An Unfortunate Experiment?

The Future of Ethical Review in New Zealand

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Abstract: This report describes the system of ethical review that was adopted in New Zealand based on the findings and recommendations from the Cartwright Inquiry in 1988. It discusses the changes made to this system under recent governmental initiatives enacted by the National Party, and some of the implications of those changes.

Keywords: research ethics; ethical review; research participants; consent

Introduction

In the 1980s, bioethics was still very much a new area of inquiry in New Zealand, and the majority of New Zealand citizens were unaware of it. Although foundational groups such as the Hastings Center and the Kennedy Institute for Ethics were well established by that time, the catalyst for the establishment of bioethics in New Zealand was the 1988 Cartwright Inquiry.[1] The Cartwright Inquiry was set up to investigate allegations of unethical research undertaken at National Women's Hospital in Auckland. The recommendations of the inquiry, along with televised coverage of the testimony, raised public awareness and served to galvanize New Zealand citizens regarding the need for ethical scrutiny of medical practice. This sociopolitical situation led to a number of changes that instantiated bioethics as a discipline and to the establishment of a robust research ethics review process as an important means for protecting patients and research participants.

In 2011, New Zealand's government entered into its second term of National Party (center right) leadership. This government embarked on a series of policy changes, including the selling of public assets, such as hydroelectric dams,[2] and, most recently, changes to the New Zealand Resource Management Act, making it easier for mining companies to prospect and mine areas of environmental significance.[3] The government's mandate for this agenda derives partly from global financial conditions that have influenced the New Zealand economy and also from the need to generate finances for the rebuilding of the city of Christchurch, the second largest city in the country, which was severely damaged in a series of earthquakes during 2011 and 2012. There are very few areas of public policy that are immune from the imperative both to reduce expenditure and to encourage the flow of funds from overseas. These two directives have also exerted their influence on the structure of research ethics committees and the ethical review process.

This article describes the system of ethical review that was adopted in New Zealand based on the findings and recommendations from the 1988 Cartwright Inquiry. It discusses the recent changes made to this system under National government initiatives, and some of the implications of those changes.

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"The Unfortunate Experiment"

The 1987–1988 Royal Commission of Inquiry at National Women's Hospital investigated allegations concerning the treatment given to women by Dr. Herbert Green, an associate professor at the hospital. These women presented with a premalignant cell condition in the neck of the womb, known as carcinoma in situ (CIS). Prevailing national and international literature showed that CIS was a precursor to invasive cancer, and conventional treatment at that time consisted of cone biopsy.[4] Associate Professor Herbert Green was of the opinion that CIS did not invariably lead to cancer of the cervix and that women were routinely being overtreated. Over the course of several years, Green managed his patients with CIS by monitoring their condition.

Some of the other most unethical research projects of the twentieth century occurred when therapeutic obligations were disregarded in order to monitor the natural progression of a disease. Two of the clearest examples of this are the Tuskegee and Willowbrook experiments.[5] "The Unfortunate Experiment" seems to take this form, although there are competing interpretations of Green's work and his motivations. It has been argued that Green was not experimenting with his patients but, instead, was adopting an unorthodox approach to the management of CIS. As Green believed that CIS did not invariably progress to cancer of the cervix, he did not think that he was failing to treat the condition, nor was he observing its natural progression; instead, he was treating it in a way that avoided unnecessary surgery and thereby was applying best practices and writing up the results.[6]

However, during the Cartwright Inquiry, it emerged that, in 1966, Green had applied to the medical committee at National Women's Hospital to conduct a study on CIS, and that this application had been approved. The study involved treating women under the age of 35 who had positive cervical smear tests and no evidence of invasive cancer with "lesser procedures."[7] However, patients who were included within his study had no idea that they were receiving experimental treatment and had not given their consent to be part of it. Despite being reviewed in 1975, the study continued until the 1980s. It was found that Green was an extremely forceful and influential figure within National Women's and had considerable influence on the medical committee that approved his study, despite it being recognized by medical colleagues as flawed from its inception.[8]

This study became known as the Unfortunate Experiment after it was exposed in the 1987 *Metro* magazine article by Phillida Bunkle and Sandra Coney,[9] and discussed in a letter by Professor David Skegg in the *New Zealand Medical Journal*.[10]

The Cartwright Report observed a number of failings at National Women's Hospital and made recommendations that altered the bioethical and medicolegal landscape of New Zealand. For example, the report stated that the University of Auckland should "(a) improve the teaching of ethical principles and communication skills at all levels of the medical degree."[11] New Zealand's medical schools in both Auckland and Otago responded to this recommendation. It also played a significant role in the creation of the Bioethics Centre at the University of Otago, and in the appointment of Professor Alastair Campbell as the center's first director.

The report also recommended changes to the research ethics approval process, stating that the director general should

> (v) (b) monitor progress and encourage improvements in ethical committees by heightening the awareness of the importance of strong ethical principles in research and new treatment or management....
>
> (d) ensure that lay representation on the ethical committee approximates one half of the membership.
>
> (e) encourage the development of better procedures for scientific and ethical assessment.[12]

In the years immediately following the Cartwright Report, New Zealand developed a comprehensive system for the ethical review of research that was consistent with these recommendations. Up until 2011, we were served by a system of seven accredited health and disability research ethics committees and seven accredited university institutional ethics committees.[13] However, the Unfortunate Experiment concluded nearly 30 years ago and the shock that the nation experienced has started to fade into history. A recent New Zealand House of Representations report argued that, although the system of ethical review is robust, it is too slow. They recommended that the system should become more efficient in order to attract pharmaceutical companies to New Zealand to conduct their clinical trials. Their proposal to the Houses of Parliament states that "the Health and Disability Ethics Committees should process expedited reviews within 30 calendar days, and other applications within 45 calendar days."[14]

This proposal seems reasonable: ethical review has the potential to delay the start of the research process, and, in cases in which the research will lead to benefits for patients, those benefits might also be delayed. So, although robust ethical review is vital for protecting the interests of research participants, it is also important that it is efficient, to minimize any delay to the research application process. However, the government chose to go beyond merely making the system more effective; they also seized the opportunity to reduce the costs and the efficacy of the review process.

In order to speed up the procedure of review, the government decided to make "expedited review" available for "low risk" clinical trials.[15] This means that a small subgroup of the research ethics committee will be able to approve many clinical trials. The government decided that the reduced workload resulting from expedited review would mean that the number of research ethics committees could be reduced from seven to four. On this recommendation, we now have four research ethics committees currently reviewing health-related research in New Zealand.[16]

But perhaps the most worrying change is that ethics committees have been reduced from having twelve members to now having eight, while at the same time retaining the Cartwright requirement that ethics committees are to be composed of an equal number of technical-expert and lay members.[17] This means that high-risk clinical trials will now be reviewed by one of four available ethics committees with only four members who have a medical or scientific background.

The argument given in favor of this is that the committees are there only to make judgments about appropriate ethical standards and not to form views about the design or scientific merit of proposed research. While this might seem like a way in which review could be made more efficient, it makes it impossible for a sound ethical judgment to be made about the research. Unless an ethically justified

view can be reached about both the likely benefits to research participants and the significance of the research more generally, it is impossible to make a judgment about whether the risks of a clinical trial are acceptable.

It remains to be seen whether the changes to New Zealand's ethics committees will speed up the process of review and encourage more overseas research to be conducted here. There is reason to think that they might. It is also possible that the way in which medical researchers, both in New Zealand and overseas, approach research has moved on since Dr. Green's study at National Women's Hospital. We hope that it has, because the system of ethical review in this country that worked to provide the necessary checks and balances has been significantly weakened.

Notes

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11. See note 1, Committee of Inquiry 1988, at 214.
12. See note 1, Committee of Inquiry 1988, at 214.
13. New Zealand House of Representatives. *Inquiry into Improving New Zealand's Environment to Support Innovation through Clinical Trials*. Wellington: New Zealand Parliament; 2011 June, at 28.
14. See note 13, New Zealand House of Representatives 2011, at 5.
15. *Government Response to the Report of the Health Committee on Its Inquiry into Improving New Zealand's Environment to Support Innovation through Clinical Trials*. Presented to the House of Representations in accordance with Standing Order 248 Wellington: New Zealand Parliament; 2011, at 5.
16. See note 15, *Government Response to the Report of the Health Committee* 2011, at 5.
17. See note 13, New Zealand House of Representatives 2011, at 8, 34, 61.