Informed consent fails to protect

MEDICAL research should be suspended until the issue of informed consent has been clarified, according to Professor Hiram Caton, head of the school of applied ethics at Griffith University, Queensland.

In an open letter to the Australian Health Ethics Committee, Professor Caton said the issue was a serious and potentially litigious one.

"We have good evidence that informed consent is not being obtained and that puts medical research into a legal limbo," he said.

His comments followed a study by Professor Yee Hing Thong from the University of Queensland's department of child health (*Australian Dr Weekly*, 30 October 1992).

Professor Caton said this study of parents who volunteered their children for an asthma drug trial revealed several problems with the practice of informed consent.

Even under "best practice" conditions of careful and full disclosure of the study, parents who gave informed consent were confused about who was protected by the consent form, the purpose and risks of the trial and their right to withdraw the child at any time.

Psychological, social and demographic profiles of the parents who volunteered their children revealed they were less educated, had less social support, consumed more habit-forming drugs and exhibited greater anxiety and lower self-esteem than parents who declined to allow their children to participate in the trial.

"There is a strong message here that the consent is due to deference to medical staff," Professor Caton said.

"This research has provided the first window into problems with the concept of informed consent, but there is a lot of anecdotal information to support the results."

Professor Caton said many senior medical people he had spoken to were not surprised by the research findings.

"Most people engaged in clinical trials do not regard ethics committees and informed consent procedures as significant with respect to the patient's safety. It is a routine they go through but they don't really believe in it."

Professor Caton said the idea that informed consent provided safeguards was illusionary.

"At the upper or public level, ethics committees and informed consent procedures appear to provide protection, but it is only a mirage type of protection. The real safety at an operational or clinic level lies with the medical practitioner. It is nonsense to think that rule-based safety can replace the personal care and attention of the doctor."

Professor Caton said there was a need for further controlled studies of people involved in medical research.

"My guess is that the socioeconomic profiles of people who consent to clinical trials will replicate the original findings. If the concept of informed consent is to identify, separate and protect vulnerable groups of people, then it is failing."

— Mardi Chapman

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OPEN FORUM

A note on informed consent

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Readers may be interested to learn of a study of informed consent, conducted in Queensland, that sheds important light on this troubling current topic.

The study was conducted on a cohort (n=68) of Queensland parents who volunteered their children to trial a drug to treat asthma, and a second cohort (n=42) of parents who declined to volunteer their children for the trial. The object was to ascertain whether there is a common motivational and demographic profile of the parents in each cohort. Previous investigations had suggested this possibility, but apparently none hitherto had applied rigorous psychological testing.

The team, led by Sharon Harth at the Mater Misericordiae Hospital, found that parents who volunteered their children for medical research were significantly more socially disadvantaged, less well educated, more prone to use habit-forming substances, lower in self-esteem and lower in psychological resilience compared with those who did not. Non-volunteering parents scored high on self-esteem, educational level, and social status.

The study confirmed the surmise that there is an invisible "psychosocial filter" selecting children from vulnerable families for medical research.

The most commonly mentioned filter is awe of medical authority. The Mater team did not find this hypothesis well confirmed. They did detect a motivation hitherto undiscussed—parental guilt feelings toward children. It works this way. Family histories of disharmony, child neglect, and misused resources leave parents with a sense that they have been remiss in parental responsibility. They compensate by viewing the opportunity to participate in a drug trial as an opportunity to give afflicted children the best care available. This positive motivation against a negative background would appear to make them less anxious about risk than parents in the non-consenting cohort.

A disquieting finding was that consenting parents are confused about the purpose of the informed consent form. Even though it was explained that the form was to protect the child, only 37% of parents knew this when subsequently questioned. 60% believed that the form was to protect the medical staff. Only 45% of the consenting cohort knew that they could withdraw the child from the experiment at any time. The remainder did not know the rule. 21% thought that parents could withdraw the child if they had a good reason, while 32% believed that the child must stay the course.

These findings would seem to be consistent with the conjecture that awe of medical authority is an element of the selection filter. The view held by most parents that they in effect lost control once the child commenced the trial is particularly telling of deference to authority. It may also be noted that the perception that the consent form was to protect medical staff is what one would predict of persons accustomed to defer to medical authority: they do not perceive themselves to be in control and *eo ipso* they are right. In highlighting their finding of the positive motivation mentioned, the Mater team may have gone too far in down-playing the authority factor.

The significance of these outcomes is proportional to the ethical vigilance observed by medical teams at the study site. Mater paediatric staff observe the medical and ethical standards of best practice. The outcome thus derives from a setting in which ethical vigilance is optimal. It is not an illustration of what can happen when standards are lax or when medical teams rush to obtain results.

The study suggests that perhaps less than half of persons participating as subjects in Australian medical research actually meet informed consent criteria. As one knows, IECs devote much of their time to examining consent protocols. But they do not interview the subjects themselves; even if they did they could not detect the details of consent that careful investigation has brought to light. This raises the troublesome question of what efficacy IECs have in protecting research subjects.

I put this question to several long-serving, medically qualified members of IECs. My straw poll obtained the following results:

* The Mater team's identification of a psychosocial filter was not surprising. The SES [Socio-economic status] profile of consenting subjects in particular was said to be known from practical experience irrespective of controlled studies.
* The safety of subjects is primarily the responsibility of the medical team. The duty to care is theirs as physicians. The duty cannot be off-loaded or even shared with persons who are not attending physicians, let alone medically unqualified IEC members.
* Despite the Mater outcome, my informants defended the efficacy of IECs. They can and do detect procedural errors and flawed safeguard measures of informed consent

protocols. In addition, the inspectional step inculcates a sense of caution and vigilance in medical staff.

While this is not the place to commence a discussion of these matters, one may note that in the absence of controlled studies of staff conducting medical research, there is only anecdotal knowledge of their attitudes toward IECs. IECs themselves tend to promote the view that medical staff regard IECs as a significant safeguard and a benign influence in ethics education. This overlooks the opposite view of medical staff that IECs are a bureaucratic rubber stamp that have no tangible or legal responsibility for subject safety and whose main impact on research is delay. A controlled study might explore these and other attitudes of medical researchers.

One may note as well that controlled studies of the perceptions of IEC members about the functions of ethics committees are in their infancy. In particular, what will be their response to a study whose purport is that those who consent are not informed, while those who are informed do not consent? Can IECs grapple with this worst case outcome, obtained when all prescribed procedures are scrupulously observed?

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