

**REPORT OF THE
MINISTERIAL INQUIRY INTO THE
UNDER-REPORTING OF CERVICAL SMEAR ABNORMALITIES
IN THE GISBORNE REGION**

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MIHI

He pukenga wai, ka puta te rākau, He pukenga tangata ka puta te kōrero Tihewa Mauri Ora

E ngā mana i ngā reo i ngā kārangarangatanga Iwi o roto i te Tairāwhiti tēnā ra koutou katoa. Kia rātou kua riro nei kei te Pūtahitanga o Rehua, kia rātou kua riro nei i te ringa kaha o Aitua, haere atu koutou, haere ki ngā tini ki ngā mano, haere koutou haere, haere.

Tēnei ra te mihi me te tangi atu kia koutou mō ā koutou manaaki ia mātou o te Pakirehua o ngā mahi whakaatu o te Waha o te Whare Tangata i roto i ngā marama e toru e noho ai mātou i Tūranganui-Ā-Kiwa. Kāhore e warewaretia e mātou ā koutou manaaki, āwhina, me ngā karakia e tukuna atu e ngā Kaumātua kia tō tātou Kaihanga mai te tūmatanga tae noa atu ki te rā whakamutunga.

Nō reira kia tau ngā manaakitanga ā Te Rungarawa ki runga ia koutou, te tūmanako, kia piki te ora ki runga i ngā mea e noho māuiui ana.

Tēnā koutou, tēnā koutou, tēnā tātou katoa.

ACKNOWLEDGEMENTS

The Committee of Inquiry wishes to acknowledge the many persons who participated in the inquiry in various roles including : the witnesses who gave evidence; those persons who provided the Committee with written submissions and other material; counsel assisting; counsel representing the parties and persons entitled to be heard; the secretarial assistance and those who helped in the transcription of evidence.

To ensure that all relevant evidence was heard in the 10 weeks which were available for that purpose the hearing times were extended. They often lasted into the evening and occasionally they extended to weekends. This placed a greater burden on counsel assisting, other counsel, other persons who appeared before the Committee, witnesses and the Committee's secretarial assistants, all of whom were obliged, at times, to be present in the evenings, on Saturdays, and

on one occasion on Sunday. In addition, the women affected agreed to reduce their number who would be giving evidence to enable the Committee to hear evidence from other witnesses whose evidence was relevant to terms of reference 3 to 8. Had it not been for the co-operation of counsel, parties and other persons who appeared at the inquiry, and particularly the women affected, the Committee would not have been able to complete the hearing of evidence within the 10 week period. The Committee wishes to record its appreciation of the efforts that so many people went to in order to ensure that the hearings were completed within time.

The Committee also wishes to acknowledge the significant work and effort that so many individuals over the years have put into the National Cervical Screening Programme. Without so much individual effort the Programme may never have started. The concerns about the Programme, which the Committee has identified in its report, are no reflection on their hard work. Much has been achieved in terms of the numbers of women now participating in the Programme. It is unfortunate that the Programme has been found to be wanting in some respects. Because the terms of reference have caused the Committee to look at these particular aspects of the Programme the other areas, where it may have been more successful, have not been addressed. This may create the impression for some that the examination of the Programme has been unbalanced and disregards the very worthwhile efforts of so many, who have worked to make the Programme successful. It is, however, a feature of committees of inquiry that they are appointed usually to examine issues of concern and not to report on successful outcomes. This report is not an examination of the entire Programme. Its focus is narrow; the Committee has looked at the Programme purely from the perspective of the terms of reference. This needs to be appreciated.

ESTABLISHMENT OF INQUIRY

The Minister of Health by letter dated 15 October 1999 appointed Ailsa Patricia Duffy QC, Druiscilla Kapu Barrett and Gordon Wright as a committee of inquiry under section 47 of the Health and Disabilities Act 1993. Subsequently in February 2000 Gordon Wright resigned and in his place on 9 March 2000 the Minister appointed Máire Angela Duggan. The Minister also extended to the Committee of Inquiry, pursuant to s.47(3) of the Health and Disability Services Act the powers of a Commission of Inquiry under the Commissions of Inquiry Act 1908.

TERMS OF REFERENCE

The terms of reference of the Inquiry were contained in the Minister of Health's letter of appointment. They directed Ailsa Duffy QC, Druiscilla Kapu Barrett CNZM and Máire Angela Duggan MD, FRCPC to conduct an Inquiry into the reading of abnormalities in cervical smears in the Gisborne region prior to March 1996, taking into account the results of the reviews of cervical cytology and histology samples carried out by the Health Funding Authority, on the following terms:

- (i) To determine whether there has been an unacceptable level of under-reporting in consequence of misreading and/or mis-reporting of abnormalities in cervical smears in the Gisborne region.
- (ii) If you determine that there has been an unacceptable level of under-reporting, to identify the factors that are likely to have led to that under-reporting.
- (iii) If you determine that there has been an unacceptable level of under-reporting, to satisfy yourselves whether or not this was an isolated case rather than evidence of a systemic issue for the National Cervical Screening Programme.
- (iv) To identify changes already made to legislation, to laboratory or other processes or to professional practices to address the risks of under-reporting of abnormalities in cervical smears.
- (v) To identify other changes agreed to be implemented, either by the Government or by professional organisations, that will further address any risks of under-reporting of abnormalities in cervical smears.
- (vi) To consider all relevant proposals that could ameliorate any risks of under-reporting of abnormalities in cervical smears and identify whether these are covered by 4 or 5 above and whether further changes are needed.
- (vii) To comment on any other issue the Inquiry Team believes to be of particular relevance.

- (viii) To make recommendations, consistent with section 4(a) of the Health and Disability Services Act 1993, as to any further action the Government or its agencies should consider taking.

1. SUMMARY OF CONCLUSIONS OF INQUIRY

Term of Reference One

- 1.1 The Committee has concluded that there is ample evidence to show that there was an unacceptable level of under-reporting at Gisborne Laboratories between 1990 and March 1996. The extent of this under-reporting can be seen from the smear tests of 16 women from the Gisborne region who have developed cervical cancer. Gisborne Laboratories had read their smear tests as normal. When the same smear tests were re-read in Sydney by Douglass Hanly Moir Pathology, they were all reported as cervical cancer or high-grade abnormalities.

Term of Reference Two

- 1.2 The Committee has concluded that the factors that are likely to have led to the unacceptable reporting in the Gisborne region can be placed in two groups. The first group of factors relates to the cytology practices followed at Gisborne Laboratories. These include : no specialised division of labour for reading cervical smear tests; inadequate internal quality control including no organised correlation of biopsy results with cytology results; inadequate systems and procedures; no external quality control; no accreditation with an independent quality control authority; Dr Bottrill's inadequate participation in continuing medical education; no awareness that the laboratory's practices put patients at risk.
- 1.3 The second group of factors relate to the delivery of cytology services in New Zealand between 1990 and 1996. These factors include : laboratories reading cervical cytology were not required to follow quality control processes or to be accredited with an independent quality control authority; *The Government Policy for National Cervical Screening (1991)* and the 1993 updated version in relation to laboratories reading cervical cytology were not well designed; the National Cervical Screening Register was not functioning optimally; there were no performance standards for laboratories, and there were no reliable data on laboratories' performance; there was no monitoring and evaluation of the performance of laboratories reading cervical cytology; the health authorities did not take heed of the warnings provided by the failures of screening

programmes in other countries; there was a failure to ensure all components of the programme were in place from an early stage. Furthermore, the Committee has concluded that the group of factors relating to the delivery of cytological services in New Zealand are all indicative of a failure to design and deliver a soundly based cervical screening programme. The Committee considers that the practices at Gisborne Laboratories which led to the unacceptable under-reporting continued for as long as they did because of the failure to deliver a soundly based cervical screening programme.

- 1.4 If those factors which the Committee considers the Programme lacked had been present the practice of cervical cytology at Gisborne Laboratories would have been improved or stopped. Either way the risk of unacceptable under-reporting would have been considerably reduced.

Term of Reference Three

- 1.5 The Committee has concluded that the under-reporting which occurred in the Gisborne region is evidence of a systemic issue for the National Cervical Screening Programme. Dr Bottrill's practice at Gisborne Laboratories cannot be seen as an isolated case of under-reporting. The factors relating to the delivery of cytological services in New Zealand between 1990 and 1996 which the Committee has concluded led to the unacceptable reporting in the Gisborne region, establish that the problem has a systemic origin.
- 1.6 The Programme lacked the essential components of an effective cervical screening programme when it was first established: it had no compulsory quality assurance of laboratories reading cervical cytology; it had a poorly designed management structure which split the responsibilities for parts of the Programme between various health agencies which resulted in confusion and consequent failure to discharge responsibilities; it had no quantitative performance standards against which to measure the performance of the various parts of the Programme; it had no central computerised registration system which would have allowed cytology, histology and cancer morbidity and mortality data to be inter-linked for each woman participating in the Programme; it failed to gather reliable relevant statistical information; it failed

routinely to monitor and evaluate all parts of the Programme's performance; it failed to ensure there was the legal power to do what was needed for the Programme to be effective; and it failed to exercise or to exercise properly legal powers that were available to achieve this end; it did not have the legal authority it required to function effectively and the existing legal authority it did have was not properly exercised.

- 1.7 Because the Committee considers that there are systemic issues for the Programme, it has reached the conclusion that the possibility that unacceptable under-reporting has occurred elsewhere in New Zealand cannot be excluded.

Term of Reference Four

- 1.8 Changes that have been made to the Programme since Dr Bottrill's retirement in March 1996 include the reconfiguration of the Register and its centralisation, thus making it more effective. The result of these changes to the Register means that technically data is now more easily available and more reliable for the purpose of statistical analysis which can be used for monitoring the Programme. The technical impediments to monitoring have now been removed. The laboratory accreditation with an independent quality control agency has been compulsory for laboratories reading cervical cytology since late 1996/early 1997. A new Medical Practitioners' Act was passed in 1995 and came into effect in 1996. This Act attempts to protect the health and safety of the public, and it provides mechanisms to ensure public practitioners are competent to practice medicine. The new Act introduces measures which ensures that medical practitioners are, and remain, competent to practice in their area of speciality. These provisions should assist in reducing the likelihood of a pathologist practising in the same or a similar manner to Dr Bottrill.

Term of Reference Five

- 1.9 The Government is presently looking at legislative change to allow monitoring and evaluation of the Programme to be carried out without the hindrance of legal obstacles which have presently prevented this valuable exercise from being undertaken.

Other Changes Agreed To Be Implemented By Government

- 1.10 Significant improvements have been made to the structure and delivery of the National Cervical Screening Programme. An effort has been made to have in place an operational policy with quality assurance standards which will enable the Programme technically to be better monitored and evaluated than in the past. There will now be quantitative performance indicators against which the Programme's performance can be measured. The work that has been done on the redevelopment of the Programme will go a long way to reducing the likelihood of an incident such as that which occurred in Gisborne happening again.

Term of Reference Six

- 1.11 The changes to legislation which are contemplated in Term of Reference Five do not in the Committee's view go far enough. The Committee is concerned that the discussion about the proposed legislation is becoming protracted and delaying the monitoring and evaluation of the Programme. The Committee considers that the choice to be made is simple. The legislation that currently regulates the Programme prohibits valuable information which is required for the monitoring and evaluation of the Programme being disclosed to independent evaluation teams without the consent of the women to whom the information relates. Unless this law is changed it is most unlikely that any effective monitoring and evaluation in respect of laboratory performance will proceed. The Committee considers that the time has come to introduce legislative change through primary legislation which will ensure that the Programme functions effectively and is safe for women. That requires legislation which will allow now-protected information to be made available to independent evaluation teams without the consent of women.
- 1.12 The Committee is also concerned to ensure that reconsideration is given to guidelines under which ethics committees operate. In the Committee's view, the decisions of ethics committees have unwittingly contributed to the delay in carrying out a comprehensive monitoring and evaluation of the Programme by an independent evaluation team. The Committee considers that the guidelines under which ethics committees operate need to be rewritten to make it clear that exercises of auditing,

monitoring and evaluation are not within the consideration of ethics committees. The Committee also considers that ethics committees may be having a detrimental affect on independently funded evaluation exercises, and indeed on medical research in respect of cervical cancer, and therefore recommends that the guidelines under which they operate be reconsidered in this respect as well.

Term of Reference Seven

- 1.13 The Committee has been requested to urge the Government to consider an appropriate method of compensating the women affected who can establish bona fide claims. The Committee's view is that Term of Reference Seven does not allow it to make this recommendation, and in any event it would be contrary to the philosophy of the Accident Insurance Act 1998, which prohibits anyone in New Zealand from suing for damages arising directly or indirectly out of personal injury covered by the Accident Insurance Act or any of the former Acts under which accident compensation has been dispensed in New Zealand. The women affected have suffered a medical misadventure and in the Committee's view they are covered by the Accident Insurance Act, or earlier accident compensation legislation, and therefore they cannot sue for personal injury. Therefore they have no legal entitlement to compensation for personal injury.
- 1.14 The Committee considers that the Kaitiaki Regulations require reconsideration. The Committee has learnt of incidents where the Kaitiaki Regulations have delayed or obstructed gaining information to Maori women's data on the National Cervical Screening Register which would be useful for the purposes of statistical analysis and monitoring and evaluating the Programme's performance. The Committee considers that consideration should be given to changing the regulations to allowing independent teams to have ready access to Maori women's data on the Register for the purposes of monitoring and evaluating the Programme.
- 1.15 The Committee has learnt that the Programme has no direct control over smear-takers and cannot therefore direct what information they provided to patients. The concern the Committee has on learning this, is that the Register is presently designed as an opt-off register, and in order for women to exercise their choice they must be told that they

have the right to opt-off. It is important that the Programme ensures that it has lines of control which it can enforce to require smear-takers to advise women of their rights as to whether or not they remain on the National Cervical Screening Register.

2. **PROCEDURE**

- 2.1 On 30 October 1999 the Committee of Inquiry had published notices in the public notice column of the New Zealand Herald, Wanganui Chronicle, Nelson Mail, Even Standard, Sunday Times (13 October), Otago Daily Times, Northern Advocate, Waikato Times, Christchurch Press, Hawkes Bay Today, Gisborne Herald, Daily Post, Bay of Plenty Times, Dominion and Evening Posts, inviting persons having an interest to register their interest with the Committee of Inquiry and explaining how to access information about the Inquiry by 0800 number, via email or through a website.
- 2.2 On 18 November 1999 the Committee of Inquiry held a preliminary conference at Gisborne. This was followed by a further preliminary conference at Auckland on 19 November 1999. The purpose of these preliminary conferences was to explain the scope and purpose of the inquiry, to discover the number of persons with an interest in attending the inquiry hearings and to provide them with an opportunity to comment on the procedures the Committee intended to follow. Subsequently Committee member Druis Barrett and Hanne Janes, one of the counsel assisting, attended a number of informal meetings and hui in the Gisborne region with the women affected by the misread cervical smear tests and other persons with an interest in the inquiry to provide further explanation about the inquiry. Then on 27 January 2000 a final pre-hearing conference and hui was held at Pakirikiri Marae, Tokomaru Bay.
- 2.3 The Committee of Inquiry held public hearings at Gisborne between 10 April 2000 and 11 May 2000. It reconvened in Gisborne on 3 July 2000 and sat until 6 August 2000. It then reconvened in Gisborne to hear submissions from 18 September 2000 until 29 September 2000. The hearings were largely conducted in public. In some cases persons who gave evidence wished parts of their evidence to be confidential and in this case suppression orders were made, but otherwise the evidence was given in public. Legal representation was permitted for those who requested it.
- 2.4 The Committee adopted an inquisitorial approach to the inquiry where possible. Persons who were given the status of parties or persons entitled to be heard under s.4A of the Commissions of Inquiry Act 1908 were permitted to lead evidence as of right

and with the leave of the Committee to cross-examine other witnesses. Leave to cross-examine was only granted when the Committee was satisfied that the area to be covered in cross-examination was relevant to the terms of reference. The Committee wishes to record that it was greatly assisted in its task by the evidence which the parties and persons entitled to be heard adduced.

2.5 Representatives of the news media, (print, audio and visual), sought and were given permission to cover and report on the Inquiry hearings. The evidence was also made available on the Inquiry's internet website.

2.6 After the close of the public hearings the Ministry of Health/HFA filed further evidence with the Committee to update it on the progress of various changes to the National Cervical Screening Programme. This evidence was circulated among the parties and persons having a recognised interest in being heard and they were given the opportunity to file evidence and submissions in response if they so wished.

3. **BACKGROUND**

- 3.1 The Minister of Health appointed the Committee of Inquiry in response to a growing public concern that cervical smear tests read at Gisborne Laboratories may have been misread with the result that cervical abnormalities were under-reported. These tests were carried out as part of the National Cervical Screening Programme.
- 3.2 The National Cervical Screening Programme was set up in response to a recommendation in the Report of the Cervical Cancer Inquiry 1988, which has come to be known as the Cartwright Inquiry. During the 1980s there was an increase in opportunistic cervical smear testing. Following on from this there was a call from some health professionals for an organised cervical screening programme. One of the medical controversies that came into focus before the Cartwright Inquiry was the value of organised cervical screening. In New Zealand the controversy was resolved by the recommendations in the Cartwright Report to institute organised cervical screening and the decision made by the Government of the day to implement the recommendations.

The Purpose Of Cervical Screening Programmes

- 3.3 Organised cervical screening is a systematic and co-ordinated programme designed to invite all women who are eligible for screening to undergo periodic sampling of the uterine cervix using the Pap test. The most frequent type of uterine cancer is a carcinoma of squamous cell type. The cancer develops over time from a pre-cancerous lesion. Pre-cancerous lesions have not invaded the tissues and are curable if detected and treated. The Pap test is named for Dr George Papanicolaou who showed that it was useful in detecting the abnormal cells shed from pre-cancerous squamous lesions of the cervix. Pre-cancerous lesions detected by the Pap test are classified as squamous intraepithelial lesions (SIL) and are subdivided into low-grade (LSIL) and high-grade (HSIL) lesions. The lesions differ in the degree of cellular abnormality and while both lesions can progress to cancer if untreated, the rate and interval varies. Cells of HSIL are more abnormal and the lesions progresses to cancer more frequently and faster than LSIL lesions. Pre-malignant lesions in biopsy samples of the cervix are also classified as LSIL and HSIL. Sometimes, however they are classified as CIN

(cervical intraepithelial neoplasia) and depending on the degree of involvement of the cervical lining by the abnormal cell proliferation, CIN is graded as CIN I (lower one third of the lining), CIN II (lower two thirds of the lining) and CIN III (upper one third or full thickness of the lining). Occasionally Arabic numerals are used instead of Roman numerals. LSIL equates with CIN I and HSIL encompasses CIN II and CIN III. The CIN terminology is sometimes used in addition or as a substitute for the SIL terminology in the reporting of abnormal smear tests.

3.4 A screening programme can be an effective tool to reduce the incidence of cervical cancer. If pre-cancerous abnormalities are detected and treated before they progress to cervical cancer the outcome for the patient will usually be good. However, these abnormalities are not easily detected by the patient or her clinician. Because they display no symptoms or signs there is nothing to alert a woman and as the pre-cancerous abnormalities are not visible to the naked eye her clinician is not likely to detect them on any visual examination of the cervix. Regular cervical smear tests should lead to the discovery of these abnormalities before the development of cancer. A Bulletin of the World Health Organisation 64(4): 607-618 (1986) titled *Control of Cancer of the Cervix Uteri* records that a 100% cure rate is possible if the presence of the disease is detected, diagnosed and treated during the pre-invasive stage. The European guidelines for quality assurance in cervical cancer screening, which were issued in 1993, state that 91% of squamous cell invasive cervical cancer cases can be avoided if women are screened every third year.

3.5 If a screening programme is to be successful cervical smear tests must be accurately read by the laboratory. Reading cervical smear tests is not a precise science. The interpretation of cervical smear tests is somewhat subjective and in some cases a smear test can be open to different interpretations. Pathologists accept that errors can occur and that occasionally a cervical smear test will be misread as a false negative or a false positive. A false negative result is one, which fails to identify someone who has a pre-cancerous abnormality or cancer of the cervix. A false positive result is one, which incorrectly identifies someone as having a pre-cancerous abnormality or cancer of the cervix. False positives will be detected because a positive smear test report will usually be followed by a biopsy (the taking of a tissue sample from the cervix) and examination of the sample would reveal no cervical abnormality. False negatives are

more difficult to detect as here an abnormal cervical smear test is misread as normal, and so it may go undetected until the woman next has a cervical smear test or has a biopsy of her cervix. A false positive cervical smear test can lead to a woman undergoing an unnecessary medical intervention in order to obtain a sample of tissue from her cervix. A false negative cervical smear test means the presence of a pre-cancerous abnormality will go undiscovered; this leaves a woman vulnerable to developing cervical cancer.

3.6 False negative reports do not only result from errors by pathologists or cytoscreeners. Other reasons may be that the smear was not taken adequately or that even though the smear was taken correctly none of the abnormal cells present were included. In a screening programme where a woman is being screened at regular intervals a false negative result will often be remedied by detection at the next screening. Cervical cancer is usually a slow-developing disease and in most cases the single under-reporting of a cervical smear test will not endanger a woman's health or life. Pre-cancerous abnormalities of the cervix can regress naturally; and if there is no regression, so long as the abnormality is detected at the next screening or before it has progressed to cervical cancer it can usually be treated successfully. Though, the longer the abnormality is left untreated the greater may be the thickness to which it has involved the cervical lining, in which case the patient will undergo a more invasive form of treatment than she may have undergone if the abnormality had been detected sooner. However, if a series of cervical smear tests of a patient are under-reported the consequences for that patient can be dire as once the disease has progressed to cervical cancer the necessary treatment has a severe impact on the patient and its outcome is more problematic.

3.7 Another respect in which accurate smear test reports are important is their impact on how a patient is treated. Because of the possibility of regression, particularly in the case of LSIL (a low-grade abnormality), the medical response to discovery is often to wait and see what develops. As HSIL (high-grade abnormality) has a higher rate of progression to cancer and a lower regression rate, standard practice is to refer the woman for colposcopic examination. Standard practice in New Zealand was for the pathologist reading the abnormal smear test to include in the report a statement with regard to the further management of the woman. This statement was dictated by the

smear findings. The colposcope is an instrument that magnifies the cervix and allows easier visualisation and biopsy of cervical abnormalities. Treatment is primarily guided by the result of the biopsy. Treatment options for pre-cancerous lesions include ablation of the lesion using laser or cryotherapy. Treatment for some lesions may require wider removal of the abnormal tissue and this may involve a cone biopsy, which can be performed using a knife, laser or electrocautery.

- 3.8 The Committee has learnt that some women regard these investigations and procedures as intrusive and unpleasant. Consequently a clinician will be reluctant to subject a patient to these procedures if an alternative approach is tenable. A clinician has to weigh the consequences for the patient of delaying investigation against the intrusion the patient may feel if referred for further investigation. Thus it is important for the patient's clinician to be given a smear test report which identifies accurately the grade of any abnormality that is present.
- 3.9 Because under-reporting of cervical smear tests can not be avoided the difficulty for health professionals and authorities is to be able to distinguish the false negative tests that are an accepted feature of cervical screening from unacceptable under-reporting. Errors of the latter type can all too easily be mistaken for false negatives which come within the acceptable range. Until a pattern of errors, which suggests something worse than the accepted false negative rate comes to light, an unacceptable level of under-reporting is difficult to detect. By the time such errors are detected the health of the women whose cervical smear tests have been under-reported may be in jeopardy. Detection of unacceptable under-reporting is made more difficult in New Zealand by the absence of any standard which defines the range of acceptable under-reporting. The consequence is that unacceptable under-reporting may go unrecognised until such time as it becomes glaringly obvious.
- 3.10 Cases of symptomatic cancer of the cervix, especially of advanced disease, in a screened population can be described as failures of a screening programme. The evidence the Committee heard from women who had participated in the National Cervical Screening Programme for a number of years and whose cervical smear tests had been under-reported makes plain the human consequences of a screening

programme failure. Their evidence was a stark reminder of the injurious impact the failure of a screening programme can have on its participants.

The Impact Of Cervical Cancer On The Patient

- 3.11 Some of the women affected by under-reporting of their smear tests were content to give their evidence in public and for their names to be published. Others were willing to give their evidence in public but they wanted their identities to remain confidential. The Committee made orders protecting the identities of those women who requested this protection. In their cases they were each given a number and this was how they were identified throughout the hearing. To enable the reader to appreciate the impact of cervical cancer on the patient the Committee has included in the report details of the experiences and the condition of some of the women affected. As these details include very personal information the Committee has chosen not to identify any of these women by name in the report.
- 3.12 Witness A was 31 years old when she appeared before the Committee. She was diagnosed as having cervical cancer when she was approximately 26 years old. At this time she was married, a mother of three children and she was working as a nurse. She and her husband hoped to have one more child. On 6 December 1994 she consulted her general practitioner as she was experiencing heavy painful periods, bleeding between periods and bleeding after intercourse. She was concerned that these were signs of cervical cancer. A cervical smear test was taken and on 7 December was reported as “ abnormal squamous cells present showing changes of a high-grade squamous intraepithelial lesion (CIN 2 or 3).” She was told by her general practitioner that her smear test result showed she had a pre-cancerous condition. Because witness A thought her condition was deteriorating she attempted to obtain an appointment with a gynaecologist. She said that she had difficulty obtaining an early appointment as she was told that she was a non-urgent case. She attributed this to her 7 December smear test report. She ultimately saw a gynaecologist on 20 February 1995; at this time a colposcopy was performed and she also had laser treatment to remove some cancerous cells. On 23 February she received a phone call from the gynaecologist; she was told she had cervical cancer and that she would need a hysterectomy. She said this news

came as a tremendous blow to her as she and her husband were planning to have another child.

- 3.13 She subsequently underwent a hysterectomy and also had 36 lymph nodes removed. Her ovaries were left, owing to her young age. Her left leg was partially paralysed and has been permanently damaged as a result of the operation. Six weeks after the hysterectomy she went for a follow up examination. At this time she was informed that the cancer had spread into her lymph nodes, that her prognosis was not good, and that without further treatment her survival rate was 50/50. She was given six weeks of external beam radiotherapy followed by internal beam radiotherapy; this treatment resulted in the destruction of her ovaries.
- 3.14 Witness A regularly had cervical smear tests. Apart from the smear test report of 7 December 1994 which had been reported as CIN 2 or 3, her other smear tests had all been reported as normal. She retrieved four of her smear tests. They had all been read by Dr Bottrill of Gisborne Laboratories Limited. Another smear test, that Medlab Hamilton had reported as normal in 1991, has not been reviewed, and, therefore, the status of this smear test is unknown. The tests were sent to a laboratory in Auckland for review. A review of witness A's smear tests showed:
- (i) A smear in November 1990 reported by Dr Bottrill as low-grade with a management recommendation that a repeat smear was required. Four independent pathologists who reviewed the smear test reported it as high-grade. A cytology review panel comprising five laboratories also read the smear test; four of the five laboratories reported it as high-grade, the other reported it as normal.
 - (ii) A smear test in December 1990 reported by Dr Bottrill as normal. The four independent pathologists read it as high-grade. All the laboratories in the cytology review panel reported it as high-grade.
 - (iii) A smear test in May 1992 reported by Dr Bottrill as normal. The four independent pathologists reported it as high-grade. Four of the five

laboratories in the cytology review panel reported it as high-grade; the other read it as normal.

- (iv) A smear test in December 1994 reported by Dr Bottrill as high-grade CIN 2 or 3. Three of the four independent pathologists reported it as invasive carcinoma, one reported it as suggestive of carcinoma, and when the cytology review panel reviewed it, five out of five laboratories reported it as invasive carcinoma.

3.15 Had any of witness A's smear tests in 1990 or 1992 been recognised then as displaying a high-grade abnormality, her disease may have been detected at a pre-cancerous or early cancerous phase. Her treatment options would have been less invasive and associated with lesser morbidity. It may be that the abnormality could have been removed from her cervix, and her uterus and ovaries left intact. When she gave evidence to the Committee she was a 31 year old woman who had lost her uterus and her ovaries, she had a permanently damaged left leg, and she was going to require hormonal therapy for a large part of the remainder of her life.

3.16 Witness B is a married woman aged 39 years, she has four children aged 17, 15, 12 and 11. Since 1989 she had regularly had cervical smear tests. She has been registered on the National Cervical Screening Register since 1992. In April 1996 she went to her GP because she felt unwell and she was experiencing a constant unpleasant discharge from her vagina. In August 1996 she returned to her general practitioner as she was experiencing incontinence. On 4 October 1996 a smear test was taken and reported by the Gisborne hospital laboratory as "atypical glandular cells of uncertain significance present. Repeat smear six months." She was advised that she did not have cancer and she was not to worry. Because the problem she was experiencing in the vaginal area did not clear up, she was referred to a gynaecologist, this resulted in a dilatation and curettage in order to sample the endometrial lining of the body of the uterus and cautery of the cervix on 10 March 1997.

3.17 Witness B's smear history is as follows:

- (i) Smear test November 1989 reported by Dr Bottrill as normal; test not available for re-examination
- (ii) Smear test April 1989 reported by Dr Bottrill as normal; test not available for re-examination
- (iii) Smear test January 1992 reported by Dr Bottrill as normal; on re-examination reported by Douglass Hanly Moir Pathology as high-grade
- (iv) Smear test April 1995 reported by Dr Bottrill as normal; on re-examination reported by Douglass Hanly Moir Pathology as high-grade

3.18 On 21 March 1997 witness B learnt that the biopsy results showed she had cervical cancer. On 16 April 1997 she had a radical hysterectomy and a bilateral pelvic lymph node dissection with conservation of her ovaries. Subsequently on 4 October 1999 she was advised that her smear test of January 1992, which had been originally read as normal had been re-read by Douglass Hanly Moir Pathology as high-grade/CIN 3. On 1 March 2000 witness B received a letter from the Health Funding Authority advising her that her smear tests of January 1992 and April 1995 had been re-read as high-grade. Her general practitioner wrote to her advising that it was likely that between 1992 to 1997 there were pre-cancerous abnormalities on her cervix:

“It appears that your original smear test in 1992 was misread and had this been read correctly at the time it is possible you may not have developed a cancer of the cervix and may not have required a radical hysterectomy. However, at that time you probably would have required some form of treatment such as a cone biopsy to treat the CIN 3 which is likely to have been present then.”

3.19 Witness C gave evidence to the Committee during the public hearings which ran from April until May 2000. At that time she was 53 years of age; married with five children. When the committee resumed its hearings in July she had died; her death can be attributed to cervical cancer. Witness C had smears taken in 1975, 1995 and 1996. Her smear test result for 1995 was reported by Dr Bottrill as normal. Her smear test result for 1996 was reported by the Gisborne hospital laboratory as normal. In March 1999 she visited her general practitioner as she had pain in her pelvis and legs, she felt

very unwell and she had some vaginal bleeding. Between March and June the vaginal bleeding increased. By 14 July she was bleeding heavily. On 14 July an attempt was made to take a smear but this was abandoned, as the smear taker was not able to access her cervix. On 18 August 1999 she saw a gynaecologist who performed a colposcopy and biopsy. A scan was also taken; this showed a tumour in her uterus. The gynaecologist advised her that she might have cancer. On 25 August 1999 she described herself as having terrible pain in the region of her stomach and her stomach was swelling. She managed to continue to go to work with the assistance of medication to relieve her pain.

3.20 On 26 August 1999 witness C was admitted to hospital for an operation. On the morning of the operation she was told that she had cancer of the cervix and the operation was abandoned; she was to have radiotherapy instead. On 2 September 1999 she had another biopsy; at this time she was told that Dr Bottrill had misread her smear in 1995, that he had read it as normal when it was high-grade, and that if he had read it correctly she could have been treated at that time. As the re-examination of smear tests the Health Funding Authority had carried out was only confined to smear tests read at Gisborne Laboratories the status of the 1996 smear read at Gisborne hospital laboratory is unknown. The Committee heard from more than one expert witness that once cervical cancer is present smear tests become very inaccurate and for that reason they are not used to diagnose cervical cancer. By 1996 witness C's condition may have advanced to the point where a smear test was no longer reliable; equally it is possible that the 1996 test was also misread. If the smear test was misread the misreading may be explainable as being a false negative which can occur in any laboratory or it may be an indication of unacceptable under-reporting from another laboratory. Unless the 1996 smear is re-examined or until a cancer audit of her case is carried out the answer to this question will not be known.

3.21 On 6 September 1999 witness C and her husband went to Palmerston North where for six weeks she had radiotherapy. She felt tired and sick. Once the tumour had shrunk, two smaller tumours were found behind it. One was on her bladder, the other on the top of her bowel. In November 1999 she received caesium rod treatment. In the last week of February 2000 it was discovered that she was passing faeces through her vagina, she was running a high temperature and she was experiencing a lot of pain.

Because of the ongoing pain she went into hospital in March 2000 and she had a colostomy. She told the Committee that she now felt useless as she was, “unable to be there”, for her family, that she had been forced to stop working which had placed a heavy financial burden on her family and that one of her daughters had been obliged to return to the family home to help care for her:

“Since my operation in March 2000 it has been even harder. I now have a bag that I have to clean and empty out. It just gets too much, but I suppose when I get used to it I will be all right. Each week I have to come into Gisborne Hospital for a check up. I continue to have good days and bad days. On the bad days I find it very hard to get out of bed. I have a lot of feelings that I cannot put into words. I feel anger and frustration – why me, why did this happen to my family?”

3.22 Witness D was 39 years old when she gave evidence. She is the mother of four children aged 19, 11, 5 and 3. She first had a smear on 26 August 1994, which was read by Dr Bottrill as normal. In August 1996 while she was in labour and due to give birth to her youngest child an internal examination of her pelvic region gave the midwife concerns about her health. Two days after her son was born she had a colposcopy and biopsy. Two days later, at a time when her son was only four days old, she was told that she had cervical cancer. On 23 September she was to have a radical hysterectomy, however, when the surgeon operated and saw the extent of her cancer, which had spread into her pelvic walls, he removed only one lymph node. She was told that radiotherapy and caesium rod treatment was the only way she could hope to improve. In October 1996 she had eight weeks of radiotherapy treatment and caesium rod treatment at Palmerston North Hospital. She returned home on 6 December 1996. The treatment made her feel very tired, nauseous and she had diarrhoea. She was unable to look after her children. At that time her children were 16 years old, 8 years old, 2½ and 5 months of age; all of them wanted and needed her attention.

3.23 In October 1997 Witness D’s marriage broke up. She said her husband left because he could not cope. In November 1997 she was advised that there was some hope that she would be all right. However, in January 1998 she felt a small lump at the edge of her vagina and when a colposcopy and biopsy was formed she was told that she was terminally ill, that there was nothing more that could be done for her, and she should get her affairs in order. But, she insisted on exploring the possibility of further

treatment and so she was referred to a specialist at Waikato Hospital. The specialist advised her that her only chance was to undergo a total pelvic clearance. The pelvic clearance was performed on 24 March 1998; witness D's cervix, ovaries, vagina and bladder were removed. From that time on she had to use a urostomy bag. While she was in hospital her children were placed in the care of Presbyterian Support Services.

3.24 On March 1999 she received a request from a member of the Cancer Society to have her smear test re-read. The smear was re-read on 21 April 1999 by Medlab Hamilton and was reported as high-grade. Later the smear was re-read by Douglass Hanly Moir Pathology who also reported it as high-grade. In November 1999 witness D was admitted to hospital with severe stomach pains caused by the adhesions and scar tissue from the pelvic clearance. On a second visit in November 1999 a routine chest x-ray discovered a lump in her lung. On 17 December 1999 a tumour was found in her lung and that, together with an infected lymph node, was removed. She was advised that the lump in her lung was a secondary cancer to the cervical cancer. She told the Committee that the damage to her children and herself has been far reaching.

3.25 The Committee also heard evidence from the daughter of witness E, who had died on February 1999 of cervical cancer at the age of 42. She was a married woman with four children. Witness E had been a nurse and her daughter described her as very health conscious. In 1997 she was told that she had cervical cancer. This bewildered her as she had regularly had smears every two to three years. Her smear test reports for 1988, 1991, 1993 and 1996 were provided to the Committee. Dr Bottrill had read the smear tests of August 1988, September 1991 and November 1993 and he had reported them all as normal. The smear test of September 1996 had been read at the Gisborne hospital laboratory and reported as "specimen is satisfactory although evaluation is limited by scant squamous epithelial cells. There is no evidence of cellular abnormality. Please repeat the smear in six months." At the time her smear was taken in September 1996 her general practitioner recorded in witness E's medical file that she was having "period problems and discharge." Witness E made a return visit her general practitioner in March 1997 and at that time her file shows the condition she had described in September was still present. Her general practitioner referred her to a gynaecologist. In April 1997 witness E was seen by a gynaecologist

who described her in his report as experiencing pelvic pain, heavy bleeding during her periods, some inter-menstrual bleeding and constipation.

3.26 Between 1997 and her death in February 1999 witness E had a number of invasive medical interventions to relieve the various symptoms she was experiencing. Her symptoms included heavy bleeding, pelvic pain and vaginal discharge. An operation report of 29 December 1997 describes her cervix as being “ completely replaced by necrotic tissue and proliferating tumour.” To relieve this she underwent an embolisation of the blood vessels supplying the tumour. On 27 January 1998 she was admitted to hospital with severe vaginal bleeding. Another embolisation was performed. On 31 March 1998 a medical report describes her as having:

“ a necrotic mass at the top of the vagina from which foul smelling discharge drains copiously. ...The odour is of concern to ...[witness E] as is her need for higher doses of morphine which she equates with increasing pain.”

3.27 In November 1998 during a visit to Christchurch she became seriously ill from renal failure; this was seen as a consequence of an extension of her pelvic malignancy. She had a nephrostomy and this meant her left kidney no longer functioned. By January 1999 she had developed a rectovaginal fistula and on 28 January 1999 to remedy the fistula she had a colostomy.

3.28 Witness F was 27 years of age when she gave evidence. She had been married for 7 years. She and her husband had no children but they had planned to have a family. However, on 1 February 2000 she had undergone a radical hysterectomy as she had early, (stage 1B), carcinoma of the cervix. She had registered on the National Cervical Screening Register in 1993. She had a regular history of smears:

- (i) In January 1991 and August 1991 smear tests were reported as normal by Dr Bottrill; these tests were subsequently re-read by Douglass Hanly Moir Pathology as normal.
- (ii) In June 1992 a smear test was reported as normal by Dr Bottrill; this test was subsequently read by Douglass Hanly Moir Pathology and reported as “abnormal squamous cells present, a high-grade lesion cannot be excluded.”

- (iii) In May 1993 a smear test was reported by Medical Diagnostics of Palmerston North as “scanty evidence of human papilloma virus present; specimen satisfactory for evaluation but limited by no endocervical component; outside normal limits, repeat in three months”. This smear test was re-read by Medlab Central of Palmerston North in March 2000 and reported as showing evidence of human papilloma virus and no dysplasia detected.
- (iv) In January 1994 a smear test was reported as normal by the Gisborne hospital laboratory. This smear test has not been re-examined.
- (v) In June 1996 a smear test was reported as normal by the Gisborne hospital laboratory. This smear test was re-read in March 2000 by Medlab Central; it was reported as normal.
- (vi) In October 1997 a smear test was reported as normal by Medlab Central. The Committee was told that this smear had been misplaced and so it was not re-examined.
- (vii) In June 1999 a smear test was reported by Medlab Hamilton as high-grade CIN3. This diagnosis led to a histological examination in August 1999. Witness F’s histology was diagnosed by Medlab Central as CIN 3. When it was re-read at National Women’s hospital in December 1999 the histology was diagnosed as squamous cell carcinoma stage 1B.

3.29 Witness F had a radical hysterectomy and pelvic node dissection. Her ovaries were conserved. This experience has had a traumatic impact on witness F and her husband. For her, there has been the physical pain that accompanies cervical cancer and its treatment. For her husband there has been the disruption to his family life and future plans and the reminder of the consequences of this disease as his cousin died of cervical cancer. Witness F and her husband had delayed starting a family until they were financially secure. They are now making inquiries about having children through a surrogacy programme. Their marriage is under strain. Witness F told the

Committee “I worry because [my husband] is still able to have his own biological children and I do not know what this will do to our relationship.”

The Unknown Scope Of The Under-Reporting at Gisborne

- 3.30 When the Committee first heard the evidence from women affected by misread smear tests it was disquieted to learn that in some cases interspersed with smear tests read as normal at Gisborne Laboratories and later found to be abnormal by the Sydney re-read, were smear tests that had been read as normal at other laboratories. The Sydney re-read of smear tests organised by the Health Funding Authority only involved a re-examination of smear tests read at Gisborne Laboratories. In some cases, for example witnesses A, C and F, they had some normal smear test reports from other laboratories that came after smear tests reports from Gisborne Laboratories. The Committee was, therefore, concerned to know if these smear tests from other laboratories indicated a more widespread under-reporting problem.
- 3.31 During the first session of the Committee’s public hearings it was advised that Professor David Skegg was attempting to carry out a cancer audit of all the cases of cervical cancer from the Gisborne region. At that time Professor Skegg thought this was the best way to determine if there had been an unacceptable level of under-reporting in the region. A cancer audit would also have revealed any errors in the reporting of other laboratories. However, the cancer audit could not proceed, as Professor Skegg was unable to gain access to the information he needed to carry out the audit. More will be said about this in the Committee’s report on term of reference three.
- 3.32 During the second session of the public hearings, the Committee learnt that Professor Skegg could not gain access to the information he needed for the audit to proceed. The Committee, therefore, proposed an approach which it considered would allow the information to be accessed. The Committee had been set up under s.47 of the Health & Disability Act. Pursuant to s.47 (3) the Minister had extended the Committee’s power by giving it the power of a Commission of Inquiry under the Commission of Inquiry Act 1908. As the information was relevant to the terms of reference the Committee considered the obstacles Professor Skegg had encountered could be

overcome if the Committee obtained the information by exercising its power under s.4D of the Commissions of Inquiry Act to subpoena the Director-General of Health to produce the information to it. The Committee could then appoint Professor Skegg as its agent under s4A and provide him with the information in order to carry out the cancer audit. Because the Committee had become concerned about the statistical information on cervical cancer incidence produced to it for other regions (Eastern Bay of Plenty and Northland) it had intended that the audit cover those regions as well as a region where the registered incidence of cervical cancer was low. Hence, the Committee issued a subpoena to the Director-General of Health requiring her to produce to it personal information of certain persons registered on the Cancer Register and the National Cervical Screening Register. It also suggested to the Ministry of Health that another way to obtain the information needed to enable the cancer audit to take place would be to appoint Professor Skegg or any other qualified person as a separate committee of inquiry under s.47 with the extended powers of a commission of inquiry.

3.33 However, by the second session of the public hearings Professor Skegg had reached the view that there was already sufficient evidence before the Committee to enable it to reach a conclusion on whether or not there had been an unacceptable level of under-reporting. For this reason he saw no need to proceed with his audit of cases of cancer in the Gisborne region. Nevertheless, the Committee continued to want the information sought in the subpoena as it considered that an audit of cervical cancer cases in three other regions would assist it to reach a view on term of reference three as to whether or not there was a systemic problem as regards the National Cervical Screening Programme.

3.34 The Ministry of Health provided information from the Cancer Registry. However, it refused to provide information from the National Cervical Screening Register. It contended that the Committee could not gain access to this information by using its powers under s.4D of the Commissions of Inquiry Act. The Committee had considered referring this question to the High Court for resolution pursuant to s.10 of the Commissions of Inquiry Act. In the end it did not do so as the Health and Disability Services Act was about to be repealed and there was no provision similar to s.47(3) in the draft version of the replacement legislation which was made available to the

Committee. This would have meant that a court ruling on the power of a committee of inquiry under s.47 to obtain this information under subpoena would have been of academic interest only.

3.35 In addition the Committee's concerns were somewhat allayed by the knowledge that the Ministry of Health's national evaluation of the National Screening Programme, which the Committee was informed would soon be underway, included a cancer audit. This would reveal any problems with other laboratories. However since the third session of the public hearings which took place in September the Committee has learnt that there has been little or no progress with the national evaluation. The circumstances surrounding this are more fully discussed in the report under term of reference three. Here it is sufficient to say that the national evaluation, which was first contracted for in June 1997, has still not been fully completed. The audit of cases of cervical cancer has not been carried out. The persons who originally formed the team responsible for the evaluation have resigned and the Ministry of Health is in the process of engaging other persons to carry out this task and is attempting to frame the evaluation in such a way that it can overcome the obstacles to obtaining certain information which up to the present time have stalled the evaluation. The result of all this is that the questions, which arise from the other laboratories' reports on smear tests for women in the Gisborne region, remain unanswered. Until an audit of these women's cases is carried out, whether or not other laboratories under-reported their smear tests will remain unknown.

The Response To The Under-Reporting Problem

3.36 Initially the nature and scope of the problem in the Gisborne region was not realised. Some persons thought that the under-reported smear tests from Gisborne Laboratories could be explained as the usual run of false negative tests which any pathologist can expect to make. But, as more errors came to light, others began to think that something more serious had occurred.

3.37 On 7 September 1995 witness A had successfully established a claim for medical misadventure before the Accident Compensation Commission. She also filed a complaint with the Medical Council. Her complaint was upheld and Dr Bottrill was

found guilty of conduct unbecoming a medical practitioner under the Medical Practitioners Act 1968. Witness A's case had been drawn to the attention of the Cancer Society's local representative in Gisborne, and the circumstances of her case (but it seems not her identity) were also communicated to the regional co-ordinator of the National Cervical Screening Programme. In 1996 Witness A commenced a civil proceeding in the High Court against Doctor Bottrill. She claimed that the misreading of her cervical smear tests was negligent. The claim failed as the evidence before the High Court did not support an award of exemplary damages, as these are only awarded to punish the defendant in cases where the negligence is gross. On 19 March 1999 the High Court found that Doctor Bottrill had acted negligently and that were it not for the Accident Rehabilitation and Compensation Act 1992 which prohibits awards of compensatory damages for personal injury, including medical misadventure, Witness A would have been awarded substantial compensatory damages. The judgment reads:

“I have no doubt that Dr B was guilty of negligence. Indeed, it would be open to a court to find negligence on the basis of one badly read slide as in *O'Shea v Sullivan and Macquarie Pathology* (1994) Aust Torts Reports 81-336. In jurisdictions where compensation is available on the establishment of fault, Mrs A would undoubtedly recover substantial damages for both her economic and non-economic loss.”

3.38 The High Court had granted Witness A name suppression and so her identity and the region in which she and Doctor Bottrill lived could not be published, nevertheless, there was extensive publicity about the nature of the High Court proceedings. This had the effect of encouraging other women whose cervical smear tests had been read by Doctor Bottrill to come forward. In March 1999 the barrister who had acted for Witness A wrote to the Ministry of Health/Health Funding Authority outlining his concerns for the safety of women who had had their cervical smear tests read by Doctor Bottrill. By this time others including the medical officer of Health of Tairāwhiti Healthcare, Dr Bruce Duncan, were becoming concerned about the possibility that Dr Bottrill had misread a number of cervical smear tests.

3.39 The Health Funding Authority began consulting with various persons on the need for a re-examination of the cervical smear tests read at Gisborne Laboratories. It prepared an initial project brief that contemplated having the cervical smear tests of the women considered to be most at risk re-examined. The impression it gained from meeting with the members of the Royal College of Pathologists of Australasia was that, apart

from considerations of maintaining confidence in the National Screening Programme, a re-examination of the smear tests was unnecessary. However, as the project brief became more widely distributed it became clear that others thought differently. No clear consensus view emerged. Some persons thought the scope of the proposed re-examination did not go far enough, some supported what the Health Funding Authority proposed and others thought nothing should be done. The Health Funding Authority's response was to set up a multi-disciplinary expert advisory group. The group included Dr Brian Cox, an epidemiologist, Dr Ronald Jones, a specialist in gynaecological oncology, Dr Norman Fitzgerald, a pathologist, and Dr Bruce Duncan. The Committee was told by Ms Tracey Mellor who gave evidence for the Health Funding Authority that at a meeting on 12 May 1999 the advisory group came to consensus fairly rapidly that a full re-examination of the smear tests was required and that there was no alternative. The Health Funding Authority had not contemplated an exercise of this magnitude. However, the advice of the advisory group was accepted that same day and on 13 May 1999 the Health Funding Authority issued a press release to inform the public of its decision.

- 3.40 Once the Health Funding Authority decided to have the cervical smear tests read at Gisborne Laboratories re-examined it moved quickly to implement its decision. It engaged Douglass Hanly Moir Pathology of Sydney to carry out the exercise. It also took various steps to alert women who were potentially at risk to that possibility. Once the results from Douglass Hanly Moir became available the Health Funding Authority realised that the under-reporting appeared to be extensive. It took various steps to respond to wider concerns which the re-examination of the smear tests from Gisborne Laboratories had drawn to its attention. The Committee has not addressed the response of the Health Funding Authority in any detail, as it has not considered it to be relevant to answering any of the specific terms of reference. However, the Committee records how impressed it has been with the Health Funding Authority's response to what occurred in the Gisborne region and how extremely hard working its officers were in carrying out their role in this response.

4. TERM OF REFERENCE ONE

Has there been an unacceptable level of under-reporting in consequence of misreading and/or mis-reporting of abnormalities in cervical smears in the Gisborne region?

4.1 The Committee of Inquiry is satisfied that there has been an unacceptable level of under-reporting of abnormalities in cervical smear tests in the Gisborne region during the period from 1991 to March 1996. The Committee has only heard evidence in regard to cervical smear test readings by Gisborne Laboratories Limited. It has heard no evidence which would have allowed it to determine whether or not there had been under-reporting of cervical smear tests read in the laboratory at Gisborne Hospital and therefore it is unable to comment on the performance of that laboratory's reading of cervical smear tests during the relevant period. Its finding on the presence and the level of under-reporting of cervical smear tests in the Gisborne region is based only upon an analysis of the performance of Gisborne Laboratories.

4.2 Because the terms of reference directed the Committee to look into the reading of abnormalities in cervical smear tests in the Gisborne region prior to March 1996 it has not heard sufficient evidence on this topic post March 1996 to be able to comment on laboratory performance since then. It has heard no evidence to suggest that there has been an unacceptable level of under-reporting of cervical smear tests from the Gisborne region since March 1996. However, as a comprehensive evaluation of the performance of the National Cervical Screening Programme has never been completed and laboratory cervical smear test reporting is still not routinely monitored the Committee considers that the quality of cervical smear test reporting for this later period is unknown.

4.3 Dr Bottrill read most of the cervical smear tests that were carried out in Gisborne Laboratories. There were times when either due to Dr Bottrill's absence on leave or because extra help was needed locum pathologists were used to read the cervical smear tests. However, the evidence shows that the reading of cervical smear tests by these persons can not account for the under-reporting which has occurred.

4.4 By the end of the inquiry hearings there was clear evidence before the Committee that among cervical smear tests that were carried out in Gisborne Laboratories, during the period under consideration positive tests had had been under-reported to an unacceptable extent. Initially, the task of determining whether or not there had been an unacceptable level of under-reported cervical smear tests in the Gisborne Region seemed intractable. The reading of smear tests is based upon a microscopic evaluation of the smear test by one or more observers. Evaluation is prone to human error for a number of reasons, chief amongst them being the difficulty in consistently maintaining the high level of concentration needed to detect the abnormal cells and also because the interpretation of the abnormal cell is somewhat subjective. Some under-reporting of cervical smear tests in consequence of misreading and/or misreporting is therefore inevitable. Even in well run laboratories with state-of-the-art technology and appropriate quality control systems cervical smear tests can be under-reported.

4.5 Failure of the laboratory to detect pre-cancer or cervical cancer cell changes when the abnormal cells are actually present in the smear test is referred to as a false negative result. A false negative result is defined in a number of ways, and consequently the false negative rate can be measured in a number of ways. One approach is to measure how many high-grade lesions confirmed by biopsy had a negative smear test report 6 months prior to that biopsy. Another is to re-read all or a proportion of a laboratory's negative smears to measure how many were actually abnormal. While there are published standards for false negative rates using these definitions in other countries, from the evidence given, the Committee understood that the false negative rate of any laboratory could only be compared to another laboratory or a published standard if the methodologies for measuring the false negative rate were the same. While the Committee was not specifically charged with investigating the over-reporting of cervical smear abnormalities in the Gisborne region, this form of laboratory error, ie the reporting of a cellular abnormality when none is present in the test, did come into evidence during the Inquiry. This type of error is also called a false positive result and similar to a false negative result can be defined and measured in a number of ways. Published standards are also in existence in some countries. The same caution must be used when comparing false positive rates from different laboratories and published standards as is used when comparing false negative rates.

- 4.6 The Committee's task was made even more difficult by the fact that standards did not exist for New Zealand and the methodologies used by the Health Funding Authority to determine the false negative rate of Gisborne Laboratories were not comparable to those of published methodologies. In some countries with established screening programmes quantitative standards for reporting cervical smear tests have been set to provide a measurement of laboratory performance. During the time that Dr Bottrill was in practice the National Cervical Screening Programme imposed no quantitative standards on laboratory performance. Apart from extreme cases of under-reporting, which on any view would be unacceptable, without clearly set standards against which to measure a laboratory's performance it is not easy to distinguish unacceptable under-reporting from the accepted level of under-reporting that is inherent in cervical smear evaluation.
- 4.7 The absence of quantitative standards over the relevant period and the inevitability of some under-reporting have meant that the Committee of Inquiry has had to determine for itself what is an unacceptable level of under-reporting of cervical smear tests. The Committee was advised by more than one expert witness of the need for it to take a common sense view of the matter. The Committee agrees with this advice. In the end it has chosen to consider the combined effect of a number of indicators to assist it to report on term of reference one. The Committee recognises that no single indicator may be sufficient to reach a conclusion on the level of under-reporting, however, it considers that the combined effect of these indicators convinced it that there had been an unacceptable level of under-reporting. The Committee considered that to reach a common sense view it would adopt the test the common law uses to determine civil issues: namely the balance of probabilities. However, having heard all the evidence the Committee was in no doubt whatsoever that there had been unacceptable under-reporting.
- 4.8 The Committee has received evidence from more than one source which shows that at Gisborne Laboratories there was a failure to read correctly the cervical smear tests of a large number of women in the Gisborne region and that many of these women went on to develop cervical cancer which could have been prevented if their pre-cancer had been detected earlier on. When the results of the re-examination of Gisborne cervical smear tests by Douglass Hanly Moir Pathology (the Sydney re-read) are compared

with the original smear test reports from Gisborne Laboratories the high level of under-reporting becomes apparent. In total 22,976 slides were sent to Sydney for re-examination. Of these slides Dr Bottrill had originally read 20,860 and the locums, employed by Gisborne Laboratories, had read 2,116. From these figures, which appear in exhibit TM/HFA/097, it can be seen that the impact of the locums' reading at Gisborne Laboratories was negligible.

4.9 The Committee has had the benefit of hearing from a number of expert witnesses whose evidence on this term of reference has been of great assistance to the Committee. The witnesses included:

- (i) Dr Annabelle Farnsworth MB BS(Hons), the director of cytopathology at Douglass Hanly Moir Pathology;
- (ii) Dr Euphemia McGoogan MB ChB, member of the Royal College of Pathologists. Her area of special expertise is cervical cytopathology. She is currently Pathology Patient Services Director for the Lothian University Hospitals NHS Trust in Edinburgh and as such is responsible for the largest combined morbid anatomy, histopathology and cytopathology service in the UK;
- (ii) Professor David Skegg BMedSc; ChB (Otago); DPhil (Oxon); FFPHM; FAFPHM; FRSNZ, Professor of Preventive and Social Medicine at the University of Otago Medical School. He has carried out extensive research on the causes and control of cancer.
- (iii) Dr Brian Cox BSc (Hons) MB ChB PhD, specialist in public health medicine and an epidemiologist. He is employed by the University of Otago as a Senior Research Fellow and he is the director of the Hugh Adam Cancer Epidemiology Unit, Department of Preventive and Social Medicine, University of Otago Medical School. He is a Fellow of the Australasian Faculty of Public Health Medicine and he is registered as a specialist in public health medicine.

(iv) Dr George Wain MB BS, Fellow of the Royal Australian College of Obstetricians and Gynaecologists. He holds the Certificate of Gynaecological Oncology of the Royal College of Obstetricians and Gynaecologists. He is the Director of Gynaecological Oncology at Westmead Hospital in Sydney and a Senior Lecturer in Gynaecological Oncology at the University of Sydney.

4.10 The Health Funding Authority provided for the Committee a report titled the Action Update Report, (received as exhibit TM/HFA/087). This report updated the results of the Sydney re-read as compared with the results of Gisborne Laboratories. In the course of her evidence to the Committee Dr Farnsworth produced a document (exhibit AF/HFA/004) which set out her analysis of the data in the Action Update Report. She elaborated on this analysis when questioned by the Committee. The analysis Dr Farnsworth provided in exhibit HF/HFA/004 produced three discrete indicators of the two laboratories' performance. These three indicators were enough to satisfy Dr Farnsworth that there had been an unacceptable level of under-reporting of cervical smear tests at Gisborne Laboratories.

4.11 For the purpose of understanding the first indicator it is important to note that in the interchange between Dr Farnsworth and the Committee the term "false positive reporting" was defined as the percentage of smear tests which were not confirmed by the biopsy or for which there were no biopsy results. However, when Dr Farnsworth came to give evidence on the second indicator the definition of false positive changed from that used in the first indicator. Here the term "false positive" referred to the percentage of women with normal histology who had been reported as having high-grade/cancer cytology. To arrive at these percentages the denominator used to calculate the first indicator included all the women with a high-grade/cancer cytology result recorded in tables 5.3 and 5.4 of exhibit TM/HFA/087 regardless of whether or not they had histology results recorded as well. The denominator used to calculate the second indicator only included those women recorded in tables 5.3 and 5.4 who had histology results and was restricted to women with negative histology. Women who did not have histology results were not included. Similarly, for the third indicator the group of women being considered, and the denominator used to calculate the

percentages, is different to the other two indicators. It follows that because the denominators for each group are different each indicator must be viewed discretely.

First Indicator

- 4.12 The first indicator is taken from the proportion of women with high-grade/cancer cytology who were later confirmed on biopsy as having high-grade/cancer histology. It is a measure of the accuracy of high-grade/cancer cytology reporting. This indicator is derived from data set out in tables 5.3 and 5.4 of exhibit TN/HFA/087. The data in table 5.3 refers to the original reading by Gisborne Laboratories and in 5.4 to the re-reading by Douglass Hanly Moir Pathology. Table 5.3 comprises 3 sub-tables (5.3(a) to (c)) of data which set out the histology results from initial colposcopy in relation to the highest original smear test result, for all women over three time periods. The three time periods were 1991 to February 1996, March 1996 to April 1999, and May 1999 to the present. Evidence before the Committee explained that the data was presented in this format in order to allow for the effect of time on the analysis and interpretation. The importance of this related to the fact that cervical pre-cancer can over time regress to normal or a lesser pre-cancerous lesion, persist unchanged, or progress to a more severe pre-cancerous lesion or cancer. Dr Farnsworth explained that for the purposes of the inter-laboratory comparison, ie the comparison of Gisborne Laboratories with Douglass Hanly Moir Pathology, the impact of time would be the same for both laboratories and would not need to be allowed for. The results in exhibit AF/HFA/004 relate to aggregated data from the three time periods.
- 4.13 From table 5.3 the proportion of women who had high-grade/cancer cytology reports from Gisborne Laboratories and who were subsequently confirmed by biopsy as having high-grade/ cancer histology can be seen. Table 5.4 also comprises three sub-tables (5.4.(a) to (c)) which set out the histology results from initial colposcopy, in relation to the highest smear result read by Douglass Hanly Moir Pathology, for all women over the same three time periods as in table 5.3. From table 5.4 the proportion of women who had high-grade cytology including cancer reports from Douglass Hanly Moir Pathology and who were subsequently confirmed by biopsy as having high-grade/ cancer histology can be seen.

4.14 When table 5.3 is compared with table 5.4 two points emerge. The first is that both laboratories had approximately the same proportion of high-grade/cancer cytology confirmed as high-grade/cancer by histology. The original smear test results showed that 37 out of 72 women who were reported as having high-grade/cancer cytology were confirmed as high-grade/cancer on biopsy. This makes the confirmation rate for high-grade/cancer cytology reported at Gisborne Laboratories 51.3%. The results of the Sydney re-read showed that 132 out of 260 women who Douglass Hanly Moir Pathology reported as having high-grade/cancer cytology were later confirmed as high-grade/cancer on biopsy. This makes the confirmation rate for high-grade/cancer cytology reported at Douglass Hanly Moir Pathology 50.7%. These results indicate that each laboratories' confirmation of their smear results of high-grade/cancer at approximately 50% was much the same. The remainder, were either not confirmed by the histology or there was no histology result yet available. Dr Farnsworth gave evidence that some of these unconfirmed high-grade/cancer cytology results could be due to false positive reporting or the reporting could be correct as their disease status was unknown until they had undergone a biopsy. The Committee understood from this evidence that the 50% confirmation rate of each laboratory was a minimum rate and that the inclusion of additional histology results might increase the confirmation rate of one or both laboratories, but would not decrease it.

4.15 Because the re-read exercise had been carried out to ascertain if women whose cervical smear tests had been read at Gisborne Laboratories were at risk there was a concern that when the smear tests were re-read at Douglass Hanly Moir Pathology the screeners, who would know that the smear tests were being re-read, would be overly cautious in their approach. If the screeners at Douglass Hanly Moir Pathology had been overly cautious this could lead them to over-report smear tests as high-grade/cancer. In this case the results of the re-reading would not provide a fair basis for comparison with the original results of the readings at Gisborne Laboratories. For this reason doubts had been raised about the usefulness to the Committee of the information coming from the Sydney re-read. However it became clear to the Committee, when it heard the evidence of Dr Farnsworth of Douglass Hanly Moir Pathology, that both laboratories had a similar rate of accuracy in reporting high-grade/cancer. If Douglass Hanly Moir pathology had over-reported the smear tests relative to Gisborne Laboratories, its confirmation rate of high-grade/cancer cytology

would have been less than Gisborne Laboratories. The similarity in their rate of accuracy was enough to allay any doubts the Committee might otherwise have had about using the results from the Sydney re-read as a basis for comparison with the original results from Gisborne Laboratories. Hence, the Committee was confident about using the information from the Sydney re-read results for the purposes of determining if there had been under-reporting of cervical smear tests at Gisborne Laboratories.

- 4.16 The second point to emerge from a comparison of table 5.3 with table 5.4, is the more significant. When the original results are compared with the results of the Sydney re-read a wide discrepancy between the laboratories in the number of reported high-grade/cancer cytology results becomes readily apparent. At Douglass Hanly Moir Pathology 132 smear tests had been read and confirmed by biopsy as high-grade/cancer which is 3.5 times more than the 37 smears read as high-grade/cancer by Gisborne Laboratories. This wide discrepancy between the number of cervical smear tests recognised by Douglass Hanly Moir Pathology as showing high-grade/cancer abnormalities, and the number recognised by Gisborne Laboratories shows that at Gisborne Laboratories there was a frequent failure to recognise the presence of high-grade/cancer abnormalities. Dr Farnsworth's evidence on this point was:

Question by Professor Duggan: I'm going to put this statement to you and perhaps you can comment on it. What these calculations [in exhibit TM/HFA/87] indicate to me is that the confirmation by the biopsy of a smear called cancer or high-grade for both laboratories over the three time periods are essentially the same?

A That's right.

Q However, the number of smears confirmed by Sydney [Douglass Hanly Moir Pathology] as high-grade is 3.5 times more than the number of smears confirmed as high-grade by Dr Bottrill's laboratory?

A That's right.

...

Q What does that result mean to you?

A It actually means to me that ...both confirmation rates are essentially the same, but it would confirm to me that the extra or the % of extra high-grades that we found were in fact true high-grades.

Q At the same rate as Dr Bottrill?

A At the same rate as Dr Bottrill's.

...

Q Dr Farnsworth, you may recall that yesterday one of the very first points I inquired of you was in relation to the histology.

A Yes.

Q Was the reading of the histology for the period for both laboratories the same?

A It would be very much the same.

Q It's the same. And any regression of disease would be the same for both laboratories?

A Exactly.

Q And thereafter is it correct to say that false positive reporting – ie the 50% that weren't recognised or confirmed by the biopsy, some of that may be due to false positive reporting or some may be due to disease that is yet to be detected?

A Yes, that's also possible.

Q but this would apply to both Dr Bottrill's results and to your results?

A That's exactly right.

Q so there is an internal standard, in terms of the histopathology and the regression of disease for both laboratories because you are comparing the same variables?

A Exactly.

Q And the only difference between the two re-reads is that your laboratory detected 3.5 times more biopsy confirmed high-grade disease than Dr Bottrill's laboratory?

A That's exactly right.

Q Now could this represent under-reporting?

A Yes.

Q By Dr Bottrill?

A Yes.

Second Indicator

4.17 The second indicator is taken from the proportion of women (in tables 5.3 and 5.4) with normal histology who had been reported as having high-grade/cancer cytology. This indicator gives a measure of the false positive reporting of each laboratory. Dr Farnsworth told the Committee that the usual denominator used to calculate the rate of false positive reporting is the number of normal histologies on biopsy. The number of normal histologies on biopsy in tables 5.3 and 5.4 was 76 so this became the common denominator for calculating the false positive reporting rate of Gisborne

Laboratories and Douglass Hanly Moir Pathology. Analysis of the data in tables 5.3 and 5.4 of exhibit TM/HFA/87 shows that over the three time periods out of 76 women Gisborne Laboratories reported three of them as having high-grade cytology and they were later found on biopsy to have normal histology. Whereas, Douglass Hanly Moir Pathology reported 22 out of the same group of women as having high-grade cytology and they were later confirmed by biopsy to have normal histology. This means that there was a wide discrepancy between the false positive reporting rates of the two laboratories in relation to the data. The false positive reporting rate of Gisborne Laboratories was 3.9% whereas the false positive reporting rate of Douglass Hanly Moir Pathology was 28.9%.

4.18 In cervical smear reading there is always a trade off between the sensitivity and specificity of a test. In the context of high-grade/cancer detection, sensitivity is the proportion of all people who have the disease who are correctly identified as such by the test. Anyone with the disease who is not identified by the test is a false negative. Specificity is the proportion of all people who do not have the disease who are correctly identified as such by the test. Anyone who does not have the disease but whose test is positive is a false positive result. Pathologists would agree that some degree of false positive reporting due to over-reporting, (sometimes referred to as over-calling) is acceptable as that increases the probability of high-grade lesions being detected and reduces the potential for under-reporting a cervical smear test. When viewed against the 28.9% rate of Douglass Hanly Moir Pathology the Gisborne Laboratories false positive reporting rate of 3.9% appears to be extremely low and likely to carry with it a greater risk of under-reporting. Dr Farnsworth's evidence on this point was:

Question by Professor Duggan: Dr Farnsworth, what does this mean?

A It means that Dr Bottrill had a very low false positive rate, especially compared to the Sydney re-read.

Q Now the Sydney re-read was geared towards ensuring that women would have the best treatment?

A That's right, yes.

Q And with that background, is it likely that you over-called?

A It is perceived as over-calling on the straight numbers. The appearances that we used to make the ...reports of high-grades are

appearances that we use in our everyday laboratory, and it may be that we do it in our normal day to day work. ...By increasing your sensitivity, which means increasing your false positive rate, you do lower ...specificity, ...And I have heard it colloquially put [as] where one sets the bar. But in a screening population where the Pap smear is designed to...sort out women who need to be further investigated from women who can then return to their normal screening interval, it is an accepted practice to in fact increase one's sensitivity at the expense of specificity for that purpose. And it is an accepted screening technique to in fact have a higher false positive rate so that one can in fact detect as many ...high-grade lesions as possible.

Q If I've heard you correctly then, you have said that it is accepted in cervical screening practices that the specificity will be compromised in order to attain a better sensitivity –

A that's right.

Q - and you are not surprised at the false positive rate [of Douglass Hanly Moir Pathology]?

A Exactly. And although a false positive rate is something that needs to be continually assessed and looked at as part of a normal laboratory's processes, it would be of great concern if your false positive rate was extremely low because it would mean that you are therefore missing a large number of the high-grade lesions that you're in fact looking for.

CHAIR Could that mean if you had a very low false positive rate that there was a greater likelihood that you may be under-reporting?

A Absolutely, ...If you have, ..., a very high ... false positive rate, ...it means that...some specificity will be lost. But that is acceptable, and in fact, arguably, it's the way Pap smears should be read.

Q Therefore, if you were looking for indicators of under-reporting could one possible indicator of under-reporting be a very low false positive rate?

A Yes.... By the way, it's important that any one indicator is not taken alone.

Q No.

A Absolutely critical.

Q But taken with other indicators a low false positive rate would be a factor that would suggest under-reporting.

A ...They should never be taken in isolation but yes in a group, but one would ...look at the false positive rate and then go straight to the false negative rate...they should balance, ...and in fact one would probably get more concerned if they didn't balance.

Q And the false positive rate that you've just given in this exhibit working through with Dr Duggan for Dr Bottrill's laboratory, do you consider that to be high, low, acceptable. I know that we don't have standards here.

A The false positive rate that we've just talked about of 3.9%?

Q Yes, what's your opinion of it.

A Well it's extremely low.

Q Right so it would be permissible to take a false positive rate of 3.9% together with other factors as an indicator of under-reporting.

A In isolation arguably it means that the cytology that was seen was in fact spot on. ...However if one is talking about a population screening exercise and one saw a very low false positive rate in association with a high false negative rate, one would be very concerned for that screening population.

Third Indicator

4.19 From the data in tables 5.3 and 5.4 the third indicator is taken from the proportion of women with high-grade/cancer histology whose cytology had been reported as abnormal. It is a measure of true positive reporting by the laboratories. Dr Farnsworth described the third indicator as showing under-reporting in the sense of failing to recognise an abnormal smear and under-reporting in the sense of failing to recognise the appropriate category of abnormality:

“... what we're looking at here is in fact under-reporting not just in the yes/no separation but under-reporting within the categorisation of those [abnormal] appearances.”

4.20 The third indicator has two parts: First, it takes the proportion of women with high-grade/cancer histology whose cervical smear tests had been reported as high-grade/cancer. Across all the time periods, table 5.3 showed that out of 216 women with cancer/high-grade histology, Gisborne Laboratories had reported 37 of them as having high-grade/cancer cytology. Whereas table 5.4 showed that for the same group of women Douglass Hanly Moir Pathology had reported 132 of them as having high-grade/cancer cytology. These calculations show Gisborne Laboratories to have a rate of 17% for detecting high-grade/cancer abnormalities whereas Douglass Hanly Moir Pathology has a rate of 61%.

Dr Farnsworth's comments on the wide variation between the 17% reporting rate for Gisborne Laboratories and the 61% reporting rate for Douglass Hanly Moir Pathology these rates were:

...

CHAIR: Is the rate of 17% for Dr Bottrill's laboratory in the third indicator, I know we don't have benchmark standards in New Zealand but

nevertheless, in your experience as a pathologist would you describe that as a very low rate, low, medium, high, whatever.

A It's extremely low.

Q Would you say was unacceptably low?

A Yes I would.

Q And can you say why?

A Back to my comments about cervical cancer remember that we are actually screening for these lesions, we are screening high-grade lesions both the Australian Government and the New Zealand Government spend a large amount of money trying to look after the women of their countries. These are the lesions we are actually looking for because it's these lesions that by finding them at this stage you can remove and actually prevent cancer. It would seem to me that if you are picking up such a small percentage of the actual disease that exists in that community of screened women, then basically you shouldn't have a screening programme at all because it's not doing any good.

4.21 The second part of the third indicator looked at the proportion of women shown in tables 5.3 and 5.4 with high-grade/cancer histology whose cervical smear tests had been reported as abnormal but to a lesser degree than high-grade or cancer. The data in the table 5.3 showed that out of 216 women with high-grade/cancer histology Gisborne Laboratories had read 111 of them as having abnormal cytology. Table 5.4 showed that out of the same group of women Douglass Hanly Moir Laboratories had read 85 of them as having abnormal cytology. The reporting rate for Gisborne Laboratories for the three time periods was 51% whereas the rate for Douglass Hanly Moir Laboratories was 40%. Dr Farnsworth's evidence, when asked to comment on these rates, was that they showed that Douglass Hanly Moir Pathology had more accurately read the cytology of the 216 women whose results were given in tables 5.3 and 5.4:

Q Now what does this indicator mean in terms of Dr Bottrill's reporting and the Sydney laboratory reporting?

A It is in fact a more specific marker of false negative cytology if one takes it globally. ...if we actually did or organised a screening programme so that one had either an abnormal category v's a normal category this particular additional data would show that in fact Sydney would have separated all the correct results into the need investigation group whereas the original laboratory would have not identified a significant percentage of women...

Q So which laboratory is better?

A The Sydney re-read would in terms of screening programmes be much more accurate because the whole purpose ...is to separate out ... the

women that did deserve to have further investigation whereas [in the case of Gisborne Laboratories's reporting]there would have been 32% of women in this particular population who had high-grade lesions who would have then been returned to the screening pool and said that they don't actually have to have another smear for 3 years.

CHAIR INTERJECTS

CHAIR: Would you just say why that is? Could you just say how you come to that conclusion?

A Again, I'm using the very simple concept of a screening programme, talking about sensitivity and leaving aside specificity, and if we take the example that a screening programme should be designed ...to detect abnormalities that are present in the screened population or the potentially screened population, and if one takes a very simplistic premise that you call that group perfectly okay, they can return and come back for their next Pap smear in 3 years as opposed to the group that needs to have something further done - and arguably that is the whole purpose of the screening programme - then the Sydney re-read would have ...put all the women who had abnormalities present and high-grade significant abnormalities, which is the one we're trying to detect, ...into the "correct" basket, for want of a better word. Whereas in the original re-read, ..., there would have been 68 women who were arguably falsely reassured that they had nothing wrong with their cervix and could just return for a further smear.

...

Q Yes. So these 68 women are women who would have [been] read ... as normal, [were] put back into the screening population, therefore, when in fact they should have gone on to colposcopy?

A Yes, exactly, which is about one third of the women.

Dr Farnsworth was questioned by the Chair on this aspect of the third indicator:

Q it seems that the third indicator falls in to two parts, this is the second part –

A that's right.

Q - which we hadn't considered before.

A That's right,...but it is further evidence.

...

Q - further evidence of –

A Of significant under-reporting.

4.22 Dr Farnsworth acknowledged that each indicator on its own was not sufficient to support the conclusion that Gisborne Laboratories had an unacceptable level of under-reporting. Indeed she was careful in her evidence to point out the dangers of relying on one indicator in isolation. She also acknowledged that the calculations from tables 5.3 and 5.4 of exhibit TM/HFA/087 only allowed a comparison between the performance of the two laboratories in relation to their reporting on the results given in

those tables. However, the combination of the three indicators signified to her that there had been an unacceptable level of under-reporting by Gisborne Laboratories:

Q And if we could just go back over to summarise, we've gone through the three indicators, if we take each of these three indicators and look at them as a group, do the three of them together go some way to providing an indication that Dr Bottrill was under-reporting?

A Yes they do.

Q And on a 10 point scale if you can, can you tell me how far does the combination of these three indicators take you?

A You want an under-reporting, 10 is high and 0 is low?

Q Yes.

...

A They indicate a very high level of under-reporting, a very high level and if one wanted to grade it from 10 being the highest level of under-reporting you could have v's 0 to no under-reporting I'd give him an 8.

Q Right. Would you say that was unacceptable under-reporting?

A Absolutely.

Q Now the other point I'd like to know is, you've come to this opinion on the basis of these three indicators. Are they sufficient to come to a view on under-reporting or do you need to take other factors into account. In other words, can you reliably say on the basis of these three indicators, there has been under-reporting to a level of an 8 which you would say is unacceptable?

A These three indicators would allow me to say that but there are other factors that I am aware of which would also influence, if you wanted to ask me again, from other points of view but alone these three indicators would indicate...an 8 level of under-reporting.

Other Evidence Showing Unacceptable Under-reporting

4.23 Other witnesses also gave evidence which supported the conclusion that the level of under-reporting was unacceptable. Professor David Skegg suggested that the Committee should consider the number of women who had developed invasive cervical cancer despite being screened regularly. Since the purpose of a cervical screening programme is to identify those women with pre-cancerous abnormalities and to offer them early treatment before the abnormalities develop into cervical cancer a successful screening programme should prevent pre-cancerous abnormalities from developing into invasive cervical cancer. If, therefore, in a population of women who are screened regularly there are a substantial number of cases of cervical cancer which

could have been prevented if detected at the pre-cancerous stage, that indicates an unacceptable level of under-reporting.

4.24 Professor Skegg said that the three indicators which Dr Farnsworth presented had demonstrated to him that there had been “a substantial under-reporting.” For him a “striking” factor, which he derived from the data in table 5.6 of exhibit TM/HFA/87, was that in the case of 16 women who developed cervical cancer Gisborne Laboratories had read their cervical smear tests as normal whereas Douglass Hanly Moir Pathology had read the same cervical smear tests as cervical cancer or high-grade/cancer abnormality. Professor Skegg considered that, even when the high reporting rate of Douglass Hanly Moir Pathology, which was high in comparison with New Zealand laboratories overall, and other limitations on the use of the data in TM/HFA/87 was taken into account, this difference in reporting high-grade abnormalities or cervical cancer was significant and showed Gisborne Laboratories to have been reporting at an unacceptable level:

A Just returning to this table [5.6 exhibit TM/HFA/87] for a moment, even though I believe one must temper one’s conclusions with the awareness that the Sydney laboratory was reporting at a much higher level than any NZ laboratory, I still think these two observations, the first is that there were 17 women who developed cervical cancer after having 1 or more normal smears is striking, and even though we may have to set aside 6 of those 17 as possibly being diagnostic, and also the dichotomy from the Sydney results, the fact that in the second two periods which I think– one can put the most reliance on, that 16 had all been reported as either normal or low-grade or ASCUS by Dr Bottrill and all [were] reported as high-grade or cancer by Sydney, I believe that that does indicate a substantial level of under-reporting.

...

Q You’ve said there is a substantial level of under-reporting. Would you be prepared to grade it on a scale from 1 to 10, 10 being the worst case of under-reporting and 1 being the least serious case of under-reporting. Where would you say this level of under-reporting fell?

A I’m sorry to be unhelpful but I think that will be very subjective and I would be unwilling to do it. All I can say is that it seems to me very substantial.

Q When you say it’s very substantial would you say that it was unacceptable?

A Yes, I would.

4.25 Dr Cox used the data in table 5.6 of exhibit TM/HFA/87 to calculate the sensitivity of the reporting of the two laboratories. He concluded that Gisborne Laboratories had a

sensitivity of 43.5% whereas Douglass Hanly Moir Pathology had a sensitivity of 95%. He described the sensitivity of Gisborne Laboratories as being unacceptably low:

A I'd like to start, if I may, on 5.6 because I believe that this table is very crucial to the term of reference 1 as has been identified yesterday. I would like to use this table to estimate the laboratory sensitivity for the detection of high-grade or cancer of both Dr Bottrill's laboratory and the Sydney laboratory. And to do that I would like to invoke an assumption that of those who've developed cancer right through to beyond May 1999 that they had either cancer or high-grade throughout the entire period.

CHAIR: What period's that?

A From 91 right through. Now I realise that it is possible, although I think a relatively small probability, that high-grade or worse has not been present throughout, and for many of these it may have been high-grade and then subsequently developed cancer. And if I invoke that, the original laboratory or Dr Bottrill's laboratory, which is 5.6b, we end up ...with an original laboratory sensitivity of 35.9% in my calculations ...which is 14 over 39, and if you [do] a similar thing for the re-read at the Sydney laboratory and I'm not including ASCUS H in at this time ...you end up with 37 out of 39 being positive which would give a sensitivity for that laboratory of 95%. Now I realise that I would also like to invoke a benchmark of say 85% laboratory sensitivity. Now I know normally in terms of Dr McGoogan's evidence that has been calculated in a very different manner to do with rereading of slides within the laboratory but if I invoke that then Dr Bottrill's sensitivity as I measure [it] is statistically significantly lower than that benchmark. Moreover the benchmark would have to be 51% for the difference between the benchmark and Dr Bottrill's laboratory to not be statistically significant and I believe that even under the assumptions I need to invoke if you like to calculate these sensitivities, a figure of 51% would not be agreed on by anybody.

PROFESSOR DUGGAN: Could I just ask you to clarify one thing. For Dr Bottrill's laboratory you are accepting as a predictor of the cancer his 6 diagnoses of cancer in the first row, the 6 of high-grade in the second row and the 5 low-grade.

A Sorry I have missed that. I take that back.

...

A I can recalculate things but I still don't think and I'm pretty sure –

CHAIR INTERJECTS

CHAIR: Could you please recalculate so we've got something.

A 43.5%. And I therefore need to do something a little different. In which case the benchmark cut off that I mentioned before would not be 51% it would be 59% and I still believe that would not be a level which would be acceptable.

PROFESSOR DUGGAN: Just for the committee how did you calculate that benchmark of 59%.

A I believe the variants for a binomial proportion which is what the laboratory sensitivity is what's called PQ/N . P which is this probability here of $.435 \times 1$ minus that figure divided by the number overall which is 39 and

the square root of that figure is the standard deviation. By taking that standard deviation and multiplying it by 1.96 which is a standard figure in the normal distribution table for 95% confidence interval or limit you get a figure of something like .15. You then have to add that to your original .435 because when you just multiply the standard deviation by 1.96 you get the difference between a benchmark and this particular figure then you have to add that difference to the figure so from that I calculate that the benchmark would need to be 59% for there not to be a statistical significant difference between Dr Bottrill's sensitivity invoking the assumptions I did and the benchmark. Obviously the re-read laboratory has a figure and I hope I got this right of 95% sensitivity and is obviously – would be very acceptable.

Q So the Sydney reporting is acceptable?

A On the basis of table 5.6 and the assumptions that I invoked except in terms of it's estimated sensitivity. There are other issues with the Sydney laboratory but not related to the sensitivity.

Q What about Dr Bottrill's result.

A Dr Bottrill's result I believe is unacceptably low.

CHAIR INTERJECTS

CHAIR: You said you've used as a reliable benchmark a figure of 85% where did you get that from?

A ...I just said I would invoke it partly because in Dr McGoogan's evidence in calculating the laboratory sensitivity a very different way which was by relooking at slides, their range of laboratory sensitivities .85 - .09, 85% or 95% for their standard as you like.

Q So your using it as a rule of thumb here.

A I was trying to use that as a rule of thumb as a starting point. I realise the benchmark and the way this is calculated is quite different and so I actually prefer to calculate what the benchmark would need to be.

Q And on that basis then you have a benchmark of 59% and in your view that would be too low by anyone's standards.

A Yes.

PROFESSOR DUGGAN: Dr Cox even if you were to evaluate this data without using the 85% benchmark put forward by Dr McGoogan, a sensitivity of 95% for Sydney versus a sensitivity of 43.5% for Dr Bottrill, could you comment on those just approaching it as an inter-laboratory comparison where variables for each laboratory are essentially controlled except for the reporting of the smear?

A Well obviously that difference is even greater than the benchmark I invoked and is highly statistically significant. The issue here is that laboratories set their own trade-off between sensitivity and specificity, which is a technical term. I think they've been defined to the Inquiry earlier. And each laboratory is probably different in the balance between sensitivity and specificity they choose. Unfortunately in some laboratories it occurs by default rather than by intent. I think here we have a situation where we have if you like, two opposite extremes where the Sydney laboratory has a high sensitivity in terms of laboratory reporting and Dr Bottrill's laboratory has a relatively low sensitivity.

...

A And the Sydney laboratory has a high specificity but it's lower than Dr Bottrill's. So we have this contrast and the trade-off is that if the Sydney laboratory had been, if you like, reading the smears through to the time period of 1991 to 1996 then we would most likely detect something like twice as many cancers and we would have had about 3., or maybe 3 times the amount of referral for colposcopy or having a repeat smear. I must say that in these calculations I have to acknowledge that there is a combination of both screening smears and diagnostic smears within the series, but I would expect that the presence of diagnostic smears to actually increase the sensitivity because most times I would expect an indication or signs or symptoms on the request form which would heighten the readers index of suspicion when reading the smears in the first place.

Q the assumption you have made that the women concerned were likely to have cancer or high-grade abnormality between 91 and 99, how comfortable are you with making that assumption – in other words, is there a high probability that that was so, a low probability, in the middle – what?

A I believe there's a high probability that great majority of those people who developed the cancer during the period will have had high-grade or as I've said earlier, low-grade or cancer present on their cervix all the way through.

Q So if you were doing this as an epidemiological study you would feel scientifically comfortable about making that assumption?

A I would feel some nervousness about making the assumption, and in a way I am disappointed in the sense that from the way the tables are created, you expect that the individual record data would allow this to be calculated in a different way that might be much more informative and reduce that possibility. So I have some nervousness about the assumption but I think, in terms of comparative purposes, it applies to both.

Yes, thank you.

4.26 A subsequent audit of the data in exhibit TM/HFA/087 by the Health Funding Authority revealed that it had wrongly recorded data in some of the tables. An audit of table 5.6, which Professor Skegg and Dr Cox had each relied upon to reach their separate conclusions that Gisborne Laboratories had under-reported at an unacceptable level, could not confirm the diagnosis of one of the 39 women recorded as having cancer. Dr Cox was asked to provide additional expert evidence to the Committee on the epidemiological impact of the one unconfirmed diagnosis in table 5.6 on the conclusions which he had reached. His evidence, which was given to the Committee in the form of an unsworn written statement, was that:

“...reducing the number of women with invasive cervical cancer by one, to 38 would not appear to be sufficient to alter the conclusion that there was a significant level of under-reporting of cervical cytology in Gisborne.”

4.27 Dr Wain, was another expert witness who considered that the statistical data contained in exhibit “TM/HFA/87” showed there had been an unacceptable level of under-reporting. Of all the women diagnosed with invasive cervical cancer Gisborne Laboratories Limited had reported only 30% of this group as having either a high-grade/cancer abnormality or had abnormal cells suspicious but not conclusive of HSIL (ASCUS-H) whereas Douglass Hanly Moir Pathology had reported every one in the group as having either a high-grade abnormality or cancer:

Q Would you agree with this summary, that all of the women who developed cancer were re-read by Sydney as cancer high-grade or ASCUS-H?

A Yes.

Q Whereas only 12, which is 30% of the women who developed cancer had their smears read by Dr Bottrill as cancer or high-grade?

A I would agree with that.

Q What do those rates mean to you?

A I think that number 1 it confirms to me that the Sydney re-read is likely to be correct in those women since they've all been subsequently shown to have cancer and number 2 that Dr Bottrill wasn't very good at picking up women with definite abnormalities on their cervix.

Q Could this be under-reporting by Dr Bottrill?

A I think it is almost certainly under-reporting.

Q Could it be anything else?

A When you compare the two I can't think of anything else that it could be.

CHAIR INTERJECTS

CHAIR: From that table alone are you able to give an indication of the level of under-reporting?

A It's extreme.

CHAIR: On a 10 point scale, with 1 being the lowest, 10 being the highest, where would you put the level of under-reporting on the basis of that table which is table 5.6 in the exhibit 87 of Mellor's supplementary?

A I feel like an olympic judge! I've heard you ask that question yesterday and thought it was a very difficult question I think this is as bad as it gets.

Q So where would you put it.

A: 10.

Q You'd give it a 10. And would you say that was unacceptable under-reporting?

A Completely unacceptable.

PROFESSOR DUGGAN: Dr Wain I have one further question about this table. You have already mentioned that in your practice the women who present with invasive cancer have not been screened and it's rare for you to manage a woman with invasive cancer who has had a Pap smear. Looking at these two tables here what can you say about these women who have developed invasive cancer in the Tairāwhiti region?

A It certainly doesn't match with my clinical experience and they have been very unlucky to have developed cervical cancer despite the fact that they've gone through the process of having Pap smears. They're a screened population but they've got no benefit from screening.

Q Thank you.

4.28 Dr Ron Jones was a part of the HFA advisory group for the Sydney re-read and was involved in providing follow up colposcopy services. The data from colposcopy is complicated (as he explained) because colposcopy is, like cytology, not an exact science. Accepting that limitation on the data, however, Dr. Jones' evidence was that the colposcopy follow up data also tended to support the accuracy of the Sydney re-read because a number of women with non symptomatic invasive cervical cancer were detected as a result of the re-read. There were more cancers than he expected to see

4.29 Because some false negative results are expected a cervical screening programme depends on women having cervical smear tests at regular intervals so that an abnormality which a laboratory misses on one occasion will be less likely to be missed on a subsequent occasion. Although Dr. Wain only considered the records of a small group of women he was struck by the number of what appeared to him to be repeat misreads. After considering the cases of more than one misread, and some cases of women with 5 and even one with 6 apparently misread slides he said:

"I am not a gambler but if you work out the probability of that happening, it must be extraordinarily rare...almost unbelievable."

4.30 The impression Dr Wain had from looking at the patient files was consistent with his expectation of the natural progression of the disease in the absence of a screening programme. Since the population seemed to him to have been well screened (meaning that there were a high number of enrolments) it was his view that:

“somewhere along the way things were going wrong very badly”

- 4.31 There were other factors which, on their own are not be reliable indicators of under-reporting, however when considered together with the above evidence they support the conclusion that there was an unacceptable level of under-reporting at Gisborne Laboratories: First, there is a marked difference between the reporting rates for high-grade abnormalities when Dr Bottrill was in practice and when he retired, and the business of Gisborne Laboratories was sold to Med Lab Hamilton. The Committee is aware that there are issues surrounding the question of whether reporting rates of abnormal test results are in themselves a reliable indicator of laboratory performance, nevertheless, it considers that the difference in the level of reporting of abnormalities before and after Dr Bottrill’s retirement is so great that the Committee can take note of it.
- 4.32 Secondly statistics which were prepared jointly by the Ministry of Health and the Health Funding Authority and produced in evidence to the Committee, show that a regional analysis of cervical cancer incidence between 1990 and 1997 puts the Gisborne region at the second highest rate of cervical cancer in New Zealand. The analysis of these statistics included the calculation of the ratio of observed numbers of cases to expected numbers of cases expressed as a percentage. This percentage was called the standardised registration ratio. The national average was expressed as 100% and standardised registration ratios higher than 100% were above the national average and conversely percentages lower than 100% were below the national average. The Gisborne region had a standardised registration ratio of 181.3% or almost twice the national average. Therefore, one would expect to see a higher rate of abnormalities being reported from this region. However, the reporting rate of abnormalities in the period from 1990 to March 1996 was low. In contrast the reporting rates for abnormalities after March 1996 when Medlab Hamilton took over the business of Gisborne Laboratories seem to fit better with the region’s significantly high rate of cervical cancer.
- 4.33 The Committee is drawn to the conclusion that it is difficult to think of any convincing explanation for the sharp increase in the number of abnormalities being reported other than that after the sale of Gisborne Laboratories Dr Bottrill had stopped reading the

cervical cytology of women in the region. Further support for this conclusion can be obtained from the anecdotal observations made by the local programme co-ordinator Ms Reid in June 1997 in her report which appears in exhibit “JMG/MOH 62” that there seemed to me more high-grade abnormalities being diagnosed than previously.

- 4.34 Thirdly, there is the evidence of Ms Tracy Mellor of the Health Funding Authority on the rate of abnormality reporting since 1991 which is the time from when women were recording their first smear on the National Cervical Screening Register. This information is to be found in exhibit “TM/HFA/85”. It shows that the reporting rates of Gisborne Laboratories for abnormalities remained about the same despite the fact that by 1994 and 1995 over half of the women enrolled on the National Cervical Screening Programme were having their second or a subsequent smear. If screening were providing a benefit one would expect to see a drop in the abnormality rates. The fact that rates did not drop over time can also be seen as an indication of under-reporting.
- 4.35 Fourthly there is the evidence of Mr. Jim du Rose on 116 smear tests reported as high-grade or cancer by Douglass Hanly Moir Pathology in TM/HFA/87 at p51, but which were originally reported as normal by Gisborne Laboratories. More than half (53.4%) of these false negative smear tests from Gisborne Laboratories were subsequently confirmed as high-grade or cancer by histology.
- 4.36 Finally the evidence the Committee heard from Dr Ron Jones, Dr Teague and Dr Tie is consistent with under-reporting. Moreover it is significant that the Committee has not heard any evidence to suggest that the rate of reporting abnormalities at Gisborne Laboratories was acceptable. Indeed Dr Bottrill himself accepted that his level of under-reporting was unacceptable.

Q: Do you now accept, from what you have seen, read of the evidence that has been given that during the period 1991 to March 1996, there has been an unacceptable level of under-reporting of cervical smears in the Gisborne Region as a consequence of your misreading and/or misreporting of those smears?

A: Regretfully yes (B3079/24).

Conclusion

4.37 In view of the evidence the Committee has heard on term of reference one it has no difficulty in concluding that there has been an unacceptable level of under-reporting in the Gisborne region in the period to which this term of reference relates. The Committee has been able to reach this conclusion even though during the relevant period there were no performance standards in place against which the performance of Gisborne Laboratories could be measured. Although at an early stage in the inquiry hearings there was evidence to suggest that the Committee might not be able to answer this term of reference without the assistance of an audit of the cases of cervical cancer, in the end on the evidence available the conclusion which the Committee has reached was inevitable.

5. TERM OF REFERENCE TWO

What are the factors that are likely to have led to the under-reporting?

5.1 Dr Bottrill was at a loss to explain why so many of the cervical smear tests read at Gisborne Laboratories had been under-reported. The only explanation he could offer was that his work performance had deteriorated after he had undergone heart surgery in July 1990.

5.2 Counsel for the women affected submitted that in answering Term of Reference Two the Committee should identify both direct and indirect factors that are likely to have led to under-reporting. However, Counsel for the Ministry of Health submitted that even if there were defects in the Programme's delivery, those defects could not have led to the under-reporting. The Committee considers that the phrase "to identify the factors that are likely to have led to that under-reporting" has a meaning which goes beyond identifying the immediate cause of the under-reporting. Clearly the immediate cause of any under-reporting is someone misreading a smear test. By directing the Committee to identify the factors that are likely to have led to unacceptable under-reporting the Minister of Health is seeking an answer which may go some way to explain how the under-reporting came about. This will inform the Minister of the steps that need to be taken to ensure that unacceptable under-reporting is avoided in the future. Unless the Minister is made aware of all the factors without which damage could not have occurred the Minister will not be best placed to determine the remedial action required. For this reason the Committee considers that Term of Reference two requires it to look for all factors which directly or indirectly materially contributed to the under-reporting.

5.3 In the Committee's view there are a number of factors that are likely to have led to the unacceptable level of under-reporting at Gisborne Laboratories. These factors fall into two groups: those that relate directly to the practices followed in Gisborne Laboratories when reading cervical cytology; and those that relate to the delivery of cytological services in New Zealand between the years 1990 to 1996. The second

group of factors directly influenced how cervical cytology was carried out in Gisborne Laboratories during this time. Each group of factors is discussed in turn below.

Factors Relating To Practices Followed In Gisborne Laboratories

5.4 The factors relating to practices in Gisborne Laboratories that are likely to have led to under-reporting of cervical smear tests are:

- (i) No specialised division of labour for reading cervical smear tests;
- (ii) Inadequate internal quality control including no organised correlation of biopsy results with cytology results;
- (iii) Inadequate systems and procedures;
- (iv) No external quality control;
- (v) No accreditation with an independent quality control authority;
- (vi) Dr Bottrill's inadequate participation in continuing medical education;
and
- (vii) No awareness that the laboratory's practices put patients at risk.

Each of these factors, their impact on the laboratory's performance and the likelihood of them leading to under-reporting is discussed below.

No Specialised Division Of Labour For Reading Cervical Smear Tests

5.5 In most laboratories cervical smear tests are screened by more than one person. The usual practice is for a specially trained cytotechnologist or cytoscreener to carry out the primary screening. This entails the careful microscopic examination of slides on which cellular material from the cervical smear is fixed. It can be a monotonous repetitive task as the examination of each slide follows a set pattern.

Cytotechnologists and cytoscreeners are trained to look for unusual-looking cells on the slide as these indicate cellular abnormalities. Their task is to sort the abnormal from the normal smears. Once the abnormal smears are identified they are sent to the laboratory pathologist who also examines them and then categorises the type of cellular abnormality.

- 5.6 The importance of a specialised division of labour when reading cervical cytology has been well recognised for some time. The World Health Organisation issued a Bulletin in 1986 titled *Control of Cancer of the Cervix Uteri* which stated:

“All smears should be processed and screened at a cytology laboratory in which the following procedures *must* be performed: staining, examination by a cytotechnologist, confirmation by a cytopathologist, communication of results to a clinician and follow-up of all cases of abnormal cytology. (emphasis added)

In the same passage the need for pathologists and other laboratory staff to maintain their competency in cervical cytology by reading a large volume of cervical smear tests and by avoiding working in isolation was also recognised:

“Cytology services should be centralised. A large volume of work contributes to the successful operation of a cytology laboratory because a specialized division of labour is possible and a large number of abnormal smears representing various pathologies will help to maintain the cytotechnologists’ skills. ...Usually single unsupervised technicians should not be placed in isolated areas or health centres, since even well trained screeners will lose their skills if not exposed to a large number of positive specimens, teaching and supervision.”

- 5.7 At Gisborne Laboratories there was no specialised division of labour when it came to reading cervical smear tests. The cervical cytology was read by one person, and this was usually Dr Bottrill. He was the only pathologist that Gisborne Laboratories permanently employed. Of the 22,976 smear tests sent to Douglass Hanly Moir Pathology in Sydney for re-reading, 20,860 had originally been read by Dr Bottrill. Gisborne Laboratories received approximately 4000-5000 cervical smear tests per annum.

- 5.8 Dr Bottrill carried out all the primary screening of the smear tests, even though he had no specialist training in cytoscreening. On the occasions when Dr Bottrill went on

leave and a locum was employed the locum also carried out the entire task. On his return from leave Dr Bottrill did not check the smear tests which the locum had read. Occasionally, when the workload became too heavy, Dr Bottrill employed a locum to assist him. Once again the practice was for Dr Bottrill and the locum to work separately on an allotted group of slides. Dr Bottrill said that for the first week he would check the locum's work by re-reading the smear tests and the reports; after that the locum was left to do his allotted work. Dr Bottrill used to rescreen 10% of the negative smear tests approximately once a week and when a locum was employed it seems that Dr Bottrill included the smear tests the locum read in the rescreening exercise. This was the limit of any sharing of the task of reading cervical smear tests.

5.9 The Committee heard no evidence to support primary screening of cervical smear tests being performed by a pathologist. Professor McGoogan, Dr Gabriel Medley and Dr Farnsworth are highly qualified and experienced cytopathologists. They each informed the Committee that they considered their skills were not suited to primary screening. In her evidence to the Committee Professor McGoogan said:

Dr Duggan Question Could I ask you for your own personal opinion on whether pathologists who have not been trained in the skills of primary screening should function as a primary screener?

A I have a very high regard for the skills of primary screeners, it is an exceptionally difficult skill to develop and maintain day in day out. It is not a skill which I have as an individual. I would have to undertake a similar training and concentrate my training in that area to achieve the same skills.

Q You, as an acknowledged expert in cytopathology, do not consider you should function as a primary screener

A Yes, I agree.

5.10 Other pathologists from whom the Committee heard evidence also did not think it advisable for a pathologist to perform primary screening. Dr Beer, a pathologist from Tauranga who gave evidence for the Association of Community Laboratories said he thought it dangerous for a pathologist to perform primary screening. Dr Teague, who gave evidence for the Royal College of Pathologists of Australasia said he did not consider himself competent to primary screen cervical smear tests and that he would not function as a primary screener. Dr Teague had organised a review of a small group of Dr Bottrill's slides for an accident compensation claim against Dr Bottrill for

medical misadventure due to the under-reporting of a patient's cervical smear test. When Dr Teague learnt how Dr Bottrill practised cervical cytology he advised Dr Bottrill to stop reading smear tests and to send the laboratory's cervical cytology elsewhere; Dr Bottrill did not follow Dr Teague's advice.

- 5.11 Dr Bottrill said that he had not wanted to act as his own primary screener and that he had done so because: between the years 1990 and 1995 there was a shortage of cytotechnologists; Gisborne Laboratories did not have enough work to employ a full time screener; and given the shortage of cytotechnologists it was too difficult to find someone prepared to do this work part time in a rural area like Gisborne. An additional reason Dr Bottrill gave for carrying out the primary screening was that he wished to offer a full service to the Gisborne region and the alternative to him carrying out the primary screening was for Gisborne Laboratories to send cervical cytology elsewhere.
- 5.12 None of the reasons Dr Bottrill gave for the laboratory following this practice justifies it. There was no question of Dr Bottrill acting out of necessity. The cervical cytology of women from the Gisborne region could have been read at a laboratory in another region. All the cervical cytology from the Gisborne region is now read by laboratories in other regions. Since Medlab Hamilton purchased Gisborne Laboratories the cervical cytology that was read by Gisborne Laboratories is read in Hamilton. The Gisborne hospital laboratory has ceased reading cytology and sends any cytology it receives elsewhere. When Dr Bottrill was in practice, but on sick leave the cervical cytology Gisborne Laboratories received was read in a laboratory in Palmerston North. Between 1990 to 1996 there was no obstacle which prevented Gisborne Laboratories from sending cervical cytology elsewhere, if it had chosen to do so.
- 5.13 The practice of working alone that Dr Bottrill followed meant there was no opportunity for a second pair of eyes to view the cervical smear tests that he screened. Consequently, unless he arranged to seek a second opinion on a smear test, there was no likelihood of any error he made in reading a smear test being picked up. The Committee heard evidence from more than one pathologist on the risk of this practice to patients. The best evidence was given by Professor McGoogan:

CHAIR: Question I will start the scenario again, a small laboratory where you have one pathologist, no-one else employed full or part time, approximately 5000 smears per annum coming into the laboratory, the single pathologist doing all screening primary and then I don't know the format he used to screen abnormal, but have you got enough in front of you now to formulate an opinion?

A Yes. this is in my experience a very unusual situation. It is difficult in a situation where there is only one person for that individual to quality control themselves and while it is not impossible to maintain quality service under those circumstances it would be extremely difficult and would require exceptional measures to be put in place by the individual to ensure competence and a quality service.

Q Can you describe how it might be done, in other words, what those quality control measures might be?

A I can think of ways but what you are really asking me is if I want to set up a bad service how would I do it with the least risk to women.

Q You have said it could be done, so please outline the measures?

A There would have to be frequent and good interaction with pathologists in another laboratory whereby there was exchange of work between the two laboratories or at least in one direction from the single handed pathologist laboratory to the other laboratory for quality control, internal quality control, there would have to be well documented processes and data collected for that quality control. Biopsy smear correlation would be imperative in that situation so that the pathologist knew that patients that he recommended be referred for colposcopy had been appropriately referred, in other words, that the majority of these patients did indeed have disease and that the biopsy reflected the disease he suspected from his cervical smear report, and that he frequently participated in external quality assurance, he frequently attended meetings of cytologists with cytology topics pertaining to cervical screening, and that he ensured that his laboratory met all external accreditation procedures and processes that were available, and even then I think there are major risks involved.

5.14 The risk of error when one person reads all the cervical cytology was heightened by Dr Bottrill's practice of cervical cytology as he did not regularly adopt any of the measures which Professor McGoogan outlined as essential to overcome the risks of a pathologist acting on his own:

- (i) He had no internal quality control of the type contemplated by Professor McGoogan;
- (ii) He did not participate in any external quality control programme;
- (iii) Gisborne Laboratories was not accredited with any independent accreditation authority;

- (iv) It had no organised programme to correlate a patient's abnormal cytology results with the later discovery of cancerous or pre-cancerous lesions by biopsy;
- (v) Dr Bottrill's contact with other pathologists and his attempts at continuing education were insufficient to enable him to overcome the risks inherent in acting as a sole practitioner in cervical cytology;
- (vi) When Dr Bottrill was asked about the measures which Professor McGoogan had outlined as necessary, if a pathologist were to practise cervical cytology on his own, he was unable to inform the Committee if his practices met these measures.

5.15 Dr Teague's view of Dr Bottrill's practice was similar to that of Professor McGoogan. He described the practice as suboptimal:

“Q Would you describe it as an acceptable practice?

A I think it would be sub-optimal the way it was done.

Q And why is that?

A Particularly for the reason that there was only one person doing essentially both the primary and secondary screening or rechecking. There was some evidence I believe that Dr Bottrill did rescreen 10% of slides and there are statistics which show in fact that if the same person rescreens a slide they may get a different answer so to that extent there will be some benefit from that, but I believe that it would not be the benefit that one would expect to from getting a different pair of eyes to look at it.”

5.16 The Committee accepts the views that these witnesses have expressed about Dr Bottrill's practice. It agrees with the view expressed by Professor McGoogan that a laboratory that employs one person to carry out this task is providing a bad service. It considers that the somewhat subjective nature of the task of reading cervical cytology makes it too risky for one person to carry out, as misread smears are less likely to be discovered. The Committee considers that the practice followed at Gisborne Laboratories of having one person read the cervical cytology is a factor that is likely to have led to the unacceptable level of under-reporting that occurred at the laboratory.

Inadequate Internal Quality Control

- 5.17 In his evidence Dr Bottrill expressed the view that quality control was something which played a greater role in large laboratories and he saw no need for it in a small laboratory like Gisborne Laboratories. The internal quality control that he employed consisted of him, approximately once a week, re-reading 10% of the smear tests that he had originally read as normal. He neither documented this exercise, nor did he compare the re-read results with the original results. He could not recall any occasion on which, when carrying out a random re-reading of slides, he had discovered a smear test which he had originally read as normal and which on rereading he found to be abnormal. Nor could he remember a time when, on re-reading a slide, he became concerned about his original report. Considering the number of under-reported smear tests that have now come to light it seems surprising that the 10% random re-screening he carried out did not reveal any of these errors. The Committee can only conclude that Dr Bottrill had “calibrated” his eyes to read smear tests with a very high specificity and that on any second view of a smear test he was only corroborating his original error.
- 5.18 Apart from the 10% random re-screening there was little else done in the way of internal quality control. In 1993 when Gisborne Laboratories had applied for TELARC accreditation, work began on a quality control manual; however, this work cannot have been taken very far, or if it was it cannot have been effective as Medlab Hamilton found it necessary to replace it with its own quality control manual when it assumed control of Gisborne Laboratories.
- 5.19 Gisborne Laboratories had no organised programme for correlating biopsy results with cytology results. Dr Bottrill’s evidence was that he did keep records of cytology/histology correlation on the occasions when the histology was sent to him for diagnosis. However, he accepted that where the biopsy was performed at the local hospital he was unlikely to receive information about the histology result. There was no formal communication between Gisborne Laboratories and the local hospital which would have provided him with this information. If Dr Bottrill had been able to conduct an organised programme correlating histology with cytology this would have

informed him of the accuracy of his reading. It may have brought to his attention his false positive rate and true positive rate which the Committee knows to have been too low. Had Dr Bottrill realised his false positive rate was extremely low that may have made him alive to the probability that he was “setting the bar too high” and consequently under-reporting too many smear tests. Had he realised his true positive rate was too low he would have known that he was failing to recognise abnormal smear tests and reporting them incorrectly as normal (false negatives). A programme of looking back at a woman’s previous negative smear tests when she was found to have a high-grade abnormality on histology to determine if those smear tests were false negatives should have alerted Dr Bottrill to his under-reporting. In the circumstances the Committee’s view is that at Gisborne Laboratories correlation of histology with cytology occurred sporadically and was not sufficient to produce the quality control benefits which come from an organised programme of histology cytology correlation.

5.20 In the Committee’s view the internal quality control followed at Gisborne Laboratories was inadequate. It did not meet the expectations of internal quality control that Professor McGoogan outlined in her evidence. Her expectations of internal quality control are consistent with those of International Accreditation New Zealand (IANZ), the national accreditation authority for quality assurance, laboratory testing and industrial design. The Committee heard evidence from Mr Graham Walker the former programme manager medical testing and radiology of IANZ on the parameters of internal quality control. In Mr Walker’s view Dr Bottrill’s internal quality control fell outside these parameters.

5.21 Mr Walker visited Gisborne Laboratories in 1993 when it had applied to the Testing Laboratory Registration Council (TELARC), which formerly carried out IANZ’s functions, for accreditation. The application did not proceed. During his visit Mr Walker noted the absence of documented laboratory procedures and recorded that this was something which Gisborne Laboratories would have to institute if it were to become accredited. An additional aspect of internal quality control that IANZ considered significant, and which was lacking at Gisborne Laboratories was the ability to have a smear test checked by a second person. In his brief of evidence to the Committee Mr Walker said:

“An important aspect of internal quality control is the ability to release apparently normal slides on the basis that a second person within the laboratory has re-screened a proportion of those slides and validated the test results. Gisborne Laboratories did not have such a second person. There was, therefore, no internal quality check, as well as there not being any opportunity for Dr Bottrill in the cytology/histology context to exchange ideas with another cytopathologist. In such a circumstance there is extreme pressure on the pathologist to get the test result right as there are no other means to intercept problems and carry out frequent and random checks on test results”.

5.22 The Committee considers that the lack of adequate internal quality control at Gisborne Laboratories is a factor that is likely to have led to the unacceptable level of under-reporting that occurred at the laboratory. Had the practices at Gisborne Laboratories conformed with the internal quality control requirements outlined above it is likely that the level of under-reporting which occurred would have been detected sooner or perhaps avoided altogether.

Inadequate Systems And Procedures

5.23 Dr Bottrill’s views on quality control being more suited to big laboratories may have coloured his opinion on the usefulness to a small laboratory of organised systems and procedures in general. The laboratory systems he followed had shortcomings: he had no procedure in place to prevent a slide mix up, although there is no evidence this had ever happened; he did not as a matter of routine carry out “look back” exercises of a woman patient’s previous smear tests; he had no system to inform him as to whether or not he had read a woman patient’s previous smear tests, (this meant that unless he was told by the woman’s smear taker that he had read her previous smear tests he had no way of knowing whether or not there were previous smear tests to look back on); he did not regularly get information about his female patients from the National Cervical Screening Register.

5.24 The deficiencies in the systems and procedures at Gisborne Laboratories would not have promoted a competent performance in cervical cytology. The Committee considers that this is a factor which, if not of itself, then certainly combined with the other factors listed herein is likely to have led to the unacceptable level of under-reporting that occurred at the laboratory.

No External Quality Control

5.25 Gisborne Laboratories did not participate in any external quality assurance programme. Dr Bottrill did not appear to place a high value on quality control. In his evidence to the Committee he said:

Q Was it your view at the time that measures such as external quality assurance and quality control systems played no part in affecting your standard of smear reading?

A Yes

Q So you didn't think they would help your accuracy, is that right?

A I think that is correct, yes

Dr Bottrill said that he liaised with a series of pathologists who were employed at Gisborne Hospital. He said he visited the hospital four or five times a week around lunchtime to have a general discussion with the current hospital pathologist and to show him or her any slides of interest or difficulty. He said that he maintained good collegial relationships by doing this and he was also able to obtain second opinions on difficult or interesting slides. However, he accepted that there was not always a pathologist employed at the hospital, that there could be periods of up to one year when nobody was there and that at those times he was the only pathologist in Gisborne. The Committee considers that the informal interaction Dr Bottrill had with the pathologists at Gisborne Hospital was insufficient to remove or reduce the risk inherent in practising as he did. It comes nowhere near the type of interactions that are carried out for the purpose of *external* quality control.

5.26 Although the evidence shows that in 1991 there was no entirely satisfactory external quality assurance programme available, and it seems that was still so in 1993, the Royal College of Pathologists of Australasia offered a programme which was a step in the right direction and over the years this programme has developed and improved. The Committee's view is that participation in an external quality assurance programme which is still in the early stages of development and which may not be entirely satisfactory has benefit nevertheless, as it should make a pathologist more alert to the possibility of error, and it should cause a pathologist to focus more on the

need to adopt measures to reduce the risk of error occurring. The external quality assurance programme which the Royal College of Pathologists of Australasia offered involved a pathologist receiving slides from the College, reading them and reporting the results to a central collating agency and subsequently receiving reports which compared the reports of his or her slide reading with the consensus view of the other pathologists who participated in the programme. In this way a pathologist was able to learn whether or not his or her reading of slides was within the average range or above or below that range.

- 5.27 Participation in such a scheme may have alerted Dr Bottrill to the likelihood that he was failing to recognise some abnormal smears and consequently he was under-reporting the abnormalities he was seeing. The Committee considers that the failure at Gisborne Laboratories to ensure that the pathologist participated in an external quality control programme is a factor that is likely to have led to the unacceptable level of under-reporting that occurred at the laboratory.

No Accreditation With An Independent Quality Control Authority

- 5.28 Throughout the time that Dr Bottrill was in practice Gisborne Laboratories was not accredited with an independent laboratory quality control authority such as TELARC. Even though the requirements for TELARC accreditation were not as demanding in the early 1990s as they are now, they still would have deterred Dr Bottrill from practising as he did. Most importantly, from 1993 onwards, it seems that so long as Gisborne Laboratories employed only one person to carry out all the cervical cytology it would have been denied accreditation. Mr Walker said in evidence:

Chair Question You have talked ... about the situation of Dr Bottrill doing all the cytoscreening on his own, in terms of TELARC IANZ accreditation again looking at it from 1993 to 1996, would TELARC accredit a laboratory where a single pathologist was doing all the cytoscreening.

A Very definitely not. I have already indicated ...those three laboratories where their cytology accreditation has been suspended, it is as a result of the loss of their last cytotechnologist. So that a single pathologist however competent would not meet our requirements of accreditation.

Q So ... one of the things that Dr Bottrill would have had to have done if he wanted to obtain accreditation for the laboratory was to hire a cytoscreener to work with him.

A Or to make arrangements for another pathologist to rescreen his work.

Q Yes.

PROFESSOR DUGGAN INTERJECTS

PROFESSOR DUGGAN: By that comment Mr Walker, it is acceptable to TELARC that gynaecological slides can be screened by a pathologist?

A Solely ...by a single pathologist, no.

Q Well no, screened by a single pathologist with the quality control done by another pathologist.

A We would have considered that as an option. It would have been unusual....

A I don't know of a pathologist in New Zealand at the present point in time that would have absolute confidence in his or her work without somebody else having reviewed a good percentage of it, that someone else could equally be another pathologist or a cytotechnologist.

5.29 In addition to ensuring that more than one qualified person was involved in cervical cytology TELARC accreditation would have led to improved systems and procedures at Gisborne Laboratories. By May 1991 TELARC had issued recommendations, which had been formulated by the Cytology Advisory Liaison Committee, and which TELARC intended its assessors to discuss with laboratories during accreditation assessments for cytology. These recommendations were not extensive, however, they required:

- (i) a recommended process for checking abnormal smear tests;
- (ii) random rescreening of 10% of negative smear tests;
- (iii) they identified maximum annual and daily limits for reading smear tests;
- (iv) they encouraged participation in an external quality control programme; and
- (v) they recommended the phasing out of off-site (home screened) smear tests.

5.30 By June 1991 TELARC had issued the New Zealand Code of Laboratory Management Practice. This document, which was produced to the Committee as exhibit BJJ/MEDH/5, set out requirements for laboratory practice. These included having in place laboratory quality control procedures; the purpose of which is to demonstrate that accurate and reliable tests are being produced, to anticipate potential sources of error in a laboratory's operations and to implement checks at appropriate control points to detect any errors that should occur.

5.31 Furthermore, from 1991 TELARC recommended that laboratories accredited for cytology participate in an external quality assurance programme. By 1993 participation in an external quality control programme had become "virtually essential" for TELARC accreditation. When asked to explain what "virtually essential" meant Mr Walker described it as indicating a requirement which an assessment team might impose on a laboratory. And although it was not an absolute requirement in 1993 it was about to become so within a short period of time, so that any laboratory which did not participate in an external quality control programme in 1993 and which wanted accreditation would have had to enrol in such a programme in the very near future if it wanted to obtain or retain its accreditation. Mr Walker told the Committee :

A Historically, in the absence of an appropriate programme of inter-laboratory comparison, the requirement of IANZ, TELARC in those days, for mandatory participation, was not in existence but as those programmes became more and more developed and more and more accepted by the industries participating in them, they became progressively more likely to become requirements of accreditation, the error that we are talking about here was at the point where it was virtually a requirement, a few years before that it would not have been a requirement and very soon after that it became a mandatory requirement.

Q ... so when you say virtually essential you are meaning that this is something that in a very short period of time is going to become essential and so you are signalling that to the reader of the letter.

A That's a very fair assessment of what I intended to say, perhaps I should have used those sorts of words.

Q And so your expectation would be then that the reader takes that phrase at their peril and either does something about it immediately or waits until it becomes an absolute requirement and that that will happen very soon.

A I have every confidence that had Gisborne laboratory taken the next step and been initially assessed, that the peer assessment team would have

required participation in that programme and that was my intent and perhaps using the words virtually essential doesn't appropriately convey that intent.

- 5.32 Accreditation does not guarantee that laboratories will not under-report an unacceptable number of smear tests. It focuses on the systems and procedures a laboratory uses to achieve its results and not on the substance of the results. What it does is set in place systems and procedures to ensure that a laboratory has appropriately trained staff, well maintained equipment and recognised methods and procedures in place. However, if these systems and procedures are properly followed they should enhance a laboratory's performance substantively as well as procedurally as they are likely to lead to good quality results and to reduce the opportunities for error.
- 5.33 Accreditation also creates a culture and an awareness of quality assurance and the benefits to be derived from it. A laboratory which is attuned to the need for quality assurance to improve work performance is less likely to produce errors in smear test reporting than a laboratory where the need for quality assurance is unrecognised. Moreover, the process of obtaining accreditation involves subjecting a laboratory to a full review by a team of experts in the field for which accreditation is sought and thereafter regular inspections. This degree of attention would be likely to bring any risk associated with a laboratory's performance to notice.
- 5.34 Had Gisborne Laboratories been accredited with TELARC by the end of 1991 the impact of the CALC inspired recommendations and the New Zealand Code of Laboratory Management Practice combined with the employment of a second person to share the reading of cervical cytology would have improved the systems and the procedures Dr Bottrill followed and this in turn is likely to have reduced his under-reporting to a more acceptable level. Certainly by 1993 accreditation with TELARC would have resulted in improved systems and procedures including the introduction of internal and external quality control and a requirement to share the task of reading cervical cytology with another person. It would have brought to an end the practices that the Committee considers are likely to have led to the unacceptable level of under-reporting. The Committee, therefore, considers that the laboratory not being accredited is a factor that is likely to have led to an unacceptable level of under-reporting.

Inadequate Participation In Continuing Medical Education

- 5.35 Dr Bottrill's specialist training was in anatomical pathology. He was appropriately trained in cytopathology given the standards of the time during which he trained, however at that time cytopathology was in its infancy. Since then, cytopathology has evolved and grown, and the practice has become more specialised. Dr Bottrill informed the Committee that he had no specialist qualification in cytology; the examination he sat in the early 1970s to become a member of the College of Pathologists of Australia had no cytology component. Dr Bottrill's qualifications and experience can be contrasted with recommendations contained in standards the Cervical Screening Liaison Advisory Committee (CSLAC) sent to TELARC in 1995. These standards reveal how the perceived need for pathologists to have training in cytology had increased. They contain a recommendation that pathologists wishing to practise in cytopathology should have a minimum of two years special supervised training. Those pathologists who have the qualifications in anatomical pathology but who lack expertise in cytopathology are advised to undertake appropriate training prior to taking responsibility for cytological reporting in New Zealand laboratories.
- 5.36 Competence in a changing field is maintained by undergoing additional formal training in an accredited training centre and/or through participation in continuing medical education activities. Dr Bottrill did not undergo additional training. Dr Bottrill's evidence was that he continued his medical education by: attending approximately six to eight local post graduate meetings per year; biannual attendances at conferences and workshops relating to cytology and histology; attending the cytology sessions of the Royal College of Pathologists of Australasia between the years 1968 to 1993; attending a conference in Mexico of the World Association Society of Pathology in 1993 and a conference by the same organisation in Auckland in 1995; and attending the New Zealand Society of Cytology meetings on numerous occasions, the last being in 1992. He also spent time reading in the library at Gisborne Hospital. It seems from the evidence the Committee heard that Dr Bottrill's participation in continuing education began to decline in 1993. Furthermore, his participation at the conferences and workshops he did attend does not appear to have

made him realise or gain any insight into the risk he was taking by practising as a sole practitioner in cervical cytology, nor did it improve his reading of cervical smear tests.

- 5.37 The Committee considers that the degree to which Dr Bottrill participated in medical conferences and workshops in the period from 1990 to 1996 was insufficient for him to improve his cytopathology practices. He could have done so by additional formal training, however he never underwent such training. In the Committee's view more focussed continuing medical education and additional formal training in cytopathology would have brought home to Dr Bottrill the danger inherent in the practices followed at Gisborne Laboratories, and the need to reform the laboratory's practices. For this reason the Committee considers that the failure of Dr Bottrill to participate in continuing medical education is a factor that is likely to have led to the unacceptable level of under-reporting that occurred.

Lack Of Awareness And Insight As To How The Laboratory's Practices Put Patients At Risk.

- 5.38 The Committee considers that another feature of the practice of cervical cytology in Gisborne Laboratories, which was not compatible with the effective or safe delivery of cervical cytology, was that Dr Bottrill had no awareness of or insight into the extent to which the laboratory's practices put patients at risk. In his evidence to the Committee he said:

"I think if I were doing it again I wouldn't make any major changes. I was completely unaware at the time that I retired that there was a problem".

- 5.39 This lack of awareness and insight as regards the risk inherent in his practice of cervical cytology probably explains why Dr Bottrill continued to read cervical cytology on his own until his retirement in March 1996, and why he failed to have in place any measures to reduce the risk of practising in this way. Dr Bottrill's view on his practice at Gisborne Laboratories is completely at odds with the evidence the Committee has heard from experts on how a laboratory should carry out cervical smear test screening and the inherent dangers when carried out by a sole practitioner. He refused to accept that the following features of his practice contributed to his under-reporting:

- (i) his lack of expertise in cytopathology and primary screening;
- (ii) his lack of appropriate continuing education;
- (iii) the laboratory's failure to take timely steps to get accredited;
- (iv) the laboratory's failure to institute appropriate internal and external quality control;
- (v) the laboratory's failure to institute a system of peer review; and
- (vi) the laboratory's failure to have systematic look-back procedure for patients.

This attitude of Dr Bottrill only confirms for the Committee his unawareness of and lack of insight into the risks his practice posed to patients.

Factors Relating To The Delivery Of Cytological Services In New Zealand Between 1990 And March 1996

5.40 From the years 1990 to 1996 cytological services in New Zealand were delivered in circumstances where:

- (i) Laboratories reading cervical cytology were not *required* to follow quality control processes or to be accredited with an independent quality control authority;
- (ii) *The Government Policy for National Cervical Screening (1991)* and the 1993 updated version in relation to laboratories reading cervical cytology were not well designed;
- (iii) The National Cervical Screening Register was not functioning optimally;

- (iv) There were no performance standards for laboratories, and there were no reliable data on laboratories' performance;
- (v) There was no monitoring and evaluation of the performance of laboratories reading cervical cytology;
- (vi) The health authorities did not take heed of the warnings provided by the failures of screening programmes in other countries;
- (vii) There was a failure to ensure all components of the programme were in place from an early stage.

All of this is indicative of a failure to design and deliver a soundly based cervical screening programme. The Committee has already identified the factors relating to the practice of cytology at Gisborne Laboratories that it considers are likely to have led to the unacceptable level of under-reporting that occurred at that laboratory. The Committee considers that but for the failure to deliver a soundly based cervical screening programme the cytology practices at Gisborne Laboratories could not have continued for as long as they did. If the factors, which the Committee considers the Programme lacked, had been operative the practice of cervical cytology at Gisborne Laboratories would have been improved or come to an end. Either way the risk of unacceptable under-reporting would have been considerably reduced. Thus the Committee considers that the failure to deliver a soundly based cervical screening programme is a factor that is likely to have led to the unacceptable under-reporting that occurred in the Gisborne region. The Committee's reasons for reaching this view are set out below.

No Compulsory Quality Control

- 5.41 Compulsory quality control including accreditation for all laboratories reading cervical cytology was not introduced until some time in late 1996. It is difficult to be precise about when these requirements were introduced as their introduction into individual laboratories was achieved at different times and through more than one mechanism.

What is clear is that before this time quality control (and accreditation) was not mandatory, even though the need for quality control of laboratories reading cervical cytology for a cervical screening programme was seen as essential by more than one authoritative source from as early as the mid- nineteen eighties. A review of some of the authoritative material is set out below.

- 5.42 The 1986 Bulletin of the World Health Organisation on *Control of Cancer of the Cervix Uteri* recognised the need for quality control to reduce the occurrence of false negative reports. It said:

“ Quality control systems *must be* developed in cytology laboratories to keep the number of false negatives reports as low as possible.” (Emphasis added)

- 5.43 In 1988 a Department of Health publication titled *Towards a More Effective Cervical Screening Service for Women* recognised the need to develop quality control measures in laboratories reading cervical cytology. It said that:

“ A review of laboratory services for cervical cytology is required. This review will need *to include the development of quality control measures* to ensure that cytological services in laboratories maintain a consistently high standard.”

In its submission to the Committee the Ministry of Health said that this publication demonstrated that the Department of Health was “well aware of the issues surrounding quality relating to a national [screening] programme, including the key issues surrounding quality in laboratories.”

- 5.44 In November 1989 the *Report Of The Ministerial Review Committee On Implementation Of A Government Policy for National Cervical Screening* was published. Section 8 of the report covered smear readers and standards of competency. It began by noting that:“ Laboratories and their staff will play a key role in the success of any cervical screening programme, as it is principally through them that cytological information will be collected and recall dates established.” Sections 8.10-8.13 set out the importance of quality controls to ensure consistency in the reporting of cervical smears.

5.45 In July 1990 Dr Judith Straton of Division of Public Health University of Western Australia was engaged by the Department of Health to review of the National Cervical Screening Programme. She produced a document titled *Review of the Government Policy for National Cervical Screening* in which review she wrote:

“Aspects of the laboratory services which need attention include accreditation and quality control. ...It seems that the accreditation of laboratories by the national laboratory accreditation organisation (TELARC) is on a voluntary basis and only a relatively small number of laboratories are accredited. I have not seen the criteria for accreditation used by TELARC but I understand that they do not at present cover all the necessary areas. I believe that there should be a system of accreditation of laboratories carrying out cervical cytology screening, which is tied to the reimbursement of laboratories for reading smears. Public hospital laboratories should also be included.” (emphasis added)

5.46 In August 1990 an experts groups which had been established in December 1989 to advise the Minister of Health on national policy and resource allocation for the National Cervical Screening Programme presented a report titled *Policy Statement Of The Government Policy for National Cervical Screening Expert Group*. Section 12 of the report dealt with laboratories. The report acknowledged that: “The efficiency of the cervical screening programme will depend on high standards of smear reading by laboratory technicians and an acceptable turn-around time for reporting on smears. ” In section 12.2 the report set out a proposed implementation strategy for the programme in relation to laboratories. This provided:

“Section 12.2.2 The expert group recommends that by 1991 all cytology laboratories serving the National Cervical Screening Programme should have applied for registration with the testing Laboratory Registration Council of New Zealand (TELARC) and should be TELARC registered by December 1993. The only exceptions will be if TELARC itself is unable to meet these deadlines or if a laboratory is newly set up, necessitating a reasonable period of time in which to obtain TELARC registration.

12.2.3 The Department of Health should be responsible for confirming that those laboratories carrying out cytology screening for the National Cervical Screening Programme meet the recommendations set out in 12.2.2. Such confirmation should become a requirement for receiving the laboratory benefit for reading National Cervical Screening Programme smears.

12.2.4 The criteria for registration by TELARC should be negotiated with TELARC by CALC and the Department of Health. The criteria will include guidelines on :

- ?? The reading of a minimum number of smears a year;
- ?? The employment of adequate numbers of suitably qualified staff;
- ?? The maximum workload for each cytoscreener;
- ?? Adequate in-service education;

- ?? A satisfactory participation of both internal and external quality assurance procedures;
- ?? Co-operation in providing cytology reports to the cytology register.

12.2.5 The Department of Health, CALC, TELARC and other relevant organisations will seek standards for the training of cytology laboratory assistants. The Department of Health is responsible for ensuring that there are sufficient training facilities to meet the cytology screening workforce requirements of the National Cervical Screening Programme.

12.2.5 Developing a mechanism for linking the histology results of cervical tissue submitted to laboratories for diagnosis to the cytology register is an urgent priority for the Department of Health. The register will also be developed so that laboratory staff have direct access to a woman's previous smear history when reading smears.

- 5.47 In July 1991 a report was published in the New Zealand Medical Journal titled *Cancer Screening 1991 Cervical Screening Recommendations: A Working Group Report*. The report commented on the need for quality control of all aspects of cervical screening including laboratory performance:

“ Quality control of all aspects of cervical screening should be a major emphasis of the National Cervical Screening Programme. To provide proper quality control there should be formal evaluation of all the components of the screening process from recruitment and recall of women to management of women with abnormal smears. A national register is the essential management tool to allow this and should be expanded to include the relevant histology results ensuring correlation and evaluation of cytology findings. Health educators, smear takers, laboratory staff, computer staff, colposcopists and therapists should all be appropriately trained and qualified. Laboratories and sites for therapy should be accredited . Legislation is essential to allow all laboratories to provide both cytology and histology results to the register.”(emphasis added)

- 5.48 In 1991 the *Government Policy For National Cervical Screening (1991)* was issued. This was the first written policy for the Programme. It was prepared by the Department of Health and approved by the Associate Minister of Health. The *Policy* was based on the recommendations that were made in the August 1990 report of the Expert Group. Part 4 of the *Policy* defined the role of laboratories in the implementation of the Programme and the expectations of their performance in this role. Part 4 incorporated most of the recommendations, for quality control of laboratories, that appear in section 12 of the Expert Group's report. It anticipated laboratories being accredited with TELARC or a similar authority by 1993; and it described the criteria for accreditation. This included: having a set minimum number of smears for reading each year; employing adequate numbers of suitably qualified staff; having maximum workloads for each cytoscreener; making provision for

adequate in-service education; participating in internal and external quality assurance procedures and providing cytology reports to the cytology register.

5.49 It seems that pathologists were not in general resistant to compulsory accreditation. The minutes of a meeting of the Cervical Screening Advisory Committee held on 12 December 1991 record the committee's discussion on how to enforce accreditation of laboratories. Dr Clinton Teague, pathologist, is recorded as saying that he did not think that accreditation would be a big problem as most laboratories were moving towards accreditation, and that compulsory accreditation had been accepted by laboratories as they had had sufficient time to gain accreditation. He is also recorded as referring to the Australian position where laboratories had to be accredited to claim Medicare subsidies. The Committee has not seen any material or heard any evidence in the course of its inquiries that would suggest that pathologists would have strongly resisted the introduction of compulsory accreditation by making receipt of government funding conditional on accreditation.

5.50 In 1992 the World Health Organisation published the Cervical Cancer Screening Programmes' Managerial Guidelines. In discussing technical resources for cytological examination the guidelines state :

“Before a screening programme is started the resources must be in place for taking the smears and a cytology laboratory must be accessible to examine and report on the smears. To ensure that the laboratory services are both efficient and cost effective they should be centralised, each laboratory being supervised by a fulltime cytopathologist *with an organised system of quality assurance* and continuous education of cytotechnologists. (emphasis added)

Later in the *Guidelines* there is a reference to an earlier World Health Organisation publication of 1988 dealing with laboratories in which it was recorded that: “ The laboratory must have adequate quality control procedures in place for cervical cytology.”

5.51 All of the above shows that at an early stage in the development of the Nation Cervical Screening Programme there was authoritative material from international and national sources on the importance of quality control in laboratories reading cervical cytology for screening programmes. The various reports to the Minister and the Department on

the establishment of a cervical screening programme all recognised the importance of quality control. Furthermore, the inclusion of quality control provisions in the *Policy* in 1991 shows that by then the Minister and the Department had accepted quality control was important. Moreover, the Committee was not referred to any material which suggested that the use of quality control processes in laboratories reading cervical cytology was unnecessary.

5.52 The Committee's view was confirmed by the evidence of Professor McGoogan. She was critical of the failure to have quality controls in place from the outset. She was shown a flow diagram that was appended to the draft report of the National Cervical Screening Workshop of 1988. This flow diagram recorded the points in the Programme at which quality control and evaluation needed to occur. Professor McGoogan considered the diagram was a good starting point for implementing quality control, but that it did not go far enough. When asked to give her opinion on the Programme's failure to adopt the diagram of quality controls and its lack of any quality controls on laboratory performance up to 1996 her response was:

“ I would be extremely disappointed because by the time the New Zealand Programme was implemented the need for quality control and evaluation for a screening programme of any kind was well recognised.

Professor McGoogan considered that if quality controls were not in place from the outset that they should have been in place by the end of the first cycle of the programme, that is: three years after its commencement and for good data to be collected from that time onwards.

5.53 It seems to the Committee that the necessity of quality control processes for reading cervical smear tests for a screening programme is incontestable. This is not an idea that has only recently become accepted. The literature to support this view has been available for many years and certainly some of it pre-dates the National Cervical Screening Programme. Furthermore the logic of the necessity for quality control is readily apparent. One significant difference between laboratory diagnostic testing for a screening programme and laboratory diagnostic testing to discover a suspected ailment is that in the latter case the patient is unwell and presents with signs and symptoms. Because the patient is unwell there is bound to be further investigation, if

the laboratory misdiagnoses the test, and this should ultimately lead to the correct diagnosis. None of this applies to a screening programme. A screening programme involves large numbers of healthy women. The whole purpose of a screening programme is to detect pre-cancerous abnormalities, which are generally asymptomatic. This means that a woman who is referred for a cervical smear test will usually not be displaying any signs. If her smear test is misdiagnosed there is nothing to alert her or her medical practitioner to that possibility. It, therefore, seems obvious to the Committee that there are, and always have been, more pressing reasons for having quality control processes in laboratories reading cervical cytology for screening programmes than in respect of other diagnostic services. So that, even though during the period under review general laboratory services were not subject to compulsory quality control or accreditation requirements, there was good reason to treat cervical cytology differently. Compulsory quality control and accreditation of laboratories reading cervical cytology should have formed part of the National Cervical Screening Programme from the outset. The Committee understands that some laboratories could not have become accredited immediately. However, those laboratories could have been accommodated by specifying a lead-in period with a definite expiry date after which only accredited laboratories would be eligible to receive funding for reading cervical cytology.

- 5.54 In 1993 the *Policy* was updated to accommodate the structural changes in the health sector. Part 4.1.2 which set out the expectation that laboratories would gain TELARC accreditation by 1993 was amended by removing the indirect reference to this date and replacing it with an expectation that accreditation *should be* achieved within a reasonable period of time. This weaker statement placed less pressure on laboratories than the earlier expectation, which at least attempted to place a time limit on the move towards accreditation. At the same time in 1993 the European Community had issued guidelines on cervical screening which recognised the importance of quality control in laboratories. Section 7 of the *European Guidelines For Quality Assurance In Cervical Cancer Screening*, which covers quality assurance in the cytology laboratory, stated:

“Quality assurance in cervical cytology is designed to achieve an acceptable reliability and consistency in the results produced in the cytology laboratory.”

Then after defining the terms “internal quality assurance” and “external quality assurance” the *Guidelines* continued: “We consider that *both schemes are essential for sound laboratory practice* ”(emphasis added). The *Guidelines* also recognised the need for accreditation of laboratories with an independent quality control agency:

“Accreditation is assessment of standards by a panel of experts. The assessment will entail a visit to the laboratory to inspect working conditions and assess working practises such as staff workload ratio, quality assurance measures, health and safety preconditions, arrangements for staff training, quality of record keeping, arrangements for follow up of abnormal smears etc”

- 5.55 It was not until late 1996 that compulsory accreditation for cervical cytology was imposed; and then it occurred in a piecemeal fashion as each of the four Regional Health Authorities was able to conclude a contract (including compulsory accreditation) with the diagnostic laboratories which provided it with services. In the case of the Gisborne region the service contract between Midland Regional Health Authority and Gisborne Laboratories, was not executed until March 1997. This was nine years after the Department of Health had first recognised the need to develop quality control measures to ensure laboratories reading cervical cytology maintained a high standard.
- 5.56 The Ministry of Health has submitted to the Committee that there are good reasons why it took so long to introduce compulsory quality control through requiring laboratories to be accredited with IANZ or a similar body. These reasons and the Committee’s views on them are dealt with in the discussion on Term of Reference Three, which looks at systemic problems with the National Cervical Screening Programme. For the purpose of answering Term of Reference Two the Committee considers that it is necessary only to report on those factors that it considers are likely to have led to under-reporting. The Committee has already described the benefits of quality control and laboratory accreditation and the effect they would have had on the practice of cervical cytology at Gisborne Laboratories. Because it considers that compulsory quality control (either through TELARC accreditation or a scheme with similar features which the Department imposed directly as a condition of payment) would have prevented Gisborne Laboratories from continuing to practise as it did, the Committee has concluded that the failure to make quality control and laboratory accreditation compulsory by 1993, at the latest, is a factor that is likely to have led to

the under-reporting in the Gisborne region, 1993 being the chosen year in the 1991 *Policy* for laboratories to have gained accreditation. The Committee is aware that mistakes can still occur in accredited laboratories, and that accreditation is not a complete answer to avoiding laboratory errors. In this case, however, accreditation would have stopped those practices at Gisborne Laboratories that led to unacceptable under-reporting.

Design Faults Of The Government Policy For National Cervical Screening (1991) As It Related To Laboratories Reading Cervical Cytology

5.57 The laboratory component of the 1991 *Policy* and the updated 1993 version was set out in clause 4 of both documents. It was much the same as the recommendations for laboratories reading cervical cytology in section 12 of the Expert Group's report of 1990. Clause 4 provided

“4.1.2 All cytology laboratories servicing the National Cervical Screening Programme should be registered with the Testing Laboratory Registration Council of New Zealand (TELARC) or other recognised authority. It is expected that laboratories not so registered will apply and gain such registration. A reasonable period of time will be allowed for laboratories to obtain registration. This may take up to two years.

4.1.3 The Department of Health will be responsible for confirming that those laboratories carrying out cytology screenings for the National Cervical Screening Programme meet the requirements set out in 4.1.4.

4.1.4 The criteria for registration by TELARC or other recognised authority will be established by the cytology advisory liaison committee. The Department of Health will be consulted. The criteria will include :

- ?? Reading of a minimum number of smears a year;
- ?? Employment of adequate numbers of suitably qualified staff;
- ?? Maximum workload for each cytoscreener;
- ?? Adequate in-service education;
- ?? Satisfactory participation in both internal and external quality assurance procedures;
- ?? Provision of cytology reports to the cytology register.

4.1.5 The Department of Health, the Cytology Advisory Liaison Committee, TELARC and other relevant organisations will monitor standards for the training of cytology laboratory assistants.”

5.58 The Committee has already discussed in the preceding paragraphs the importance of quality control, including laboratory accreditation. Here, the focus of the Committee's interest is on the special accreditation for laboratories reading cervical cytology that

was planned in clause 4 of the *Government National Cervical Screening Policies* issued in 1991 and 1993. The clause specified a number of criteria for inclusion in TELARC's general criteria for accreditation. These were additional criteria which the *Policy* intended the Cytology Advisory Liaison Committee (CALC) to develop in consultation with the Department and then for TELARC to apply them when it came to accreditation of laboratories reading cervical cytology. Clause 4 demonstrates the *Policy's* intent to shape the criteria for TELARC accreditation for laboratories reading cervical cytology to include requirements which had been recognised overseas as being beneficial to the success of a screening programme. Three paragraphs of clause 4 are significant; these are: 4.1.2; 4.1.3 and 4.1.4

- 5.59 Though the inclusion of clause 4 demonstrates that the Minister and the Department recognised the importance of quality control for laboratories, and that the intent of the *Policy* was for laboratories servicing the Programme to be accredited with an independent quality control authority, the poor design of the *Policy* did nothing to guarantee that occurred. Paragraph 4.1.2 did no more than to state that laboratories “*should be*” registered with an accreditation authority. This is different from stipulating that laboratories *must be* accredited. There is nothing in the language of paragraph 4.1.2 that compelled the Department to ensure a laboratory became accredited. The paragraph does no more than exhort laboratories to gain accreditation. In the Committee's view, once the importance of accreditation was accepted, and provision made for it in the *Policy*, the design of the *Policy* should have ensured that accreditation would happen.
- 5.60 In the 1991 *Policy* paragraph 4.1.2 contained an expectation that laboratories that were not accredited would be given a reasonable period of time to do so, (up to two years). This expectation was ineffective. If laboratories resisted or were dilatory in taking steps to gain accreditation there was nothing that the Department could do under the *Policy*, or otherwise, to compel them to become accredited. This was so, even though diagnostic laboratories reading cervical cytology were fully paid for this service from government funds. The Committee comments in its report on Term of Reference Three on the Ministry of Health's explanation for how this came about. What the Committee is concerned to report on here is its view that a well designed cervical screening policy is one which recognises the need for quality control and accreditation

of laboratories and is designed to ensure these features are in place. The 1991 *Policy* could not do this. This is one of the reasons why the Committee considers the 1991 *Policy* to be poorly designed. Compulsory accreditation, based on the criteria in paragraph 4.1.4, would have brought the practices followed at Gisborne Laboratories to an end. In so far as the *Policy* permitted Gisborne Laboratories to continue to practice its poor design is a factor that is likely to have led to the under-reporting at Gisborne.

5.61 The criteria in 4.1.4 are important. For example: the criterion regarding a minimum number of smears per annum. In 1991 and up to the time of Dr Bottrill's retirement Gisborne Laboratories was reading no more than 5000 smears per year. At the time the internationally recommended minimum number was well in excess of this number. The World Health Bulletin on *Control of Cancer of the Cervix Uteri* had stated in 1986 that:

“Cytology services should be centralised. A large volume of work contributes to the successful operation of a cytology laboratory because a specialised division of labour is possible and a large number of abnormal smears representing various pathologies will help to maintain the cytotechnologists skills. In general laboratories that screen fewer than 20,000 specimens annually are not cost-efficient and cannot support either a training programme or a full-time cytotechnologist. Preferably the annual number of specimens should be 50,000 or more.

A publication from the Council On Scientific Affairs, American Medical Association JAMA 1989 *Quality Assurance In Cervical Cytology*(exhibit RGB/MOH/3) reported that the American Society of Cytology would only accredit laboratories that received a minimum of 10,000 gynaecologic smears per annum or maintained staff of at least one cytopathologist and one full time cytotechnologist.

5.62 In the *Review of the National Cervical Screening Programme*, which was written in 1990, Judith Straton reported on the need for setting a minimum number of smear tests. She saw no practical difficulty in implementing this requirement as she considered that smear tests could be easily transported to those laboratories which were reading a large number of smears and which could meet a compulsory minimum requirement. She realised that a compulsory minimum number would exclude some

laboratories from reading cervical cytology but it appears to the Committee that in her view this would only benefit the Programme. She said:

“ The issue of the minimum number of screening smears which are essential to maintain a competent screening service is one which needs to be addressed. Apparently there are laboratories in New Zealand which are reading fewer than 50 smears per year, compared with the minimum in the United Kingdom of 15-20,000 smears per year. Obviously with a smaller and more scattered population one may not be able to use quite such stringent criteria, but communications in New Zealand are good and smears can easily be sent from place to place. *This problem needs to be addressed urgently.* It would be very difficult for laboratories reading as few as 50 smears per year to maintain a suitable level of competence or have any systematic quality control, and *this issue must be faced.* Women have the right to expect a minimum level of competence in the reading of their smears.”(emphasis added)

5.63 From the material the Committee has seen it is clear that everyone working with the Programme thought, in principle, that a compulsory minimum number of smears was needed to maintain screeners' competence. And, that 5000 smears per annum was a low number of smears to read in order to maintain competence. However, by setting a minimum number the Programme would have excluded some laboratories, including hospital laboratories, from reading cervical cytology. In New Zealand cervical cytology had always been read by any laboratory that wanted to do so. Furthermore, there was no history of the Department or the Ministry of Health preferring certain laboratories to others when it came to funding for diagnostic services. Therefore, the setting of a minimum number required a major change in approach. It seems to the Committee that ultimately the issue was too difficult to face and nothing was done, even though the *Policy* intended a minimum number of smears to be set and everyone recognised the benefits of laboratories which read a large number of smear tests. Once again the *Policy* had no means of ensuring that its intent was achieved.

5.64 The issue of setting a compulsory minimum number of smears for reading per year was finally faced in 2000 by the Health Funding Authority when, in its proposed standards for laboratories reading cervical cytology, it proposed a minimum of 12,000 smears per year. The rationale behind setting a minimum number of smears per annum is that unless a laboratory processes a sufficient number of smears the screeners cannot maintain their competence. Simply by ensuring that a set minimum number of smears for reading each year (which reflected international minimum numbers) was actually

in force the *Policy* would have excluded Gisborne Laboratories from reading cervical cytology.

5.65 Clause 4.1.3 placed the responsibility on the Department of Health to confirm that laboratories carrying out cytology reading for the policy met the requirements of 4.1.4. However, as accreditation was not compulsory clause 4.1.3 had little effect, and the evidence is that the Department of Health did little to ensure that laboratories met the requirements set out in 4.1.4.

5.66 The Committee heard evidence from Mr Mules, the former Chief Executive of the Midland Regional Health Authority. He had previously been employed as the General Manager of the Bay of Plenty Area Health Board. In this capacity he would have had experience of how the *Policy* of 1991 worked in relation to area health boards. He had also undertaken work for the Health Reforms Directorate of the Department of Health. He appeared to the Committee to be a witness who was informed about the Programme and how it functioned prior to the health restructuring in 1993. He told the Committee that one of the aims of the Programme prior to 1993 had been to introduce quality standards for laboratories reading cervical cytology but that the method by which such standards would be enforced was unclear to him as in his view there was no appropriate accountability structure in place:

“One of the aims of the National Cervical Screening Programme was to introduce quality standards around the reading of slides by pathologists, a process that requires the pathologist to exercise their professional judgement after actually viewing the slide and cannot be automated. Those aims were explained under the heading “*Laboratories*” at page 5 of the 1991 *Policy*”. ...

Mr Mules then referred to the 1991 Policy, which stated that the Department of Health would be responsible for confirming that laboratories carrying out cytology screening met TELARC requirements and said:

“To my knowledge this was the first time that an attempt was made to have private laboratories agree with an external agency (in this case Department of Health) to develop and implement quality standards. *How this is to be enforced in the absence of an appropriate accountability structure is unclear.*” (emphasis added)

5.67 Mr Mules evidence on the 1991 *Policy* confirms for the Committee the impression it gained from other evidence that the 1991 *Policy* was designed without any provision put in place to enforce the *Policy*, should the need arise. The overall tenor of the *Policy* as regards laboratories is to set out statements that essentially describe good practice and then to leave it to the good will of the laboratories to respond to these exhortations. In the Committee's view this is insufficient. A well designed *Policy* should require laboratories to practise quality control and to be accredited with an appropriate authority, and it should ensure that there is a means of compelling laboratories to comply with the *Policy's* intent if they fail to respond.

5.68 When the *Policy* was updated in 1993, to take into account the structural changes in the delivery of health services, the amendments to clause 4 only exacerbated its poor design. It has already been noted in the report that the two year time frame within which accreditation was *expected* to be achieved was removed. More importantly, the division of responsibility in the updated *Policy* between the new Ministry of Health, (which had replaced the Department of Health), and the four new Regional Health Authorities, (which had assumed much of the Department of Health's operational responsibilities), was poorly designed. This was so even though the updated *Policy* described itself as being:

“ revised and updated to accurately reflect the structural changes to the health sector, the changes to the National Cervical Screening Programme and Register... The purpose of this revision is to update the policy for regional health authorities, the Public Health Commission and for cervical screening programme managers and service providers. The update makes no changes to the goals, objectives, or targeting sections of the 1991 policy document.”

The wording of clause 4 remained the same except that the Ministry of Health was substituted for the Department of Health and the statement in clause 4.1.2 that TELARC accreditation may take up to two years was removed. No account appears to have been taken of the new policy-making and advisory role of the Ministry and its reduced ability to carry out operational activities. This change from a government department to a ministry with a policy-making role meant that the new Ministry of Health was less well placed than the Department of Health to carry out the role clause 4.1.3 gave to it.

- 5.69 The Ministry did consider whether it was appropriate for the Programme to remain with the Ministry, given its role in the new health structure. An internal memo of 18 March 1993 from Sonja Easterbrook-Smith to the Director-General acknowledges that the role of nationally co-ordinating the Programme was anomalous in a policy advice Ministry. Nevertheless, a decision was made to retain that role, and the responsibilities the *Policy* of 1991 had imposed on the Department of Health, within the Ministry. Once a decision was made to retain those features of the Programme within the Ministry, the 1993 updated *Policy* should have been designed to ensure that the effective delivery of the Programme was not compromised by any resulting anomaly.
- 5.70 Ms Judith Glackin, who gave evidence for the Ministry of Health, told the Committee that the Ministry could not carry out the role of confirming that laboratories met the criteria in 4.1.4 as the Ministry had no means of discharging this task. She said that the Ministry sought, instead, to discharge this task by ensuring that laboratories were TELARC accredited:

“Paragraph 4.1.3 could be read as intending that the Ministry would in some way be responsible for confirming that laboratories were meeting all the criteria required for TELARC registration. This was clearly not possible, as the Ministry had no direct relationship or influence over laboratories after RHA [Regional Health Authority] contracts replaced the previous payment arrangements under Part II of the Social Security Act 1964. Ensuring that laboratories were accredited by TELARC or another suitable quality assurance programme was seen as the way of ensuring that laboratories met quality standards.

However, the evidence shows that the Ministry did nothing to *ensure* that laboratories were TELARC accredited. All that it did was to include in its funding agreements with the regional health authorities a provision that they use “ reasonable endeavours to ensure” laboratory accreditation. To ensure something is done is to make certain, to secure or to guarantee that it is done. Requiring regional health authorities to use their “reasonable endeavours to ensure accreditation” does not amount to making certain, guaranteeing or securing accreditation. Thus the Ministry failed to discharge its responsibilities in clause 4.1.3, however that clause may be interpreted.

5.71 The Ministry's inability to perform the role clause 4.1.3 placed upon it was recognised by the Cytology Liaison Advisory Committee. In June 1994, when the 1993 *Policy* was being reviewed, this committee commented in a submission for the review that:

“The Ministry of Health does not have the expertise and nor would it seem an appropriate function of the Ministry of Health to confirm that laboratories were meeting detailed requirements relating to TELARC accreditation.”

However, because of delays in the completion of the policy review the wording in the 1993 *Policy* remained unchanged until a new *Policy* document was issued in June 1996. This was after Dr Bottrill's retirement.

5.72 Ms Glackin referred to the 1994/95 Funding Agreements between the Ministry and the Regional Health Authorities which required the authorities to use their ‘*reasonable endeavours to ensure*’ that all laboratories providing laboratory services for cervical cytology and histology were registered with TELARC or an equivalent quality assurance programme. She said that these funding agreements were between the Minister and the Regional Health Authorities and that they were “the primary accountability documents”.

5.73 All the funding agreements from 1994 until 1997/98 refer to the 1991 *Policy*, even though that *Policy* was based upon a health structure of a Department of Health and 14 area health boards. The Committee received no explanation for why the funding agreements referred to the 1991 *Policy*. Although the 1993 *Policy* had been updated to make specific reference to the new health structure involving the Ministry of Health and the regional health authorities the funding agreements failed to record this. By the 1997/98 funding agreement a new policy had been published in 1996 and the 1997/98 funding agreement referred to the new *Policy*. The Committee was told that, the performance monitoring branch of the Ministry of Health – which was the branch responsible for issuing the funding agreements – was not advised about the updated version and so until 1996 the funding agreements referred to the 1991 *Policy*. Although the funding agreements may have referred to the 1991 *Policy*, from the evidence it appears that everyone understood that it was the 1993 updated version that applied. It would have been difficult to apply the 1991 *Policy* after the health

restructuring as that *Policy* allocated responsibilities to the Department of Health and the area health boards.

5.74 Clause 10.4 of the 1994/95 funding agreement read :

“10.4 The RHA agrees to use its *reasonable endeavours to ensure* –
10.4.4 All laboratories providing laboratory services for cervical cytology and histology -
(b) are registered with TELARC (the Testing Laboratory Registration Council of New Zealand) or an equivalent quality assurance programme;”
(emphasis added)

Clause s4.11.5 of the 1995/96 funding agreement and clause s5.3.20 of the 1996/97 funding agreement also repeated this requirement. However, in addition to these clauses, clause 10.3 of the 94/95 funding agreement, clause 4.11.4 of the 95/96 funding agreement and clause 5.3.19 of the 96/97 funding agreement, provided that the National Cervical Screening Programme, and the cervical screening services, were to be consistent, inter alia, with the *Government Policy for National Cervical Screening (1991)*.

5.75 Ms Glackin accepted that the impact of clauses 10.3, 4.11.4 and 5.3.19 was to incorporate the 1991 *Policy* document as a term of the funding agreement :

“Q It seems that the 1991 *Policy* was actually incorporated into the funding agreements for 94/95?

A Yes, that is how it reads.

Q And if you would turn next to the funding agreements 95/96 and go to page 112, ... once again the 1991 policy document is made a term of the funding agreement is it not?

A It is

Q Anyone reading the funding agreements seeing that the 91 *Policy* was part of the funding agreement and going to the 91 *Policy* para 4.1.3 would conclude that the Ministry of Health would be responsible for confirming that the laboratories met the requirements set out in 4.1.4?

A Yes.

Q And I understand your evidence is that practically speaking, because the Ministry had no direct relationship or influence over laboratories, it couldn't discharge its responsibility which it had under 4.1.3 of the *Policy*?

A The mechanism available to the Ministry was through the Regional Health Authority funding agreement and as you have pointed out that referred to the 91 *Policy* so yes it would appear that was the case.

Q So it seems then that the Ministry ... knowingly allowed itself to be placed in a situation where it could no longer responsibly carry out its responsibilities under 4.1.3.

A I believe that's the case and I think the problem associated with this is the one I refer to later in my brief, which is a delay in the review of the *Policy*. At the time the *Policy* was reviewed in 1993 it was envisaged that the review would be completed in 1994, in fact it was not completed until 1996 which meant that the *Policy* stood as it had been originally worded.

5.76 This means that, although the updated 1993 *Policy* intended the Ministry to be responsible for confirming that laboratories carrying out cytology screening for the Programme met the accreditation criteria in clause 4.1.4, this could not be done and, therefore, it was not done. Ms Glackin accepted that there was nothing about clause 4.1.3 which was ambiguous about the responsibility it conferred on the Ministry. She accepted that on reading the *Policy* document it appeared the Ministry was responsible for carrying out clause 4.1.3.

“Q The *Policy* document says the Ministry of Health will be responsible and is it fair to say on reading 4.1.3 there is nothing ambiguous about that responsibility?”

A There is nothing ambiguous about the wording, the problem there was no apparent way in which that responsibility could have been carried out.”

Thus the 1993 updated *Policy*, produced by the Ministry of Health, gave to the Ministry a role which it could not fulfil. Hence, between 1993 and 1996 the intent of the Programme's policy document did not reflect the reality of the Programme's delivery.

5.77 Mr Mules gave evidence on the 1993 *Policy* which suggested to the Committee that the Midland Regional Health Authority's understanding of its responsibilities to the Programme was confused by the difference in the allocation of responsibility in the *Policy* and the Funding Agreements. He said that the Midland Regional Health Authority had not treated the laboratory component of the Programme as a priority because it considered that it was the Ministry's responsibility. He described the 1993 *Policy* in this way:

“The responsibilities of the Ministry of Health, the Regional Health Authorities, Public Health Commission, Cervical Screening Advisory Committee and the Cytology Advisory Liaison Committee are explained at page 8 of the 1993 Policy. The responsibility of the Ministry of Health for introducing quality standards around the reading of slides by pathologists was continued from the role of the Department of Health in the 1991 Policy.”

For the Regional Health Authorities the specific laboratory component of the National Cervical Screening Programme was a relatively low priority because we believed that the Ministry was responsible for it. Our National Cervical Screening Programme priorities were enrolment of women, improving access to screening and treatment services, and ensuring collection and communication of data from the local programme directly to the Ministry.”

5.78 Later in his evidence Mr Mules confirmed his views on the relationship between the funding agreements under which the regional health authorities were operating and the *Government Policy for National Cervical Screening*. He said :

“Between 1991 and 1996 the Department/Ministry of Health was responsible for laboratory quality in respect of the National Cervical Screening Programme, covering both definition of the criteria for TELARC registration, and confirmation of which laboratories were eligible to carry out National Cervical Screening Programme screening work. The Department/Ministry also controlled the data from the National Cervical Screening Programme Register that allowed comparative monitoring and analysis of laboratory activity. Midland did not have such access.”

5.79 When Mr Mules was asked whether or not, to his knowledge, the Ministry was aware that the Midland Regional Health Authority did not consider itself responsible for confirming whether or not laboratories were TELARC accredited, his response was that it was commonly understood amongst all parties that the Regional Health Authority focus was on enrolment and colposcopy in respect of the Programme.

“Q I want to be clear then, you can only give evidence of your experience of dealings with the Ministry during this time, but from your dealings with the Ministry did you gain the impression that the Ministry was aware Midland Regional Health Authority believed because of the cervical screening policy in 4.1.2 and 4.1.4 that the laboratory component of the Programme was the responsibility of the Ministry.

A If you are referring to those aspects of the laboratory components as described in 4.1.2 to 4.1.5, yes. I was never party to any discussions that would have made people think otherwise. We were responsible in the context of moving from section 51 to laboratory contracts that would have introduced TELARC registration, but that was in a generic sense.

Q As I read your evidence you are saying the Regional Health Authority believed the Ministry was responsible for the laboratory component of the screening Programme.

A Yes, as laid out in *Policy* guidelines.

Q The point is if that was the understanding of the Regional Health Authority, then whether or not there was any monitoring and evaluation of the laboratory component of the Programme would depend very much on whether the Ministry recognised that it was responsible for that part of the Programme, wouldn't it?

A Yes, it would depend on their interpretation of the *Cervical Screening Policy* and the funding agreement.

Q What I am trying to find out from your knowledge is whether or not the Ministry was aware of the Regional Health Authority view.

A I've got no reason to believe that they weren't, and Jane Hudson was in frequent communication with the national co-ordinator and as you've seen from the service requirement definition Jane has carried forward the *Policy* into those documents. I would have thought she would not have done that if she had a contrary view.

Q The outcome would be if the Regional Health Authority relying on the documentation believed the Ministry was responsible for the laboratory component of the Programme in terms of monitoring and evaluation, but if the Ministry itself believed that it couldn't carry that out as heard from Ms Glackin, it would really mean no-one was doing the job, wouldn't it?

A One can assume that.

5.80 Mr Lambie was responsible for the unit that prepared and negotiated the funding agreements. He was asked to comment on Mr Mule's evidence about the regional health authorities' understanding of their obligations under the funding agreements. Mr Lambie accepted that there was some ambiguity between for example clause 10.3 and 10.4 of the 94/95 funding agreement, however, he said that no regional health authority had taken this up with the Ministry at the time the agreements were being negotiated:

“Q ...if you go to 10.3... it says the regional health authority is to purchase cervical screening services ...this Programme and the cervical screening services are to be consistent with ... the government's 1991 policy for national cervical screening. And then under 10.4 it says the regional health authority is to use reasonable endeavours to ensure a number of things including TELARC accreditation...I think the difficulty is that in 10.3 there is the reference to the purchasing of service being consistent with the government's 1991 *Policy*. So I think what Mr Mules was saying, well under the 1991 *Policy* certain responsibilities remained with the Ministry ...in terms of paras 4.1.2 to 4.1.4 of the *Policy* therefore you you've got a tension within the funding agreements between, by incorporating the 1991 *Policy*, that puts a responsibility on the Ministry, which also para 10.4 appears to be putting on the regional health authorities. What do you do when you've reached the end of the year and you say “ well who should have done what?”

A I accept that there is some potential ambiguity. However, if that ambiguity had been recognised at the time I think it would have been cleared up. I think that the key part of this funding agreement was under 10.4.

Q And to the best of your knowledge did the regional health authorities ever say to the Ministry, “well we actually think the incorporation of the government’s 1991 *Policy* ...means the Ministry has certain obligations about laboratory services and cytology as set out in that *Policy* agreement which conflict with our funding agreement responsibilities?”

A To the best of my knowledge that never occurred.

- 5.81 There was clearly confusion between the two health agencies in relation to their respective roles under the 1993 *Policy*. Each agency appears to have had its own interpretation of the responsibilities that the *Policy* and the funding agreements placed upon them, and they each appear to have been totally unaware of their different interpretations. Because of this neither said anything to the other about the confusion.
- 5.82 The presence of this confusion is confirmed for the Committee by the review that the Ministry of Health carried out for the Associate Minister of Health in April 1996. At the time it was considered that accountability arrangements between the Ministry and the Regional Health Authorities were contributing to problems with the Programme. Ms Glackin informed the Committee that the official’s report dated 11 April 1996 identified three key problems for the Programme. One of these was confusion between the Ministry and the Regional Health Authorities over “accountabilities for the Programme”. The Ministry appears to have recognised at the time of the review that the Regional Health Authorities “saw themselves as purchasing a series of individual components which contributed to a programme owned by the Ministry rather than purchasing an integral service for women.”
- 5.83 The practical effect of this confusion is that it seems from 1993 until the new *Policy* in 1996 the Ministry of Health considered that it could not carry out the responsibilities the *Policy* placed upon it in clause 4 and, therefore, it did not specifically attempt to do so. But the Regional Health Authorities were not stepping into the breach created by the Ministry’s inability to carry out its responsibilities because as they saw it the *Policy* placed the responsibility for the laboratory component of the Programme on the Ministry. The end result of this confusion was that little, if anything, was done in terms of clause 4 of the *Policy*.

5.84 Certainly, in response to their contractual requirements under the funding agreements with the Ministry, the Regional Health Authorities were working towards requiring all laboratories to gain accreditation for all of their services. Even then, the funding agreements only required Regional Health Authorities to exert “reasonable endeavours” to achieve accreditation. But, as Mr Mules acknowledged, this was different from the specialised accreditation that the *Policy* contemplated in clause 4.1.4 for laboratories reading cytology for the Programme. The funding agreements did not reflect the content of the *Policy*; they made no attempt to distinguish cervical cytology laboratory services from other laboratory services by requiring cervical cytology to be read only by TELARC accredited laboratories. No one was doing anything meaningful to ensure that the criteria envisaged in clause 4.1.4 were actually being developed, and once in place adhered to. There were many discussions with various advisory groups about what should be done, but ultimately nothing meaningful was done by the Ministry in relation to its role in clause 4 of the *Policy*.

5.85 There is another aspect to this confusion. On 24 November 1994 the Women’s Health Action group wrote to the Minister of Health regarding a woman’s false-negative smear result and asked, inter alia, what structures were in place to monitor laboratory quality and what information did the Programme have about false negative rates in laboratories used by the Programme, how were false negative rates monitored and how were they reduced in laboratories where the rate was high. The Associate Minister responded to the Women’s Health Action group on 30 March 1995 by advising them that:

“A variety of measures are in place or are being developed to ensure that the quality of smear reading is as high as possible. The 1995/96 *Policy* guidelines for regional health authorities state that regional health authorities must ensure that all laboratories providing cervical cytology and histology services are registered with ... TELARC or an equivalent programme. The National Cervical Screening Programme anticipates that all laboratories will have TELARC (or equivalent accreditation) by the end of 1996. Several years ago the cytology advisory liaison committee made a number of recommendations to TELARC relating to performance of cytology in medical laboratories. These recommendations which were accepted by TELARC at that time, have been recently revised and upgraded and a provisional list of recommendations is currently being considered by TELARC.

As part of the TELARC registration process laboratories are required to demonstrate both internal and external quality assurance participation. While TELARC guidelines do not specify which quality assurance procedure

should be followed in relation to external quality assurance the great majority of laboratories are now registered with the Royal College of Pathologists of Australasia Quality Assurance Programme in Cytology. With regard to internal quality assurance there are a number of procedures which follow...

Further on in the letter the Associate Minister said:

“With the reconfigured National Cervical Screening Register and the comparison of histology and cytology data, New Zealand will have potentially one of the strongest national monitoring capabilities in the world. At this early stage, however, I am advised that there is insufficient data to monitor particular laboratories. I understand, however, that laboratories operate on an informal process of review where false negatives are identified.

5.86 This letter illustrates the confusion which abounded around the Programme at that time. Although the Associate Minister writes that the *1995/96 Policy Guidelines For Regional Health Authorities* state that regional health authorities must ensure all laboratories providing cervical cytology are registered with TELARC, the *1995/96 Guidelines* do not say that. They were issued annually and outline the Government’s priorities for health and disability services and the services to be purchased by regional health authorities. The *1994/95 Guidelines* said, in relation to cervical screening, that regional health authorities:

“Are to ensure that their purchase arrangements for laboratory services for cervical cytology and histology reflect the requirement that all laboratories servicing the National Cervical Screening Programme *should be* registered with TELARC.” (emphasis added)

The *1995/96 Guidelines* (to which the Minister had referred in her letter) said:

“Regional health authorities are to ensure that their purchase arrangements for laboratory services for cervical cytology and histology reflect the following requirements that all laboratories serving the National Cervical Screening Programme :

?? Forwarding cervical smear test results (not accompanied by written notice of objection) to the National Cervical Screening Register in the agreed format;

?? Provision of timely cervical smear test results to smear takers.”

Nothing else is said in the *1995/96 Guidelines* about accreditation of laboratories with TELARC or any other authority. When the Associate Minister wrote in March 1995 that regional health authorities *must ensure* all laboratories providing cervical cytology were registered with TELARC, she was incorrect. Under the funding agreements of that time they were obliged to use no more than their reasonable endeavours to ensure laboratories were accredited. The Associate Minister had misunderstood the true

effect of the Programme's *Policy* documents of 1991 and 1993, the *Policy Guidelines To Regional Health Authorities* and the Funding Agreements in force at that time. Nowhere in any of those documents, covering the period from 1993 to 1996, was there an obligation specifying that all laboratories providing cervical cytology *must be* registered with TELARC or an equivalent authority.

- 5.87 The Associate-Minister's response shows that the officials advising her did not realise the true effect of these documents. This is confirmed by exhibit GRB/MOH/24 at page 36 which is a Ministry action sheet. It records the officials' advice to the Associate Minister to enable her to respond to the Women's Health Action Group. The action sheet records that the "National Cervical Screening Programme is the first programme which has ever made registration compulsory through TELARC." This statement is plainly wrong. At the time the advice was given (sometime between November 1994 and March 1995) TELARC accreditation of laboratories reading cervical cytology for the Programme was not compulsory. This appears to have been picked up in the Associate Minister's letter as that states that the Programme anticipates all laboratories will be TELARC accredited by the end of 1996. This statement contradicts the earlier (incorrect) statement that regional health authorities must ensure all laboratories reading cervical cytology are TELARC accredited. All of this demonstrates that neither the Associate Minister nor her officials had a clear understanding of the Programme's *requirements* of laboratories reading cervical cytology.
- 5.88 The 26 July 1995 minutes of the Cervical Screening Liaison Advisory Committee show that the Programme's national co-ordinator also had no clear understanding of the Programme's requirements of laboratories. She is recorded as asking the advisory committee for "clarification on what the Programme would do if a laboratory had not improved with the insistence of TELARC". The minute records that the advisory committee "acknowledged such a situation would have to be investigated and may require further action." This minute shows that the national co-ordinator was unclear about what to do if a laboratory was not bringing itself up to accreditation standard. The reality is that as at July 1995 there was nothing that the Programme could do. The Programme had no authority over laboratories; there was no direct contractual relationship between the Minister/Ministry of Health and laboratories. At that time

laboratories contracted with regional health authorities. The contracts did not require laboratories to be accredited with TELARC or any other quality control authority, therefore a laboratory did not need TELARC's approval to perform cervical cytology. If the Programme staff became concerned about the performance of a laboratory the only legal means of addressing the problem would have been to request the regional health authority which had contracted with the laboratory, to exercise any contractual powers it may have had to suspend the laboratory. The other possibility would have been for the Minister of Health to issue a directive to the regional health authority pursuant to his or her power in s.40 of the Health and Disability Services Act. However, the exercise of a s.40 directive would have been an extreme measure. In any event the effectiveness of either an informal request or a s.40 directive would have depended on whether or not the regional health authority had the contractual power to suspend a laboratory from reading cervical cytology. What concerns the Committee is that the national co-ordinator appears not to have understood the legal position, and she did not know that the Programme could take no steps against a poorly performing laboratory. She should have known that under the new health structure the Programme's staff had no power to take remedial action against a laboratory that was either performing poorly or failing to meet TELARC's requirements. This is a further indication to the Committee of the lack of understanding and confusion among those working in the Programme regarding the requirements it placed on laboratories and how the *Policy* fitted with the Guidelines to Regional Health Authorities and the funding agreements.

- 5.89 The confusion surrounding the accountability arrangements and the impact this had on the delivery of the responsibilities in clause 4 of the *Policy* can be attributed to the poor design of the 1993 updated *Policy*. The design failed to ensure that the structure of the *Policy* and the allocation of responsibilities under that structure fitted well with the newly re-structured health sector and the accountability arrangements between the Ministry and the Regional Health Authorities (even though the 1993 *Policy* recorded that it had been revised and updated to accurately reflect the structural changes to the health sector). If the Ministry could not carry out its responsibilities in clause 4.1.3 these responsibilities should have been placed with an agency in the new health structure, which was well placed to carry them out.

- 5.90 The *Policies* of 1991 and 1993 were operative throughout the time that Dr Bottrill was practising at Gisborne Laboratories. The inclusion in both *Policies* of an intention that quality control be assured by accreditation with TELARC or another similar authority shows that the Department and the Ministry accepted the importance of accreditation and saw that it was needed.
- 5.91 However, both *Policies* had no intrinsic means of compelling accreditation. Nor were they designed around extrinsic means of compelling accreditation. Prior to 1993 the Ministry believed it was powerless to enforce accreditation. Dr Boyd told the Committee that, once the National Cervical Screening Programme was in operation, the Department had sought advice on making laboratory accreditation with TELARC or a similar authority a condition of payment under the Social Security (Laboratory Diagnostic Services) Regulations from one of its in-house solicitors. The advice the Department received was that it was doubtful as to whether the regulations permitted this. After 1993 the power the Ministry had through the funding agreements with the regional authorities was not exercised in a way which would have secured compulsory accreditation. This was implicitly accepted by Dr Lambie, the Deputy Director-General, Corporate in the Ministry of Health. Dr Lambie's evidence was that many of the service obligations in the funding agreements between the Ministry and the regional health authorities were *qualified* by the words "reasonable endeavours." At the time the Ministry had three types of service obligation which it imposed on regional health authorities through the funding agreements. These were: mandatory obligations; obligations to use "best endeavours to ensure" something was done and obligations to use "reasonable endeavours to ensure" something was done. Of the three types of obligation, the obligation to use reasonable endeavours was the weakest. The end result was that the National Cervical Screening Programme was powerless *to ensure* that the cytology of the women, whom the Programme was designed to benefit, was competently read.
- 5.92 Mr Lambie also accepted that in terms of an attempt to measure the progress towards TELARC accreditation, that would be more easily achieved if there were a finite time frame in place. And that once the finite period of two years in paragraph 4.1.2 was removed from that paragraph in the 1993 updated version of the *Policy*, progress towards accreditation became more difficult:

“Q For example, under the 91 policy when you got to 93, if you could see that laboratories were still unaccredited at that time it would be very clear to you that the intent in the 91 policy had been completely achieved.

A Absolutely.

Q But when you move to a circumstance where there is no finite period and the move to accreditation is dependent on a reasonable period of time, it then requires a subjective decision on what is a reasonable period of time in order to be able to determine whether the move towards accreditation is proceeding slowly or quickly or somewhere in between, is that right?

A That’s right.

Q In that sense, then, in wanting to assess whether or not the move towards accreditation is happening in a manner with which you are happy, it is much more difficult to do that without a finite timeframe, isn’t it?

A I absolutely agree.

Q And it would also be more difficult to be critical of laboratories that hadn’t become accredited if you hadn’t imposed a finite timeframe by which they should be.

A Yes.”

5.93 The Ministerial Review Committee of November 1989 had advised the Minister of Health that the success of a cervical screening programme turned on all aspects being developed simultaneously as each was an integral part of achieving success. Unfortunately the National Cervical Screening Programme was not planned in this way. Compulsory quality control and laboratory accreditation was seen by everyone from the Programme’s outset as important and necessary. Yet it did not become an integral part of the programme until some time after Dr Bottrill’s retirement.

5.94 Section 12.2.2 of the *Policy Statement Of The Government Policy For National Cervical Screening Expert Group* had recommended that all laboratories reading cervical cytology be accredited with TELARC or an equivalent authority by 1993. Section 12.2.3 had recommended that the Department of Health should be responsible for confirming that laboratories reading cervical cytology were TELARC-accredited and that without this confirmation a laboratory could not be paid. Had this entire recommendation been placed in the *Government National Cervical Screening Policy 1991* it would have ensured that all laboratories were accredited by 1993.

5.95 Ms Grew, who was the National Co-ordinator during the time when the *1991 Policy* was being developed, told the Committee that she had received oral legal advice that it was not possible to tag payment to laboratories in that way. However, the Department promoted legislation in 1993 to allow for an opt-off register and the recording of histology results. It seems to the Committee that if the Department believed that it did not have the legal authority to require TELARC accreditation as a condition of payment for laboratories and it considered that laboratories should be TELARC-accredited it should have promoted legislation to achieve this end. Apart from evidence that the Department was informed by its legal advisers that it had no power to make TELARC accreditation compulsory the Committee has seen no evidence of the Department taking any further steps to attempt to procure for the Minister or the appropriate departmental officer the necessary authority to permit TELARC accreditation to be made compulsory.

5.96 The Committee did not receive a satisfactory explanation for why nothing was done to ensure that the design of the *1991 Policy* mandated TELARC accreditation by a specific date. The explanation the Committee received suggested that at the relevant times the national co-ordinators were overly reliant on the advisory groups and did not act to ensure that the design of the *Policy* and its implementation carried out the intent, which it seems everyone had, for laboratories to be accredited. Certainly, in the Committee's view, making TELARC accreditation a condition of payment would have forced those laboratories that wanted to continue reading cervical cytology to become accredited. These issues were raised with a panel of Ministry officials who gave evidence at the final day of the public hearings :

“Q At the moment we're talking about 1990 and there is a report that the expert group has prepared in 1990 saying that reading smear tests by laboratories payment should be tagged to TELARC accreditation. Now we haven't seen anything set out dealing with what the Ministry's response was at the time. What we have seen is a screening policy statement of 1991 which picks up some of what is in paras 12.2.2 to 12.2.4, but it certainly omits the requirement that the laboratory benefit payment be tagged with a TELARC accreditation requirement. Can you comment on that?

A - Ms Grew In the first six months of my job I have to say that dealing with this particular aspect of the *Policy* was not attainable in the first six months.

Q What about after?

A – Ms Grew Even afterwards it was not possible. I did obtain oral advice which I asked legal to put in writing in 1992, but it was consistent that I had to change the law. I considered the other requests from the expert group which were that it was extremely important to ensure that the Register was not opt-on as it was; that I should change that, and also that it was vital for histology to be linked with cytology register. Those were the two priorities ...

Q To come back ... to this other point about TELARC accreditation, it just goes beyond the period you were there, so anyone else can answer too. Certainly legislation was amended in 1993 with s.74A and it could have been possible, if primary legislation was needed, to amend legislation at that time to enable a regulatory requirement for laboratories reading cytology to be TELARC accredited to be put in place, couldn't it?

A – Ms Grew It could have. I wouldn't like to underestimate the huge task involved in simply getting the consultation around the opt-off register and also getting laboratories to agree to use the Bethesda coding system to enable the same reporting and to also get the laboratories to agree to send the opt-on women's cytology results to the registers around the country. That in itself was a big task for the laboratories to adjust to, and I would suggest to you that getting agreement to be TELARC accredited on top of all of that, which I'm sure you've heard in evidence, is expensive, would have been a huge ask for the laboratories and the consultation itself would have been quite significant.

Q Are you saying that you were concerned that the laboratories would refuse to do cytology work if a regulation had been passed requiring TELARC accreditation?

A – Ms Grew No I'm not saying that. I'm saying that we required a great deal of co-operation from the laboratories and they were very co-operative in terms of all agreeing to use the Bethesda coding system, or agreeing to send cytology smear results on disk to the registers. I also have to say that Clint Teague consistently assured me that the laboratories were all moving towards TELARC accreditation. I did raise it as a concern, and it's minuted further down the track in the Cervical Screening Advisory Committee minutes.

Q But it's clear that as at 1993 when the screening *Policy* was redone to accommodate the Ministry rather than the Department of Health, the requirement in 4.1.2 of the *Policy* that TELARC accreditation be achieved by 1993 because the 1991 *Policy* said within two years had not occurred, and the Ministry's response at that time was to leave the matter on the basis that TELARC accreditation would be achieved within a reasonable period. Why did the Ministry chose to do that when it wrote the 1993 *Policy*?

A – Ms Dahl I'll answer that question. The 1993 update of the 91 *Policy* occurred in my time. I started in January and we started to update that soon after. The reason for updating that was to reflect the health reforms, to reflect the changes in the health structure. We did not review the *Policy*, we updated the *Policy*. The removal of the two year clause, I can't exactly remember how it occurred, but it was not to make it more lukewarm or to reduce its impact. It was based on advice that laboratories were working towards TELARC accreditation. Many of them were already there, and we didn't need to put something in there that said two years, there were other ways to make that occur. Meanwhile, we had also started to review with the Cytology Advisory Liaison Committee the TELARC criteria for accreditation, and there was no expectation at the time that that was going to take as long as it took. There was an expectation that that would have been finished within several months.

Q At the time, TELARC was accrediting laboratories wasn't it?

A – Ms Dahl Yes it was.

Q It had its own standards which it used for the purposes of accrediting medical laboratories, didn't it?

A It did. We did have some meetings with TELARC in the early parts of 1993 to discuss what they were accrediting against, and the adequacy of those criteria, and there was agreement with the CALC Committee that they needed to be reviewed, that in the meanwhile there were criteria but they did require review.

Q My understanding was that there are medical laboratories that are accredited, and then you accredit different departments differently. You can be accredited for one department and not another, and that when it came to cytology, it was really there was a need to look at whether there ought to be other criteria over and above what was already in existence. Is that right?

A – Ms Dahl That's correct.

Q And my understanding is that the *Policy* itself as a result of the expert group's meeting had determined some criteria which it thought should be in the TELARC accreditation, which would include standards set such as how many minimum smears per year were read, employment of adequate numbers of suitably qualified staff, maximum workload for each cytoscreener, adequate in-service education, satisfactory participation in internal / external quality assurance procedures and co-operation in providing cytology reports to the cytology register. Now they were criteria that the Department of Health under the 91 *Policy* and the Ministry of Health under the 93 *Policy* saw as being important for the purposes of the Programme, and those criteria could be imposed either through TELARC accreditation or some other means really if the Ministry had wanted to ensure that the criteria was in place. Isn't that right?

A I would have been unsure what other means there would have been. My advice came from the CALC committee, I was not a technical expert on laboratories, and my understanding from that Committee was that laboratories were moving towards accreditation, everything was okay and that they would work on reviewing the criteria for the TELARC accreditation and that was the advice that I worked on in the period that I was there.

Q Another possibility would have been for the Ministry as part of the Programme to have drawn up its own standards and to have said that those laboratories that wanted to do cytology screening for the Programme must adhere to those standards.

A – Ms Dahl That's correct ma'am, and in many instances that type of process occurs in various Government departments and it's a very appropriate process. At the time that we're talking about that was not the process that was working within the Department of Health, Ministry of Health. We were very reliant on expert groups and they were the groups that were advising us and we were following through on that process. Hindsight may prove that may not have been the best way.

5.97 Had the Programme been able to ensure that all laboratories reading cytology were accredited that would have stopped the cytology practices that were carried out at

Gisborne Laboratories between 1990 to March 1996. The Committee has already said that it considers that these practices are likely to have led to unacceptable under-reporting. Had they been prevented then the under-reporting would have been avoided. In the Committee's view a programme with a well-designed policy that was well implemented would have had in place measures to ensure laboratories practised quality control and were accredited. And the persons responsible for the Programme would have applied these measures if a laboratory failed to comply. For this reason the Committee considers that the poor design and implementation of the Programme's policy in relation to laboratories is a factor that is likely to have led to the unacceptable reporting in the Gisborne region.

Failure To Ensure The National Cervical Screening Register Functioned Optimally

5.98 During the time Dr Bottrill was in practice the National Cervical Screening Register had two major flaws:

- (i) When the National Cervical Screening Programme began instead of a central register there were 14 stand-alone registers, each of which was located in an area health board region. The 14 registers were unable to correlate a patient's histology results with her cytology results. Nor were the registers able to inter-link with each other in relation to a patient's cytology results;
- (ii) The registers were initially "opt-on" registers. This meant that women had to request that their cytology results be recorded on the registers. Many were either not given the choice or opted not to have their results registered. The number of women whose results were recorded on the registers was not sufficient to enable statistically meaningful information to be derived from the registers.

The Committee will address each of these flaws below.

No Centralised Register Capable Of Correlating Histology With Cytology

- 5.99 A centralised cytology register which linked histology with cytology results was considered, by all the authorities on cervical screening to which the Committee was referred, to be pivotal to a successful screening programme and an essential management tool for proper quality control. The National Cervical Screening Programme did not have such a register until 1997.
- 5.100 It appears that the original plan for the Programme's register was to have a nationally computerised register which was to be managed locally by area health boards. This is recorded in *The Report of the Ministerial Review Committee* of November 1989. This design is consistent with the recommendation made in the Cartwright Report for a centralised register based on a "regionalised" network. The Review Committee reported its support for the view that a population-based programme required a national computer based register. The Review Committee said that it was essential to extend the cytology register to include histology information so as to enable cytology and histology results for women to be correlated. The purpose of this recommendation was to allow an assessment of the overall effectiveness of the Programme to be conducted, and to provide a means of assessing the quality and uniformity of smear reading across the country.
- 5.101 On 30 May 1990 the National Cervical Screening Programme Expert Group reported to the Minister. The report recommended the establishment of three nationally based and inter-linked registers. A national cytology register with the cervical smear test results of individually identified women; a population register which would eventually contain the names of all women in the population; and a histology register which contained the results of biopsies to determine the rates of pre-cancerous abnormalities and cervical cancer. The Expert Group said that each of the three registers was integral to the Programme and that the failure of any one of them would jeopardise the Programme. Subsequently in August 1990 the Expert Group produced the *Policy Statement Of The National Cervical Screening Programme Expert Group*. In this document the Expert Group said that:

“...the expansion of the cytology registers to include relevant *histology was an urgent priority*, not only to ensure that women with abnormal smears are being properly followed up but also to *evaluate the quality of smear reading in laboratories.*” (emphasis added)

5.102 Judith Straton in her review of the Programme in 1990 emphasised the importance of a register which linked cytology with histology results:

“...the provision of histology to the Register is essential for the correlation of cytology and histology reports, which provide *an important measure of the quality of the screening.*”(emphasis added)

5.103 It appears from reading the Straton Report that Judith Straton was also aware of the decision to locate a cervical screening register with each area health board. Like the Ministerial Review Committee she too favoured having the registers in each area health board linked to a central register. Also in 1990, the National Cervical Screening Programme Expert Group recommended that the Programme be linked to the Cancer Registry to provide correlation of smear reading results with proven cancer, even though the histology specimen may have been reported by another laboratory at a later date.

5.104 The *Cancer Screening 1991 Cervical Screening Recommendations A Working Group Report* described a *national* register as: “the essential management tool to allow a proper valuation of all the components of the screening process”. It also said that a register should, “include relevant histology results to allow co-relation and evaluation of cytology findings.”

5.105 The *World Health Cervical Cancer Screening Programme Managerial Guidelines*, issued in 1992, recommended:

“...an efficient monitoring requires a system of linked records. A population register (or available substitute) allows periodic call back for re-screening at appropriate intervals. The cytology register when linked with a cancer register (which should be ad hoc and specific to cervical cancer) permits women with cytological abnormalities to be recalled for repeat screening diagnosis and therapy. Evaluation of the programme can then be carried out with regard to the assessment of :

- ?? Management of women with positive smears;
- ?? False negative smears;
- ?? Cancers which are detected during the interval between consecutive screens;

?? Groups missed in the target population.

5.106 The benefits of correlating histology with cytology results were confirmed for the Committee by Dr Boyd. He told the Committee that correlation of histology and cytology results can be considered as an external and internal quality assurance activity. He said that as an external check on a laboratory's performance the Register can provide statistics to show the proportion of women having colposcopy whose histology results confirm the result of a previous smear reading; and those whose histology results do not confirm previous smear readings. Either way the histology results provide helpful information when it comes to assessing laboratory performance in smear reading. If the histology results confirm the cytology results, that confirms the laboratory's accuracy in reading smear tests. If the histology results do not confirm the cytology results that would mean either the cytology results were false or the biopsy did not sample the lesion detected by the cytology. It could also be due to the misreading/misreporting of the histology. The proportion of false positives and false negatives that a laboratory produces can indicate whether or not the laboratory's performance is acceptable, and consequently whether or not unacceptable under-reporting is occurring.

5.107 Dr Boyd described the Register's usefulness as an internal quality control to the Committee in the following way:

“ ... the correlating of cervical cytology reports generated within the laboratory with the histology reports obtained following colposcopy and the reports of cancer incidence from the cancer registry provides an opportunity to re-examine the previous slides with a higher index of suspicion. The laboratories develop their own protocols for this look-back. The look back should not be restricted to the most recent slide. In one laboratory I visited an arbitrary figure of five years has been selected, so that all previous slides for that woman over that period are re-examined.”

Professor Skegg described the correlation of cytology results with histology results as being of “fundamental importance” and he said it was “inexcusable that so many years elapsed before it was done”.

5.108 During the early stages of the Programme's development, all the advice to the Minister and the Department of Health from the various advisory groups, consultants and the available overseas literature favoured a centralised register which linked

histology with cytology results. The only variation in this advice was between the view that there should be one national register or alternatively a series of regional registers which inter-linked with a central computer. Nevertheless, when the National Cervical Screening Programme began it was not designed around a centralised register. Instead there were 14 stand-alone registers each associated with an area health board. There was no linkage between these registers, and since the histology results were not recorded, the registers did not allow histology results to be correlated with cytology results. This arrangement caused problems and prevented the Register from functioning optimally. One of these problems was that the usual capability of a screening register as a tool for quality assurance was seriously compromised. The Register could not be used as a source of information to show if there was unacceptable under-reporting of smear test results.

5.109 The 14 stand-alone registers were installed in all 14 area health board regions between December 1990 and September 1991, and they were all fully operational by early 1992. The Department of Health supplied each area health board with the same software and hardware, however, the computer systems were not linked electronically. This meant that all transfers of information between local sites were done by paper. This state of affairs continued until the registers were finally reconfigured into a central register, which was completed in 1997.

5.110 Ms Glackin told the Committee that not having a centralised system: “Did create a problem and was very time consuming when women moved to a different region.” She said that the fourteen separate registers led to difficulties with tracking women who moved, and that this compromised the Register’s recall functions. The Registers could not verify personal data electronically between them. Women who may have been enrolled in one region re-enrolled in another region. This led to duplication in enrolments. Until the 14 stand-alone registers were combined, each register could only give the smear histories of women who were enrolled in the region where that register was located. Only since 1997 has data for the whole of New Zealand been accessible from any regional co-ordination site. The software programme for the 14 registers did not allow histology to be linked with cytology. But, even if the software had allowed it, because there was no centralised system which could track women

when they moved to other area health board regions the histology results still could not have been effectively linked with the cytology results.

5.111 The Committee learnt from Ms Sandra Matcham, who is the National Register Co-ordinator for the Programme, that once the 14 registers got underway, there were difficulties with some regional sites. She said that 11 of the smaller regional sites had sufficient capacity for their processing requirements, but that the Wellington and Canterbury sites began to show signs that their systems could not cope with the volume of work and by 1994 the Auckland site had reached the point where processing the information had become difficult for the staff, and they were progressively getting behind with the work. This pressure helped to delay the progress of the re-configuration of the registers. It is also another example of the difficulty created by having 14 stand-alone registers.

5.112 The Committee heard from Ms Gillian Grew who was the first National Co-ordinator of the National Cervical Screening Programme from June 1990 to July 1992, and from Ms Susan Dahl, who was the National Co-ordinator from January 1993 to September 1994 about the difficulties the 14 registers caused them. Ms Grew told the Committee that not having a single database was one of the difficulties the Department encountered when it came to prepare the first statistical report for the Programme. Ms Dahl, who was the co-ordinator at the time the second statistical report was prepared said that it was :

“Very difficult to do the second statistical report and that related to the fact that we did have 14 registers at the time.”.

5.113 She told the Committee that the Ministry had to create programmes to get the information downloaded from the 14 sites and then compile the information in Wellington. She said that once the Register was reconfigured the Ministry believed that data would be more readily available, and therefore it would be easier to prepare statistical reports. Since its inception the Programme has prepared only three general statistical reports and one statistical report on for Maori women. The Committee also learnt from Ms Grew that quite early on in the Programme area health boards began to tinker with the registers’ software programmes, and this had the effect of

“confounding” the national statistics. Ms Grew’s comments on the impact of the 14 standalone registers on the Programme were :

‘In the first place I couldn’t see why New Zealand needed 14 registers and it became very apparent that that was highly undesirable given, you know, the fact that women moved around the country. Although there were arrangements for electronic transfer on disk it seemed incredibly inefficient to do it that way, and I do think that having 14 different sites dealing with the software there were high risks, and I know from the register people now that they had to clean up the data considerably when they reconfigured into one register.’

The Committee also learnt from Ms Grew that until the Register became an opt-off Register which was capable of correlating histology results with cytology results she was unable to quantitatively monitor the quality of laboratory performance. She said that was why she worked to get “opt-off” registers which recorded and correlated histology with cytology.

5.114 The first support the Committee was able to find in the evidence for regionally based registers was in a report dated 21 November 1988 by Azimuth Systems Limited for the Department of Health. The Committee understands that Azimuth Systems Limited was a computer consulting company. The report was titled *Proposal for a National Co-ordinated New Zealand Cervical Screening Programme*. The Azimuth report referred to the planned establishment of area health boards and recorded that as a result the Department of Health would no longer be directly involved in the delivery of healthcare through its regional health development units. It then reviewed implementation options for a screening programme. These were: a single national system with remote access provided for each area health board or a separate system in each area health board region with linkages through a national master patient index. It described the national system as having all data and processing carried out using a single facility with each area health board having remote terminals and printers. Data was to be partitioned so that each area health board only had access to and control of its own data. The advantages of this system were said to be: simplification of day to day operations, provision of a uniform system throughout the country, simplification of data transfers on women who move between areas, simplification of the interface to a national patient index. The disadvantages of a single national system were said to be a need for extensive co-ordination between area health boards, providers and “the

national level”, separation of both physical and control aspects of the computer system from the cervical screening programme users and the impact on strategic data processing options and initiatives of individual boards since it would require them to use equipment and facilities which may not be suitable to them. The Azimuth report then described the second option of having separate systems for each area health board. This option was said to require a means of accessing a national patient index to maintain name and address information and to identify women who have not yet had cervical smears. The report also noted that a regionally based system must allow for information to be exchanged with other regional systems when women move between areas. The advantages of this option were described as: having a minimal impact on area health boards’ autonomy in selecting hardware and software for local information processing, providing area health board centres with autonomous control over the operation of their service, allowing integration with other systems operated by area health boards, being more responsive to local needs without impacting on the national screening programme. The disadvantages were described as being: the need for a national co-ordinating function to set the minimum requirements and the protocols for information exchange and to monitor the national register. Secondly, full implementation of the national programme was dependent on the slowest implementation by an area health board. After having reviewed these two options the report concluded by recommending a separate registration system for each area health board. The reason for preferring this option was said to be the present policy intent to decentralise health care management:

“ Given the present strategic direction of decentralising health care management responsibility to area health boards then a separate system for each AHB [area health board] Centre is proposed. Each AHB Centre will have access to a nationally maintained patient index and an investigation of the existing National Master Patient Index system should be undertaken to determine if it is suitable for this role.”

There is no reference in the Azimuth Report to any authoritative literature on screening programmes that would support the establishment of 14 separate registers. The recommendation appears to emanate from policy considerations arising from the decentralisation of health services rather than to have been driven by sound principles relating to the organisation of screening programmes.

5.115 Another reason supporting regionally based registers appears in Judith Straton's Report. She describes the presence of a widespread suspicion about the Register among women and health professionals. She says that this suspicion was partly related to the perception that the Register was primarily based in Wellington. She says the suspicion may have lessened if the registers were promoted as regional area health board registers with only non-identifying data going to Wellington. She also said that the notion of the register for national audit had been over-emphasised and that the register "needed to be brought down to the level of the individual woman with an indication of what the benefits are to her." She continued in this vein by stating that:

" Giving women too many details about the workings of the Register, while laudable, is quite likely to be counter-productive, as women may be intimidated by it. This applies particularly to women who are most at risk, who tend to be older and less well educated, and may have good reason to be suspicious of government bureaucracy."

The Committee considers that if reasons such as these influenced the Minister of Health in the choice of stand-alone registers it is a matter of regret. There was good reason for either a regionally based but inter-linked centralised register or for one register to hold all the information. There is no good reason to support having 14 stand-alone registers which were incapable of sharing information. All such registers could do was to record a woman's smear tests during the time she resided in a register's locality and act as reminders to her when the time had come for another smear. They could not reliably be used as a quality assurance tool to allow monitoring and auditing of the programme, (and included within that is laboratory performance), or as a source of epidemiological information to help reduce the incidence of cervical cancer because there could never be any certainty that the information recorded on a register about a woman gave a complete record of her cervical history. In the Committee's view it would be a very short-sighted woman who did not appreciate the benefits to herself of these wider measures. It is of concern to the Committee that in 1990 an assumed timidity and ignorance on the part of women could be given as a reason not to inform them fully about the Programme.

5.116 A further reason for regional registers appeared in the evidence of Ms Sandra Coney. She informed the Committee that in the beginning in some regional areas people were concerned about information going outside their region and they felt they would have

more control over it if it were recorded on a register based in their region. This is similar to the view expressed in the Straton Report. However, it is not a view which justifies running 14 stand-alone registers. The inefficiencies, which result from this structure, clearly outweigh any concerns about misuse of information. These concerns could have been accommodated in other ways. Furthermore it is difficult to see what is to be gained in storing information regionally; that in itself does not guarantee the protection of the information's confidentiality. The type of protections that do keep information confidential can work just as well on a national basis as they can on a regional basis.

- 5.117 Against these reasons are the sound epidemiological reasons for having a central register which recorded the smear histories of women throughout the country and which allowed cytology results to be correlated with histology results. The *Ministerial Review Report* of 1989 emphasised the importance of ensuring that the links required to build the regional system developed by Azimuth into a national system needed to be put in place. The Expert Group's report to the Minister on 30 May 1990 emphasised the need for a national based cytology register. The *Policy Statement Of The National Cervical Screening Programme Expert Group* dated August 1990 recommended a regional system of cytology registers which were linked to a central register.
- 5.118 Ms Glackin told the Committee that a decision was made early in the development of the Programme that there would be 14 stand-alone register sites. Even though the Azimuth Report had supported having separate regional registers it is difficult to see why this advice was followed. The limitations of 14 stand-alone registers should have been obvious from the outset. The Straton Report had at least favoured registers in each area health board region which were linked to a central register.
- 5.119 Ms Matcham told the Committee that it would have been technically possible to have net-worked the regional computer data bases to a central site between 1990 and 1991, as a register was set up in each area health board's region, but at significant cost. She said that a much larger central computer would have been necessary and that telecommunication lines 10 years ago were more expensive than they are today.

5.120 No-one from the Ministry gave the Committee an explanation as to why, from the outset, a single computer located in one site could not have been used to hold the cytology results for all women whose results were being recorded. The relevant female population for screening in New Zealand is not large. It could easily all have been accommodated on one centralised register. The expense Ms Matcham spoke of was for the type of system now in place where the 14 regional computer sites are networked to a central site. While this may have been expensive in the early nineteen nineties it does not follow that at the outset a single computer based in one locality would have been more expensive than the system of 14 separate computers which was adopted. If a centralised system of regionally inter-linked computers was too expensive, a single computer with systems in place to ensure that laboratories throughout the country forwarded their results to the computer could have worked. Although a larger computer would have been needed, it would be surprising if the cost of one computer to hold all the information would have been more costly than a centralised system of regionally inter-linked computers. It may also have been less costly, once all the duplication and consequential inefficiencies were taken into account, than the 14 stand-alone computers of a smaller size. The Committee has learnt that the laboratories forward information on floppy disk to the regional co-ordination site. The information is then read into the database and validated. Rather than laboratories sending information by floppy disk to regional co-ordination sites, it is difficult to see why from the outset they could not have sent the information to a single computer. For those laboratories unable to send the information electronically, they could have sent it in paper form.

5.121 With the change to a decentralised health system which used area health boards to deliver health services, the Minister may have considered that a centralised system of inter-linked regional registers was too expensive at that time and that a single nationally-based register, for which the Department was responsible, was at variance with the move towards a more regionally based health system. While the concern for expense and the desire to adhere consistently to an adopted philosophy for health delivery is understandable, it should not have been allowed to affect detrimentally the design and implementation of the National Cervical Screening Programme. The design of the Register was fundamental to the success of the Programme. Professor

Skegg had written of this in his article in the New Zealand Medical Journal of October 1989 titled *How Not To Organise A Screening Programme*. He wrote:

“Schemes based on inadequate registers are doomed to fail.”

Although Professor Skegg was writing primarily about the decision to have opt-on registers, it is clear to the Committee that he did not support regionally based separate registers as he referred with approval to the notion of a comprehensive population based register. The Committee considers that Professor Skegg’s comment on the impact of inadequate registers on screening programmes can be read as being of general application to any material inadequacy. When his comments are read with the comments from the Ministerial Review Committee and the Expert Group supporting a national cytology register this should have signalled a warning against having 14 stand-alone registers.

5.122 There was sufficient authoritative material at that time about the importance of a well-designed register. None of the authoritative material the Committee has seen recommends having a discrete series of registers that cannot communicate with each other. Nor was the Ministry able to point the Committee to any material that would support the idea of having fourteen stand-alone registers in a country the size of New Zealand. Whatever may have prompted the setting up of 14 stand-alone registers, there is nothing in any material that the Committee has seen to suggest that it was a sound way to set up a cervical screening programme’s register. If the decision to have 14 stand-alone registers was influenced by a concern to ensure that the register fitted in with the new decentralised health structure it is most unfortunate. The effectiveness of the register should not have been compromised by considerations of that kind.

5.123 By February 1993 the Minister and the Ministry of Health had accepted that the 14 standalone registers needed to be inter-linked nationally. In February 1993 the Associate Minister approved the release of a discussion paper dealing with future reconfiguration of the Registers. By April 1993 consultation over the options for reconfiguration was completed with the majority support being for a national register with remote access. Final approval for the reconfiguration was given on 12 January

1994. Final approval to start tenders to allow the reconfiguration to be implemented was given in late 1995. The reconfiguration started in May 1996 and was completed in February 1997. Since 1997 there has been one centralised stand-alone database with regional access from 14 sites.

- 5.124 Although the need to link histology with cytology was recognised relatively early on in the Programme's implementation this was not achieved until late 1996. Without a national register, which linked histology with cytology, it was impossible to gain sufficient information to evaluate laboratory performance. The benefit of correlating histology and cytology results can be seen from what happens now. At present a laboratory can request from the Register reports which give details of the histology reports for all women for whom the laboratory in question has read cytology results in the previous five years. Where there has been a negative smear reported within five years prior to a high-grade histology result, that information is highlighted automatically by the Register when generating the report. Thus the type of information which can immediately bring to a laboratory's attention a suspect cervical history is readily accessible. This allows a laboratory to check whether or not earlier negative smear results are correct or result from under-reporting. This type of "look back" investigation using the Register has two benefits : it can assist laboratories to discover errors in their reporting; and it can be used by Programme staff to detect laboratory errors. It has only been available since February 1998.
- 5.125 If, from the outset, the Register had been configured as a single national register with correlated histology results with cytology results, an effective tool to monitor laboratory performance would have been available to pick up Dr Bottrill's under-reporting. Once one of his patient's had a biopsy with positive results the computer could have generated a report showing the patient's cervical smear history. Certainly before any use could be made of this information someone would have to request it. However, if Dr Bottrill had known this information was readily available he may have done so. Equally, the Programme could have employed someone to request routinely the smear histories for women with positive histology with a view to checking the results of their earlier smear tests as part of a regular monitoring exercise.

- 5.126 The Committee has already concluded that the failure at Gisborne Laboratories to have an organised programme which correlated a patient's cytology results with her histology results and which looked back on her previous smear history was a factor in the unacceptable under-reporting at that laboratory. The Committee considered that had Gisborne Laboratories carried out this procedure it may have alerted Dr Bottrill to his very low false positive rate and so caused him to realise that he was being overly critical and "setting the bar too high" when reading smear tests. This in turn should have alerted him to the probability that he was under-reporting too many smear tests.
- 5.127 A centralised screening register, which was designed to correlate a patient's cytology results with her histology results, would have been an effective substitute for, if not an improvement on, a laboratory organised programme to correlate cytology with histology. If the National Cervical Screening Register had been in this form during the time Dr Bottrill was in practice it would have been a source of information to alert him to signs that he was under-reporting smear tests. For this reason the Committee considers that the inability of the Register to provide Gisborne Laboratories with access to this information during the time that Dr Bottrill was in practice is a factor that is likely to have led to unacceptable under-reporting.

"Opt-on" Registers

- 5.128 When the Programme began it was based on an opt-on register. Women had to actively exercise a choice to go onto the Register. The result was that enrolment was not as high as the Department would have liked, and the Register was insufficient to be able to derive any statistically meaningful information. Studies in New Zealand and overseas showed that an opt-on register was likely to recruit only 30-40% of women having a smear, and that with such low enrolments there was risk that there would be too few women enrolled on the Register for the Programme to meet its objectives of increasing coverage and reducing mortality and the incidence of cervical cancer.
- 5.129 In October 1989 Professor Skegg published an article in the New Zealand Medical Journal titled *How Not To Organise A Screening Programme*. In this article Professor Skegg was very critical of the use of opt-on registers. He wrote:

“There is abundant evidence from other countries that it is possible to spend vast sums on cervical screening without achieving much. We cannot afford to repeat their mistakes. Despite the lack of details one aspect of the New Zealand scheme sounds particularly ominous. Considerable emphasis is being placed on computer-based registers which will be restricted to women who have indicated that they wish to be part of the programme. Apparently no information will be put on these registers without the signing of written consent forms on every occasion.

The full potential of cervical screening can only be realised with effective systems to invite all women for screening, and to check that appropriate action has been taken on positive results. Computer-based schemes appear to offer the best opportunities and the main characteristics of successful programmes are that they consumer oriented but service initiated. Schemes based on inadequate registers are doomed to fail.”

- 5.130 In May 1990 the National Cervical Screening Programme Expert Group recorded in its report to the Minister its support of Professor Skegg’s article. It went on to recommend that the Programme should be designed to allow automatic participation in the Programme with the ability to opt out, and that legislation to enable this to occur should be passed. The opt-off option was supported because it was considered it would encourage greater participation in the Programme, provide greater choice, provide greater ability to assure quality, result in less data fragmentation, and allow the identification of targeting requirements to provide a better basis for policy development. It is difficult to see why the initial opt-on registers ever found favour.
- 5.131 In November 1991 the Associate-Minister of Health endorsed a requirement for legislation to bring about an opt-off register for the Programme. This required an amendment to the Health Act 1956; the amendment was passed in 1993. Once the Register became an “opt-off” register there was a dramatic increase in enrolments, and therefore data. Overnight, 80-99% of all smear results from various laboratories were being forwarded to the Register (as opposed to 20-40% prior to the introduction of the legislation). Enrolments rose to 55% of eligible women in 1994, 69% in 1995 and 81% by 1996. The Committee was told that by the end of the calendar year in 1999, enrolments on the Register had risen to 91% with 84.6% having had a smear in the previous 5 years. This exceeded the projected target set in the 1996 *Policy* and compared well with cervical screening programmes internationally. However, the use of an “opt-off” register only became possible by 1993 and then it was caught up with the need to reconfigure the register into a national register. The impact of this was that it was not until after Dr Bottrill retired that the Programme was able to generate

information from the register that gave any reliable indication of a laboratory's diagnostic performance.

5.132 The Programme began with a register system that was sub-optimal. The system did not become fully effective until 1997 when it was reconfigured into a national centralised register. Although it was recognised early in the Programme that the system of 14 stand-alone registers was not operating effectively, and that this in turn was having a detrimental impact on other facets of the Programme, it took until 1997 to reconfigure the registration system into an optimal form. The system's two major flaws were features which were contrary to all the expert advice that was available during the time the Programme was being set up. The Committee considers that the detrimental impact the sub-optimal registration system had on the Programme is perhaps best explained in this interchange between the Committee and Ms Grew.

“Q When you look back now it seems that all the work, however well intentioned it was from the outset up until 1993, has turned out to be misplaced in the sense that all the work that went into setting up 14 different registers, being opt-on registers, then had to be redone with the national Register in circumstances where it was opt-off, which was one of the early recommendations coming through from the expert group.

A All I can say ... is that there were some givens. My job was to set up the Programme within the constraints already in place and that is that there were 14 registers. I did get policy approval to look at rationalising those down to one, so it was clear even in the very early days that we were asked to set up something that was not ideal at the end of the day, *and my first job really was to set up something and then obtain approval to change it so that it was more effective.*” (emphasis added)

With a sub-optimal registration system the Programme was never going to operate effectively; in particular the registration system could not be used to monitor the performance of laboratories and so it could not be used to detect under-reporting. Professor Skegg told the Committee that he found it “ extraordinary [that] we have spent millions of dollars each year establishing and maintaining these registers [the National Cervical Screening Register and the Cancer Register] but we are not using them in the way they could be used to advance the health of women.” In the Committee's view the sub-optimal character of the National Cervical Screening Register and the impact it had on the effectiveness of the Programme is a factor that is likely to have led to the unacceptable under-reporting that occurred in Gisborne.

Failure To Put In Place Laboratory Performance Standards And To Make Reliable Data Available

5.133 Throughout the time that Dr Bottrill was in practice at Gisborne Laboratories the National Cervical Screening Programme had no laboratory performance standards in place and it had no reliable data. Therefore, it was not possible to monitor and evaluate laboratories' performance. Without doing this it was not possible for those responsible for the Programme to detect incidences of unacceptable under-reporting.

No Laboratory Performance Standards

5.134 There was no dispute from any of the witnesses heard by the Committee that performance is more easily measurable if standards are in place. By performance "standards" the Committee means quantitative benchmarks which a laboratory must achieve as opposed to something which a laboratory should aspire to achieving. Performance standards are a measure against which those monitoring performance assess whether or not a laboratory is performing according to expectations. Performance standards specify the expectations of a health service. Without performance standards it is not possible to monitor adequately, if at all. The importance of this has always been well recognised. From the evidence the Committee heard there appeared to be no dispute that monitoring, if it is to be done properly, requires the imposition of performance standards. Professor McGoogan told the Committee that it was very difficult to evaluate data without pre-set standards. In addition, it was difficult to measure quality of performance without pre-set standards. In Professor McGoogan's opinion, the absence of standards did not reflect well on the New Zealand Programme:

"Q Could you offer an opinion on the New Zealand approach to creating the national average and how that would impact on one's evaluation of laboratory practise relative to the national average?"

A I've said before in evidence that the measurement of quality is the degree to which one conforms to pre-set standards. The three statistical reports provide interesting data about what is happening to women in New Zealand who are registered with the screening Programme, but it is very difficult to evaluate this data without a standard against which to compare it. It seems to me these standards have never been set.

Q Well it appears that a standard may have been set for laboratory reporting by pooling the results of all laboratories and creating an average.

A The principle is an average if New Zealand wishes to set its standard as the average of all the laboratories. It number one should say so and number two it should justify it. When one makes an average you take a wide range of laboratories whose practice may differ enormously, and averages notoriously hide excellent practice and very poor practice within them. That was the specific thing we wished to avoid in the UK in setting the standard in 95.

Q What does it tell you about the New Zealand Programme if there were no standards set?

A Unfortunately it does not reflect well on the New Zealand Programme. There seems to be a belief that simply doing the work is good enough, not necessarily doing it to a high standard or at least an acceptable standard ... Again I'm very impressed with the effectiveness of the New Zealand Cervical Screening Programme. You have reduced the incidence of cervical cancer in both your Maori population and in the rest of your population, so your screening Programme is effective, but without quality standards in place you cannot evaluate how much more effective it might have been.

5.135 In New Zealand the importance of having performance standards for laboratories reading cervical cytology was recognised as early as 1989. Section 8.13 of the *Report Of The Ministerial Review Committee On Implementation Of A Government Policy for National Cervical Screening*, which was published in November 1989, recommended the development of a set of minimum standards of competency for laboratories and smear readers. An example of overseas authority supporting the need for performance standards is the *European Guidelines for Quality Assurance In Cervical Cancer Screening* published in 1993:

“A pre-condition of quality assurance is the establishment of standards. The aim of the quality assurance programme is to ensure that these standards are met.”

5.136 A departure from the view that performance standards are essential for a programme can be seen from the minutes of the Cervical Screening Liaison Advisory Committee on 26 July 1995. At the meeting there was discussion about analysis of laboratory statistics which were contained in a draft report of the Programme's performance (the Second Statistical Report). Copies of laboratory statistics had been taken from the draft report and circulated to the members of this committee. Those who were present at the meeting on 26 July 1995 are recorded in the minutes as agreeing to each laboratory being supplied with its individual statistics for comparison with national ranges and averages produced in the draft Second Statistical Report. This committee

thought it was too early to set performance standards as it considered that appropriate statistical ranges were yet to be established. The minutes recorded that:

“One of the problems with assessing laboratory performance is that the appropriate statistical ranges for cytology screening have not yet been established. Cytology is a very subjective science and it is difficult to set numerical standards. There is a danger that any standard set would be so wide that they are hardly worth setting.”

5.137 However, the Committee considers that this was insufficient reason to delay the setting of performance standards as these are not dependent on knowing the statistical range of laboratory reporting. The use of national averages to measure individual laboratory performance was criticised by Professor McGoogan. She pointed out to the Committee that the difficulty with taking a national average is that over a wide range of laboratories practice may differ enormously, and averages can hide excellent practice and poor practice within them. She said that was the very reason why in the United Kingdom they chose to set a performance standard instead. The Committee can see the wisdom of the United Kingdom approach. It seems, however, that the Cervical Screening Liaison Advisory Committee was not as alert as Professor McGoogan was to the masking effect of using a national average to provide a measure of comparison for a particular laboratory.

5.138 The Committee has heard other evidence about the importance of performance standards. The Committee rejects the view expressed by the Cervical Screening Liaison Advisory Committee. It considers that as at 1995 there was sufficient authoritative material from overseas to provide a guideline for setting appropriate numerical standards. It was unnecessary for any numerical standards that were set to reflect the performance of New Zealand laboratories; that approach belies the whole basis of having performance standards. Appropriate standards should be set according to objective measures of good performance and laboratories should be required to meet those standards. It is not a matter of discovering how laboratories are performing and then tailoring standards to reflect the average performance. Furthermore, to use the national average rate for reporting abnormalities as a standard is dependent on the assumption that the national average rate is in itself an appropriate benchmark. For example, if all New Zealand laboratories had been under-reporting to a greater or lesser degree, then the national average would in itself be a poor performance standard

and to attain it would be falsely reassuring. New Zealand laboratories should have been required to ensure that their performance met numerical standards similar to those in place for cervical screening in overseas programmes. There is no reason why a New Zealand cervical screening programme should adopt lower performance standards for laboratories than programmes in other countries. New Zealand could have done the same as the United Kingdom. In addition, the view of the Cervical Screening Advisory Committee overlooks the importance of pre-set standards for monitoring and evaluation. If the Advisory Committee thought the subjective character of cytology made it too difficult to set numerical standards, it is hard to imagine how the Committee contemplated the Programme could be monitored and evaluated. The Advisory Committee's comments demonstrate to the Committee how unaware the Advisory Committee must have been to what thorough monitoring and evaluation of the Programme entailed. It is clear to the Committee that Professor McGoogan saw no value in the New Zealand approach:

“Q You had the opportunity to look at the three statistical reports produced by the New Zealand Programme, and I am sure you have noted the laboratory reporting rates in the table. From those tables you can see that the New Zealand average for reporting rates of various pap smear abnormalities have been determined by including all laboratories that are reporting and then determining the average and the minimum and the maximum.

A Yes.

Q Now this contrasts with the approach that the UK took, which was to take the practice of 12 quality laboratories and to use their results to establish their benchmark. Is that correct?

A That is correct.

Q Could you offer an opinion on the New Zealand approach to creating the national average and how that would impact one's evaluation of laboratory practise relative to the national average?

A I've said before in evidence that the measurement of quality is the degree to which one conforms to pre-set standards etc.”

5.139 Throughout the time that Dr Bottrill was in practice no laboratory performance standards were in force. This was recognised by the Health Funding Authority when, as a result of the under-reporting at Gisborne, it came to review the performance of other laboratories. It identified certain factors relating to the Programme including:

“The lack of specific standards or targets for cervical cytology in New Zealand during the period covered by ... [the] review.[1990-99];

5.140 The *Government Policy for National Cervical Screening 1991* provided that performance indicators for area health boards were to be developed by the Department of Health and negotiated with area health boards. The 1993 updated *Policy* provided that performance indicators for regional health authorities would be developed by the Ministry of Health and Public Health Commission and negotiated with regional health authorities. In the course of the Inquiry the Committee’s attention was never drawn to the performance indicators for area health boards. The Committee considers that it can be safely assumed that if such indicators had covered laboratory performance then they would have been brought to the Committee’s attention. As regards performance indicators for regional health authorities, these were specified in the funding agreements and related purely to waiting times for colposcopy examinations, enrolment of women and improving access to screening and treatment services. No performance indicators were ever developed in relation to laboratory reading of cervical cytology. It is clear to the Committee that the provision in both *Policies* for the development of performance indicators, which the Committee assumes to be a diluted version of quantitative performance standards, was recognition that some measure of performance was necessary to enable the Programme to be monitored and evaluated. It is unfortunate that nothing was done to develop performance indicators for measuring laboratory performance.

5.141 Ms Glackin told the Committee that she considered it was not true to say there were no standards for the Programme. She accepted that there were no quantitative performance standards. However, she said this did not mean there were no standards in place. She pointed to the *National Cervical Screening Programme Policy* of 1996, which she said had expectations in a large number of areas associated with the Programme. Inevitably it seems to the Committee that responses from witnesses may turn on semantics. To the Committee an expectation is not a standard. A standard is something which must be adhered to and which is capable of being enforced. When it came to laboratory performance there was nothing of this nature in place throughout the time Dr Bottrill was in practice, and even after that time. It is only since the Health Funding Authority commenced working on setting performance standards that

standards, which are capable of measuring performance and being enforced, have been formulated. The 1996 *Policy*, which came into effect after Dr Bottrill had retired did not contain compulsory standards capable of measuring laboratory performance.

- 5.142 The Committee considers that the failure from 1990 to 1996 to impose performance standards on laboratories reading cervical cytology is a factor that is likely to have led to the unacceptable under-reporting in the Gisborne region. Without performance standards the laboratories could not be adequately monitored, and, therefore it was impossible to be sure that they were reading cervical smear tests adequately. Furthermore, a requirement to meet set performance standards would have been a signal to Gisborne Laboratories that laboratory performance could be measured against those standards. Performance standards coupled with sanctions for failure to meet the standards would have caused Gisborne Laboratories either to improve its practices or to cease reading cervical cytology.

No Reliable Data

- 5.143 For the effective operation of a screening programme it is essential to have timely and reliable data available. This enables an analysis of the Programme's performance to be undertaken. Within this context the availability of reliable data on laboratory performance in reporting cervical smear tests enables those who are responsible for the Programme to detect if any misreporting is occurring. If the data is made available to laboratories it enables them to analyse the quality of their performance and to discover errors. The importance of statistical data for monitoring and evaluating a cervical screening programme was recognised in World Health Organisation Bulletin of 1986 titled *Control of Cancer of the Cervix Uteri*; the World Health Organisation's *Cervical Cancer Screening Programmes Managerial Guidelines* of 1992 and the *European Guidelines for Quality Assurance In Cervical Cancer Screening*. The last publication sets out 18 different tables for tabulating data required for monitoring a cervical screening programme.
- 5.144 Throughout the time that Dr Bottrill was in practice, no reliable data on laboratory performance was available. This meant that Dr Bottrill never received any information from the Programme that could have alerted him to the possibility that he

was under-reporting an unacceptable number of cervical smear tests. Dr Bottrill told the Committee that he thought he was detecting a reasonable number of high-grade abnormalities each year.

“ Q: ... you didn't know how your results compared with anybody else did you?

A: No

Q: In 1995?

A: I didn't. However, I was seeing about 30 high-grade lesions a year and without knowing any statistics it seemed a reasonable sort of number for the population we were dealing with. I can't go any further than that because the figures just weren't available.

The lack of statistical data also meant that those responsible for the Programme were unable to detect if any of the laboratories reading cervical cytology were misreporting the results.

5.145 The National Cervical Screening Programme was unable to produce reliable data for the period before 1993 because no meaningful data could be derived from the “opt-on” registers then in use, due to the number of registrations not providing a sufficient sample of the population. Secondly, until the 14 stand-alone registers were reconfigured into a centralised register the data was not reliable due to the confounding effect of women being recorded on more than one register. Ms Grew told the Committee that when she was national co-ordinator she could recall some early statistical information on laboratory performance. However this information had not been published and she agreed that it was because the data was not considered to be sufficiently robust. When the Committee asked for a view from the past national co-ordinators about whether or not there had been minimal monitoring and feedback provided by the Programme Ms Grew's response was:

Ms Grew “I'm just struggling to remember that data that I referred you to earlier, that laboratory data – I do recall there was concern obviously because then numbers were so small and it was decided definitely not to publish them but I may be wrong, but I understand each laboratory was going to get its own but I don't know what – I can't imagine what value it could have been, given there was not the ability to sort of compile a national average or anything like that that was reliable.”

5.146 It was not until 7 August 1996, by which time Dr Bottrill had retired from practice, that statistical information about laboratory performance in the form of the 1996

National Cervical Screening Programme Statistics first became available. The forward to these statistics recorded that it had always been the intent of the Programme to provide laboratories with information, but that until recently the Programme had insufficient data to allow meaningful analysis for most laboratories. These statistics were intended to provide an analysis of all cervical smear tests stored on the Registers to the period June 1994. The evidence the Committee heard was that information began to be recorded in 1990, therefore, it can be assumed that the 1996 statistics cover the period 1990 to 1994.

5.147 The period from 1990 to 1994 was a time when Dr Bottrill was practising at Gisborne Laboratories. Therefore, the statistics are relevant in that they provide a reflection of Dr Bottrill's performance in comparison with other laboratories. The forward to the statistics stated that:

“The intent of the report is to provide information to be used in the your [sic] laboratory's quality assurance processes. One of the NCSP's major principles has been the *implementation and emphasis on quality assurance with the aim to reduce the number of false negative results.*” (emphasis added)

5.148 Interestingly, the statistics place Gisborne Laboratories' reporting rates within the acceptable range. They recorded that 86% of the smears read at Gisborne Laboratories were reported as being within normal limits. The average rate for community laboratories making these reports was 80.9% and the range was 68.7-94.7%. Gisborne Laboratories was recorded as having reported 0.6% of abnormalities with high-grade codes. The average rate was 0.8% and the range was 0.4%-2.0%. Thus, if Dr Bottrill had received these statistics while he was in practice, they would have shown him that there was nothing exceptional or unacceptable about his reporting rate. They would have given him no cause for concern about the accuracy of his reporting. Indeed they are likely to have reassured him that his performance was competent.

5.149 However, in the course of the Inquiry the Committee has been told by a number of witnesses that the 1996 National Cervical Screening Programme Statistics were unreliable. Mr Du Rose of the Health Funding Authority accepted that they were unreliable and said he would not put a lot of weight upon them. He accepted that, in a national monitoring exercise, they would not have been a helpful indicator. He also

agreed that they could be falsely reassuring. For example, Dr Bottrill's false negative rate was within the acceptable range and it was not the lowest rate recorded. Mr Du Rose also accepted that the statistics may well have been falsely reassuring to members of the Royal College of Pathologists of Australasia when issues were raised about whether or not there should have been a review of cervical cytology from the Gisborne region.

“Q Given that it is accepted that there will always be false negatives in cytology, reading a statistical report which shows that generally the readings from the laboratory within a certain period of time have been within the range, again could be falsely reassuring, it could make you think if there was a problem with a couple of slides, its just a false negative problem, as opposed to a bigger problem, do you agree?”

A Yes, its possible, yes. I think it also points to the lack of not having something where you are actually measuring against.”

“Q From the perspective of a pathologist working a laboratory presumably not thinking a lot about statistical information all the time, having a document like that (the statistics) come in through the mail to him, looking at it seeing that his reporting rate is within a similar range to other laboratories, I suggest that it's likely to reassure him that his practices are okay, rather than to signal to him there could be a problem.

A Yes I agree.”

5.150 Professor Skegg was also critical of the 1996 National Cervical Screening Programme Statistics. He was concerned that the statistics took no account of the underlying prevalence of cervical cancer; they did not record whether or not the cytology diagnoses were accurate; as at June 1994 fewer than 50% of women eligible for screening were recorded on the Register/s. He said that the opt-on character of the Registers may have confounded the data, as in his view, the type of women who opt-on to a register have been found to be at a lower risk of cervical cancer than those who do not choose to go onto a register. He also said that the data were based on the number of smear tests which were reported in different ways and not on numbers of women. This meant that no account was taken of the presence of more than one smear test for the same woman. Variations in medical practice could mean that in a particular circumstance some clinicians would take more than one smear and others would not. If two smears were taken from the same woman within a short timeframe, and they were both reported as abnormal, this would influence the overall proportion of smears reported as high-grade. Professor Skegg was very critical of statistical analyses based on the numbers of smears rather than numbers of women:

“ I think analyses based on the numbers of smears rather than numbers of women are fraught with problems.”

5.151 Professor McGoogan also found the 1996 National Cervical Screening Programme Statistics unhelpful. She considered that no conclusions could be drawn from them:

“Q What are your concerns about this document?”

A Well it’s not clear whether this is cumulative year on year data or whether it refers to a shorter period of time. In an opt-on register situation the early years are likely to have fewer smears than later years. Laboratories reporting fewer than 1,000 smears are excluded. If a laboratory reported 1,000 in the last six months it would be excluded from the starter. I note it doesn’t tell me whether – this is a smear collection statistic, it doesn’t tell me anything about women – about whether you have had one smear per woman or ten smears/women in this period of time. If there had been repeated smears from normal women at six monthly intervals for example, it could sway the results. The corollary is if we were reporting smears from the women with high-grade abnormality as she passed through different caregivers, but the smears were sent to the same laboratory, that would also skew the results. Unless the statistics are collected in such a way to avoid these biases then it is difficult to make any comparisons between laboratories simply by looking at smear numbers. I am also concerned that the community laboratory range starts at naught (zero) for various things – I’m not sure how meaningful therefore the range is as a means of comparison of the laboratory in question.”

Q You are saying then that without some standardisations and explanations of the data collected and who the population is, it is not very beneficial.

A I don’t think you can draw any conclusions from it. In the UK for example there are some colposcopy services who prefer to take a repeat cervical smear the first time they see a woman in the clinic. Laboratories are required to remove those from their reporting profiles so they are not duplicating two abnormal smears from one woman in their reporting profiles before they submit their statistics, so that they don’t build in a bias, so its very important when collecting the statistics that you collect the same thing from each laboratory or at least you know when you are not.”

5.152 It was the lack of statistical information which had a negative impact on the performance of Gisborne Laboratories and that is a factor that is likely to have led to under-reporting. The 1996 statistics had no impact on the practice at Gisborne Laboratories as they did not become available until after Dr Bottrill had retired. They did, however, have a negative impact when it came to deciding if a review of all of the smears read at Gisborne Laboratories was necessary. Their impact on the Royal College of Pathologists of Australasia is most concerning. When the Health Funding Authority sought the views of the College on a review of the cervical smear tests from

the Gisborne region the College's response was influenced by the 1996 statistics. It used these statistics to compare the rates at which different laboratories around the country had reported abnormalities. Because Gisborne Laboratories' rate was not significantly different from the national average, and because Gisborne Laboratories did not have the lowest reporting rate, the College went so far as to say:

“Dr Bottrill exceeded the performance of almost one fifth of Australian laboratories judged by today's standards.”

At the time the College was unaware of the deficiencies in these statistics. It was only in the course of the inquiry when a number of expert witnesses were asked to look closely at these statistics and to comment on their usefulness that their unreliability was recognised. However, the detrimental influence the statistics had on the judgment of the College when it came to advise on the need for a review shows how dangerous and damaging unreliable statistics can be. If the Health Funding Authority had decided to follow the College's advice there would have been no review of the smear tests by Douglass Hanly Moir Pathology and the unacceptable level of the under-reporting at Gisborne Laboratories may not have been revealed.

5.153 Apart from the 1996 National Cervical Screening Programme statistics which were sent to each laboratory, there were a total of four official statistical reports for the Programme which the Ministry published. Three of these were general reports and the fourth was a Maori statistical report. The first statistical report was dated 18 August 1992 and it was released in August 1993. The second statistical report was an analysis of data to 30 June 1994 and it was released in October 1995. The third statistical report was an analysis of data to 31 December 1995 and it was released in 1998. The Committee was interested to hear how helpful these statistical reports would be to a pathologist wanting statistical data to determine whether or not his or her laboratory was providing a quality service in terms of smear reading. The Committee was told by Professor McGoogan that she would not have found any of the three statistical reports helpful.

“Q First, can you tell me as a pathologist, are those reports – would those reports be helpful to you in deciding whether or not you were happy with the performance of smear reading in your laboratory?”

A It wouldn't help me at all."

5.154 Professor McGoogan was then questioned about the timeliness of the data. Professor McGoogan informed the Committee that it was important for a pathologist to receive statistical information which was close enough to the period of time for which the analysis was made to allow the pathologist to make adjustments to his or her performance. She considered that an annual supply of statistical analysis of a laboratory's performance was appropriate. Her reaction to the timeliness of the three statistical reports differed. In her view the first statistical report was understandably the best that could be delivered at that particular time, given the nature of the opt-on register, and also it was delivered a year after the period for which the analysis was made which was not unreasonable. The second report was delivered in October 1995, which was two years later, but it dealt with data to June 1994, therefore there was a 15-month delay in delivering the information. Professor McGoogan described this as "not too bad but drifting out from what is being helpful if one thinks that a practice needs to be improved or adjusted". She also pointed out that if other statistical information needed to be collected, it was already too late to do so, and as the second statistical report was delivered in October 1995, any new or better statistics could only be collected thereafter. She was particularly disappointed with the third statistical report. Her description of this report was as follows:

"It is extremely disappointing that the third report, which dealt with analysis of data up to the end of December 95 took until June 98 to be delivered. It's further disappointing that the quality of the statistical information leaves a lot to be desired and the authors of the report have done their best to identify the limitations of the quality of the information in the report. While producing the statistics, it's simply telling you what the data is on the Register, but not saying it is perfect, so how do you interpret it?"

"Q As a pathologist wanting to measure the performance of your laboratory how helpful are each of these reports?"

A Not very helpful, particularly the last one is very unhelpful."

5.155 Professor McGoogan did not evaluate the Maori statistical report. She did, however, comment that the bigger the database the more accurate the conclusions drawn from it, and the smaller the database the more difficult it is to derive meaningful and significant statistics. She, therefore, thought the numbers in the Maori statistics may not be large enough and, although of interest to Maori to see what was happening to

them, there may have been insufficient numbers to allow meaningful conclusions to be drawn. When asked by the Committee to comment on the fact that the Maori statistical data was at least four years old when first published in the Maori statistical report, Professor McGoogan's response was:

“It may have been useful four years ago, but it doesn't tell you whether things are different now, better now, or worse now, and we need to know what's happening now.”

5.156 The Committee learnt that annual statistical reports were intended. However, their publication was hampered by the difficulties that the Programme encountered in obtaining reliable data. This was due to the fragmentation that resulted from having 14 stand-alone registers. Secondly the involvement of 14 area health boards had a detrimental effect. The Committee learnt that some of the area health boards altered the software of the registers in their regions and this affected the collection of statistical data. Secondly the number of area health boards allowed room for divergence in viewpoints to arise which led to actions differing from region to region. For example the first statistical report, which was released in August 1993 and which presented data to 18 August 1992, was first of all delayed, because the Wellington Area Health Board would not provide data from its region, and finally the report was published without data from Wellington. The release of the Wellington data was held up by the security protocols of the Wellington Area Health Board's Ethics Committee. Furthermore, the Programme delayed issuing a second statistical report until the Wellington data became obtainable. The second statistical report was released in October 1985 and it presented data to June 1994. It could not present data beyond that date because no data from the Auckland Area Health Board region was available beyond June 1994. The third statistical report was released in June 1998 and it presented data to December 1995. Professor McGoogan, Professor Skegg and Dr Cox were critical of the statistical reports in terms of their limited value for methodological reasons, and also because the data was well out of date by the time the reports were published. When those criticisms were put to Ms Grew her response was that not having one database made it very difficult to produce statistical reports. Her view was the first statistical report was affected by lack of data, but she thought that subsequently it should have been possible to have got into a routine, and once there was only one database it should have been “really easy to produce an annual report or

even three monthly, six monthly”. Ms Grew was then asked to explain from her perspective as a former national co-ordinator of the Programme why it was that only three general statistical reports had been produced. She could not offer an explanation. Ms Dahl said that until the register was reconfigured into one database it was too difficult.

“Q From your perspective are you able to explain why there have only been three statistical reports in the period?

A – Ms Grew I can’t explain that.

A – Ms Dahl I can explain it was very difficult to do the second statistical report and that related to the fact that we did have 14 registers at the time. We had to create programs to get the information downloaded at the 14 sites and compiled in Wellington so that we could do that reporting. I would have envisaged that once we had the register reconfigured that the data would be more readily available and it would have been an easier thing to do.”

5.157 There was also no compulsory requirement to report incidences of cancer and deaths from cancer until the passing of the Cancer Registry Act 1994. An effective Cancer Registry is essential to enable a screening programme to be monitored and evaluated. One way of testing the effectiveness of a screening programme is to carry out an audit of the cases of cancer by retrospectively investigating the smear history and clinical treatment of the women concerned. To do this there needs to be a reliable record of the number of cases of cancer. On 5 April 1990 the Expert Group wrote to the Minister of Health advising her of the urgent need for up-to-date statistical information on cancer cases. The letter stated:

“ The Expert Group is resolved that it is impossible for it to adequately perform its task if the Cancer Registry is not adequately functional. The Expert Group therefore recommends as a matter of urgency the Cancer Registry is resourced with equipment, staff and legislative framework to provide a complete up-to-date and confidential registry of all cancers and cervical dysplasias in New Zealand.”

Ms Gillian Grew who was the first national co-ordinator of the Programme was asked if she was aware of the Expert Group’s views and whether or not she agreed with them. She said she was aware of their views and she agreed with them:

“Q Were you aware that the Expert Group had that concern and what to your knowledge was done about it?

A Ms Grew: I was aware when I arrived in the department that they had a concern and there was quite a lot of work going on to actually secure the future of the Cancer Registry at that time.

Q Do you agree with the sentiments in the letter

A Certainly.”

5.158 Other experts from whom the Committee heard evidence also thought that a cancer registry was necessary for the Programme to function effectively. Furthermore, this type of advice in various forms was both available and given to the Department of Health during the developmental stages of the Programme. This is stated in the World Health Organisation Bulletin of 1986 titled *Control of Cancer of the Cervix Uteri*; the World Health Organisation’s *Cervical Cancer Screening Programmes Managerial Guidelines* of 1992 and the *European Guidelines for Quality Assurance In Cervical Cancer Screening*. However, it was not until 1994 that the legislation setting up a cancer registry with mandatory reporting provisions was passed. Since then there have been problems with the completeness of the Cancer Registry data. In addition during the course of the Inquiry the Committee learnt that the Cancer Registry was not releasing data in accordance with the law and was imposing an unnecessary obstacle by requiring compliance with the Health and Information Privacy Code, even though the Code had no application to processing requests for Cancer Registry information.

Failure To Conduct Any Comprehensive Exercise To Audit, Monitor And Evaluate The Performance Of Laboratories Reading Cytology

5.159 It is important to be clear about the meaning given to the words “auditing,” “monitoring” and “evaluation” as their meaning can differ depending on the user. The Committee has chosen to adopt the definition of these words that is set out in exhibit JMP/HFA/0023, the November draft of the Health Funding Authority’s Evaluation and Monitoring Plan for the National Cervical Screening Programme. “Monitoring” means:

“...the continuous supervision of an activity for the purpose of checking whether plans and procedures are being followed.

Within the meaning of “monitoring” is the act of “auditing” which is:

“a subset of monitoring 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

“Evaluation” means:

“ 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.

“...other purposes of evaluation ...[are]:

?? a systematic way of learning from experience and using lessons learnt to improve current activities and promote better planning by careful selection of alternatives for future action.

?? Programme evaluation is a diligent investigation of a programme’s characteristics and merits. Its purpose is to provide information on the effectiveness of projects so as to optimise the outcomes, efficiency and quality of health care.”

Throughout the time that Dr Bottrill was in practice, and subsequently, the National Cervical Screening Programme has not carried out a comprehensive evaluation of its overall performance, including the performance of laboratories reading cervical cytology. Nor has it monitored the performance of laboratories reading cervical cytology. The Ministry of Health took steps in 1995 to have a national evaluation of the Programme carried out by an independent team of experts but as at September 2000 this national evaluation was incomplete and there are uncertainties still as to when, and in what form it will be completed.

5.160 When the Health Funding Authority recognised that the level of under-reporting at Gisborne Laboratories suggested there was a significant problem with its smear test reporting, the Health Funding Authority reviewed the cervical cytology of other laboratories which it had identified as being potential poor performers. This exercise was a response to the problem that had arisen in the Gisborne region and, although it provided information of a type which could come from a monitoring exercise, it can not be seen as having been undertaken for the general purpose of monitoring and evaluating laboratory performance. The Health Funding Authority acknowledged this in its published report titled *Review of Cervical Cytology Practice in New Zealand Community Laboratories: 1990-1999*. The *Review* states: “...this review does not represent a thorough assessment and evaluation of the quality of cervical cytology services.”

- 5.161 The Committee considers that the failure to set up from the outset a National Cervical Screening Programme with performance standards in place and with a means of gathering reliable statistical data to enable laboratory performance to be monitored and evaluated adequately are factors that are likely to have led to Dr Bottrill's under-reporting of cervical smear tests. The Programme's lack of performance standards for reading cervical cytology, and the absence of reliable data, made it difficult to monitor and evaluate laboratory performance adequately.
- 5.162 The importance of monitoring and evaluation is made clear in the World Health Organisation Bulletin of 1986 titled *Control of Cancer of the Cervix Uteri* which states: "A cervical cancer control programme should not be initiated prior to the establishment of adequate evaluation procedures. It is essential to assess progress of the screening programme periodically both from the procedural standpoint, to determine how effective the operations actually are, and in terms of achievement, to analyse the extent to which morbidity and mortality have been reduced in the population group covered." The need for reliable data in order to monitor and evaluate is clearly spelt out in the literature on cervical screening programmes. The World Health Organisation's *Cervical Cancer Screening Programmes Managerial Guidelines* of 1992 state: "For evaluation and monitoring purposes the data must be maintained in a form that permits identification and linkage at an individual level, and the information system should be so designed that it is accessible for such purposes.". The *European Guidelines for Quality Assurance In Cervical Cancer Screening* state that: " Before cervical screening can be implemented mechanisms for gathering essential data for the day to day operation of the programme and for statistical purposes must be in place."
- 5.163 However, the lack of reliable data and performance standards should not lead to nothing being done. When the Health Funding Authority had to carry out the *Review of Cervical Cytology Practice in New Zealand Community Laboratories: 1990-1999* it overcame the absence of performance standards by focusing "on the assessment of risk to women by examining markers of possible under-reporting of abnormalities." It recognised that this type of exercise did not enable a thorough assessment and evaluation of quality in laboratory performance to be carried out. Nevertheless, it allowed the Health Funding Authority to obtain some information about the

performance of other potentially poor-performing laboratories. However, in the case of the National Cervical Screening Programme even this type of evaluation was not carried out.

- 5.164 It is of course possible that once the 1996 Cervical Screening Programme Statistics on laboratory performance became available any evaluation of Gisborne Laboratories' performance, which covered the period prior to March 1996, may have failed to detect under-reporting. Those statistics placed the laboratory's reporting rate within what the Programme was treating as an acceptable range. The Committee heard expert evidence that this information was misleading. This highlights the danger of attempting to monitor a programme by poor methods. However, if the Programme had monitored and evaluated laboratory performance adequately from an early stage, even by looking for indicators of under-reporting as the Health Funding Authority did, the extent of the under-reporting of cervical smear tests at Gisborne Laboratories may have been detected much sooner. This would have reduced the number of women affected by misread cervical smear tests.
- 5.165 The Committee has already commented on the failure to develop the performance indicators to which the *Policies* of 1991 and 1993 referred. Both *Policies* in their sections on evaluation and monitoring refer to the development of performance indicators. The Committee has interpreted this reference to performance indicators as an acknowledgement that some means of measuring performance was essential to enable the Programme to be monitored and evaluated. Nevertheless, no performance indicators were developed for the purpose of measuring laboratory performance.
- 5.166 The Ministry of Health maintained that some monitoring of the Programme was undertaken, although they conceded that this monitoring gave no information on laboratory practice. The Ministry also conceded that the National Cervical Screening Programme had never been subject to a comprehensive evaluation. At the outset of the Programme, when it came to laboratory practice in reading cervical cytology there was a complete reliance on the professional integrity of the medical practitioners responsible for the performance of this service. No attempt was made to ascertain the accuracy of the practitioners and those working under their supervision in reading cervical smear tests. Although, at this time the Social Security (Laboratory Diagnostic

Services) Regulations 1981 were in force, there was no attempt to utilise the authority they gave to inspect laboratory equipment and apparatus in order to check on laboratories' performance. The Committee realises that the Ministry of Health now submits that this part of the regulations is *ultra vires*. It will deal with this submission under term of reference three. Nothing changed after the health reforms in 1993; laboratory practice in reading cervical cytology was neither monitored nor evaluated.

5.167 Both the 1991 and 1993 *Policies* provided that the National Co-ordinator would be responsible for ensuring that the National Cervical Screening Programme was monitored and evaluated nationally, and that evaluation of projects and services nationally would be co-ordinated by the Department of Health and subsequently by the Ministry of Health. The *Policy* also provided that on a regional level it was the responsibility of the area health board and subsequently the regional health authority to monitor and evaluate the Programme in their area. However, Mr Mules of the Midland Regional Health Authority told the Committee that the Midland Regional Health Authority could not carry out this role as it did not have access to the necessary information to enable monitoring and evaluation to take place. The information was held by the Department and then subsequently the Ministry of Health. Once again, it seems to the Committee that the design of the *Policy* did not reflect accurately the capability of those given responsibilities under the *Policy* to discharge that responsibility.

5.168 What is of most concern to the Committee, however, is the failure of the Department of Health and subsequently the Ministry of Health to monitor and evaluate the Programme at a national level. Under the *Policy* the National Co-ordinator was made responsible for ensuring that national monitoring and evaluation took place. However, it is clear from the job description of the National Co-ordinator and from the evidence the Committee has heard of the role, that she had no authority to ensure that the national monitoring and evaluation of the Programme was in fact carried out. The Committee considers it is a design flaw of the *Policy* that it gave a responsibility to the National Co-ordinator without ensuring that she had intrinsic or extrinsic power to discharge that responsibility by requiring national monitoring and evaluation to be carried out. Secondly, the *Policy* imposed a responsibility on the Department of Health and subsequently the Ministry of Health to co-ordinate the monitoring and

evaluation of the Programme. Again, the evidence shows to the Committee that the Department of Health and subsequently the Ministry of Health was unable, sometimes for practical reasons and other times for legal reasons, to discharge this responsibility. The end result was that although both *Policy* documents made provision for monitoring and evaluation of the Programme at a national level, including the monitoring and evaluation of laboratory performance, it never occurred during the time that Dr Bottrill was in practice. Indeed, from the evidence the Committee has received it seems that the first attempt to carry out a national comprehensive evaluation of the Programme is still incomplete. Dr Peters, who gave evidence for the Health Funding Authority is the manager of the unit in which the National Cervical Screening Programme has been housed since 1998. She accepted that there still has not been a comprehensive evaluation of the national Programme.

“Q Dr Peters, I understand that you accept that at the moment there has been no comprehensive evaluation of the nation Programme, is that correct?”

A Yes.”

5.169 She also informed the Committee that from her perspective, quality standards and monitoring and evaluation were just beginning.

“Q In respect of bringing in quality standards, monitoring and evaluation, are you really starting from scratch with the programmes in terms in that aspect of it?”

A Well I feel as though I am.”

5.170 The Committee has learnt that there has never been an audit of cases of cervical cancer even though this is considered to be one of the most effective ways of measuring the effectiveness of a cervical screening programme. As early as 1986 the World Health Organisation in its bulletin on *Control Of Cancer Of The Cervix Uteri* had stated that:

“Screening programmes can be evaluated by their failures. Cases of symptomatic invasive cancer of the cervix, and especially of advanced disease can be regarded as failures of a screening programme. Knowledge of the age distribution of such cases and of their screening history provides information of the effectiveness of the programme in reaching the intended age groups and the quality of the screening being carried out.”

This form of monitoring and evaluation is particularly useful when a cervical screening programme has no performance standards in place, however, it does depend on access to reliable data on cancer incidence and mortality and smear test history. Apart from the World Health bulletin the Committee was informed by: Professor McGoogan, Professor Skegg, Dr Medley, Dr Peters, Dr Cox and Dr Teague that an audit of cases of cervical cancer was the gold standard for measuring the effectiveness of a cervical screening programme.

- 5.171 Such an audit has never been carried out in New Zealand. An attempt has been made to carry it out as part of the national evaluation of the programme, but that has run into legal and ethical obstacles. Ms Glackin acknowledged the difficulties that had prevented this exercise from being carried out in New Zealand and said that Ministry of Health officials had understood that ultimately this exercise would be carried out routinely.

“I don’t think there is any disagreement about the advice that following people with cancer through was a gold standard in relation to treatment. And in the light of that I’m not sure what people – whoever was dealing with this - felt in 1993, but you would have expected that issue might have been addressed then.

- 5.172 If the Programme had carried out an audit of cervical cancer cases by looking back at the cervical smear history of women who had developed cervical cancer and investigating those who were registered as having normal smear tests within a set time frame, such as five years prior to diagnosis, that is likely to have alerted the Programme to the likelihood that there was an unacceptable level of under-reporting in the Gisborne region. However, for reasons which will be covered in term of reference three, it appears that access to the register for this purpose has not been permitted. In any event it was not until December 1999 that the Ministry realised there was a legal barrier to using the register as an audit tool. This indicates to the Committee that no meaningful attempt had been made to use the register in this way before then:

Question: The evidence of, certainly Dr Cox was that this clinical audit or retrospective look at women who developed invasive cancer should, as Ms Glackin said, be a routine occurrence. Would you accept that if that had occurred early on in the Programme the problems with s.74A would have been understood much more quickly than it has been now”

Answer Ms Glackin: I would, but I should make the comment that from a technical perspective there are issues with having, apparently, sufficient numbers of women enrolled to make

evaluation feasible. One of the issues with this programme is that until after the opt-off in 1993 we had quite small numbers. So I understand there were some technical issues about when the evaluation could be done.

This comment from Ms Glackin indicates the major difficulties the Programme faced. Evaluation was not possible before the Register became an opt-off single database. Once it could be used for evaluation, which was by 1997 when it was reconfigured and had sufficient numbers of women registered to provide meaningful data, the Ministry discovered that s.74A of the Health Act 1956 posed a barrier to using the Register for this purpose. The outcome is that during the time Dr Bottrill was in practice the Register could not be used effectively to allow laboratory performance to be monitored.

5.173 In June 1996, which was after Dr Bottrill had retired a new *Policy* for the Programme was published. This *Policy* is relevant because if it had been designed to ensure that the Programme was effectively monitored it would have revealed the extent of Dr Bottrill's under-reporting earlier than has happened and this may have meant that the high-grade abnormalities or cervical cancers of some women were detected earlier and therefore they may have been more responsive to treatment.

5.174 Like the earlier *Policies* the *Policy* of 1996 provided that the main responsibility of the Ministry of Health was to monitor and evaluate the National Cervical Screening Programme and to monitor and analyse the state of public health regarding the incidence of cervical cancer and associated risk factors in New Zealand. The *Policy* also provided that regional health authorities were responsible for monitoring and evaluating the Programme in each regional health authority region. Once again, there was the difficult tension between the *Policy's* placement of responsibility for national monitoring and evaluating on the Ministry of Health with the responsibilities the funding agreements imposed on regional health authorities. Ms Glackin said to the Committee that under the 1996 *Policy* it was a requirement on the Health Funding Authority to purchase the Programme in line with that *Policy*. However, the impact of the split accountability between the Ministry of Health and the Health Funding Authority and the design of the 1996 *Policy* meant that the regional health authorities left monitoring and evaluating to the Ministry of Health.

“Q The difficulty was that, Ms Glackin, we had evidence from Mr Mules that the regional health authorities considered that under the 96 funding agreement responsibility for monitoring and evaluating the Programme remained with the Ministry of Health, and he referred to that in his evidence to say this is why, as far as he was concerned, the Midland Regional Health Authority did not consider that it had to do that because it was looking at the screening policy documents and under those policy documents responsibility for monitoring and evaluating the Programme remained with the Ministry of Health.

A – Ms Glackin Yes, and that issue of split accountability was actually canvassed in the 1996 review. I think the Ministry has no difficulty with recognising the problems that arose from that division. I would just make a point though in relation to evaluation that the Ministry initially put funding in its budget and began initial work on a formal evaluation in 1996.”

It should be noted that the formal evaluation that Ms Glackin speaks of is the one that is still to be completed.

5.175 Ms Glackin told the Committee that the evaluation was first discussed in 1995 and the Ministry decided to proceed with a national comprehensive evaluation in 1996. Tenders were put out and in January 1997 a contract was signed with the University of Otago for a scoping of the evaluation. The first draft of the evaluation was received in May 1997 and that proved to be too expensive. There was then much consultation about what should occur. Ultimately a shortened form of evaluation was agreed covering three specific areas and a contract to carry that out was signed with the Ministry in May 1999. As at 6 August 2000, when Ms Glackin was giving her evidence to the Committee, of the three areas to be evaluated one had been completed, one had received Ethics Committee approval three weeks earlier, and the third, which was the audit of cervix cancer incidence and mortality, was not proceeding because of the difficulties in gaining access to information. Had a national evaluation been carried out anytime after Dr Bottrill’s retirement in March 1996 it ought to have detected earlier the unacceptable level of under-reporting in the Gisborne region. That knowledge should have led to women receiving treatment earlier on and it may have avoided cancer mortality or severely invasive treatment for cancer.

5.176 Without monitoring and evaluation it is impossible for a pathologist to be aware of the accuracy of his or her reading of cervical cytology. All screening programmes that involve analysis of cellular material are dependent upon the accuracy and competency

of the practitioner responsible for reading the cellular material. Unless the practitioner's work is monitored and evaluated mistakes are not likely to be detected until the deteriorating health of the screening subject causes the practitioner's work to be reviewed. By that time it can often be too late to cure the patient, or if the disease is still curable severely invasive treatment may be required to achieve a cure.

5.177 The success of the National Cervical Screening Programme depended on pathologists and other laboratory workers reading cervical smear tests competently and accurately. If the Programme had monitored the performance of laboratories reading cervical cytology the unacceptable level of under-reporting at Gisborne Laboratories would have been detected much earlier on and, therefore, fewer women would have been harmed. Furthermore, the information gained from monitoring laboratory performance could have been used to inform Gisborne Laboratories that the cervical cytology read at the laboratory was not being read competently. As it was, throughout the time that Dr Bottrill was in practice at Gisborne Laboratories, neither Dr Bottrill nor any other director or officer of the company was provided with information, from any Crown body or agency responsible for the Programme, which would have informed them that there was an unacceptable level of under-reported cervical smear tests. The Committee considers that to run a screening programme that is dependent on laboratories performing their role competently without providing them with any feedback on their performance, is a factor that can lead laboratories to under-report the tests they carry out. Consequently it considers that the failure to provide this information to laboratories is a factor that is likely to have led to the under-reporting at Gisborne Laboratories.

Failure To Take Heed Of Overseas Screening Failures

5.178 Between 1993 and 1994 there were three incidents overseas of a laboratory causing a failure in a cervical screening programme by under-reporting cervical cytology. These incidents occurred in Australia and the United Kingdom. The Cervical Screening Advisory Committee brought these screening failures to the attention of the National Co-ordinator of the Programme and the Ministry of Health, and they were published in the National Cervical Screening Programme's newsletters. In addition in June 1994 a hospital pathologist at Goodhealth Wanganui was found to have misread biopsy

specimens. The pathologist was 62 years of age and had been diagnosed with Parkinson's Disease in late 1993. A review of his work revealed that he did not participate in quality assurance activities; he did not participate in continuing medical education and he was working in an isolated environment. It was recognised that all of these circumstances may have impaired his work as a pathologist.

5.179 Given the information that was available about the mis-reporting in Australia and the United Kingdom, and the findings from the Wanganui investigation it is surprising that neither the Programme nor any other unit within the Ministry of Health initiated a review of New Zealand laboratories reading cervical cytology; particularly those laboratories, like Gisborne Laboratories, which in some respects resembled the practice at Goodhealth Wanganui. The Programme's staff would have known that laboratory performance in reading cervical cytology had never been properly monitored and evaluated, so that the quality of the laboratories' performance was not definitively known. These local and foreign incidences of laboratory error were a signal to the Programme that laboratory error can occur and when it did it could have a damaging impact on patients' health. While the Programme had no direct power to take any action against laboratories it was the entity under the *Policy* which was responsible for ensuring that the Programme was monitored and evaluated nationally and so in the Committee's view it should have responded by initiating a review of laboratory performance.

5.180 The overseas screening failures occurred during the time that Ms Dahl was the national co-ordinator. The incidents were noted in the Programme's newsletter. The Committee learnt from Dr Cox who was on the Cervical Screening Advisory Committee that after the second incident the Advisory Committee advised the national co-ordinator (Ms Dahl) that this type of event could occur in New Zealand and that appropriate quality assurance was needed to minimise the risk of it occurring. Ms Dahl told the Committee that she could not recall Dr Cox specifically saying that at the meeting, but she did recall that at the time she was working with the Advisory Committee to develop quality assurance processes, monitoring processes, and evaluation processes so she said that she could only surmise that it was considered as part of what was being done in relation to that. When asked to comment on why the Programme did not respond to these incidents by initiating a review of laboratory

performance in New Zealand, her response was that the overseas incidences of misreporting had not brought home to the Programme the need for a review.

“Q When I asked Dr Cox whether or not – I asked him both in respect of each article [in the Programme’s newsletter] they provided a wakeup call, and he said they did, and I then said well in view of the first two wakeup calls, once a second had been received what do you think should have happened, and he said as a matter of urgency I would expected a review of laboratory practice processes to reduce the chances of a similar event occurring in New Zealand. What comment do you have on that?”

A – Ms Dahl The only comment that I can have is that the wakeup call was not sufficiently loud to have that occur.”

- 5.181 In his evidence Dr Cox referred to a Programme newsletter of January/February 1993 which contained an article on the accuracy of smear tests of 237 women referred to the Royal Hospital for Women in Sydney for invasive cervical cancer. The article noted that a worrying aspect was the number of patients whose previous smears on review showed frankly malignant cells but were originally reported as normal.
- 5.182 In a second Programme newsletter of March/April 1994 there was an article on a screening failure in Great Britain which described how a group of 2,000 women were recalled in Grennock where smears had been wrongly read for five years in a laboratory described as understaffed, antiquated and isolated. Dr Cox said that the Advisory Committee advised the national co-ordinator that “This type of event could occur in New Zealand and that appropriate quality assurance is needed to minimise the risk of such an event occurring.”.
- 5.183 The Midland Regional Health Authority did respond to the Wanganui incident by writing to all of its laboratory providers including Gisborne Laboratories. In his response Dr Bottrill told Midland that the laboratory had applied for TELARC accreditation in histopathology and cytology, he advised that he did not participate in any external quality control programmes, but said that he did attend at least one national or international conference or course every year. He concluded his letter by stating “There is little likelihood of a major misdiagnosis of the type you refer to in your letter.”

5.184 Dr Malpass of the Midland Regional Health Authority judged the response from Gisborne Laboratories to be unsatisfactory and referred it to the Chief Executive, (Mr Mules), to determine what action, if any, should be taken. Mr Mules decided that the Regional Health Authority had no power to refuse to fund laboratory services from Gisborne Laboratories. At the time the legal relationship between the regional health authority and the laboratory was governed by a notice issued under s.51 of the Health and Disability Services Act. Mr Mules believed that the laboratory was not in breach of any of the terms of the s.51 notice and there were no other sanctions that the regional health authority could apply against it. For this reason it seems no action was taken as a result of Dr Bottrill's unsatisfactory response, and the Midland Regional Health Authority conducted no investigation into his laboratory's practices or processes.

5.185 The Committee considers that s.51 of the Health and Disabilities Act permitted regional health authorities to issue notices which contained terms and conditions that gave to them the power to require laboratories to adopt quality assurance measures, including TELARC accreditation, and to suspend laboratories from receiving payment if their services were a risk to public health. The Committee's reasons for reaching this conclusion are set out in the section of the report on term of reference three. It was also possible to change the terms and conditions of s.51 notices on the giving of appropriate notice. Therefore, the Committee considers that the Midland Regional Health Authority should have carried out an investigation of Gisborne Laboratories. If the investigation had shown that action was warranted the Midland Regional Health Authority could then have taken steps under s.51 to change the terms and conditions of the notice to allow for appropriate action to be taken.

5.186 The opportunity, in 1994, which the Programme and the Midland Regional Health Authority had to uncover the presence of unacceptable under-reporting at Gisborne Laboratories was missed, with the consequence that Dr Bottrill continued to practise until his retirement in March 1996. During this time more women had their smears misreported and, therefore, they did not receive the appropriate follow up treatment. In the Committee's view the failure by either the Programme/Ministry of Health or the Midland Regional Health Authority to follow up the local and foreign incidents of laboratory error which in turn led to a loss of opportunity to discover the under-

reporting at Gisborne Laboratories earlier is a factor that is likely to have led to the under-reporting that occurred from 1994 onwards.

Failure To Ensure All Components Of The Programme Were In Place From An Early Stage

5.187 There was a failure to ensure that all the components of the National Cervical Screening Programme were in place from the outset or, alternatively at an early stage in the Programme's development. If all the missing components had been in place from an early stage in the Programme, that is: reliable statistical data, performance standards, monitoring and evaluation of laboratory performance and compulsory quality assurance of laboratories, they would have prevented Dr Bottrill from practising as he did.

5.188 The need to have all the components of the Programme in place from an early stage was recognised early in the Programme's development, by the Ministerial Review Committee in its November 1989 report *On Implementation Of A National Cervical Screening Programme*. The Ministerial Review Committee stated:

“For a cervical screening programme to be successful all aspects must be developed simultaneously as each is an integral part of achieving success.”

5.189 Ms Glackin accepted this and told the Committee that over time the Programme had been progressing towards having everything in place.

“Q And do you agree this really reinforces what the World Health Organisation was saying to run a programme effectively you really need to have all aspects in place at once, or if you are building up good data from the cancer register and the screening register and you can make the necessary links, and if you can make the necessary links between cytology and histology all these factors go to help you identify more readily cases where the programme might be failing in respect of under-reporting of smear tests.

A – Ms Glackin I would agree with that, and I think, looking over time what we have been doing is progressing towards that state. I think the Inquiry is well aware of how long various aspects of that have taken. I should perhaps make the point of course which the Inquiry is well aware of, that the cancer registry deals with cancers of all sorts.”

However, the progress Ms Glackin referred to is still to be completed. The re-configuration of the Register was completed by 1997 and since that date reliable data

should have been available to monitor and evaluate the Programme. Compulsory TELARC accreditation has been in place since 1997. However, there have been other obstacles to surmount. The end result is that even today some of the components are still missing. Reliable data is still hard to access because of legal and ethical barriers and the Programme has still not been comprehensively monitored and evaluated. This is ten years after the Programme was operative in the Gisborne region.

No Compulsory Reassessment Of Medical Practitioners

5.190 There were no compulsory requirements for medical practitioners to undertake formal continuing education, or for them to have their competence reassessed. The Committee considers that this too was a factor that is likely to have led to the unacceptable under-reporting in the Gisborne region. Had Dr Bottrill been required to undergo formal continuing education and a re-assessment of his competency as a medical practitioner it is unlikely that he would have continued to practice as he did. The impact of formal continuing education could well have brought home to him the risk his practices posed to patients. A re-assessment of his competency would most likely have revealed that he was being overly cautious in diagnosing abnormalities; that he had “calibrated” his eyes to read smear tests with a very high specificity and that he needed to increase the sensitivity of his reporting. The Committee has concluded that Dr Bottrill was unaware of the risk his practices posed to patients. Compulsory participation in a formal course of continuing education and re-assessment of his competence should have remedied this. For this reason the Committee has concluded that the absence of any requirement to participate in continuing education or any formal re-assessment of competency are factors that are likely to have led to the unacceptable under-reporting in the Gisborne region.

Conclusion

5.191 The Committee has identified those factors directly relating to Dr Bottrill’s practice which it considers are likely to have led to unacceptable under-reporting in the Gisborne region. It has also identified factors relating to the delivery of cervical cytology services during the time that Dr Bottrill was in practice and afterwards which it considers are likely to have led to under-reporting in the sense that it was the

presence of these factors which enabled Dr Bottrill to practise as he did and which meant that the under-reporting was not detected sooner. If Dr Bottrill had not been able to practise on his own, carrying out all the primary screening in circumstances where there was no internal or external quality control at Gisborne Laboratories, and where the laboratory was not registered with TELARC or any other quality control authority, it is unlikely that he would have under-reported for as long as he did and at such an unacceptable level. An effective, well-designed and well-implemented programme would have prevented him from practising in this way. Ultimately, it was the flaws in the National Cervical Screening Programme that permitted Dr Bottrill to practise as he did. In August 1990 the Expert Group's *Policy Statement of the National Cervical Screening Programme* recognised that screening can fail because of poor quality in either the smear taking or *smear reading*. The *Policy Statement* noted that there had been reports of deficiencies in these aspects of screening in parts of New Zealand. The *Policy Statement* went on to emphasise the importance of management systems in ensuring that poor quality in smear taking or smear reading did not cause a programme to fail:

“In an organised programme, the management system can minimise the possibility of such failures by measuring the technical quality of the screening process and by monitoring the follow up of women with abnormal smears.”

It is unfortunate that the recognition in 1989 of the importance of a screening programme's management system did not flow through to ensure that it was well designed and well implemented.

6. TERM OF REFERENCE THREE

Whether or not the under-reporting by Dr Bottrill was an isolated case rather than evidence of a systemic issue for the National Cervical Screening Programme?

6.1 The Committee considers that the under-reporting by Dr Bottrill is evidence of a systemic issue for the National Cervical Screening Programme. It does not consider that the under-reporting can be seen as an isolated case of error on the part of Dr Bottrill. In reporting on term of reference two, the Committee has set out the factors that it considers are likely to have led to the under-reporting. Many of these factors relate to flaws in the Programme. In essence, the Committee's view is that a well-designed, soundly based and well implemented screening programme would have eliminated those aspects of Dr Bottrill's practice that were responsible for the under-reporting. The practices followed by Dr Bottrill, and on rare occasions others at Gisborne Laboratories, would either have been replaced with better, more appropriate practices or the reading of cervical cytology at Gisborne Laboratories would have stopped. In either event, the risk of under-reporting would have been reduced. Smear tests would either have been read at Gisborne Laboratories with improved practices or they would have been read elsewhere at laboratories with better practices.

6.2 Dr Bottrill does present as an extreme case. The Committee is aware of no other pathologist at a community laboratory who was practising in quite the same way as Dr Bottrill (and the locums Gisborne Laboratories employed from time to time). However, the evidence the Committee has heard has convinced it that the issues relating to the under-reporting at Gisborne Laboratories extend beyond the practices adopted in that laboratory. The Ministry of Health submits that Dr Bottrill's method of practice was unlike that followed by any other pathologist and, therefore, it constituted an isolated case. However, the question for the Committee to report on under term of reference three is whether or not the unacceptable under-reporting was an isolated case. In that regard the Ministry accepts that the presence of other unacceptable under-reporting over the last decade cannot be ruled out. This is consistent with Dr Gabrielle Medley's comment on the Health Funding Authority's National Laboratory Review, which was carried out to determine if other women were

at risk. Dr Medley is a cytopathologist from Australia who was engaged by the Health Funding Authority to assist it with this review.

“I would not believe that this review could reassure you about the years 1991 to 1996 in a wholehearted manner.”

6.3 Term of Reference Three requires the Committee to focus on the under-reporting which occurred and to form a view on whether or not that was the result of an isolated case or a systemic problem for the National Cervical Screening Programme. In the Committee’s view an isolated case of under-reporting is one that occurs irrespective of the wider context in which it takes place. It is something that could have occurred irrespective of the quality of the Programme. Whereas, under-reporting which represents a systemic problem for the Programme is something that occurs because the Programme has permitted it to occur. False negative smears will occur from time to time in the best of screening programmes and when they do they can be seen as isolated cases where there has been an understandable failure to read a smear test correctly. A sustained unacceptable level of under-reporting which spans a period from 1990 to 1996 and which goes unrecognised by the pathologist responsible for reading the smear tests and by the Programme is something different. That can only occur because the Programme lacked the systems and procedures to prevent it. The deficient practices followed at Gisborne Laboratories, which led to the under-reporting, carried on for as long as they did because there was no system or procedure in place either to detect them or to stop them. Those factors which the Committee has identified in its report on term of reference two as being likely to have led to the unacceptable under-reporting were the result of an environment where there was little control on how laboratories delivered their diagnostic services; even though their services were fully funded by government money. The way in which the Programme was designed and operated did nothing to prevent laboratories lacking quality control processes, from misreading smear tests. Without quality control there was a greater likelihood this would happen and without effective monitoring and evaluation of laboratory performance there was no way of detecting misreporting if it did happen. This set of circumstances could only arise if there were systemic problems with the Programme.

- 6.4 There is a mass of literature on what constitutes an effective cervical screening programme. This literature, which was available from the late 1980s onwards, recognises the possibility of false negative reports in screening programmes and the dangers that flow from them. The view the Committee has formed on what are the essential attributes of an effective screening programme is based on this early literature and not on later literature. The Ministry of Health submitted to the Committee that it must not allow “hindsight bias” to colour its judgement. The Committee is confident that it has not done so. It has formed its views on literature that was published between 1986 and 1993 at the latest and the reports of various advisory groups between 1990 and 1991. Further, there is nothing fundamental in the 1993 literature (the *European Guidelines For Quality Assurance In Cervical Cancer Screening*) that was not already stated in the World Health Bulletin on *Control of Cancer of the Cervix Uteri* which was published in 1986. The 1993 literature has been relied on simply as confirmation of the recommendations in the earlier literature.
- 6.5 In the Committee’s view, an effective screening programme is one which has in place, from an early stage, systems and procedures which are designed: to reduce the likelihood of false negative tests occurring; secondly to avoid them going unnoticed for a long time, when they do occur; and thirdly to prevent, where possible, whatever is directly responsible for the false negatives from continuing to produce them. Because the National Cervical Screening Programme did not have such systems and procedures in place throughout the time that Dr Bottrill was reading smear tests (and even after his retirement), he was able to continue with his sub-optimal practices until his retirement in March 1996. The Programme did nothing to raise concerns about the quality of his reporting. Such concerns were raised by women who, as a result of their cervical disease becoming clearly apparent, learnt that their earlier smear tests had been misread as normal. The Committee considers that this shows the Programme has systemic problems. Because some of these problems continue to this day the Committee will not confine this section of the report to the time frame in which Dr Bottrill was operating. For ease of reference it is better if current systemic problems which originate during the time Dr Bottrill was in practice are dealt with under this heading rather than under the subsequent terms of reference.

6.6 To report on this term of reference it is necessary for the Committee to form a view on when the National Cervical Screening Programme began. The Ministry of Health submitted to the Committee that the Programme did not begin until the 14 screening registers were in place. This would be January 1992. The Committee disagrees with this view. It considers that the Programme cannot be seen as having a single commencement date; its beginning is best seen as a series of developmental phases. Its genesis was a recommendation in the Cartwright Report for a national cervical screening programme. That Report was published in July 1988. After the public release of the Cartwright Report the Minister of Health announced his commitment to establishing a cervical screening programme. Between 6 and 8 December 1988 there was a national cervical screening workshop held in Porirua (the Porirua Workshop). Approximately 100 people who were broadly representative of the groups and organisations concerned with the provision of an appropriate cervical screening service participated in the workshop. Subsequently on 20 December 1988 the Minister met with his officials to discuss the recommendations of the Porirua Workshop. Decisions were made at that meeting which were intended to advance the establishment of a national cervical screening programme. Subsequently a new Minister of Health formed the view that the programme's progress was being unduly delayed, and 25 August 1989 she sent a memorandum to the Director General of Health outlining her concern about the slow pace in setting up the Programme and requiring the appointment of a ministerial advice group to speed up progress. A ministerial advisory group (the Ministry Review Committee) was appointed and it reported to the Minister in November 1989. Its main recommendations, which were accepted, included: abandoning the planned national launch of the Programme, instead the Programme was to commence in each area health board region when the necessary programme components were in place, (this explains why it is not possible to fix a point in time for the Programme's beginning); appointing a national co-ordinator, including a Maori co-ordinator; and appointing an expert advisory group. An expert advisory group was appointed and it had its first meeting in December 1989. The first national co-ordinator was appointed in June 1990. The first written policy for the Programme, the *Government National Cervical Screening Policy 1991*, was released in 1991. The 14 cervical screening registers became operational during 1991 with the last one, (the Wellington register), becoming operational in January 1992.

6.7 Thus the chronological history of the National Cervical Screening Programme can be divided into a series of phases. The first phase is from July 1988 to December 1988 when the decision to set up the Programme was made. The second is from January 1989 until December 1990 when the Programme was being designed. The third is from January 1991 to January 1992 when its implementation began, as each of the 14 cervical screening registers were set in place and began to operate in its area health board region. After January 1992 the Programme commenced operating nationally.

6.8 A Department of Health document dated October 1992 entitled *Expenditure of the Cervical Screening Programme at the Area Health Board Level 1990-91 the First Establishment Year* records 1990 to 1991 as being the first year of the establishment phase of the Programme. This fits with the Committee's view. As has already been noted in this report the *Government National Cervical Screening Policy* of 1991 contemplated all laboratories being TELARC accredited by 1993. The Committee considers it is a reasonable assumption to make that in 1991 the Government contemplated that by 1993 the Programme would be fully operational in the sense that by 1993 all components of the Programme would be in place. By the end of 1993 approximately two years would have passed since the Programme became operational. It may have seemed to persons responsible for the Programme in 1991 that by 1993 laboratories would have had sufficient time to gain accreditation; registers would be up and running and the women who had enrolled when the registers first became operational would have been appropriately processed. The plan was that a woman would have two smear tests 12 months apart and if they were both normal she would then move to having one smear test every three years. The years between 1988 and 1989 can be seen as the design phase, the years between 1990 and 1993 can be seen as the establishment phase, and from 1993 onwards the Programme should have been fully operational.

Essential Components of a Cervical Screening Programme

6.9 Systemic problems can be avoided if a screening programme is well designed and well implemented. The essential components of an effective cervical screening programme are: a clearly expressed written policy which spells out the aims and purpose of the programme; and a clearly expressed written operational plan which spells out how the

policy will be achieved. Where possible, quantitative performance standards should be specified so that the programme's success in achieving its aims can be properly measured. It also requires an effective computerised registration programme which records cytology and histology data of women enrolled on the programme. The registration system should also either contain cancer mortality and morbidity data, or be linked to a cancer register which records such data. The registration system should be set up in such a way that it comprises a national record of the women enrolled on the programme. To the extent that any work on the registration system is done in a regional area, that work should be under the direct control of the central office responsible for the cervical screening programme. The direct control can either be through a contract based system, so that the regional work is performed by independent contractors, or persons based in a regional area who are employed by the central office. In any event, work done in any regional area has to be subject to authority and sanctions exercised by the central office; that is the only way in which national consistency of the registration system can be achieved. The data that is recorded on the registration system should be accessible by those persons working for the programme, be they employees or independent contractors. The type of data recorded and how it is used should be determined by the epidemiological benefit to be obtained from the data. In the Committee's view the examples given in the *European Guidelines for Cervical Screening Programmes* are a good example of the type of data required to run a screening programme effectively. Because a screening programme is dependent on the quality of smears taken and smears read, it is essential that both the smear taking and the smear reading process is subject to quantitative standards which include sound quality control processes, both internal and external. The programme should be capable of routinely monitoring and evaluating its progress. There should not be an imbalance of attention and focus given to any one component of the programme.

- 6.10 Essentially, a cervical screening programme is a medical programme. Medical practitioners with specialist qualifications and experience in public health and epidemiology know what is essential for a screening programme to be successful and what can safely be left out. These persons are best able to make decisions on the design and implementation of a screening programme. Once a screening programme is established it should be managed from a central office by someone with both

medical and management expertise, who has sufficient authority to ensure that what needs to be done, is done. The manager should have overall control of all parts of the Programme including sufficient authority to require actions to be taken and to impose sanctions when they are not. Without this structure confusion over responsibilities and consequent inaction will result.

Systemic Problems Of The National Cervical Screening Programme

- 6.11 All of the components of the National Cervical Screening Programme were not in place from an early stage. Instead the Programme began with a misplaced focus on increasing the number of women having smear tests taken at the expense of other components of the Programme. Secondly, the Programme's design was influenced by non-medical persons who perhaps failed to recognise the essential medical requirements of a screening programme. Consequently components which needed to be in place from the outset were not, such as a registration system which enabled linkages between cytology and histology results and cervical cancer morbidity and mortality. Compromises were made in respect of their inclusion in the Programme. The end result was that the Programme was vulnerable to systemic failures. Although steps were taken later to remedy the systemic problems created by this imbalance, even today the Programme has not fully recovered from it.
- 6.12 The Committee has reached the view that during the time Dr Bottrill was in practice there were a number of systemic problems which the Committee considers allowed the unacceptable reporting to occur and to go undetected for as long as it did. Some of these problems have already been identified in Term of Reference Two as factors that are likely to have led to the unacceptable under-reporting. Other problems underlie those identified earlier.
- 6.13 The systemic problems in total are :
- (i) No compulsory quality assurance of laboratories reading cervical cytology;

- (ii) A poorly designed management structure which split the responsibilities for parts of the Programme between various health agencies which resulted in confusion and fragmentation of the Programme;
- (iii) No quantitative performance standards against which to measure the performance of the various parts of the Programme;
- (iv) No central computerised registration system which would have allowed cytology, histology and cancer morbidity and mortality data to be inter-linked for each woman participating in the Programme ;
- (v) Failure to gather reliable relevant statistical information;
- (vi) Failure to routinely monitor and evaluate all parts of the Programme's performance;
- (vii) Failure to establish strong centralised leadership with sufficient authority and qualifications to ensure what needed to be done was done;
- (viii) Failure to follow the advice of various experts on the Programme.
- (ix) Failure to ensure there was the legal power to do what was needed for the Programme to be effective; and failure to exercise or to exercise properly legal powers that were available to achieve this end.

6.14 The matters listed in (i) to (vi) above have all been discussed in the Committee's report on Term of Reference Two. There is no need to elaborate further on them. The matters listed in (vii) to (ix) will be outlined below.

Failure To Provide Strong Centralised Leadership With The Appropriate Qualifications And Authority To Initiate Action

6.15 A feature of the Programme throughout the time Dr Bottrill was in practice, was the splitting of leadership functions between central (Department of Health/Ministry of

Health) and regional (area health boards/regional health authorities) agencies. In addition, those leadership functions which were the responsibility of the central health agency were often further split between the agency's various business units. The Programme's management structure was unnecessarily complex.

6.16 From the outset there was a failure to provide for strong centralised leadership of the Programme which had the appropriate authority to ensure it could carry out the task of establishing and maintaining a cervical screening programme. This absence of strong leadership continued throughout the time that Dr Bottrill was in practice. Secondly, the Department of Health/Ministry of Health officials who were involved with the Programme lacked the appropriate qualifications and expertise to appreciate fully the implications of the Programme's design and implementation. The national co-ordinators had a nursing background. They were not medically qualified. The Committee considers that the national co-ordinators lacked the necessary knowledge and experience to recognise the Programme's systemic problems and the risk they carried.

6.17 In 1988 at the Porirua Workshop the Minister of Health gave an opening address in which he posed the question :

“What we need to know in essence is : what do we need to get a national screening programme up and running as soon as possible?”

Subsequently, at a meeting on 20 December 1988 Health Department officials who had considered the recommendations coming from the Porirua workshop presented the Minister with their recommendations to “get a national screening programme up and running”. These included, *inter alia*:

- (i) The formation of an executive group with decision-making power to control the National Cervical Screening Programme and to allocate funding for the Programme to area health boards;
- (ii) The creation of the role of national co-ordinator of the Programme, with the national co-ordinator being accountable to the executive group. It was

envisaged that there would be two national co-ordinators, both women, and at least one of whom was Maori;

- (iii) The provision of specific and separate funding for the screening Programme that was additional to that presently allocated to Vote : Health.

6.18 If these recommendations had been accepted the Programme would have started with a strong foundation. An executive group with funding control would have been in a strong position to progress the design and establishment of the screening programme. Dr Boyd told the Committee that this was one of the recommendations on which everyone at the workshop had reached a consensus, and that those who attended the workshop were persons whose opinions were valued. However, the Minister did not accept the recommendations. Instead:

- (i) He approved the appointment of a national co-ordinator; and
- (ii) He decided that instead of an executive group with decision-making power he would appoint a *steering group with an advisory role and with no executive functions*. This group was to have a “time-limited” role with advisory and monitoring functions. The note records that the ability to go public would be its final sanction.

6.19 The Committee questioned Dr Boyd on the wisdom of appointing an advisory group instead of an executive group to develop the National Cervical Screening Programme. The Committee considered Dr Boyd to be a witness who was competent to provide expert opinion evidence as a clinician on matters of health care and its delivery in New Zealand, including the provision of cervical cytology and the National Cervical Screening Programme. He has been employed in the Ministry, and before that the Department of Health, in various roles connected with the delivery of health services since 1980. He has been a registered medical practitioner since 1964 and he is registered with the Medical Council of New Zealand in the specialities of general practice and public health medicine. Dr Boyd was asked to provide his opinion as a clinician on the appropriateness of an advisory group in preference to an executive group. His view was that an executive group of the size envisaged by the persons who

made the recommendation would have been difficult; he thought that a board of management with a chief-executive would have been a better option.

“Q I note your reply that you did not think that an executive group of the size envisaged would have been workable. Can I ask you in comparison with the advisory group, would a small executive group with decision-making control and funding have been preferable to an advisory group?

A Yes, indeed. But there would also need to be one other factor again from my reading the British experience, that is a chief executive or somebody who is accountable to the board for the management and doesn't expect an advisory group to make all the decisions and someone who also can give the programme a profile.

Q So to summarise then is it fair to say you think the ideal delivery for the programme would have been a small executive group similar to a small board of directors with a chief executive who had a largely public profile and was seen as the day to day decision-maker?

A With plenty of opportunity for input and consultation from stakeholders, affected people, and particularly the women concerned, none of that I envisaged was achieved in the Programme, but as I say it was not my decision to make.

Q Could you outline to the Committee just to clarify matters, what it was that you envisaged?

A I think as I've described, a person to be held accountable for the success or failure of the programme and who was answerable to a group of, I call them a board of directors, who would be chosen by the Minister for their skills and recommendations of affected groups, but also with advice and input from organisations, groups, whanau, whoever, to represent the users of the service as well as the technical people involved.

...

Q The model that you have described - has anything resembling that model ever been put in place in respect of a New Zealand cervical screening programme?

A No it hasn't.”

6.20 The Committee agrees with Dr Boyd's opinion. From the evidence the Committee has seen, it is clear that the Programme needed a chief-executive in whom sufficient power was vested to ensure that the Programme was established and run properly. The Programme's management structure, from its design in 1989/1990 until 1998, with split responsibilities between a number of individuals, groups and entities resulted in a confused understanding of who was responsible for what, and it made it difficult to attribute any responsibility for inaction or failures in the Programme to any one person, group or entity. This was acknowledged by Ms Glackin in her evidence. She told the Committee: “ the point I have attempted to make is it is difficult given the

structure of the Ministry to assign personal responsibility to individuals for things as complex as the delivery of this Programme”. Furthermore, it is hard to see how any individual, group or entity could be held responsible for defects or failures in the Programme when they lacked the power to remedy such defects or failures.

- 6.21 The design of the Programme provided for a national co-ordinator who was responsible for ensuring the effective management and co-ordination of the Programme. This was not what happened. The Programme’s services were delivered by a complex chain of different health providers. The national co-ordinator did not have the necessary power to ensure the Programme’s effective management and co-ordination. She had no authority to require action to be taken or to impose sanctions when nothing happened. All she could do was request others to carry out whatever action she thought advisable.
- 6.22 Ms Glackin described the national co-ordinator as having available to her at any given time only the powers of the particular organisation in which her position was placed. However, this is an over-statement because the national co-ordinator could not exercise that organisation’s powers. All she could do was to persuade the persons within that organisation who did have authority to exercise it. She had no power to require them to do so. Because the Programme had no control over funding, if a person or entity was failing to perform, the sanction of denying payment was unavailable. Secondly, the extent to which the organisation could act depended upon the scope of the authority it had over the failing person or entity. In its submissions to the Committee the Ministry said that when the national co-ordinator was located within the Department or Ministry of Health “she had access to the full range of powers open to the Ministry, including regulatory advice to the Minister and contracting mechanisms.” The difficulty the Committee has with this submission is that the history of the Programme shows that these extensive powers were never used. The contracts the Ministry had with the regional health authorities from 1993 did not result in TELARC accreditation being made compulsory until 1996/97; prior to that the power the Department had to impose TELARC accreditation by regulations was never exercised.

6.23 The Ministry also submits that the national co-ordinator had to operate within the framework of the Department/Ministry's management structure and that as a third tier manager her ability to advance issues depended upon her ability to identify them, make a case for action and influence colleagues. In the Committee's view the Programme needs to be managed by someone who has the authority and the means available to do whatever needs to be done. The Programme should not have to depend upon a co-ordinator's ability to plead a case for action. Secondly, this highlights the need for a medically qualified manager. Such a person would have been in a better position to outline to more senior persons in the Department or Ministry the dangers of inaction.

6.24 The national co-ordinator was expected to liaise with advisory groups on various aspects of the Programme. Over the years these groups included: the Expert Group, the Cytology Advisory Liaison Committee, the Cervical Screening Advisory Committee and the Cervical Screening Liaison Advisory Group. None of these advisory groups had any power to require actions to be taken or not to be taken. Professor Skegg outlined the difficulties the advisory groups faced in this way.

“... The people who are on the advisory committees are actually not meeting with the people making the decisions [within the Ministry], they are advising co-ordinators who then have to lobby within the Ministry of Health for something to be done.”

6.25 Apart from working with the advisory groups, she was also required to establish a close working relationship between herself and the regional Programme managers in the area health boards and the Maori regional co-ordinators. Because the area health board managers were not Department of Health employees and there were no direct lines of accountability between the area health board Programme managers and the national co-ordinator, she could do nothing to force them to act or to desist from acting in a way which was detrimental to the Programme. If her powers of persuasion failed to achieve her intentions there was little else she could do. If others chose not to listen to her she could inform the manager of the unit of the Department within which the office of national co-ordinator had been placed. However, there was little that the national co-ordinator's unit manager could have done. For example when the Wellington Area Health Board refused to release information from its screening

register, the Department was forced to prepare the Programme's first statistical report without the Wellington data.

6.26 The Department of Health contracted with area health boards to carry out various health services. The control the Department had over area health boards was through these contracts. It seems to the Committee that any concerns the national co-ordinator had, about the performance of area health boards, could only have been authoritatively addressed through these contracts. There is no evidence that this ever occurred. Because so much of the Programme was actually delivered by persons who were not Department of Health employees, there was little, if anything, that anyone in the Department could do if these areas were failing. For example no one in the Department had the power to hire and fire employees of the area health boards.

6.27 However, the Department did have direct control over some aspects of the Programme's delivery. For example it was responsible for paying laboratories for their diagnostic services. But, when the health system was restructured in July 1993 even this degree of control was lost. From then on the delivery of services for the Programme was through regional health authorities. Hence the restructuring exacerbated the fragmentation of the Programme's leadership structure. Ms Glackin conceded that under the health service structure that prevailed from 1993 until 1998 the Ministry could not directly control the delivery of the National Cervical Screening Programme. This was because the regional health authorities assumed the role of funding the providers for the Programme:

“Q Just to follow on from one of your answers before, if the Ministry couldn't influence the funding to providers is it fair to conclude that the Ministry had no way to directly control the delivery of the Cervical Screening Programme?

A That is correct.”

The Ministry was left with only an indirect means of controlling the Programme's delivery through its contracts with the regional health authorities. However, as these contracts were generic they did not provide sufficient authority to allow the Ministry to exercise any significant influence over providers for the Programme. An example is the provision the funding agreements made for TELARC accreditation during the time

Dr Bottrill was practising. Ms Glackin told the Committee that the Ministry monitored the performance of regional health authorities through the formal funding agreements it had with these entities. Clearly this monitoring was based upon an examination of whether or not the regional health authorities were meeting their performance targets. Because there were few performance targets in these agreements that related to the Programme this form of monitoring was not going to detect any defects in performance .

6.28 The tasks and responsibilities of the Programme did not change under the restructured health system, but how they were delivered did change.

“Q Is it correct to say that the tasks and responsibilities of the Programme hadn’t changed, how they were being purchased and delivered changed, and the job description of the national co-ordinator had changed? Would it be fair to say the context of all these changes, they still had to be delivered and the only way to ensure that they would be delivered was for them to be contracted and agreed to by the regional health authorities?”

A I believe yes that is generally so, and I think the comment was made earlier that now in fact the Programme and health funding authority is perhaps close to being delivered in the way that was envisaged in 1989 where the functions are the responsibility of one manager in the Health Funding Authority now, including the Register.”

6.29 Between 1993 and 1998 the split in responsibilities between the Ministry and the regional health authorities did not work well for the Programme. There was no overall body which had the responsibility for, and the power to supervise, the running of the entire Programme. It was not until 1998 when the Programme passed to the Health Funding Authority that full responsibility and power to manage the entire Programme became vested in one entity. Even then some divided responsibilities still remained; the responsibility for evaluating the Programme remained with the Ministry. Ms Glackin accepted that the division of responsibilities was detrimental for the Programme

“Q Does that mean that at the present time the Health Funding Authority has entire responsibility and power to manage the entire Programme?”

A Except for the monitoring of its contracts the Ministry’s monitoring of the Health Funding Authority and also the evaluation of the Programme, that contract has remained with the Ministry of Health. The Ministry also, as I said earlier, collects outcome data which it does at part of its health status monitoring nationally.

Q In the years between 92 and 96 clearly the management of the entire Programme was split between a number of bodies, each of whom were responsible only for components of the Programme, is that correct?

A National co-ordination and the Register were the responsibility of the Ministry, as was overall policy advice, but the actual purchase of services related to the Programme was the responsibility of regional health authorities.

Q Does that mean that overall the Programme was split between the Ministry and the regional health authorities?

A Certainly, that's what's dealt with in the review of accountabilities. It talks about the fact that it is considered the regional health authorities saw themselves as purchasing components of a Programme, rather than a Programme itself.

Q Do you think given your experience in the position you hold now in the Ministry that this split in responsibility had any impact on how well the Programme ran as a whole?

A In my brief I give an example of a problem with the Auckland Cervical Screening Register which I believe illustrates the issues that arose for a regional health authority when they considered that they did not have full responsibility for the Programme.

Q So can the Committee conclude from that that the split in responsibility had a detrimental impact in the overall running of the Cervical Screening Programme?

A That is the view that the Ministry put to the Associate Minister in 1996. The organisational structure meant that there was little that the Ministry could do to remedy any failures in the Programme"

6.30 After the health restructuring in 1993, all that the national co-ordinator could do was either exercise persuasive powers on the regional health authority or fall back on the powers available to the Ministry of Health under its funding agreements with regional health authorities. However, the latter course of action would only have been of assistance if the funding agreements contained specific contractual terms relating to the Programme. As the funding agreements did not, there was little that the national co-ordinator could do here, other than whenever a funding agreement was in the process of being re-negotiated, attempt to influence the Ministry of Health negotiators to include provisions relating to the Programme.

6.31 There were some lengthy periods when the Programme was without a co-ordinator. The first co-ordinator, Gillian Grew, was appointed in June 1990 and remained in the position until July 1992. When she resigned in July 1992 the position was vacant until January 1993 when Sue Dahl was appointed, and she remained in the position until

September 1994. From September 1994 until June 1996, Teenah Handiside was the national co-ordinator. From June 1996 until December 1996 the position was vacant. In December 1996 Di Best was appointed national co-ordinator until April 1998 when the position was transferred to the Health Funding Authority.

6.32 Both the area health board and regional health authority systems of health service delivery compromised the Programme's effectiveness. Ms Glackin agreed that it would have been easier to implement the Programme using a single entity with someone in a chief-executive role which had sole responsibility for developing and implementing the Programme. She also agreed that under the regional health system the result for the Programme was that there were a: "plethora of bodies involved in running the Programme".

6.33 The national co-ordinator's lack of medical qualifications may have resulted in a failure to appreciate fully the implications of laboratories not being accredited. Ms Dahl told the Committee that when she was national co-ordinator it did not concern her that some laboratories were not accredited. She was not aware of the repercussions which could result from this:

CHAIR: Well as the national co-ordinator were you not concerned that laboratories that were just starting up, and couldn't reach the quality of standard to get TELARC accreditation straight off, were able to read cytology for the screening programme?

MS DAHL: I wasn't concerned, no, because I had nothing to make me feel concerned. I was being assured by the committee and the people who were expert in that field that this process was occurring and I was never alerted to there being a major danger related to it.

CHAIR: Well, could this perhaps be an example of a situation where you as the employee within the Ministry didn't have sufficient knowledge yourself to realise that if laboratories were being run without any accreditation and without any standards being imposed upon them for the reading of smear tests for the screening programme that there was a greater likelihood of under-reporting than if those laboratories were having to perform according to specified standards and they were accredited laboratories?

MS DAHL: My understanding was that laboratories did have processes – QA processes; they did have accreditation processes in place. They had peer review processes. They were working in a professional manner. I visited a variety of laboratories, at the time I was the national co-ordinator, and I spoke to a variety of pathologists and people who were reading smears. I also had a close working relationship with Dr Teague and the committee, and it may have been that I did have a lack of technical knowledge in terms of the absolute specifics of what should be occurring in a laboratory, but I was not advised in any way of the repercussions that could have occurred in terms of why we're here now.

CHAIR: But that's the point. A medical person might well have realised the repercussions, they may not have needed to be advised of what the repercussions would be.

MS DAHL: With hindsight that may have been the case, however I was working with a group of 6 to 8 professional people on that committee, and it was their role to advise me on issues relating to laboratories, and I felt confident that I had that expert advice at my fingertips when required.

CHAIR: Did you ever contemplate doing an audit of all laboratories for the purposes of finding out whether they were TELARC accredited, whether they ran quality assurance programmes, internal or external; whether they had peer review in place?

MS DAHL: No, I didn't.

Other evidence from Ms Dahl also confirmed for the Committee that a non medical person in the role of national co-ordinator may not realise when to press for action:

“Q: You seem to be saying that CALC wasn't concerned about it, but at what point in time would you, as the Ministry official, consider saying, “well, whatever they say, this has been going on for too long, something has to be done about this”, and so go off and speak to someone within the Ministry about getting it done?”

MS DAHL: Well, that's a good question, ma'am. CALC was my main adviser. I did not take it further, other than trying to get it in the funding agreement.

Q:: Did you not become, yourself, frustrated at times with the way – looking at it from your perspective where you say CALC kept saying all the time, “it's going to happen, it's going to happen” but it hadn't completely happened, did you ever get frustrated by that and think “what can be done to make it happen”?

MS DAHL: I don't recall becoming frustrated specifically with that. I felt that progress was being made and that we had put into place meetings and whatever to make that happen. Meanwhile, I was also had other workload, there were other priorities at the time which appeared to be equally pressing.

Q:: Had anyone brought home to you at the time, or was there any appreciation at the time of how dependent on quality performance from laboratories the programme was, in the sense that if there was under-reporting it would let the programme down?

MS DAHL: There were discussions about under-reporting. At the time we were also looking to get histology results onto the Register, and that was a major priority in terms of what that would enable us to do in terms of quality checking.

6.34 In the Committee's view a medically qualified manager would have realised, long before 1996, that something needed to be done to introduce compulsory accreditation. Furthermore, a medically qualified person with sufficient authority to ensure accreditation was compulsory would have made sure it happened. The need for good operational management with a “public health perspective” was recognised in the Cervical Screening Advisory Committee's Report of 1994: *Monitoring And Evaluation Of The National Cervical Screening Programme: The First Three Establishment Years*. Although this is described as a monitoring and evaluation report it does not present an evaluation of the Programme's effectiveness. It instead

analyses what has actually occurred within the Programme since its beginning. This report stated that the lack of appropriate staff with appropriate expertise in the fields of public health and epidemiology was a barrier to monitoring and evaluation of the Programme. The report recommended the use of salaried appointments rather than advisory groups to carry out tasks of monitoring, compiling performance measures and identifying concerns about the Programme when they arose.

- 6.35 Another example of the need for a medically qualified manager is in relation to the original design of the screening register. The Straton Report was critical of the paucity of medical input into its design. This meant that, in the beginning, there was a failure to recognise the importance of the register as a database and an epidemiological tool. Dr Straton also considered that there needed to be one person who had sole responsibility for the screening register; she envisaged this role being separate from that of the national co-ordinator:

“It is clear that the implementation of the cervical screening register nation wide is an enormously complex task requiring liaison and consultation with many different groups and the making of many key decisions with respect to the functioning of the area health board registers. Some of the problems with the register seemed to relate to the fact that too much responsibility has rested on the computer consultants, *especially recently, and there has not been enough consistent input to decision making from a person with knowledge of the realities of medical practice, as well as the functional requirements of the system.* The loss of expertise associated with the turnover of experienced health professional staff in the Department of Health has exacerbated the situation, but I believe that the register has mainly suffered through not having a single person responsible for it.”

- 6.36 One result of the lack of leadership was the undue emphasis placed upon consultation, facilitation and consensus. Government agencies have legal obligations to consult. However, these obligations require the agency to provide persons who are affected by any proposal with the opportunity to comment on it before it is implemented. The agency must keep an open mind and be prepared to modify its proposal as a result of the consultation but ultimately the power of decision remains with the agency. Consultation does not require a negotiated result to be achieved. The consultation relating to the Programme was long and protracted. The Committee was advised that this was due to the ownership of the Programme, which women and women’s groups felt that they had.

MS JANES: We've seen that consultation seems to take anywhere from 2 years on. Is there any way that some of these things can be consulted on more rapidly for the advantage of the programme?

MS DAHL: I'd like to make a comment about consultation in that consultation was considered exceedingly important with this programme. The women who had been involved, or a lot of women's groups had a lot of ownership over the Cervical Screening Programme and it was considered to be really important that they were fully consulted. Therefore I believe the consultation process probably took longer than they would now on other policy issues.

MS GLACKIN: Could I just comment on that as well. I think this is illustrated by the fact that in 1996, when the Ministry completed what from our perspective was a relatively straight forward review of accountabilities with the intention to consult on the implementation of that review, there was a great deal of concern and in fact that resulted in Katherine O'Regan expressing very clearly her wishes that there be extensive consultation on that issue. And I think that in dealing with the Cervical Screening Programme the Ministry has always been very conscious of the degree of interest and the degree of ownership which women feel for the programme, presumably, today. Although I can't comment on that directly.

CHAIR: Do you think that concern and this need for women ownership of the programme and the high expectations upon you to consult so much with so many diverse groups has actually hindered the effective development and delivery of the programme because it's resulted in such long delays and consultation?

MS GREW: I think it's an advantage and a disadvantage. The disadvantage obviously is the time factor involved in consultation. The advantage is that if you do consult with population groups you tend to get better buy-in to changes or ways of co-operating with changes.

6.37 The recognition of women and women's groups is laudable. However, it must not be forgotten that a screening programme is a medical programme. If its medical requisites are tinkered with for non-medical reasons a screening programme will not function effectively. For example opt-on registers were originally chosen to give women the power to choose whether or not they enrolled on the Registers. While this approach gave women the opportunity to exercise their power of choice actively, it rendered the Register ineffective for the purpose of providing a database for monitoring the Programme. Opt-off registers do not empower women as directly as opt-on registers do. But they are more effective because most women do not exercise their choice to opt-off, and so there are now sufficient numbers on the Register to make it a useful data base. Professor Skegg warned of this problem in his article *How Not To Organise A Cervical Screening Programme*, however his concerns were not heeded. Ultimately something which was done to benefit women was actually detrimental to them. Those who elected to enrol on the opt-on Registers were participating in a handicapped Programme that could not yield data suitable for evaluation:

MS GLACKIN: I would, but I should make the comment that from a technical perspective there are issues with having, apparently, sufficient numbers of women enrolled and to make the evaluation feasible. One of the issues with this programme is that until after opt-off in 1993 we had quite small numbers. So I

understand there were some technical issues about when the evaluation could be done.

6.38 The Committee has seen from a Ministry memorandum of April 1996 that one of the features of the National Cervical Screening Programme is consumer ownership. The memorandum states :

“The current structure and configuration of the Programme cannot be separate from its origins, in the context of the inquiry into cervical cancer treatment at National Women’s Hospital. The Programme was seen as an attempt to redress some of the harm done by those events. It has attracted, and continues to attract, close scrutiny from the women’s lobby groups. The philosophy of the Programme has always focussed strongly on the rights of women and protection of their interests.”

6.39 The Committee freely supports the sentiments set out in this paragraph, however the medical character of a screening programme must not be overlooked. To do so is to risk the effectiveness of a screening programme. For this reason the Committee is sure that most women would be more concerned to ensure that the National Cervical Screening Programme worked effectively and materially helped to reduce the incidence of cervical cancer in New Zealand than they would be with exercising rights of ownership of the Programme. Certainly the evidence the Committee has heard from the various consumer groups which appeared before it is consistent with this view.

6.40 The Committee has concluded that from the time of the Programme’s design, through to its implementation and its operation up to 1998 it has lacked strong leadership. Furthermore this lack of leadership has prevented it from recognising and remedying the systemic problems which the Committee considers were factors that are likely to have contributed to the unacceptable under-reporting at Gisborne. Everyone associated with this Programme has known of the importance of quality assurance and TELARC accreditation; monitoring and evaluation of the Programme; and having measurable performance standards and reliable data. These are the essential features of an effective screening register and yet during the years that Dr Bottrill was practising no one was able to ensure that these important components were in place from an early stage. Instead the Programme began with a sub-optimal registration system which had to be reconfigured; it has never been comprehensively monitored and evaluated; it took until late 1996/early 1997 before TELARC accreditation

became compulsory even though that had been envisaged as being in place from 1993; there are still problems with gaining access to reliable data and it is only since the Programme shifted to the Health Funding Authority in 1998 that steps have been taken to implement measurable performance standards. The Committee considers that had the Programme been subject to strong leadership which had the necessary authority to ensure the Programme was well designed and well implemented and which could initiate remedial action quickly when it was needed, those systemic problems which have been identified as factors that are likely to have led to under-reporting would either have not occurred, or if they did, they would have been cured much earlier on in the Programme.

Failure to Follow the Advice of Various Experts on the Programme

- 6.41 There appears to have been a consistent failure to follow the advice of experts. This was in relation to how the Programme was established and certain essential features such as monitoring and evaluation and laboratory accreditation. This indicates a systemic deficiency in the Programme.

Failure To Accept Expert Advice On The Need For Monitoring And Evaluation

- 6.42 Ms Glackin accepted that from 1990 onwards there was very clear advice on the importance of evaluation for the Programme.

“Q I want to go back to Stratton please ... on page 62 and 63 she included a section on evaluation, monitoring and research and said that a major deficiency so far has been the failure to incorporate any formal evaluation into any of the pilot projects or any other aspects of the Programme. Evaluation of the pilot community projects is now being planned, but the evaluation should be planned right from the outset. So again, there was very clear advice from at least 1990 onwards of the importance of evaluation wasn't there?

A Yes, although the specific reference is to the need to start to collect data.

Q Yes, but in the general context of the importance of evaluations.

A Yes. That is true.”

Also, the expert group in its report in 1990 had emphasised the importance of evaluation :

“Q This is an important section on evaluation and monitoring and in 14.1.2 they stress that no single indicator, except perhaps a mortality rate, exists to measure good performance. Total picture can only be developed by monitoring all aspects of the Programme and under 14.2.4 where they talked about aspects of the Programme requiring evaluation next page fourth point quality of smear reading, it was clearly identified as a matter for evaluation wasn't it?

A Yes.”

Ms Glackin was then taken through reports from the Cervical Screening Advisory Committee 1990 and 1991 which also emphasised the importance of evaluation for the Programme.

“Q So there was a very clear emphasis wasn't there from Cervical Screening Advisory Committee from the beginning on comprehensive evaluation?

A Yes, that is correct.”

6.43 In addition in 1990 the Straton Report had emphasised the need to ensure the appropriate epidemiological information was available to allow monitoring and evaluation to be undertaken. Dr Straton recommended that a small working party should be established, including an epidemiologist and a biostatistician, to define the data required for monitoring the Programme and to determine ways of extracting such data from the database. She noted that epidemiological information for monitoring was not routinely available, and that there was no provision in the specifications of the Registers for the generation of tables. She said that this question had apparently not been considered; partly because the need for these types of reports had not been considered and partly because of failure to obtain agreement about what information was needed. She described a major deficiency of the Programme when she saw it in 1990 as being a failure to incorporate any formal evaluation into any of the pilot projects or any other aspects of the Programme. She said evaluation of pilot community projects was being planned, but the evaluation should be planned right from the outset so that the appropriate data can be gathered. In the absence of any guidelines about the data required, those establishing the pilot projects did not know what was needed. She noted that the absence of any formal evaluation of the pilot

projects had limited to some extent what could be learnt from them. She noted that careful thought needed to be given to the data required for monitoring, and how to extract it from the register on a routine basis. She said that as well as ongoing monitoring of the Programme through data on the register, there was a need for evaluation studies which were formative in nature, and aimed at improving the various aspects of the national programme. She recommended that steps be taken to incorporate an evaluation component into the planning of future cervical screening projects, including the delivery of services and the establishment of the cervical screening register and further area health boards with funds being specifically earmarked for evaluation. She said ideally such evaluation should be co-ordinated nationally.

6.44 The advice and recommendations made in the Cervical Screening Advisory Committee's Report of 1994 titled *Monitoring And Evaluation Of The National Cervical Screening Programme: The First Three Establishment Years* identified the need for strong leadership, the need for a separate operational unit for the Programme within the Ministry (which by that time had primarily a policy-making role), the need for routine monitoring and evaluation including annual statistical reports and regular feedback to smear takers and laboratories regarding quality of performance.

6.45 Nevertheless, no comprehensive monitoring and evaluation exercise has been carried out. Nor did the Programme, during the time that Dr Bottrill was in practice, have any of the tools needed for monitoring and evaluation in place. This continued up until 2000. At that time the Health Funding Authority which had gained responsibility for the Programme in 1998 began to put in place the essential requisites to allow effective monitoring and evaluation to occur. Before then any monitoring and evaluation exercises which did occur related to other aspects of the Programme such as numbers of women enrolled. Laboratory performance in reading cervical cytology was never monitored or evaluated. Annual statistical reports were never produced and throughout the time Dr Bottrill was in practice laboratories did not receive from the Programme feedback on the quality of their smear reading.

The Committee was told by Dr Cox that he resigned from the Cervical Screening Advisory Committee because the failure to follow advice made him feel professionally unsafe:

“Q Dr Cox has said that he ultimately resigned from CSAC because he considered that he was professionally unsafe because CSAC had made, in his view, a number of recommendations; it was responsible for advising on the monitoring and evaluation of the programme. He had got to the point where he was concerned that a circumstance such as has happened in Gisborne would occur, and he considered himself professionally unsafe. Do you have any comment on that?

MS DAHL: I will make a comment on that. At the time that I was working with the CSAC committee we worked very hard to actually establish some specific evaluation criteria. We reviewed what had been done to date, what hadn't been done, where the gaps were, and looked forward in terms of what should happen next. At the period that I was there I don't think that Dr Cox had expressed those views. He may have been frustrated by some of the departmental type processes that had to be gone through, but I never heard him express anything as explicit as that.”

The Ministry's counsel did not cross-examine Dr Cox on this issue and so the Committee is unaware of what his response would have been to Ms Dahl's evidence on this point. That is unfortunate, as cross-examination is the best means of resolving disputed evidence. Even so, the impression the Committee gained of Dr Cox, when he gave evidence, was that he was a truthful witness. Whether or not he expressed his feelings to the Ministry officials at the time he resigned does not mean he did not have such feelings. The Committee accepts his evidence.

6.46 Ms Dahl was then referred to a Health Funding Authority memorandum of 1999 headed Public Health Operation Group – Non-discretionary Project. The name of the project was National Cervical Screening Programme and the project's classification was, “inability to perform core business”. The memorandum noted that since the Programme was established there had been “no national quality standards developed, little monitoring or evaluation carried out and no strategic review of programme configuration or direction”. It also noted that the Programme did not have adequate procedures and structures in place to ensure the safety of women. It drew on the potential under-reporting in Gisborne to support this view. The memorandum stated that “the ability of the situation to develop to the extent that it had can be largely attributed to the lack of quality systems and monitoring of the Programme.” The

memorandum went on to acknowledge: that there had been ongoing calls for monitoring and evaluation of the Programme “since its inception in 1991 by various groups including the Cervical Screening Liaison Advisory Group, programme providers and women’s health groups; secondly that the Programme was never set up with any ongoing monitoring or evaluation in place, and as such no budget was transferred to the Health Funding Authority from the Ministry of Health for this purpose”. The memo then referred to the independent evaluation being carried out by the Otago team and referred to correspondence between the Chief Executive of the Health Funding Authority and the Ministry of Health in which the Health Funding Authority had written that it was primarily concerned in establishing ongoing quality mechanisms for the National Cervical Screening Programme. Ms Dahl’s comment on the memorandum was that it seemed harsh:

“MS DAHL: I think it’s a very harsh interpretation, the way it’s put I believe it’s very harsh. I believe that every endeavour was made in the period that I was there to actually assess what had been done. There had been process evaluations, small evaluations done. There’d been small monitoring reports, there’d been statistical reports, there’d been sort of a lot of ad-hockery, and so the focus when I was there was to try and move from that into some systematic way of actually monitoring and evaluating the programme. My expectation would have been that that would have occurred.”

- 6.47 This memorandum initiated the development of detailed policy and operational documents for the Programme by the Health Funding Authority including quantitative performance indicators and other mechanisms to ensure good quality control. The memorandum outlined the risks of not carrying out this project. One of the risks in not ensuring good quality control through monitoring and evaluation was said to be the likelihood that further women will develop invasive cervical cancer because of a lack of quality standards and monitoring in place, with the attendant organisational costs of investigating and managing each of these incidents. The memorandum gives a good indication of the views of the Health Funding Authority at that time and the concerns it had over the Programme’s operation. It shows how that entity understood and applied expert advice on screening programmes, and its view on the operation of the New Zealand Cervical Screening Programme. The memorandum confirms for the Committee that the earlier advice of experts on the need for monitoring and evaluation of the Programme’s performance was correct and ought to have been heeded.

Failure To Accept Expert Advice On The Need For Laboratory Accreditation

6.48 The evidence the Committee heard from Dr Teague, who was a member of the Cytology Liaison Advisory Committee, was that this committee had regularly advised the Department and the Ministry of Health on the need for laboratories to be TELARC accredited. His evidence was that this committee had confidently expected TELARC accreditation to be compulsory by 1993 and that accreditation could be enforced by withholding payment from unaccredited laboratories. Ms Dahl accepted that when she was national co-ordinator the Cytology Liaison Advisory Committee had advised her that laboratories should be working towards TELARC accreditation and that this was occurring.

6.49 From the evidence which the Committee has seen it is clear that in the early stages of the Programme the advice from the various other experts (Dr Straton, Ministerial Review Committee and Experts Group) was that laboratories should be accredited with an independent quality control authority. Up to 1996 the advice was not followed in the sense that the Department and subsequently the Ministry failed to put in place a fail-safe mechanism which *required* laboratories to be accredited. After 1996 the Ministry did include in the *Policy* document a requirement that laboratories be accredited and regional health authorities then began the process of including this requirement in their agreements with the laboratories.

Failure To Follow Expert Advice On The Need To Have All Parts Of A Screening Programme In Place From The Outset

6.50 The Programme's design appears to have been influenced by lay persons, who seem not to have recognised that a screening programme has certain essential requirements, and that their absence will jeopardise the programme's effectiveness. The expert advice at the time the Programme was being established was that all parts of a screening programme needed to be in place from the outset. This advice was not followed. During the Programme's design phase there was a misplaced focus on increasing the number of women having smear tests taken; this was at the expense of other parts of the Programme. This misplaced focus created an imbalance between smear taking and other essential parts of the Programme.

6.51 The emphasis on smear taking appears to have resulted from a political concern that the Programme's establishment was not occurring in a timely fashion. This political concern caused the Minister of Health, on 25 August 1989, to send a memorandum to the Director General of Health outlining her concern about the slow pace at which the Programme was being set up. Unfortunately, the memorandum had two detrimental results : it imposed time pressures on officials which resulted in unrealistic deadlines; and secondly it caused a shift in focus away from a balanced screening programme to one which placed an emphasis on increasing the number of women having smear tests taken. This shift in emphasis was at the expense of other parts of the Programme.

6.52 The memorandum said :

“In my view the current state of misinformation and concern among those groups who have an interest in the success of this Programme clearly shows that the Department has not been successful in developing a Programme which has the support of the community and can feasibly be put into operation by the end of the year.

There is widespread concern that there has been too much emphasis placed on the development of the national register and the computing system necessary to operate a register and recall system, at the expense of action on developing smear-taking programmes. I share this concern.

My objective is to use the money made available by Government to raise the awareness of the *necessity for smears* among those women not currently being screened, and to encourage all women to have regular smears. *The importance of the register and ensuring all women are enrolled should probably be secondary to that.*”(emphasis added)

The memorandum continued by stating that the Minister wanted a ministerial review team set up to look at the progress of the Programme to date, and to recommend the appropriate course of action and appropriate allocation of available funds:

“It should not be assumed that the funding split between computing, administration costs and smear benefits is in any sense fixed. I believe it is likely that *we should be spending more of the money in paying for smears* and ensuring that those groups not currently being smeared are provided with easy access to smear takers.” (Emphasis added)

She concluded her memorandum by stating :

“I am not committed to launching a national register by the end of this year. I am committed to ensuring that the proportion of women having smears increases over the year and that we make steady progress towards a co-ordinated national cervical screening programme.”(emphasis added)

6.53 The Minister’s concern to increase the momentum of establishing the Programme is understandable. The lack of strong leadership was having a detrimental effect on the Programme’s establishment. One of the reasons given for the delays was poor communication. This is understandable given the absence of a chief-executive with the necessary authority to advance the Programme’s establishment. After the Cartwright Report there would have been immense public pressure to establish a cervical screening programme. The requisites for a screening programme to be fully effective are not easily communicated to lay persons and so there may have been difficulties in communicating this information to the public. The Committee may not have heard all the evidence it would have liked to receive on this point. The passage of time has meant that the Committee has had to rely upon whatever documentary evidence can still be located and on witnesses’ memories. The Committee can understand that a Minister faced with this predicament would respond by putting pressure on officials to have something in place within an early time frame. However, the decision to place the emphasis on increasing the number of women having smears taken and the continued use of advisory groups was not ultimately helpful.

6.54 There is little authoritative material to support giving priority to increasing the number of women having smears taken at the expense of other components of the Programme. The only support the Committee is aware of comes from the Azimuth Report which stated that *smear taking* is the key factor affecting the success of a screening programme:

“It must be recognised that smear taking is the key factor affecting the success of a screening programme. The delivery of the screening service must meet the needs of New Zealand women.”

It also stated:

“This investigation has shown that while there are medical issues involved in the establishment of a cervical screening programme it is primarily a management and administration problem and should be tackled as such. The perception is that medical details have dominated to date and contributed to the slow progress.”

The Azimuth Report was written by a firm of computer consultants who were hired to develop the computerised screening register. Apart from this report there is no other material before the Committee which supports placing an emphasis on smear taking and to treat other aspects of the Programme, such as a screening register and enrolment of women, as secondary. Perhaps these comments caused the Department officials to begin to doubt the advice being given from medical experts. There is no direct evidence one way or the other. However, the issue is important because unless the lessons to be learned from the failure to accept expert advice are understood, similar mistakes can still be made.

- 6.55 The Committee considers that there was no point in encouraging women to have smear tests taken when their smear tests were being read at laboratories whose performance was accepted on trust and which may have been performing inadequately. This imbalance was subsequently recognised by Dr Straton in her report.

“ High quality laboratory services are a vital link in the establishment of an effective screening programme, yet this aspect of the programme seems to have received much less attention in New Zealand than the recruitment of women to be screened. *There is no point in putting a great deal of effort in encouraging women to be screened if the quality of the screening service is inadequate* and there are long delays in receiving results.” (emphasis added)

- 6.56 The Straton Report, which was prepared in 1990 noted that there were aspects of laboratory services which needed attention. These included accreditation, quality control, training of cytoscreeners, coding of results and the interface between the laboratories and the registers. She said there was a concern that there had been insufficient consultation and inadequate assessment of the resources needed to provide proper screening services at laboratory level.

- 6.57 The Ministerial Review Committee (1989) recognised the need to have all parts of the Programme in place. One of its major conclusions was that :

“Attention should not be focused on any particular aspect of the Programme. For a cervical screening programme to be successful all aspects must be developed simultaneously as each is an integral part of achieving success.”

Nevertheless, the Programme's design and development from November 1989 onwards is not consistent with that recommendation being adopted. The Ministerial Review Committee had recognised the importance of correlating histology with cytology on the register and had urged that it be given immediate attention. However, the software for the 14 stand-alone registers did not allow for this. Nothing was done to ensure laboratory performance was adequate and nothing was done to ensure that monitoring and evaluation could take place.

6.58 The Ministerial Review Committee referred to such things as minimum numbers of smears to be read at laboratories, correlation of histology with cytology, training of cytologists, it recommended that a set of minimum standards of competency for laboratories and smear readers should be developed, and that performance indicators that would enable compliance with these guidelines to be assessed, should also be defined. It even suggested performance indicators in its report. However, none of these components of the Programme were in place when it began.

6.59 The decision to use opt-on registers was not supported by expert advice. In its submission to the Committee the Ministry describes the use of opt-on registers as occurring almost by default. The submission states;

“ The opt-on register decision had not been made at this stage [approximately 1988] Rather a refusal to promote the necessary legislation for an opt-off Register was (sic) by the Minister after the Ministerial Review Committee and the Expert Group had reported in 1990.

In responding to criticism from other parties in the inquiry regarding the use of 14 stand-alone registers and the original decision to exclude histology from the register the submission says that the source of these decisions cannot now be traced:

“The decisions to exclude histology from the initial register and to set up 14 separate registers were given at an early stage. It is not known whether these decisions were made at the departmental or ministerial level, but we do know the very tight timeframes imposed by respective Ministers to the Programme.”

6.60 The Ministry in its submission emphasised the tight timeframes which were placed on establishing aspects of the Programme. It refers to Ms Sandra Coney's evidence that the Ministerial Review Committee were convinced by the Department that significantly delaying the start of the Programme was not acceptable. The Ministry in

its submission says that this was the view of the Minister, and that while she was not committed to launching the Programme on 30 November 1989 as originally planned she wanted to be able to show continued progress.

- 6.61 The Ministry rejects the submissions of other parties to the Inquiry that the Government implemented the Programme with undue haste, and against the advice of the expert group. The Ministry submits that both the Ministerial Review Committee and the expert group recommend that the Programme not be delayed until Register issues were resolved and the evaluation of pilot programmes completed.
- 6.62 The Committee has read both the reports of the Ministerial Review Committee and the expert group. Its impression of these reports is that in principle both advisory groups considered that it was important to have all the components of a screening programme in place from the beginning. Their reports reveal an awareness of strong pressure to advance the Programme's establishment. Their willingness to go along with the Programme being established in a piecemeal fashion seems to the Committee to be more shaped by a pragmatic realisation of what was going to be achievable, rather than by what they considered to be the best approach.
- 6.63 The manner in which the Programme was established may have worked if the initial components which were in place had been appropriate, and if the foundation of existing health services on which the Programme was to be built were sound and had been thoroughly checked out. The overseas literature recommends that when a programme is going to be built upon existing services they should first be fully evaluated. A programme that is built upon existing services will be inherently flawed if the services themselves have flaws.
- 6.64 In respect of the New Zealand Cervical Screening Programme there were two problems which made its piecemeal establishment more detrimental to the Programme than it might otherwise have been. The first was that the components that were initially put in place were not appropriate. A system of 14 stand-alone opt-on registers was unworkable. The Programme could never be an effective cervical screening programme while set up in this way. Secondly, the existing health services upon which the Programme was based were not evaluated, and therefore the quality of their

performance was unknown. An important component of the existing services was laboratories. They were not subject to any quality control or accreditation processes and their work performance had never been assessed. Therefore, when the Programme was established using existing services, nothing was known about the performance quality of the laboratories. Ideally, if existing services are going to be used, they should be thoroughly evaluated, and any deficiencies in them corrected before the Programme begins. The Department of Health did send a team of persons around to look at laboratories and evaluations were carried out of the various pilot cervical screening programmes which were tried in various regions, however, none of these evaluation studies were designed to detect poorly performing laboratories. There was never any critical evaluation of the quality of laboratory performance before the Programme began.

- 6.65 The need for a full evaluation of the existing services that will be used in a new screening programme, which critically assesses the quality of their performance is clearly stated in the authoritative literature the Committee has read on establishing cervical screening programmes. The outcome for the National Cervical Screening Programme was that its piecemeal establishment was built on a shaky foundation, and some of its initial components ultimately had to be replaced. This meant that those persons charged with the responsibility for implementing the Programme were faced with a task whereby they had to work towards developing the later stages of the Programme, while at the same time having to redo the first stage work.
- 6.66 Thus by 1993 it had become clear to the Department of Health that the Programme which was in place needed to be redesigned. The screening registers needed to change from opt-on to opt-off and the fourteen stand-alone registers in the area health board regions needed to be combined into a single national database which allowed histology to be correlated with cytology. In the Committee's view there is no reason why these things could not have been put in place from the outset. The expert advice did not support the Programme's original design.
- 6.67 It seems to the Committee that anxiety in 1989 to ensure that the Programme proceeded at a reasonable pace, her concern that smear taking be encouraged in priority to other aspects of the Programme and the decision to deliver the Programme

using area health boards to establish, operate and monitor 14 stand-alone registers, created systemic problems in the Programme which needed correction if the Programme was to perform properly. The response to the perceived delay in establishing the Programme, while intended to facilitate its establishment, only created other problems for the Programme because it resulted in an imbalance of its parts. Until this imbalance was corrected the Programme was never going to function properly. For example, until quality assurance of laboratories was in place and effective monitoring and evaluation carried out, the Programme was never going to be able to identify if smear tests were being adequately read.

6.68 There was a failure to recognise the value of the screening registers as a means of managing the Programme. The Ministerial Review Committee had said in its report that it acknowledged the register was being developed primarily as a system to facilitate cervical screening and recall. In the Committee's view, a cervical screening register as part of a cervical screening programme should be more than this. It should also be able to provide information which would be of assistance in managing the Programme. While the information the system provided was helpful in terms of smear taking, it was not able to provide sufficient information in respect of smear reading to be of any use until it was reconfigured and histology was added to it. This was not completed until 1997.

6.69 The Ministry has contrasted the establishment of the cervical screening programme with the establishment of the breast screening programme. Both these programmes were piloted at the same time, but the Ministry says :

“With the Cervical Screening Programme being imposed largely on existing screening services and under intense public and political pressure. The National Breast Screening Programme, by contrast, was not launched until December 1988 after standards and procedures had been worked out.”

6.70 The Ministry appears to suggest that had the same approach been taken to the National Cervical Screening Programme as was taken to the Breast Screening Programme, they both may not have been launched until December 1998. The difficulty with this submission is that the Committee did not hear full evidence on the establishment of the Breast Screening Programme, and it therefore has no idea why it took until 1998 to

launch a breast screening programme that was first piloted in 1989. It, therefore, cannot make an appropriate comparison with the two programmes. Secondly, there was no evidence as to how long it would have taken to have the National Cervical Screening Programme in place, if its launch had been delayed until all its components were present.

6.71 Furthermore, if the Programme had not been in place during the time Dr Bottrill was in practice, women in Gisborne would not have relied upon it, and therefore they may have been more alert to protecting themselves from developing cervical cancer. It cannot be assumed that without a programme women simply would not have had cervical smear tests. They may have resorted to opportunistic screening and had more cervical screening tests than they did under the Programme. Because the Programme was not fully effective, women were unknowingly relying upon a defective programme to protect them from developing cervical cancer. Thus it cannot be argued that, without the Programme, women would have been in the same position or worse off. At the very least they would not have had the false sense of comfort.

6.72 In addition, one of the reasons why some members of the medical profession appear to have been initially reluctant to accept there was a significant under-reporting problem in Gisborne which required investigation, was because laboratories can make false negative reports and the women who were participants in a screening programme had a history of normal smears. The presence of the Programme also appears to have given the women's medical practitioners a false sense of comfort. From the files the Committee read there were women with signs of cervical cancer who were initially assured by their clinicians that they could not have cancer because they had a history of normal smear tests. Were they not participating in a screening programme, their clinicians may well have considered the possibility of cervical cancer more readily. The thrust of the Ministry's submission seems to be that it was better that the Programme be in place in its defective form than not at all. The Committee's view is that this is not an answer to the deficiencies of the Programme. The Committee heard from witnesses that a defective programme can create a false sense of assurance. It may well have been better to have nothing, and therefore no assurance at all, than the false comfort that the Programme provided. This is the impression the Committee gained from Professor Skegg's submission. He is an experienced epidemiologist with

a world renown reputation. He submitted to the Committee that it may be better to abandon screening programmes if adequate steps are not going to be taken to monitor the quality of the process or of the outcomes achieved:

“Unfortunately the problems I have described [in gaining access to essential information and inability to audit] are not isolated or unusual incidents. Unless such problems can be resolved, it could be argued that New Zealand should consider abandoning national programmes such as those for the control of cervical cancer and breast cancer. It seems unethical to exhort apparently healthy people to undergo medical procedures, when adequate steps cannot be taken to monitor the quality of the process or the outcomes achieved.

This submission suggests to the Committee that Professor Skegg does not favour the view that an inadequate screening programme is better than nothing at all. While it can be said that the Programme has reduced cervical cancer morbidity and mortality in New Zealand, that is on a national basis. The Programme did little to assist the women in the Gisborne region. It can be little comfort to them to know that nationally there has been a reduction in cases of cervical cancer.

6.73 The Programme got off to a bad start. By the time the need for change was recognised there were already women enrolled on the Programme, and so the Department of Health and subsequently the Ministry of Health was faced with the prospect of having to redesign a programme which was already in operation. This meant that instead of being able to focus on getting the design and implementation right, energy was divided between running the Programme in its sub-optimal state and having to deal with the problems thus created, while at the same time trying to introduce the necessary changes to the Programme. The impact on the Programme of the failure to have everything essential in place from the outset is exemplified by the interchange between counsel assisting, the Committee and Ms Glackin:

MS JANES: The evidence of certainly Dr Cox was that this clinical audit or retrospective look at women who developed invasive cancer should, as Ms Glackin has said, be a routine occurrence. Would you accept that if that had occurred early on in the programme the problems with s74A would have been understood much more quickly than it has been now?

MS GLACKIN: I would, but I should make the comment that from a technical perspective there are issues with having, apparently, sufficient numbers of women enrolled and to make the evaluation feasible. One of the issues with this programme is that until after opt-off in 1993 we had quite small numbers. So I understand there were some technical issues about when the evaluation could be done.

CHAIR: But I understand Ms Glackin that in terms of the clinical audit of cases, ... if in an area you are having women develop cancer and if

you go back to their smear test history and you see that within a certain period of time – say 5 years – they’ve had 2 normal smear tests, if you get more than 1 case of that occurring it can be an indicator (quite a strong indicator) that there is under-reporting. So, if you had just been able to compare the two sets of data from two registers and look at the pattern of the smear histories it could have been a red flag to the need for further investigation to see if there was under-reporting in that area.

MS GLACKIN: Yes, indeed, if the data were available from the Cancer Registry, yes.

CHAIR: And do you agree this really reinforces what the World Health Organisation was saying to run a programme effectively you really need to have all aspects in place at once, or if you are building up good data from the Cancer Register and the Screening Register and you can make the necessary links and if you can make the necessary links between cytology and histology all these factors go to help you identify more readily cases where the programme might be failing in respect of under-reporting of smear tests?

MS GLACKIN: I would agree with that, and I think, looking over time, what we have been doing is progressing towards that state. I think the Inquiry is well aware of how long various aspects of that have taken. I should perhaps make the point, of course, which the Inquiry is well aware of, that the Cancer Registry deals with cancers of all sorts.”

This evidence shows that the Programme, which was designed between 1989 and 1990 and fully operational from early 1992 onwards, still does not have in place all of its essential components.

Failure To Ensure That There Was Legal Power To Do What Was Needed For The Programme To Be Effective And Failure To Exercise Or To Exercise Properly Legal Powers That Were Available To Achieve This End

6.74 An effective cervical screening programme requires sufficient legal power to ensure that whatever needs to be done is done. In addition it is helpful if these powers are clearly stated as otherwise there will be confusion when it comes to exercising them. The Committee has been dismayed to learn that the National Cervical Screening Programme lacked certain necessary legal powers throughout the time that Dr Bottrill was in practice. These necessary legal powers continue to be absent. Secondly, there has been a failure to recognise the availability of existing legal powers and so these have been unexercised. Thirdly, at times existing legal powers have not been properly exercised, to the disadvantage of the Programme. The resulting legal quagmire has been a real obstacle to the Programme’s effectiveness; its presence is indicative of a systemic deficiency within the Programme. An effective screening programme would have the necessary legal power and ability to achieve its purpose and to allow it to

work effectively. This is something which should have been recognised and put in place from the beginning. Similarly any structural or other changes to the Programme should have been accompanied by whatever legal adjustments were necessary to allow these changes to work effectively. Unfortunately this was not done.

6.75 Legal inadequacies have been of most concern to the Committee in relation to:

- (i) The monitoring and evaluation of the Programme
- (ii) The compulsory imposition of quality assurance processes on laboratories reading cervical cytology;

No Monitoring and Evaluation

6.76 The Ministry of Health has always had responsibility under the *Policy* documents for monitoring and evaluating the Programme. The *Policy* documents of 1991, 1993 and 1996 all placed this responsibility on the Ministry. As late as 1996 the *Policy* stated in para 3.6.2 that it was the Ministry of Health's responsibility to ensure that the Programme was monitored and evaluated nationally.

“3.6.2 Monitoring and Evaluation

The Ministry of Health is responsible for ensuring that the NCSP is monitored and evaluated nationally. It is responsible for ensuring that any necessary response is made to information obtained from the NCSR, performance indicators, routine or other analysis. It is the Ministry of Health's role to make sure that progress towards achieving the goal and objectives of the NCSP is evaluated and fed back to providers and the community. To ensure this is achieved, the Ministry of Health is beginning an evaluation of the NCSP in the 1996/97 year. This will include evaluation of the NCSP's provisions to priority groups and other sub-populations, evaluation of the NCSP's acceptability to consumers, and evaluation of expenditure on the NCSP.

The NCSP is unique in that the NCSR, which is located in the Ministry of Health, contains much of the information for effective monitoring and evaluation.

The effectiveness of the NCSP will be judged ultimately in terms of the incidence of and rates of deaths from cervical cancer. There will be considerable lag, however, before the impact of changes in cervical screening are reflected in lowered incidence and mortality rates. Data collection and analysis of interim measures are carried out for quality assurance of service delivery, comparative assessment of providers and monitoring and evaluation of processes and outcomes along the screening pathway. To ensure cost-

effectiveness of monitoring and evaluation, the amount of data collected should be the absolute minimum to adequately address the relevant issues.”

And in August 1997 Ms Glackin wrote to all laboratories attaching a report of an analysis of the laboratories’ smear test results. The letter stated:

“One of the NSCP’s major principles has been the implementation and emphasis on quality assurance with the aim to reduce the number of false negative results.”

- 6.77 The reality is that when the Ministry came to carry out many of these actions it found that there were legal barriers to doing so. Clearly these legal barriers were not foreseen by the persons responsible for writing the 1996 *Policy*, or by anyone else in the Ministry at that time. The first time the Ministry realised there were legal barriers to the comprehensive monitoring and evaluation exercise going ahead was in 1999 when the independent evaluation team it had engaged could not access vital information held on the National Cervical Screening Register or the Cancer Register. The independent evaluation team could not investigate whether invasive cervical cancers were detected by regular screening or by another method, as Ministry of Health staff would not allow them to access information from the Cancer Register which identified women with invasive cervical cancer. Nor would the evaluation team have been able to access information on the National Cervical Screening Register to learn the screening histories of these women, as s.74A of the Health Act denied them access to this information. Although, as stated in the *Policy 1996*, this Register is now a source of information which can be used for effective monitoring and evaluation, there are legal barriers which prevent it from being used in this way.
- 6.78 Initially the National Cervical Screening Register could not for practical reasons be used as a tool for monitoring and evaluation until it became an opt-off register which had been reconfigured into a centralised registration system, and the data on the Register had been audited to ensure its reliability. However legislation which permitted these necessary changes also introduced the legal barriers which now prevent the data on the Register from being utilised by an independent evaluation team.

6.79 In response to the Ministry's call for an independent evaluation of the Programme in 1996 an independent team of medical experts from Otago University tendered its proposal for the evaluation in June 1997. This proposal was rejected on the grounds of cost. The Committee has learnt in evidence from Dr Cox who was part of the independent audit team, and from Dr Peters, who is currently responsible for the Programme, that the evaluation as envisaged in the June 1997 tender is worthwhile and should be carried out. The Ministry then called for further tenders for a partial evaluation of the Programme. A second tender was put forward by the same independent team from Otago University, and this was accepted in 1999. This limited evaluation plan comprised three phases. Ms Glackin told the Committee that when cost had ruled out the comprehensive evaluation these three phases were chosen because the Cervical Screening Advisory Committee considered them to be the highest priority. The first phase was able to be completed without meeting any legal obstacles. However, the second and third phase foundered as a result of legal problems relating to access to essential information.

6.80 The second phase of the evaluation involved looking at the appropriateness of follow-up and treatment for women with abnormal smears. The aim of this phase was to assess whether the treatment offered to women with abnormal smears was in accordance with the guidelines for the management of abnormal smears in the Programme, and whether all women with abnormal smears were followed up; to assess the proportion of women who continued to have abnormal smears after treatment of low-grade squamous intraepithelial lesions and high-grade squamous intraepithelial lesions; to assess the timeliness of follow up for women who have abnormal smears and assess the specificity of cervical screening in New Zealand. At the time of the public hearings, the Committee was told that the second phase could not be completed. This was due to the evaluation team being unable legally to gain access to the information it needed from the National Cervical Screening Register in order to carry out this phase. The legal barrier that prevented them from doing so was s.74A of the Health Act. That section was also given as a reason for the Director-General refusing to respond to the Committee's subpoena issued under s.4d of the Commissions of Inquiry Act. The Committee had ordered the Director-General to produce certain information about identifiable women which was held on the Register. The correctness of the Ministry's legal interpretation of s.74A in this regard was to be

referred to the High Court. However, because it became clear to the Committee that any High Court judgment on this issue would be of academic value only, owing to proposed new legislation which would remove the powers of a Commission of Inquiry in relation to ministerial committees. Thus, the reference to the High Court was abandoned.

6.81 Section 74A was intended to protect the confidentiality of women's information on the Register. It, therefore, limits the circumstances in which data on identifiable women can be obtained. Access to data on identifiable women is so circumscribed by s.74A that persons contracted by the Ministry of Health to access the data for the purposes of evaluating the performance of the Register and the Programme, cannot legally do so. The Committee was appalled to discover that qualified medical persons engaged under contract by the Ministry of Health to evaluate the Programme could be prevented from evaluating a pivotal part of the Programme by legislation which the Ministry itself had promoted. Ms Glackin accepted that at the time of promoting this legislation the Ministry had failed to appreciate its true force. She told the Committee that the official in the Ministry of Health who was responsible for managing the evaluation had thought s.74A did not prevent the evaluation team from having access to the Register:

“MS GLACKIN: ...I've discussed this with Dr Kate Scott who is managing the evaluation for us, who has also discussed the issue with Dr Cox, one might have expected that all the time that went in to developing the draft scoping plan that these difficulties with the proposal would have been identified. In fact their view is that they had, as lay people, read this section and mis-interpreted it to believe that, in fact, what was proposed was possible, and it was not until Dr Cox wrote to Dr Peters at the Health Funding Authority, in December last year, setting out in some detail what he was proposing, and then the Health Funding Authority sought a legal opinion as to the application of this section, that this issue was revealed as we now know to actually prevent the release of data without informed consent.

Q: Can you comment on how it is that the Ministry which was responsible for promoting the legislation in 1993 does not appear to have understood its true force?

A: I think that is a fair supposition, with the light of hindsight now we are quite clear.”

Moreover it was not until December 1999 that the Ministry discovered the problem s.74A created for evaluation.

“Q You have a situation here where section 74A is drafted in such a way that it puts severe limitations on gaining access to the Screening Register which can be a source of valuable information to those who are running the Programme, and the section, the way it is drafted, then allows for the making of regulations, which, by those regulations, allow access for persons studying cancer. So, in other words, the legislation puts up a barrier but with the provision to make regulations to exempt certain persons and the query I have is, given that there is a recognised need for certain persons to have access to the Screening Register, why such regulations weren’t made?”

A And I guess Ms Glackin’s response is that the barrier was first recognised in December 1999.”

6.82 The Committee first learned of the difficulty the evaluation team was encountering when it heard evidence from Professor Skegg. The Committee was keen to see if there was a way around the barrier which s.74A created. It appeared that either s.74A must be amended, or a way through the legal barrier found, or the second phase of the evaluation could not be carried out. The Committee learnt from evidence filed after the public hearings that this phase is now proceeding. It is anticipated that this part of the evaluation will be completed by 1 June 2001, however the project is about eight months behind schedule. This phase was originally included in the comprehensive evaluation plan put forward in June 1997. If all goes according to plan the first evaluation of the appropriateness of follow up and treatment of women with abnormal smears will be available by June 2001, some 10 years after the Programme’s implementation.

6.83 Section 74A does contain a power to make regulations which do permit persons to have access to data of identifiable women on the Register. However, no such regulations have been made. Secondly, the regulation-making power does not specifically cover the release of this information for evaluation purposes. The section refers to the release of information only to persons studying cancer. In its present form s.74A would only permit regulations allowing an evaluation team to access data on the Register which identifies women if the task of the evaluation team amounted to a study of cancer. On a very wide interpretation of this phrase it can be said that a screening programme is a tool to avoid cervical cancer; an evaluation is a study to see if a screening programme is effective in this capacity; or an evaluation is a particular aspect of such a study; therefore it is within the meaning of the section. But this is not satisfactory. Legislation should be more specific than this. 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 of the Register. There should be no room for doubt about the legality of access to the Register.

6.84 In the Committee's view s.74A indicates a systemic deficiency in the Programme. Whoever in the Ministry was responsible for preparing a draft of the section and instructing Parliamentary Counsel to draft the Parliamentary Bill to amend the Health Act failed to provide evaluation teams with access to the protected information. This indicates a breakdown in communication between this official in the Ministry and the officials having responsibility for the Programme.

6.85 Secondly, since no official who had responsibility for the Programme recognised the true effect of s.74A no attempt was made to use the regulation-making power allowing persons studying cancer to have access to the protected information. Regulations were made under s.74A(7) controlling access to data on Maori women enrolled on the Register but no other use was made of the regulation-making power. The Ministry officials were unable to provide the Committee with an explanation for this:

“Q: With 74A it is contemplated by sub-section 7 that regulations may be passed for the following purposes: one is, a), regulating access to the Register by persons studying cancer, and it might be that you could bring in persons doing an evaluation of the programme to see if it's effectively preventing or reducing the rate of cancer to be a study of cancer; and the other one, d), regulating the use, disclosure and publication of information from the Register. Now apart from the Kaitiaki Regulations, there have been no other regulations passed, and if regulations had been passed those regulations could have made provision for persons such as Doctors Cox/Richardson when carrying out an external audit of the programme to have access to the Screening Register. So could you tell me please why the Ministry has never passed such regulations?”

MS GLACKIN: I can't comment, as I said before, in relation to why they weren't in fact passed at the time of the Kaitiaki Regulations. I don't think there is any disagreement about the advice that following people with cancer through is the gold standard in relation to treatment. And in the light of that, I'm not sure what people – whoever was dealing with this felt in 1993, but you would have expected that issue might have been addressed then.

Ms Glackin accepted that subject to carrying out appropriate consultation, regulations could be made at any time. She advised the Committee (on 6 August 2000) that the

Ministry was presently working on regulations to overcome the obstacle that s.74A presented to the evaluation team.

- 6.86 None of this would happen in a well designed and well implemented screening programme. It is essential that the necessary legal foundation for a screening programme is in place from its outset and if the Programme is subsequently altered the legal implications which flow from this should be thought through and understood before the change is made.
- 6.87 The third phase of the evaluation plan is an audit of the screening histories and management of women with invasive cervical cancer. The aim is to assess the results and frequency of previous cervical smears of women with invasive cervical cancer; to review the management of previous abnormal smears in women who have developed invasive cervical cancer; and to review the cytological and histological results of women who have recently been diagnosed with invasive cervical cancer. This phase is essentially the cancer audit, which is described in Term of Reference Two.
- 6.88 The Committee has already stated in its conclusions under Term of Reference Two that it considers a cancer audit to be the gold standard for assessing the success or failure of a screening programme. It is an effective way of detecting under-reporting. However, the most recent evidence the Committee has received on the status of the evaluation shows that this phase has still not been carried out. The reason for this is complex. To carry out this phase of the evaluation the evaluation team required access to information of identifiable women held on the Cancer Register. The Cancer Registry staff would not release the information to the evaluation team without them having Ethics Committee approval for the evaluation. The Cancer Registry acted in this way because it considered that rule 11(2)(c)(iii) of the Health Information Privacy Code 1994 governed the disclosure of information to the evaluation team. The effect of this rule is that researchers wanting access to health information must satisfy the entity holding the information that they have obtained ethical approval from an ethics committee. However, it did not apply to the request the evaluation team had made.
- 6.89 The law governing the release of official information is complex. Some information is specifically protected by statute. An example is the information on the National

Cervical Screening Register which is protected by s.74A of the Health Act. However, usually access to official information is not covered by specific legislation like s.74A, in which case either the Privacy Act and any code made under that Act or the Official Information Act will apply. The Cancer Registry Act 1994 imposes no restrictions on access to the information held on the Cancer Register. Therefore, depending upon the circumstances either the Privacy Act or the Official Information Act will apply. When the information has been requested by the person to whom it relates the Privacy Act, and in the health sector the Health Information Privacy Code, governs the release of the information. Secondly, any voluntary release of information about a natural person by a government department is governed by the Privacy Act and in the health sector by the Health Information Privacy Code. Thus, government departments cannot, of their own volition, chose to release official information which identifies an individual. Finally when official information which identifies an individual has been requested by anyone other than the individual to whom the information relates the Official Information Act 1982 governs its release. This legislation takes precedence over the Privacy Act and any Codes made under it. The information on the Cancer Register is information held within a government department and, therefore, it is subject to the Official Information Act 1982.

6.90 There is no mystery about how the Official Information Act fits with the Privacy Act. Since both pieces of legislation have been enforced, the Privacy Commissioner has published information explaining which Act applies in given circumstances. The latest publication is the Health Information Privacy Code reprinted in June 2000. That document states that :

“Public hospitals, the Ministry of Health and a number of other public bodies are subject to the Official Information Act 1982. Information held by such organisations can be requested under Part 2 of that Act and requests may be refused only for the reasons set out in it.

Certain requests do not fall within the ambit of the Official Information Act. For instance, requests made by individuals for information about themselves must be dealt with in accordance with the Privacy Act and this Code.

When a request is made for official information (which is not about the requester), a public sector agency [Ministry of Health] must consider the application under the Official Information Act. One of the purposes of the Official Information Act is to protect official information to the extent consistent with the public interest and the preservation of personal privacy. Accordingly, one of the permitted reasons for withholding information is

privacy. Section 9(2)(a) provides for information to be withheld if it is necessary to protect the privacy of a natural person including a deceased natural person. If section 9(2)(a) applies the agency must also consider whether in the particular circumstances the need to withhold is outweighed by other considerations which make it desirable in the public interest to make the information available.”

The Code continues :

“If an agency refuses to release information in response to an Official Information Act request it must give its reasons in appropriate terms relevant to that Act (eg : I consider it necessary to refuse the request under section 9(2)(a) of the Official Information Act to protect the privacy of the person concerned as I do not consider any other public interest consideration outweighs that interest in this case). The Privacy Act should not be cited as the reason for refusing a request under the Official Information Act even if Privacy itself is a reason for withholding the information.”

- 6.91 The evaluation team were seeking information which identified women recorded on the Cancer Register as having cervical cancer and therefore their request should have been dealt with under the Official Information Act. Section 9 of this Act protects the privacy of individuals, but it also favours release of such information where the public interest outweighs protecting an individual’s privacy. In view of the importance of a cancer audit, its dependence on obtaining information from the Cancer Register and the medically qualified persons involved in the audit, the public interest in releasing the information would outweigh protecting the privacy of the women on the register, especially since the release would have been limited to the evaluation team. However, the ministry officials at the Cancer Registry did not apply the test under s.9 of the Official Information Act. They instead mistakenly applied rule 11(2)(c)(iii) of the Health Information Privacy Code to the evaluation team’s request. Consequently they required the evaluation team to obtain ethics committee approval for the evaluation task before they would release the data.
- 6.92 The ethics committee required the evaluation team to obtain the consent of the women before gaining access to the women’s data. However, the evaluation team could not obtain consent from these women because until they saw the Cancer Register data they did not know the women’s identities and so they could not contact them to obtain their consent. This placed the audit team in a “Catch 22”; to obtain consent from the women whose data they wanted to access they needed to know the women’s identities, and they could not know who they were until they saw their data on the Cancer Registry. The Ethics Committee then suggested that the Cancer Registry staff write to

the women concerned. The evaluation team considered this was not workable and it did not occur. This state of affairs meant that a crucial part of the evaluation plan, which would identify under-reporting, was not carried out. Once again the Committee learned of this from Professor Skegg's evidence.

6.93 The Committee was concerned to learn if under-reporting had occurred in other regions. It issued a subpoena requiring the Director-General to produce information from certain specified regions. This information was produced and the Committee made it available to Professor Skegg. However, other information which the Committee also wanted to give to Professor Skegg was withheld by the Ministry under s.74A. The Committee ultimately abandoned its intention of having Professor Skegg carry out an examination of other suspect regions where there was a high incidence of cervical cancer because in September 2000 it was assured by counsel for the Ministry of Health that the work the independent evaluation team was to carry out would identify under-reporting if it had occurred in other regions.

6.94 The Ministry now accepts that the evaluation team's access to identifiable data on the Cancer Register is governed by the Official Information Act. Correspondence from the Director-General to the evaluation team confirms this. However, as at November 2000 this part of the evaluation was still not being carried out. Ms Grew in her affidavit described it as being the most difficult part of the evaluation project. She said that the Ministry was now to resume responsibility for the cancer audit and that it would engage appropriate expertise under contract where necessary. It seems that, as at November 2000, the medical experts on the evaluation team are unwilling to proceed without the women's consent now that they have been required by an ethics committee to obtain their consent. This may have changed subsequently; the Committee has not received any further evidence to update its understanding of events. It is not for the Committee to comment on the evaluation team's actions. These events happened after the public hearings and the Committee has not had an opportunity to question those involved. It cannot, from the written accounts of the various persons involved, which at times are disputed, reach a view on what has occurred. It does, however, record its deep regret that this much-needed exercise still seems to be unable to be carried out.

- 6.95 What is clear to the Committee is that the mistaken actions of Ministry officials have stopped the cancer audit from proceeding and this may have been avoidable. If the request for information had been handled under the Official Information Act the information could have been given to the evaluation team and they would then have been in a position to contact women for their consent to any further examination of their past treatment.
- 6.96 The Committee cannot understand why ethics committee approval is necessary for an evaluation of treatment as opposed to research. The guidelines to ethics committees which set out their areas of influence are issued by the Minister of Health. Unfortunately these guidelines are not well expressed. Even though the use of independent consultants to carry out tasks for the Ministry is common, the Guidelines permit internal audits to be carried out without ethics committee approval but they do not expressly include an independent external evaluation. Thus they leave room to argue that ethics committee's approval is required for these tasks.
- 6.97 The third phase of the cancer audit stopped at the point where the Ministry incorrectly refused access to essential information. However, the other aspects of the third phase, such as reviewing the management of previous abnormal smears in women and reviewing their cytological and histological results, would involve either access to the National Cervical Screening Register, or to the actual laboratory results. Section 74A would have prevented the evaluation team from having access to the Register, and without consent, it is hard to see how under the current privacy laws it would be possible to access laboratory information. So the third phase of the evaluation may well have encountered other obstacles if the women's consent was not obtained.
- 6.98 The need to obtain consent before gaining access to protected information poses practical and technical problems. Women are not always easily traceable. Secondly for the conclusions 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 protected 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.

6.99 The Committee was interested to hear from the Ministry's witnesses on how this legal quagmire had come about. The impression the Committee gained from the evidence was that the Ministry officials were as surprised as it was:

Q: ... It says in the World Health Organisation bulletin, and this was in 1986 this came out, that "screening programmes can be evaluated by their failures. Cases of symptomatic invasive cancer of the cervix, and especially of advanced disease can be regarded as failures of a screening programme. Knowledge of the age distribution of such cases and of their screening history provides information of the effectiveness of the programme in reaching the intended age groups and the quality of the screening being carried out. Ideally if the complete registration of cases of cancer and of all deaths by cause is in existence prior to the introduction of a screening programme this permits the evaluation of the effective screening on the trends and mortality and invasive disease", and it goes on to say that "in some areas of the world such data is not available but that shouldn't prevent the introduction of screening." It seems to me here that that particular study is the third aspect that Doctors Cox/Richardson intended to carry out for the evaluation. They have run into difficulties. There are difficulties gaining access to the Cancer Register and there is the greater difficulty with the Screening Register because legally the Cancer Register has no bars on gaining access to information whereas 74A of the Screening Register prevents such information. Now can you tell me why it is that these legislative obstacles to carrying out what – apart from the World Health Organisation bulletin we have heard from Doctors Teague, Professor McGoogan, Dr Medley and Dr Peters as well as Dr Cox and Professor Skegg, that this is the gold standard for measuring the effectiveness of a Cervical Screening Programme. How has it come to be that it seems no-one has even recognised the difficulties until the evaluation programme was going to be carried out?

MS GLACKIN:: I cannot answer for the way the legislation was drafted in the first place, and I'm not aware that anyone else is able to explain that. Certainly, my understanding has always been, from what I have been told, particularly by Di Best, who was the co-ordinator in my time mostly, that this was indeed the gold standard and in fact something that we would hope to do quite routinely. I think what I can explain is why, in fact, it wasn't dealt with at the beginning of the evaluation. That in fact is because the issue was simply not recognised.

Q: No. It seemed to me that the fact that it wasn't recognised until the evaluation, which if I just use as a key date Dr Cox's draft plan of June 97, if you go back before that in time it seems that it wasn't recognised, and I stand to be corrected on this, I assume because no-one at that stage took sufficient steps down that track to encounter the legal obstacles that you do.

MS GLACKIN: I think that is true, but I would say as well, and I think this has been pretty well canvassed too, that there were problems with the completeness of the Cancer Registry data which actually imposed some difficulties on that and they were certainly identified by Di Best in the time that she was co-ordinator.

CHAIR: Did you say that Di Best had an expectation that these audits could be carried out routinely?

MS GLACKIN: No, my understanding was always that the programme practice should ultimately be to carry those out routinely, and in a sense what was being done in the evaluation was a catch up.

So it seems that the Ministry always intended cancer audits and other evaluation studies of the type being undertaken by the independent evaluation team. However, for reasons which were unknown to the officials who appeared before the Committee the legal foundation to allow these exercises to go ahead had never been put in place.

6.100 In essence, what this legal quagmire reveals to the Committee is a failure on the part of the Programme, when originally designed and subsequently, to ensure that an essential legal foundation was present. Monitoring and evaluation was provided for in the *Policies* from 1991 onwards. It was recognised by the various expert advisory groups advising the Department of Health in 1989 and 1990, and by international literature, as an essential component of a screening programme. That a necessary legal foundation to allow it to occur is and always has been absent and secondly that Ministry officials could misapply the present law, shows that this essential aspect of the Programme has not been properly thought through.

6.101 The Committee considers that from the outset the Ministry should have ensured that the necessary legal power and ability was available to allow the Programme to be comprehensively monitored and evaluated. Monitoring and evaluation of a screening programme's performance is a statistical exercise, and unless it involves a sufficient number of women any analysis of the information will not be reliable. The question of whether or not something as important as monitoring and evaluating the Programme's performance through a cancer audit, or looking at the appropriateness of follow-up and treatment for women with abnormal smears, should not turn on whether or not an evaluation team can obtain the consent of a sufficient number of women to make the evaluation statistically worthwhile. There is nothing unusual about allowing medical experts access to this type of information. The literature on cervical screening programmes emphasises the importance of these exercises.

Legal Issues in Relation to Compulsory Imposition of Quality Assurance Processes On Laboratories Reading Cervical Cytology

- 6.102 The Ministry of Health has maintained in its submissions that until the health reforms of 1993, which introduced a contracts-based system for health funding, it was not possible to compel laboratories to adopt quality assurance measures either directly through a regulation-based quality assurance scheme, or indirectly through a requirement that laboratories be accredited with TELARC or another independent quality control authority. The Committee does not accept that prior to 1993 there was no power to compel laboratories to use quality assurance processes, and it will address this issue separately in this section of the report. However, if the Ministry is correct and there was no power to compel laboratories to adopt quality control measures, then this is a serious systemic flaw in the Programme. A well-designed screening programme would have ensured from the outset that there was clear and specific legal power to require laboratories to adopt quality assurance measures. To design a programme without making sure that this necessary legal power was available is to create a systemic deficiency in the Programme.
- 6.103 When the Programme was in its design stage the Department of Health, as a government department, was in a position to promote primary legislation to enable compulsory quality assurance processes to be imposed. Given how important quality assurance of laboratory performance was for the Programme, the Department of Health should have taken steps to ensure that the necessary power to impose it was available. At the latest, by the time the *Policy 1991* was prepared the Department should have taken steps to learn if it could impose quality assurance on laboratories and if not, the Minister of Health should have promoted legislation to achieve this. The Committee considers that the Department should have obtained a Crown Law opinion on the existing law to compel quality assurance, and if the advice was that this was insufficient it should have advised and encouraged the Minister to take steps to change the legislation.
- 6.104 The Committee has been told that officials believed that TELARC accreditation was not a problem because most laboratories were moving towards it. Nevertheless, the Department should have ensured that it had the legal power either to impose its own

quality assurance scheme under regulations or to require laboratories to become TELARC accredited within the timeframe envisaged in the *Policy 1991*. These obligations should have been backed up with the power to apply sanctions against non-compliant laboratories. It should have been obvious to the Department that without such legal compulsion there would be some laboratories that would not take steps to become TELARC accredited; or if they did, that any steps towards accreditation would be cursory. There was no economic incentive for laboratories to adopt quality assurance or to become accredited with TELARC. Laboratories were not at risk of becoming liable for compensatory damages as a result of any negligence on their part in diagnosing a test because of the Accident Compensation legislation, which prohibits legal actions based upon personal injury. More is said on this in term of reference seven. Secondly, all laboratories received the same funding for their diagnostic services (they were paid a specific sum per smear test). Quality assurance processes, including TELARC accreditation are an additional expense for a laboratory. For example: TELARC accreditation required a laboratory to upgrade its processes and often its equipment and staff. In this environment there was no economic incentive for a laboratory to adopt quality assurance processes including TELARC accreditation; indeed it was economically rational for a laboratory not to do so as this meant it kept its costs lower for the same return as laboratories which did adopt quality assurance and TELARC accreditation. All of this should have been apparent to the Department at the time.

- 6.105 Throughout the period that Dr Bottrill was in practice there were other changes to legislation relating to the Programme. Once the decision was made to move to a centralised opt-off register the Health Act 1956 was amended to allow for this, and to allow a patient's histology to be correlated with her cytology. The Minister of Health was, therefore, successful in introducing this legislative change and having it passed by Parliament. Furthermore new legislation, in the form of the Cancer Registry Act 1994, to make registration of cancer data compulsory was also successfully introduced into and passed by Parliament. The majority of community laboratories supported quality assurance measures including TELARC accreditation, so it is not as if any legislation to compel the adoption of these measures would have been controversial. The bulk of the services provided by community diagnostic laboratories have always been fully funded either directly or indirectly from government funds, so it does not

seem unreasonable to require adoption of these measures as a condition of payment. However, the evidence shows that neither the Department nor the Ministry of Health took steps to advise the Minister of the need to promote such legislation and so nothing was done to bring it about.

- 6.106 Until 1993 community laboratories were funded directly by the Department of Health through regulations made under the Social Security Act 1964. The last regulations to be made under that Act were the Social Security (Laboratory Diagnostic Services) Regulations 1981. The Committee did not find it necessary to look at any of the earlier regulations for the purposes of this report. However hospital laboratories are and always were funded differently. Regulation 10 of the Social Security (Laboratory Diagnostic Services) Regulations did not allow payments to be made to hospital laboratories. The funding of hospital laboratories is and was included in the bulk funding which all hospitals have received from the various government agencies having responsibility for funding public hospitals throughout the various forms of health delivery which have prevailed in New Zealand.
- 6.107 After the restructuring of health services in 1993 four Regional Health Authorities became responsible for funding the diagnostic services of community laboratories. This was done initially pursuant to notices issued under section 51 of the Health and Disability Services Act 1993, and then as each Regional Health Authority was able to negotiate a contract with the community laboratories in its region, pursuant to that contract. The Regional Health Authorities received their funding from contracts they had made with the Ministry of Health. Subsequently the Regional Health Authorities were merged into one entity which ultimately became the Health Funding Authority. At the time of the Inquiry the Health Funding Authority was in the process of being merged with the Ministry of Health to form a new Ministry.
- 6.108 The Midland Regional Health Authority, which was the authority responsible for the region in which Gisborne Laboratories operated, did not complete the negotiation of its contract with the community laboratories in its region until after the business of Gisborne Laboratories had been sold to Medlab Hamilton and Dr Bottrill had retired. All the payments for cervical cytology read at Gisborne Laboratories were made under either regulation 8 of the Social Security (Laboratory Diagnostic Services) Regulations

1981 or notices issued under section 51 of the Health and Disability Services Act 1993. Neither form of payment was linked with requirements for quality assurance. It is a feature of the funding of community laboratories throughout the time Dr Bottrill practised that the government agencies responsible for paying for their services did no more than to rely on the professional qualifications of the persons who worked in the laboratories to ensure that every laboratory performed competently.

6.109 Between 1990 and March 1996 the only direct control on community laboratories that was relevant to terms of reference two and three was the Medical Laboratory Technologists Regulations 1989. Regulation 9 of these regulations required cervical smear test reading to be carried out by a medical practitioner, a registered medical technologist or someone working under the supervision of either of these persons. It is notable that the regulations did not require the medical practitioner to be a registered pathologist. Dr Boyd told the Committee that under the Medical Practitioners Act 1968, which was the legislation in force throughout the time Dr Bottrill was in practice, the medical profession was self-regulating and that:

“Monitoring the professional competence of an individual practitioner, so far as the Department/Ministry was concerned, relied largely on appropriate entry standards into the profession, and the sanctions applied by disciplinary bodies established under the Act [Medical Practitioner Act 1968] to any doctor found guilty of professional misconduct or disgraceful conduct. ... the Department’s primary method of influence until 1993 was through the payment of benefits and the threat of non-payment.”

Furthermore under the Medical Practitioners Act 1968 once a medical practitioner had obtained registration on the specialist register of his or her particular speciality there was:

“... no requirement for maintaining competency and names were maintained on the register until the practitioners asked to have their name removed, died, were not able to be contacted by the Medical Council or were struck off as a result of disciplinary action by the Council.”

This might suggest that there was little that the Department/Ministry of Health could do to ensure medical practitioners retained their competency in their field of practice. However, Dr Boyd acknowledged in evidence that the Minister of Health could indirectly exert control on community laboratories through the Social Security (Laboratory Diagnostic Services) Regulations 1981. And from 1993 onwards the s.51

notices gave the Regional Health Authorities sufficient authority to impose quality control requirements on community laboratories

Social Security (Laboratory Diagnostic Services) Regulations

6.110 Under the scheme of the Social Security (Laboratory Diagnostic Services) Regulations payments for publicly funded diagnostic services performed at community laboratories were made to persons who qualified under the regulations as “recognised pathologists.” The regulations made no provision to pay community laboratories which operated as limited liability companies for the services they provided. Dr Boyd informed the Committee that the payments to “recognised pathologists” included payment for those services that were actually performed by laboratory technicians such as cytotechnologists or cytoscreeners. He said that the “recognised pathologist was expected to provide appropriate supervision of other laboratory staff, and that this meant that the head pathologist at a laboratory received payment for the services at that laboratory, and in turn he or she was expected to ensure adequate service:

“Subsidies were almost universally paid to a named registered medical practitioner (for example a pathologist), even when the service was provided in a laboratory by a cytologist or a cytotechnologist, or from a clinic or when the subsidy related to services provided by a practice nurse. The expectation was of appropriate supervision by the responsible named practitioner. So, for example, the head pathologist at a laboratory received payment for services at that laboratory. He or she was looked on to ensure adequate service.”

6.111 Regulation 5 gave the Minister of Health the power to recognise medical practitioners as pathologists for the purpose of the regulations. The Minister was assisted in the exercise of this power by the Laboratory Services Advisory Committee. Dr Boyd said that this Committee advised the Minister on aspects of the Laboratory Diagnostic Services Benefit, including its administration. Dr Boyd also said that complaints about the quality of service at a laboratory which came to the Department’s attention could be taken to this committee for advice.

6.112 Later in his evidence Dr Boyd explained to the Committee how pathology was recognised as a speciality of medicine and that pathologists could apply to have their names included on the specialist register under the Registration of Specialists Regulations 1971. As a separate process the Department maintained and published a

list of specialists eligible to claim specialist benefits under the Social Security Act 1964. Included in this list would have been those pathologists whom the Minister of Health had “recognised” pursuant to regulation 5 of the Social Security (Laboratory Diagnostic Services) Regulations. Dr Boyd informed the Committee that the Laboratory Services Advisory Committee dealt with applications for recognition as a pathologist under the Social Security (Laboratory Diagnostic Services) Regulations. He said:

“Pathologists seeking recognition were required to describe the laboratory services that would be provided, the laboratory equipment and staffing and their qualifications which would make them suitable for supervising the laboratory service to be provided. A recommendation went from the Committee to the Minister of Health when the Committee considered a pathologist suitable to claim benefits.”

- 6.113 Regulation 6 enabled the Minister to refuse to recognise a medical practitioner as a pathologist. Under regulation 6(2) the Minister could make the recognition of a medical practitioner subject to any conditions which he or she thought fit to impose, so long as they were not inconsistent with the regulations. Under regulation 6(3) the Minister could, on giving one month’s written notice in writing, revoke any recognition given by him or her under the regulations or alter the conditions attached to the recognition.
- 6.114 It appears then that the Minister had some measure of control over community laboratories through the decision to grant recognition to a pathologist or to impose conditions on the recognition of a pathologist; because this determined whether or not the pathologist could be paid for providing diagnostic services. However, there was no attempt to use the regulations to impose quality assurance on community laboratories under Department of Health supervision. The Committee heard no evidence to indicate that Department of Health officials had ever considered the possibility of the Minister using the power to impose conditions under regulation 6(2) to specify a requirement for quality control and the form it should take. The Committee did hear evidence of the Ministry requesting legal advice in 1992 on whether or not it could impose TELARC accreditation as a condition of payment. The evidence the Committee heard shows that Department of Health officials made one attempt to introduce a quality control measure into community laboratory practice in

the early stages of the National Cervical Screening Programme. Dr Boyd told the Committee that, once the National Cervical Screening Programme was in operation, the Department had sought advice on making laboratory accreditation with TELARC, or a similar authority, a condition of payment under the Social Security (Laboratory Diagnostic Services) Regulations. However, the Department was advised by one of its inhouse solicitors that it had no power under the regulations to do this.

6.115 After the close of the formal hearing, the Committee sought written submissions on whether or not the regulations gave the Department the power to impose a quality assurance scheme as a condition of payment. Counsel for the women affected filed submissions which contended that the regulations gave the Minister the authority to impose a quality assurance regime as a condition of recognition under regulation 6(2). The Ministry of Health filed written submissions which had been prepared by its inhouse solicitors. They submitted: that the Social Security Act 1964 under which the regulations were made did not authorise regulations which imposed a quality control regime on pathologists; and that in so far as the Social Security (Laboratory Diagnostic Services) Regulations purported to allow the imposition of conditions relating to the recognition of a pathologist under the regulations they were *ultra vires* and therefore unlawful. In addition they submitted that, for the same reason that the current regulations were *ultra vires*, it would not have been possible to make new regulations which provided the authority to impose quality control on laboratories

6.116 Since the Ministry of Health now submits that regulation 6(2) of the Social Security (Laboratory Diagnostic Services) Regulations is *ultra vires* it is necessary to look at the regulation-making power in the Social Security Act 1964 in order to determine if the Minister/Department of Health could as a condition of payment impose a quality assurance scheme or require laboratories to be accredited with TELARC or any other similar authority. There would have been no legal impediment to imposing such a scheme on hospital laboratories as these were funded through the bulk funding the Department provided to Area Health Boards. The bulk funding was provided via a contract system with the Area Health Boards, therefore, it should have been legally possible to impose by contract a requirement that hospital laboratories reading cervical cytology participate in a quality assurance scheme which mirrored any scheme imposed by regulation on community laboratories.

- 6.117 Essentially the Ministry of Health's submission is that the very general power to make regulations, which was to be found in s.132 of the Social Security Act, was not as wide-ranging as it appeared to be. The Ministry contends that the power in s.132 must be read in the context of the scheme and purpose of the Act. And since the purpose of the Act was to provide benefits to persons, including health benefits, the Act's scheme and purpose did not permit the imposition of conditions on the recognition of persons eligible to receive payment of these benefits. Following on from this submission the Ministry contends that it would not have been lawful to amend the Social Security (Laboratory Diagnostic Services) Regulations by including a specific regulation imposing a quality assurance regime or a requirement for accreditation on laboratories. The submission is surprising. The regulations were in place from 1981 until 1993 and throughout that time no-one questioned whether or not they were lawful. They would have been prepared by Ministry solicitors and Parliamentary counsel.
- 6.118 To support its submissions the Ministry of Health filed an affidavit from Mr Jamieson, Parliamentary Counsel. The thrust of Mr Jamieson's affidavit was that a new regulation under the Social Security (Laboratory Diagnostic Services) Regulations which created a quality assurance scheme, or expressly provided the Minister with the power to impose a requirement for laboratories to be TELARC accredited before being eligible for payment, was not possible, as it was likely to be ultra vires. He said that if he had been asked to prepare such a regulation he could not have supported doing so.
- 6.119 The difficulty with this submission is that the Committee is aware that regulation 6(2) of these regulations already expressly permitted the Minister to impose conditions on recognition of pathologists, which in turn affected whether or not they were paid for their services. Regulation 6(2) would have been prepared in conjunction with Parliamentary Counsel and would have required Parliamentary Counsel's approval. Therefore, the Committee must balance against the information it now has from Mr Jamieson its knowledge that on an earlier occasion another Parliamentary Counsel saw no difficulty with including in these regulations a power to impose conditions on pathologists.

- 6.120 While the recent evidence from Mr Jamieson and the inferences to be drawn as regards the opinions of an earlier Parliamentary counsel are interesting, ultimately it is a question of statutory interpretation. Traditionally legal opinions on matters of domestic law have not been admissible in evidence and the present conflict of evidence shows that there is good reason for that.
- 6.121 The Ministry submits that reg 6(2) offends a well-recognised principle that regulations made under provisions like s132 can only be for the purpose of carrying into effect what is already in a statute; and they cannot widen, depart from or vary the legislative scheme in their empowering Act. The Ministry's view is that ss. 123 and 116 define the relevant purposes of the Social Security Act when it comes to payment of benefits for laboratory services. It contends that s.123 of the Act provides a scheme for making payments to specialists and if there is any power to confine making payments to specialists (pathologists) it must be found in that section and not in any regulation made under s132. Because under s.123 there was no power to make payments conditional on the performance of certain acts, it could not be done. The Ministry also submits that it was unlawful for the regulations to give the Minister a general discretionary power to recognise pathologists. It contends that this is an unlawful delegation and that the criteria for recognition must be set out in the regulations.
- 6.122 The Committee accepts that the scheme and purpose of the Social Security Act can confine a general regulation-making power like s.132. However, it does not accept the remainder of the Ministry's submissions on this issue. The Ministry's submissions rely upon a particular interpretation of s.123 of the Social Security Act which the Committee does not accept. The Committee considers that s.123 does not apply to the Social Security (Laboratory Diagnostic Services) Regulations. The Committee's view is that s.116 is a stand-alone provision to pay supplementary benefits which contains its own power to make regulations for that purpose. The only provisions that were relevant to the power to make payments to laboratories were ss.116 and 132.
- 6.123 The Social Security Act made wide provision for payment of benefits of many types. Part II of the Act provided the statutory mechanism for a public health system. It made provision for a number of health related benefits. Section 89 sets out the classes

of benefits; these are: medical benefits; pharmaceutical benefits; hospital benefits, maternity benefits, and supplementary benefits.

6.124 However, when the Act is looked at as a whole it appears that there is a divide between supplementary benefits under s.116 and the other benefits, including payments to specialists. Section 116(1) refers back to a series of benefits, these are: medical benefits; pharmaceutical benefits; hospital benefits; and maternity benefits. Section 116 provides:

“Without limiting the general power to make regulations conferred by section 132 of this Act regulations may be made under that section prescribing such supplementary benefits as in the opinion of the Governor General are necessary for the effective operation of the several classes of benefits expressly provided for by the foregoing provisions of this part of this Act or as in his opinion are necessary to maintain and promote the public health.”

Section 116(2) continues :

“Without limiting the provisions of subsection 1 of this section *that section shall be deemed to authorise the making of regulations to provide for treatment at hospitals or elsewhere for outpatients for physiotherapy services for radiological and laboratory services.*”(emphasis added)

In the Committee’s view because s.116(2) deems laboratory services to be within the provisions of s.116(1) this indicates that were it not for s.116(2) such services would not come within subsection 116(1). In other words, supplementary benefits are additional to and separate from the other benefits in Part II. When the classes of benefits provided in the foregoing provisions to s.116(1) are examined, they do not appear to cover laboratory services. Furthermore, if laboratory services did come within one of those classes there would have been no need for the legislature to include laboratory services in s.116(2). Secondly, s.123(2) specifically refers to regulations made under s.116(1) or s.123(1) of the Act. This sentence is disjunctive and reinforces the divide between s.116 benefits and other benefits. For these reasons the Committee considers that s.116 coupled with s.132 provides sufficient authority to make regulations to pay for laboratory services and that none of the other provisions in Part II of the Social Security Act are relevant to these payments.

- 6.125 Given that laboratories received public money for their services it does not seem inconsistent with the Act that laboratories should be subject to providing those services in accordance with certain conditions. The Committee considers that the imposition of a quality assurance scheme or TELARC accreditation was something that was incidental to the execution of the Act's specific provisions. Therefore, the Committee considers that regulation 6(2) was within the scope of the combined regulation making powers of s.116 and s.132. Hence, it was legally possible to impose quality assurance and accreditation requirements as a condition of payment under regulation 6. It also considers that there is nothing in conflict with the Act to permit the Minister to recognise pathologists for the same reasons.
- 6.126 Having concluded that regulation 6(2) was lawful, the Committee must now consider whether or not that regulation permitted the imposition of a scheme of quality assurance measures which were subject to inspection by persons to whom the Director-General of Health had delegated this responsibility. The scheme and purpose of the regulations was to direct payment to those medical practitioners who had satisfied the Minister that they should receive recognition as pathologists, and to provide a measure of control over the performance of recognised pathologists. For example regulation 6(2) specifically permitted the Minister to impose conditions which made all equipment and apparatus used by the pathologist subject to inspection by persons authorised by the Director-General of Health. The express reference in regulation 6(2) to inspecting equipment and apparatus used by the pathologist can only have been for the purpose of ensuring it worked properly and did not impact badly on the pathologist's performance in the laboratory. The express reference to inspection of laboratory equipment and apparatus being made subject to conditions shows that the authority to impose conditions, under regulation 6(2), was not intended to be confined to the pathologist but could extend to his or her work environment as well.
- 6.127 There is nothing about the imposition of a requirement to carry out quality assurance or coupled with a power to inspect its discharge that is inconsistent with the regulations. Once quality assurance had become an acceptable part of a pathologist's laboratory practice there was no legal impediment to making it a condition of recognition under regulation 6(2). The use of quality assurance would have been another feature of a pathologist's work environment which affected the quality of his

or her performance, and which was capable of being inspected and assessed like the laboratory equipment and apparatus the pathologist used. By the early nineteen nineties quality control measures were operating in a number of New Zealand community laboratories. In Australia quality control in the form of accreditation with the Australian equivalent of TELARC had been a mandatory condition of a diagnostic laboratory receiving Medicare funding since 1987.

6.128 In the Committee's view by the early nineteen nineties quality assurance was seen as a standard practice of good pathologists, and therefore it would have been a reasonable condition to impose under regulation 6(2). Given that pathologists' services were being funded from public funds and they were a health service that was provided for the public good an attempt by the Minister to ensure that the services being funded were of good quality would have complied with the Minister's legal obligations to act reasonably and in accordance with the regulations.

6.129 For the same reason that it considers regulation 6(2) enabled the Minister to impose a quality control scheme directly on pathologists the Committee can see no reason why the Minister could not have made accreditation with an agency such as TELARC a condition under regulation 6(2). The demands of accreditation would have improved the performance of those who worked in a laboratory in much the same way as the direct imposition of a quality control scheme under regulation 6(2). For the same reasons that the Committee considers the regulations permitted a regulatory quality control scheme to be imposed, the Committee is at a loss to see how it could be thought that the regulations did not permit a condition requiring accreditation with TELARC. The Committee's view that the regulations permitted the imposition of mandatory accreditation as a condition of pathologists' recognition under the regulations was accepted as correct by the Ministry's counsel at the hearings before the Committee.

6.130 The legal advice the Department of Health received from its inhouse solicitor on the use of the regulations to impose mandatory accreditation is sparse. It is no more than paragraphs and gives no reasons to support the conclusion reached. There was no evidence that the advice was ever queried, or that a second opinion was sought. There was no evidence of any request for advice on this subject being made to the Crown

Law Office. Ms Judith Glackin who a senior Ministry of Health official. She said that if she had received such advice she would have queried it. The Committee considers that the response Ms Glackin outlined to it is appropriate and it should have been taken at the time. It is unfortunate that the advice of the inhouse solicitor was accepted without demur. By not pursuing this matter further the Department of Health officials who sought the legal advice lost an opportunity to ensure that the government policy to require TELARC accreditation by 1993 was achieved.

- 6.131 The *Government Policy for National Cervical Screening (1991)* contemplated that all laboratories reading cervical cytology would be accredited by 1993. If the Minister had imposed accreditation as a requirement of payment under regulation 6(2) there could have been a lead-in period to allow laboratories sufficient time to bring their practices up to accreditation standard. At the time approximately 22 laboratories were already accredited. Once the chosen lead in period had expired all cervical cytology work could have been directed to the accredited laboratories. There may have been resistance from some laboratories which found it difficult to obtain accreditation, however the Minister and Department of Health officials should have been prepared to respond to such resistance and to meet any legal challenge that was brought. The need for accreditation of laboratories by 1993 was part of the government's policy for the National Cervical Screening Programme; it was a sensible policy which would have been of direct benefit to women having cervical smear tests and of indirect benefit to their families through the health benefits which women enjoyed as a result of having cervical smear tests. The Minister and the Department of Health should have been prepared to do whatever they each had to do to ensure the policy was achieved.

Funding Under Section 51 of the Health and Disability Services Act 1993

- 6.132 When the public health system was restructured in 1993 a number of the operational functions formerly carried out by the Department of Health passed to four Regional Health Authorities. One of these functions included the tasks which Department officials had carried out under the Social Security (Laboratory Diagnostic Services) Regulations. The regulations were repealed by the Health Reforms (Transitional Provisions) Act 1993. The new health system was introduced through the Health and Disability Services Act 1993. In consequence of the restructuring of the health system

the *Government Policy for National Cervical Screening (1991)* was updated in October 1993 to take into account the structural changes. The change to the *Policy* document has been outlined in the section on Term of Reference Two.

- 6.133 With the restructuring of the health system came a shift in attitude towards health management. The new approach relied upon a series of contracts between health funders and health providers to manage health delivery in place of the traditional exercise of executive authority. The new Ministry of Health provided bulk funding to the four Regional Health Authorities pursuant to contracts negotiated annually. In turn the four Regional Health Authorities each contracted annually with health providers for the services required to maintain the publicly funded health system. Within the various contractual arrangements provision was made for medical laboratory diagnostic services and cervical screening.
- 6.134 The contracts between the Regional Health Authorities and the health providers were unable to be agreed immediately, and as an interim measure the Regional Health Authorities obtained services from health providers by issuing notices under s.51 of the Health and Disability Services Act 1993. The s.51 notices were issued on 23 June 1993 and took effect from 1 July 1993. They remained in force until the Regional Health Authorities had negotiated a contract with their health providers. The contract for laboratory diagnostic services between Gisborne Laboratories and the Midland Regional Health Authority was not negotiated until the end of 1996; and the formal document was not executed until 26 February 1997. By this time there had been a change of ownership as Dr Bottrill had retired in March 1996. Throughout the time that he practised under the new system the s.51 notices were in effect.
- 6.135 The Committee heard evidence from Dr Boyd of the Ministry of Health and Mr Mules the former Chief Executive of the Midland Regional Health Authority about the interim management of health services under the s.51 notices. Dr Boyd said that in general the approach of the Regional Health Authorities to cervical screening was to continue with the previous arrangements the Health Department had with health providers. Mr Mules confirmed that this had occurred in regard to Midland Regional Health Authority's arrangements for laboratory services. He also acknowledged that

the Midland Regional Health Authority could have specified minimum quality assurance provisions in the s.51 notice but had not done so.

- 6.136 Section 51 of the Health and Disability Services Act gave Regional Health Authorities sufficient authority to enable them to require laboratories to become accredited with TELARC or to adopt a quality control scheme of the Regional Health Authority's design. Section 51(1) allowed the regional health authority to give notice of the terms and conditions on which the authority would pay someone. Acceptance of payment was deemed to constitute acceptance of the terms and conditions of payment. Any change of terms and conditions required four weeks' notice. Section 4 set out the scheme of the Act which was to provide for the people of New Zealand the best health and the best care. A change of condition of payment to require TELARC accreditation would have been entirely consistent with the Act's scheme. Provided the legal requirements for notice and consultation were followed it would have been possible to alter the s.51 notices to include this requirement.
- 6.137 No attempt was made to use the powers under s.51 of the Health and Disability Services Act 1993 to impose quality control measures including TELARC accreditation on laboratories. The situation remained as it was before the revocation of the Social Security (Laboratory Diagnostic Services) Regulations. Rather than use the powers available to it under s.51 to introduce improvements by requiring TELARC accreditation of laboratories the Midland Regional Health Authority focussed on achieving changes in health service provision through contractual negotiations with health providers. This focus was in accordance with government policy. Mr Mules informed the Committee that while it was possible for a Regional Health Authority to manage using s.51 notices this was seen as undesirable and contrary to the *Policy Guidelines for Regional Health Authorities* issued by the Minister of Health.
- 6.138 The Midland Regional Health Authority's approach may have been consistent with the philosophy of the time, however, it made the introduction of TELARC accreditation as envisaged in the *Government Policy for National Cervical Screening (1991)* and in the 1993 update of the *Policy* subject to the time taken to negotiate the general contracts with laboratories. These negotiations were subject to delays unrelated to TELARC accreditation. Mr Mules said in evidence that:

“The providers were not opposed in principle to the quality standards requirements proposed by Midland. The major issues which required resolution before the providers would agree to enter contracts were economic rather than related to quality”.

6.139 The result of handling matters in this way was that the introduction of a quality control measure for cervical screening which had always been seen as necessary, and which initially was intended to be in place by 1993, was delayed until the end of 1996. This delay enabled Dr Bottrill and the locums he employed from time to time to continue to practice without quality control.

Has Unacceptable Under-Reporting Occurred Elsewhere?

6.140 The Committee cannot be satisfied that the systemic problems have not resulted in unacceptable under-reporting in other regions in New Zealand. The Committee has seen evidence in looking at the files of the Gisborne women affected that on occasions slides read at Gisborne Laboratories are interspersed with slides read at other laboratories. The other slides have sometimes been read as normal. The fact that these normal slides appear with slides which were misread at Gisborne Laboratories as normal, and were later found to be abnormal, is a cause for concern. The slides read at other laboratories have not been reviewed, and so why they were read as normal is unknown.

6.141 In New Zealand the Programme has prepared national statistics which determining the national average for reporting high-grade abnormalities, and it has then checked to see whether or not individual laboratories are within a particular range of that average. These statistics were criticised by witnesses before the inquiry. This approach of using the national average as a benchmark was also used by the Health Funding Authority's National Laboratory Review study written by Mr Du Rose. The difficulty with this approach is that because laboratory performance has never been monitored and evaluated, there can be no certainty that the national average has not itself been fundamentally influenced by under-reporting. Comparison with other countries (for example Australia), is not always helpful because New Zealand has a higher rate of cervical cancer. The notion of using national averages and seeing where individual

laboratories were placed in comparison with that average was criticised by Professor McGoogan. Her view was that a standard should be set and laboratories compared to that standard. The difficulty, however, with setting a standard is knowing what is an expected percentage of high-grade abnormalities. In New South Wales, the standard for high-grade abnormalities is 0.5%, but there is a lower cervical cancer rate in that state.

6.142 In the Committee's view there is little comfort in taking the national average and seeing where laboratories lie in comparison with that average. Because it has been derived from a time when laboratories were not monitored and evaluated, and not all of them were TELARC accredited or subject to any compulsory quality control, it is possible that the national average is not an accurate reflection of the rate of high-grade abnormalities. For example Professor Skegg pointed out to the Committee that the Sydney re-read of Gisborne smear tests had produced a high-grade reporting rate of at least 2.5% and maybe 3.7%. Dr Bottrill's high-grade reporting rate was 0.5%. The figures on which the national average is based include Dr Bottrill's rate of 0.5%. If, however, the Sydney re-read high-grade rate is more correct the national average will have been calculated using at least one false reporting rate. There would only need to be a few similar incidences before the national average would become flawed. Thus, using it as a measure to determine if there are other laboratories which are under-reporting may not be helpful to answering this question. This is another reason why the independent evaluation by the Otago University team must be carried out.

6.143 The Committee was concerned to know what reliance it could place on the National Laboratory Review study written by Mr Du Rose. There was conflicting evidence on whether or not the review should set the Committee's mind at rest regarding under-reporting in other regions. The Ministry of Health relies upon the Du Rose study to establish that there is no real cause for concern for women in other regions. However, other witnesses and parties had reservations about the study.

6.144 Professor Skegg was one of these witnesses. He told the Committee that he had doubts about the Review. He was critical of it being based only on cervical smears and not on women. He said he considered that to be a fundamental weakness, because the proportion of smears reported as abnormal can be markedly affected by the

patterns of medical practice in different areas. Where it is the practice to take smears at or after a diagnosis of cervical cancer there will inevitably be a higher reporting rate than in those areas where the clinicians do not follow this practice. Professor Skegg was also critical of there being no adjustment in the data for factors such as age or socio-economic status or ethnicity. He considered that the use of places having either a higher or lower than average Maori population was an extremely crude approach to the problem. He said that given that there was a screening register with information about the smear histories of individual women, he could not understand why the study used proportions of smears and not women.

6.145 The use of places having a higher or lower than average Maori population as an indicator of a higher or lower rate of high-grade abnormalities concerned the Committee. The Committee noted that the information on the population of Maori was derived from demographic statistics and deprivation statistics. It seems that the Health Funding Authority did not use the Register to extract data about Maori women. The Committee was concerned to learn if the Kaitiaki Regulations had been an obstacle to using the Register. The Committee did not receive an adequate explanation for why the ethnicity data on the Register were not used for this purpose. The use of demographic and deprivation statistics seemed a clumsy tool by comparison. This information should have been on the Register and it should have been accessible to someone like Mr Du Rose.

6.146 The Committee raised this issue with Professor Skegg and asked him, as an epidemiologist, what did he think of that approach.

“Q I actually asked Mr Du Rose specifically about a particular laboratory in a region where there was a high Maori population. It’s at page 44 of his exhibit 1. It says there that the laboratory serves an area that is greater than average with respect to the Maori women population aged 20-69, however no figures are available in respect of the ethnicity of the screened population. And Mr Du Rose said that they had taken the demographic statistics and noted that the area had a population of Maori women higher than average, and also the deprivation statistics when they had not gone to the Register to look at the ethnicity of the women concerned. As an epidemiologist what do you make of that approach?”

A Well I think it was a very incomplete approach because the data are on the Register, and I think it would have been desirable to say not just to look at the area but to look at the actual women who had their smears read by that laboratory who may actually come from more than one area.”

6.147 More significantly Professor Skegg's view was that the Du Rose study may not have identified Gisborne Laboratories as an outlier if it had been simply another laboratory in the study. Professor Skegg referred to evidence from the Du Rose study which gave Gisborne Laboratories a high-grade reporting rate of 0.57% which was above the 0.5% threshold the study had set as a benchmark to identify outliers. Four laboratories in New Zealand had a lower rate of reporting high-grade abnormalities than Gisborne Laboratories. He also referred to evidence which had emerged from the Inquiry which showed that of 216 women with high-grade abnormalities or cancer, Gisborne Laboratories had reported only 37 of those as high-grade or cancer. Professor Skegg said that this gave Gisborne Laboratories a false negative rate of more than 80% and yet when the tables in the Du Rose study were looked at Gisborne Laboratories had a high-grade reporting rate of 0.5%. Thus the laboratory did not emerge as a clear outlier. Furthermore the study was not able to identify its very high false negative rate. Professor Skegg said:

“If one looks at exhibit 1 in Mr Du Rose's evidence it can be seen that the Gisborne laboratory had a percentage of high-grades of 0.57% which is above the threshold and there were four laboratories in New Zealand with a lower reporting so here we have on the one hand an extremely high false negative rate in Gisborne, you know I would be surprised if there were any other study like this in the world which would show such poor identification of high-grade abnormalities or cancer and yet when one looks,... on the basis of the analysis he [Dr Bottrill] does not emerge as an outlier.”

6.148 The study left Professor Skegg uncertain as to whether or not there was a systemic problem of under-reporting in New Zealand. His concern was that overall the rate of high-grade reporting in New Zealand was much lower than the Sydney re-read rate and that raised the question of whether or not there was systemic under-reporting:

“ Q: Either the Sydney report has a large number of false positives and it has over-read a lot of slides or perhaps generally there is a tendency in New Zealand to under-call slides or under-report slides

A: Yes or it could be a combination of those factors which may well be the most likely explanation.

6.149 Ultimately Professor Skegg concluded :

“I was not comforted by Mr Du Rose's evidence to the extent that we could deduce that what has happened in Gisborne is totally exceptional and that

there might not be some other areas where similar problems could exist or could have existed in the past.”

6.150 When Professor Skegg was asked what could be done to find out whether there are such problems, his view was that the national evaluation should go ahead. Professor Skegg stated :

“First of all I think that the work that the Health Funding Authority has started could be developed, but I think the other thing which needs to be done as a matter of some urgency is to start the national evaluation that has been talked about for probably more than a decade, and that the Ministry of Health commissioned last year but is still not fully underway.”

6.151 There were other technical difficulties identified regarding the way in which the Du Rose study was set up. Indeed the study accepts that “ it is does not represent a thorough assessment and evaluation of the quality of cervical cytology services”. Dr Medley, who was engaged by the Health Funding Authority to assist with setting up the study said the Committee could not rely upon it to reach a view as to whether or not under-reporting was isolated to Gisborne. The Committee was left unsatisfied as to whether or not under-reporting is or had occurred in other regions of New Zealand. It considers that the question of the discrepancy between the Douglass Hanly Moir Pathology high-grade reporting rate and the New Zealand average requires urgent attention.

Conclusion

6.152 Ministry witnesses have described the Programme as successful because it has reduced the rate of mortality and morbidity of cervical cancer in New Zealand. It may have done so. However, in the Gisborne region, 16 women developed cervical cancer. Their smear tests were read as normal at Gisborne Laboratories. The same smear tests were subsequently re-read at Douglass Hanly Moir Pathology as high-grade or cancer. In the Committee’s view, a successful well-designed and well-run screening programme does not allow something like this to happen.

6.153 The need for quality control of laboratories reading cervical cytology, quantitative performance standards, a central computerised registration system linking cytology, histology and cancer morbidity and mortality data, easy access to relevant reliable

statistical information, routine monitoring and evaluation and the consequences of not having these features in place are illustrated by what occurred in the Gisborne region. These essential components of a screening programme were not present throughout the time Dr Bottrill was in practice. Any attempts the Programme may have made at achieving these essential components were not effective; that is shown by the unacceptable level of under-reporting which occurred. A screening programme which had these essential components in place would not have permitted Dr Bottrill to practice as he did; it also would have been able to detect unacceptable levels of under-reporting.

- 6.154 The systemic problems occurred because there was a failure to appreciate that a cervical screening programme has certain essential features and that these must be in place from the outset for the National Cervical Screening Programme to be effective. The Programme did not begin with all the essential features in place; nor were they all in place during the Programme's design stage, implementation stage or operational stage. Secondly, this failure to recognise what features could not be compromised if the Programme was to be effective meant that it was originally shaped to fit and later forced to accommodate the prevailing ideologies on health delivery. Many of its features and functions were split between regional health agencies (area health boards and regional health authorities) and the central health agency (Department/Ministry of Health) for reasons which were not conducive to a well run screening programme. The end result was that the Programme was vulnerable to systemic failures. Throughout the life span of the Programme it has been shaped to fit the Procrustean bed of the prevailing ideologies on health delivery. This has created systemic problems in the Programme and has been at the expense of its effectiveness.

7. TERM OF REFERENCE FOUR

What changes have already been made to legislation, to laboratory or other processes, or to professional practices, to address the risks of under-reporting of abnormalities in cervical smears?

The Committee has interpreted this term of reference as applying to those changes that have been made since Dr Bottrill retired from practice which will address the risk of under-reporting of abnormalities. Therefore, the Committee will address changes made after March 1996. Some of these changes have already been referred to in other sections of the report.

Changes To The Programme's Components

- 7.1 The changes include an ability to co-relate histology results with cytology results (achieved in 1996); the reconfiguration of the 14 stand-alone screening registers into a centralised register (achieved in 1997). It is now possible for a laboratory *that reads the cytology* to request a correlation report between a patient's cytology and histology. The report gives details of the histology results for all women for whom the laboratory in question has read a cytology result within five years prior to a high-grade histology result. Where there has been a negative smear report within five years prior to a high-grade histology result that information is automatically highlighted. Unfortunately s.74A limits others having access to this information. Access to information about identifiable women on the Register is limited to the woman, her smear-taker and the laboratory reading the smear test.
- 7.2 Since the Register has been reconfigured the data held on it is more reliable as a result of the centralised system which has reduced the opportunity for regional deviation. Technically data is now more easily available and more reliable for the purpose of statistical analysis.
- 7.3 Since 1996/1997 TELARC/IANZ accreditation or accreditation with a similar authority has been compulsory for laboratories reading cervical cytology. This change was introduced through the *Policy 1996* requiring laboratories to be accredited. The

Policy was made a term of the funding agreements between the Ministry of Health and the regional health authorities. The regional health authorities then made compulsory accreditation a condition of payment under their agreements with the laboratories. As each regional health authority completed its funding agreement with laboratories at a different time the Committee cannot report precisely on the dates when all regional health authorities completed these agreements. In the case of the Midland Regional Health Authority the agreement was executed in March 1997. The evidence the Committee has heard is that by 1997 all laboratories reading cervical cytology were legally required to be accredited. In fact all the laboratories reading cervical cytology had been accredited since February 1996.

- 7.4 The Committee considers that compulsory TELARC accreditation would have reduced the unacceptable under-reporting of abnormalities in Gisborne, because it would have prevented those practices of Dr Bottrill that are likely to have led to under-reporting. In a more general sense, although TELARC/IANZ accreditation can reduce the likelihood of under-reporting, errors can still occur in accredited laboratories. Accreditation is focussed on process as opposed to assessing the substantive quality of the work being performed. Accreditation can influence the substantive quality by putting in place procedures that are likely to assist in good performance but that is all it can do. Accreditation is not a substitute safeguard for comprehensive monitoring and evaluation. The work of accredited laboratories must still be checked.

Changes To Legislation

- 7.5 New legislation regulating the medical profession was introduced in 1995. The Medical Practitioners Act 1995 attempts to protect the health and safety of the public by providing mechanisms to ensure medical practitioners are competent to practise medicine. The Act permits the Medical Council to review a doctor's competence in response to concerns raised by a patient, a colleague, a medical college or the Health and Disability Commissioner.
- 7.6 The new Act introduces measures which should ensure that medical practitioners are and remain competent to practise in their area of speciality. The Committee was informed by the Medical Council witnesses that the Act has set up an inter-linked

system whereby a registered medical practitioner is unable to practise in isolation or without some monitoring of his or her performance. This is achieved by: mandatory education and supervision for probationers; oversight of general registrants (with a specific exemption in some cases for the first five years of the Act); re-certification for vocationally registered doctors and conditions on practice of temporary registrants. Vocationally registered doctors are those who were registered on the Register of Specialists and Register of General Practitioners under the previous Act. Re-certification programmes have been introduced and if vocationally registered doctors do not comply with re-certification procedures (which are yet to be made compulsory) they risk losing their vocational registration or even risk suspension from the register of medical practitioners.

- 7.7 The Act has also put in place new procedures regarding registration. Restrictions are now placed on the Registrar's power to issue practising certificates if an applicant cannot demonstrate competence or has been absent from practice for a significant time. Practitioners who have been suspended are required to surrender their practising certificates. A medical practitioner cannot practise without a practising certificate.
- 7.8 These provisions should assist in reducing the likelihood of a pathologist practising in the same or a similar manner to Dr Bottrill.

8. TERM OF REFERENCE FIVE

What other changes agreed to be implemented, either by the Government or by professional organisations, will further address any risks of under-reporting of abnormalities in cervical smears?

Legislative Change

- 8.1 The Government has agreed to look at legislative change to allow monitoring and evaluation of the Programme to be carried out without the hindrance of the legal obstacles which presently prevent this valuable exercise from being undertaken. However, in the Committee's view the proposals it has seen do not go far enough, especially given the period of time which has already elapsed. There is the potential for the proposed change to become bogged down in long consultation and attempts to reach a consensus view on an issue which does not lend itself to a solution which is likely to be amenable to all interest groups. For this reason the Committee considers that in their present form the proposed changes can not be described as something which will further address any risks of under-reporting of abnormal smears. It, therefore has considered the legislative proposals under term of reference six.
- 8.2 The national evaluation which was to be carried out by an independent team, and which was unable to be performed due to difficulty in accessing information, has now been taken over by Dr Peters and the unit within the Ministry which is responsible for the Programme. It is believed that by carrying the project out as an internal audit the problems that the independent evaluation team encountered in gaining access to protected information will be avoided. The Committee has been told that the project is complex and it could take up to seven months to complete preparatory work. Dr Peters advises the Committee that she acknowledges previous work has been done on the project, but she says much work now needs to be done to ensure that the complications that have previously arisen do not impede the project in the future. Whether or not this new plan to gain access to much-needed information actually works, is still to be seen.

Proposed Changes To The Operation Of The National Cervical Screening Programme

- 8.3 When the National Cervical Screening Programme moved to the Health Funding Authority it came under the control of Dr Julia Peters, a specialist in public health. Since the incident of under-reporting in the Gisborne region has surfaced considerable effort has gone into improving the National Cervical Screening Programme's effectiveness. She is the person responsible for managing the National Screening Team.
- 8.4 New policies and quality standards for the Programme were developed. These were produced in draft form to the Committee during the Inquiry hearings. The Committee found these draft documents impressive. Expert witnesses commented on them favourably. Since the conclusion of the public hearings the Committee has received affidavit evidence from Dr Peters to update it on further progress. It has learnt that *National Cervical Screening Policy Interim Operation Policy and Quality Standards October 2000* has now been finalised. The Committee's view is that the policies and quality standards, which this document contains, must be implemented as a matter of urgency. Every support should be given to Dr Peters and her team to ensure that the *Interim Operation Policy* is put into action. In the Committee's view the implementation of this document will do much to improve the effectiveness of the Programme.
- 8.5 In her affidavit Dr Peters described the current members of her team. The team comprised a permanent staff allocation of 7.5 fulltime equivalent staff, four fulltime fixed term contractors and approximately 6.5 fulltime equivalent consultants. She had recently received approval from her general manager to appoint a finance manager and an information technology manager to the team. They would be permanent appointments. She had also received approval to appoint an additional staff member for the National Cervical Screening Register. The Committee learnt that she had advised her manager that a significant number of additional staff with clinical epidemiological public health contracting and quality assurance and monitoring skills were also required in the team. The Committee supports Dr Peters' views on this point. While advisory groups can be of assistance, it is essential that the Programme

has its own in-house qualified personnel. Epidemiological public health skills, contracting skills and quality assurance and monitoring skills all relate to areas where in the past, the Programme has been found wanting. The lessons to be learned from the last decade are that reliance on advisory groups cannot provide the same input that persons with these qualifications can if employed by the Programme. Furthermore the Committee's views are consistent with the views expressed by the Cervical Screening Advisory Committee in its final report in 1994 to the Minister. In that report the Committee emphasised the importance to the Programme of skilled staff including epidemiologists and biostatisticians.

- 8.6 It is clear from the evidence that between July 1998 to June 2000 there were no specific performance measures for the Programme while it was with the Health Funding Authority. The impetus that the experience at Gisborne gave to the Health Funding Authority must be continued. It is important that the Programme receive all the resources that Dr Peters believes essential for it to operate effectively.
- 8.7 Dr Peters also advised the Committee that by 23 November 2000 the national laboratory contract has been completed and signed by all 12 community laboratories. It makes compliance with the *National Cervical Screening Policy Interim Operational Policy and Quality Standards October 2000* and the *IANZ Quality and Services Standards for Medical Testing Laboratories* a contractual requirement. The *IANZ Quality and Services Standards for Medical Testing Laboratories* are included in the contract as an appendix. In the Committee's view the national laboratory contract will go a long way to ensuring quality performance of laboratories.
- 8.8 The Committee was advised that there has been a policy decision to impose three minimum volume standards on laboratories. These are: each fixed laboratory site will process a minimum of 15,000 gynaecology 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. In the Committee's view these minimum standards must be implemented. It considers them to be good, however it notes that Dr Peters envisaged that during the next eight months the national screening team would be working with all relevant parties to ensure transition issues are appropriately managed. It is important that the minimum volume

standards be imposed within six months. Minimum standards were first suggested a decade ago.

- 8.9 The Committee notes that an independent monitoring and audit group for the Programme is to be appointed. The Committee supports this. A contract has been agreed between the University of Otago and the Health Funding Authority for the establishment of a National Cervical Screening Programme Independent Monitoring Group. The first quantitative monitoring for the Programme against the national indicators in the *Operational Policy and Quality Standards Manual* is to commence using data from women screened from 1 October to 30 January 2000. Reporting on this data is due in April 2001. The Committee supports this and considers that it must go ahead. An independent monitoring group is vital for the Programme's effectiveness. It is also important that this group get full access to the information it needs to enable the monitoring exercise to be carried out. The progress of the audit and whether or not it reports by April 2001 need to be watched.
- 8.10 The Committee also considers that thought needs to be given to the European Guidelines on Cervical Screening with a view to seeing whether or not those parts of the Guidelines that are still not included in the *Operational Policy and Quality Standards Manual* should be included. During the Inquiry the Committee heard from Dr Cox who was very supportive of all the monitoring criteria in the European Guidelines. The Committee is aware that these Guidelines are not in operation in a number of European countries, however that does not detract from their value
- 8.11 Dr Peters advised that she was also considering what processes would be required to establish a successful audit of the Programme. She noted that there needed to be: a comprehensive audit framework for the Programme; customised audit for specific provider groups; a comprehensive pre-audit data collection process was required; auditors would need to be independent and appropriately trained; full audit reports would need to be provided; the national screening team will need to develop processes to address all issues revealed at audit. Added to this should be the qualification that the Programme should ensure that the auditors will not encounter any legal obstacles in carrying out the exercise. It is important that these audits are carried out.

8.12 Dr Peters has advised the Committee that from 1 July 2001 the National Screening Team will have operational, contractual and financial responsibility for the Programme. She said that a National Cervical Screening Programme unbundling and financial model had been developed and agreed within the Health Funding Authority and the financial transfer approved. The Committee supports this entirely. It recommends that by 1 July 2001 the Programme should be in a position where it has complete responsibility for the operational contractual and financial management within the team responsible for it (national screening team).

8.13 Dr Peters' evidence was that there is a move towards centralisation of all national aspects of the Breast Cancer Screening Programme and the National Cervical Screening Programme and development of quality assurance processes within both programmes. The Committee has been advised that a separate national screening unit has been formed and the structure was approved by the Director-General of Health on 7 November 2000. This unit will be staffed by 33 fulltime equivalent staff and will undertake all the functions necessary for the national management of the two cancer screening programmes. There will be six teams, namely Information Management, Contracts and Finance, Maori Screening and Development, Breast Screen Aotearoa, National Cervical Screening Programme, Quality Monitoring Analysis and Audit. The most senior appointee will report to the Deputy Director-General of Public Health. There will be a clinical director who will be a public health medicine specialist, and ideally the two managers of the National Cervical Screening Programme and the Breast Screen Aotearoa will also be public health medicine specialists. Provision has also been made to appoint a part time epidemiologist to the quality monitoring analysis and audit team. A number of part time consulting clinical experts will also be appointed. Dr Peters outlined the advantage of the structure as being :

?? It delivered internationally recognised key organisational components for successful screening programmes;

?? It provided clear reporting structures with a reasonable span of control for managers;

?? Its current reliance on contractors for critical positions will cease;

?? It provides professional development and management within an individual's chosen career, thus providing a strong platform for recruitment and retention of quality staff;

?? The model is sustainable across a range of scenarios, for example differing health service configurations;

?? It established an experienced base and benchmarks which can be built onto should other national screening programmes be developed.

8.14 Dr Peters advised that all current term and national screening team staff will be confirmed in positions within the new national screening unit. Development of detailed position descriptions has commenced and recruitment for vacant positions will commence as soon as these are finalised. The Committee agrees with these plans. It considers that the National Cervical Screening Programme should be run through a centralised management system. The fragmentation that resulted from the earlier models under the area health board and later regional health authority system was detrimental to the Programme. A Programme of this nature is best run as a national programme from a centralised office. It is particularly important that with the current restructuring of the health sector and the use of 22 district health boards (something on which the Committee has received no updating evidence) the Programme should not be subject to the threat of any further fragmentation.

8.15 The Committee considers that the changes that have come about as a result of the Gisborne incident bode well for the Programme. It should be a much better programme. It is unfortunate that it took a tragedy to bring this about. Many of the changes that are now being implemented were recommended when the Programme was being established.

9. TERM OF REFERENCE SIX

All relevant proposals that could ameliorate any risks of under-reporting of abnormalities in cervical smears and identify whether these are covered by the terms of reference four or five, and whether further changes are needed.

Changes To Legislation

- 9.1 This proposal is referred to in Term of Reference Five. By far the most important change which is required to make the National Cervical Screening Programme fully effective is the removal of the legal barriers which are preventing the comprehensive evaluation of the Programme from proceeding. Since the closure of the public hearings the Committee has received affidavit evidence from the Ministry of Health which informs it of proposed legislative changes to remove these barriers. Although it appears the Government is committed to addressing the problem presented by these legal difficulties, the information the Committee has received does not indicate how the problem will be solved, nor do the proposals go far enough in grappling with the difficulties which the proposed legislation is intended to overcome.
- 9.2 The advisory papers which the Committee have seen admit the existence of the problem, set out options and suggest there should be wide consultation before anything is done. There appears to be a concern that any departure from requiring a woman's consent before her protected information is made available to an evaluation team will be contrary to notions of informed consent, the recommendations made in the Cartwright Report, and will cause women to leave the Programme to the extent that there may be insufficient numbers left to make analysis of the information worthwhile. No empirical basis to support this view is put forward.
- 9.3 The Committee has seen ample evidence to support the need for a comprehensive national evaluation of the Programme which includes a cancer audit. It has also seen ample evidence to convince it that no cancer audit is likely to go ahead, if consent of the women being audited is required. For example Professor Skegg proposed carrying out an audit of 42 women from the Gisborne region who had developed cervical

cancer. The purpose of the audit was to enable the Committee to report on term of reference one. At the time of the proposed audit it was thought that it was the only way of learning whether or not there had been an unacceptable level of under-reporting in Gisborne. Professor Skegg could not get ethics committee approval for his audit unless he obtained the consent of the women concerned. There were problems with identifying the women and obtaining their consent. In addition there was the further problem that some of them might not consent to their medical case being audited. He told the Committee that to require him to obtain the consent of the women concerned posed significant problems for the audit because if only 30 women out of 42 consented “ it would then be difficult or impossible to draw any firm conclusions relating to term of reference one.” The Committee has heard from a number of expert witnesses about the necessity to have a sufficient number of subjects to be able to learn anything meaningful from any epidemiological study or an evaluation exercise.

9.4 The cancer audit was identified by the Cervical Screening Advisory Committee as one of the three high priority phases in the proposed 1997 evaluation which must go ahead. As at March 2001 it still has not been completed. In a briefing paper to the Minister of Health the Ministry accepted that the cancer audit will enable defects in systems or treatment to be detected and will improve the Programme’s safety and effectiveness. However, the briefing paper sets out a number of concerns about the impact any change in legislation will have on the privacy of women. The paper appears to be driven by a concern that unless the privacy of women participating in the Programme is given top priority women may stop participating in the Programme. It, therefore, suggests that before any change is made there should be extensive consultation with women and women’s groups.

9.5 From the material the Committee has seen there appears to be an undue focus on informed consent. The material quotes a recommendation from the Cartwright Report which states that:

“ Permission might be sought for purposes other than implementing the screening programme when research and evaluation of results was contemplated. There should be consultation with authorities in the field of privacy law to ensure that confidentiality will be guaranteed to all women whose names and identifying details are contained on the register”

However, it needs to be remembered that this recommendation was made in an entirely different context and that the Cartwright Report was not inquiring into a failure of a screening programme as has occurred in Gisborne. What has occurred in Gisborne emphasises the need for effective monitoring and evaluation of all aspects of the Programme.

- 9.6 The present circumstance is different from that which was considered in the Cartwright Inquiry where women found themselves the subject of medical experimentation without their consent. Here all that is involved is allowing persons to examine information already obtained from women for the purpose of checking to see if they were appropriately treated. In the Committee's view, this evaluation could be viewed as a necessary part of the treatment the women have received, rather than separate from it.
- 9.7 The lesson to be learned from unduly focussing on informed consent should have been learned from the deficiencies of the opt-on screening registers. The choice of opt-on registers was motivated by concerns to accommodate women exercising informed consent. The result was sub-optimal registers which had to be replaced three years later. There is little point in encouraging women to have smear tests if the quality of the smear test diagnosis is never checked. Professor Skegg described the absence of any comprehensive monitoring and evaluation exercise for the Programme 10 years after its establishment as being "outrageous and unethical." The Committee agrees with this view.
- 9.8 The choice for the Programme is stark. Effective evaluation can not be guaranteed if women's consent is required; if the right of an individual to consent to access to her now-protected information is to predominate the Programme cannot effectively evaluate its effectiveness and therefore the safety of all women participants is potentially at risk.
- 9.9 There is nothing to be gained from adopting a procedure which requires an evaluation team first of all to approach women to request access to their now-protected information, but then, in order to preserve the value of the study, allows the team

access to this information when consent is not forthcoming. A right of consent which can be overridden in this way is not a true right of consent. It would be insulting to women's intelligence to offer them such a hollow right.

- 9.10 There are many instances where personal privacy concerns must yield to the need to gain access to private information. The issue is not one of giving general public access to the National Cervical Screening Register. All that is being sought is for medically qualified persons and their assistants to have access to the Register for the purpose of checking that things were done properly.
- 9.11 Today quality assurance and audit and evaluation are so much a part of health delivery that it could be said that it is no more than one of the components of the original treatment, which happens to be carried out later on. On this view treatment which does not include a subsequent audit could be seen as incomplete treatment. At present there is no barrier to laboratories auditing their work on smear tests because they are seen as the women's original health provider. A laboratory can access from the National Cervical Screening Register a print-out of a woman's smear test history and any recorded histology results for the purpose of carrying out an audit of its work. Looked at realistically a woman's experience when her medical case, including smear test history, is audited is no different whether that is done by the laboratory which read her slide, or by an evaluation team which is engaged by the Ministry of Health. In both cases she is unlikely to know that the audit has occurred unless something irregular is found. In that case in the Committee's view she has a right to know of the irregularity.
- 9.12 The Ministry of Health has received legal advice that the evaluation could go ahead without women's consent, if the evaluation team lost its independent character and became employed agents of the Ministry. Thus by a change of legal status the same people would then be able to see the same information that they were previously denied access to. An important exercise like the national evaluation should not turn on such legal technicalities.
- 9.13 The Committee considers that the failure to carry out a cancer audit is denying those women whose treatment has been irregular this knowledge. Women have a right to

know whether or not their treatment has been irregular and as that is something that is difficult for them to discover for themselves, and costly where the irregularity is disputed, the Programme has an obligation to ensure that women receive this knowledge. In its present form the Programme has no effective quality assurance for its performance since the gold standard test for determining its effectiveness cannot be carried out for legal reasons.

9.14 If this state of affairs is to continue, then women enrolling and enrolled in the Programme should be clearly informed. They should be told that they are participating in a Programme which cannot carry out the most effective means of monitoring the Programme's success. Only then will they be in a position to exercise informed consent to participate in the Programme. The Programme issues written material which gives the impression that monitoring and evaluation of all aspects of the Programme is being carried out. This is not correct. Some aspects of the Programme are monitored and evaluated, however, nothing effective is being done to monitor and evaluate laboratory performance. The exercises which are carried out are nothing like the cancer audit. Women should be told that the monitoring and evaluation which is now carried out is not able to detect misread smear tests. Without this knowledge they can not exercise an informed choice as to whether or not to participate in the Programme or opt for opportunistic screening on a more regular basis than the three-year time frame used by the Programme. It is demeaning to women to place an emphasis on their rights of informed consent (when considering legislative change which removes their right to refuse access to their now-protected information), and yet to not be open about the limitations of the Programme in which they are encouraged to participate.

9.15 There appears to be a concern or fear that if women receive any bad news about the Programme they will leave it. In the Committee's view while the concern is understandable, it is not acceptable to act in this way. In the Committee's view it is unethical to encourage women to participate in a programme without letting them know of the Programme's limitations.

9.16 In the Committee's view the time has come for the Government to introduce legislative change through primary legislation which will ensure the Programme

functions effectively and is safe for women. To achieve this goal independent evaluation teams of medically qualified persons must be given unhindered access to now-protected information. Concerns about consumer ownership of the Programme and how that might be harmed by reduced protection of information must take second place. A simple legislative scheme contained in primary legislation which allows comprehensive evaluations to occur, by both external teams or Ministry-led teams, without the need for consent from the subjects or ethics committees is the best and most effective solution.

Changes To Guidelines Under Which Ethics Committees Operate

9.17 The proposal is not covered by Terms of Reference Four or Five. The Committee has had first hand experience of encountering difficulties in obtaining information which requires ethics committee approval. Initially, Professor Skegg proposed a cancer study as a way of providing evidence for the Committee to answer Term of Reference One. He submitted a protocol to the Tairawhiti Regional Ethics Committee and late in April that Committee gave consent for the study to proceed, but on the condition that the consent of all the women first be obtained. Professor Skegg was of the view that the study could not go ahead on this basis because of the need to have as complete a sample of cases as possible. The purpose of Professor Skegg's study was to look at the treatment of 42 women who had developed cervical cancer with a view to discovering whether or not their treatment provided evidence of unacceptable under-reporting by Gisborne Laboratories. The study never went ahead. The Committee was able to rely on other evidence to be able to reach a conclusion under Term of Reference One. However, if this other evidence had not been available, the Committee could well have found itself in a position where a reliable means of obtaining evidence to answer Term of Reference One was barred to it. Professor Skegg was understandably critical of the role of ethic committees in this regard. He expressed certain concerns including :

?? That the committees suffered from a lack of oversight and they had not been evaluated;

?? Regional ethics committees gave rise to a fragmented approach, as committees around the country reached different decisions;

?? Committees sometimes fail to see the cost of not doing things, for example the cost in terms of lives lost because of failure to do a proper audit evaluation on the Cervical Screening Programme.

9.18 Professor Skegg expressed concern about the way in which Committees approach the Health Information Privacy Code and how they interpreted it. He made the point that if current concerns about protection of privacy and ethics committees' approval had prevailed at a time when the medical research upon which the article in Metro that led to the Cartwright Inquiry was written, that inquiry may never have happened. It was the assemblage of material by McIndoe et Al that was necessary for the independent assessment of Professor Green's research. It was the McIndoe et Al research which alerted the authors of the Metro article to the events at National Women's Hospital. Without that research the Metro article could not have been written, and there may never have been an inquiry into the unfortunate experiment at National Women's Hospital. The medical research was written at a time when there was no Privacy Act and the requirements for research to be subject to ethics committee approval was less rigorous. Similar sentiments were expressed by Dr Cox.

9.19 Professor Evans initially disputed this possibility, however, as a result of information provided to the Committee by Mr Rennie, counsel for the Royal College of Pathology of Australasia all parties to the Inquiry, including counsel for the Regional Ethics Committees, accepted that Dr McIndoe and the other medical practitioners who contributed to the research were not involved in the care of the women upon whom the research was based. Furthermore, the Cartwright Report records that Professor Bonham referred to McIndoe et Al as reviewing the cases of other consultants without approval. In the Committee's view Professor Skegg is most probably correct. If McIndoe et Al were not participating in the care of the women involved they would have had difficulty obtaining access to the women's records without their consent. As it would be unlikely for persons in McIndoe et Al's position to approach women for their consent the more likely outcome would have been that the research was not done. Thus it seems that the Cartwright Inquiry may never have happened if the current

ethical and legal requirements for conducting medical research had been in place at the time the unfortunate experiment was being conducted at National Women's hospital.

- 9.20 Professor Skegg gave an example of the first statistical report omitting Wellington data because the local ethics committee would not agree to its release. He described them at times as being a barrier to research, and said that the culmination of ethics committees, privacy concerns and s.74A had created a logjam insofar as a cancer audit of the cervical screening was concerned.
- 9.21 The Committee also heard from Professor Evans who is a professor of bioethics at Otago University, and is on the Otago Regional Ethics Committee. Having heard all the evidence it has become clear to the Committee that at present, ethics committees are operating under *National Guidelines For Ethics Committees In New Zealand*, these are issued by the Minister of Health. They also take heed of international documents such as the Helsinki Declaration and the CIOMS Guidelines.
- 9.22 The Helsinki Declaration and the CIOMS Guidelines do not expressly refer to audits or evaluation of medical programmes or medical treatment. Professor Evans' view was that they did, but that was by implication. When he was taken to these documents, in the Committee's view, he did not provide a satisfactory explanation for reading this implication into them. The Committee, therefore, does not find them relevant to audits or evaluations of medical treatment.
- 9.23 The *National Guidelines For Ethics Committees In New Zealand* are somewhat different. The difficulty with these guidelines is that they are not well expressed. The Committee's view is that they need to be reconsidered. The confusion concerning these guidelines arises because they contain three separate references to auditing and monitoring. Clause 3.1 headed Research or Innovative Treatments Involving Human Participants states : all proposed health and disability research investigations must be submitted for appraisal by an accredited ethics committee where the investigation involves human participants whether health or disability service consumers, healthy volunteers, or members of the community at large, and ... involves access to personal information for purposes other than direct patient care or *internal clinic audit*. Thus, clause 3.1 excludes internal clinical audit from ethics committee approval. Clause 3.3

declares the matters not requiring ethical appraisal, and says that these are outlined in greater detail in appendix 5 and that they include audit, which can be defined as examining practice and outcomes in a particular time and place to see whether they conform with expectations with a view to informing and improving management rather than adding to general knowledge, and access to personal health information for the purpose of monitoring the quality of care.

- 9.24 Appendix 5 which is headed Matters Not Requiring Ethics Committee Appraisal states : Audit - where the audit is undertaken by or under supervision of senior members of the healthcare or disability services team directly responsible for the care of that group of health and disability support service consumers, and where there is no access to confidential medical information by persons who do not owe a professional duty of confidentiality to those consumers. Audit can be defined as examining practice and outcomes in a particular time and place to see whether they conform with expectations with a view to informing and improving management rather than adding to general knowledge. This means that the patient's caregivers can use the patient's private information to audit treatment. Whether or not an independent evaluation team comprised of medical experts and their assistants can do so is questionable. These persons would, as medical practitioners, owe an ethical duty to preserve the confidentiality of the patient's information. However, there is no patient-doctor relationship between the evaluation team and the patient. It is unlikely that the evaluation team can be said to owe a professional duty of confidentiality to those consumers, for the reason that there is no professional relationship between them.
- 9.25 Under the heading Access to Personal Health and Disability Information for the Purpose of Monitoring the Quality of Care it is said – access to personal health and disability information for the purposes of monitoring the quality care. At an institutional level this may go beyond the processes involved in internal clinical audit and may require expertise possessed by members not involved in a healthcare or disability services team, for example expertise in statistical methods, pathological diagnosis or classification. Ethical committee review is not required for this process as long as all persons involved in the process are operating under the same professional standard as the individual's caregiver. This may cover the independent evaluation team. The medical practitioners working under that team would be

operating under the same professional standards as the individual's caregiver. This provision contemplates persons not involved directly in healthcare having access to the information.

9.26 In the Committee's view the evaluation to be carried out by the independent evaluation team fits the description of monitoring the quality of care. That provision in appendix 5 also appears to provide for persons not directly involved in the healthcare or disability services team to be involved in the monitoring process. However, the ethics committees which applied these guidelines to the national evaluation obviously considered that their approval was necessary, otherwise they would have refused to deal with the application on the basis that their approval was unnecessary.

9.27 The Committee considers that whoever drafted the guidelines obviously intended to exclude monitoring and auditing exercises and therefore evaluations as well. It is important, therefore, that the guidelines are expressed in such a way that they accurately reflect the reality of how monitoring and evaluation is carried out in the health sector today. The Committee has heard evidence that it is usual to use independent contractors under short term contracts to carry out these tasks. This is because the Ministry does not itself employ persons with all the necessary skills to be able to carry out the exercises using in-house personnel. If this is so, and if it is also the reality for other sections of the health sector, it is important that the guidelines to ethics committees clearly exclude exercises of this type from the need for ethics committee approval. Otherwise, the result will be, as can be seen from what has occurred with the national evaluation, a logjam in which the monitoring and evaluation exercise is either delayed or never carried out.

9.28 Since the closure of the public hearings the Committee has received an affidavit from the Director-General of Health. This affidavit advises the Committee that the Ministry has carried out extensive researches into practices overseas with a view to highlighting general health ethical issues that have international support. Dr Poutasi advised the Committee that an extensive comparison of ethical review practices overseas had shown that international ethical review bodies do not and should not have a mandate to ethically review service evaluation activities. She said that the international consensus

that is currently emerging suggests that research and audit/quality assurance activities need to be differentiated in order to guide ethics committees. That whereas ethical oversight was appropriate in research activities, it was superfluous in quality assurance activities. The Committee thoroughly supports this approach. The Committee has seen at first hand how the intervention of ethics committees in audit and evaluation activities can result in those activities not being carried out. Dr Poutasi noted that in New Zealand and elsewhere ethics committees appear to believe that they have jurisdiction in both research and quality assurance activities, and that it was desirable to clarify when ethical oversight is appropriate. The Committee considers that this must be done as a matter of urgency. For too long the evaluation of the National Cervical Screening Programme has lain dormant. A major contributory factor to this is the decisions of ethics committees. The Committee can see no logical reason for involving ethics committees in approving audit / quality assurance activities. In today's climate these activities should be seen as an integral part of a patient's treatment. Indeed, what has occurred in regard to the evaluation of the National Cervical Screening Programme has for the moment, in the Committee's view, rendered the Programme unethical in the sense that women are participating in this Programme without being told of its limitations.

- 9.29 The Committee also considers that further thought needs to be given to the status of independently funded evaluation studies. The Committee learnt from Professor Skegg that, as an epidemiologist, he considered that he would not be able to gain access to sufficient information to allow him to carry out an independently funded evaluation study of the Programme if he wished. The Committee considers that there is a place for independently funded evaluation studies of medical treatment.
- 9.30 There is much to be gained from a health system where private medical researchers are free to carry out such studies. For example, the Committee learnt from Professor Skegg that, in his view, there was a need to do a study of breast cancer, because New Zealand has the second-highest death rate in the OECD, and he believed that some of the high mortality may be due to women not receiving the best treatment. He said that someone needed to do an audit of the treatment of breast cancer in New Zealand. In his view he did not think that anyone would even propose doing such a study at the moment because they would not expect the ethics committees to approve it.

- 9.31 Whether that statement about ethics committee approval is accurate or not, it is an indication of how medical researchers currently view access to information. Granting such persons access to information has an additional benefit where a health authority may not be carrying out the task. For this reason the Committee thinks that when reconsideration of the guidelines to ethics committees occurs, thought should be given to making provision for private evaluation studies of medical treatments to go ahead in a less confined environment than the researchers now believe applies.
- 9.32 The impression the Committee gained from Professor Evan's evidence was that there was ethics committees were confused about the inter-relationship of the Privacy Act, the Privacy health and Information Code and the Official Information Act. This suggests to the Committee that the ethics committees would benefit from having at least one legally qualified person on each regional committee.
- 9.33 The Committee was also concerned to hear that the presence of regional ethics committee caused researchers problems when the research covered more than one area. The different regional ethics committees have caused problems for the Programme, for example the decision of the Wellington Ethics Committee not to release data from that region to the Programme for the preparation of the First Statistical report. This suggests that for national studies there should be a national ethics committee.

10. TERM OF REFERENCE SEVEN

Any other issues which the Committee believes to be of particular relevance:

- 10.1 The Committee has interpreted this term of reference which permits it to report on other issues of particular relevance to which in the context of terms of reference one to six issues must be read in context with the other more specific terms of reference in keeping with the *ejusdem generis* rule. It follows then, that the meaning of the more specific terms of reference limit the apparently general meaning of term of reference seven.

Compensation For Women Affected

- 10.2 Counsel for the women affected made submissions to the Committee that under terms of reference seven and eight the Committee should “urge the Government to consider an appropriate method of compensating all those women who establish bona fide claims”. This submission is difficult for the Committee to deal with. It is aware that the women affected have been severely injured by the unacceptable under-reporting.
- 10.3 However, it considers that there are legal barriers which prevent the Committee from making such a recommendation. First, it is questionable whether or not any recommendation the Committee might make on compensation is relevant to the terms of reference. Although term of reference seven is very wide, in the Committee’s view the general language of this term of reference must be read in context with the other more specific terms of reference in keeping with the *ejusdem generis* rule. It follows then, that the meaning of the more specific terms of reference limit the meaning of term of reference seven.
- 10.4 The Committee has not been specifically directed to consider the impact of the consequences of the unacceptable under-reporting on the women affected. The essence of the terms of reference are to look at whether or not there has been under-reporting, if this has occurred to report on what has led to it, and then to inquire into what changes have already occurred and what changes still need to occur to reduce the likelihood of unacceptable under-reporting occurring in the future. The impact of the under-reporting on the women affected falls outside the specific terms of reference. Therefore, insofar as the specific terms of reference limit the general language of term of reference seven, it may be that the question of compensation is a topic which is too remote for the Committee to consider under that term of reference.
- 10.5 Term of reference eight directs the Committee to take into account s.4 of the Health & Disability Services Act. That section says nothing, which is relevant to questions of compensation.
- 10.6 Secondly, and more importantly, there is the conundrum that a claim for compensation as a result of medical misadventure or personal injury presents in the context of

New Zealand's Accident Compensation legislation. Since 1972 New Zealand has followed a legislative scheme which is based on the philosophy of not finding fault or holding persons accountable under the common law for the injuries that they may cause others on the ground that accidents are a fact of modern life; and that it is for the community to carry this burden rather than to use common law actions to make the culprit compensate the injured victim. The current prohibition against bringing legal proceedings to recover compensation for personal injury is to be found in the Accident Insurance Act 1998.

- 10.7 Section 394 of the Accident Insurance Act 1998 prohibits anyone in New Zealand from suing for damages arising directly or indirectly out of personal injury covered by the Accident Insurance Act or personal injury covered by the former Acts (being the Accident Rehabilitation and Insurance Act, 1992, the Accident Compensation Act 1982 and the Accident Compensation Act 1972). Section 39 provides that a person has cover under the Act if they suffer a personal injury in New Zealand that is caused by an accident or by medical misadventure. Section 29 defines a personal injury. It includes: death, physical injury and any mental injury, which is a consequence of a physical injury. Under this legislation personal injury by accident and personal injury by medical misadventure are two discrete categories of injury. The same injury cannot be both a personal injury by accident and by medical misadventure. It was possible for a personal injury to qualify as both under the Accident Compensation Acts of 1972 and 1982. Section 28 defines an accident as including: a specific event or series of events that involves the application of a force or resistance external to the human body. Section 35 defines personal injury caused by medical misadventure as being a personal injury caused by medical error or medical mishap. A medical error is defined as a failure of a registered health professional to observe a standard of care and skill reasonably to be expected in the circumstances. It includes a negligent failure to diagnose an insured's medical condition. Medical mishap is an adverse consequence of treatment. Medical error involves much the same tests as the common law applies in negligence claims based on medical misadventure. Thus the factual circumstances which will give rise to a successful common law claim will also meet the Act's definition of "medical error". This means that any injury the women affected have suffered which would entitle them to compensatory damages under the common law of negligence, or any other pertinent civil cause of action, will also come within the

scope of s.394 of the Accident Insurance Act, and so they will be prohibited from bringing any such claim.

- 10.8 The common law of negligence has traditionally followed a philosophy of finding and apportioning fault on those persons who are found to have caused injury to another, with the result that those who are found to be at fault are liable to compensate the injured victim for the harm suffered. If the common law principles of negligence (and other pertinent common law actions) were still available in New Zealand for cases of personal injury, it is very likely that the women affected would bring legal proceedings for compensatory damages against Dr Bottrill, Gisborne Laboratories Limited and the Crown, which would be sued on behalf of the Department of Health/Ministry of Health and the Minister of Health. However the no fault principle of the Accident Compensation legislation prevents any such claims from being brought.
- 10.9 The Committee is aware that in *Childs v Hillock* [1994] 2 NZLR 65, a woman who suffered pelvic inflammatory disease as a result of using certain intra-uterine contraceptive devices sued the medical practitioner and the Minister of Health, Director-General of Health and the Department of Health for negligently approving and permitting the distribution of these devices in New Zealand. The Crown defendants were sued for compensatory damages. Without making any examination of the merits of the claims, the court struck out the claims against the Crown defendants on the basis that they were for compensatory damages and the Accident Compensation legislation did not permit such claims to be made. In *Green v Matheson* [1989] 3 NZLR 564, Mrs Matheson who was one of the women badly affected by what has come to be known as the unfortunate experiment at National Women's Hospital (which was the focus of the Cartwright report), brought proceedings in negligence against Dr Green, Dr Bonham, Dr Warren, the Auckland Hospital Board and the University of Auckland. She alleged three causes of action : trespass to the person, breach of fiduciary duty and negligence (including negligence arising from administrative shortcomings resulting in a lack of an informed consent). Mrs Matheson claimed compensatory and exemplary damages. Her claim for compensatory damages was struck out by the court on the ground that all the consequences for which she was suing were physical or mental consequences within the meaning of the Accident Compensation Act 1982. They were all part of the

alleged medical misadventure and the damages claimed arose directly or indirectly out of it. For that reason, Mrs Matheson could not sue for compensatory damages as a result of the damage she had suffered, which included contracting cervical cancer as a result of a failure to treat properly the pre-cancerous abnormality of her cervix. The cases of *Green v Matheson* and *Childs v Hillock* were used as test cases to determine if a legal claim could be brought and in that sense they were representative of other claims brought by other women who had suffered the same injury.

10.10 In *Brownlie v Good Health Wanganui* (Unrep 10/12/98 CA 64/97) a claim in negligence was brought by eight plaintiffs (the majority of whom were women) who, between 1982 and 1993, had each had a histology sample taken for pathological examination and diagnosis for abnormality, particularly for the presence of cancerous or pre-cancerous conditions. The pathologist who carried out the examinations detected no malignancy or pre-cancerous condition, and the plaintiffs were so advised. Subsequently, following an audit of the pathologist's work and the hospital's laboratory practices and procedures, the hospital became aware that a number of patients, who had undergone surgery since 1982, may have been misdiagnosed as a result of incorrect pathology reports prepared by the pathologist. There was a possibility that some 54 persons, (including the eight plaintiffs), may have been misdiagnosed during those years. The remedies the eight plaintiffs sought in their claim included compensatory damages for the injuries they had suffered as a result of their disease not being detected, and therefore going untreated. Their claims for compensatory damages were struck out on the ground that such claims were prohibited by the Accident Compensation legislation.

10.11 Because the Accident Compensation legislation removed the payment of lump sums for pain and suffering in 1992, the women affected will be eligible for little, if any, financial entitlements under the legislation. Those women who are not wage earners will not be eligible for earnings related compensation. Medical treatment and rehabilitative care are the most that the women affected are likely to receive. In other jurisdictions, if they were able to establish claims for compensatory damages they would be likely to receive large financial payments.

- 10.12 The submission made by counsel for the women affected that the Committee should urge the Government to consider an appropriate method of compensating the women, is in essence a submission that: the Committee should urge the Government to treat the women affected differently from any other person who suffers personal injury as a result of an accident or medical misadventure; that in this particular instance the Committee should urge the Government to depart from the general philosophy of Accident Compensation legislation which prevailed in this country since 1972, and which in the past has prevented women like Mrs Matheson, Ms Childs and Mrs Brownlie from suing for compensatory damages.
- 10.13 Equal treatment under the law is a keystone principle of our legal system. It is difficult to see any reason why in principle the women affected by the unacceptable level of under-reporting at Gisborne should be treated differently from the women in *Childs v Hillock* and *Green v Matheson*, the plaintiffs in *Brownlie v Good Health Wanganui*, or indeed any other person in New Zealand who suffers a personal injury. Because a recommendation to pay compensation would be contrary to the legal principles which have been operating in New Zealand since 1972; and it would mean the women affected were treated differently from other persons who have suffered a personal injury either by accident or by medical misadventure the Committee considers it is unable to make any recommendation on compensation.
- 10.14 An additional reason against the Committee making a recommendation to compensate the women affected is that the Committee conducted its hearings for the purpose of answering the terms of reference. An inquiry under the law of negligence would involve looking at: the existence of a duty of care (which involves questions of proximity and public policy), causation, remoteness of damage, contributory negligence and the negligence of third parties. None of these issues have been directly traversed in evidence, or submissions. Therefore, the Committee is in no position to make any comment on whether or not the women affected have established, or can establish, bona fide claims. Furthermore, to attempt this exercise would involve the Committee commenting on who it considered to be at fault. It is beyond the power of this Committee of Inquiry to make findings of blame.

10.15 It is possible in New Zealand to bring common law actions in negligence and other causes of actions for exemplary (punitive) damages. This is possible because exemplary damages are different from compensatory damages. Exemplary damages, unlike compensatory damages, are not awarded to compensate the plaintiff, but to punish the defendant for high-handed disregard of the plaintiff's rights, or similar outrageous conduct. For this reason the New Zealand courts have found that claims for such damages are outside the scope of the Accident Compensation legislation. It is not appropriate for the Committee to make any recommendations in respect of payment of moneys which could be seen as akin to exemplary damages. First, there has been no request from the women affected for such damages. Their submission is to urge the Committee to recommend to the Government a payment of compensation. Secondly, as the purpose of exemplary damages is to punish the defendant, any recommendation must be based on findings of fault and blame. It is not appropriate for this Committee to make findings of fault or blame in respect of any person.

10.16 The Committee has provided a lengthy account of why it cannot recommend compensation for the women affected because it considers they are entitled to a full explanation. They relied on a screening programme to protect their health. In this instance the screening programme has been unable to deliver to them the benefits which would usually flow from a well-designed and well-run screening programme.

Access To Maori Women's Data And The Kaitiaki Regulations

10.17 In the course of the public hearings the Committee learned that there have been occasions when obtaining access to Maori women's data on the National Cervical Screening Register has been delayed by the National Kaitiaki Group which is responsible for managing applications under the Kaitiaki Regulations. These regulations control access to aggregate non-identifiable data of Maori women on the Register. The Ministry of Health now submits that these regulations have not been responsible for the delays in obtaining this data.

10.18 However, the Committee has seen evidence which shows that at times the Kaitiaki Regulations have frustrated the Ministry's ability to utilise Maori women's data. A Ministry memorandum of April 1996 headed National Cervical Screening Programme

– An Overview comments on the Kaitiaki Regulations. Under the heading “Protection of Data” the Ministry’s memorandum records that because of the sensitivity around the personal nature on the Register, and a desire to encourage Maori women to accept the Register, s.74A of the Health Act had been introduced to allow special treatment of women’s data on the Register, and subsequently under this section the Kaitiaki Regulations were promulgated. The Kaitiaki Regulations were initiated as a compromise that was reached at the time the Register changed from opt-on to opt-off. Maori women at that time were concerned to have special protection for their data because of its significance to them and the importance of the sanctity of Te Whare Tangata. Their first choice would have been to have an entirely separate register; the Kaitiaki Regulations were a compromise.

10.19 The memorandum notes that one impact of the Kaitiaki Regulations has been to reduce the supply of all data by ethnicity on the basis that this would, by default, identify Maori data. It then states that Pacific Island women are now seeking similar protection, and that although the Minister was opposed to a regulation, a group had been set up to approve requests for the release of Pacific Island data on an interim basis.

10.20 Under the heading “Monitoring and Evaluation” the Ministry’s memorandum refers to what is described as “lock-out” of ethnic data and states that this has frustrated the Cervical Screening Advisory Committee.

“Because of the way the Programme has developed, there have been significant problems extracting data to report on progress. With reconfiguration it is expected that the situation will improve significantly. This lack of data (compounded by the lock out of ethnic data) has been frustrating for the Cervical Screening Advisory Committee and also identified as an obstacle by the Committee reviewing screening recommendations. CSAC’s terms of reference explicitly include advice on monitoring and evaluation. Longstanding Committee members are of the view that they have given all the advice on this they can, but the Ministry has failed to act on it. The review of cervical screening policy has been done in the absence of data on current performance of the National Cervical Screening Programme. (The usefulness of data would be limited in any case by the fact that prior to the introduction of an opt-off policy, numbers on the Register were too small to be of much use for monitoring.)

10.21 The Committee also learnt in evidence from Ms Earp of the Ministry of Health, that even Ministry of Health officials have to apply to the Kaitiaki Group to access

aggregate data on Maori women from the Register. Professor Skegg was asked to comment, as an epidemiologist, on these circumstances. He saw them as inhibiting the delivery of a high quality programme to Maori:

“Q The Committee of Inquiry has learnt from the witness Ria Earp that even the Ministry of Health has to apply to the Kaitiaki Group to access summary data on Maori women. From your experience as an epidemiologist, given that this information is health information on registers run by the Ministry of Health, what comment do you have to make on the requirement that the Ministry itself must apply to the Kaitiaki Group for permission to access the data.

A I can see that this is a legal requirement under the provisions made, but I must say I think it was unwise for them to be framed in that way. My concern is that, I suspect that, although I cannot speak for Maori women, that many Maori women would be concerned if mechanisms such as these were inhibiting the delivery of a high quality programme to Maori as well as non-Maori.”

Professor Skegg also told the Committee that he was aware that some proposals for evaluating the Programme were not going ahead in their full form because the Kaitiaki Group had declined access to the information.

“Q Does the restriction the Kaitiaki regulations place on accessing Maori women’s data, summary data, have a detrimental impact on the Screening Programme?

A I think it does. I think that probably researchers and people involved in health evaluation are inhibited from even asking for the information because they are aware that there is this mysterious group that controls it. I am conscious today even some proposals for evaluating the Screening Programme are not going ahead in their full form because the Kaitiaki Group has declined access to information which does not identify women.”

10.22 The Committee understands the particular sensitivity of Maori women to strangers having access to data on the National Cervical Screening Register. It also understands Maori concerns that aggregate data of Maori women may be applied in a way which reflects negatively on Maori. 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.

10.23 The Committee is concerned to learn that Ministry of Health officials who were working in the Programme could not access aggregate Maori data. The rate of

cervical cancer in Maori women is far higher than in other women. It is only by learning as much as possible about the incidence of cervical cancer in Maori women that this disparity can be addressed, and hopefully reduced. Once again, the Programme's needs in order for it to function effectively as a medical programme appear to be at odds with non-medical philosophies and concerns. The extent to which the Programme's medical features are compromised for non-medical reasons has an impact on how it operates as a medical programme. This has to be accepted. The Committee thinks that it would be worthwhile, when the question of access to now-protected information is reconsidered, that the question of access to aggregate data of Maori women be looked at afresh. Consideration needs to be given to whether or not the sentiments expressed in the Ministry's memorandum of April 1996 are correct, and whether there is a detrimental impact on the Programme. If so, Ministry officials should have better access to this data.

- 10.24 One possibility that was put forward in submissions to the Committee is that an exception be made to the regulations where research is being done under the Programme for the benefit of the Programme, for example the evaluation to be carried out by the independent evaluation team, or an audit of the type suggested by Professor Skegg, or even simply the compilation of statistical reports for the Programme. This approach would mean that the focus of the Kaitiaki Group would be on applications for release of data to "outsiders" where the need for protection is probably at its greatest, rather than to those who have an obvious and legitimate need of the information to ensure the running of the Programme.

Programme's Inability To Control Smear-takers

- 10.25 In the course of reading material concerning proposed legislative change to s.74A of the Health Act, the Committee has discovered an issue which it considers to be of particular relevance to Term of Reference Seven.
- 10.26 A memorandum the Ministry prepared for the Cabinet Social Policy and Health Committee to discuss options to overcome the barrier s.74A presented to the planned national evaluation raised particular concerns for the Committee. One of the suggested means of overcoming the section's prohibition on access to information was

to obtain routine consent to use of now-protected data for audit purposes at the time women enrolled on the Register. The memorandum further states, however, that there are approximately 5,000 smear taking providers and that most of them do not have a contractual relationship with the Programme and, therefore, they cannot be compelled to use the appropriate National Cervical Screening Programme form. This memorandum suggests to the Committee that the Programme has no means of controlling the information smear takers give to women about the Programme, since it has no confidence smear takers will properly inform women that if they are enrolled on the Register their information will be available for monitoring and evaluation purposes.

10.27 This raises a wider issue. If the Programme cannot control what information smear takers pass on to women, how can the Programme be certain that smear takers are properly informing women of their right to opt-off the Register? The essence of the Programme, since the Register became opt-off, is that all women are enrolled on the Register, except for those who decide to opt-off. This requires all women to be told of their right to opt-off. Furthermore, in order for women to make an informed choice about whether or not to opt-off they need to know what is entailed in remaining on the Register. They depend upon their smear takers to give them this information. But, it seems the Programme has no control over what smear takers tell women. Thus there are probably smear takers who are not telling women of their choice to opt-off the Register or if they are, they may not be fully informing them about what the decision to remain on the Register entails. Therefore women are not able to make an informed choice. The implied consent to be on the Register which is derived from a woman not deciding to opt-off the Register may not be an informed consent. The Committee considers this issue requires urgent attention.

10.28 In the course of the Inquiry the Committee learned that smear tests for women in Gisborne are now being read at Medlab Hamilton Limited (Medlab Hamilton). This company purchased the business of Gisborne Laboratories Limited and now runs it as Gisborne Medical Laboratory Limited (Medlab Gisborne). Cervical cytology is no longer read at Medlab Gisborne (the former Gisborne Laboratories Limited). The Committee learned that the records of women patients of Gisborne Laboratories

Limited were stored at Medlab Gisborne. The storage was not ideal, and there seemed to be no way by which Medlab Hamilton could readily retrieve these records.

10.29 Medlab Hamilton carries out the practice of reviewing previous smear tests when it reads a smear test as abnormal. The advantage of this exercise is that it may reveal any earlier smear tests that have been misread. Although Medlab Hamilton carries out this practice in respect of women patients whose records are stored at Hamilton, the “look-back” exercise is not regularly carried out for those patients from Gisborne whose smears are read at Hamilton, but who are likely to have records of earlier smears stored at Gisborne. The Committee understands that this is because the records are not easily retrieved. This means that for those women the opportunity to carry out a look-back exercise to see whether or not earlier smears have been misread is reduced.

10.30 The Committee was concerned to hear this. It considers that a legal obligation is needed to require the vendors of laboratory businesses (either through the sale of that laboratory’s business or through a sale of shares in the company owning the laboratory), to be held legally responsible for ensuring that the records of their former patients are stored and archived in such a way that the information is readily accessible and retrievable by any laboratory which subsequently reads these patients’ smear tests. How this legal obligation can be imposed on the vendors will need to be determined. Any present absence of legal authority to impose such an obligation should not be a deterrent.

11. TERM OF REFERENCE EIGHT

Recommendations, consistent with section 4(a) of the Health and Disability Services Act 1993, as to any future action the Government or its agencies should consider taking.

Counsel assisting the Committee submitted in respect of Term of Reference Eight that it is a sad fact that practically all of the most obvious recommendations that might be suggested have either already been made or have been generally recognised for years as being important features of cervical screening programmes. The Committee fully agrees with this submission. Many of the recommendations the Committee makes in this report have been made before. Many of the improvements which have recently been made to the Programme in response to the Gisborne incident (described in Term of Reference Five) were also recommended from the early stages of the Programme.

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 systemic problem of under-reporting in New Zealand laboratories cannot be excluded.

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.

- 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 11.1.
- 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.
- 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.
- 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.
- 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 weakness in the program. these must be remedied in a timely manner
- 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.

- 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.
- 11.10 There needs to be a balanced approach, which recognises the importance 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.
- 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.
- 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.
- 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.

- 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 s.74A of the Health Act to permit such persons to have ready access to all information on the National Cervical Screening Register.
- 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.
- 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.
- 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.
- 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.

- 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.
- 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.
- 11.21 Ethics committees require guidance regarding the weighing up of harms and benefits in assessing the ethics of observational studies.
- 11.22 A national ethics committee should be established for the assessment of multi-centre or national studies.
- 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.
- 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.
- 11.25 The National Cervical Screening Register needs to be electronically linked with the Cancer Register.
- 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.

- 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.
- 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.
- 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
- 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 be 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.
- 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.

- 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
- 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.
- 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.
- 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 there may be a public health risk involved. If that concern is present the Tribunal should be required to inform the Minister of Health.
- 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.
- 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.

- 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.
- 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.
- 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 cytoscreeners if they want to function as primary screeners.
- 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.
- 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 .
- 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.

- 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.
- 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 than reactive in the delivery of the programme would be useful
- 11.46 A process to ensure that the recommendations made by the Committee are implemented should be put in place.

STAFF ASSISTING THE COMMITTEE OF INQUIRY

Counsel Assisting Royden Hindle
 Hanne Jannes

Registrar Tracey Curtin

Stenographers Grace Rogers
 Aisling Sunderland
 Lisa Hart

Clerk Toni Watson

PARTIES AND PERSONS HAVING AN INTEREST IN BEING HEARD

Women Affected by the Under-reporting of Abnormalities in Cervical Smears
in the Gisborne Region

Ngati Porou Hauora, Community Teams Kaitiaki / Maori Women Affected

Turanga Health

Ministry of Health

Health Funding Authority

Royal College of Pathologists of Australasia

Cancer Society

Medlab Hamilton

Medlab Gisborne

Tairawhiti Healthcare Limited

Regional Ethics Committee (excluding Tairawhiti Regional Ethics Committee)

Tairawhiti Regional Ethics Committee

Women's Health Action Trust

Women's Health Information and Resource Trust

Association of Community Laboratories

Dr Michael Bottrill

Medical Council of New Zealand

WITNESSES WHO APPEARED BEFORE THE COMMITTEE

Name of Witness

Patient 1

Kerri May Tombleson

Deborah Crawford Murphy

Raewyn Marie Page

Patient 8

Patient 7

Patient 5

Patient 6

George Robert Boyd

Judith Glackin

Michael Bottrill

Lorraine Ria Earp

David Christopher Skegg

Euphemia McGoogan

Christopher Philip Mules

Sylvia Sax

Heni Materoa Sunderland
and
Robin Ehu Thompson

Tracey Tangihaere

Tracy Mellor

Julia Peters
Graham Douglas Walker

Diane Van der Mark

Sharon Reid

John Maxwell Robertson

Bruce Montgomery Duncan

Michael Anthony Hugh
Baird

Kenneth John Thomson

Georgina Alice Jones

Ian Beer

Doctors Tie (Dr Graves &
Professor Davies sworn but
do not give oral evidence)

Clinton Adam Teague

Dr Ronald Jones

Annabelle Farnsworth

Gerard Wain

James Du Rose

Brian Cox

Gabrielle Medley

Sandra Coney

Brian Linehan

Brian Robert Morris

Janet Alison Wilson

Andrea Militia Winmill

Wendy Joy Ure

Eleanor Jane Vertongen

Patient 11

Janice Hobbs

Betsy Marshall

Sandra Matcham

Victoria Sheldon and James
Fraser

Teenah Handiside

Timaringi Huirwai

David Lambie

Donald Evans

Karen Poutasi

Susan Dahl
Gillian Grew

***IN ADDITION TO ABOVE ORAL WITNESSES THE FOLLOWING EVIDENCE WAS
ADMITTED BY WAY OF AFFIDAVIT:**

Name of Witness

Patient 15

Patient 16

Patient 17

Patient 18

Patient 19

Patient 20

Lucy Wright (Solicitor,

Rainey Collins Wright)

John Ian Jamieson

(Parliamentary Counsel)

LIST OF FORMAL PUBLIC SUBMISSIONS FILED WITH THE CERVICAL SCREENING INQUIRY

AUSTIN, Frances	Acting Chief Executive	Ministry of Women's Affairs
BAILLIE, Barbara	Member of the Public	
BARWICK, Barbara	Member of the Public	
BEER, Ian	Chairman	Association of Community Laboratories
BURROWS, Hillary	Member of the Public	
CHURCHOUSE, Michael	Member of the Public	
CLARK, Margaret	Health Chair	New Zealand Federation of Business and Professional Women Incorporated
EARDLEY-WILMOT, Maureen	National President	
COPPELL, Kirsten	Smear Taker and Health Professional	National Cervical Screening Programme (Otago)
DAVISON, Glenis	Member of the Public	
GASKIN, Nona	Chairperson	Gisborne Community Health Committee and for and behalf of: ?? Arthritis Foundation ?? Cancer Society ?? Parkinson's Society ?? Multiple Sclerosis Society ?? Stroke Support ?? Schizophrenia Fellowship ?? Head Inquiry Society ?? Gisborne district Council – Community Development Section ?? A Patient Advocate ?? 2 Health Service Consumers ?? Kidney Foundation
HANSEN, Peter	Member of the Public	
HENRY, Gary	Manager	National Women's Hospital
HERA, Jean and Anne	Not Stated	Palmerston North Women's Health Collective Incorporated
SANKO		Cervical Screening Advisory Committee (1991-1994)
MARSHALL, Betsy	Chairperson	
MOORE, Alison	Supporter of the Women of Gisborne and their Families	
PONTER, Elizabeth	Submitter	Regional Programmes of the National Cervical Screening Programme
	and	
	Manager	Manawatu-Wanganui National Cervical Screening Programme
ROBINSON, Raewyn	Member of the Public	
SAVAGE, Arthur	Member of the Public	
SLATER, Stuart	Member of the Public	
TOLLEMACHE, Nadja	Chairperson	Health Research Council Ethics Committee
WILLIAMS, Lynda	Co-ordinator	Auckland Women's Health Council
WILSON, Janet	Laboratory Manager	Medlab Gisborne

GLOSSARY OF LEGAL AND MEDICAL DEFINITIONS

For the assistance of lay people

ABNORMAL BLEEDING

- (a) Post-coital - after intercourse
- (b) Intermenstrual - between menstrual periods
- (c) Post menopausal - after menopause
- (d) Haemorrhage

ABNORMAL SMEAR All smears showing epithelial cell abnormalities, including atypical squamous cells of undetermined significance (ASCUS), and atypical glandular cells of undetermined significance (AGUS), but not including benign cellular changes (i.e. infection and reactive epithelial cell changes)

ADENOCARCINOMA Malignant lesion of glandular (endocervical) cells of the cervix

ADEQUATE SMEAR A smear that contains both squamous and endocervical or squamous metaplastic cells

AETIOLOGY (etiology) The cause of disease

AGE-ADJUSTED (OR AGE-STANDARDISED) RATES Mortality or morbidity rates in which there has been an adjustment for differences in the age distribution of populations being compared

AGUS Atypical glandular cells of undetermined significance. These are glandular cells which demonstrate changes which exceed those normally expected in benign reactive processes but which are insufficient for a diagnosis of AIS or adenocarcinoma

AIS Adenocarcinoma in situ

ASCUS Atypical squamous cells of undetermined significance. These are minor epithelial cell changes whose nature is uncertain but which may result from inflammation and repair processes, human papilloma virus (HPV) effect or minor squamous or glandular intraepithelial neoplasia

ASYMPTOMATIC Without symptoms

ATYPIA Deviation from the normal or typical state

BENIGN TUMOUR A tumour that is not malignant, which usually remains a uniform shape enclosed in a fibrous sac. It does not spread to other parts of the body, and usually does not recur after being removed. A benign tumour does not indicate cancer

BETHESDA SYSTEM A systematic method of reporting cervical smear results

BIOPSY Removal of a sample of tissue from the body, for examination under a microscope, to assist with the diagnosis of a disease

CANCER (Ca.) A general term for a large number of diseases which all display uncontrolled growth and a spread of abnormal cells. Also called a malignant tumour

CANCER PRECURSOR Pre-cancerous

CARCINOMA A malignant new growth or tumour made up of epithelial cells that may infiltrate surrounding tissues and give rise to metastases

CARCINOMA IN SITU (CIS) A high grade abnormality confined to the squamous cell epithelial layer of the cervix. Without treatment it may develop into invasive cancer. This is synonymous with CIN-3

CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN) Abnormal, potentially pre-cancerous cell changes of the cervix. The abnormality can be graded as mild (CIN-1), moderate (CIN-2) and severe/CIS (CIN-3)

CERVICAL SMEAR TEST A screening test for the detection of squamous intraepithelial lesions, in which a sample of the surface cells of the cervix or vagina/vault is taken, preserved immediately and sent to the laboratory for examination

CERVIX (Cx.) The neck of the uterus

CIN Cervical intraepithelial neoplasia

CIN-1 Mildly abnormal cervical squamous cell changes

CIN-2 AND CIN-3 Moderately and severely abnormal cervical squamous cell changes

CLINICAL Matters relating to the health and care of patients

COITUS Sexual intercourse

COLPOSCOPE An instrument which allows the cervix and vagina to be examined in more detail. It is a lighted magnifying instrument resembling a small mounted pair of binoculars. A colposcope may have a camera attached that enables a woman to view her cervix on a television monitor

COLPOSCOPY An examination of the lower genital tract using a colposcope to examine for abnormal tissue. Colposcopy has a central role in diagnosis and management of premalignant disease of the cervix. It is a diagnostic technique involving the examination of a woman's cervix using a low powered microscope and to facilitate biopsy for histological examination as appropriate. Treatment may also be carried out under colposcopic examination

CONE BIOPSY, CONE EXCISION Surgical removal of a cone-shaped section of the cervix to remove abnormal cells. The procedure is diagnostic and may be curative

COVERAGE The number, percentage, or proportion of eligible women reached by the NCSP

CYTOLOGY The study of cells. Cervical cytology aims to detect squamous cell carcinoma or the precursors of cervical carcinoma. The cells are examined under a microscope for signs of abnormality:

- (a) Positive cytology (smear) - an indicator of the presence of disease
- (b) Negative cytology (smear) - an indicator of the absence of disease

CYTOPATHOLOGY The science of the study of diseased cells

DIAGNOSIS Identification of disease

DIAGNOSTIC SMEAR A smear taken outside the normal screening interval as part of the diagnostic assessment of a woman who has signs or symptoms which might indicate cervical cancer

DIFFERENTIATION The process by which abnormal or immature cells are distinguished by individual characteristics which are attributes of normal cell types

DOH Department of Health

DYSPLASIA Abnormal cell growth

DYSPAREUNIA Difficult or painful coitus (sexual intercourse) in women

ECTOCERVIX External aspect of the cervix

ENDOCERVIX Internal aspect of the cervix

ENROLMENT The process of entering a woman's cervical smear information and results on the NCSR

EPIDEMIOLOGY The study of the distribution and causes of diseases and events in populations and the application of this study to the control of health problems

EPITHELIUM Cells which make up the lining of the external surface and some internal linings of the body, i.e. the skins, the lining of the lungs, the genital tract, the bladder

EJUSDEM GENERIS The rule that where particular words are followed by general words, the general words are limited to the same kind as the particular words.

GLANDULAR Epithelial cells that produce a secretion

HFA Health Funding Authority and any successor to the HFA

HIGH GRADE LESION A cytological diagnosis encompassing CIN-2 and CIN-3 (moderate dysplasia, severe dysplasia and carcinoma in situ), high grade squamous intraepithelial lesion (HSIL), and adenocarcinoma in situ (AIS)

HISTOLOGY The microscopic study of the minute structure and composition of tissues by tissue sections. Within the context of the NCSP this includes:

- (a) Cervical histology
 - ?? Biopsies whether diagnostic or treatment
 - ?? Polyps
 - ?? Cervical component of hysterectomies with a diagnosis on the cervical component
- (b) Vaginal histology
 - ?? Biopsies
 - ?? Polyps

HISTOPATHOLOGY The science of the study of diseased tissues

HSIL High grade squamous intraepithelial lesion. A cytological diagnosis encompassing CIN-2, CIN-3 and CIS (moderate dysplasia, severe dysplasia and carcinoma in situ)

HUI Generic term for Maori gathering, meeting or conference (typically held on a Marae) and organised according to Maori protocol

HUMAN PAPILLOMAVIRUS (HPV) A group of wart viruses, a high proportion of which are sexually transmitted

HYSTERECTOMY Surgical removal of the uterus. The operation may be recommended for persistent or recurrent CIN. Radical hysterectomy is performed in certain cases of early invasive cervical cancer. In a total hysterectomy the uterus and cervix are both removed and in a subtotal hysterectomy the cervix remains - so that regular smears are still necessary

INCIDENCE The number of new cases of a specified disease which are diagnosed or reported during a defined period of time in a specified population

INTRAEPITHELIAL NEOPLASIA Abnormal cells in the epithelium of the lower genital tract. See CIN, VAIN, VIN

INVASIVE CANCER OF THE CERVIX (INVASIVE SQUAMOUS CELL CARCINOMA) Condition where cancerous cells spread beyond the surface epithelium into the underlying tissues. It may be diagnosed by clinical examination with biopsy in women who present with abnormal bleeding and discharge. The cervical smear is not a reliable method of diagnosing cervical cancer. Classified in four stages, from Stage I where the cancer has not spread beyond the cervix, to Stage IV where it has extended beyond the pelvis. Cold knife cone

biopsy or an extended hysterectomy (involving the upper vagina and lymph nodes) may be used to treat early stage disease. Late stage disease is usually treated by radiation therapy

KAIMAHI Maori cervical screening co-ordinators, educators and smear takers

KAITIAKI Caregivers or guardians. The National Kaitiaki Group refers to the group set up to oversee the disclosure, use, and publication of Maori women's summary data held on the NCSR under the Health (Cervical Screening (Kaitiaki)) Regulations 1995

LAY SMEAR TAKERS Smear takers who have successfully completed an accredited educational course in smear-taking and have no formal medical, nursing, or midwifery qualifications

LESION An area of tissue damaged by disease or injury

LLETZ Large Loop Excision of the Transformation Zone

LOW GRADE LESION A cytological diagnosis encompassing the changes previously described as HPV infection and or CIN-1 (mild dysplasia) and atypical glandular cells - favouring dysplasia

LSIL Low-grade squamous intraepithelial lesion

MALIGNANT TUMOUR A cancer. A tumour that grows and invades surrounding tissue and infiltrates the blood and lymphatic vessels. It eventually destroys the surrounding tissue and may spread to other parts of the body (metastasis) (See cancer)

MALIGNANCY A condition which if unchecked usually develops into serious illness and may cause premature death. When applied to tumours, may be described as an uncontrolled growth of cells.

MANAGEMENT The complete care of a patient including advice, information, treatment and follow-up treatment or monitoring of a condition

METASTASES Malignant cells which have spread via lymph or blood vessels from the original site to another site in the body

MOH Ministry of Health

MORTALITY The number of deaths from a specified disease during a defined period of time in a specified population

NCSP National Cervical Screening Programme

NCSR National Cervical Screening Register

NEOPLASTIC Cancerous (See cancer/malignant tumour)

NON-MEDICAL SMEAR TAKERS People trained and approved to take cervical smears. A non-medical smear taker is usually a registered or enrolled nurse with a current practising certificate but may be lay. If the trainee smear taker is a lay person additional teaching is given to enable them to practice safely

NORMAL SMEAR A smear result which is reported to be within normal limits

PAPANICOLAOU TEST (SMEAR) A simple painless test used to detect pre-cancerous or cancerous changes in the genital tract. Often called Pap smear or test. This term is not generally used in NZ. The preferred term is cervical smear test

PATHOLOGY The study of the essential nature of disease, particularly changes in body tissues and organs which are caused by disease

PLAINTIFF One who brings an action at law

PRE-CANCEROUS Disease which has not invaded tissue outside the original site. In the context of this Inquiry, it refers to changes confined to the epithelium or lining tissue, and is denoted by the classifications CIN-1 to CIN-3 and AIS

PRECLINICAL Before disease becomes recognisable by symptoms or appearance

PREVALENCE RATE The number of cases of a specified disease in a given population at a designated time

PROGNOSIS Forecast of the probable course and outcome of a disease including prospects of recovery

PUNCH BIOPSY Very small specimen of tissue taken with special biopsy forceps which allows microscopic examination by a pathologist

RADIUM A highly radioactive material used in the treatment of malignant diseases

RECURRENCE The return of symptoms after a period during which they have disappeared or reduced in intensity, or the reappearance of overt disease

RHA Regional Health Authority

SCREENING The routine search for unsuspected disease (or medical investigation which does not arise from the patient's request for advice for a specific complaint)

SCREENING TESTS Tests which sort apparently well women who probably have a disease from those who probably do not. Screening is an initial examination only; those with a positive test require a more definitive diagnostic examination

SENSITIVITY OF A TEST The proportion of truly diseased persons in the screened population who are identified as diseased by the screening test. Sensitivity is a measure of the probability of correctly diagnosing a case, or the probability that any given case will be identified by the smear test

SMEAR TEST See Papanicolaou test

SNOMED CODES Systematised Nomenclature of Medicine. A coding system for recording histological diagnosis

SPECIFICITY OF A TEST The proportion of truly non-diseased persons who are so identified by the screening test. It is a measure of the probability of correctly identifying a non-diseased person with a screening test

SQUAMOUS CELL CARCINOMA Cancer arising in the squamous epithelium identifiable microscopically by its scaly or plate-like appearance. The most common form of cervical cancer arising from squamous cells in the epithelium (tissue which lines the vagina and outer layers of the cervix)

SQUAMOUS CELLS A type specialised cell, which lines the vagina and outer layers of the cervix

STANDARD A standard is a minimum requirement upon which practice can be measured

TRANSFORMATION ZONE The region of the cervix where columnar cells have changed or are changing to squamous cells. The metaplastic process (change from one cell type to another) may become abnormal due to various factors such as viruses. It is the transformation zone that needs to be completely sampled when a smear is

TREATMENTS/THERAPY Management or care of a patient in combating a disease or disorder

TUMOUR An abnormal growth of tissue. A benign tumour remains localised. It does not spread to other parts of the body. A malignant tumour (cancer) invades surrounding tissue and may infiltrate the blood and lymphatic vessels. A malignant tumour may spread to other parts of the body.

ULTRA VIRES An act in excess of the authority conferred by law, and therefore invalid.

UNSATISFACTORY SMEAR A smear that cannot be evaluated by the laboratory

UTERUS (WOMB) The hollow muscular organ in which the fertilised egg normally becomes embedded and in which the developing embryo-foetus is nourished. The uterus is a pear-shaped organ consisting of the body of the uterus (or corpus) which narrows to form the cervix or neck of the womb. The Fallopian tubes enter the uterus at its upper outer aspect, and at its lower end the cervix opens into the vagina or front passage

VAGINAL VAULT The upper part of the vaginal cavity into which the cervix projects

VAIN Vaginal intraepithelial neoplasia (See intraepithelial neoplasia)

VAULT SMEAR A smear taken from the top of the vagina after a hysterectomy or radiation treatment for cancer of the cervix

VIN Vulval intraepithelial neoplasia (See intraepithelial neoplasia)

WEDGE BIOPSY a surgically-excised, wedge-shaped piece of tissue (large than the punch biopsy) taken for examination by a pathologist

WHO World Health Organisation

