients thought and continue to think and Miriam Shuchman appears to have once thought, and now portrays as a hazard for any of the men who come into Olivieri's ambit. Second, she's been sacked by the University of Toronto department head, as have I. Third she works clinically, as do I. Fourth she's been subject to what seems a highly personal attack, as was I.

Lets lay some of these conflicting forces out on the table. While lecturers and researchers perhaps risk something similar from disgruntled students or colleagues, clinicians are in a very tricky situation when it comes to 'whistle blowing'. People, at their most vulnerable, come to them with a myriad of anxieties and expectations, and some of these people are inevitably frustrated. They may be frustrated by a failure of communication or by the very real mistakes that happen when practice has to be conducted in situations of dangerous uncertainty. Bottom line is if you want to dig up dirt on

even a sainted and fabulously wise clinician, there will always be patients happy to talk about simmering grievances, and colleagues who can point to 'errors'. It should be possible to get material like this with little risk of the patients writing in afterwards to claim they have been misrepresented – as has happened following the publication of this book.

If you queer the pitch for some drug, from which a pharmaceutical company stands to make millions, and you later ask that company under freedom of information provisions for material they hold on you, or you have a chance to hunt through their archives, what might you find? You might find instructions to have people planted in the audience to challenge claims you make. You might find debates as to whether you can be sued for claims made. You might find efforts to target your junior staff. You might find policies to refuse funding for meetings you organise or in which you participate. You might find notes from phone conversations with people you thought were close friends and who you thought agreed with your point of view, and these notes seem to show them saying pretty much the opposite to some company person to what they may have said to your face only a few days before. Now why, when there is lots of material germane to the drug's hazards that probably should be in the archive but isn't, would something like this fall into your hands instead?

And what do colleagues, who of course are uninfluenced by pharma commercialism and deplore its influence on others daily before breakfast, and who think the industry is populated by scurvy knaves, do when one of their own blows the whistle on some industry practice? In most clinical settings, there are annual awards of good citizenship bonuses, designed explicitly to be given for standing up for patients' interests, or for discovering something or bringing it out in the open – awards that sound tailor made for a clinician who goes out on a limb. So does Nancy Olivieri get any awards of this sort? No whistle blower does. Pretty soon, you realise it's not just the things you know you're not getting that you're not getting, you're also not getting the things you don't know you're not getting.

Now if this isn't enough to induce paranoia, there are what might be termed the academic stalkers. For instance in my case, a series of letters to newspapers, and posts on listserves and finally an article on the martyrdom of DH. Some of the claims made in these pieces when first outlined were ones that I had only seen made by pharmaceutical companies before that, and it was difficult to see how they could be made without access to pharmaceutical company sources.

Since then I've come across emails from third parties claiming to know the truth about Healy, reiterating points made by Coyne (2005). I've had phone calls from friends in various parts of the world telling me they've had senior figures from world psychiatry pass through their institutes who warned them that Healy was trouble and would soon be in trouble – and this was even before I lost my job. The interesting thing about these figures was that none of them knew me or had ever heard me talk to the issues, on which I supposedly held dangerous

views. And when invited to participate in debates, they balk, or if present at lectures I have given, none of it seems get round to pointing out any errors or even asking questions. How this all ties in to company PR documents that list Healy as a problem to be handled is anyone's guess.

Having investigated the Olivieri case, long before this book came out, I can say that there are lots of similar background events in this case that just do not feature in *The Drug Trial*. I can also say that again and again, the specific details outlined in this book seem to me simply wrong. But if we cut to what is a bigger issue - the biggest difference between Nancy Olivieri's case and mine aside from the fact that she was sacked more than once - this lies in the extent to which she has been attacked personally. Nothing like this book by Miriam Shuchman has happened to me.

If you read this pacily written book without having first been beguiled by Nancy Olivieri, what are you likely to take out of it? Well given that even I with all my conflicts found myself thinking at times the author sounded pretty even handed, I can only imagine that someone much less biased than I but also less aware of some of facts would find it pretty persuasive. On this account, Nancy Olivieri in all likelihood got the science wrong, and her claims to be a heroine are based not on the science but on a stunning public relations coup that has fooled almost everyone, except a few Executives in the Hospital for Sick Kids, whose efforts to put the record straight have been thwarted at every turn.

Again and again the events are seen through a prism of sympathy for those who have been portrayed elsewhere as the villains of the piece. Take Gideon Koren, an early collaborator in the deferiprone trials, and in many respects Shuchman's hero in this tale. Until recently Koren had an unbelievable annual output of articles, some on issues that he had limited expertise in. For instance, on the basis of relatively small samples of pregnant women he claimed that there was little risk from taking SSRIs during pregnancy and it would be much worse to leave a depression untreated. Much larger samples now point to a significantly increased risk of birth defects from the drugs Koren endorsed. Shuchman touches on none of this.

In the midst of this saga, Koren sent a string of anonymous hate mails to Olivieri's colleagues. As Shuchman reports and is documented in Thompson et al (2001), Koren was the principal witness in proceedings against Olivieri while he simultaneously was sending anonymous harassing letters against her and her strongest supporters. His testimony against her was eventually proven incorrect and Olivieri was fully exonerated by independent inquiries. In contrast, Koren was disciplined by Sick Kids' Hospital and the University of Toronto for misconduct in sending the anonymous letters, and in then repeatedly denying responsibility until he was identified as author by DNA evidence. He was subsequently disciplined also by the College of Physicians and Surgeons of Ontario (CPSO) for his 'vicious diatribes against his colleagues ... His actions were childish, vindictive and

dishonest.’

I’ll leave it to the reader to guess how Miriam Shuchman might portray this episode in a manner that generates sympathy for Dr Koren.

In the case of the difficulties the leaders of the Hospital for Sick Kids and the University of Toronto had in getting to grips with the issues, Schuchman sets these in the context of a series of events that took place at a time when the interface between academia and industry was changing and new rules for regulating the interactions of academics and industry were being worked out. Now that the rules have been worked out, it’s implied, nothing similar could happen again. You’d never guess from this book that other academic freedom cases blew up in Toronto after the Olivieri affair.

It is important that the author have sympathy for all parties as disputes like this will often be events that involve perfectly decent people making mistakes and getting caught up in new forces they only dimly understand rather than events that have been perpetrated by agents of outright evil. But the sympathy should be even-handed and in these pages Olivieri comes over as manipulative, mean and more concerned about her looks than anything else and her supporters seem like duped innocents. The least worst assessments are that driven people can be difficult, and the concession that she is a wonderful public speaker – but so are many dangerous people. She is criticised for not recognising the hazards that others suspected before she used the drug and criticised for her later conviction there were hazards when others were less certain.

Olivieri is accused of having a PR agent, but there is no effort to record whether the Hospital or University had PR agents. The idea that Apotex might have any idea what a PR agency is as far off the radar of this book as mentioning Per Rectal examinations might be in polite company. Olivieri is portrayed as surrounded by lawyers, but there is little emphasis placed on the fact that she and her supporters and the Canadian Association for University Teachers had to fork out for substantial legal bills, while in contrast the Hospital for Sick Kids and the University retained some of the most expensive lawyers in Canada and in this case the fees came out of taxpayers’ money.

But writing sympathetically should be just a first step to reaching the issues beyond the personalities, and the real problem with this book is that the author doesn’t get to any issues. There is no questioning of what is happening in our universities, which were once places where poorly paid academics behind a bastion of tenure could question the power of Church or State. But our universities are no longer bastions of intellectual liberty. It is perilously easy for an academic to lose their post if they don’t sign on to the new corporate agenda, while a growing string of exposures that academics from some of our most prestigious institutions have had their articles ghostwritten for them or been in receipt of up to a million corporate dollars per year has led to none of them being sacked or even censured. In fact it’s difficult to think of anything that academics might do today in terms of

working for business, short of a lengthy jail sentence, that might give them problems on our new corporate campuses. The current situation would have been unbelievable a few years ago, and is worsening, but there is not a hint of that from this book.

Starting right from the subtitle, *The Drug Trial* dodges the key issues by claiming that this is a scientific rather than an ethical scandal. If Olivieri got the science wrong, she ipso facto got the ethics wrong, and to say that she was right to speak out, that this was about academic freedom rather than scientific accuracy, is soft-headed. Pitching the issues this way pitches ethics against science. But in fact science is pretty well by definition never right - today's truth is tomorrow's shibboleth - and the ethical pressures get ever more intense the more ambiguous the details a scientist is faced with. If it turns out that Apotex's drug has some benefits for the heart in some patients with thalassemia, as the book suggests, this would no more invalidate the call that Nancy Olivieri made than recent findings that thalidomide is an excellent treatment for leprosy now invalidate the efforts of Siegfried Lenz to raise concerns about its teratogenic effects.

The key issue is whether in the face of ambiguous clinical trial data, a clinician treating patients should err on the side of the patient or on the side of the corporation that hopes to make money out of future patients. Shuchman glides over this by arguing we learn to live with the problems that many two-faced drugs cause by warning about hazards, but Apotex resisted warnings and recent experience with a range of drugs across all medical fields shows that corporations have to be dragged to court before they warn. From Chemie-Grünenthal, the makers of thalidomide, through to Apotex, it has always been possible to convene panels of experts who will come up with other explanations for inconvenient data, and will dismiss safety concerns as premature.

Shuchman cites Floyd Bloom, a former editor of *Science* and Chief at Scripps, as saying that researchers contracted the way Nancy Olivieri was hand over their rights. The company owns the data. But this is far from clear. This book offers no legal basis for saying Apotex in this case, or other companies in other cases, own the data. And there is a third party to these contracts, the patient. The consent form patients sign is a contract, but one that misses out a critical detail - namely that the company will seek to withhold all data from study participants, their clinicians or other clinicians in the future. *The Drug Trial* could have usefully asked a wider public what they think of this.

There are many compelling dilemmas that this book could have addressed. Instead it focuses exclusively on the swirling torrent of forces rushing through a particular controversy, the influences of money, power, fame and revenge. The facts, like rocks, occasionally protrude above the surface. With goodwill we might all agree on what's visible, but as outsiders we can only dimly make out or guess at what lies beneath. In the torrent that is the Olivieri case is it possible to hop from rock to rock and get to the far side? Not if you read this book. There have been two inquiries held, one instituted by the Hospital for Sick Kids, that found the Hospital and University blameless, and the

other commissioned by the Canadian Association for University Teachers that found unequivocally for Olivieri. Shuchman passes both off as partisan, without rebutting any of the points made in the latter, leaving us stranded in mid-torrent. But Olivieri's case has also been reviewed by the College of Physicians and Surgeons of Ontario who found her behaviour 'exemplary', and this would seem to provide a bridge to the far side.

But if Olivieri's behaviour was exemplary, how come we now have a book casting doubt on this verdict? The field of bioethics focuses heavily on questions about the influence of private money and company corruption on research, and many ethicists back up tough talk by refusing to take a cent from company sources. But these are relatively straightforward and superficial issues. If bioethicists are going to get to grips with what's going on in science today, they will have to get down deep and personal. The field will need to have some method for taking into account the fact that everyone who has spoken out about a drug from Siegfried Lenz to Nancy Olivieri has had their public detractors who commonly rely heavily on unnamed sources. There are enough examples now that they cannot each be dismissed as *sui generis*. Maybe it's just my conflicts of interest acting up, but I'd like to know more about the ethics and motives behind an *ad hominem* academic mugging of this sort and what bioethicists plan to do about it.

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# **ETHICS COMMITTEE REFLECTION**

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## **Medical research and participants with disabilities**

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### **The functions of consent to research**

The modern history of research ethics has emphasised the need for potential participants to give free and informed consent to their involvement. One common philosophical explanation for this emphasis is that it gives expression to the ethical principle of respect for autonomy, but an historical perspective offers a different explanation.

Although the Nuremberg Code of 1946<sup>1</sup> required that subjects give their consent to participation in research, the function of that requirement was to prevent harm that could follow unwitting participation. As Rhodes has recently argued<sup>2</sup>, it is surprising that consent became the emphasised principle of the Nuremberg Code when the most grievously unethical aspect of the research to which the Code was a response, was its cruelty and injustice.

When the World Medical Association developed the Helsinki Declaration<sup>3</sup> in 1964, the focus on consent remained despite the fact that medical research to which the Declaration was directed was assumed to be beneficial. There was no longer any need for consent to protect research subjects from the harm of torture masquerading as research.

In both the Code and the Declaration, little attention was given to the worth of research as a criterion of acceptability. In the former, there was no worth and in the latter, the worth was assumed. More recently, the need to consider the worth of research has re-emerged because of the benefits research promises not the risks it threatens. Tension has developed because the benefits of some research can only be realised if exceptions are made to the usual requirements for consent. Some present day researchers see the usual need for consent functioning to block the benefits of research. The insistence on prior, free, competent and informed consent threatens to prevent some research being conducted at all, they argue. As a result, any promise of benefit is not even tested, let alone proved. The heated debate over the RARE SALAMI trial in Sydney<sup>4</sup> was an example of this tension and the recent discussion paper<sup>5</sup> of the Victorian Civil and Administrative Tribunal (VCAT) is another opportunity to revisit these important issues.



### **The VCAT Discussion Paper**

The discussion paper addresses exceptions to the need for consent on behalf of people with short or long-term disabilities that prevent them giving their consent to research. The current Victorian regime for these situations required VCAT to review and approve research proposals and all recruitments to such research on behalf of those whose disabilities prevented them deciding.

The central issue in the discussion paper is whether this insistence on VCAT review and approval of both the research and recruitment of each participant remains necessary. The reasons given for suggesting that it may not be are that:

- there have not been cases of concern where current procedures are followed, and
- the time taken for VCAT approval may mean that a person cannot participate and that their treatment is compromised.

In these two reasons, the tension between the functions of a requirement for VCAT approval - as protection on the one hand and as obstruction on the other - exactly mirror the tension about historical and current insistence on consent.

### **VCAT's Proposal**

In summary, the VCAT proposal is that participation by people with disabilities in medical research that has been approved by a human research ethics committee (HREC) can be given in one of four situations:

- (a) if it is feasible to wait for a person with a short term disability to recover their capacity to consent, then their consent will be required;
- (b) where an emergency exists and the research intervention is, in the reasonable opinion of the medical practitioner, necessary to save the person's life, prevent serious damage to their health or prevent significant pain or distress, the intervention can be conducted without consent;
- (c) where neither of these situations applies, consent can be given by the person responsible for the participant, acting in their best interests; or
- (d) where the person is not capable of consenting, a person responsible cannot be found after reasonable efforts and it is not feasible to wait, the procedure may be conducted without consent, if it is intended to be therapeutic, poses no greater risks than those of the person's condition and present treatment and is not contrary to the person's best interests. Further efforts must continue to locate a person responsible and seek their consent to the person continuing in the research.

### **Scope of the new regime**

Paragraph 31 of the discussion paper makes clear that the new regime applies to all patients with a disability and not only those with a short-term disability, of the kind involved in the Rare Salami trial. In such situations, it can be persuasively argued that the requirements for consent obstruct the realisation of the benefits of the research for these people and for others in the same situation. That argument is strengthened if the research in question is into the condition that has caused the short-term disability. The VCAT proposal is not so limited, so that the research in question can relate to any treatment, whether related to the disability or not.

One reason for this wide scope may be the intention to apply the proposal not only to those with short-term disabilities but to those with other disabilities. It follows that time issues will not always be important. For research involving people with long-term disabilities, the focus on consent will be more about protection against exploitation or undue pressure. The change in procedure is probably not necessary to achieve this protection. The focus of the need for the change is on reducing the exclusion of people with short-term disabilities from the benefits of research. If that is really the basis of the change, it may be appropriate to consider whether the proposal should be confined to research on the condition that has caused the disability.

### **Medical research procedures**

It is intended to develop a new definition of 'medical research procedure' after consultation and the discussion paper suggests that it is likely to be confined to clinical acts, the administration of medication or use of equipment or a device in a clinical trial. One possible effect of this definition is that research that uses other interventions with people who have long-term disabilities will not be dealt with under the new regime. If the result of this is that VCAT will still need to review and approve these, then this may be a further consideration for confining the scope of the reforms to research that is about the disability that participants have.

### **The procedure for the new regime**

Paragraph 37 describes a two stage procedure: review and approval by an HREC followed by determination of whether any one of four situations obtains. Those are whether:

- the participant will recover in time to consent
- there is a medical emergency
- there is a medical treatment agent, guardian or next of kin who can consent for the patient, and
- procedural authorisation criteria are met.

The formulation appears based on the current practice of VCAT, i.e. a project approval followed by a participant's specific recruitment. One difficulty with this formulation is that HRECs do not function in

this way: they review a proposal once and address all the recruitment issues at that time.

### **Waiting to see if participant recovers**

The first of the factors is whether it is feasible to wait until a participant can consent. The judgment appears to be given to the researcher and for this reason, it is difficult to see how this respects the autonomy of the participant. The researcher is likely to have an interest in the recruitment of the participant, and where the research depends on early recruitment, to leave this judgment to the researcher places her in a conflicted situation. Instead, this appears to be the kind of judgment that someone independent of the research ought to make: someone more likely to respect participants' autonomy by deciding what is in their best interests.

The discussion paper does not address the ethical considerations that arise for researchers who are also health professionals caring for potential participants. This is a significant oversight as the issues are well recognised in the National Statement and the Declaration of Helsinki.

Paragraph 41 states that it will not be necessary to wait if this would compromise the research. This test appears too easy to satisfy. Arguably, every recruitment that is lost by waiting will compromise the research by reducing the sample size. If the participant's autonomy is to be respected, this decision ought to that of the person responsible and be based on an assessment of what is in the participant's best interests: to wait for recovery, to consent to immediate participation or to decline to participate and accept standard treatment.

### **Medical emergency**

Paragraphs 37, 41 and 42 contemplate that if an emergency exists such that intervention is necessary to save the participant's life, prevent serious damage to their health or prevent the patient from suffering significant pain or distress, then the procedure can be carried out without consent.

This appears to be an extrapolation to the research context of a well established legal and ethical position in clinical care, on which much emergency treatment rests. Although there are significant ethical differences between clinical and research contexts, it is said that this is already provided by section 42A of the Act.

Section 42A permits the use of medical or dental treatment for this purpose, and not special procedures, i.e. not research procedures. To make special procedures that include research procedures available as interventions in emergencies ignores the important ethical assumption that the intervention, to be justified, is one that is likely to have the intended effect. Only if the intervention is *known* to be effective will it be more beneficial than no intervention. Research interventions are, by definition, uncertain in their effect and using the concept of a medical emergency to justify experimenting on patients

appears to ignore this. In paragraph 44, it is recognised that rarely will there be reasonable grounds to believe that a research intervention will be effective. However, the judgment is left to the researcher who will have interests in taking advantage of the opportunity to use the emergency exception – not the least because of the statutory protection from liability that is attached.

Paragraph 45 argues that the opportunity to rely on research or novel procedures in emergencies is needed to ensure that there is no gap in the authority to provide emergency care. However, in this argument and in the discussion of emergencies, there appears to be confusion between innovative treatment and research intervention. Innovation is a recognised feature of clinical care – health professionals are acknowledged to exercise a degree of freedom to innovate on a case by case basis. Accordingly, medical treatment would already include innovation.

### **Seeking consent from the person responsible**

Paragraph 46 permits reliance on the consent of the person responsible if either the participant is not likely to recover in a reasonable time or waiting is not feasible. These are low thresholds for such a decision. It is not stated who will make these judgments, but it appears that it will be the researcher.

It is not clear when waiting would not be feasible, except where the delay will result in the participant ceasing to be eligible for participation or in an emergency situation. It will frequently be feasible where the participant's disability is not temporary. It would be clearer to relate the question of feasibility to compromising of research, as is the case in paragraph 53.

Reliance on the person responsible is a welcome change from administrative formality to a decision maker familiar with and trusted by the patient. However, it will be necessary that the person responsible and the exclusion of those close relatives that the participant does not trust be decided in advance and that the decision is recorded and readily accessible.

The obligations of the person responsible set out in paragraph 50 contain some demands that appear unnecessarily difficult to meet and omit some matters that are ethically relevant to any decision about participation in research. A person responsible is required to take into account the wishes of any nearest relative and any other family members of the patient. Clarification is needed that the nearest relatives referred to exclude those to whom the patient has objected and how widely the person responsible is required to inquire among other family members.

The matters that are listed in this paragraph could usefully include:

- that the intended procedure is a research procedure,
- the purpose and methods of the research,
- the available alternative interventions , and
- the known risks and benefits of the alternatives and the intended intervention.

### **Procedural authorisation**

Paragraphs 52 to 55 outline a proposed authorisation procedure whereby recruitment into research can be achieved without consent. The procedure is available where the patient cannot consent, no person responsible for the patient can reasonably be identified and contacted and the researcher holds, on reasonable grounds certain specified beliefs. It is said that elements of the procedure draw on paragraph 6.9 of the National Statement. 6

The National Statement requires an HREC rather than the researcher to be satisfied of the conditions, which are that:

- reasonable efforts have been made to find and contact a person responsible,
- it is not feasible to wait to seek the patient's consent,
- an HREC has approved the research in the knowledge that a patient such as the one in question may be include without any consent,
- the research project is therapeutic,
- the procedure poses no greater risks than that inherent in the patient's condition and alternative treatment,
- the research is based on valid scientific hypotheses that support a reasonable possibility of benefit over standard care, and
- inclusion is not contrary to the patient's best interests.

### **Respecting autonomy**

If respect for the patient's autonomy is the key value, who should make these judgments? An HREC can decide what type of patients can be included without their consent, whether the research project is therapeutic, and whether it is based on valid hypotheses. A researcher can decide whether it is feasible to wait to seek consent, whether the patient is of the type that the HREC has approved and, on the basis of information provided, whether reasonable efforts have been made to find and contact a person responsible. However, who can (and should) make the critical decisions whether the procedure poses no greater risks than are otherwise present and whether inclusion is not contrary to the patient's best interests? In the absence of a person responsible, ought these to be the judgment of the researcher, a health professional responsible for the patient's care or an HREC?

The re-examination and resolution of these questions is essential as there is a proposal to create an offence of performing a medical research procedure on a patient if a researcher does not reasonably believe that all the statutory criteria for the procedural authorisation have been met. Those criteria are the matters listed above but it is not clear whether they also include those listed in paragraph 55.

That paragraph provides that a procedurally authorised intervention cannot be conducted if it is likely to be contrary to the wishes of the patient. It is not clear who must make this judgment. The fact that a researcher is not designated with this task and

therefore the responsibility to have reasonable grounds for a relevant belief suggests that it is less important than the matters certification of which is required. The inquiries that need to be made to determine this are left undefined in a way that leaves this as a somewhat empty expression of respect for autonomy.

Another difference is that the National Statement requires that, in approving such recruitment, an HREC must be satisfied that as soon as reasonable possible after the intervention, the patient's relatives or legal representatives will be informed of the inclusion in the research and of the option to withdraw. Such a requirement is not a condition of approval of the procedural authorisation proposed. Rather, it is proposed that, in relation to the procedure, patients must be informed as soon as possible if they regain capacity and asked if they consent to their continuing participation. In addition, if the patient's participation is ongoing and they do not regain capacity, the obligation to contact a person responsible continues. It may be clearer to require that that obligation continues in any event, especially in light of the requirement that the researcher certify to the Office of the Public Advocate on a monthly basis that the statutory criteria continue to be satisfied.

### **Accountability**

Notification to the Office of the Public Advocate and to the relevant HREC that the researcher holds the specified beliefs is required within 48 hours. The reasons given for this are that they may be audited or used in any inquiry into the operation of the Act. It seems unnecessary that an HREC would need to be involved for the second of these purposes and it is not clear why HREC notification will be needed. The remaining obligation to monitor the research can be fulfilled by a report from the researcher at a cumulative stage rather than in relation to each recruitment.

VCAT retains a power to receive applications in respect of the research from a person responsible or some with a special interest and to appoint a plenary or limited guardian.

### **Conclusion**

The resolution of the questions raised about the VCAT proposal is closely related to the observations about the function of consent that opened this article. If the function is no longer the protection of the participants, because the research is required to be therapeutic and in the patient's best interests, then the judgments that in effect replace the consent of patients should achieve respect for their autonomy.

### **ENDNOTES:**

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- 1 The Code is contained in *Trials of War Criminals before the Nuremberg Tribunals under: Control Law no. 10*, vol.2, Washington D.C., U.S. Government Printing Office, 1949, pp. 181-182

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- 2 Rhodes R, 'Rethinking research ethics', *American Journal Of Bioethics*, vol. 5 no. 1, 2005, p. 7.
  - 3 World Medical Association, *Declaration of Helsinki*, available at <http://www.wma.net/e/ethicsunit/helsinki.htm>
  - 4 Rasmussen HH, Hansen PS, Koyama Y, Adelstein BA, O'Connell AJ and Nelson, GIC, 'Trial of a trial by media', *Medical Journal of Australia*, vol. 175, 2001; pp. 625-628; Kennedy MC, 'Clinical trials without consent: some experiments simply cannot be done', *Medical Journal of Australia*, vol. 177, no. 1, 2002, pp. 40-42; Rasmussen HH, Hansen PS and Nelson GIC, 'Rare salami trial revisited', *Medical Journal of Australia*, vol 177, no. 8, 2002, p. 462.
  - 5 Victorian Civil and Administrative Tribunal, *Medical Research Procedures involving Patients under a Legal Incapacity*, August 2005.
  - 6 NHMRC, *National Statement on Ethical Conduct in Research involving Humans*, 1999.