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Revisiting New Zealand's "Unfortunate Experiment": Is medical ethics ever a thing done?

SHARON BATT

Abstract

An experiment dating from the 1960s in New Zealand has eerie similarities to research begun in 1976 in India. In both cases, women with evidence of early cervical cancer or pre-cancer went untreated, despite known treatments that could have prevented their condition from worsening. This Comment on carcinoma cervix research grew out of my reading of a new book by Ronald W Jones about the New Zealand experiment. Jones, a recently retired obstetrician/gynaecologist, worked at the hospital where the controversial research took place and was a whistleblower in the case. His book provides a meticulous account of internal struggles within the hospital over what has been called "the unfortunate experiment." Readers might fairly ask whether a detailed examination of a decades-old research scandal in New Zealand can usefully inform ethics debate in India today, where conditions are so different. I argue that Jones's account does indeed provide valuable insights for understanding research wrongdoing in other contexts, including low-income countries. Jones challenges some widespread assumptions about why such cases occur and how to combat them, as do several other recent analyses of research scandals.

Introduction

Medicine has a sad legacy of research scandals, and discussions of how to eliminate them are central to medical ethics. Among the most infamous is the Tuskegee study, in which researchers at the US Public Health Service followed 400 African American

men with syphilis for 40 years and withheld treatment, in order to understand the progression of the disease (1). Similar in many respects is a study of women with cervical cancer in situ (CIS), carried out in New Zealand from 1966 to 1988, and the subject of a new book, *Doctors in denial: The forgotten women in the 'Unfortunate Experiment.'* (2). Herbert Green, a professor and senior physician at the National Women's Hospital (NWH) in Auckland did not believe CIS was a precursor to invasive cancer of the cervix and, to prove his point, continued to record the untreated lesions of dozens of women, even as their cancers progressed and some patients died. In *Doctors in denial*, Ronald Jones describes the New Zealand case as an insider with a strong point of view.

Two questions come to mind. First, does Jones's book on the New Zealand case add to the existing mountain of documentation, analysis and debate that this particular experiment has already generated? And if Jones does offer new insights, do they have any relevance to medical ethics in India, which has its own cervical cancer scandals? The answer to both questions, I argue, is an emphatic "yes."

Pitfalls and potential of cross-cultural comparisons

First, some valid concerns. In an editorial in this journal in 2012, Mala Ramanathan and Amar Jesani noted that ethics teaching and scholarship in India tend to foreground international research cases from high-income countries, to the exclusion of home-grown scandals (3). They pointed out that, to spur the development of a homegrown bioethics movement, India's own local cases need to be written about, debated and discussed as part of bioethics teaching. Excessive focus on international cases, they cautioned, might breed complacency, sending the implicit message that such breaches only happen elsewhere. Furthermore, these cases from high-income countries might obscure local realities central to ethics in India,

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such as high rates of illiteracy, which complicate informed consent, and the different standards that limited national resources impose on India's public system of healthcare.

At the same time, international examples may provide useful lessons for addressing ethics scandals in India. Eric Suba of Kaiser Permanente in California deems three American-funded clinical trials carried out in separate Indian centres so indefensible he labeled them "Tuskegee 2.0" (4). The trials compared cervical cancer screening to no screening among low-income women. Noting that President Clinton apologised in 1997 for the Tuskegee study, Suba calls on the funders of the trials in India - the US National Institutes of Health (NIH) and the Bill and Melinda Gates Foundation - to do likewise.

Yet another study in India has striking similarities to the experiment in New Zealand. Beginning in 1976, Indian researchers followed the natural history of dysplastic cervical lesions in 642 women in New Delhi (5). Ramanathan and Jesani note that when the New Zealand scandal became public, Judge Silvia Cartwright conducted an inquiry (6), which led to important structural changes, including a system of research ethics committees, a cervical screening programme, and a Code of Patients' Rights (3). In India, similar misconduct was exposed (notably, inadequate consent and failure to treat), yet no new structures were put in place; the problems were quickly forgotten and little changed. These authors concluded that the new structures and the debate in New Zealand thus created a lasting legacy that enhanced patients' rights and set new standards for medical practice. They urged health professionals and the public in India to follow the New Zealand example and take local transgressions seriously: write about them, learn from them and, above all, do not bury and forget them.

Lasting legacy, pyrrhic victory

In Ronald Jones's telling, however, the "lasting legacy" of the scandal in New Zealand is as much myth as reality - "a pyrrhic victory" (2:p 139). Jones is a retired obstetrician and gynaecologist who worked at the Auckland hospital where Herbert Green's research took place. He was a crucial actor in the New Zealand drama - a whistleblower before the term was commonplace. His central claim is that New Zealand *has* forgotten the lessons of the case that haunted his whole career. Jones has not forgotten: for years, he kept meticulous records from many sources, which he uses not only to reconstruct what happened, but to understand why.

Jones acknowledges the positive institutional changes that followed the Cartwright report: a national cervical screening programme was set up, a health and disabilities commissioner was established, ethics committees were improved; and health-related organisations and universities reflected upon and recommended strategies to prevent similar tragedies (2: p 14). Jones asserts that these structures have been widely welcomed and successful. The incidence of and mortality from cervical cancer is half what it was before the screening programme was introduced, for example, and now compares to "the best in the world" (2: p 14).

Yet, as his account makes clear, New Zealand's medical community remains divided over Green's research; indeed, opposing sides have become more entrenched. Jones also makes clear that the NWH already had institutional mechanisms in place in the 1960s to promote accountability on the part of physicians and researchers. Two committees reviewed and approved Green's proposal to conduct a large study of the natural history of CIS (2:p 54). The hospital had a medical superintendent (2:p 106) and the hospital board had a superintendent-in-chief (2:pp 76, 85, 118), to whom concerns could be and were reported, to no avail (2: p 144). The head of the obstetrics and gynaecology department, Dennis Bonham, had the authority to intervene but did not (2: p 163). Difficult issues were raised with several hospital committees (2:pp 54, 69, 85-86). Green presented his early results at conferences and published articles in journals, where distinguished experts frequently rebutted his claims and strongly condemned him for pursuing the project (2:pp 66, 69, 71). These mechanisms failed and Jones wants to know why: Why did colleagues continue to support one rogue doctor, even as evidence mounted that his research premise was wrong? Why did they do nothing when the health of patients was in jeopardy? (2:p 14).

Documenting "dark secrets"

In his search for answers, Jones shines a light on power relationships. In 1973, as a young obstetrician/gynaecologist from a working class background, he eagerly joined the staff of the NWH, which had developed an international reputation for excellence in obstetric and gynaecological research, teaching and care. He soon discovered the hospital's "dark secret" (2:p 13) - Green's unorthodox experiment. At that time, CIS had been established as a condition that progressed to cancer in 20-30% of cases (2:p 40), a progression that timely detection and treatment could prevent. Initially Jones remained uninvolved, focused on securing his position; over time, however, deeply disturbed by the hospital's tolerance of the research, he could not remain silent. He and two like-minded colleagues documented their concerns and tabled reports at hospital meetings. They appealed to the medical superintendent and three successive superintendents-in-chief. In 1984, they documented research irregularities and the suffering of some participants in a prestigious international journal (7). The three believed that the publication of their paper "would result in definitive action" (2: p 114) - and yet the project continued, even after Green's retirement, carried on by his followers.

Finally, in 1987, two feminists, journalist Sandra Coney and university lecturer Phillida Bunkle, discovered the 1984 paper and wrote an exposé published in *Metro*, a local weekly magazine (8). The result was public outrage that rocked the entire country. The New Zealand government appointed Judge (later Dame) Silvia Cartwright to carry out the public inquiry, which produced a scathing report and recommended reforms to protect patients (6).

Much of this narrative is on public record and might suggest the case is settled. Not so, says Jones. Powerful opposing factions jockeyed to discredit the report and these efforts continue. At a September 1988 meeting, a motion to support the report and to express sympathy for the women was passed unanimously, but was overturned a week later (2: pp 140-141). In 1990, the same *Metro* magazine that broke the story about the experiment published an article expressing "second thoughts." (9). In 2009, medical historian Linda Bryder published a book in which she argues that Green did not experiment on the women, he simply provided them with an acceptable form of less invasive treatment (10). And as recently as 2014, Cochrane Collaboration co-founder Sir Iain Chalmers chastised the investigative quality of the Cartwright Inquiry via a video link to a meeting at the NWH (2:pp 196-7); (see also 11,12). Shamefully, writes Jones, no apology has ever been offered to the women who suffered, or to the families of those who died.

The high price of resisting patriarchy in medicine

Jones draws on his detailed knowledge of the hospital politics: the many players and their allegiances, the meetings and the memos, the hallway conversations, and the discussions over tea or Scotch in private homes. Based on this insider evidence, he convincingly refutes the claim that Green simply provided an accepted, minimally invasive treatment that spared women the risk of side-effects. He analyses the divided perspectives within the hospital culture and the persistent bitterness over the Cartwright Report. Some years after the inquiry, to cite just one example, a younger colleague returning to New Zealand complained to Jones, "Bloody Cartwright has fucked up my whole career." (2:p 195)

The environment at the NWH when Jones arrived was patriarchal and hierarchical. Family connections were important and the surest way to gain entry to medical school was to be the son of a surgeon (2:p 171). A small group of senior physicians, including Green and Bonham, were gods, given to bullying and tantrums. Fiercely competitive and wedded to British elitism, the senior physicians clung to the privileges of clinical freedom and academic independence, which could translate into "the divine right of doctors to do whatever they felt was best for their patients." (2:p173) In this environment, poor women were especially vulnerable, as they depended on the public clinic at the hospital, and were directed to Green's care. Patients from private clinics who were referred to the hospital with CIS of the cervix were managed by specialists on a different team and their lesions were treated, in keeping with hospital protocol (2:p 59).

Jones identified with a younger cohort, whose egalitarian perspective included a willingness to challenge injustices. Women in New Zealand were entering the professions and children from working class backgrounds, like Jones, were increasingly being afforded the opportunity to attend medical school. When he arrived at NWH in 1973, however, Jones encountered a "powerful tribal hierarchy" (2:p 172).

These competing belief systems dictated collegial loyalties and friendships in ways that stacked the deck against those who wanted the experiment stopped. Bonham consistently supported Green. Mont Liggins and William Liley, internationally renowned researchers in obstetrics who had the status to challenge Green, also protected him. The three were close friends and partners in a forestry venture and they apparently avoided discussing the awkward topic of Green's research while together (2:p 184).

Jones, hired at the bottom of the hierarchy, quickly bonded with two colleagues: William McIndoe, an expert in colposcopy, who was also low on the totem pole, and Jock McLean, the head pathologist. Both spent their days examining abnormal cell specimens, including those of Green's patients. When the trio was unable to stop the research internally, they shared their alarm with colleagues at conferences abroad and, ultimately, in their critical article about the experiment. But junior faculty and technical staff were expected to display blind loyalty to those above them and to uphold the hospital's stellar public image. Colleagues froze them out and, as they watched women sicken and sometimes die, their political impotence took an emotional toll. Jones (whose wife was undergoing treatments for breast cancer which eventually killed her) describes himself as "a broken man, but I could not run away." (2: p 119)

Bonham and Green did not escape judgement. Following the Cartwright Inquiry, the New Zealand Medical Council charged Bonham with "disgraceful conduct" for not intervening (2: p 144); Green was deemed too sick to be charged, but the careers of both ended "in tatters" (2:p 192). The inquiry exposed additional scandals. To supplement his experiment on the women, Green took vaginal swabs from female newborns without parental permission and, consistent with his belief that CIS was not a precursor to cancer, he actively opposed a national cervical cancer screening programme that had been proposed as early as 1959 (2:pp 68-71). The programme, which finally began in 1991, was certainly a positive outcome of the Cartwright inquiry; but during the 32 years its implementation was stalled, an estimated 3,100 New Zealand women suffered avoidable cervical cancer. (2:p 149)

Scandal as an unreliable catalyst for change

How can this grim account be squared with the fact that the scandal and subsequent inquiry spawned both debate and tangible structural changes? Jones' decision to highlight the internal culture at NWH rather than the external signs of progress is consistent with two recent analyses. In the first, Carl Elliott suggests that we over-rate institutional structures as bulwarks against wrongdoing in medical research (13). Based on a compilation of research scandals in medicine, he concludes, "Dissenters who try to use internal institutional channels to expose the abuse of research subjects rarely succeed." One reason is that witnesses to corruption or safety violations typically remain silent. They fear blowing the whistle will be futile, and they fear retribution. "Unfortunately,

both of those fears appear well-founded," Elliott writes. In the cases he examined, justice was done only when the media exposed a scandal.

True to Elliott's analysis, Jones describes the article he published in *Obstetrics and Gynaecology* with Bill McIndoe and Jock McLean as a "smouldering fuse" that only "burst into flame" three years later, when Coney and Bunkle's article appeared in *Metro* (2: p 116). As long as awareness of the scandal remained in-house, most of the hospital staff and medical faculty at the university preferred to look the other way. Even the three whistle-blowers, although they hoped and expected their paper to bring the experiment to an end, were initially uneasy about Coney and Bunkle's initiative. It was one thing, Jones says, to expose the scandal to medical colleagues, but "in those days doctors on the lower rungs of the hierarchy," would never have dreamt of taking their case to the media (2: p114). By the end of the book, however, Jones is won over. "New Zealand women should be grateful that angry feminists challenged the academic hierarchy at NWH," he asserts (2: p 197).

A second analysis suggests that scandals in medical ethics are over-rated as agents of change. Sociologist Adam Hedgecoe used archival and interview material spanning several decades to study regulatory changes in research ethics review committees in the UK from the late 1960s to the late 1980s (14). Although numerous research scandals occurred in that jurisdiction in the study period, Hedgecoe found that policies governing prior ethics review of medical research evolved gradually, through a series of small changes initiated by physician groups and the Department of Health. Their goal was not to increase protection for patients; rather, both parties shaped institutional rules to serve their own interests. Medical researchers sought to maximise opportunities for obtaining research funds and government policy makers sought to attract research from the pharmaceutical industry to boost the national economy. When consumer organisations tried to strengthen written consent requirements, they met resistance (12: p 582); the tone of a 1996 report was so pro-researcher that a group representing consumers asked to have its name removed because the document failed to represent its views (12: p 587).

Preventing future research scandals: Go public

Like Jones, Elliott and Hedgecoe dig beneath the surface of medical scandals and the structures created in the name of research ethics. Their analyses prompt us to rethink how we study these cases, structures and debates. They use archival, interview and ethnographic material spanning years or decades to understand the local history, politics, resources, values and actors inside the "black box" of ethics-related policy decisions. Structures are critically assessed; power relationships are exposed. Hedgecoe rejects what he terms "assumed isomorphism" – the temptation to extrapolate from one jurisdiction to another. Rather, both analysts construct complex narratives of the local culture and its connections to the international community.

A recent detailed assessment of the "unfortunate experiment" (15) based on Ronald Jones's book illustrates the potential of these narratives for cross-jurisdictional comparisons. Carl Elliott argues that the New Zealand scandal provides a better model for how to respond to abusive research than the Tuskegee syphilis experiment. In the United States, "alarming reports of mistreated research subjects have continued to emerge ... at regular intervals for the past forty years," he writes; medical research in New Zealand, by contrast, has been "scandal-free for nearly thirty years" (15). Elliott points to differences in the way the two scandals were ultimately handled, as well as the national context in which each took place. The Cartwright inquiry was a publicly televised, exhaustive examination that heard patients' stories and uncovered additional ethical breaches that sent shockwaves through the country for six months. Greene and Bonham were held responsible and censured, while the researchers involved in the Tuskegee experiment faced no sanctions. Elliott also contrasts the "sensible" post-Cartwright structural reforms in New Zealand to those in the United States post-Tuskegee. New Zealand now has a legally enforceable code of rights for health consumers; further, the country established ethics committees that are open to the public and independent of the institutions where the research takes place. Ethics committees in the United States usually operate in private, within the research institution conducting the research. New Zealand's cultural environment also provided fertile ground for the reforms to take hold, says Elliott. The country is small, with only two medical schools, and socially progressive with a vibrant women's movement (not only was the "unfortunate experiment brought to public awareness by two feminists, Judge Cartwright herself openly declared her feminism). New Zealand's universities are publicly funded and less affected by the wave of corporatisation that has transformed universities in the US and elsewhere.

Such local details are paramount, but certain themes do recur across time and place: Everywhere, the poor are most likely to suffer, as seen in the Tuskegee, New Zealand and Indian experiments. Another parallel: Jones recounts that the University of Auckland wanted to apologise to the women damaged by Green's experiment but refrained, based on legal advice; *BMJ Global Health* recently withdrew a critique by Eric Suba and colleagues about the US-funded research on cervical cancer screening in India, citing defamation concerns (16).

The American writer Archibald MacLeish famously wrote that democracy "is never a thing done. Democracy is always something that a nation must be doing." (17) If I were to sum up the lesson of *Doctors in denial*, it is that medical ethics, too, is never "a thing done"; but rather, something that concerned parties everywhere must always be doing.

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Comparison of ethical issues in Indian and New Zealand prospective studies of cervical pre-cancer

CHARLOTTE PAUL

Abstract

The aim was to compare the ethics of historical Indian and New Zealand prospective studies of cervical pre-cancer in terms of: scientific justification, potential harms and benefits to subjects, informed consent procedures, monitoring and stopping, and exploitation.

The New Zealand study had poorer scientific justification, greater harm to subjects, absence of informed consent, and greater exploitation.

Reasons proposed for on-going criticism of the Indian study are: semantic confusion, lack of consistent detail about informed consent procedures, and failure of a professional obligation to provide on-going medical care. Such criticisms might have been set on a firmer basis, or rejected, if there had been a public judicial inquiry, as happened in New Zealand. Current disagreement about the ethics of randomised trials of cervical screening in India might be resolved through a public inquiry.

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Introduction

There are striking similarities, as well as important differences, between two Indian and New Zealand prospective studies of cervical pre-cancer that gained public attention for alleged unethical practices. The allegations centred on dangers to women subjects, whose pre-cancer was followed but not treated, and inadequacies of informed consent. For the Indian study, it has also been alleged that there were substantial delays after referral for treatment when the disease had progressed.

These are historical studies: New Zealand's "Unfortunate experiment" on women with carcinoma *in situ* (CIS) of the cervix started in the 1960s and came to public attention in the 1980s (1); the Indian "observational study" of cervical dysplasia started in the 1970s and came to public attention in the 1990s (2). Both were investigated by a judge: in New Zealand a committee of inquiry led by Judge Silvia Cartwright was established by the government in 1987; in India a seven member inquiry committee headed by a retired judge was set up in 1997(2).

Though both studies were investigated independently, more facts about the New Zealand study are known - because the inquiry was held in public and a detailed report published - whereas the Indian inquiry was held in private and no report is available, though the inquiry exonerated the researchers (personal communication). Moreover, a "case study", based on the Indian study, published by the World Health Organisation