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## **MISREPRESENTATION OF THE NATIONAL WOMEN'S HOSPITAL IN AUCKLAND, NEW ZEALAND**

The article “The Rationalization of Unethical Research” by Paul and Brookes refers to a study of rural sharecroppers with syphilis in Tuskegee, Alabama, and a study of women with cervical carcinoma in situ (CIS) in Auckland, New Zealand.<sup>1</sup> We show here that the article draws invalid parallels between these two situations and misrepresents what happened in Auckland, as did the 1988 judicial inquiry into the management of CIS at the National Women's Hospital in Auckland—the Cartwright Inquiry, for which Paul was an adviser.

The fundamental difference between the Tuskegee syphilis study and the management of CIS at Auckland's National Women's Hospital has been pointed out previously.<sup>2</sup> In Tuskegee, treatment known to be effective and safe (penicillin) was unethically withheld from patients with syphilis; in Auckland, no treatment known to be effective and safe was unethically withheld from women with CIS.

The introduction of Papanicolaou smears in the 1950s led to an explosion of diagnoses of CIS and to differences of opinion about how to manage the condition, contrary to Paul and Brookes' claim that there was no dispute about management of CIS by the 1960s. The range of management strategies reflected the fact that an estimated 90% to 95% of women presenting with CIS would not develop invasive cancer: invasive management thus carried a substantial risk of overtreatment with interventions (hysterectomy and cone biopsy) that could have serious adverse effects. Using hysterectomy as a treatment entails not only the immediate complications of a major surgical procedure, but also an end to a woman's hopes of having (further) children. Cone biopsy, although less radical, sometimes causes substantial morbidity from bleeding and infection in the short term, and increases the likelihood of a second trimester miscarriage in the longer term. Debate about appropriate management of CIS, which existed from the 1950s and was not subjected to any controlled trials, as noted by Professor Cochrane in the 1970s, continues today; there is still no obviously superior surgical technique for treating cervical intraepithelial neoplasia in terms of treatment failures or operative morbidity.<sup>3</sup> The situation could hardly be more different from penicillin treatment of syphilis.

Paul and Brookes' article misrepresents the management of CIS at Auckland's National Women's Hospital, where gynecologist Herbert Green was particularly concerned about the dangers of overtreatment of the condition in the 1960s. In 1966 he proposed to the Hospital Medical Committee that he and his colleagues should manage CIS conservatively in women referred to the hospital, using careful follow-up and avoiding unnecessary surgical intervention. The minutes of the meeting at which this new management protocol was agreed, record that, “If at any stage concern was felt for the safety of the patient, a cone biopsy would be performed.” Like gynecologist Per Kolstad, the author of a long-term study in Norway, Green stressed the importance of using the new diagnostic aid of colposcopy in managing cases of CIS.<sup>4</sup>

Paul and Brookes state incorrectly that Green attempted “to prove that CIS is not a pre-malignant disease.”<sup>1(p.e13)</sup> In support, they cite the minutes of the 1966 meeting reproduced in the Cartwright Report, neglecting to point to the extended discussion in the Cartwright Report as to whether the word “invariably” (i.e., that CIS was not *invariably* a premalignant disease) had inadvertently been omitted from the minutes of the meeting.<sup>4</sup> Green made his views clear in his own publications, for instance writing in 1966: “These then are still the two uncertain factors—the length of the pre-invasive phase and the proportion going on to invasion. Clinical evidence is tending to show, but cannot prove that the latter is small—probably much less than 10 per cent.” In other articles (1969 and 1970), he again addressed the current state of knowledge and the uncertainty as to whether “the invasive potential in in situ cancer is as high as has been claimed.” In addressing this uncertainty, he was following authorities such as George Knox, Professor of Social Medicine at the University of Birmingham, England, who stated in 1966 that population and pathological evidence could suggest not one but two diseases—“a benign one and some hitherto unidentified lesion”; they simply did not know.<sup>5</sup> The role of the human papillomavirus was not identified until the 1980s.

The treatment protocol agreed in 1966 was not a research project; there were to be no controls, and patients were to be treated and monitored case-by-case by one of the four gynecological teams at the hospital. Green audited the results of the treatment regimen by drawing on hospital data, and the first long-term analysis of cases diagnosed with CIS at the hospital was published by staff members McIndoe et al. in 1984,<sup>6</sup> two years after Green had retired. If women were not told this conservative treatment was other than “conventional” (for instance, in the 1960s, hysterectomy was still a common response in the United States), this was in keeping with the mores of the day, when informed consent was not the norm and it was assumed that “the therapeutic relationship would automatically predominate over the scientist-subject relationship.” Evidence provided at the time of the Cartwright Inquiry suggested that Green kept his patients more informed about their options than did many of his contemporaries in New Zealand and elsewhere, despite the claim made by Paul and Brookes, without any supporting evidence that Green “misled” his patients.” (1 p.e.2)

Paul and Brookes erroneously state that a 1984 scientific article from the hospital<sup>7</sup> published “the results of Green’s study.”<sup>1(p.e16)</sup> McIndoe et al. had assembled data from women presenting at the hospital between 1955 and 1976 with a diagnosis of CIS (and seen by any one, but generally several, of the hospital’s medical staff), and divided them retrospectively into two groups: one with women whose abnormal cytology had resolved and the other with women whose cytology remained abnormal two years after the initial diagnosis.<sup>6</sup> In a 1987 article that sparked the Cartwright Inquiry, the authors misinterpreted the 1984 article as presenting a prospective and randomized study carried out by Green of alternative treatment strategies rather than a retrospective study by McIndoe et al. This misrepresentation persisted in the Cartwright Report, and has allowed such a flawed comparison with Tuskegee to be made.

Paul and Brookes are not the first to attempt to liken the inappropriately designated “Unfortunate Experiment” to Tuskegee and the Nazis. A similar suggestion was published six years ago in the Health Research Council of New Zealand’s online *Ethics Notes* by another staff member from Paul and Brookes’ own institution.<sup>8</sup> Four of us responded in letters published on the HRC Web site (for these and other references, see the supplement to the online version of this article at <http://www.ajph.org>). Remarkably, Paul and Brookes make no reference to this earlier debate; indeed they imply there has been no debate when they state, “It would be wrong to exaggerate the importance of the new defenses.”<sup>1(p.e12)</sup> As references to

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published responses contributed by us and others make abundantly clear, this is a gross  
misrepresentation. Readers who wish to make their own judgments need not take our account  
on trust: we have cited the published references in support of our account, so that people can  
decide for themselves.

M.|A.|H. (“Tony”) Baird, MBChB

Norman Barlev, MBChB

Linda Bryder, DPhil

Amanda Burls, MSc

Robin W. Carrell, MBChB, ScD, PhD

Iain Chalmers, DSc

Garth J.|S. Cooper BSc (Hum Bio), MB ChB, Dip Obs, DPhil

Derek A. Dow, PhD

Kevin Hicks, PhD

Marc Keirse, MD

Colin Mantell, MBChB, PhD

Peter Nobbs, MBChB

Elizabeth Overton

Helen Overton MBChB

Paul Patten, MBChB

Josie Sandercock, BA MSC

Valerie Smith

Ronald Trubuhovich, BDS, MBChB

## **ABOUT THE AUTHORS**

M.|A.|H. (“Tony”) Baird is with Auckland Urogynaecology, Auckland, New Zealand. Norman Barlev, is specialist anesthetist, Denmark. Linda Bryder is Professor of History, the University of Auckland, New Zealand. Amanda Burls is Professor of Public Health, City University, London, UK. Robin W. Carrell is Emeritus Professor of Hematology, University of Cambridge, Cambridge, UK. Iain Chalmers is Co-founder of The Cochrane Collaboration and Coordinator of the James Lind Initiative, Oxford, UK. GJS Cooper is a Professor in Discovery and Experimental Medicine, Faculty of Medical and Health Sciences, and Director, Centre for Advanced Discovery and Experimental Therapeutics, University of Manchester, Manchester, UK. Derek A. Dow is Honorary Senior Lecturer, University of

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Article Type: LETTERS AND RESPONSES; Collection Codes: , , , , ,  
Auckland. Kevin Hicks is Senior Research Fellow, the Auckland Cancer Society Research  
Centre, University of Auckland. Marc Keirse is Professor and Head of Department of  
Obstetrics and Gynecology, Flinders University, Adelaide, Australia. Colin Mantell is  
Emeritus Professor of Obstetrics and Gynecology, University of Auckland. Peter Nobbs is a  
neonatal pediatrician, Auckland. Elizabeth Overton, Auckland. Helen Overton is a general  
practitioner, New Zealand and Denmark. Paul Patten is an obstetrician and gynecologist,  
Auckland. Josie Sandercock is a medical statistician, Birmingham, UK. Valerie Smith is an  
independent researcher, Dannevirke, New Zealand. Ronald Trubuhovich is a retired intensive  
care specialist, Auckland.

Correspondence should be sent to Tony Baird, Birthcare Building, 20 Titoki St  
Parnell, Auckland 1052, New Zealand (e-mail: [tonybaird@xtra.co.nz](mailto:tonybaird@xtra.co.nz)). Reprints can be  
ordered online at <http://www.ajph.org> by clicking the “Reprints” link.

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## CONTRIBUTORS

All authors contributed equally to this letter.

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