



## **Reassessing Cartwright—understanding the factual record**

I hope that my delayed entry into the public controversy concerning the Cartwright Inquiry may help clarify some of the many points raised in the 30 July 2010 issue of the *New Zealand Medical Journal*.

### **The nature and role of the ‘1984 paper’**

A number of assumptions and assertions concerning this paper and its role demand elucidation.

**A retrospective study**—Professor Linda Bryder stated in her book<sup>1</sup> and at a seminar at the University of London on 16 June 2010 that Sandra Coney has ‘admitted’ that the authors of the 1987 original Metro article<sup>2(pp.47–64)</sup>, Sandra Coney and I, had not understood the retrospective nature of the 1984 analysis.<sup>1 (p.35)</sup>

This is a misrepresentation. Coney explained in her book<sup>3</sup> that, on first reading the 1984 paper in 1985, it was not clear who was responsible for the clinical management of the patients whose cases were reported there. However, her book went on to describe how, having undertaken extensive research, including interviewing all the authors of that paper, and having seen the internal hospital memoranda concerned, we were quite clear, well before writing the Metro article in 1987, that it was a retrospective analysis. Coney was describing our research process not making an ‘admission’ of error.<sup>3(p.17)</sup>

**The validity of the Cartwright Findings is independent of the 1984 paper**—It has been asserted by both Professor Bryder<sup>1(p.35)</sup> and Helen Overton<sup>4</sup> that the Cartwright Inquiry made the same alleged error. Close reading of the Cartwright Report shows that this is incorrect.

The 1984 paper was not central to the Inquiry process or its findings. The Inquiry had access to thousands of original clinical case notes of women treated at National Women’s Hospital during the relevant period. These case histories provided the critical evidential base of the Inquiry and showed a most significant gap between what various Parties said, especially Dr Green, and what had actually been performed on patients.

### **The important role of the patient case notes**

Parties to the Inquiry had full access to this case evidence on condition of preserving the anonymity of individual patients. These cases were the subject of intensive cross examination of expert witnesses. Case material also provided much of the content presented in the three submissions by Phillida Bunkle, Sandra Coney and Dr Forbes Williams<sup>5–7</sup> as well of many other Parties.

I believe it was because this case evidence was so compelling that none of the Parties appealed the Inquiry findings.

Unfortunately, researchers who were not involved in the judicial process do not have access to this crucial evidence. This places severe limitations on attempts to reassess the evidential base of the Inquiry.

Professor Bryder seeks to overcome these limitations, by:

- Reference to the 2 case histories published in the appendix to the Cartwright Report,<sup>10(pp.268–286)</sup>
- Analysis of the crucial cross examination of international expert witnesses about these cases, and
- Use of evidence from patients either in letters or presented to the Inquiry.<sup>1(pp.4,48-52,53-54,57-59,61-65,132,134-135)</sup>

In the absence of access to the case notes this procedure is, however, weak. The Inquiry identified 131 cases similar to the two contained in the Appendices and it is only by considering the detailed facts of those notes that the crucial issue of treatment of curative intent can be illuminated. Moreover, it is difficult to decipher the import of the cross examination without access to the clinical records the witnesses referred to.

Finally many of the letters from women were solicited by counsel for Dr Green, Professor Bonham and the University of Auckland. They were often from women who did not yet know what had happened to them; most were not subject to cross examination and, hence, rate as inferior to evidence based on case histories or expert testimony that was subject to cross-examination by Parties of all persuasions.

Professor Bryder also quotes from the cross examination of two patients who gave evidence publicly. For example, she quotes from one woman who was very satisfied with her treatment and appreciative of Dr Green's care.<sup>1(p.49)</sup> This case, however, demonstrates the difficulties of evaluating such evidence without access to the patient's case notes.

What the judge, counsel and Parties were aware of, but the patient and Professor Bryder were not, is that the patient had been repeatedly observed as a research subject without treatment for many years while CIS spread throughout her vagina. Rather than support the view that Dr Green provided excellent care, this patient's statements demonstrated how uninformed she was and how seriously her trust in National Women's Hospital was misplaced.

### **The significance of the Cartwright Inquiry as a judicial inquiry.**

It is important to clarify that the Cartwright inquiry was a *judicial* inquiry with status, process and rules of evidence equivalent to those of the High Court. It examined the second-hand evidence of the 1984 paper but only accepted its findings in so far as they were corroborated by its own evidence base as interrogated by international experts.

The appropriate appeal of findings of such an inquiry is via an application to the High Court for a Judicial Review by participating Parties. Presumably, had counsel for aggrieved Parties judged that there had been weaknesses in the evidence or the process of its evaluation, they would have recommended an appeal. None did so.

An attempted application for Judicial Review by a member of the public friendly with Dr Green was struck out, in part on the grounds that the applicant had no standing with the Inquiry, was not familiar with the issues, and because it was considered that it was wrong for an unconnected person to launch an appeal when the Parties themselves had not chosen to do so.<sup>8</sup>

**Evidence in a judicial process**—It is important to understand that the Inquiry independently examined this body of original evidence. The team of medical advisors, which consisted in Professor Eric McKay, a gynaecologist from Australia, Dr, later Professor Dame Linda Holloway, a pathologist, and Dr, later Professor, Charlotte Paul an epidemiologist.

The team of medical advisors were officers of the inquiry not witnesses. They did not give evidence. They advised the judge.

It also follows from the judicial status of the Inquiry that when its findings are contested in the media the judge cannot defend herself. (Imagine the consequences if every court decision was publicly contested by the judge.) It has, therefore, been appropriate that members of the medical advisory team, Professors Holloway and Paul, who are familiar with the evidence, have played a role explaining the findings of the Inquiry.

### **Definitions of ‘conventional treatment’**

Professor Sir Iain Chalmers criticises Professor Paul for not providing the Inquiry with a definition of ‘conventional treatment’.<sup>9</sup> It is not the role of the medical advisory team to give evidence; they are not witnesses and are not cross examined. A judge relies on the advice of experts who can be cross-examined. These expert witnesses are responsible for reviewing the published evidence (of much of which they were the authors) in giving their opinions. The judge noted that the experts’ advice was ‘derived from an examination of medical literature, a review of research projects and personal experience in practice’.<sup>10(p.106)</sup> Counsel representing Parties of all interests participated in cross examining these experts.

The judge concluded that: ‘the appropriate treatment of CIS, if invasive cancer is to be avoided, is to remove the lesion. The patient must then be monitored so that further treatment can be offered if there is persisting disease or a recurrence...’.<sup>10(p.106)</sup>

The judge also found that: ‘All overseas authorities were agreed that since the mid-1950’s the aim in treating a patient with a diagnosed cancer precursor, including CIS, has been to eradicate the disease. The method of treatment has always depended on the available skills and equipment, but the aim remains unchanged....’.<sup>10(p.107)</sup>

The definition of ‘treatment’ is eradication of the lesion rather than a protocol of specific interventions. None of the experts thought, however, that diagnostic wedge or punch biopsies were ‘treatment’ even though such biopsies very occasionally have the effect of eradicating lesions. ‘Treatment’, thus, implies curative intent not just a particular procedure.<sup>10(p.104)</sup>

A series of propositions flows logically from this definition:

- Whatever eradication procedure was used, whether the more usual cone biopsies or the less common hysterectomy or other forms of excision, follow-up was necessary to ensure complete eradication, with more extensive removal if abnormal cells continued to be detected.
- Those patients who continued to have positive smears, sometimes for years, without attempts to remove the abnormality can be considered to have been inadequately treated.
- Procedures that were not directed at removing abnormal tissue were not 'treatments of curative intent'.
- 'Treatments of curative intent' can be distinguished from those procedures which are not, according to whether their purpose was to remove abnormal tissue or not.
- Counting the number of surgical procedures each patient eventually had does not show that no women with CIS was untreated<sup>4:1</sup>. In some cases, intention changed. Long periods of interventions with no curative intent, were followed by drastic procedures to eradicate malignancy.<sup>1(p.149)</sup>

Case notes, the original research proposal<sup>10(4-70)</sup> and his many publications showed that Dr Green, was following some women who had had only diagnostic biopsies. For instance, in 1970, he described following '75 patients with untreated or incompletely treated CIS'.<sup>11</sup>

Further, these were not the only form of non- or inadequate treatment; patients with cervical micro-invasion, vaginal and or vulval CIS, and other abnormalities of the genital tract were also involved.<sup>10(232-233)</sup> Professor Joe Jordan, an expert witness, for example, noted that there was 'another group where a definitive diagnosis of microinvasive carcinoma was made and ignored'.<sup>12(p.28)</sup> The judge subsequently found evidence of 'cases where microinvasive carcinoma has not been treated with even the least radical procedure'.<sup>10(p.113)</sup>

Finally the definition of treatment identifies that for many women their *CIS* was not treated. It is true that they may *eventually* have had extensive surgical procedures, after diagnoses of microinvasive or invasive cancer had developed. But even then there were frequently delays of years.

Thus, it is not the case, as Professor Bryder claims, that there is no evidence of non-treatment or that it is impossible to distinguish groups which differ by treatment.

### **The support of Professor A Cochrane**

Professor Chalmers is concerned that there is inadequate recognition of Professor Cochrane's support for randomised trials to settle the issues involved.<sup>9</sup>

The Inquiry found evidence that such trials were considered unethical even at the time. Evidence to the Inquiry showed that Dr Green cited Professor Cochrane's support in his internal memorandum of 1973 justifying his research.<sup>10(p.82)</sup> In his own evidence to the Inquiry, Dr Green also testified, in two places, that Professor Cochrane supported the ethics of his research.<sup>10(pp.77,79)</sup> He neglected to say, however,

that when he and Professor Cochrane had applied to the Medical Research Council in the UK for support for a randomisation of Green's practice, it was rejected as unethical. Under cross examination Dr Green eventually conceded that he was aware of this.<sup>10(p.82)</sup>

The judge concluded that 'This is one occasion when I cannot accept that there was an oversight or memory loss on Dr Green's part'.<sup>10(p.82)</sup> The judge also concluded that the issue should have been followed up by the hospital since the MRC's refusal would have prompted them to reconsider the ethical legitimacy of Dr Green's activities because 'the validity of the 1966 trial would have appeared far more questionable'.<sup>10(p.82)</sup>

### **The construction of Professor Bryder's evidence**

Professor Chalmers concludes his article by citing, with approval, the conclusion of Professor Bryder's third chapter. This passage reads:

'What then was the conventional treatment' that the patients at National Women's were apparently denied by Herb Green? According to Cartwright it was not hysterectomy which had already been rejected throughout the world as a routine response to CIS in favour of cone biopsy or local excision by the 1960's. Yet many gynaecologists still believed that hysterectomy was the appropriate response to the problem, including star witness to the Inquiry Ralph Richart. A significant minority of gynaecologists was questioning the appropriateness of hysterectomy and cone biopsy, both of which were far from benign procedures. Kolstad might have queried Green's clinical decisions, but he was the first to admit that there were no clear cut answers. Jordan might also have been critical of Green's approach, but he did acknowledge the 'dilemmas' in deciding appropriate treatment for asymptomatic women when the treatment options themselves carried a 'high morbidity'. Jeffcoate recommended cone biopsy only when smears repeatedly continued indicative of malignancy'.<sup>9(p.111)</sup>

It is quite understandable that without access to the case history evidence Professor Chalmers could accept this summary at face value especially as he is not familiar with the archival record. However, this passage encapsulates a number of problems with Professor Bryder's study. Professor Jordan, for example, is quite clear. He said of some of the women whose clinical notes he reviewed 'the patients, in fact, were not treated. I think that's the point, not even inadequately. They weren't treated'.<sup>12</sup>

One of the most serious concerns is that Professor Bryder sometimes misconstrues critical passages. For example, she uses the quotation concerning Jordan's 'dilemma' five times to suggest that other clinicians sympathized with Dr Green's position.<sup>1 (pp. 40,50,51,55,149)</sup> In fact, Jordan made two references to clinical dilemmas during his cross examination concerning the terrible fate of women whose CIS had been merely observed while it spread throughout the vagina and in some cases other areas of the genital track.<sup>13 (pp. 2-5)</sup> These women had the highest mortality. By the time of the Inquiry, 7 of the women who developed vaginal invasion had died of the disease.<sup>10 (p. 233)</sup> At least 15 of the 19 women identified as having CIS of the vagina, had a previous history of cervical abnormalities. 13 of these 19 developed invasion<sup>10 (pp. 232-233)</sup> and it was the difficulty in treating these women that posed the dilemma to which Jordan referred.<sup>13 (pp. 2-5)</sup>

The 'dilemma' Jordan referred to in the passage quoted by Professor Bryder, was a discussion about the decision to be made about patient 60/64 in 1981. The decision was difficult because treatment at this late stage entailed the excision of the vagina

and possibly other genital organs with a very high risk of damage to bladder and colon.<sup>13 (p.4)</sup>

The sentence in Jordan's statement which occurs immediately before that quoted by Professor Bryder,<sup>1(p. 40)</sup> but which she omits, could not be more explicit. He said, '*I think that some definitive treatment to the vaginal vault lesion should have been instituted in the early 1960's, and at the latest in October 1965, when the vaginal vault biopsy confirmed the presence of severe dysplasia.*'<sup>13(p.4)</sup> The full text of Jordan's evidence to the Inquiry, thus, makes clear his view, that the 'dilemma' was created by the more than twenty years of prevarication about diagnosis and delays in treatment. Jordan was extensively cross examined concerning these cases and he is quite clear that the predicament was created by non treatment and delay.<sup>12</sup> This is forthright professional criticism not sympathy, as Professor Bryder would have us believe.

## Conclusion

In conclusion, I would like to emphasise that in contributing to this discussion I do not want to leave the impression that I consider any reconsideration of the Cartwright Report to be undesirable. On the contrary, we should always be prepared to objectively reassess its conclusions and recommendations in the light of new knowledge. An objective reassessment would be of far more value to New Zealand women than the current dispute.

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