

Health (National Cervical Screening Programme) Amendment Bill

Submission from the Auckland Women's Health Council

The Auckland Women's Health Council is a voluntary organisation of individual women and women's groups who have an interest in and commitment to women's health issues. The organisation was formed in 1988 to provide a voice on women's health issues in the Auckland region.

The Council has a special interest in patient rights, informed consent and decision-making in health care, health consumer advocacy, the Code of Health and Disability Services Consumers' Rights, the National Cervical Screening Programme, and ethics – issues that were highlighted during the 1987-88 inquiry into the treatment of cervical cancer at National Women's Hospital and in the recommendations contained in the report known as the Cartwright Report.

The Council has actively supported the establishment and ongoing development of the National Cervical Screening Programme.

The Auckland Women's Health Council has made submissions in the past on matters to do with the National Cervical Screening Programme and the National Cervical Screening Programme Register. In light of the founding of this organisation, in the immediate aftermath of and in no small way influenced by the Cartwright Inquiry and report, all matters to do with cervical cancer and cervical screening are central to the concerns and work of Council.

The Auckland Women's Health Council (AWHC) Executive Committee has discussed the Health (National Cervical Screening Programme) Amendment Bill (henceforth referred to as the Amendment Bill) at several monthly Committee meetings, and at a dedicated sub-committee meeting in the lead up to making this submission, and has discussed this widely among members of the Council via phone and email.

General Comments

While the AWHC understands the need to update the legislation regulating the National Cervical Screening Programme Register (NCSP-R), to ensure it is fit for purpose and that those regulations keep pace with at times rapidly changing technology, we have considerable concerns about the sweeping powers allowed for in the Amendment Bill. Of particular concern is the issue of women maintaining confidence in the security and privacy of their personal health information both now and well into the future. The AWHC would not be happy with enactment of this legislation without stringent access regulations and a regular audit process to be applied to the accessing of the NCSP-R by whom, at what frequency and for what purpose.

Consultation

The AWHC would like to express its considerable disappointment that the Council was not involved in any consultation whatsoever in the development of the Amendment Bill, and only found out about the Amendment Bill and the submission process via contacts outside the National Screening Unit and the Ministry of Health. This is despite the Council's long history as an organisation with an expressly stated interest in both the National Cervical Screening Programme and the Register. The AWHC has made a number of submissions on the cervical screening programme and the NCSP-R in the past (1999, 2001, 2006, 2011, 2015), and in a 2006 submission on the NCSP Register wrote:

Given our history the Auckland Women's Health Council is very concerned at the lack of consumer involvement in the consultation process on the NCSP register. There are a number of women's health groups who are definitely stakeholders in the NCSP and who expect to be sent all discussion and consultation documents regarding the NCSP. It is outrageous that the Auckland Women's Health Council is not included in the list of stakeholder groups on page 6 of the discussion paper. The lack of acknowledgement or awareness of the part that women's groups played in lobbying for and supporting the establishment of the NCSP and the Register in the late 1980s and 1990s is an unfortunate oversight. It is also unacceptable that feedback only be obtained from National Screening Unit advisory or consumer groups within the NSU.

The AWHC is therefore seeking an undertaking from the NSU that the Council as well as other women's groups are in future included in any list or database of stakeholders and are sent all discussion papers and consultation documents.

It is obvious that concerns about stakeholder and consumer consultation that were quite clearly communicated by AWHC in 2006 have been ignored, and it leaves us as consumers and representatives of consumers, with little confidence that the consultation process has been entered into in good faith.

Direct (Look-Up) Access to the NCSP-R

In theory the AWHC supports amendments that would enable direct (look-up) access to the register for health practitioners, such as GPs, smear-takers, colposcopists, etc., that would improve the speed and convenience of access, reduce waiting times for information, and make information available outside traditional business hours. Such improvement of access to the register may improve access to screening for vulnerable groups of women who may not necessarily have regular interaction with, or access to health practitioners, and for whom cervical screening may require an opportunistic approach.

However, the AWHC has considerable concerns over the breadth of access described in the amendment bill, with almost any person potentially being given access by a single NCSP manager:

Clause 112J(2) (f):

a person authorised by the NCSP manager, for the purpose of providing information to any person authorised to receive it under subsection (3) or (4).

Then in subsection 3:

(3) Register information may be disclosed by a person referred to in subsection (2)(f), to—

(a) a person authorised to access the NCSP register under subsection (2), for the authorised purpose; or

(b) a person engaged by the Ministry of Health or a district health board, and **any other person or class of persons authorised for that purpose** [our emphasis] by the NCSP manager, for the purpose of enabling results from a screening test or a diagnostic test to be followed up; or

(c) a person engaged by the Ministry of Health or a district health board, and **any other person or class of persons authorised for that purpose** [our emphasis] by the NCSP manager, 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.

The AWHC opposes such future-proofing regulatory creep that is so broad and all-encompassing that in the future it might be possible to justify the authorisation of almost anyone to have access to the NCSP-R under these regulations. The responsibility for giving authorisation to **any other person or class of persons** rests with a single person, the NCSP-R manager. The AWHC sees that the only way in which women's data can be sufficiently protected and the NCSP-R not compromised resulting in a loss of confidence in it, is by the introduction of extremely robust processes managing access that provide for total accountability and transparency.

The only way in which such sweeping regulations and “future-proofing” can be applied and still enable women to have confidence that their personal health information is secure, confidential and protected from abuse is to have extraordinarily closely tracked, monitored and audited access to the NCSP-R. This must include:

- a thorough and vetted application process by all persons requesting access to the NCSP-R;
- the issuing of unique login/identifiers and passwords for each and every individual who requests access;
- levels of authorised access dependent on the status of the authorised person. For example, health practitioners, such as GPs, smear-takers, colposcopists, would have access to all information held on an individual in the NCSP-R, while administrative and support staff could have access to name and contact details, date of last smear, but no medical information (e.g. smear results) or information that requires medical knowledge to interpret;
- regular annual auditing of access to the NCSP-R to monitor and search for potential misuse and abuse. Authorised persons would be only able to access the information for women to whom they directly provide health services, except under extenuating circumstances (e.g. transient patients with no fixed health practitioner, irregular or limited prior contact with health practitioners, erratic or no screening history). Excessive access by people to data on multiple women to whom they do not provide health services would need to be audited and adequate justification for such access to be provided.

While the Explanatory note to the Amendment Bill states that “access to the register will remain an auditable activity” the bill does not specify in what manner and how often such an audit will take place, or what it will include.

Similarly, it is insufficient to say that there are existing offence provisions that apply to the disclosure of information from the NCSP-R. This is of faint comfort to a woman whose personal data has been misused or abused, and the provisions only apply after the fact and if the perpetrator is caught. There are recent examples of health professionals wilfully and knowingly accessing health information on patients for whom they were not providing health services for prurient and voyeuristic purposes (e.g. Patients unaware of staff prying in their files, *NZ Herald*; https://www.nzherald.co.nz/business/news/article.cfm?c_id=3&objectid=11568355)

Penalties for an offence should be a final deterrent, not the only approach to ensuring compliance, and the effectiveness of penalties is directly proportional to the chance of being caught. If there is little or no chance of being caught misusing or abusing the NCSP-R because monitoring and auditing of access is inadequate, then no level of severity of penalty is going to function as any sort of practical deterrent.

Vulnerable Women

It is clear that abuses of access to personal health information do occur and it would be naïve to think that the people who are caught misusing and/or abusing their access rights or the information itself represent the sum total of occurrences of this behaviour. The AWHC is particularly concerned that vulnerable women are offered utmost protection. For example, women in or having escaped from violent relationships must have complete confidence that their personal information, in particular their contact details, are safe and secure from misuse and abuse. Direct (look-up) access offers the potential for the health and well-being of vulnerable women and their families to be endangered if strict controls on access to personal information are not maintained.

Access of Women to Their Own Health Information

The AWHC would be very disappointed if any amendments to the NCSP-R and legislation governing it, or processes introduced as a result of such amendments, resulted in a reduction, or loss of access by women to their own information. If anything, access by individual women to their own health information regarding the NCSP should be made easier.

Women currently have the ability to phone register staff for their own cervical health history. This function should be maintained through a centralised service and clearly communicated as part of the informed consent process. Similarly, the process for opting off the register should be clearly communicated where women do not want their details recorded on the register.

Research

Registers such as the NCSP-R, the breast cancer registries and a future bowel cancer registry, among other databases of health information have the potential to provide an amazing volume of quality data on the health of New Zealanders, to understand links between diseases and conditions, lifestyle choices, treatments, medications and outcomes. In particular for understanding and formulating prevention strategies on one hand, and tailoring health services and treatments for the best health

and longevity outcomes on the other, research on such data will increasingly become an important tool for the health and wellbeing of New Zealanders.

However, the rights of consumers/patients must not be in any way at all overlooked, undermined or lessened because their information may form part of a valuable contribution to understanding the health and well-being of New Zealanders in the future.

The provisions in the Amendment Bill are not sufficiently robust to protect the rights of patients.

The Amendment bills 112J (4) states that:

NCSP information may be accessed and disclosed by a person authorised for that purpose by the NCSP manager, if the disclosure is—

...

(c) for the purpose of research, in accordance with regulations made under section 112ZF(1)(a); or

(d) for the purpose of enabling the compilation and publication of statistics that do not enable the identification of the women to whom those statistics relate, in accordance with any regulations made under section 112ZF(1)(b).

While clause (d) specifies that statistics must “not enable the identification of the women to whom those statistics relate”, clause (c) does not make the same specification.

The AWHC believes that no data should be made available for any research unless it has been de-identified prior to its release for research purposes. Researchers ***MUST NOT*** be authorised to access the NCSP-R and must only be given access to data already stripped of all identifying information.

In addition, any research that proposes to use data from the NCSP-R must go before an ethics committee to ensure that the personal health information of patients is managed and used appropriately and that the research protocols have the appropriate processes to protect this information.

The AWHC notes that clause 112J(4)(c) states that the data may be disclosed for the purpose of research, in accordance with regulations made under section 112ZF(1)(a):

112ZF Regulations

“(1) Regulations ***may be made under this Part*** [our emphasis] for any 1 or more of the following purposes:

“(a) regulating access to information held by the NCSP by persons researching cancer:

However, there appears that there have not been any regulations made under this part for the purposes of research (according to a search under Legislative Instruments on www.legislation.govt.nz and confirmed with NSU by a member of the AWHC and FWHC). So, one part of the legislation is relying on regulations made under another part that have in fact not ever

been made. If there are no regulations made under section *112ZF Regulations* then data cannot be disclosed in accordance with such regulations, as they don't exist.

It seems that the Amendment Bill is insufficiently robust on the issue of research and provisions for the use of NCSP-R data for the purposes of research to give us any confidence that women's rights to the privacy and the security of the personal health data will be upheld.

Consent

The AWHC is concerned that the process of informed consent by which women agree to cervical screening, enrolling in the NCSP and having their data stored in the NCSP-R is not sufficiently robust. We cannot comment on the processes by which consent is obtained by health practitioners and smear-takers around the country. However, a review of the NSU website reveals that the path to finding information on how records are stored, how they may be used and who has access to that data is not intuitive or straightforward, even for a person who knew what she was looking for, and could be easily overlooked by women unaware of the implications of how their personal health information is stored.

With any amendment that broadens access to a large number of unspecified people, that includes administrative and support staff who may have no medical knowledge or training, the onus is on the NCSP and health providers to ensure that truly informed consent is obtained and that women understand exactly what having their data stored in the NCSP-R entails, who may have access and for what purpose.

It is important that all women currently on the NCSP-R be advised of the amendments to the legislation governing the NCSP-R, whatever form those amendments ultimately take, and when they are passed, so that women have an opportunity to make an informed decision about remaining on the register.

All women on the register **must** be contacted and advised of any changes to the way in which authorised persons can access their data, and that access to the register has been widened to include not just health practitioners, but support and administrative staff, as well as researchers, and that the amendments include provisions for the manager of the NCSP-R to authorise access to "any other person or class of person" that the manager sees fit to authorise. Women must be given the opportunity to opt-off the register under the new access regulations and provisions, and the fact that the amendments were open to public submissions should not be regarded as having sufficiently informed all women enrolled in the NCSP of the changes.