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Do you know your legal obligations with regard to the National Cervical Screening Programme?

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ABSTRACT

Under Part 4A of the Health Act, 'National Cervical Screening Programme' (NCSP), practitioners have a statutory duty to provide women with detailed information about the NCSP and also to make available to evaluators of the NCSP the personal health information of their patients 'free of charge'. Non-compliance with an evaluator's request for information is punishable by a 'fine not exceeding \$10,000', while the fine for failing to provide women with information about the NCSP is a fine of '\$500'.

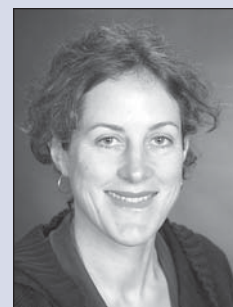
This duty to provide information has significant compliance cost implications for practitioners working in the primary care sector (where most screening smears are taken) and provides little in the way of benefit to women.

Part 4A of the Health Act thus adds to the burdens of the primary care practitioner (by increasing the cost of providing cervical screening, by overriding doctor-patient confidentiality, by threatening practitioners with hefty fines, and by turning evaluations of the NCSP into a medico-legal risk for practitioners) and further erodes the reputation of primary care as an attractive career option for doctors, at a time when the primary care sector is already struggling to attract and retain practitioners.

Keywords

Cervical screening, Health Act Part 4A, practitioners' duties

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Introduction

The purpose of this article is to outline for practitioners their obligations under Part 4A of the Health Act. Part 4A was passed in 2004 and came into effect in 2005 with the stated intention of 'providing for the continuation of the NCSP' and of 'facilitating the operation and evaluation of the NCSP by enabling access to information and specimens by screening programme evaluators'.

Under Part 4A section 112E the NCSP remains an 'opt off' programme (a woman is automatically enrolled in the NCSP when she has a smear taken unless she takes action otherwise) and, under s.112X, evaluators of the NCSP are given unfettered access to all personal health information relating to any 'relevant woman'. A 'relevant woman' is defined as any woman, dead or alive, who is registered with the NCSP or who has developed cervical cancer irrespective of whether she is registered with the programme (s.112X(1)).

The duty to provide information to women having their first smear in New Zealand

Section 112L, 'Duties of persons taking specimens for screening tests', was introduced as a possible foil to the privacy implications of s.112X (which allows programme evaluators unfettered access to primary care records) and provides practitioners with new statutory duties to provide women with information about the NCSP.

- (1) Every person who takes a specimen from a woman for the purpose of a screening test, and who believes that it is that woman's first screening test in New Zealand, must –
 - (a) explain the procedure and provide information about the importance of having regular screening tests, the objectives of the NCSP, 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; and

- (b) *advise the woman that she will be enrolled in the NCSP, but that she may prevent or cancel that enrolment by advising the NCSP manager under section 112G.*

This duty to provide women having their first smear in New Zealand with information is an onerous one. Smear takers 'must':

- 'explain the procedure'

Such an explanation would involve a discussion about the female genital anatomy, about speculums and brooms, brushes or spatulas, about scraping the cervix for cells and about bleeding or spotting, about slides and pathologists, about anxiety, discomfort and relaxation, and about cervical cancer, its prevention and treatment. There should also be a discussion about the smear result and a plan made as to how the woman will get her result.

- 'provide information about the importance of having regular screening tests'

This would include information about the fallibility of the smear procedure and the possibility of cervical abnormalities developing in the future and hence the recommendation for a repeat smear in one year and three-yearly thereafter.

- 'provide information about the objectives of the NCSP'

These 'objectives' are defined in section 112D as being to:

- promote high quality cervical screening...with a view to reducing the incidence and mortality rate of cervical cancer; and*
- inform women and the community of the risks, benefits, and expected population health gains from participation in the NCSP; and*
- promote the regular recall of women who are enrolled in the NCSP for screening tests; and*
- facilitate continuous quality improvement by allowing and performing regular evaluations of the NCSP; and*
- ensure that information that is collected for the purposes of the NCSP is –*
- available, in a reliable, accurate, and timely manner, to persons*

authorised under this Part, or any other enactment, to have access to it; and

- safely stored, including on the NCSP register; and*
- provide information to women about the quality and effectiveness of the NCSP including, if it is appropriate, information based on the results of evaluations.*

Providing information about all of these objectives would not only be largely futile but would also be time consuming. The extent of information about these objectives that must be provided is not specified in the legislation, however it would seem prudent for practitioners to have at least a cursory discussion about these objectives if one is to attempt to comply with the legislative requirements.

- 'Provide information about the risks and benefits of participation in the NCSP'

This would include information about the recall and back-up services offered by the NCSP as well as information about the potential anxiety and harm caused by false positive results and unnecessary investigations and the potential harm from false negative results leading to a delay in the diagnosis and treatment of cervical abnormalities.

Another 'risk of participation' is the threat to health information privacy that an evaluation of the NCSP poses. Section 112X gives programme evaluators 'full access to' 'all health information' (including the entire primary care record) of any 'relevant woman'. And section 112Y permits evaluators to pass on this personal health information to the Medical Council (MCNZ) 'for the purpose of referring a concern about the competence of a health practitioner' and to the Accident Compensation Corporation (ACC) and the Health and Disability Commissioner (HDC) 'for the purpose of assisting an investigation into concerns about the competence of a health practitioner'. It should be pointed out, however, that women who do not participate in the NCSP also face this risk to

health information privacy, should they be unlucky enough to develop cervical cancer.

- Provide information about 'who has access to information on the NCSP register and the uses to which that information may be put'

Section 112J governs the information on the NCSP register and states that:

- No person may disclose information from the NCSP register...if that information identifies a woman unless that information is disclosed –*
 - With the consent of the woman... or*
 - To a screening programme evaluator...or*
 - To a review committee...or*
 - To a health practitioner...for the purpose of assisting that health practitioner to provide health services to that woman; or*
 - For the purpose of enabling results from a screening test or a diagnostic test to be followed up; or*
 - For the purpose of enabling notices related to the NCSP to be sent to women who are enrolled in the NCSP, including reminder notices to women who are due for another screening test; or*
 - ...to persons researching cancer; or*
 - ...for the purpose of enabling compilation and publication of statistics that do not enable the identification of the women...*
- ...a screening programme evaluator may disclose information in accordance with section 112Y(2)(a) to (d).*

A smear taker must therefore inform a woman having her first smear that her identifiable information on the NCSP register may be accessed by NCSP staff, by evaluators of the NCSP, by review committees, by researchers and also that it may, in accordance with s.112Y, be passed on to the HDC, ACC and MCNZ without either her knowledge or her consent.

- 'Advise the woman that she will be enrolled in the NCSP, but that she may prevent or cancel that

enrolment by advising the NCSP manager under section 112G'

Section 112G states that:

- (1) *A woman who is enrolled in the NCSP may, at any time, cancel that enrolment by advising the NCSP manager in the manner and form specified by the NCSP manager.*
- (2) *A woman who is not enrolled in the NCSP, and who does not wish to be enrolled, may, at any time, notify the NCSP that she does not wish to be enrolled.*
- (3) *A notification under subsection (2) must –*
 - a. *Be in the manner and form specified by the NCSP manager; and*
 - b. *Include information that will enable the NCSP manager, in the future, to identify the woman as a woman who must not be enrolled in the NCSP (which information may be kept on the NCSP register and used by the NCSP manager for that purpose).*

The manager of the NCSP has not, to my knowledge, specified the 'manner and form' that she wishes such notifications to take, however, in my experience a simple letter is sufficient.

This onerous duty to provide information is at odds with the recommended patient-centred approach. If, in a smear-taking consultation, practitioners 'must' provide all this information then less time will be available for practitioners to concentrate on the specific needs of the patient. Alternatively, if extra time is allowed for all smear-taking consultations, then the cost of providing cervical screening would increase. And, as no additional funding was provided for taking screening smears, presumably it was expected that this cost would be borne by practitioners or passed on to women. This seems a shame when one considers that the single best way of reducing the incidence of cervical cancer would be by improving the uptake of regular screening opportunities through improved ease of access to screening. This legislation might have the exact opposite effect. In addition, the provision of some of

this information may be an exercise in futility. How much information is a woman in this position (i.e. having her first smear taken) able to take on board? It is possible that information about the 'objectives of the NCSP and the uses to which information on the NCSP register may be put' is better given at some other time. And, in fact, the legislation requires that this same information is given to women by the manager of the NCSP at the time a woman is enrolled in the programme (s.112F(1)). It seems somewhat superfluous to require that practitioners 'must' also provide this information at what may be an inopportune moment.

The duty to provide information to women having a subsequent smear

The second part of s.112L is somewhat less prescriptive and more reasonable than the first part. S.112L(2) outlines the statutory duty to provide information to women having subsequent smears:

'Every person who takes a specimen from a woman for the purpose of a screening test, and who believes that it is not that woman's first screening test in New Zealand, must provide that woman with information about the procedure and about the NCSP to the extent that is reasonable in the circumstances.'

The information that would be considered 'reasonable in the circumstances' is not defined in the legislation. Nor is it stated who determines what might be considered 'reasonable' in the circumstances. Is it reasonable to provide more or less information about the NCSP during a repeat smear? Is it reasonable to provide less information about the NCSP because a woman having a repeat smear is likely to already know something about the NCSP? Or is it reasonable to provide more information about the NCSP as the smear-taker will need to spend less time explaining the procedure to a woman who has experienced it before?

Right 6 of the Code of Health and Disability Services Consumers' Rights, the 'Right to be Fully In-

formed', states that 'every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive'. Practitioners know, therefore, that the information they must provide is the information that a 'reasonable consumer, in that consumer's circumstances, would expect to receive' (or at least the information that the, reasonable or unreasonable, Health and Disability Commissioner would expect the reasonable consumer to expect). This does not, however, necessarily help interpret what is 'reasonable in the circumstances' according to the Health Act.

Should a dispute arise, and should a practitioner be found to have failed to comply with this duty to provide information to women, then the practitioner is subject to section 136 of the Health Act ('General penalty for offences') and is 'liable to a fine not exceeding [\$500] and, if the offence is a continuing one, to a further fine not exceeding [\$50] for every day on which the offence has continued.' This would be in addition to, and separate from, any breach of the Code of Health and Disability Consumers' Rights.

The duty to make medical records available to evaluators 'free of charge'

According to Part 4A s.112ZB, 'Duty of health practitioners', practitioners must provide evaluators of the NCSP with the medical records of their patients 'free of charge'.

- (1) *Every health practitioner must make available, free of charge, to a screening programme evaluator, for the purpose of enabling that screening programme evaluator to perform the screening programme evaluator's functions, any health information and specimens that relate to a relevant woman.*
- (2) *The Director-General may specify, by notice in writing to the health practitioner, the manner and form in which health information or specimens that are required to be made available under subsection (1) must be made available, and*

that information or those specimens must be made available in that manner and form.

Providing evaluators with information takes time and costs money and, prior to the introduction of Part 4A, practitioners were compensated for this service. Now, however, practitioners are expected to provide information 'free of charge'.

Should a practitioner refuse to make available the requested personal health information (for example out of a duty of confidentiality to a woman with cervical cancer who has chosen not to be part of the NCSP) then that practitioner is subject to a 'fine not exceeding \$10,000' (s.112ZP). This seems rather a hefty fine when one compares it to the fine for other breaches of the Health Act (such as the failure to provide women with the specified information): \$500.

In summary, Part 4A of the Health Act has a significant impact on practitioners involved in cervical screening – largely those in the primary care sector. Part 4A places a heavy burden on practitioners to provide detailed information about the NCSP to women, it overrides doctor–patient confidentiality and demands that practitioners provide the personal health information of their patients to evaluators 'free of charge', it also threatens practitioners with a hefty fine for non-compliance. In addition, Part 4A turns evaluations of the NCSP into a medico-legal threat for practitioners whose work forms part of an evaluation by permitting evaluators of the programme to pass on personal health information to the MCNZ and the HDC in order to report a concern about a practitioner's competence.

In this way Part 4A adds to the burdens of primary care practitioners, without providing any real benefit to women, at a time when the primary care sector is already struggling to attract and retain practitioners.

Competing interests

None declared.

Investigating irritable bowel syndrome

'Why do clinicians continue to order tests for suspected IBS despite data that show that these tests generally have a low diagnostic yield? In light of the medical-legal interface in the US, one possibility is that some clinicians believe that diagnostic testing is a form of inoculation against litigation. Clearly this is an inappropriate reason to pursue diagnostic testing, especially as data indicate that the quality of the physician-patient relationship is a critical predictor of outcomes and probably a more important predictor of litigation than testing proclivity. A second possibility is the belief that even negative diagnostic tests are useful because they can allay patient concerns about serious illness and provide reassurance. We have shown, however, that a negative colonoscopy, in particular, is not associated with reassurance or improved quality of life in young IBS patients. In fact, we found a nonsignificant trend towards less reassurance in patients who received a negative colonoscopy versus no colonoscopy at all. A third possibility is that IBS patients with multiple unexplained somatic complaints and physical illnesses potentially related to their underlying psychosocial distress are sometimes misclassified as having several underlying organic conditions, and subsequently undergo diagnostic tests to chase these symptoms. We found a linear and highly significant relationship between levels of such somatization and the amount of diagnostic testing in IBS, which suggests that clinicians should be aware of somatization in patients with IBS, and aggressively treat or refer such patients in lieu of performing potentially unnecessary tests. The most common reason for diagnostic testing in IBS, however, might be that the Rome criteria have a 98%, rather than a 100%, positive predictive value, therefore, no matter how strong the evidence is that diagnostic testing has a low yield, a real possibility of underlying organic disease remains.'

Spiegel BMR. Do physicians follow evidence-based guidelines in the diagnostic work-up of IBS? *Nat Clin Pract Gastroenterol Hepatol.* 2007; 4(6):296-297. ©2007 Nature Publishing Group. http://www.medscape.com/viewarticle/558644_print accessed 28 June 2007.

Surgery and irritable bowel syndrome

'Surgery has no role in treating irritable bowel syndrome (IBS), the prototypic functional bowel disorder. Nevertheless, since Ryle reported a high appendectomy rate in such patients nearly 80 years ago, descriptive case series, population-based studies and comparisons of patients with IBS with subjects without IBS and patients with inflammatory bowel disease have shown that patients with IBS are predisposed to surgery. In two large groups of patients with IBS, cholecystectomy and hysterectomy, which are mainly elective procedures, were increased threefold and twofold, respectively, and the primarily emergency operation, appendectomy, was also increased twofold. Other abdominopelvic operations, especially colon resection, are also increased, as is back surgery. Much of this increased surgery must be unnecessary, and high surgical rates have been reported from the UK, Western Europe, Scandinavia, North America, Latin America and South Africa.'

Longstreth GF. Avoiding unnecessary surgery in irritable bowel syndrome. *Gut* 2007; 56:608-610; doi:10.1136/gut.2006.115006.