A response to criticisms of *The History of the 'Unfortunate Experiment' at National Women's Hospital*

Linda Bryder

The publication of my recent book *The History of the 'Unfortunate Experiment' at National Women's Hospital* has generated a lively debate concerning the conclusions of the 1988 Cartwright Report.1 As the most trenchant criticism of my book appeared in Charlotte Paul’s chapter in *The Cartwright Papers*, I will use this editorial to address her criticisms.

Professor Paul states that I ‘insinuate’ that the Inquiry was biased by her involvement.2 I make no such claim. My book is not concerned with her involvement, but rather with understanding what happened at National Women’s Hospital and how it was represented at the Inquiry and publicly. Her further claim that my book was the result of a ‘particular relationship’ I had formed with certain gynaecologists in the course of my research does not merit a response.3

Charlotte Paul and I offer opposing interpretations of Green’s understanding of CIS and of his management compared to others working in the field, and it is these differences I will address here. In engaging with these debates, I will take issue with Paul’s criticisms of my use of evidence, and look critically at her own use of evidence. I will conclude by considering the contributions to the debate in the recent article in the *Australian and New Zealand Journal of Obstetrics and Gynaecology* by Paul and colleagues.4

In *The Cartwright Papers* Paul states that Green ‘wrote repeatedly of his belief that CIS was a benign condition’.5 While she provides no reference following this statement, in the 2008 *Lancet Oncology* article, of which she was a co-author, the same claim is referenced to an article Green wrote in 1966. Yet what he actually wrote there was: ‘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’.6 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’.7,8 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’;9 they simply did not know. The role of the human papillomavirus was not identified until the 1980s.

Regarding Green’s 1966 proposal to the Hospital Medical Committee I do not accept Paul’s claim that I tried to misrepresent it as ‘conservative treatment by cone biopsy’.10 Indeed it was obvious that this was not the case, given that the proposal was to ‘diagnose and treat by lesser procedures than hitherto’; one of the ‘hitherto procedures’ had been cone biopsy. The important point was careful follow-up. As the
minutes of the meeting recorded, ‘If at any stage concern was felt for the safety of the patient a cone biopsy would be performed’.

As Green told the Medical Superintendent a few years later, ‘It was always a calculated risk that invasive cancer could be overlooked, although it was hoped that colposcopy, clinical examination, and repeated directed biopsies would minimise, if not actually avoid, this.’ He cited several authorities in support of this (see my book p25). Had Green believed that CIS was totally benign, as Paul suggests, he would not have insisted on such careful follow-up.

Paul incorrectly states that I ignored the considerable discussion at the Inquiry on the use of the word ‘invariably’ in the minutes of the meeting at which Green put forward his proposal (see my book p30). Furthermore, in her discussion of the 1966 proposal, Paul credits his colleagues with little intelligence. Green said at the Inquiry that, had he proposed that CIS was harmless when he took his protocol for conservative management to the Hospital Medical Committee in 1966, he was sure the committee would never have agreed to the proposal. Paul asks, ‘What does this mean? If he had told the committee that CIS was harmless, they wouldn’t have agreed to a trial of no treatment? Surely they would have agreed more willingly to no treatment for a benign condition.’

What Green knew, and he was correct, was that no gynaecologist regarded CIS as invariably benign and they would clearly have thought him crazy if he had suggested it, and would not have approved his proposal.

Paul states that I misinterpreted the differences between a study by Norwegian Professor Per Kolstad and Green’s ‘trial’. The difference was, she said, that Kolstad followed patients after treatment and Green followed patients without treatment. Yet Cartwright criticised Green for following patients after treatment. She declared in her Report, ‘One outstanding fact ought to have been clear to [Green] and to others—following (without treating) patients with positive smears, whether after cone biopsy, or after hysterectomy, was unsafe, as a proportion of those women would subsequently be shown to have invasive cancer.’

Like Green, in the 1970s Kolstad advocated a cautious approach to treatment of CIS. He hoped that the use of new technology, specifically colposcopy, would help reduce the need for cone biopsies as treatment. He advised caution as, ‘many of these [in situ lesions] occurred in young women of childbearing age, for whom hysterectomy and even cone biopsy could mean considerable trauma to the reproductive tract’.

Paul states that in the period 1965–74 Green, unlike Kolstad, was not using cone biopsies; elsewhere in the article she complains that in the same period he was doing too many cone biopsies; she can’t have it both ways. Nor can she retrospectively distinguish between cone biopsies for diagnostic purposes and for curative purposes, as is further discussed below in relation to the 2010 article.

Both Kolstad and Green were opposed to an aggressive approach to the management of cases of CIS. They were supported in this by a textbook written by a British Professor of Obstetrics and Gynaecology, Sir Norman Jeffcoate. Paul claims I distort his advice, since he was only advising caution during pregnancy. She is mistaken; as I explain on page 41 of my book, he advised, ‘When cervical smears repeatedly contain cells indicative of malignancy or severe dyskaryosis [dysplasia], the next step is to carry out cervical biopsy ... This operation is not free from immediate and late
hazards and fatalities are reported; so it is wise to be sure that it is really necessary before proceeding to it.’ (his emphasis). He then went on to discuss the particular concerns during pregnancy.\textsuperscript{18}

In Australia, Malcolm Coppleston became renowned for advocating conservative treatment for CIS, and was a major influence on Green. Like Green and Kolstad, Coppleston hoped that with the use of colposcopy-directed punch biopsy, the use of cone biopsies could be reduced. Yet again, Paul argues that I misinterpret his ‘conservative’ approach. She states that Coppleston’s ‘punch biopsies’ were to be followed by ‘definitive treatment’ which she defined as ‘excisional biopsy, cryosurgery, therapeutic conisation, hysterectomy, or irradiation’.\textsuperscript{19} This was not necessarily the case; in his 1977 contribution to \textit{Recent Advances in Obstetrics and Gynaecology}, Coppleston made the following statement:

Preliminary results from several sources indicate that many such lesions, which would have previously been treated by the more expensive and more hazardous sequence of diagnostic conisation followed by hysterectomy or by therapeutic conisation, have been thoroughly evaluated and safely treated by either cryosurgery, electrocautery or electrodathermy, or multiple punch biopsy...’ (my emphasis).\textsuperscript{20}

Indeed, in 1970 Coppleston lamented that ‘much present-day management of cervical lesions is imbalanced, illogical and too radical’ because the clinician abdicated his ‘traditional captaincy to the pathologist or exfoliative cytologist’.\textsuperscript{21}

Charlotte Paul notes that I refer to Sir Richard Doll in chapter 4 on patient consent, and opines that his comments did not apply to Green’s ‘trial’. The important thing to remember about Doll is that he supported Green in his research until Green retired in 1982, and wrote references for him to the Medical Research Council (see p.206, n121 of my book). He also praised Green highly during a symposium in Auckland in 1973 for not automatically adopting a radical approach to CIS.\textsuperscript{22} Regarding Professor Archie Cochrane and Paul’s surmise that he would have disapproved of Green, Paul should know otherwise if she attended the Cartwright Inquiry—Cochrane’s invitation to Green to collaborate in a research proposal was discussed there.\textsuperscript{23}

Paul states that Sir Graham Liggins acknowledged at the Inquiry that Green was ‘doing a prospective study that entailed withholding treatment’.\textsuperscript{24} She provides no reference for this, and Liggins did not give evidence at the Inquiry. What can be referenced, however, is Liggins’s published oration to the 1990 General Scientific Meeting of the Royal Australasian College of Surgeons in Wellington, in which he commented on the fact that the 1984 McIndoe article on which ‘the cervical cancer enquiry was based, was misinterpreted by the authors of the Metro article and by the judge’.\textsuperscript{25} This misinterpretation consisted of regarding it as a prospective study rather than a retrospective study.

Discussing the 1984 McIndoe paper Paul writes, ‘Bryder’s claim that there was no difference in treatment between Groups 1 and 2 also leaves her with no explanation for the fact that the rate at which cancer appeared in Group 2 was twenty-five times higher than in Group 1. Again, she has made an illogical and incoherent claim’.\textsuperscript{26} Yet it is Paul herself who is not being logical here. These women were placed in Group 2 by McIndoe and his co-authors retrospectively because they had persistent positive smears and so they would be more likely to develop cancer than those whose smears
had returned to normal. The groups were constructed according to outcomes. Treatment did not enter the study, as McIndoe himself told Sandra Coney in 1985 (see my book p33).

Despite Paul’s claims to the contrary, I do distinguish between follow-up of CIS and dysplasia; see for instance, page 45 of my book: ‘Some follow-up studies were designed to follow mild lesions only, though the categorisation of smears was far from a precise science’; I then refer the reader to the more detailed discussion in chapter five. Here, among others, I cite (p.75) an American authority, Professor Leopold Koss, who declared in 1978, ‘Truly it can be repeated that one man’s dysplasia is another man’s carcinoma in situ ... There is no publication on this subject where one could not reshuffle the photographs and substitute pictures labelled as dysplasia for those labelled carcinoma in situ and vice versa.’ The reclassification of slides which Paul refers to was discussed at the Inquiry, and pathologist Jock McLean said this was ‘quite open’ and the result of disagreements; it was not dishonest manipulation (see my book, pp78-9).

In other places in her critique, Paul distorts or misrepresents what I have written. When I responded to Ron Paterson’s claim that no empirical evidence of the ‘revisionists’ had been published, I was referring to the evidence of the uncertainties and debates surrounding the meaning, interpretation and treatment of CIS, discussed in my 2008 article in the Journal of Epidemiology and Community Health. When she addresses my coverage of the 1990 Medical Council decision Paul writes that I provide no evidence that there were any debates in the 1960s. My 2008 article and the earlier chapters of my book provide this in abundance. Also in her discussion of the Medical Council findings, she claims that I overestimated McIndoe’s grasp of colposcopy, citing Coppleson that McIndoe ‘only briefly attended his colposcopic clinic in Sydney and was keenly aware of his own lack of expertise’. She fails to note that in 1968 McIndoe visited America and Europe to study the current use of colposcopy, funded by the Auckland Medical Research Fund and the Cancer Society of New Zealand, and in 1972 he attended the First World Congress of Colposcopy in Argentina.

Paul criticises me for ignoring the medical survey reported in Appendix 3 of the Cartwright Report. She refers specifically to Table 2. It is difficult, however, to see how meaningful the increases during the period 1966-1974 really are, as presented here, when the numbers are so small—one case in 1965, reaching a maximum of four women in 1968 and 1974, declining to three in 1975. Moreover, as an epidemiologist surely Paul should be wary of attributing any trends to one single factor. Such changes could be related to the prevalence of the human papillomavirus, or the use of the contraceptive pill, or, as Professor Skegg later suggested in 1985, the ‘sexual revolution’. The new retrospective analysis of data reported in the 2010 article is addressed below.

I also take issue with Paul’s use of evidence in her critique of my book. She writes, ‘Cartwright commented on the “remarkable degree of unanimity” among the overseas authorities in their conclusions from reviewing patients’ files.’ This looks less impressive when it is viewed together with the immediately preceding sentence in which Cartwright explained, ‘Some of the overseas authorities who gave evidence were invited to carry out case studies on selected patient files...’ (my emphasis).
Paul states that Kolstad concluded at the Inquiry that some women suffered ‘severe’ and ‘terrifying mismanagement’. In his evidence the ‘terrifying mismanagement’ comment applied to one woman, not ‘some’ women. That woman was Clare Matheson and under questioning at the Inquiry Kolstad admitted that his source of information on this was primarily the Metro article.

The 2010 Australian and New Zealand Journal of Obstetrics and Gynaecology article continues along the same theme as previous publications by Paul, i.e. that Green ‘withheld treatment of curative intent’ and thereby engaged in unethical behaviour. I have several reservations with the arguments of this article. The first reservation relates to the definition of ‘treatment of curative intent’. The authors define this as hysterectomy, amputation of the cervix and cone biopsy, and exclude wedge and punch biopsy. Yet Professor Koss stated in 1963 that even a small punch biopsy could be curative. Coppleson also saw punch biopsy as a possible treatment, as noted above. Similarly in Scandinavia by the mid-1970s a debate was launched as to whether cone biopsy was ‘over-treatment’ for CIS.

If ‘treatment of curative intent’ meant doing at least a cone biopsy, then my second reservation relates to the period defined for the ‘clinical experiment’ in the 2010 article. The 1984 McIndoe paper stated that no-one at National Women’s Hospital practised less than cone biopsy after 1970 (‘the few clinicians who initially performed punch or wedge biopsy alone had abandoned the practice by 1970’), so the period in which doctors at National Women’s were ‘experimenting’ by not giving cone biopsies should presumably have been 1965 to 1970. On the other hand, one of the authors of the 1984 and the 2010 articles, Dr Ron Jones, stated in a recent letter to the New Zealand Medical Journal, that if only McIndoe had succeeded in publishing his views in 1974 he might have been able to stop the ‘experiment’, suggesting that he did not see 1974 as the cut-off point for the ‘experiment’. In other words, choosing the period 1965 to 1974 as the period of the ‘trial’ is an artificial contrivance on the part of the 2010 authors.

Thirdly, there is no evidence in the article that the patient records reviewed were Green’s patients. The authors write of an ‘excess of inappropriate follow-up interventions for women diagnosed in 1965-74’—these follow-up interventions presumably continued well beyond 1974 (the article states that follow-up continued until death or 31 December 2000). These follow-up interventions were provided by a wide range of doctors at the hospital, including Jones himself (Green retired at the beginning of 1982). Jones told the 1987–8 Inquiry that from the time he arrived in the hospital, the mid-1970s, treatments at the hospital were in accord with international standards; now he is saying otherwise.

Fourthly, it is not true to say that women in the early 1960s were more likely to be unscreened than in the period 1965–74. The early 1960s saw a number of screening programmes initiated and reported in the New Zealand Medical Journal, in Thames and elsewhere, which were short-lived, and from 1960 all women attending clinics at National Women’s Hospital were given smear tests.

Fifthly, a retrospective study cannot prove unethical behaviour, which implies intent not to do best for one’s patients. Management choices in medicine might not always be the right ones in retrospect, and Green was the first to acknowledge this.
Finally, where is the authors’ evidence that ‘follow-up biopsies were often intended to exclude invasive cancer rather than to diagnose and treat CIN3’? Again they are attributing ‘intent’ with no evidence to support this.

The management of CIS following the introduction of Pap smears in the 1950s caused considerable debate, and these debates were not merely academic. As one commentator explained as late as 1991, the ‘medical dilemma’ in relation to CIS was ‘to know when to treat the abnormality and when to leave it alone because no harm would result from doing so, whereas intervention could lead to a variety of unintended negative consequences’. These were serious issues which Green amongst others was attempting to grapple with.

The recent article does not, as has been alleged, settle the debates. The debates about what happened at National Women's Hospital raise wider issues about medical practice which are overlooked by those who try to present the past as one-dimensional (i.e. portraying Green as a 'villain', and McIndoe as a 'hero'). The wider issues, still relevant for medical practice today, are concerned with how medicine deals with uncertainties, how doctors are more likely to be criticised for undertreatment than overtreatment, even if the latter does more harm than good, and how medicine and society interact, particularly where there is any hint of the possibility of the dreaded disease, cancer.

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**Author information:** Linda Bryder, Professor, History Department, University of Auckland

**Correspondence:** Linda Bryder, History Department, University of Auckland, PO Box 92019, Auckland, New Zealand. Email: l.bryder@auckland.ac.nz

**References:**

3. Ibid. p118.


17. Paul 2009. p123.


33. Paul 2009. p132


45. Bryder 2009, p17-18

