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## **Cervical screening legislation is unethical and has the potential to be counter-productive**

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### **Abstract**

Part 4A of the Health Act 1956—‘National Cervical Screening Programme’ (NCSP)—provides programme evaluators with unprecedented powers of access to personal health information, overriding both a woman’s right to health information privacy and a doctor’s duty of confidentiality. Such overriding of important ethical concepts is not justified, at least in the primary care setting where much of the information that may be accessed is irrelevant to a programme evaluation and that which is not irrelevant is not essential.

In addition to being unethical, Part 4A is unnecessarily offensive to practitioners: it imposes increased compliance costs onto practitioners who take cervical smears, it threatens them with hefty fines for non-compliance, and also introduces liability into previously protected quality assurance activities.

By offending both women and practitioners, and by undermining the trust that necessarily exists between them, Part 4A risks the support of those on whom the NCSP relies for its ongoing success—women and practitioners.

### **Background**

Part 4A of the Health Act 1956—‘National Cervical Screening Programme’ (NCSP)—was developed in response to recommendations from the Gisborne Cervical Screening Inquiry.<sup>1</sup> This Inquiry found that the NCSP had failed in Gisborne, and that it had been allowed to run unchecked for nearly a decade since its introduction, in part because the programme “lacked the essential components of an effective cervical screening programme when it was first established” and that it “failed to exercise or to exercise properly legal powers that were available [to enable it to be effective]”.<sup>2</sup>

### **Part 4A authorises a breach of health information privacy and confidentiality**

Part 4A of the Health Act was introduced to rectify the perceived problems with the NCSP and to “facilitate the operation and evaluation of [the] NCSP” (s.112A).

To achieve this Part 4A provides that “a screening programme evaluator has full access to all health information” “held by any health practitioner” that relates to any “relevant woman” (s.112X). A “relevant woman” is defined as any woman, dead or alive, “who is enrolled in the NCSP” or “who is not enrolled in the NCSP but who has developed any cervical cancer”.

Women may still ‘opt off’ the NCSP (s.112G) however they may not ‘opt out’ of these access provisions: should a woman develop cervical cancer (when an evaluator is most likely to want to access her information) then an evaluator may access her information regardless. Practitioners must provide the information to the evaluators “free of charge” (s.112ZB) or face a \$10,000 fine (s.112ZP).

Programme evaluators have the power to access the entire primary care record pertaining to relevant women—even though much of this information is likely to be irrelevant to an evaluation and some of it may be of a particularly sensitive nature with significant privacy concerns. It is not possible for evaluators to selectively access only relevant information in primary care records (because of the chronological nature of the information) and in any case, evaluators will not know that the information is irrelevant until after they have read it.

This constitutes a breach of women’s right to health information privacy, and while this breach may not be a breach of the worst sort (evaluators are not tabloid journalists after all), it remains nevertheless a breach.

### **The ethical notions of health information privacy and doctor-patient confidentiality**

The right to health information privacy is about the right to control the use of one’s personal health information and stems from a commitment to autonomy.<sup>3</sup> The Cartwright Inquiry<sup>4</sup> provides an illustration of the harm that may result when autonomy is ignored and, although the circumstances in this situation are somewhat less extreme (women don’t stand to die if evaluators access their information without consent), it is the same basic principle of autonomy that is at stake.

The ethical concept of confidentiality is related to, but not identical to, that of health information privacy. Confidentiality pertains to a relationship between two people and is present when one person voluntarily discloses private information, in confidence and trust, to another who pledges not to divulge that information to a third party without permission.<sup>5</sup> Underpinning the concept of confidentiality in healthcare is the need to protect the special relationship, based on trust, which exists between a patient and a doctor. ‘Trust’ is about keeping promises; when promises are broken, trust is diminished and a relationship is damaged.<sup>6</sup>

Concern for autonomy is not, of course, everything. Nevertheless, if programme evaluations can take place without the violation of autonomy then (unless there are good reasons otherwise) that is the path that should be taken. In the case of an NCSP audit, the ‘good reasons’ that have been put forward as possible justifications for setting aside a woman’s right to health information privacy include validity and cost: if the consent provision is waived then the information of all relevant women can be included in an audit (not just that of consenting women) and at a reduced cost.

## **Sufficient women will consent, if asked, and the cost of asking is not prohibitive**

The 2002 NCSP audit, conducted under the pre-existing legislation, revealed that it is not necessary to waive women's right to consent in order to successfully evaluate the NCSP:

“376 (85%) of the eligible women consented to at least one form of data collection and 349 (78%) consented to all forms of data collection. Consent rates for Māori women were the same as those for non-Māori... These results indicate that, with appropriate resources and processes, it is possible to obtain high consent rates from both Maori and non-Maori women for interview and access to medical records.”<sup>7</sup>

The 2002 audit, which studied the information of fewer than 400 women, cost in the region of 3½ million dollars.<sup>8</sup> It strains good sense to suppose that, with a budget in the millions, the cost of obtaining consent from the 150–200 women who are diagnosed with cervical cancer in New Zealand each year<sup>9</sup> prior to accessing their personal health information would be considered prohibitive.

And in any case, any saving to the evaluation budget does not equate to an overall saving to the health budget. Part 4A, in an attempt to mitigate the privacy threat that this legislation introduces, provides practitioners with new obligations to provide women with information about “the risks and benefits of participation in the NCSP, who has access to information on the NCSP register, and the uses to which that information may be put” (s.112L).

Part 4A also, in what has been described as a “neat little transfer of risk”,<sup>10</sup> provides that practitioners may “oversee that access” by evaluators (s.112X(6))—as if overseeing a breach of privacy somehow lessens the breach. These new duties come at a cost to practitioners making any ‘cost savings’ afforded by waiving the consent provision in reality more of a ‘cost transfer’ from the evaluation budget to the primary care budget.

But even if genuine savings were to be achieved by waiving the consent provision, we would not automatically be obliged to take advantage of such savings: there is an important ethical principle at stake here and just because there is a price to pay does not mean we should not pay that price.

## **Primary care records are not essential to an evaluation of the NCSP**

If cost were to be the determining factor, then cheaper and less thorough but still useful programme evaluations could be conducted without the inclusion of primary care information.

In the 2002 programme audit, the auditors claimed that:

“The most important reason for obtaining primary care records was to ensure that the smear histories of Audit women were as complete as possible.”<sup>11</sup>

Smear histories, however, are also available in laboratory records and on the 'reliable' NCSP register (“almost all smears are on the NCSP-R, making it [the register] a reliable source of screening histories and monitoring information”<sup>12</sup>). If cost were to be the determining factor then, it would not be unreasonable for evaluators to rely on the ‘reliable’ information available from sources other than primary care records. And

should they do so without consent, they would inflict a far less serious breach of health information privacy.

## **Primary care records are required to monitor Primary Care Practitioners**

The Health Select Committee (which considered the Amendment Bill and recommended waiving the consent provision) claimed, in contrast to the above claims by the evaluators, that:

“The main purpose for accessing primary health care records is to evaluate whether women who develop cancer or early signs of cancer were properly referred and treated by their general practitioners.”<sup>13</sup>

The intention of providing evaluators with unfettered access to primary care records, then, was to monitor the performance of general practitioners.

If evaluators consider that general practitioners are not performing their job adequately then, according to section 112Y, evaluators may pass a woman’s information on to the Medical Council “for the purpose of referring a concern about the competence of a health practitioner”, having first “obtained the consent of the Director-General”.

Evaluators may also pass a woman’s personal health information on to the Health and Disability Commissioner, without the woman’s consent, “for the purpose of assisting an investigation into concerns about the competence of a health practitioner”.

Section 112Y not only provides an additional threat to the privacy of women’s personal health information, it also means that, in future, programme evaluations will pose a medicolegal threat to the practitioners whose work forms part of an evaluation.

## **This medicolegal threat is unhelpful and unnecessarily hostile to practitioners**

Evaluators are not competent to assess the competence of practitioners; they are not themselves practitioners, they are not trained in the competence assessment of practitioners nor are they given any guidance in the legislation as to the standards against which they should be judging practitioners.

The impact of any single primary care practitioner on the failure (or success) of the NCSP is likely to be small, and so allowing evaluators to refer individual practitioners is unlikely to have much impact on the success of the NCSP. There is little evidence to show that allowing evaluators to report practitioners leads to any improvement in the NCSP or in the healthcare of women. Although it might be alleged that primary care practitioners claim the obligation of confidentiality merely to hide their incompetence, this does not in fact appear to be the case. The 2002 NCSP audit found that, generally, primary care practitioners were treating and referring women properly.<sup>12</sup>

Unfounded accusations of incompetence against practitioners are not without their harm<sup>14</sup> and the creation of an environment where such accusations are a possibility has the potential to make practitioners less well disposed towards the NCSP and less inclined to encourage their patients to participate in such national screening programmes.

A less hostile approach to practitioners who participate in audits was taken in the Health Practitioners Competence Assurance Act (HPCAA) 2003. In contrast to Part 4A of the Health Act, the HPCAA aimed to “encourage effective quality assurance activities...by protecting the confidentiality of information...and giving immunity from civil liability to persons who engage in such activities in good faith” (HPCAA s.52).

In any case, it is, and should remain, the prerogative of women to use their personal health information to refer their practitioner to the Medical Council or Health and Disability Commissioner.

### **This legislation is unethical and has the potential to be counter-productive**

It was never necessary to offend women by overriding their right to control access to their personal health information: as the 2002 audit proved sufficient women will consent to access when they are asked.

It was never necessary to offend practitioners by authorising a breach of their ethical duty of confidentiality; nor was it necessary to threaten practitioners with hefty fines for non-compliance nor to impose increased compliance costs for the pleasure of enrolling their patients in the NCSP. Nor was it necessary to permit untrained evaluators to judge and to report practitioners: the failure of the NCSP was never due to incompetent primary care practitioners.

The 2002 NCSP audit identified inadequate screening as the single most important factor resulting the screening programme’s failure to prevent cervical cancer.<sup>15</sup> The reasons behind women failing to take advantage of screening opportunities will no doubt be multi-factorial, however, a lack of trust in the medical profession and poor (or non-existent) relationships with practitioners are likely to play a part. Part 4A undermines the trust that a woman necessarily places in her practitioners, meanwhile implying that practitioners are not to be trusted and that it is necessary for evaluators to check up on them.

The common good of a safe and effective screening programme can only be achieved with the goodwill and cooperation of both women and practitioners, and then only if trusting relationships exist between women and practitioners.

By offending both women and doctors, and by damaging the relationship between them, Part 4A risks the very thing that it aimed to preserve: the “continuation of the NCSP”. Irrespective of these consequences, however, the legislative changes are unethical and could, and should, be repealed without compromising the safety and efficacy of the National Cervical Screening Programme.

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