

**MEMORANDUM TO THE CABINET EDUCATION AND HEALTH COMMITTEE**

**LAW CHANGES TO SUPPORT AUDIT, MONITORING AND EVALUATION OF THE  
NATIONAL CERVICAL SCREENING PROGRAMME**

**PROPOSAL**

- 1 This paper proposes legislative amendments to the Health Act 1956 in order to improve the operation of the National Cervical Screening Programme (NCSP). A number of the proposals seek to allow access to personally identifiable data to facilitate monitoring and evaluation of the NCSP. The additional proposals seek to assist the operation of the NCSP by eliminating the difficulties with the current legislation.

**EXECUTIVE SUMMARY**

- 2 In October 1999, the then Minister of Health appointed a Committee of Inquiry to inquire into the apparent under reporting of cervical smear abnormalities in the Gisborne Region prior to March 1996. The Committee of Inquiry delivered its report on 10 April 2001. The Inquiry Report recommended that a number of legislative changes be made to ensure the effective operation of the NCSP.
- 3 In response to these recommendations, a public discussion document was released. This discussion document asked for feedback on the proposals to allow access to all NCSP-Register data, to all cervical slides, and to the clinical records of women who have developed invasive cervical cancer, in order to evaluate and monitor the NCSP. One hundred and one submissions were received and analysed.
- 4 In addition to the proposals contained in the discussion document, a number of other legislative changes are considered necessary to improve the operation of the NCSP. The additional proposals include:
  - (a) addition of a purpose statement;
  - (b) addition of definitions, to aid interpretation;
  - (c) extension of the information that is held on the NCSP-Register to include colposcopy and treatment data;
  - (d) clarification of the 'opt-off' provisions;
  - (e) safeguards and confidentiality provisions for information;
  - (f) retention of cervical cytology and histology slides.

These additional proposals have not yet been the subject of public consultation, however there will be a chance for the public to make submissions on these proposals at the Select Committee stage.

- 5 A number of the proposals contained in this paper may be contentious. In particular, the proposal to access clinical records, as recommended by the Committee of

Inquiry, was opposed by the majority of submitters. Due to the opposition, I have altered the proposals so that consent will be sought where practicable, before the clinical records are accessed. However, this compromise may still be contentious.

## **BACKGROUND**

### **Committee of Inquiry**

- 6 In October 1999, the then Minister of Health appointed a Committee of Inquiry to inquire into the apparent under reporting of cervical smear abnormalities in the Gisborne Region prior to March 1996. During the Committee of Inquiry, it became apparent that comprehensive evaluation of the NCSP was being obstructed by statutory barriers that prevented access to essential information.
- 7 In October 2000, Cabinet agreed that regulatory and legislative changes are required to facilitate access to identifiable personal information held on the NCSP-Register for researchers studying cancer and in order to audit the NCSP [CAB (00) M35/4 refers].
- 8 The "Report of the Ministerial Inquiry into the Under Reporting of Cervical Smear Abnormalities in the Gisborne Region" was released on 10 April 2001. This report made a number of recommendations for legislative change in order to facilitate evaluation, monitoring, and audit of the NCSP.

### **Discussion Document**

- 9 Following Cabinet approval on 14 May 2001 [CAB (01) 15/6 refers] the Ministry released a discussion document asking for public comment on proposed changes to the Health Act to implement the recommendations of the Inquiry. Submissions were received between 6 June and 16 July 2001. An analysis of the submissions is attached at Appendix III.
- 10 Pacific fono were held in seven regions to provide Pacific women and their families with an opportunity to discuss the proposals contained in the discussion document.
- 11 In addition to the proposal contained in the public discussion document, a number of other legislative proposals are discussed in this paper. These additional proposals have not been consulted on, but have been signalled by the Inquiry report, and are considered necessary to have a NCSP that operates as effectively as possible.

## **COMMENT**

### **Definitions**

#### ***NCSP-Register***

- 12 The NCSP-Register holds enrolled women's demographic details, their smear results, their histology results, and details of smear-takers, health centres, and laboratories. As a clinical management tool for the programme it is used to produce a number of reports and letters. The NCSP-Register is also used to monitor aspects of the NCSP.

### **Monitoring, evaluation, and audit**

13 The terms “Monitoring”, “Evaluation”, “Audit” are used throughout this paper. For ease of understanding these terms are defined as

(a) *Monitoring*: The continuous supervision of an activity for the purposes of checking whether plans and procedures are being followed.”

(b) “*Evaluation*” is a comparative assessment of the value of an intervention, in relation to criteria and using systematically collected and analysed data, in order to decide how to act. Evaluation in this case includes *Clinical Audit*”

(c) *Audit*: falls within the meanings of “monitoring” and “evaluation” and is an investigation into whether an activity meets explicit standards, as defined by an auditing document, for the purpose of checking and improving the activity audited”.

14 If the changes proposed in this paper are agreed to, then the Health Act 1956 should also be amended to include appropriate definitions of audit, monitoring and evaluation, the programme, slides, and clinical records. The Ministry of Health will work with Parliamentary Counsel Office to develop appropriate legal definitions.

## **PROPOSALS FOR LEGISLATIVE CHANGE**

### **Purpose statement**

15 I propose that a purpose statement be added that extends the scope of the section beyond the NCSP-Register to include the ambit of the entire NCSP and its aims. The inclusion of a purpose statement will make it clearer that the intention of section 74A is to provide for an organised screening programme; to ensure the safety and effectiveness of that Programme through audit, monitoring and evaluation; a reduction in the incidence and mortality of cervical cancer through early detection; and to facilitate research into cancer via the regulation making process.

### **Extend NCSP-Register to colposcopy and treatment data**

16 I propose that the NCSP-Register is extended to include the assessment and treatment history, and whether further treatment is recommended/required. The reasoning behind this is that while the programme is set up to reduce the incidence and mortality rates from cervical cancer through the early detection of precancerous squamous cell changes, without timely and adequate treatment there is little point in detecting the precancerous cells. I propose that the legislation requires the colposcopy and treatment data to be supplied.

### **Clarification of opt-off provisions**

17 Currently there is a lack of clear definition around what it means to be enrolled in the NCSP. Enrolment in the NCSP-Register, and thus the NCSP, occurs when a woman has a cervical smear taken. Section 74A of the Health Act 1956, as currently drafted, requires that every time a woman has a smear taken from her cervix, or a histology biopsy taken, she must be advised that her results will be entered onto the NCSP-Register unless she objects. Prior to a smear or biopsy being taken it is expected that the smear-taker will explain the clinical procedure, the importance of having regular smear tests, the purpose of the NCSP and NCSP-

Register and determine whether a woman objects to having her results forwarded to the NCSP-Register.

- 18 A woman can request that a particular test result not be sent to the NCSP-Register at the time of the smear test or the taking of histology. If a woman wishes to “opt-off” a particular result from the NCSP-Register, her smear taker indicates this to the laboratory. The NCSP does not receive any notification of the decision to “opt off” that particular result from the NCSP-Register. Because “opting off” one result, does not constitute an exit from the NCSP this can lead to the appearance of a complete history for the woman on the register, when in fact one or more results may be missing. Incomplete screening histories impede the effective monitoring, audit, and evaluation of the NCSP.
- 19 In addition to this there are also difficulties for laboratories and smear-takers that may be reliant on the smear-history from the NCSP-Register, particularly for new patients. The Committee of Inquiry recommended “The cervical smear test and histology histories of women enrolled on the National Cervical Screening Register should be made electronically available online to all laboratories reading cervical cytology”. It will only be useful to implement this recommendation if the results stored on the register are accurate and complete. Otherwise, laboratories will be relying on a source of information that is incomplete. This creates a risk for the laboratories reading the slides, and for the woman involved.
- 20 I propose that the Health Act be amended so that women cannot choose to opt *particular* smear results off the Register. Instead the NCSP becomes an opt-off programme. Women would still be able to decide either to opt-off the NCSP or to remain enrolled on the NCSP. This change will mean that the NCSP, NCSP providers and women can be more confident that a woman’s screening history on the NCSP-Register is complete. If a woman chooses to opt-off the programme consent will be sought to have her information sent to NCSP-Register in a non-identifiable form. If this consent is obtained the medical professionals involved in the collection of this information will be required to forward it to the NCSP-Register.
- 21 This proposal has not been consulted on at this stage. However, there will be a chance for the public to make submissions on these proposals at the Select Committee stage. This proposal is not considered to be controversial.

### **Consent and Authorisation to access relevant information**

- 22 Much of the information that needs to be accessed for monitoring and evaluation purposes is subject to requirements of consent or authorisation from the woman to whom it relates. Requirements to gain informed consent and/or authorisation were identified by the Committee of Inquiry as a potentially significant barrier to effective and efficient monitoring, evaluation, and audit of the NCSP.
- 23 The Committee of Inquiry<sup>1</sup> found that

“the need to obtain informed consent before gaining access to protected information poses practical and technical problems. Women are not always easily traceable.

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<sup>1</sup> AP Duffy, DK Barrett, MA Duggan, Report of the Ministerial Inquiry into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region, April 2001.

Secondly for the conclusion of an evaluation to be statistically meaningful and therefore informative to medical experts the evaluation exercise must cover a sufficiently large group of women. If only a small number give their consent the exercise will be pointless. The Committee considers that faced with these problems the best choice is to permit medical experts who have been engaged for the purpose of evaluating the Programme to have access to the information without the need to obtain women's consent. It is difficult to see why women might object to an independent evaluation team seeing information to which those medical persons who are involved in their treatment have unrestricted access. If evaluation is seen as an integral part of a woman's treatment under the Programme there is no difference." (Para 6.98)

- 24 The concerns of the Committee of Inquiry about participation in audits are supported by recent experience. An evaluation of the management of women with abnormal screening histories has recently been undertaken by experts from Otago University on behalf of the Ministry of Health. Provisional results indicate that of the 415 women selected as the sample for this study (using 1999 information) complete data were collected for 231 individuals, a response rate of 55.7 percent. Of the remaining 184, 80 women (19.2 percent) declined to participate (and 101 women (24.3 percent) could not be located. There were much lower response rates among Māori and Pacific women (27.9% and 31.3 % respectively). Māori women were both more likely to refuse to participate (26.2%) and more difficult to locate (46.8% not located either for consent or interview) compared with non- Māori, non-Pacific women (11.8% and 24.5 respectively). Pacific women were also difficult to locate (41.9% not contacted their for consent or interview)<sup>2</sup>. The woman invited to participate in this evaluation were women who had smears taken in 1999. The fact that less than two years after their smears were taken almost 25% percent of the women could not be located is significant.
- 25 It is due to these difficulties in locating women and seeking authorisation that legislation requiring access to relevant data is proposed as discussed in paragraphs 26-47.

#### **Access to NCSP-Register data**

- 26 Section 74A of the Health Act 1956 currently prevents identifiable information on the NCSP-Register being disclosed to persons carrying out any audit, monitoring or evaluation of the NCSP, unless the woman has given informed consent.

- 27 The Inquiry stated that:

“ One of the core purposes of the Register is to provide information for the purpose of monitoring and evaluating the Programme's effectiveness. Therefore, legislation relating to the Register should clearly and unreservedly permit an evaluation team engaged by the Ministry to have access to all information on the Register. There should be no room for doubt about the legality of access to the Register.” (Para 6.83)

- 28 The Inquiry Report recommended that:

“the Health Act 1956 should be amended to permit the National Cervical Screening Programme to be effectively audited, monitored and evaluated by any appropriately qualified persons irrespective of their legal relationship with the Ministry of Health. This requires an amendment to section 74A of the Health Act to permit such persons

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<sup>2</sup> Dr Diana Sarfati et al *“the Management of Women with Abnormal Cervical Smears”*

to have ready access to all information on the National Cervical Screening Register”.  
(Para 11.15)

- 29 The discussion document proposed that the law be amended so that identifiable information from the NCSP-Register can be provided to external auditors where it is necessary for audit, without the requirement to obtain informed consent from each woman.
- 30 Forty of the 101 submissions received commented on access to NCSP-Register data. While some submissions opposed the proposal to allow information on the NCSP-Register to be disclosed for auditing, monitoring and evaluating the NCSP-Register, there is a great deal of support for the proposal that information held on the NCSP-Register be able to be disclosed for monitoring, audit, and evaluation purposes. This proposal is supported by:
- (a) Health and Disability Commissioner
  - (b) New Zealand Medical Association
  - (c) Nursing Council of New Zealand
  - (d) Medical Council of New Zealand
  - (e) Hawkes Bay Cervical Screening Programme
  - (f) Women’s Health Action Trust
  - (g) Breast Cancer Network (NZ) inc
  - (h) National Women’s Hospital, Auckland
  - (i) Rural Women New Zealand
  - (j) The Hawkes Bay Women’s Health Committee
  - (k) Federation of Women’s Health Councils
  - (l) Auckland Women’s Health Council
  - (m) The Cancer Society.
- 31 I propose that section 74A of the Health Act 1956 be amended to allow identifiable information held on the NCSP-Register to be disclosed to persons undertaking evaluation and monitoring activities on behalf of the Ministry.

#### **Access to and Use of Cervical slides**

- 32 Currently, access to slides for the purpose of evaluating the programme is governed by Right 7(10) of the Code of Health and Disability Services Consumer’s Rights.
- 33 The Health and Disability Commissioner’s view is that “...*consent to re-reading for quality assurance purposes may be implied, so long as there was express consent to the original reading of the slide. The tissue sample is being used in the same manner and for the same purpose that it was originally provided. Both readings are provided as part of the Programme’s screening service, and are designed to detect cervical cancer in individual women, albeit as part of a broader quality assurance audit.*”
- 34 However this does not mandate release of the slides to the auditors. A smear reader who may feel culpable could well resist attempts to obtain slides. Any legislative amendment would need to require laboratories that hold slides to make them available for the purpose of monitoring, audit, and evaluation of the NCSP.

- 35 The discussion document proposed that “the Government amend the law so that slides will be made available without informed consent where it is necessary as part of the audit of the programme.” 62 percent of the submissions that commented on this proposal supported slides being made available for audit and evaluation. Ensuring quality review of slides and laboratories was the predominant rationale for supporting the proposal. Those who support this proposal include:
- a) Health and Disability Commissioner
  - b) New Zealand Medical Association
  - c) Medical Council of New Zealand
  - d) National Council of Women of New Zealand
  - e) The Hawkes Bay Cervical Screening Programme
  - f) Women’s Health Action Trust
  - g) Breast Cancer Network (NZ) Inc
  - h) National Women’s Hospital, Auckland
  - i) Rural Women of New Zealand
  - j) Federation of Women’s Health Councils
  - k) Auckland Woman’s Health Council
  - l) Morningson Health Centre
  - m) Cancer Society.
- 36 I propose that section 74A of the Health Act is amended to require all cervical cytology and histology slides of all women who have results recorded on the NCSP-Register and/or who have cervical cancer to be made available for the purpose of routine monitoring, audit, and evaluation of the NCSP.

### **Access to Clinical Information**

#### ***Current Legal Situation***

- 37 Generally, access to a person’s clinical records is governed by the Health Information Privacy Code 1994. Under Rule 11 of the Health Information Privacy Code the health agency that holds the clinical records is only allowed to disclose the records on certain grounds. Those that may be relevant for these purposes include:
- (a) disclosure is authorised by individual concerned (or their representative); or
  - (b) disclosure is a purpose for which the information was obtained; or
  - (c) it is not desirable or practicable to obtain individual authorisation and the disclosure is for a directly related purpose; or
  - (d) it is not desirable or practicable to obtain individual authorisation and the individual is not identified; or
  - (e) it is not desirable or practicable to obtain individual authorisation and disclosure is for research purposes and the information will not be published in a form which could reasonably be expected to identify the individual concerned; or
  - (f) it is not desirable or practicable to obtain individual authorisation and disclosure is for accreditation, quality assurance, or risk assessment programmes.
- 38 These grounds are permissive. The health agency is *allowed* to, but not required to, disclose the information in these situations. Most health professionals are likely to be reluctant to disclose a patient’s clinical records without first obtaining the consent

of that patient, and/or without ethical approval and/or if they are concerned about possible ramifications.

39 The Committee of Inquiry recommended that:

“the Health Act 1956 be amended to enable the Ministry of Health and any appropriately qualified persons it engages to carry out (external or internal) audits, monitoring or evaluation of cervical cancer incidence and mortality to have ready access to all medical files recording the treatment of cervical cancer by all health providers who had a role in such treatment.” (para 11.17)

40 The discussion document stated “the Government proposes allowing auditors access to clinical records where they are required for audit of the Programme. This will involve changing the law to require doctors, nurses, specialists, or hospitals to make relevant records available where they are essential for audit (evaluation)”.

41 An overwhelming number of submitters were opposed to clinical records being accessed without authorisation. Of the 69 submissions received on this proposal, 51 of them were opposed.

42 In particular this proposal was opposed by:

- (a) Federation of Women’s Health Councils
- (b) The New Zealand Federation of Business and Professional Women
- (c) The Hawkes Bay Women’s Health Committee
- (d) New Zealand Nurses Organisation
- (e) MidCentral Sexual Health service
- (f) Auckland Women’s Health Council
- (g) Women’s Health Action Trust
- (h) Cancer Society of New Zealand
- (i) Ministry of Women’s Affairs
- (j) Ministry of Consumer Affairs.

43 Because of the overwhelming opposition from the public to the proposal that clinical records be made available without authorisation from the woman to whom they relate, I propose that:

- (a) Efforts will be made to seek consent from the women involved. Where a woman gives her consent to her medical records being used, the person who holds the medical records will be **required** to make them available.
- (b) Efforts could be made to obtain consent prospectively at the time of colposcopy, treatment or in the case of the cancer audit at the time of registration on the Cancer Registry.
- (c) When consent is unable to be sought (i.e. because the woman has died or cannot be traced) the Director-General of Health will be empowered to **require** the health professional to provide the **relevant** information.

44 While this proposal does not meet the recommendations of the Committee of Inquiry, it addresses some of the issues that will hamper effective ongoing monitoring and evaluation - that is, access to information where the woman cannot be located or has died. As noted in paragraph 24 the recent evaluation conducted

by the University of Otago has been severely hampered by an inability to locate almost 25% of the women initially identified for the evaluation despite up to twenty attempts at locating and contacting them. This option allows women who can be contacted the opportunity to authorise the use of their information. The Ministry of Women's Affairs disagrees with this option as they think it violates informed consent. They feel that this option provides an incentive not to trace women and use the powers of the Director-General to release women's records.

- 45 I disagree with this view. This issue can be dealt with at the drafting stage, to ensure that reasonable attempts to trace women are made before the Director-General can require clinical records to be released. The Health and Disability Commissioner also prefers this option, as the power is reserved to the Director-General of Health, and excludes the records of women who decline to give consent.
- 46 This compromise proposal may mean that the gold standard audit recommended by the Committee of Inquiry may not be able to be completed. As noted in paragraph 23, during a recent evaluation that sought consent, 19.2 % of the women involved declined to participate and that may well compromise the audit. Such a high decline rate may compromise the results of an audit.
- 47 If health professionals are not required to make relevant medical records available, and substantial numbers of women cannot be traced in order to seek consent or authorisation, then evaluation and monitoring activities may not be able to give results that can be relied upon, resulting in an inability to guarantee the safety and effectiveness of the NCSP. This creates risks of:
- (a) undetected systemic errors in the NCSP;
  - (b) litigation against the Crown for failure to detect systemic errors;
  - (c) unacceptable clinical risk for both the women and clinician relying on NCSP data;
  - (d) resources being spent on attempts to trace women and seek authorisation for an exercise that may not provide enough comprehensive information in order to establish whether there are any systemic errors.

#### **Proposed safeguards and confidentiality provisions for information accessed for audit purposes**

- 48 It is important that appropriate safeguards are put in place to protect the information used to evaluate and monitor the NCSP.
- 49 I propose that the legislation place conditions of confidentiality and security on the further use and disclosure of personally identifiable data to any person. I propose that the amended legislation:
- (a) prohibit the person to whom the information is disclosed from further using or disclosing the identifiable health information for any purpose other than for the purpose of audit;
  - (b) require the person to whom the information is disclosed to demonstrate and maintain safeguards as necessary to ensure that the health information is not used or disclosed except for monitoring, audit and evaluation purposes;

- (c) require the person to report to the Ministry any use or disclosure of the protected health information of which the auditor becomes aware that was not one of the purposes for which the information was disclosed;
- (d) require the person to ensure that any subcontractors or agents agree to the same restrictions and conditions that apply with respect to the information before they can gain access to the information;
- (e) require the person to return all personal information once the purpose for which it was disclosed is complete;
- (f) require the person to make available its internal practices, books and records relating to the use and disclosure of protected health information, to the Ministry.

50 I propose that there be one exception to these safeguards. I propose that where there are concerns about the competency of a health professional, the persons undertaking the audit be able to refer the matter to the appropriate registering body for a competency review.

51 I also proposed that the amendment should be drafted so that a breach of any confidentiality conditions is considered an offence. The Health Act 1956 currently contains the following offence provision:

“Every person who commits an offence against this Act, or against any regulations made under this Act, for which no penalty is provided elsewhere than in this section 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. “

### **Process Safeguards**

52 It is important that where the provisions that empower information to be accessed without authorisation from the women to whom it relates are utilised, that there is a transparent process in place.

53 I propose that the Health Act be amended to contain criteria that must be met before the empowering provisions are used. Such criteria would include who could access the information (i.e. appropriately qualified persons), and for what purposes. These criteria will be finalised during the drafting of the amendment.

### **Extension of relevant provision to other screening programmes**

54 It has been suggested that the access to information and evaluation provisions should be able to be extended to all screening programmes, for example Breast Screening. In particular, Professor David Skegg of Otago University has made public calls for an evaluation of the Breast Screening programme to be undertaken. Any evaluation of breast screening, for example an audit of interval breast cancers, will encounter many of the same issues that evaluation of the NCSP has encountered, in particular access to a woman’s diagnostic mammography films and treatment records.

55 I propose that the provisions put in place to enable access to information for monitoring, evaluation and audit of the NCSP, be able to be extended to other screening programmes, where relevant, by an Order in Council, after appropriate consultation with stakeholders has been carried out.

### **Retention of cervical cytology and histology slides**

- 56 The Committee of Inquiry recommended that legal obligations be placed on laboratories to retain cervical cytology and histology slides for minimum periods, in safe storage.
- 57 Currently, the Health (Retention of Health Information) Regulations 1996 require health information to be retained for a minimum of 10 years from the date the health professional last saw a patient. While these regulations do not currently apply to cervical cytology and histology slides, the retention of records, cytology smears and histology specimens of patients is something that is closely linked with these regulations.
- 58 I propose that the regulation making power in the Health Act for the retention of health information be amended to allow these regulations to be extended to cervical cytology and histology slides.

### **Kaitiaki Regulations**

- 59 The National Kaitiaki Group is established under the Health (Cervical Screening (Kaitiaki)) Regulations 1995. These regulations control access to the data of Māori women on the NCSP-Register.
- 60 The Kaitiaki Regulations were put in place to encourage Māori participation in the NCSP, by recognising the importance of, and maintaining the confidentiality of, Māori women's data. Conversely, Māori women experience a high rate of cervical cancer, and access to their data is important both in terms of being able to audit the effectiveness of the NCSP, and also reduce the incidence of the disease among Māori.
- 61 The Committee of Inquiry stated:

, "...The Committee understands the particular sensitivity of Māori women to strangers having access to data on the National Cervical Screening Register. It also understands Māori concerns that aggregate data of Māori women may be applied in a way that reflects negatively on Māori. However, at the same time, it needs to be realised that for the Programme to function effectively the more data that is available to a person working on the Programme, and indeed other medical researchers, the more effective the Programme will be."

- 62 The Committee of Inquiry recommended that there be a reconsideration of the Kaitiaki regulations and that:

"The Ministry of Health and any appropriately qualified persons engaged by it (be they independent contractors, agents or employees) require ready access to the information currently protected by the Kaitiaki Regulations in order to carry out any audit, monitoring or evaluation of the Programme."

- 63 I propose that the legislation be amended so that information from the NCSP-Register that is required for monitoring, audit and evaluation purposes, does not need that approval of the National Kaitiaki Group before it can be used and disclosed.

- 64 This will have implications for the number of applications that the National Kaitiaki Group receives, and the ability of the National Kaitiaki Group to protect the information of Māori women on the NCSP-Register. Consultation about the future role and scope of the NKG will take place later this year with Maori women and their communities.

### **Legal evaluation of NCSP**

- 65 As recommended by the Gisborne Inquiry, a lawyer is undertaking a thorough evaluation of the NCSP to determine whether those persons charged with tasks under the NCSP have the necessary legal authority to discharge them. This evaluation will not be completed until later this year. It is possible that the evaluation will recommend further legislative changes, not already proposed in this paper. If that is the case, further advice will be provided.

### **CONSULTATION**

- 66 The following government departments and agencies have been consulted during the development of this paper: Te Puni Kokiri, Treasury, Health and Disability Commissioner, Privacy Commissioner and Ministries of Justice, Economic Development, Consumer Affairs, and Women's Affairs and Pacific Island Affairs.
- 67 A public discussion process has been carried out on the proposals to enable auditors to access NCSP-Register data, slides, and clinical records. Additional proposals will be the subject of public consultation, at the Select Committee stage.
- 68 The Ministry of Women's Affairs and the Ministry of Consumer Affairs noted that the opportunity to present submissions at Select Committee is not a satisfactory substitute for consultation in policy development. Both Ministries have strongly advised that there be further consultation on the policy, including public meetings, before any proposed legislation is drafted.
- 69 I consider that the number of submissions received from women's groups and individual women in response to the discussion document, indicate that this has been an effective way of encouraging women to provide feedback. Further consultation at this time will considerably delay the Government's implementation of the recommendations of the Gisborne Inquiry report, and I believe that consultation through the select committee process is sufficient.

### **FINANCIAL IMPLICATIONS**

- 70 The costs associated with the implementation of the proposed legislative changes will be met within the Vote: Health baseline. In the unlikely event that costs exceed expectations and cannot be met within baselines, the Ministry of Health and Treasury will report to Cabinet.

### **LEGISLATIVE IMPLICATIONS**

71 A large number of the proposals contained in this paper will require some form of legislative amendment in order to be implemented. It is likely that these legislative amendments will form part of a proposed Comprehensive Bill, expected to be introduced to the House later this year.

#### **REGULATORY IMPACT STATEMENT**

72 A Regulatory Impact Statement is attached.

#### **PUBLICITY**

73 It is likely that there will be media interest and public interest in the proposals outlined in this paper. Because of the likely public interest in the proposals contained in this paper I propose to make this paper publicly available.

**ON 3 SEPTEMBER 2001, FOLLOWING REFERENCE FROM THE  
CABINET EDUCATION AND HEALTH COMMITTEE (EHC), CABINET:**

CAB Min (01) 27/17

**National Cervical Screening Programme: Law Changes to Support  
Audit, Monitoring and Evaluation**

**Background**

- 1 **noted** that in October 2000 Cabinet agreed that regulatory and legislative changes are required to facilitate access to identifiable personal information held on the NCSP-Register for monitoring, audit and evaluation of the National Cervical Screening Programme [CAB (00) M 35/4];
- 2 **noted** that the Committee of Inquiry into the Under-reporting of Cervical Smear Abnormalities in the Gisborne Region recommended a number of legislative amendments in order to facilitate monitoring, audit, and evaluation of the NCSP and all cases of invasive cervical cancer;
- 3 **noted** that a discussion document was released on 6 June to seek submissions on proposals to access personally identifiable data for the purposes of monitoring, auditing and evaluating the NCSP;
- 4 **noted** that a number of the recommendations made in the paper under CAB (01) 492 are a departure from those made by the Inquiry;

**Proposals for Legislative Change**

- 5 **agreed** that a purpose statement be added to section 74A of the Health Act 1956;
- 6 **agreed** that definitions of the NCSP, audit, monitoring, evaluation, slides and clinical records be added to section 74A of the Health Act 1956;
- 7 **agreed** that the Health Act 1956 be amended to enable the data collection powers of the NCSP-Register to extend to colposcopy and treatment data;

**Clarification of Opt-off Provisions**

- 8 **agreed** that the Health Act 1956 be amended so that the NCSP becomes an opt-off Programme and that the results of individual smear-tests cannot be opted-off the NCSP Register;
- 9 **agreed** that where a woman notifies the NCSP that she has decided to opt-off the NCSP, any information pertaining to her then be removed from the NCSP-Register;

- 10 **agreed** that where a woman has not opted off the NCSP, that her NCSP-Register data and slides be available for audit, monitoring and evaluation purposes;

#### **Access to NCSP-Register Data**

- 11 **noted** that the ability to monitor, audit and evaluate the NCSP is obstructed by the restrictions on disclosure of NCSP-Register data;
- 12 **agreed** that the Health Act 1956 be amended to allow identifiable information held on the NCSP-Register to be disclosed for the purposes of monitoring, audit and evaluation activities;
- 13 **noted** that women will be provided with information about the NCSP and the use of their personally identifiable data at the time of enrolment on the NCSP;

#### **Access to and Use of Cervical Cytology and Histology Slides**

- 14 **noted** that the ability to re-examine cervical cytology and histology slides is essential in order to enable monitoring, evaluation and audit to take place;
- 15 **agreed** that the Health Act 1956 be amended to require the cervical slides of all women who have results on the NCSP-Register to be made available for purposes of evaluation and monitoring of the NCSP;
- 16 **agreed** that the Health Act 1956 be amended to require that the cervical slides of all women who have cervical cancer be made available for the purposes of evaluation and monitoring of the NCSP;

#### **Consent to Disclosure of Clinical Records**

- 17 **noted** that the Committee of Inquiry recommended that persons carrying out audit, monitoring or evaluation should have ready access to all medical files recording the treatment of cervical cancer by all health providers who had a role in such treatment;
- 18 **noted** that access to clinical records is a contentious issue, and that 74% of the submissions received on this issue were opposed to the Inquiry's recommendation;
- 19 **agreed** that informed consent to the disclosure of clinical records must be sought either as close to the time of registration on the Cancer Registry as is practicable, or at time of treatment, for women who have been diagnosed with invasive cervical cancer;
- 20 **noted** that the Ministry of Health will consult with relevant professional groups and women's groups to develop appropriate protocols for seeking consent;
- 21 **agreed** that where a woman with cervical cancer has died, and it is unclear whether she has consented to her records being used or not, reasonable attempts to trace her next of kin will be made, in order to seek consent;

### **Requirements to Disclose Records**

- 22 **agreed** that disclosure of clinical records be required where women who are enrolled on the NCSP have consented to their use for audit, evaluation and monitoring purposes;
- 23 **agreed** that disclosure of clinical records be required where women who have cervical cancer have consented to their use for audit, evaluation and monitoring purposes;
- 24 **agreed** that disclosure of clinical records be required where a woman who has invasive cancer has died, and her next of kin have given consent to the disclosure of the records for audit, evaluation and monitoring purposes;
- 25 **agreed** that where consent is unable to be obtained from women who have invasive cervical cancer (because the woman cannot be traced, or the woman has died and her next of kin are not known or cannot be traced) the Director-General of Health be empowered to require the persons who hold the information to release the relevant data;
- 26 **noted** that women will be informed of any adverse findings identified for audit, evaluation and monitoring activities, unless they have indicated that they do not wish to be informed;

### **Confidentiality and Security Provisions**

- 27 **agreed** that the Health Act 1956 be amended to place conditions of security and confidentiality on the further use and disclosure of personally identifiable information used and disclosed for audit, monitoring and evaluation purposes;
- 28 **agreed** that criteria be included in the amendment to the Health Act 1956, defining when the provisions empowering the Director-General of Health to require information to be disclosed can be used;
- 29 **agreed** that any breach of confidentiality and security provisions will be a breach of the Health Act 1956;

### **Additional Proposals**

- 30 **agreed** that the proposed amendments related to access to information be able to be extended to other screening programmes as appropriate, by Order in Council;
- 31 **agreed** that the Health Act be amended to enable the Health (Retention of Health Information) Regulations 1995 to be extended to cervical slides and histology specimens; requiring laboratories to retain cervical cytology and histology slides and reports in safe storage for a minimum period, as recommended by the Committee of Inquiry;

- 32 **noted** that an independent lawyer is evaluating the NCSP to determine whether those persons with responsibilities under the NCSP have the necessary legal authority to discharge them, and that further proposals for legislative change may arise from this evaluation;

#### **National Kaitiaki Group**

- 33 **noted** that the National Kaitiaki Group controls access to, and use of, data on the NCSP Register that relates to Maori women;
- 34 **agreed** that access to NCSP Register data continue to be subject to any regulations made under section 74A(7) (eg the Kaitiaki Regulations) and that further consultation will be undertaken before any changes are made to the Kaitiaki Regulations;
- 35 **noted** that consultation with Maori women and their families will take place later in 2001;

#### **Financial Implications**

- 36 **noted** that the costs associated with the implementation of the proposed legislative changes will be met within the Vote Health baseline. In the unlikely event that costs exceed expectations and cannot be met within baselines, the Minister of Health, in consultation with the Minister of Finance, will report further to the Cabinet Education and Health Committee;

#### **Drafting**

- 37 **invited** the Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to amend the Health Act 1956 to implement the above proposals;
- 38 **noted** that the legislative changes to be made to section 74A of the Health Act are intended to be included as part of a comprehensive bill which will address a number of safety and quality issues across the health and disability sector.