Report on the
National Cervical Screening Programme
and progress towards
Implementation of the
Gisborne Inquiry Recommendations.

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Summary of main findings and recommendations.

1. I recognise that a vast amount of activity has occurred over the past three years and a structured National Cervical Screening Programme (NCSP) is emerging. The progress to date is the result of a great deal of effort on the part of a whole range of individuals in the National Screening Unit and in related Government departments, as well as among Professional Bodies and individual health care professionals. The NCSP continues to mature month on month. However, there is still much work to be done if New Zealanders are to realize their hope of having the best cervical screening programme in the world.

2. **Progress on implementation of Gisborne recommendations as at January 2003** (see Appendix 1)
   - Ten recommendations have been completed or implemented (11.5, 11.6, 11.9, 11.12, 11.25, 11.29, 11.38, 11.39, 11.40, 11.46)
   - Seven recommendations are in the process of being implemented (11.4, 11.7, 11.10, 11.24, 11.27, 11.37, 11.43)
   - Work has begun on seven recommendations but much has still to be done (11.1, 11.3, 11.26, 11.28, 11.31, 11.32, 11.41)
   - A decision has been taken not to implement two recommendations: after consultation, Cabinet decided to retain status quo with respect to the Kaitiaki regulations (11.15) and the National Cervical Screening Programme is not medically led as intended by 11.13.
   - Six recommendations are being addressed as part of the remit of the National Ethics Committee which had its first meeting in April 2002 and is due to report in November 2003 (11.18, 11.19, 11.20, 11.21, 11.22, 11.23).
   - Eight recommendations are being addressed as part of the legislative changes currently before Parliament – outcome yet unknown (11.14, 11.16, 11.17, 11.30, 11.34, 11.35, 11.36, 11.44).
   - I am unclear whether six of the recommendations will be implemented at all or partially implemented (11.2, 11.8, 11.11, 11.33, 11.42, 11.45).

3. I would ask you to note my evaluation of the NSCP with respect to the World Health Organisation guidance and recommendations (paragraphs 9-13).

4. **Main observations and comments**

- I do not believe there is as yet a good understanding of the principles of public health screening programmes generally within the Ministry of Health, among health professionals or by the public in New Zealand (paragraph 4). The benefits to the whole population, the limitations of the screening test and the limited ability of a single cervical smear to "protect" individual women is generally poorly understood.
- I have identified some important deficiencies and barriers to delivering a fully effective National Cervical Screening Programme (paragraphs 5-13).
- The NCSP does not yet have access to a population register for inviting women nor is it able to identify all women attending for screening since some "opt off" the Screening Register. Thus the ability to monitor and evaluate the NSCP is compromised. Participation in screening has to be estimated against census data. Primary care teams who take the vast majority of smears have yet to be embraced as full and essential members of the cervical screening "team", open to audit and quality assurance in the same way as the other component members of the programme. These are fundamental deficiencies of the NCSP that the public must either change or accept the limitations they impose (paragraphs 12-16, 43).
- The Cancer Audi Group has overcome many difficulties and the audit is now progressing well. I believe this will provide much useful information in due course. However, the outcome will not be known until the end of 2004. This will be three years longer than the six months recommended by the Gisborne Inquiry. In addition, I have been informed that the methodology of the audit will not address whether there was systematic under-reporting in the late 1990s. I regret that there is still no explicit evidence that the NCSP at that time was safe and effective. I cannot accept that New Zealand women will not be given this reassurance (paragraphs 18- 28).
- I remain unconvinced that the culture that had been developing in the HFA regarding management of the NCSP under the influence of Dr Julia Peters has been maintained (paragraph 36).
- I remain concerned that despite the increased number of clinicians in the National Screening Unit, some are part-time and their level may prevent them from having appropriate influences on the screening policy and implementation. Thus I cannot

agree that the NCSP is medically led as intended by Recommendation 11.13 (paragraph 37).

- I note that legislative changes are in progress and that a National Ethics Committee has been set up. I must await the outcome of these to see whether full implementation of the Gisborne recommendations transpires (paragraphs 38-40).
- I have serious concerns that there are inadequate appropriate training and development courses available in New Zealand for all groups of health professionals involved in cervical screening. I am particularly alarmed that the NSCP has not specified or required any additional training before laboratory staff report liquid based cytology samples (paragraph 41).

5. **Main Recommendations**

- New cases of cervical cancer should not just be "reviewed" but be fully audited as soon as they arise (paragraph 27).
- In view of the absence of explicit evidence that the National Cervical Screening Programme was safe and effective in the late 1990s, consideration should be given to implementing Recommendation 11.2 at least in part (paragraphs 29-31).
- Great care must be taken when interpreting and publishing the results of the re-read of slides as part of the Cancer Audit particularly with respect to those slides considered equivocal or atypical.
- Since the NCSP is a public health programme, I recommend that consideration be given to finding a way of directing NCSP smear tests to appropriate laboratories irrespective of commercial interests so that comparison of laboratory reporting rates can be evaluated with respect to geographic areas, and the training of medical and technical staff can be facilitated (paragraph 34).
- A national external quality assurance scheme should be established for laboratory staff to monitor continuing competence.
- More work needs to be done on the development of Information Technology systems to allow easier transfer of information between smear takers, laboratories and colposcopy clinics and the Screening Register (paragraph 42).
- The National Screening Unit, its clinical leadership, management structure and location within the Ministry of Health should be kept under critical review.

Report on the National Cervical Screening Programme and progress towards implementation of the Gisborne Inquiry Recommendations.

1. I visited New Zealand initially in November 2001, again in April 2002 and for a third time in January 2003 in order to review progress towards full implementation of the 46 Gisborne Inquiry recommendations and the overall development of the New Zealand Cervical Screening Programme (NCSP). Unfortunately my third visit was cut short due to a family bereavement but I had managed to speak to most of the individuals and groups that I felt were essential before I had to leave. I also had a teleconference with the Director General, Assistant Director General and the National Screening Unit Manager following my visit on the 27th February 2003.

2. I produced an Interim Report following my first visit in November 2001. I did not submit a second report after my visit in April 2002 since there was still much progress to be made and it became apparent that a general election was on the horizon. This second report is intended as my final report.

3. I understand that my Interim Report was not universally well received in New Zealand. Some people have intimated that a "critical" report was considered negative and could result in women not attending for smears and consequently developing cervical cancer. Some perceived my report as unfairly critical of them as individuals or groups. Neither was my intention. I believe that my forthright approach resulted in some individuals and groups with whom I met during my subsequent visits being wary or overly cautious in their discussions with me. However, I was pleased to note tremendous support in many quarters and was impressed at the willingness of various agencies and individuals to attempt to better understand, to recognise the deficiencies and to try to address them in a sensible manner. It can be summed up in one comment made to me on my second visit "We believe it is good to have the independence of your advice which is crucial because we were becoming alarmed". I note that many of the additional recommendations I made in my Interim Report have been accepted and are being implemented.

4. I do not believe there is as yet a good understanding of public health screening programmes generally within the Ministry of Health, among health professionals or by

the public in New Zealand. This is not to say that it has not improved over the last few years and I am pleased to note the recent Report of the National Health Committee: *Screening to improve health in New Zealand: Criteria to assess Screening Programmes.* However, it is important to recognise and confront the serious barriers to implementing a successful cervical screening programme in New Zealand. New Zealanders must decide how to remove or manage those barriers or accept their limitations, rather than focus on one or more components of the screening programme that might have deficiencies. I do not believe New Zealand has yet achieved a fully effective Cervical Screening Programme.

5. I think it is worth pointing out that the value of a screening programme is greater than the sum of its individual component parts and it is the coherence of a well organized, structured, quality assured, population based programme that brings the full benefits to all women in a country. It can be likened to a jigsaw puzzle. We may know how many pieces we should have, we may have put some together but we do not achieve the completed picture until each is connected properly to the other pieces and only then do we recognise if there are some pieces missing or defective. I believe that most of the "pieces", the component parts of a Cervical Screening Programme are present in New Zealand but these are organised and monitored to varying degrees and some parts are further developed than others. They have still to come together to create a cohesive picture.

6. As far back as 1968, Wilson and Jungner defined the aims and principles of screening. (Wilson JMG, Jungner G. Principles and Practice of Screening for Disease. World Health Organisation 1968). The authors stated that the aim of screening programmes is to sort out those who <u>probably</u> have the disease from those who <u>probably do not</u>.

7. The principles were listed as:

- The disease should pose an important health problem for the individual and the community;
- The natural history should be well understood with a recognizable early stage;
- An appropriate and acceptable screening test should be available and offered at suitable intervals;
- Treatment at an early stage should be advantageous;

- There should be adequate facilities for the diagnosis and treatment of abnormalities identified;
- The chance of physical or psychological harm must be less than the chance of benefit;
- The costs of the screening programme should be balanced against the benefits it provides.

8. Cervical screening meets the above criteria. The effectiveness of screening programmes based on cytological smears in reducing mortality from carcinoma of the cervix and the incidence of invasive disease has been well established for some decades as evidenced by experience in Scandinavia.

9. In the 1980s the World Health Organisation (WHO) issued guidance on the requirements for a successful cervical screening programme. WHO recommended that for screening to be effective, it is especially important that the programme be organised according to an agreed policy. The essential elements of such a policy are:

a. the target population has been identified;
b. individual women are identifiable;
c. measures are available to guarantee high coverage and attendance, such as a personal letter of invitation;
d. there are adequate field facilities for taking smears and adequate laboratory facilities to examine smears;
e. there is an organised programme for quality control of smear taking and laboratory interpretation;
f. adequate facilities exist for diagnosis and for appropriate treatment of confirmed neoplastic lesions and for the follow-up of treated women;
g. there is a carefully designed and agreed referral system, and an agreed link between the women, the laboratory and the clinical facility for the diagnosis of an abnormal screening test, the management of any histological abnormality found and providing information about normal screening tests;
h. evaluation and monitoring of the whole programme is organised in terms of incidence and mortality rates at the level of the total target population among those **attending**, and among those **not attending**. Quality control of these epidemiological data should be established.

10. WHO also recommended that cervical screening must be run as an organised system with objectives, criteria to measure progress towards those objectives, standards and targets. The outcome indicators to measure effectiveness of the programme are a fall in incidence and mortality from cervical cancer. A secondary indicator could be a shift in the stage (degree of spread) of the cancer at the time of diagnosis (i.e. more are found at the micro-invasive stage and fewer with distant spread round the body).

11. If I look carefully at how well the NCSP meets these WHO requirements, I can identify some important deficiencies and barriers to delivering a fully effective Cervical Screening Programme. I have highlighted the important ones.

a. the target population has been identified (women aged 20 to 69 years of age in New Zealand);

b. **individual women are not identifiable since there is not yet a population register from which eligible women can be identified.** Women must present themselves for a cervical smear and agree that they may be identified on the Screening Register.

c. Only limited measures are being implemented to guarantee high coverage and attendance. Most smears are taken in general practice although a significant proportion continues to be taken in Family Planning or Well Women clinics and in hospital clinics. General Practitioners are not contracted to undertake cervical screening at present and it is to their credit that participation is generally high. Only some General Practitioners send out a personal letter of invitation after the appropriate screening interval. No funding is given to General Practitioners to undertake education as to the benefits and limitations of cervical screening. Guidance on informed consent is patchy. Women must pay a fee for their smear to be taken by the doctor or a practice nurse. Some women may not be able to afford a cervical smear nor understand the benefit that can be derived from regular screening. Most women attending for a cervical smear do so during a consultation at which they wish to discuss other medical problems thereby limiting the time available. Many New Zealand women are never sent a personal invitation to attend for a cervical smear.

d. there are adequate field facilities for taking smears and adequate laboratory facilities to examine smears. However most smears are reported in commercial laboratories where there are economic pressures limiting the training and development for technical and junior medical staff. These commercial laboratories are often geographically distant from where the woman lives.

e. there is not yet an organised programme for external as well as internal quality control of smear taking and laboratory interpretation. While **t**he Independent Monitoring Group monitors the laboratory output and issues quarterly, there are no national external quality assurance (EQA) schemes

(proficiency testing scheme) organized by and specifically to assess the continuing competency of individuals in the NCSP. Many laboratory staff participate in the Australian EQA scheme but the results of this are confidential and not made available to the NSU. In addition, the reporting terminology is that used in Australia.

The NSCP standards covering smear taking cannot be enforced. The numbers of inadequate smears by smear taker is monitored for women on the Register but there is no audit for those not on the Register.

f. adequate facilities exist for diagnosis (colposcopy clinics and histopathology laboratories for reporting cervical biopsies), and for appropriate treatment of confirmed neoplastic lesions (colposcopy clinics and gynaecological oncology units). **While adequate resources exist for the follow-up of treated women, these apply only to women who are on the Screening Register. The follow up of women who opt off the Register remains the responsibility of the individual gynaecologist.**

g. there is a carefully designed and agreed referral system, and an agreed link between the women, the laboratory and the clinical facility for the diagnosis of an abnormal screening test. **However, the failsafe procedures for ensuring appropriate follow up of women with an abnormal smear test only apply to women on the Register. The follow up for women who opt off the Register is the responsibility of the individual smear taker. The same caveats apply to the management of any histological abnormality found.** The National Screening Unit provides information booklets about normal screening tests to all health professionals.

h. evaluation and monitoring of the whole NCSP cannot be organised in terms of incidence and mortality rates at the level of the total target population among those attending, <u>and</u> among those <u>not</u> attending, since there is not yet a population register to identify all eligible women and no way of identifying those women who have a cervical smear test but choose to opt off the Register. Quality control of these epidemiological data is being established subject to the limitations listed above.

12. The three principal factors influencing how much benefit can be obtained in any population are the proportion of eligible women who are screened (measured accurately

and not simply by estimate using out of date census data), the sensitivity of the screening test in detecting high grade pre-invasive disease (a combination of the quality of smear taking, slide preparation and laboratory assessment) and the adequacy of colposcopic investigation and treatment. The NCSP does not yet have access to a population register and the primary care teams who take the vast majority of smears have yet to be embraced as full and essential members of the cervical screening team, open to audit and quality assurance in the same way as the other component members of the programme.

13. Until all parts of the programme are appropriately in place and audited regularly, women will not see the full benefits that come from an effective screening programme. I am aware that the cervical cancer rate is decreasing in New Zealand but the same is true in many countries without a cervical screening programme. While much progress has been made in New Zealand, I believe that a fully effective screening programme would result in an accelerated decrease in the invasive cancer rate and the number of women dying from cervical cancer in New Zealand.

14. However, in order to achieve this, it is necessary to be able to identify all eligible women from a population register, identify all women attending for screening and to make primary care teams where the vast majority of smears are taken full partners in the NCSP. The appropriate parts of primary care records must be as available for audit as the records in other areas of the programme. These are fundamental deficiencies of the NCSP that the public must either change or accept the limitations they impose.

15. Another international expert, Professor Jocelyn Chamberlain, who was invited to undertake an independent review of BreastScreen Aotearoa in February 2002, shares my concerns about the lack of a population register. In the summary of her report she refers to " a number of factors that make the organisation and administration of efficient public health screening programmes difficult in New Zealand." She states that "The principle constraint ... is the lack of a national population register and public health information system. As a result the proportion of eligible women who are participating in the (breast screening) programme is unknown …".

16. There are several concerns and recommendations in her report that apply equally to the NZ Cervical Screening Programme. Professor Chamberlain commented that, despite their obvious dedication to their work, there was poor communication between groups of staff working in different aspects of the programme. This is also true for the NCSP. I was pleased that she found comprehensive systems in place to safeguard against poor performance. Unfortunately the same is not yet true of the NCSP.

17. As far as the Gisborne recommendations are concerned, there has been a vast amount of activity over the past three years and a cohesive, structured, well organized cervical screening programme is emerging. However, there is still a great deal of work to be done. Some of the recommendations have still to be implemented while others have proved difficult or impossible to implement (see Appendix 1).

18. The most important recommendations that have not yet been completed relate to the delays in the Cancer Audit (Recommendation 11.1).

19. Dr Colin Tukuitonga, Director of Public Health is now leading the Cancer Audit Group. Some unfortunate circumstances led to several key people resigning from the Cancer Audit Group between my first and third visits.

20. I was concerned to learn that the results of the first sample of the Cancer Audit will not be available until late 2003 and the second sample will not be completed before the middle of 2004. Thus the final audit outcome will not be known before late 2004. I am aware that ever since the publication of the Gisborne recommendations in April 2001, many have expressed concern that a 6 months timeframe was unachievable. However, this will be **three years longer** than the six months recommended by the Gisborne Inquiry. As I stated in my Interim Report following my visit in November 2001, **I cannot accept that New Zealand women must wait till late 2004 for reassurance that their National Cervical Screening Programme in the late 1990s was effective.**

21. I do not mean to infer that the Cancer Audit Group has been dilatory or negligent in their implementation. Quite the reverse. They have been very active. Some of the delay has been due to the need to obtain all 13 Ethics Committees' permission to approach women. This was not received until May 2002. Obtaining the individual women's

consent for participating in the Audit has been relatively successful but this has also proved to be a slow process. Other delays have related to the number of women requesting a face to face interview and the difficulties in extracting information from primary care records once consent has been obtained.

22. At the time of my visit in January 2003, the Group had not yet identified and agreed a contract with laboratories in Australia to undertake the review of cervical smears prior to women developing cervical cancer. Furthermore many laboratory staff in New Zealand have expressed concerns that a re-read in Australia may reflect badly on them simply due to the review laboratory staff being aware that these slides came from women who developed cervical cancer and to the different reporting practices in Australia. I understand that a contract is now in place and that the re-read has started.

23. I understand that the two pathologists on the Cancer Audit Group have been fully involved in designing the protocol for this re-read and I know that they have tried to meet the concerns of the laboratories as far as possible. While I understand the need to avoid bias and to utilize large laboratories with spare capacity in order to have the slides re-read in as short space of time as possible, I am sympathetic with the New Zealand laboratories' points of view. I hope that these concerns will be taken into consideration in interpreting the outcome of such a review and in the way any results are presented if published. This is particularly important for any slides re-read as equivocal or atypical.

24. There has been confusion within the medical fraternity about the purpose and methodology of the Cancer Audit. However, although initially cautious, I understand that the Royal Colleges are now supportive and have advised their members to co-operate. The Audit Group felt it was important to emphasize that the Cancer Audit is not designed as an audit of individual cases nor individual practitioners.

25. I have expressed concern about the small numbers of women in the two samples but have been advised that these are adequate to answer the questions posed. While I have been assured that the full sample will not be less than 500, there will not be 100 Maori women in the final audit as was intended. Of the 368 women with invasive cancer identified for the first sample, only 261 were found to be eligible for inclusion in the audit (71%). A further concern is that a significant number of women (the exact number

was not known) had a diagnosis of micro-invasive carcinoma. Micro-invasive cancers are very early cancers that do not produce symptoms and are usually diagnosed following an abnormal smear test in the same way as pre-invasive cancer (CIN3). They are normally treated in the same way as CIN3 with a "loop" or "cone biopsy". The more deeply invasive cancers usually produce symptoms that lead to the diagnosis and usually require more radical treatment such as hysterectomy. I am anxious that micro-invasive cancers may skew the results of the Cancer Audit if they form a significant proportion of the study group.

26. Furthermore I was disappointed to learn it is the view of the epidemiologist on the Cancer Audit Group, a view supported by the Director of Public Health, that **the Audit would not be able to answer whether there was a systemic problem of under-reporting in New Zealand in the late 1990s**. The epidemiologist felt there was a need to communicate to the right people that this Audit will not answer this question. She suggested that in order to establish whether or not there was systemic under-reporting, there would be a need to investigate the current individual laboratory performance and what had their previous performance been. This could involve a re-read of a substantial number of slides at independent laboratories. I understand that the National Screening Unit Manager has been informed of this. This has serious implications for Recommendation 11.2 (see comments paragraph 28). Nonetheless, the Cancer Audit Group is adamant that this does not detract from the value of the Audit and I share their belief that this audit will deliver important and useful information in due course even though it will not answer the question posed by the Gisborne Inquiry.

27. I am also concerned that a decision has been made not to carry out a full audit of all new cases of cervical cancer as they are diagnosed. I highlighted this in my first report and on each of my subsequent visits. I understand that each case is now being "reviewed" but not fully audited. I find the decision not to audit new cases as they arise, with the consent of the woman, incomprehensible. The woman's gynaecologist could request her consent soon after diagnosis and the audit carried out contemporaneously. The results could be combined into anonymised annual reports or three yearly reports but any specific deficiencies identified could be remedied immediately. **It is not best practice to carry out only periodic audits of women who develop cervical cancer**.

28. In view of the delay incurred in the Cancer Audit described above and the concerns that the Cancer Audit, as currently designed, will not address the question of systematic under-reporting in New Zealand in the late 1990s, **I regret that there is still no explicit evidence that the NCSP was safe and effective at that time.** I have pointed this out during each of my three visits.

29. At the time of my first visit in April 2002 and despite the delays to the Cancer Audit that were apparent even then, I was reluctant to push for immediate implementation of recommendation 11.2 (if there is doubt about systemic under-reporting then all women should be offered two smear tests 12 months apart). Laboratory quality assurance processes were only being introduced and I could not be sure that repeat tests would necessarily be reported to a better quality standard that that in place in the late 1990s. Laboratory quality standards have now been fully implemented for over 12 months and the monitoring in place at present suggests that an acceptable standard is being achieved. Since the routine screening interval is 3 years, most women on routine screening attending for a further smear test till end of 2004 will have had their smears read by laboratories meeting the current quality standards. Furthermore, I suspect that smear takers and the laboratory capacity might not be able to deliver a mass repeat testing programme within a shorter timescale.

30. However, serious consideration will have to be given to this when the Cancer Audit report is available if there is even a suggestion of systemic under-reporting or even localised under-reporting in some parts of New Zealand. In the meantime, it may be that particular consideration should be given to women who had been screened prior to 2002 before the laboratory quality assurance programme was fully implemented and who will not return for repeat testing (e.g. have reached the upper age limit for recall).

31. If the results of the Cancer Audit throw any doubt there had been an unacceptable level of under-reporting then recommendation 11.2 must be implemented either in full or in part. Since there is potential for a false negative result due to sampling during smear taking, I would recommend that women have their smear test repeated under the present quality assurance conditions rather than have their previous slides reviewed. I note that the Ministry of Health asserts that they must await the outcome of the Cancer Audit

before considering what to do about Recommendation 11.2. However, in my view, the Ministry must be held responsible for choosing to do nothing as regards this recommendation at this point in time.

32. The evaluation of the NCSP has been taken forward on several fronts but is limited by the failure to complete the cancer audit and to implement an ongoing audit of new cervical cancers.

33. Since the National Screening Unit does not contract directly with General Practitioners, there have been delays in implementing standards for smear takers. It has also been impossible to implement standards for private colposcopists. Women should be aware of this and insist that the same standards are met as for the hospital colposcopy service when attending for a private colposcopy. Women should follow the same approach for any non-public provider of any part of the screening programme.

34. The Independent Monitoring Group produce statistical reports on laboratory activity at regular intervals. Unfortunately smears are often sent to a community laboratory outside the geographic area. Thus laboratory profiles cannot be compared to the regional incidence of disease. However, since the NCSP is a public health programme I suggest that consideration be given to finding a way of directing NCSP smear tests to appropriate laboratories irrespective of commercial interests.

35. In implementing Recommendation 11.10, much attention has rightly been placed on standards for laboratories and colposcopy services. However, the quality of smear taking and enrolment of women into the NSCP still merit equal attention. The advice and direction of senior medical personnel is crucial to achieving a balanced approach to all aspects of the NCSP.

36. I remain unconvinced that the culture that had been developing in the HFA regarding management of the NCSP under the influence of Dr Julia Peters has been maintained. I was sad, but not surprised, given the concerns I expressed in my Interim Report, to note Dr Peter's resignation as Clinical Director in early 2002. I was also concerned to discover that the Cervical Screening Programme Advisory Group whom I met with on my first and second visits has been disbanded. Professional guidance, advice and

support from such a forum are essential. I understand that the National Screening Unit is in the process of establishing a new set of groups.

37. As discussed in my Interim Report, the Manager of the National Screening Unit is not medically qualified as specified in Recommendation 11.13. I note with interest that the NSU has restructured following my first visit and has introduced two new part-time Clinical Leader posts, one for BreastScreen Aotearoa and one for the National Cervical Screening Programme. These Clinical Leaders are at a fourth tier level and, as I understand it, share line management responsibility for staff with the full-time operational managers. A Public Health Leader for Screening has also been introduced at the third tier level but again this doctor has no line management responsibility for the cervical screening staff. I doubt whether the new clinical staff have the time and authority to ensure that all clinical risks are appropriately identified and managed through the operational processes. I remain concerned that despite the increase in the number of clinicians in the National Screening Unit, their level may prevent them from having appropriate influences on the screening policy and implementation. Thus I cannot agree that the NCSP is medically led as intended by Recommendation 11.13.

38. I do not feel it is appropriate that I should comment on the New Zealand legislative process. I am aware that delays consequent upon Parliamentary process have been the cause of considerable frustration. I note that legislative changes are in progress. While these changes appear to go a long way to meeting many of the Gisborne Recommendations, they fall short in some areas such as including primary care teams. It is my personal view that these changes will do little to facilitate ensuring a safe and effective NCSP and may indeed hinder it by restricting audit which to my mind is part and parcel of health care delivery and not an additional extra.

39. I understand that following a period of consultation, Cabinet decided in June 2002 to remain with the status quo as far as Kaitiaki Regulations are concerned. I must accept this decision but again I have concerns about how this impacts on monitoring and evaluation of the NSCP and the ability to ensure it meets the needs of Maori women. While I understand the sensitivities about selecting out the epidemiological data for ethnic groups, I believe that all women require the same protection as Maori women.

There may also be a need to protect the aggregated data for immigrant women and other minority groups.

40. A National Ethics Committee was established in 2002. The Minister of Health has agreed a work programme and the committee will report to the Minister in November 2003. This appears to be progressing in a sensible and structured way. However, I must await the outcome to see how this will impact on the NCSP and the implementation of the Gisborne Recommendations.

41. A workforce development strategy for the NCSP has been agreed and is in the process of being implemented. This recognizes the continuing problems attracting trained staff to New Zealand. A good start to delivery of training within New Zealand has been made with the training day attached to the National Cytology Meeting in 2002 which was a great success. However, the availability of appropriate training and development courses within New Zealand for all groups of health professionals involved in cervical screening is still inadequate. Much more needs to be offered to staff of all disciplines and within reasonable geographic distance to their normal places of work. Fees should be waived or at least affordable so that they do not become a barrier to participation.

There are no agreed processes for evaluating new technologies before these are implemented in the NSCP. I note that several commercial laboratories are using liquid based cytology as a routine screening test. While I am happy that this methodology can deliver benefits within a screening programme, I am not aware of appropriate training being required or even available within New Zealand for all laboratory staff screening and reporting the liquid based cervical samples. Nor does there appear to be specific standards and monitoring of outcome measures for liquid based cytology samples. Since other technologies such as automated screening, molecular markers and reflex human papillomavirus testing are commercially available, the NSU must control if, when and how these might be implemented as part of the NCSP.

42. While laboratories receive printouts of previous histories of women whose smears are being processed, this information is not yet available electronically in real time. Work has begun but much more work needs to be done on Information Technology systems to

allow easier transfer of information between smear takers, laboratories and colposcopy clinics and the Screening Register.

43. The lack of access to a population register to identify eligible women is a major deficiency of the NCSP. The National Screening Unit should work closely with the group developing a National Health Index Register and should lobby for this to be implemented as soon as possible. I support the statements of Professor Chamberlain in section 5.8 of her report. "I found the level of concern about protecting privacy extraordinary, even some health professionals I met expressing the view that they would suspect an invitation to be screened, … to be an invasion of their privacy. This attitude assumed to be in the public interest by guarding individuals' rights, has the converse result of lessening the public's chance of benefiting from preventative services. ….. If the popular view remains "Privacy at all costs", then it must be recognised that one of those costs is ineffective and inefficient public health systems. But if the public, as represented for example by women's groups and by Maori community leaders can be convinced of the benefits of using a population register, opinion at large will realise that excessive concern with privacy issues is harmful to health."

44. Other issues to which serious consideration should be given include:

- I believe that there is still poor communication between agencies. This was also highlighted in Professor Chamberlain's report. Several groups of professionals have said to me, *"We have a great will to make this right and we have expertise, ask us and listen to what we are saying"*.
- Communication with the public could be improved. I believe that institutional 'speak' and jargon is commonly used in reports that are published but the general public and even many health professionals do not understand it e.g. 'aggregate data of women'.
- The NCSP Registries have been rationalised to fewer sites but, for a population the size of New Zealand, further rationalisation should lead to even greater efficiencies. Effective electronic links between the Screening register, smear takers, laboratories and colposcopy clinics as well as the Cancer Register need to be implemented as soon as possible.

APPENDIX 1

MY EVAUATION AS TO PROGRESS WITH THE 46 GISBORNE INQUIRY RECOMMENDATIONS

Recommendation 11.1

The remaining two phases of the national evaluation designed by the Otago University team must proceed. Until those phases are completed the Programme's safety for women cannot be known. It is imperative that this exercise is completed within the next six months. Particular attention should be given to the discrepancy between the average reporting rate of high-grade abnormalities of Douglass Hanly Moir Pathology (2.5%-3.7%) for the re-read of the Gisborne women's smear tests and the current New Zealand national average for reporting high-grade abnormalities (0.8%). Unless this exercise is carried out the possibility that the national average is flawed and that there is a systematic problem of under-reporting in New Zealand laboratories cannot be excluded.

WORK BEGUN BUT MUCH STILL TO BE DONE see paragraphs 18-28

Recommendation 11.2

If the national evaluation throws doubt on the accuracy of the current national average then the Committee recommends that all women who are or who have participated in the Programme should be invited to re-enroll on the register as new entrants and they should be offered two smear tests 12 months apart. Women who have never enrolled on the Register or who have had their names removed from the Register should be invited through notices in the print media to also go through the process of having two smear tests twelve months apart

NOT YET IMPLEMENTED see paragraphs 29-31

Recommendation 11.3

A comprehensive evaluation of all aspects of the National Cervical Screening Programme which reflects the 1997 Draft Evaluation Plan developed by Doctors Cox and Richardson

should be commenced within 18 months. This exercise should build upon the three phase evaluation referred to in recommendation 1.

WORK BEGUN BUT MUCH STILL TO BE DONE see paragraphs 18-28

Recommendation 11.4

The Policy and Quality Standards for the National Cervical Screening Programme and the Evaluation and Monitoring Plan for the National Cervical Screening Programme prepared by Dr Julia Peters and her team must be implemented fully within the next 12 months.

BEING IMPLEMENTED (apart from primary care smear takers and private colposcopists).

Recommendation 11.5

There needs to be a full legal assessment of the Policy and Quality Standards for the National Cervical Screening Programme and the Evaluation and Monitoring Plan for the National Cervical Screening Programme to ensure that the requisite legal authority to carry out these plans is in place.

COMPLETED

Recommendation 11.6

The National Cervical Screening Programme should be thoroughly evaluated by lawyers to determine whether or not those persons charged with tasks under the Programme have the necessary legal authority to discharge them.

COMPLETED

Recommendation 11.7

The National Cervical Screening Programme should issue annual statistical reports. These reports should provide statistical analysis to indicate the quality of laboratory performance. They should also provide statistical analysis of all other aspects of the Programme. They must be critically evaluated to identify areas of deficiency or weaknesses in the program. These must be remedied in a timely manner.

BEING IMPLEMENTED. The 1990 – 2000 NCSP statistical report was not yet published at the time of my visit in January 2003 but the 2001 report was underway.

Recommendation 11.8

Meaningful statistical information should be generated from both the National Cervical Screening Register and the Cancer Register on a regular basis. Attention must be paid not only to laboratory reporting rates but also to trends and the incidence of the disease, assessed by regions that are meaningful to allow some correlation between reporting profiles laboratories and the incidence of cancer. Because cervical smear tests may be read outside the region in which the smear test is taken, a recording system needs to be devised which identifies the region where smears are taken.

NOT YET FULLY IMPLEMENTED see comments paragraph 34

Recommendation 11.9

The compulsory setting of a minimum number of smears that should be read by laboratories each year must be put in place. The proposal to impose three minimum volume standards on laboratories must be implemented. These are each fixed laboratory site will process a minimum of 15,000 gynaecological cytology cases; each pathologist will report at least 500 abnormal gynaecological cytology cases, cytotechnical staff must primary screen a minimum of 3,000 gynaecological cytology cases per annum. This should be implemented within 12 months

IMPLEMENTED These standards form part of the laboratory quality assurance contract

Recommendation 11.10

There needs to be a balanced approach, which recognises the important of all aspects of the National Cervical Screening Programme. The emphasis on smear taking and increasing the numbers of women enrolled on the Programme needs to be adjusted.

BEING IMPLEMENTED see paragraph 35

Recommendation 11.11

The culture which was developing in the Health Funding Authority regarding the management of the National Cervical Screening Programme under the management of Dr Julia Peters needs to be preserved and encouraged now that the Health Funding Authority has merged into the new Ministry of Health.

NOT YET IMPLEMENTED **see paragraph 36**

Recommendation 11.12

The National Cervical Screening Programme must be managed within the Ministry of Health as a separate unit by a manager who has the power to contract directly with the providers of the Programme on behalf of the Ministry. The Programme's delivery should not be reliant on the generic funding agreements the Ministry makes with providers of health services. For this purpose the unit will require its own budget.

IMPLEMENTED

Recommendation 11.13

The National Cervical Screening Programme should be under the control of a second or third tier manager within the Ministry. The Manager of the unit should as a minimum hold specialist medical qualifications in public health or epidemiology. As a consequence of the Programme's link with the Cartwright Report it has always had a female national co-ordinator. While there are understandable reasons for having the Programme managed by a woman it is not necessary for cervical screening programmes to have female managers. The cervical screening programme in New South Wales is managed by a male medical practitioner. The time has arrived for the National Screening Programme to be treated as a medical programme which is part of a national cancer control strategy. In the past its link with the Cartwright Report has at times resulted in its purpose as a cancer control strategy being compromised for non-medical reasons.

DECISION NOT TO IMPLEMENT **see paragraph 37**

Recommendations 11.14

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 to have ready access to all information on the National Cervical Screening Register.

IN PROGRESS Bill before Parliament

Recommendations 11.15

There needs to be a reconsideration of the Kaitiaki Regulations, and the manner in which those regulations currently affect the Ministry of Health gaining access to aggregate data of Maori women enrolled on the National Cervical Screening register. 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.

REVIEWED - BUT CABINET DECISION NOT TO IMPLEMENT

Recommendations 11.16

The present legal rights of access to information held on the Cancer Registry need to be clarified. The Ministry and any appropriately qualified persons it engages to carry out (external or internal) audits, monitoring or evaluation of cervical cancer incidence and mortality require ready access to all information stored on the Cancer Registry about persons registered as having cervical cancer.

IN PROGRESS Bill before Parliament

Recommendations 11.17

The Health Act 1956 requires amendment 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 the cervical cancer by all health providers who had a role in such treatment

IN PROGRESS Bill before Parliament

Recommendation 11.18

There needs to be change to guidelines under which ethics committees operate to make it clear that any (external and internal) audit, monitoring and evaluation of past and current medical treatment does not require the approval of ethics committees.

PART OF THE REMIT OF THE NATIONAL ETHICS COMMITTEE

Recommendation 11.19

There should also be a review of the operation of ethics committees and the impact their decisions are having on independently funded evaluation exercises and on medical research generally in New Zealand.

PART OF THE REMIT OF THE NATIONAL ETHICS COMMITTEE

Recommendation 11.20

Ethics Committees require guidance regarding the application of the Privacy Act and the Privacy Health Information Code. Ethics Committees need to be informed that the interpretation of legislation relating to personal privacy is for the agency holding a patient's data to decide. They would, therefore, benefit from having at least one legally qualified person on each regional committee.

PART OF THE REMIT OF THE NATIONAL ETHICS COMMITTEE

Recommendation 11.21

Ethics committees require guidance regarding the weighing up of harms and benefits in assessing the ethics of observational studies.

PART OF THE REMIT OF THE NATIONAL ETHICS COMMITTEE

Recommendation 11.22

A national ethics committee should be established for the assessment of multi-centre or national studies.

PART OF THE REMIT OF THE NATIONAL ETHICS COMMITTEE

Recommendation 11.23

The procedures under which ethics committees operate need to be re-examined. Consideration should be given to processes to allow their decisions to be appealed to an independent body.

PART OF THE REMIT OF THE NATIONAL ETHICS COMMITTEE

Recommendation 11.24

The National Cervical Screening Programme requires its own system to deal with complaints regarding the Programme's delivery. It also needs to have in place a user-friendly system which can respond to complaints of Programme failures, such as under-reporting. The difficulty that witness A experienced in having her medical misadventure recognised as a failure of the Programme and a failure of Gisborne Laboratories must be avoided in the future.

A PROTOCOL FOR COMPLAINTS IS BEING IMPLEMENTED

Recommendation 11.25

The National Cervical Screening Register needs to be electronically linked with the Cancer Register

IMPLEMENTED

Recommendation 11.26

Performance standards should be put in place for the National Cervical Screening Register and the Cancer Registry. The currency of the data on both Registers needs to be improved. The Cancer Registry should be funded in a way that enables it to provide timely and accurate data that is meaningful.

WORK BEGUN BUT MUCH STILL TO BE DONE

Recommendation 11.27

Standards for the National Cervical Screening Programme should be reviewed every two years and more frequently if monitoring indicates that some of the standards are inappropriate

BEING IMPLEMENTED Standards were agreed in 2001 but these require to be reviewed this year.

Recommendation 11.28

The Government in consultation with other bodies or agencies needs to ensure that there are sufficient trained cytotechnologists and cytopathologists and that there are appropriate training sites for them. There should also be a review of the training requirements and maintenance of competence of smear test readers and cytopathologists.

WORK BEGUN BUT MUCH STILL TO BE DONE (part of the workforce strategy) see paragraph 41

Recommendation 11.29

The Medical Laboratory Technologists Regulations 1989 should be amended to permit only registered medical practitioners with specialist qualifications in pathology and appropriate training in cytopathology or appropriately trained cytoscreeners to read cervical smear tests.

IMPLEMENTED (addressed through scopes of practice of Health Professionals Competency Act)

Recommendation 11.30

Legal obligations in addition to those mandated by IANZ must be imposed on all laboratories reading cervical cytology requiring them to retain records of patients' cytology and histology results (including slides, reports and any other material relating to the patient) in safe storage for a period of no less than five years from the date on which the results were reported. Secondly all laboratory owners must made legally responsible for ensuring that a

patient's records are readily accessible and properly archived during the five year storage period irrespective of changes in the laboratory's ownership through a sale of shares or a sale of the laboratory's business. The vendor of the shares or the laboratory's business should carry a primary legal responsibility to store the records, though the option to transfer this legal responsibility as a condition of the sale to the purchaser should be permitted. Similar provisions should apply to laboratory amalgamations. In this case the newly merged entity should be responsible for storing the records

IN PROGRESS Bill before Parliament (but I am uncertain whether this will address storage of records.)

Recommendation 11.31

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.

WORK BEGUN BUT MUCH STILL TO BE DONE

Recommendation 11.32

Standards must be developed for ensuring the accuracy of laboratory coding and this aspect of the National Cervical Screening Register must be subject to an appropriate quality assurance process.

WORK BEGUN BUT MUCH STILL TO BE DONE

Recommendation 11.33

The National Cervical Screening Programme should work towards developing a population based register and move away from being the utility based register that it now is.

NOT YET IMPLEMENTED see paragraphs 12-16 and 43

Recommendations 11.34

There should be a legal obligation on the Accident Compensation Corporation, the Medical Council and the Health and Disability Commissioner to advise the National Cervical

Screening Programme's manager of complaints about the professional performance of providers to the Programme when complaints are made to those various organisations about the treatment of a patient in relation to the Programme.

IN PROGRESS Bill before Parliament

Recommendation 11.35

Consideration should be given to the addition of an express requirement in the provisions governing medical disciplinary proceedings which would oblige the Tribunal seized of the facts of any given case specifically to consider whether there are any grounds for concern that here may be a public health risk involved. If that concern is present the tribunal should be required to inform the Minister of Health.

IN PROGRESS Bill before Parliament

Recommendation 11.36

There should be an exchange of information between the Accident Compensation Corporation and Medical Council regarding claims for medical misadventure and disciplinary actions against medical practitioners.

IN PROGRESS Bill before Parliament

Recommendation 11.37

It is recommended that the Programme liaise with the Royal College of Pathologists of Australia. In its submissions the Royal College advised that it believed that the collaborative relationship the college had with the Federal Government in Australia might be a model worth consideration by the Inquiry. It was suggested that it was appropriate to use medical colleges as an over-arching body to provide advice on issues. The benefit of this is, if the College is asked to provide an opinion on issues such as professional practice, quality or standards, it has access to the views from multiple professionals and also a critical evaluation of current literature in contemporary standard practices. It is suggested that the National Cervical Screening Programme, which has achieved a great deal, would benefit from greater professional input at a College level. In particular, it is suggested that a National Cervical Cancer Register and a Cervical Cancer Mortality Review process be a means of continually

evaluating the Programme's effectiveness. The Committee supports the College's submission and recommends that it be acted upon.

BEING IMPLEMENTED The National Screening Unit has been in discussion with all professional groups.

Recommendation 11.38

The Programme must provide women with information to enable them to make informed decisions about screening and provide them with information regarding potential risks and benefits. Until the Programme has been monitored and evaluated in accordance with the current three phase national evaluation the Programme has an obligation to inform women that the quality of the performance of some of its parts has not been tested. Women should also be informed that screening will not necessarily detect cervical cancer

IMPLEMENTED Information leaflets have been distributed. These will require to be updated when legislative changes are completed so that women are fully informed.

Recommendation 11.39

Medical practitioners need to be reminded that cervical smear tests are not a means of diagnosing cervical cancer. They need to be alert to signs of cervical cancer, and they should not place too much reliance on a patient's smear test results to discount the possibility of cervical cancer being present.

IMPLEMENTED

Recommendation 11.40

Primary screening of cervical smears should only be performed by individuals who are appropriately trained for that task. Consideration should be given to requiring pathologists to train as cytocreeners if they want to function as primary screeners.

IMPLEMENTED. As of 2002, no pathologists in New Zealand were primary screening cervical smears.

Recommendation 11.41

If cytology is a significant component of a pathologist's practice then he or she must participate in continuing medical education in that subject.

WORK BEGUN BUT MUCH STILL TO BE DONE (part of the workforce strategy)

Recommendation 11.42

If cytology is a major component of a pathologist's practice, it is desirable that he or she should have added qualifications in cytopathology; either a fellowship slanted towards cytopathology or a diploma in cytopathology. Consideration should be given to making this a mandatory requirement.

NOT YET IMPLEMENTED The Royal College of Pathologists has not progressed its Diploma in Cytopathology and no other suitable qualification is currently available.

Recommendation 11.43

Pathologists should be more open minded and critical of laboratory performance. They should be alert to the possibility that their practice or the practice of their colleagues may be sub-optimal.

BEING IMPLEMENTED

Recommendation 11.44

The Medical Council should ensure that systems are in place whereby medical practitioners are not deterred from reporting to it their concerns about the practice of an individual medical practitioner. Complainants should be assured that their reports will not result in them being penalised in any way.

IN PROGRESS Bill before Parliament

Recommendation 11.45

The screening programme should have in place a system over and above the audit and monitoring reports, to identify deficiencies in its process. A form of survey of users so that they can be proactive rather then reactive in the delivery of the programme would be useful.

NOT YET IMPLEMENTED

Recommendation 11.46

A process to ensure that the recommendations made by the Committee are implemented should be put in place

IMPLEMENTED