

PostScript

LETTERS

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Palliative care and cancer trials

Two of the most important concepts in medicine are “curing” and “caring”. Patients should enter clinical trials with the understanding that they benefit from the treatment or that there may be some benefit to others. In many cancer trials, for example, the best that can be hoped for is a prolongation of life. Whether or not life is prolonged, we argue that there exists an obligation which can be termed a “bond of responsibility” to provide appropriate palliative care within the patient's own cultural context.

The Declaration of Helsinki,¹ the principal code governing the conduct of medical research, shows this “bond of responsibility” to be at its core. A number of statements stand out: “the health of my patient will be my first consideration”² and “a physician shall only act in a patient's best interest when providing medical care which might have the effect of weakening the physical and mental health of the patient”.³ Article 10 reads: “It is the duty of the physician in medical research to protect the life, health, privacy and dignity of the human subject”. These three statements formulate in broad but very strong terms the intrinsic duty of medical researchers to act in much more than a neutral or disengaged manner. They cannot be concerned only with limiting harm from the trial itself; they imply a role of beneficence rather than mere non-maleficence.

Finally, article 30 in the Declaration of Helsinki states that “at the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study”. Although this refers specifically to benefits from the study in question, we feel there is undoubtedly a strong ethic of commitment to non-abandonment of the patient, which essentially represents the action of beneficence over a longer period. It does not, however, deal in specific terms with participants who may eventually become terminally ill. How then can researchers maintain this

“bond of responsibility” when they investigate patients with life limiting diseases?

The last 40 years have seen the worldwide development of the discipline of palliative care with the ethos of non-abandonment at its core. Patients with cancer are known to suffer considerably, with many studies pointing to measurable burdens of pain and other symptoms.⁴ For instance, around 60% of patients with advanced cancer have severe pain requiring opioids and 25% have dyspnoea. Palliative care has been shown in many settings to be very effective in minimising the suffering not only from late stage cancer but also from other terminal diseases.

Most clinical trial protocols address the problem of patient follow up in the context of collecting data for statistical analysis. Loss to follow up is an accepted aspect of protocol design. It is possible that advancing disease prevents many subjects from attending follow up appointments. Patient follow up is therefore an ethical issue as well as a research problem.

We suggest there is a strong link, a “bond of responsibility”, between researcher and participants in clinical trials, especially in the situation where the participant faces a potentially terminal illness. We feel there should be consideration of an amendment to the Declaration of Helsinki that would address the question of care for patients with potentially life limiting diseases who are recruited into clinical trials.

Where the option of appropriate palliative care is not already available, the researchers and their funding agencies should ensure that such a service is provided (and incorporated into the budget) before recruiting patients. This is particularly important in emerging countries where for many patients palliative care is the only treatment option for their more advanced cancers. We are aware that the provision of palliative care, especially in these developing countries, can be difficult.⁵ There have, however, been many successes in the past as well as recent initiatives.^{6,7} We are also aware that there is the potential problem of researchers undertaking an open ended commitment for supporting patients and providing services that could be prohibitively expensive. What we advocate is that practicable provision of palliative care be a component for those clinical trials where the participants are likely to enter the terminal stage of their disease. The people who are subjects of such trials would not be abandoned and the benefits of medical intervention would persist.^{8,9} Then the “bond of responsibility” that binds researcher and patient will be preserved.

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Reporting of informed consent and ethics committee approval in genetics studies of stroke

The study of low penetrance gene variants in a complex genetic disorder such as stroke does not pose the same risks and benefits as a study of highly penetrant mutations.¹ Because of the nature of their disease, however, stroke patients may not understand the information given when they are asked for consent to participate in research and are potentially vulnerable subjects. In a systematic review of publications on ischaemic stroke genetics, we assessed the way in which informed consent and ethics committee approval are reported.

Methods

We searched the MEDLINE database for stroke genetics studies published in English between January 2000 and January 2002, using the medical subject heading term “cerebrovascular disorders, genetics of” plus the text words “ischaemic” and “stroke.”² We included only original clinical trials and observational studies of human genetic risk factors for ischaemic stroke.

Both authors independently reviewed every article. We used standardised forms to record

Table 1 Reporting of measures for ethical protection of subjects participating in 41 studies on genetics of ischaemic stroke

Type of protection measure	No of studies	%
Informed consent		
Yes	29	71
Not reported	12	29
Ethics committee approval		
Yes	26	63
Not reported	15	37
Both informed consent and ethics committee	21	51
No protection measures reported	7	17

whether an explicit statement described informed consent and institutional review board (IRB) procedures. We also recorded whether the consent was given orally or in writing, whether it was witnessed, and whether family members and caregivers were involved in the process. In addition, we recorded whether the ethics committee or IRB was identified (named or identified as "the local ethics committee"). We also recorded whether articles referred to previous publications of the same study, the country where the study was done, and the journal in which it was published. We settled any disagreements by consensus. Because this study did not involve human participants or medical records, institutional review board approval was neither required nor obtained.

Results

In 24 separate journals, 41 articles met search criteria.² The number of articles per journal was one for 17 journals, two for four journals, three for two journals, and 10 for one journal.

Informed consent was reported more frequently than was protocol approval by an IRB or ethics committee (table 1). About half reported both obtaining informed consent from the patient and receiving protocol approval from an ethics committee, and 17% did not mention any measures taken to protect patients.

Details regarding the mechanism by which informed consent was obtained were rarely reported (table 2). It was also rare for articles to report whether the use of familial or non-familial surrogate consent was permitted if the subject was not competent to give informed consent. The IRB or ethics committee was identified by name in 24 (92%) of the 26 articles that reported receiving approval.

For 40 articles, no distinction was reported between ethical protection measures for subjects who had a history of stroke and stroke free subjects. One article stated that both ethical protection measures were in place for stroke free controls but did not report whether the same protections were in place for the stroke affected study subjects.³ One investigative group studying stroke genetics in children published two articles in the same year and in the same journal. One article reported the use of familial consent,⁴ and one article did not.⁵

Discussion

After the introduction of the Uniform Requirements for Manuscripts Submitted to

Table 2 Details of informed consent reported in 41 studies on genetics of ischaemic stroke

Detail	No of studies	%
Articles containing at least one detail	10	24
Type of detail reported*		
Written	7	17
Oral	0	0
Familial, granted by parent/guardian for a child	1	2
Familial, granted by family member for an adult	2	5
Non-familial, granted by legal proxy	0	0
Non-familial, granted by caregiver	1	2
Witnessed	0	0

*Articles that contained more than one type of detail were counted more than once.

Biomedical Journals,⁶ the number of articles reporting use of informed consent in clinical trials increased from 64% to 82%, and the number reporting ethics committee approval increased from 59% to 82%.⁷ The percentage of articles reporting these ethical protections for stroke genetics studies published in 2000 or later appears to be similar to that for clinical trials published before 1997. It is possible that in some studies ethical protections were in place but were not reported, and it is not known whether selection factors influence such reporting.

Only rarely did articles report using consent from a legally authorised representative if the prospective study subject was not competent to give informed consent. Knoppers and colleagues⁸ point out that it is difficult to establish a blanket set of ethical guidelines with respect to the participation of incompetent adults in genetics research. It may not be possible to know whether participation in a genetics study would conform to previous personal values or preferences of a person rendered incompetent by acute or chronic stroke.

The debate over competence of stroke patients to participate in clinical research has focused on therapeutic trials, because truly emergent consent is rarely required in stroke genetics research.⁹ Patients who are enrolled in such trials are on average more severely affected by stroke than population based stroke cohorts. The recovery of decisional capacity of patients with stroke may, in some instances, parallel recovery of neurological deficit. Patient genotype may, however, influence survival after stroke¹⁰ and response to acute therapies.¹¹ Thus, to avoid survival bias it may be important for stroke genetics protocols to have as an option the enrolment of subjects using the combination of personal assent and consent by a legally authorised representative.

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Response to: increasing use of DNR orders in the elderly worldwide: whose choice is it

I read Dr Cherniack's article regarding do not resuscitate (DNR) orders with interest.¹ One of the problems with DNR orders is the patients' assumption that if there is no DNR order they will survive resuscitative efforts. This of course is far from the truth. In my hospital these orders have been modified to "do not attempt to resuscitate" orders. One cannot be truly autonomous without being informed. Long term survival, as measured only by being alive, following inhouse cardiac arrest, is about 15% over all age groups.² In sick elderly patients over 70 years of age who survive a cardiac arrest, the subsequent hospital mortality approaches 100%. This fact, and concerns about harm, influence physicians' attitudes, particularly where the general public have wildly unrealistic expectations of the results of resuscitation, as mentioned in the paper by Godkin and Toth.³ Significant neurological disability is common following cardiac arrest: up to 50% of the survivors of cardiopulmonary resuscitation (CPR) in one study.⁴ Medical staff are clearly aware of the hazards of resuscitation, doctors have been shown to be highly selective as to when they would wish resuscitation to take place for themselves,⁵ and in one group of emergency workers few were found who were willing to undergo full resuscitation as "currently practised".⁶ While age as such is not necessarily a predictor of

poor outcome of intensive care⁷ advancing age is associated with an increasing incidence of systemic diseases, which do predict poor outcomes following arrest.^{8,9}

As a society we seem to strive to prevent death, pursuing the next line of treatment at any cost and this struggle against disease has been described as “trench warfare against death”.¹⁰ Patients and their relatives expect physicians, as fiduciary agents, to do everything in their power to help cure them and save their lives, but there comes a point where not doing something is the better thing to do. Physicians tend to endeavour to do all that they can, as Morreim puts it “embracing a technological imperative that favours action over inaction”.¹¹ The fact that we would not wish it upon ourselves, however, says a great deal about what we think of resuscitation in the sick elderly patient. Dr Cherniack comments that when information about CPR is presented more negatively then fewer elderly will choose it. He seems to imply that one could be more positive if only one wanted to. I fail to see how one can be positive about brain damage, a stay on the intensive care unit (ICU), and the near certainty of death. In certain circumstances CPR is simply harmful. Outcome statistics and the high incidence of morbidity have led one group to conclude that “treating our elders this way is maleficent”.¹²

It is a moot point whether there is any moral obligation to discuss treatment options that are not really treatment options, particularly where the potential to do harm far outweighs any benefit. Survivors of resuscitation are transferred to ICUs. Patients who have spent time on ICUs report nightmares, depression, and high levels of distress, and up to 40% have recollection of pain.^{13,14} Is this a beneficent act if survival is not a realistic possibility? I think not, but of course a vitalist would disagree. By all means we should ensure that we respect patients’ autonomy by asking their preferences, but we have to be totally frank about outcomes. Not to be so would be to infringe patient’s autonomy as much as disregarding their preferences.

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BOOK REVIEWS

Genetic privacy: a challenge to medico-legal norms

G Laurie. Cambridge University Press, 2002, £50.00 (hbk), pp 335. ISBN 0521660270335

The conflation of autonomy with consent that is typical of current approaches to medicolegal dilemmas reduces the means of respecting individuals to one solitary event—the obtaining of informed consent... [which] means that informed consent has come to be the primary, and arguably the only, legitimate way of empowering individuals in their dealings with health care professionals and researchers. This is also true in the spheres of intellectual property and biotechnology. But this need not and should not be so (p 310).

The above quotation illustrates the jurisprudential depth and philosophical reach of the arguments in what might be wrongly assumed to be a technical treatise on confidentiality concerning genetic data. Developing a wider notion of property rights in the person, Laurie offers prescriptions of potentially enormous relevance to current debates in public policy, including the deliberations of the Retained Organs Commission and the simultaneous wider Department of Health consultation *Human Bodies, Human Choices*. My own view is that precisely what is wrong with the DOH consultation document is that it views informed consent as the be all and end all in patient empowerment. Properly understood, property rights in the person can function as a useful partner to informed consent in protecting vulnerable individuals and groups from unauthorised taking. (Indeed, this view—similar to Laurie’s—does underpin another recent policy document, the Human Genetics Commission’s May 2002 report *Inside Information*, the report of a working group

chaired by Laurie’s Edinburgh colleague Alexander McCall Smith.)

Laurie divides his book into three sections, the first an extended discussion of what basis there may be for attaching value to privacy in health care. The second of the two chapters in this section, “Privacy: antisocial concept or fundamental right?”, includes a neatly analytical section on the feminist critique of privacy, which comes as a pleasant surprise on two counts. It is still unjustifiably rare to see feminist theory picked up and used in non-feminist texts, and the first chapter gives little reason to expect anything other than the conventional interpretation of privacy as intertwined with fundamental democratic freedoms. Indeed, at times in the early pages of the book Laurie sounds rather worryingly Thatcherite: “it is the development of a public interest in the welfare of individuals that has proved to be one of the greatest threats to individual privacy in the last century... . Western societies are typified by a glut of legislation stemming from paternalistic attitudes of the state towards its citizens” (p 9). These already large generalisations are outdone a few pages later, with such assertions as “The rise of Western liberal democracy has spawned a very egocentric society”, and an ensuing diatribe against the “cult of the body” and health promotion more generally (p 11). What begins to sound like the ramblings of a crank is mercifully brief, but this first section does detract unnecessarily from the overall high analytical level of the book. Laurie appears to view it as imperative to begin this way in order to justify his choice of the health care setting as a context for his discussion of genetic privacy, but surely the issues on which the rest of the book concentrates are serious enough not to require any such tendentious justification. Even though Laurie maintains that “one sign of a democratic system is the extent to which the state takes an interest in the lives of individuals” (p 16), it is well to remember that Stalin took quite a definite interest in the private lives of his people.

By the end of the second chapter Laurie has come to a more measured evaluation of privacy, making good use of the sceptical arguments offered by feminism and communitarianism. He acknowledges that privacy—not to be equated simply with confidentiality—is an amorphous concept, but correctly remarks that the indeterminacy of the concept “should not lead to the conclusion that it should go unprotected by law or that it cannot be so protected. Many ill defined and indeterminate terms—such as good faith, recklessness, the public interest, and the reasonable man—are used in the law” (p 51). (Indeed, one might add, the common law is bound to develop such vague definitions by the process of accretion of cases which is its fundamental dynamic.) He now begins to develop his original concept of privacy as a state of separateness from others, which can be extended in the usual way to personal information as “an intimate adjunct to individual personality” (p 64). In particular he concentrates on a notion of “spatial privacy”, conceived, however, as a supplement to the more familiar notion of informational privacy.

As a zone of privateness surrounding the individual, spatial privacy should not be invaded without due cause, but those sorts of invasions can be either physical—as in an unauthorised treatment—by unwarranted observation, or—crucially—by the revelation

of genetic data to a patient, whether or not she wants to know. Protecting the right not to know is notoriously difficult through the usual channels of informed consent, since giving the patient the right “not to know” usually requires telling her something about whatever information is concerned—by which time the right “not to know” has already been breached. What Laurie seeks to do with his notion of spatial privacy is to provide another means of protecting that right, in a manner that does not depend entirely on the notion of informed consent. In a footnote he belatedly acknowledges that invasion of the right not to know can come from private corporations as well as from government, and that there “the greatest current threat to privacy now comes from private enterprise and not the state” (p 66).

Section two of the book dissects the existing models relating to confidentiality and privacy in genetic information, moving on to “a new privacy paradigm” in section three. Throughout Laurie smoothly integrates case law, consultative commission reports, professional guidelines, and statutes with recent developments in genetic testing and screening; the book would be worth having for its wealth of information alone, even without the more philosophical analysis. That analysis is sometimes very perceptive indeed, as when Laurie remarks that the risk of discrimination arising from misuse of genetic information “is as much a threat whether or not there is any scientific or logical basis for the belief that differences are meaningfully discernible. The potential for harm arises out of the perception that there is a difference, not out of the essential nature of the information that is seen to justify the differential treatment” (p 108).

Chapter six “Privacy and property?”, contains the most original and far reaching of Laurie’s analyses, his attempt to reformulate the concept of privacy to rectify its usual negative nature, as a right of non-interference rather than a positive entitlement. Here Laurie draws on examples from other legal systems, such as the German statute of 1993 (*Personlichkeitsrecht*) protecting the body as an aspect of the right to personality, so that unauthorised taking of tissue can be prosecuted as a breach of this law. Many of the muddles in our own Anglo-American (non-)system of property in the body may be merely historical rather than inevitable; in the wake of the Alder Hey scandal, and, more positively, in a period of intensive governmental scrutiny of how patients and their families can be protected against such unauthorised takings of organs and tissue, a great deal can be learned from other jurisdictions. What can be said of tissue can also, by indirect parallel, be said of genetic information, and Laurie argues cogently for extending the narrow range of intellectual property rights to protect individuals as well as their more usual beneficiaries, researchers, funders, and universities. This, he asserts, is the only way to

stem “an undeniable public crisis of confidence in genetic research, even though the promise of great benefits is well recognised” (p 309). This atmosphere of mistrust will not be dispelled only by invoking the gift model—since a one way gift, as I have argued elsewhere,¹ is better termed exploitation—or by the related stratagem of ensuring a properly informed consent to “downstream” uses of genetic information or tissue. Reviewing a series of related developments towards a coherent property model, Laurie concludes that protection of the personality can best be effected by combining the property and consent models, rather than by viewing them as mutually inconsistent.

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The Prenatal Person: Ethics from Conception to Birth

N M Ford. Blackwell, 2002, US\$59.95 (hbk), US\$24.95 (pbk), pp 256. ISBN 0631234926256

In *The Prenatal Person: Ethics from Conception to Birth* Norman Ford has provided an important, thoughtful, accessible account of a natural law view of early human life. Ford has written an engaging book that puts this fundamental moral position about persons and prenatal life in conversation with critics of the position, common morality, the Christian tradition, and many of the complex clinical problems of contemporary medicine. The book is a timely contribution to bioethics and many of the controversies surrounding embryonic stem cell and cloning research. It takes up one of the most important positions in these debates and gives a clear, concise development of the natural law tradition. Ford very clearly lays out a natural law position on early human life and then draws out the implications of that position for many current and important issues in bioethics. He writes with clarity as he works through the foundational issues to the complex clinical and research questions.

Of course there are many different views of the issues surrounding early human life. The moral controversies about early human life are further complicated by the fact that there are several different methodologies deployed in framing these views. Ford is mindful of these different audiences and conversation partners as he develops the book. He pays careful attention to other views.

In the first chapter he engages in an explanation of fundamental moral questions. He engages many of the issues raised by Peter

Singer and utilitarian thinkers. Ford also engages contemporary understandings of the person that are part of Singer’s work and which are often very much a part of discussions in contemporary bioethics even when they are not explicitly articulated. Ford sets the Singer positions in conversation with a traditional view of morality and traditional conceptions of the person. He examines Singer’s stance on “interests” as the defining characteristic of the moral community. Ford is convinced, however, and argues accordingly, that the focus on interests alone leads to a subjective view of the person. While the subjective view is important, Ford argues that ethics also needs an objective approach which is the foundation of the person’s subjectivity and capacity as a moral agent.

In contrast Ford argues that the traditional concept of the person and traditional morality offer a more comprehensive view of morality and the person. The human nature view of the person also provides a way to talk about early human life—especially prenatal life—in the language of persons. Ford then goes on to show how the Jewish and Christian Scriptures contain a number of themes that are important to issues of morality and medicine.

In the third chapter, he describes the basic ethical principles for health care that follow from the foundational position he has laid out. In doing so he tries to set out these principles from both philosophical and theological perspectives. Having set out a framework in the natural law tradition, Ford then moves to particular issues about prenatal human life. In so doing he enters a conversation with many of the most difficult issues in contemporary medicine and health care.

In the chapters that follow Ford moves from the foundations to examine many of the issues surrounding prenatal human life. The human embryo, the pregnant woman and the fetus, assisted reproduction technologies, and prenatal screening are all explored. Ford thoughtfully examines some issues surrounding newborns.

The book provides an in depth, clear examination of a particular moral position that has been, and remains, important to many people in bioethics and the practice of medicine. The book is an excellent examination of this tradition of thought and applies that tradition well to many difficult and contentious issues. It is also to be recommended as an attempt to put the natural law tradition in dialogue with other key lines of thought in contemporary bioethics. It is well written, insightful, and touches on some of the most controversial issues in the field. Even if one disagrees with the arguments and the foundational position, it is a book that ought to be part of the ongoing debates around these issues.

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