Investigation into Cervical Screening in the Tairawhiti Region

Health Funding Authority

Final Report

This report is the final version of an interim report provided to the Gisborne Cervical Screening Inquiry by the Health Funding Authority

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Foreword

In 1999, the Health Funding Authority (HFA) took the lead in investigating allegations of under-reporting of cervical smears in the Tairawhiti region. This was a large and complex task involving the re-reading of almost 23,000 smears, and impacted on the lives of 12,000 women who had smears read by Gisborne Laboratories between 1991 and 1996.

The Gisborne Cervical Screening Inquiry was established by the Minister of Health following the interim results of the slide re-reading, which showed significant under-reporting of abnormalities.

The Inquiry concluded that the level of under-reporting was unacceptable and identified a number of contributing factors associated with the delivery of the National Cervical Screening Programme during the 1991–1996 period.

The HFA worked with the local community to identify and meet the treatment and support needs of the women involved, their families and whānau.

This report outlines the steps taken by the HFA in its investigation and updates information originally provided to the Inquiry. It includes the results of a review of the information provided to women and health service providers.

The Inquiry made a number of recommendations for improvements, many of which have already been implemented or are in progress. I am committed to further improving the programme by building on the progress made over the past 2½ years and ensuring that New Zealand women have a world class cervical screening programme.

Karen O Poutasi (Dr)
Director-General of Health
November 2001

Mihi

Kei te mihi atu ngā wāhine katoa o te Tairawhiti me o koutou whānau, i pā ki tēnei raruraru. Hei taonga mō te hinengaro kia tātau i roto i o koutou mamae. Mā te Atua koutou e Manaaki.

We wish to acknowledge and salute the women of Tairawhiti, who have been patient and gracious throughout this ordeal. We also thank the many people who have supported the women and their families, all those who have been there for the women in what must have seemed their darkest hours.

Acknowledgements

Many people have been affected by, and involved in, this investigation. It is not possible to acknowledge all of them, but I would like to thank the many people who gave their time and energy both to the carrying out of the investigation and to the support of those involved. Without them all, the investigation would have been very much harder. I would also like to personally acknowledge the following.

In Tairawhiti:

- the Mis-Read Smear Support Group (women affected, the local branch of the Cancer Society, and particularly Janice Hobbs), for their unfailing dedication to ensuring affected women received the best possible advice and support
- local providers (Tairawhiti Healthcare Public Health Unit, general practitioners and smear takers, Ngāti Porou Hauora, and Turanga Health), for their ongoing commitment to finding women, and ensuring they received the best possible advice and treatment
- Marie Burgess and her team, for ensuring the smooth operation of the re-reading exercise and for their efforts to trace women with abnormal results.

In the former Health Funding Authority:

- Jim DuRose and Eve McMahon of the Quality Improvement and Audit Team, for managing the project and for paying attention to the details so that it could progress effectively
- Julia Peters, National Cervical Screening Programme Manager, for recognising the issues and keeping the focus on addressing them
- Sandie Matcham and Phillip Saysell of the National Cervical Screening Register, for meeting our endless requests for urgent advice and information on top of their day-to-day work
- Di Best, for coding all results, providing advice on processes, and following up women with abnormal results
- the Communications Team, and especially Emma Teahan and Kallon Basham, for their support in providing public information
- the Locality Team, particularly Tane Cassidy, for their work with the local providers and community
- senior managers in the former Health Funding Authority, for trusting us to manage the investigation with the fewest possible bureaucratic hurdles
- colleagues throughout the former Health Funding Authority, and especially Laura and Robyn, for their continued support and encouragement.

Others:

- the advisory group (Romia Whaanga, Bruce Duncan, Ron Jones, Brian Cox and Norman Fitzgerald), for their advice, and for challenging us to get it right
- the staff of Douglass Hanly Moir Pathology, and especially Dr Annabelle Farnsworth, for their dedication to re-reading all the slides within the agreed timeframe.

Finally, I would also like to thank our families and friends for recognising the importance of the investigation, and for supporting us while we did our best to meet its demands.

Tracy Mellor
Project Leader

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Executive Summary

This report completes the project the Health Funding Authority (HFA) undertook to investigate reports of under-reporting of cervical cytology by Dr Michael Bottrill during the period 1991–1996. An interim report was provided by the HFA to the Gisborne Cervical Screening Inquiry.

The HFA appointed an external multidisciplinary advisory group to provide it with expert advice on a range of matters relating to the investigation.

The goals of the investigation were to:

- ensure women received the appropriate treatment for their health and wellbeing
- determine the extent of the problem concerning Dr Bottrill and assess whether there was a systematic mis-reading / under-reporting of cervical cytology
- identify those women at risk and determine the appropriate action to take to address this risk
- maintain public confidence in the National Cervical Screening Programme and actively encourage enrolment in it as the best protection against cervical cancer.

The tasks and key outcomes of the investigation are outlined below.

- Re-read all cervical cytology read by Dr Bottrill's laboratory between 1991 and his retirement on 4 March 1996: this was undertaken by Douglass Hanly Moir Pathology laboratories in Sydney and involved the re-reading of approximately 23,000 slides belonging to 12,000 women.
- Develop a follow-up plan to ensure that all women received appropriate follow-up assessment and treatment as they required: this involved vigorous tracing and contacting of all women with high-grade and one or more low-grade re-read cytology results to inform them of their results and assessment and treatment options.

  At the time of publication there were six women who still hadn't been contacted. These women had no evidence of seeking further assessment and had results indicating follow-up was necessary.
- Provide a range of services to assist and support women and their families/whānau: these included free smears, GP consultations, counselling, and consultations for assessment and treatment. In addition Special Circumstances Support services were provided to assist women access assessment, treatment and counselling. Special Circumstances Support included home support, and assistance with transport and childcare, and was designed to meet additional costs incurred by women who had to travel to undergo assessment and/or treatment.
- Implement a communications plan to ensure the Tairawhiti community, local practitioners and women were informed of the progress and steps in the investigation: an 0800 number was established, and regular meetings were held with the local provider group to ensure there was effective liaison with the HFA and between services.

An independent review of the information and services provided to both women and health service providers reported that overall services provided by the HFA were useful and met their needs. Comments indicated women would have liked services to be available sooner, and some women reported they did not know of the specific services available to them, especially the opportunity for free smears. The communication from the HFA to women was generally informative and easy to understand. Women learnt about the investigation from the media, and as planned the majority learnt their results through a personal letter sent from the HFA to each woman. The HFA had arranged for women with high-grade results to first learn their results from their GP or smear taker. The review reported this strategy was only partially effective.

Service providers in Tairawhiti reported that overall they were well informed throughout the investigation and that the number of women requiring smears and referral for further assessment had been managed as efficiently as possible.

- Develop a separate database for the cytology, histology and other results associated with the follow-up of the women.

The major findings of the investigation have been reported to address four key questions.

1. **What were the cytology results reported by the re-reading laboratory compared with those by Dr Bottrill's laboratory?**

   A total of 22,976 smears from 12,099 women were re-read. The vast majority of the smears (82 percent) were reported as normal by both Dr Bottrill's laboratory and after re-reading by Douglass Hanly Moir Pathology.

   Douglass Hanly Moir Pathology reported that of 22,096 smears Dr Bottrill had read as normal, 10 percent (2244) they re-read as abnormal; 255 of these results were reported as *high grade cannot be excluded*, and 307 were re-read as *high grade* or *cancer*.

2. **To what extent did women have smears reported with different results?**

   The smear results of 12,099 women have been reported. Dr Bottrill and the re-read laboratory reported the same result for 9748 women. Of these, 9580 women had normal results. For 1787 women Dr Bottrill's laboratory had reported a lower degree of abnormality than the Douglass Hanly Moir Pathology laboratory on re-reading the smears.

   A comparison of the abnormality reporting rates for those women with high-grade histology results indicates that 32 percent of the women with high-grade abnormalities had received abnormal cytology results from Dr Bottrill's laboratory. This compares with 96 percent of these women receiving abnormal cytology results from Douglass Hanly Moir Pathology on re-reading.

3. **How many women have been diagnosed with cancer or with high-grade abnormalities since the investigation began in May 1999?**

   Fourteen women have been diagnosed with cervical cancer since May 1999, and 102 women with histologically confirmed high-grade abnormalities. Of the 102 women, 91 had their cytology result originally reported by Dr Bottrill as normal.

4. **How many women have died of cervical cancer?**

   Of the 12,099 women included in the investigation, 304 have died. For nine of these women the cause of death was cervical cancer.

Data is presented from two perspectives: some reports on the results of the reading of smears, while some reports the outcomes for the women involved. Data to support the findings is derived from the re-read database.

1 Introduction

In May 1999 the Health Funding Authority (HFA) instigated an investigation into the reading of cervical smears by a community laboratory in the Tairawhiti[1] region of New Zealand. Concerns had been raised about the work of a pathologist who was the defendant in a High Court case judgment in March 1999, and who practised in the area until his retirement on 4 March 1996.

The HFA was the government agency responsible for the national co-ordination of the National Cervical Screening Programme. Appendix 1 summarises the New Zealand health system during 1999–2000 and the management of the National Cervical Screening Programme.

This report on the *Investigation into Cervical Screening in the Tairawhiti Region* (the 'final report') is the third in a series of three reports, and includes material from the two previous reports:

- the interim report, which was published to inform the community of the process and initial results of the re-reading exercise
- the action update report, which included the final results of the re-reading exercise and the data on outcomes for women that was available at that time.[2]

Part I of this report outlines the steps the HFA took to identify the extent of any problem caused by mis-reading of cervical cytology, and the measures implemented to ensure the women affected received appropriate assessment and follow-up treatment. Part II includes the final results of the re-reading and describes the diagnoses and treatment received by women affected. It also includes the findings of a review undertaken to assess the women's views of the services they received.

Early signs of concern about Dr Bottrill's work, March/April 1999

Around 24 March 1999 the HFA became aware of a High Court case in which a pathologist, who was believed to have been practising in the Gisborne region, had mis-read a woman's smears. This awareness grew from a letter to the HFA from the woman's solicitor, newspaper articles in the *New Zealand Herald*, a television item, and telephone calls from the New Zealand Cancer Society and the local National Cervical Screening Programme site.

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1 **Tairawhiti** includes the city of Gisborne and surrounding districts. For the investigation, it does not include Wairoa because the laboratory in Hawke's Bay serviced this area.

2 These reports were presented to the Gisborne Cervical Screening Inquiry.

In the High Court case the plaintiff (Mrs A) alleged that a pathologist (Dr Bottrill) had been grossly negligent in reading and reporting the results of four of her cervical smears, and that this under-reporting had led directly to Mrs A's developing invasive cancer of the cervix. The court case initially suppressed the name of the pathologist, which created some difficulties in identifying and advising the affected area. This order was later lifted with Dr Bottrill's consent. The name of the plaintiff remains suppressed.

Although the High Court judge accepted that Dr Bottrill's method of practice was suboptimal, he also stated that there was no evidence in this case to suggest any systematic pattern of under-or over-reporting of cervical cytology. The judge ruled that Dr Bottrill had been negligent but that his actions did not constitute gross negligence so did not warrant the award of exemplary damages. The Medical Practitioners' Disciplinary Committee had also found Dr Bottrill guilty of conduct unbecoming.

Information about the High Court case was initially reviewed by the manager of the National Cervical Screening Programme (Dr Julia Peters). She considered that the issues raised, and the risk of undermining confidence in the programme, were such that further investigation should be undertaken. The case was subsequently referred to the HFA Personal Health operating group, which was responsible for funding and investigating laboratory services.

From an early stage the option of formally reviewing at least some of the pathologist's smear reading was considered. Clinical advice was sought and a similar case at the Kent and Canterbury Hospital in the United Kingdom was reviewed. In addition, the current owners of the laboratory were contacted in order to establish both the extent to which previous slides were still available and the nature of the transfer of the business on Dr Bottrill's retirement.

The slides referred to in the High Court case were read between 1990 and 1994. Dr Bottrill retired from practice in February 1996 and sold all assets in his company (Gisborne Laboratories Limited) to another laboratory company. The new owners did not take over the previous company.

The laboratory confirmed they still had all slides left by Dr Bottrill, including all abnormal slides prior to 1991, and all slides from 1991 onwards. It was later discovered that some earlier slides reported as normal prior to 1991 were also available. While practising, Dr Bottrill was responsible for reading 90 to 95 percent of all cytology smears in the area. Current cervical screening register information (based on 1999 population projections) suggested that approximately 12,000 eligible women reside in the area, of whom 90 percent were enrolled in the programme, with the five-year coverage rate just under 86 percent.

During April the HFA was informed of another instance where re-reading of slides indicated that the same pathologist (Dr Bottrill) had not detected abnormalities. It was confirmed that this case was separate from the case that had previously been heard in the High Court but further details could not be established at that time. On 20 April 1999 urgent approval was given to a formal project plan detailing the proposed initial review of slides. The plan was to re-read all cervical smear slides from women at most risk and to review other work undertaken by Dr Bottrill during 1995 and 1996. The group of women identified at most risk were those women whose last smear Dr Bottrill had reported as normal, and who had not had a subsequent smear. A Gisborne-based project co-ordinator was appointed to co-ordinate all re-reading, and continued to play a crucial role in the management of the re-reading exercise and the tracing of women.

However, it quickly became apparent that the project plan did not have the full support of all who were consulted, and it was agreed that a multidisciplinary advisory group should be established to guide the HFA's response to the concerns. The advisory group immediately recommended a re-reading of all slides read by the laboratory between 1991 and February 1996. This final report documents the implementation and outcomes of that decision.

The Ministerial Inquiry into the Under-reporting of Cervical Smear Abnormalities in the Gisborne Region

In response to initial re-reading results announced in September 1999, the then Minister of Health, Wyatt Creech, announced a Ministerial inquiry into the Tairawhiti situation. The inquiry sat in Gisborne between April and August 2000.

The *Report of the Ministerial Inquiry into the Under-reporting of Cervical Smear Abnormalities in the Gisborne Region*, published in April 2001,[3] concluded there was 'ample evidence to show that there was an unacceptable level of under-reporting at Gisborne Laboratories between 1990 and March 1996' (p 8). The inquiry team made 46 recommendations addressing systemic issues that arose during the inquiry and related to the management of the National Cervical Screening Programme. The terms of reference for the inquiry and summary of conclusions are documented in Appendix 11.

[3] The inquiry report is available on http://www.csi.org.nz

Part I:
Implementation of the Health Funding Authority Investigation

2 Components of the Investigation

This section outlines the three components of the HFA investigation. Although each is described discretely, they are inevitably inter-related.

Advisory Group

An external multidisciplinary advisory group, comprising four recognised experts and a consumer representative, was appointed. The advisory group was established to provide overall guidance to ensure that women were provided with the right advice and support to maintain confidence in the National Cervical Screening Programme and to provide the HFA with expert advice on a range of matters related to the investigation.

The members of the advisory group were:

- Romia Whaanga, Māori and consumer representative
- Bruce Duncan, public health physician
- Ron Jones, gynaecologist
- Norman Fitzgerald, pathologist
- Brian Cox, epidemiologist and public health physician.

Both Romia Whaanga and Bruce Duncan live and work in the Tairawhiti region.

Appendix 2 provides the terms of reference for the advisory group. Its initial meeting was held on 12 May 1999. It met a total of 11 times, with its final meeting on 18 October 2000. All meetings were chaired by the HFA's project leader (Tracy Mellor). They were attended by the Gisborne-based project co-ordinator (Marie Burgess), representatives of the National Cervical Screening Programme, and other members of the HFA investigation team.

Project brief

The project brief was devised to ensure the safety, health and wellbeing of the women concerned. Its objectives were to:

- ensure women received the appropriate treatment for their health and wellbeing
- determine the extent of the problem regarding the pathologist concerned by assessing whether there had been a systematic mis-reading/under-reporting of slides by the pathologist
- identify those women at risk and determine the appropriate action to address this risk
- maintain public confidence in the National Cervical Screening Programme and to actively encourage enrolment in it as the best protection against cervical cancer.

The tasks of the project were to:

- re-read cervical cytology
- develop a follow-up plan to ensure that the women involved received appropriate assessment and treatment, where relevant
- provide Special Circumstances Support services
- develop a plan for liaison with the Tairawhiti community
- develop a re-read database.

Each of these elements is described in some detail in later sections of this final report.

Re-reading of cervical cytology

The primary objective of the re-reading was the safety, health and wellbeing of the women concerned. It was considered that re-reading of the cervical cytology slides would assist in determining the extent of any problem related to Dr Bottrill's reading of cervical smear tests.

The advisory group recommended that, if possible, the exercise should begin with re-reading a representative sample of slides to enable an initial assessment of the extent of the problem. However, implementing this recommendation was not possible due to the storage and records arrangements at Gisborne Laboratories Limited. The group's second recommendation was that the HFA move immediately to obtain a re-reading of all cervical smears read by Dr Bottrill's laboratory between 1991 and Dr Bottrill's retirement on 4 March 1996. The laboratory confirmed that all cervical cytology slides from Dr Bottrill's laboratory were available from 1991; prior to 1991 the availability of slides was variable. Slides that had been sent to other laboratories for screening were not included in the re-reading.

It was recommended that, if at all possible, the slides should be re-read outside of New Zealand, to ensure independence from the court case and minimise the impact on the day-to-day running of the National Cervical Screening Programme. Criteria were devised to select laboratories (see Appendix 3). Sonic Healthcare Limited (Australia) and its main pathology laboratory Douglass Hanly Moir Pathology were contracted to re-read all the cervical smears to be included in the re-read, between 1 July and 31 December 1999.

A detailed process to manage the re-reading was developed and tested (by Jim DuRose, quality improvement and audit co-ordinator). Slides were sent in batches of four boxes (400 slides) with their corresponding information on electronic disc. Each shipment comprised three batches, which would enable a workflow of 1200 slides to be read per week. Results were received electronically.

Key points concerning the re-reading exercise are as follows.

- A six-month timeframe, starting in 1 July 1999, was set for the project. A total of 22,978 slides were read and the project was completed on time.

- The re-reading laboratory received a copy of the original requisition form with the slide. They did not know the original result, but the slides could be identified as different from those they dealt with in their routine work.
- Douglass Hanly Moir Pathology reported results in their usual coding (which differs slightly from the New Zealand Bethesda coding format). These were electronically mapped, using an agreed mapping system, so that all results were reported electronically using the New Zealand system. Electronic results were sent to the HFA on a regular (weekly) basis. Hard copy reports were issued in the re-reading laboratory's usual report format with Australian terminology.
- All electronic reporting of cervical cytology slides was done in accordance with the Bethesda coding system as used by the New Zealand National Cervical Screening Programme. Hard copy reports were issued in the re-reading laboratory's usual Australian terminology report format.
- A separate and confidential database was built for the re-reading exercise.
- It was recognised that, as with any normal cervical cytology screening that meets expected professional standards, it was still possible for some false negative and false positive results to be reported.

In the final report to the HFA on the re-reading exercise (see Appendix 4), Dr Farnsworth (Douglass Hanly Moir Pathology) noted:

> *The condition of the slides was remarkably good ... and no slides required re-staining. Approximately 50% of the slides did however require re-coverslipping, as up to 20% of the material in these cases was not captured by the original coverslip ...*
>
> *Standard quality assurance measures ... were applied throughout the project. Rapid rescreening was not performed and targeted rescreening was used as per routine protocols ...*
>
> *The criteria used to make the cytopredictions were the conventional appearances described initially by Papanicolaou, Koss and others in the 1940s and 1950s. The terminology has changed somewhat since then but the appearances are essentially the same.*
>
> *The increased incidence of high-grade abnormalities in the slides was readily apparent ... It was quite apparent from the first batch that both the numbers of abnormalities and the detected appearances were very different from those which we normally encounter. All laboratories participating in the project made this observation ...*
>
> *The project was remarkable for the unusual cytopathological changes detected in the cohort of abnormal slides. The **number** of abnormal cells per slide was remarkably high. The remarkably severe nuclear and cytoplasmic changes were also notable, with large keratinising cells and tumour diathesis, more akin to the changes originally described by George Papanicolaou than those normally seen in routine cytological practice.*

The results of the re-reading exercise indicated significant differences in the rate of reporting of abnormal cervical cytology between Gisborne Laboratories and the staff of Douglass Hanly Moir Pathology. The extent of these differences is described and discussed in Part II.

3 Informing Women, Providers and the Wider Community about the Investigation

The primary purpose of the re-reading exercise was to identify and address any risks to the health and wellbeing of the women whose slides had originally been read and reported by Dr Bottrill's laboratory. As the results of the re-reading became available, it became apparent that these re-readings were identifying a significant number of women with cytological abnormalities. Those women with high-grade abnormalities (including ASCUSH, or 'high grade cannot be excluded' – see Section 8 and Appendix 7 for definitions) were the first to be followed up.

The HFA was concerned to provide support for all women while they were awaiting the results of the re-reading of their slides, and particularly for those women whose slides were re-read as abnormal. All local providers and smear takers were kept fully informed of the progress and findings of the investigation. Regular media releases were prepared to ensure the progress of the investigation was communicated as widely as possible.

This section provides more detail about the processes of advising women and their smear takers of the re-reading results, and of following up women with abnormal results. It also describes the services provided to support women throughout the investigation. Most of these services continued until the end of December 2000 (approximately 18 months after the investigation began). Early in 2001 women affected by the investigation were surveyed, to assess their perception of the information and support services provided. The results of the survey, which included a postal questionnaire and focus groups, are reported in Section 10.

Advice and support to all women

As soon as the name suppression order was lifted, the HFA confirmed publicly that Gisborne was the affected area. All Tairawhiti local GPs and smear takers were notified that Tairawhiti was affected, and advised to be cautious when relying on smear results from the Gisborne laboratory. From 10 May 1999 Tairawhiti Healthcare Limited provided an 0800 number to advise and inform any woman concerned about the re-reading. Several public meetings were also held.

Information about the investigation was sent to all households in the Tairawhiti area during the week beginning 7 June 1999 (Appendix 6). It included a form for women to return to the HFA if they did not wish to have their slides re-read; 148 forms were returned. After a review of the early re-read results in October, those women who had chosen not to have their slides re-read were contacted and it was recommended they review their decision. Forty-five women confirmed their decision not to have their slides re-read.

Although every effort was made to ensure that slides belonging to these 45 women were not included in the re-reading, 12 of these slides were re-read. If the re-reading indicated abnormalities that had not been previously detected, the woman was contacted; in all other cases no further action was taken. In all cases the results were not included in the analysis of information used in this report.

Public meetings

Two series of public meetings were held in Gisborne and on the East Coast. The first series, held in May 1999, was to inform the community of the situation, the HFA's steps to protect and support women who might be at risk, and the re-reading exercise. The importance of regular smears and enrolment in the National Cervical Screening Programme were emphasised.

The second series of meetings was held in early April 2000, ahead of the commencement of the Ministerial inquiry. These meetings provided an opportunity for the HFA to ensure people knew about available services, to offer an open forum where issues could be raised, and to answer questions. Confusion over the different purposes of the Ministerial inquiry and the HFA investigation were addressed. The meetings also highlighted the need for support services for women wishing to attend the inquiry.

A final public meeting was held for women in conjunction with the advisory group in October 2000. Its purposes were to enable women to ask questions about the investigation and cervical disease, and to inform people that the investigation was complete.

All meetings were attended by the HFA's project leader, and by Bruce Duncan and Romia Whaanga of the advisory group.

Communication with GPs and smear takers

Three open meetings for GPs and smear takers were held (August and December 1999, March 2000) to provide an update on the progress of the investigation, and to discuss details and implications of the investigation.

There was frequent communication with GPs and smear takers by fax to keep them informed about pre-publication media releases, advice from the advisory group, the investigation's progress, administrative details and any other relevant issues. Bruce Duncan, as a member of the advisory group and as the local Medical Officer of Health, also provided a consistent link between local GPs and the investigation.

Local provider meetings

A local provider advisory group was established and co-ordinated by Tairawhiti Healthcare Limited. It included representatives from all relevant providers (Tairawhiti Healthcare Limited, iwi health providers, smear takers, and GPs), the New Zealand Cancer Society, and women affected (the Mis-read Smear Support Group, and the Māori Cancer Support Group). The group met regularly to discuss issues relating to the co-ordination and provision of services to women. Central agencies, such as the HFA and the Accident Compensation Corporation (ACC), also attended occasionally to discuss matters of concern.

A further series of meetings of providers delivering co-ordination and support services was held between April and September 2000. The facilitator was Romia Whaanga, who also attended the provider advisory group meetings and many other local meetings, thus providing the investigation with an invaluable link to local Māori and consumers.

0800 number

Tairawhiti Healthcare Limited established and staffed an 0800 number from early in May 1999. This service initially identified three key messages for women.

- If you have not had a smear in the last three years, and particularly since before February 1996, have another smear taken.
- If you have had an abnormal smear since February 1996, your treatment programme is being managed by your smear taker / GP, and we are providing them with ongoing advice in relation to any changes that may be recommended. If you have any concerns, contact your smear taker / GP.
- If you have any other concerns, the key person to talk to is your normal smear taker / GP.

Later in the investigation the service was used to provide information to people concerned about the quality of other work done by the laboratory. Women were also able to request their results if they had not yet received them, and to update their details on the National Cervical Screening Register.

The HFA in Wellington managed the follow-up of women with abnormal results who no longer lived in the Tairawhiti area. As it became apparent that a considerable number of women were in this category, the HFA's 0800 number was also made available to people seeking information on the investigation. This service was used by women in Tairawhiti who preferred to speak to someone who was not based in Tairawhiti, as well as by women from outside the area.

Media strategy

Throughout the investigation national media interest was intense. A series of media releases was issued to keep the wider community informed of progress and activity relating to the investigation. Key local stakeholders, such as GPs and smear takers, were sent copies of media releases prior to publication.

The project leader acted as spokesperson throughout the investigation, supported by the HFA's communications team. Key messages were disseminated by responding to requests for interviews – both locally and nationally – from television, radio and newspaper reporters. Two full media conferences were also held.

In addition, a substantial number of associated media inquiries concerning broader cervical screening issues were handled by the manager of the National Cervical Screening Programme.

4 Supporting Women

The HFA was concerned to minimise the barriers to women accessing services. It also aimed to establish personal support services, such as counselling, to assist women, particularly those with high-grade re-read smear results, to manage the impact of these results on their lives. To meet the needs of all women involved, a range of providers was contracted to provide services, and the definition of these services was flexible.

Free smears

On 13 May 1999 the HFA announced that all women in the Tairawhiti region, and any women who had had smears in the Tairawhiti region prior to March 1996, could have a smear funded by the HFA. This initiative supported the advice to be cautious about relying on smear results from the Gisborne laboratory. GPs and smear takers were advised to invoice the HFA for the costs of all these smears. Contracts were awarded to two local Māori providers to enable them to take steps to encourage local women to access the free smears.

Approximately 1700 women were identified who had not had a smear since 1996. The HFA wrote to each of these women specifically to offer them free smears. The free smears were initially available until 30 June 1999, then this was extended until the end of December 1999. Free smears were available to women who had a low-grade result from the re-reading and who had had fewer than two smears since 1996.

GP consultations for women concerned about their results

In addition to providing free smears, the HFA agreed to fund a consultation for any woman concerned about the investigation, and particularly the implications of her re-read results, so that she could discuss these matters with her GP or smear taker. In most cases, the GPs and smear takers used this facility to discuss abnormal re-read results and to decide on the appropriate course of action with the woman.

An unexpected outcome of the notification of results was the level of concern among those women whose results were confirmed as normal. The Gisborne Provider Advisory Group reported anecdotally that many of these women subsequently sought advice and reassurance from their GP or smear taker about the reliability of the smear test. The HFA met the costs of these consultations.

Special Circumstances Support

Support services were established from June 1999 in recognition of the exceptional circumstances of this investigation. These services were designed to help and encourage

women to access assessment and treatment, as well as to provide some tangible support to assist women and their families/whānau to deal with the impact of the re-read results. Support services remained in place until 31 December 2000 and were available for the women involved within the Tairawhiti region, and throughout New Zealand.

Limited support was available for women living in countries where the costs of medical care were not covered by a reciprocal arrangement.

Special Circumstances Support was intended to provide assistance with transport/petrol costs and child care so that women could attend treatment, including diagnosis (colposcopy), or counselling, and to provide assistance with home support to the family/ whānau while a woman was receiving hospital treatment. Special Circumstances Support was available to meet additional food, telephone and other costs incurred by women who had to travel to undergo assessment and/or treatment. Formal counselling was through ACC-registered counsellors, although with the HFA's holistic interpretation of counselling it included, for example, support group meetings and whānau support gatherings.

Tairawhiti Healthcare Limited administered the Special Circumstances Support as part of the co-ordination and support service within the Tairawhiti region, while the HFA administered the services for women in the rest of New Zealand. This service operated continuously from May 1999 to September 2000, and remained available until the end of 2000. Between April and September 2000 the two local Māori providers were contracted to provide additional co-ordination and support services to women who had not been accessing the full range of information and services established as part of the investigation. Under the co-ordination and support service, women were helped to identify and access a wide range of available public services (for example, the service linked with ACC to ensure women had access to good advice about making ACC claims).

5 Follow-up of Women with Abnormal Results

The initial task for the Gisborne-based project co-ordinator was to co-ordinate the shipping and tracking of slides. This role was extended to include contact with and follow-up of the women affected by the re-reading exercise. The project co-ordinator managed the tasks of tracing, contacting and advising women of the outcomes of the re-reading, and implemented steps to follow up women within Tairawhiti. Women no longer living in the Tairawhiti region were referred to the HFA in Wellington.

Contact tracing was a major exercise. The 616 women with high-grade (including ASCUSH) results were prioritised for immediate advice. Strategies to trace women for whom the HFA lacked up-to-date contact details included use of local knowledge of the Tairawhiti community and its networks, the National Health Index number and the electoral roll. Many local GPs and smear takers put considerable effort into tracing these women and providing new contact details; their work on behalf of the women was invaluable.

The next priority was women with low-grade abnormalities. Women whose results were all normal were notified in the last stage in the process.

Women referred for colposcopy

Women identified for priority follow-up included:

- those with re-read results reported as cancer, high-grade or ASCUSH
- those with two low-grade results (women whose re-reading reported one or more slides as low grade and who had a second confirmed low grade, either in a second re-reading result, or subsequently reported by another laboratory).

All women whose re-read results indicated priority follow-up were advised to have a colposcopy, unless they had already received appropriate diagnosis and/or treatment. This advice accorded with the standard protocols for managing women with abnormal smears, as outlined by the National Cervical Screening Programme (1998a).

The National Cervical Screening Programme recommends further diagnosis by colposcopy is necessary for women with persistent low-grade results and for all high-grade cervical abnormalities. Colposcopy is used for further diagnosis rather than for treatment, although treatment and/or further tests can be undertaken at this time. During a colposcopy any abnormalities in the cervical region can be examined in detail by shining a light on the cervix.

Whether a colposcopy is urgent depends on the degree of abnormality indicated by the smear. It is recommended that women with high-grade abnormalities have a colposcopy within one month. For women with two low-grade abnormal smears, colposcopy should be carried out within six months of receipt of the second low-grade result.

In its guidelines the National Cervical Screening Programme (1998a) recommends that all women with high-grade lesions should be colposcoped because the women in whom progression will occur cannot be identified.

Tairawhiti Healthcare Limited arranged additional colposcopy services for women within the Tairawhiti region referred for colposcopy. Its aims were to ensure women were seen as quickly as possible and to minimise disruption to routine gynaecology work in the region. These clinics were conducted regularly between October 1999 and June 2000. Arrangements were made with five experienced colposcopists in other areas of New Zealand to provide equivalent colposcopy services to women no longer living in Tairawhiti.

Because of the large number of women involved, Tairawhiti Healthcare Limited also organised a four-week block of colposcopy clinics (between mid-February and mid-March 2000), when women with two low-grade abnormalities were advised of their results and to have a colposcopy. Most clinics were held at Gisborne Hospital, while a small number were held at Te Puia Hospital so that women living on the East Coast could access them easily.

Arrangements were made for National Women's Hospital, the principal gynaecological teaching hospital in New Zealand, to read and report all histology for these women. This step was considered important to ensure the quality and consistency of histology readings, so that women could have confidence in their results. If required by the local hospital, their normal laboratory also read the histology.

Contacting women with high-grade abnormalities

Women whose slides were reported as high grade (including ASCUSH) were given priority throughout the investigation. As soon as a high-grade result was received from the re-reading laboratory, the woman's GP or smear taker was notified and asked to advise the woman of the result.

The GP or smear taker was advised to immediately refer the woman to an experienced colposcopist, unless she had already received appropriate treatment. It was recommended that all colposcopy be provided as a matter of urgency within two weeks. The woman was also informed that she was entitled to Special Circumstances Support to help her gain access to diagnosis and treatment services (details of which were given to all GPs and smear takers).

Once confirmation had been received from the GP or smear taker that they had contacted the woman, the HFA wrote to her to confirm the result formally. The letter (see Appendix 6) included advice about the availability of additional support services, and a leaflet giving contact details of the local Mis-read Smear Support Group. The letter also stated that the woman would receive a final notification letter once the re-reading exercise was completed, which would detail all her original and re-read results.

Women living overseas were advised to make contact with their GP or smear taker as soon as possible. Their letter contained one package of information for themselves and another for their GP or smear taker. The information outlined the nature of the investigation, the woman's results, and follow-up advice, in accordance with that recommended by the advisory group.

Contacting women with two low-grade abnormalities

Women with two low-grade results were identified and contacted during February 2000. The same process was used of notifying GPs and smear takers first and then contacting the women as described above.

Under normal circumstances the National Cervical Screening Programme (1998a) advises that women with a first low-grade abnormality and a normal smear history have their next smear taken at six months. If this smear is also abnormal, it recommends colposcopy examination to enable a definite diagnosis. This examination should be carried out within six months of referral. As a part of the investigation, the HFA Authority notified all women who had two low-grade results, including one such result picked up in the re-reading.

Women referred for further smears

Follow-up of women with a single low-grade abnormality, or a single unsatisfactory smear, commenced in February 2000. For women with one low-grade smear result not previously identified, the advisory group recommended that treatment follow the National Cervical Screening Programme guidelines for managing abnormal smears. Hence the advisory group recommended encouraging women to have at least two smears following the low grade identified by the re-reading.

Women who had not had a subsequent smear were to be prioritised and advised to have another smear as soon as possible.

Notification of final results to women

On Monday, 6 March 2000, letters were sent to each woman (a total of 12,099) to notify them of their result from the re-reading. Information on the availability of support services and the opportunity to discuss their results with their GP or smear taker was included. A range of letters was used, according to the re-read results for each woman. Appendix 6 includes a copy of the letter sent to women whose results were all confirmed as normal.

Women whose slides had not been re-read because they had not initially been read by Dr Bottrill's laboratory were advised of this as part of the notification of all results.

6 Re-reading of Other Pathology Specimens

Throughout the investigation the HFA was aware that it might be necessary to look more closely at all pathology reported by the Gisborne laboratory. However, as almost all the evidence of potential mis-reading was based on cervical cytology, it was decided that this particular aspect of pathology would be the initial focus of the investigation.

When the extent of the difference between the original and re-reading results became apparent, the HFA decided to look more closely at histology reporting from the Gisborne laboratory. The advisory group recommended that breast tissue specimens be re-read, as in this area it was still possible to change outcomes for patients if any under-reporting was identified, and it would provide an accurate indicator of any potential problems.

The HFA arranged for Dr James White (a specialist in breast pathology) to re-read 380 breast histology specimens. Dr Norman Fitzgerald (a pathologist and member of the investigation's advisory group) compared the results from Dr White to those initially reported by the Gisborne laboratory. In 17 cases the Gisborne laboratory results differed from those reported by Dr White.

Professor John Collins (an expert breast surgeon) reviewed these cases. He concluded that in most the differences were minor, but that in two cases the differences were clinically significant. The people affected were advised of these differences by the practitioner currently responsible for their care.

The advisory group considered the results of this review, together with information about a small number of other cases in which it appeared that histology might have been misreported. On the basis of the information available to them, the advisory group recommended that no further re-reading be undertaken. The HFA accepted this recommendation in March 2000.

7 The Re-read Database

Establishing the database

A distinct, separate database was built for the cytology re-reading exercise. To save time and cost, the National Cervical Screening Register software and format were used. The re-read database is currently maintained and managed by the National Cervical Screening Register staff in the Ministry of Health as a separate entity from the Register.

All the original results were either copied across from the National Cervical Screening Register or manually entered for women who were not on the Register. Ethnicity data was recorded only where it was already available.

On completion of the re-reading exercise the database was extended (by Eve McMahon, quality improvement and audit co-ordinator) to assist follow-up of the women involved in the investigation. It was anticipated the database would:

- enable the HFA to ascertain that all women affected by the re-reading of slides had been contacted and offered appropriate follow-up diagnosis and treatment
- enable analysis of the outcomes of the re-read exercise
- enable a detailed understanding of the impact of the differences in results reported by the original and re-reading laboratories.

Data was accessed from a range of sources, including the National Cervical Screening Register, original cytology and histology forms, colposcopy data from the colposcopists who undertook further assessment and treatment of women, and the outcome of HFA activities to trace women.

There has been a request to anonymously link the database with the slides. However, a legislative change would be required before this link could be made. In the meantime, MedLab Hamilton holds the slides in storage.

Privacy and confidentiality

Advice was sought to ensure the HFA had the legal authority to collect data from the National Cervical Screening Register and from the providers involved in delivering services associated with the investigation.

The letter sent to all women on 6 March 2000 with their smear results advised of the HFA's intention to establish a re-read database. It stated that the database would be made available to government agencies and health researchers to enable the health sector to research and understand the wider implications of the investigation. Women were invited to contact the HFA if they did not wish to have their data included in the re-read database, and a small number of women have done so. Their data has been excluded from the database, and is not included in this report.

In view of the limited number of women wishing their data to be excluded from the re-read database, the HFA has proceeded on the basis that most women affected want, and expect, the information from the investigation to be used in ways that will help to improve services available to women, and understanding of cervical screening and the development of cervical abnormalities. In particular, it is hoped the information gained can improve understanding of the extent to which the quality of any one component of the National Cervical Screening Programme can impact on the outcomes for individual women.

Ethnicity data

The National Kaitiaki Group has given permission for Māori data obtained from the National Cervical Screening Register to be analysed and published. The further release of this data is subject to approval by the National Kaitiaki Group.

Separate data on Pacific women has not been published as the numbers involved are very small and could lead to identification of individual women. All women who have recorded an ethnicity other than Māori are classified as non-Māori in the results.

Ethical issues

The Tairawhiti Regional Ethics Committee was advised of the HFA's intentions in relation to the establishment and use of the database.

Data quality

In constructing the database, detailed procedures were developed to ensure accuracy in identifying slides and individual details.

Most of the data, in particular cytology and histology data, has been obtained and entered from electronic sources. The remainder has been manually entered by an experienced clinical coder using a single data-entry process. The data-entry process has included internal checking procedures.

To complete an audit of such a large amount of data in a limited timeframe would be very labour intensive, so relatively small samples were drawn. Statistical advice was sought to determine a sampling protocol, and an audit of a random sample of three subpopulations of women was undertaken.

All cytology reports – both the original and the re-read – for each woman in the sample were audited against five fields: name, date of birth, smear number, date of smear and smear result. The audit consisted of three parts, as follows.

1 All cytology reports of a random sample of 500 (5 percent) of the 10,000 women with normal original and re-read results were audited.

Finding: no errors identified.

2 All cytology reports and colposcopy records of a random sample of 164 (15 percent) of the 1064 women with abnormal results and who were recommended for colposcopy were audited. Colposcopy records were audited against six fields: National Health Index number, date of colposcopy, status of the colposcopy (satisfactory or unsatisfactory), colposcopy diagnosis, treatment, recommendation for follow-up.

Findings:
- *two cytology errors identified*
- *five errors in colposcopy data.*

3 All cytology records of the 39 women reported with cervical cancer were audited. In addition, the Cancer Registry was asked to confirm the diagnosis and date of diagnosis for the women recorded as having cervical cancer.

Findings:
- *no errors in cytology data identified*
- *the Cancer Registry could not confirm the diagnosis for one woman who was recorded as having cervical cancer diagnosed between 1991 and 1996.*

Altogether 1564 cytology reports were audited from the 703 women. It was initially assumed that the cytology data was in good order due to the rigorous checking processes at the time of both data entry and the ongoing follow-up of women. The report on the data audit to the inquiry concluded the cytology data demonstrated an error rate 'consistent with data entered once in a large database and is not unreasonable'.

Using the database for research

It is anticipated that interested researchers from universities, hospitals and other institutions will seek to access the database for research purposes. Appropriate requests for access to the data are encouraged to ensure that knowledge of cervical disease increases as a result of the experiences of the women in Tairawhiti.

Data can be made available to approved researchers in an anonymous form with appropriate ethical and/or other relevant approval. Requests for access to the database should be made to the Clinical Director of the National Screening Unit.

Any requests for data identifying Māori women should be made to the National Kaitiaki Group, Ministry of Health, in accordance with the Kaitiaki regulations.

Research proposals must conform to the standard protocols for ethical research.

Part II:
Outcomes for Women

8 Outcomes Information

In this part the aim is to answer the questions most commonly asked in relation to the investigation.

The core question and four specific questions

The core question is, *How many women have required further assessment and treatment as a result of Dr Bottrill's performance and as identified by the investigation, and to what extent have they required such assessment and treatment?*

The core question is approached by addressing these four specific questions.

1 What were the results reported by the re-reading laboratory in comparison with those reported by the original laboratory?

2 To what extent did women have smears reported with different results?

3 How many women have been diagnosed with cancer or with high-grade abnormalities since the investigation began in May 1999?

4 How many women have died of cervical cancer, and when were they diagnosed?

In cases where the question cannot be fully answered, the reasons for the difficulty are outlined and some possible answers suggested.

First, however, a number of factors are identified that should be taken into account when considering the outcomes information.

Complexity and accuracy of data

The findings from the investigation involve a complex and diverse range of issues, so it is not always possible to draw conclusions from the information available. The findings have been presented clearly and simply so that they are readily understandable. Rather than introducing a wider range of questions, this document focuses on reporting the findings for the women involved in the investigation and addressing the specific questions identified above.

For greater clarity, the data has been simplified by defining outcome categories for the women. In general these categories have been derived from the highest grade of abnormality reported on the re-read results, as these were used as the basis of the follow-up protocols to ensure women received appropriate ongoing assessment. One consequence of this categorisation is a loss of detail and complexity, which means the approach carries a risk of oversimplification.

The data used in these reports is based on the data entered in the database. Data has been provided only where it was considered accurate as at 30 June 2001.

Where data can be verified by external sources such as those managed by the New Zealand Health Information System (NZHIS) Cancer Registry and the Mortality Registry, this work has been undertaken. Hence, each woman reported as having cervical cancer or as having died, including those who died from cervical cancer, has been confirmed by NZHIS at the NHI level.

Comparison of read and re-read techniques

In comparing the re-read results with the original results (reported by Dr Bottrill's laboratory) it is important to remember that the cervical smear test is essentially the same process today as it was in the early 1990s. In the re-reading of almost 23,000 slides from Gisborne originally read from 1991 to March 1996, the techniques used were similar to those in the original reading. The re-reading laboratory manually screened each slide with only a copy of the original request form. The key difference was that the ASCUSH code was used for the re-reading, while it was not used in New Zealand until 1998 (see below).

The Douglass Hanly Moir Pathology screeners were able to identify the slides as different from their normal work, and it is possible that they had a heightened awareness of potential problems when re-reading the slides. It is widely accepted that such awareness is likely to result in greater sensitivity, and the identification of more abnormalities than would be expected with normal workflow and processes. However, the director of the main laboratory undertaking the re-reading has expressed her confidence that in all smears reported as cancer or high grade, the abnormalities are clearly apparent and the results of any possible increased sensitivity would be contained within the ASCUSH category.

ASCUS, ASCUSH and ASCUSL coding

ASCUS is a Bethesda reporting category for Atypical Squamous Cells of Undetermined Significance (see Appendix 7 for definitions). The National Cervical Screening Programme now uses one subcategory of ASCUS (C3A1E) to indicate that a high-grade lesion cannot be excluded. This category has been commonly used in Australia, and was used by the re-reading laboratory. It has been mapped to ASCUSH, and was included in the definition of high-grade abnormalities for the purposes of referring women for colposcopy. Since this category was introduced into New Zealand in 1998, its use by laboratories has been variable.

The remaining ASCUS codes are categorised as low-grade abnormalities, and have been mapped to ASCUSL. In reporting a few ASCUSL codes, Douglass Hanly Moir Pathology also recommended that the women be referred for colposcopy. For these women, the referral recommendation was passed on, and their slides were classified as low grade in summary comparisons.

Quality of re-reading

It is recognised among laboratories that read cervical cytology slides that a percentage of abnormalities will not be identified. This principle also applies to the results reported by the re-reading laboratory. The HFA and the advisory group acted on the basis the re-read results were accurate.

The re-reading laboratory could not report a result for 1206 slides due to the unsatisfactory state of slides. Among this group were 86 smears reported by the Gisborne laboratory as unsatisfactory. The original results from 59 slides were missing, and could therefore not be compared against the re-reading results.

The data presented have been selected to address the specific questions identified above. The presentation assumes the re-read results are accurate. However, in a number of instances the original results indicate a higher grade of abnormality than that reported on the re-read.

To balance any bias inherent in this report, data is presented from the perspectives of both:

- the original results, as reported by Gisborne Laboratories Limited (jointly owned by Dr Bottrill and a partner)
- the re-read results, as reported by Douglass Hanly Moir Pathology, Sydney.

Division of data into three periods

The data presentation refers to three periods:

1 from 1991 to March 1996, while Dr Bottrill was practising as a pathologist at Gisborne Laboratories Limited

2 from April 1996 to April 1999, after Dr Bottrill's retirement and before the investigation started

3 from May 1999, when the HFA investigation began, to 31 March 2001, when the data was updated for this report.

The data has been divided in this way to allow us to identify the extent to which abnormalities were detected while Dr Bottrill was practising, and the extent to which they were found as a result of the investigation. However, because of the complexities of both the natural history of the disease, and of the National Cervical Screening Programme during this period, it is not possible to draw direct conclusions from this information.

Defining high-grade abnormalities

For the purposes of this report, a diagnosis of high-grade abnormality is defined as a histologically confirmed high-grade abnormality. The limitations of histology in providing an absolute diagnosis are acknowledged.

9 The Impact on Women

This section draws on the re-read database to address the four specific questions identified as a concern for this report:

1 What were the smear results reported by the re-reading laboratory in comparison with those reported by the original laboratory?

2 To what extent did women have smears reported with different results and what action was taken as a result?

3 How many women have been diagnosed with cancer or with high-grade abnormalities since the investigation began in May 1999?

4 How many women have died of cervical cancer?

It also includes a comparison of the abnormality reporting rates for those women with a histologically confirmed high-grade abnormality.

Answering Question 1: comparing results of the two smear readings (original and re-read)

As part of the investigation, 22,976 smears from 12,099 women were re-read. The vast majority of smears (82 percent, or 18,751 smears) were reported as normal by both the original and the re-reading laboratories. However, there were significant differences in the reporting of other results.

The re-reading laboratory reported that, of 22,096 smears originally reported as normal, 10 percent (2244) were abnormal. Of these 2244 abnormal smears, 307 were re-read as high grade or cancer, and a further 255 were re-read as ASCUSH (high grade cannot be excluded).

Appendix 5 presents details of the smear results from the original and re-reading laboratories.

- Table A5.1 compares all smear results and distinguishes between results reported as cancer and high grade, and between those reported as low grade and ASCUS.
- Table A5.2 compares all smear results that both laboratories reported as A1 (slides considered fully adequate for reporting).
- The ‘outside normal limits’ category used by the Gisborne laboratory is analysed in detail.

Answering Question 2: extent of differences for individual women between the two readings

For almost 10,000 women, all results reported were the same from both laboratories; the smears of 9580 women were originally reported and re-read as normal. However, 1995 women were advised of abnormalities, many of which had been previously unreported.

Throughout the investigation the priority was to advise women of abnormal results reported by the re-reading, and to ensure they received appropriate advice, treatment and support. Of the women with abnormal results from the re-reading, 616 were advised of 'high-grade' results (cancer, high grade or ASCUSH) and referred for colposcopy if appropriate diagnosis and/or treatment had not been provided already.

Of the 616 women with 'high-grade' re-read results:

- for 375 women, all their original results (from more than one smear in some cases) had been normal
- for 56 women, their most severe original results had been ASCUS
- for 88 women, their most severe original results had been low grade.

Table 1 provides further detail. Because it is not possible to directly compare smears reported by either laboratory as unsatisfactory, 'outside normal limits', or for which no result was reported, these have not been included in this table. Table 1 therefore refers to a total of 11,708 women (97 percent of the total number of women in the re-read exercise).

Table 1: Highest original cytology results compared with the highest re-read cytology results, for all women*

Original result categories	Re-read result categories					
	Cancer	**High grade**	**ASCUSH**	**Low grade**	**ASCUS**	**Normal**
Cancer	9**		1†			1
High grade	9‡	77	1	11		7
Low grade	1	78	9	46	28	53
ASCUS	2	40	14	21	35	72
Normal	4	198	173	357	881	9580
Total	**25**	**393**	**198**	**435**	**944**	**9713**

Notes:

* Women have been classified according to the highest degree of cervical smear abnormality reported.

** The grey boxes show the number of women for whom both the original and the re-reading laboratories reported the same result.

† The area above the shaded line shows data where the re-reading laboratory reported a lower grade of abnormality than the original laboratory.

‡ The area below the shaded line shows data where the original laboratory reported a lower grade of abnormality than the re-reading laboratory.

As Table 1 shows, the reporting patterns of the original and the re-reading laboratories were quite different. In the original reading, 95 percent of women received reports of normal smears, whereas the re-reading laboratory reported only 81 percent as normal.

Figures 1 and 2 clearly demonstrate this difference: Figures 1a and 1b display the original cytology results reported for all women, while Figures 2a and 2b show the re-read cytology results. Figures 1a and 2a present the cytology results for all women, whereas Figures 1b and 2b provide a breakdown of those whose slides were read as abnormal. It is clear from both figures that normal results were reported for most women. The data for these figures is included in Appendix 8 (Tables A8.1 and A8.2).

Figure 1: Original cytology results

1a Original results for all women **1b Breakdown of abnormal original results**

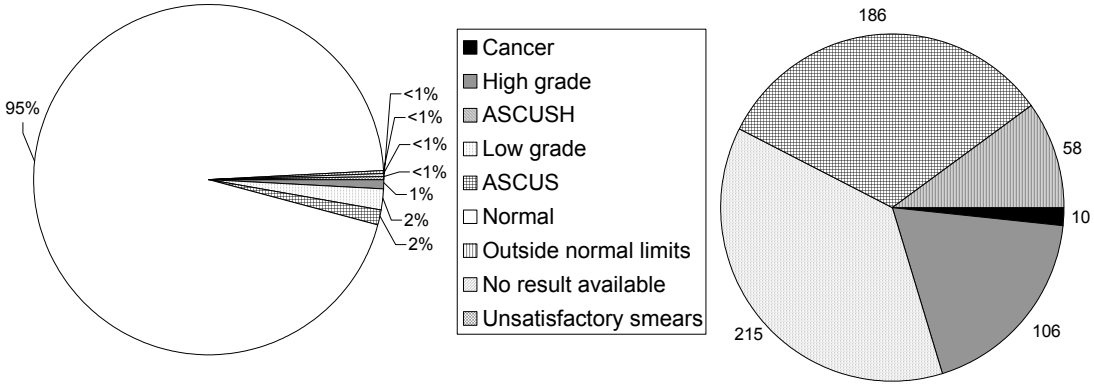
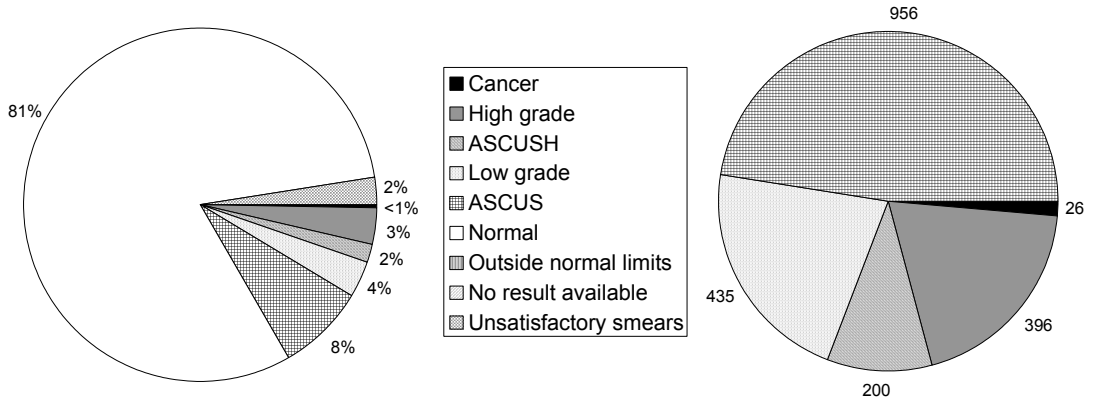


Figure 2: Cytology results from re-reading

2a Re-read results for all women **2b Breakdown of abnormal re-read results**



Answering Question 3: number of women and timing of diagnoses of cervical cancer or high-grade abnormalities

Since 1991 at least 45 women have been diagnosed with cervical cancer. A comparison of time of diagnosis of cervical cancer against the original and re-read results is included in Appendix 10 (Table A10.5). Table 3 shows that 14 of these women have been diagnosed with cervical cancer since the investigation began in May 1999. These have been confirmed with the Cancer Registry.

Table 3: Number of women diagnosed with cervical cancer

	Period of first diagnosis		
	To February 1996	**March 1996 – April 1999**	**May 1999 – June 2000**
No. of women	22	9	14

Appendix 10 presents a series of detailed tables that describe the time period when women first had a colposcopy, whether a biopsy was taken, the diagnosis reported on histology (or reported without histology, if this is the only information in the records), and histology results for all women who have had a colposcopy since May 1999. The key results from these tables are summarised in this section.

Since 1991 at least 236 women have been diagnosed with a high-grade (CIN 2/3) abnormality. Of these, 102 have been diagnosed following a first colposcopy carried out since May 1999.

Table 4: Number of women with high-grade abnormalities

	Period of first colposcopy		
	To February 1996	**March 1996 – April 1999**	**May 1999 – June 2000**
No. of women	65	69	102

For 91 of these women their original result was normal (Tables A10.3c and A10.4c).

As a result of the re-reading exercise 577 women have undergone an initial colposcopy since May 1999 (Appendix 10, Tables A10.1 and A10.2).

Answering Question 4: number of deaths from cervical cancer

Of the 12,099 women affected by the investigation, 304 have died. For nine of these women the cause of death was cervical cancer.

It is important to note that death has not been linked to either the time or severity of first diagnosis. Clinical audit would be required to adequately identify if any women could have entered treatment earlier. The cause of death has been confirmed through the Cancer Registry.

Comparison of the abnormality reporting rates for those women with high-grade histology results

This section illustrates the extent of the differences in cytology reporting by identifying the percentage of women with high-grade abnormalities which were histologically confirmed and comparing these to their original and re-read cytology results. Percentages are derived from Tables A10.3 and A10.4.

Between 1991 and 2001 a total of 260 women had histologically confirmed high-grade abnormalities (CIN 2/3 and cancer) immediately following an initial colposcopy.

For 40 (15 percent) of the 260 women their original cytology result had been reported as high grade (including cancer) and a further 46 (18 percent) women had some other abnormal cytology result (low grade, ASCUS, ASCUSH).

For 142 (55 percent) of these same 260 women, the re-reading result was reported as high grade (including cancer), and a further 106 (41 percent) women received re-read results indicating some other abnormality.

In total, 33 percent (86) of the 260 women with histologically confirmed high-grade abnormalities had originally received abnormal cytology results. This compares with a total of 95 percent (248) of the 260 women who had received abnormal cytology results from the re-reading exercise.

10 Concluding the Investigation

In concluding the final report this section covers:

- the process of tracing women whose smears were read by the Gisborne laboratory
- women's perceptions of the services provided as part of the investigation

Tracing women

The women were the main focus of the investigation. A prioritised approach was adopted to tracing and contacting women, with the greatest priority being given to those with the most severe abnormalities reported by the re-reading laboratory.

Where the appropriate information was available, details of a single low-grade or unsatisfactory result were sent to the woman's smear taker. All women have been sent a final notification letter. No further action was taken to trace women with all normal results, or women with a single low-grade or unsatisfactory result and evidence of further smears, colposcopy or histology.

All methods at the HFA's disposal were used to trace women for whom colposcopy was recommended (those with a re-read result reported as cancer, high grade, ASCUSH, or two low grades). Women with a single low-grade re-read result and no evidence of a subsequent smear, colposcopy or histology were also traced.

At the time of publication there were nine women still to be contacted. These women had no evidence of seeking further assessment and had either high-grade or low-grade results indicating follow-up was necessary.

For any woman enrolled on the National Cervical Screening Register with whom contact has not been made, a flag has been placed on the Register. In this way, when they next present for screening or assessment they can be informed of their results and advised appropriately.

Women's perceptions of the services provided

A review was undertaken on behalf of the HFA to determine the effectiveness of the communication strategy and services put in place.

There were two parts to the review. First, a survey was sent to a sample of 3854 women alive and living in New Zealand, which included all women who had abnormal results and a sample of women with normal re-read results. There were 945 questionnaires returned and included in the analysis, an overall response rate of 26.5 percent. The survey asked women to identify:

- the way in which the HFA made information about the re-reading project and support services available to women

- whether the HFA provided sufficient information to women about the services available
- whether services required by women were available to them.

Second, a series of interviews was undertaken with women living in Tairawhiti and local providers to further explore matters relating to the availability and delivery of services from the perspective of each of the providers and women.

The overall response rate to the survey for women with normal re-read results was approximately 50 percent higher than the response rates for women with abnormal results, while non-Māori were twice as likely to respond to the survey as Māori. The media, particularly television, were the main source for women to learn about the re-read project. The key results from the report are provided below.

- The letter from the HFA was the principal source for women with normal and low-grade results to learn about their re-read results. However, for women with a high-grade result, the GP or smear taker were equally as likely to be the first source of notification.
- Of all the women who had abnormal smear results, approximately two-thirds of those who responded thought that the information they received was very informative, while over 85 percent of women who responded thought the information was easy to understand.
- In order of magnitude, the GP or smear taker, HFA pamphlets and media releases were the main sources for women learning about the services available, regardless of smear result type.
- A free appointment was the most common service used by women who had a high-grade result, followed by a free smear and transport assistance. Free smears were the most common service used by women with at least one low-grade result along with free appointments.
- Women with abnormal smear results living outside the Tairawhiti region were less likely to access services than women living in the Tairawhiti region.
- For seven of eight criteria rated, more than 50 percent of respondents agreed or strongly agreed that services met their needs. On the criterion *service was easy to access through the 0800 number* less than 50 percent of women agreed or strongly agreed that service was easy to access through the 0800 number.
- Māori women were less likely than non-Māori to think that services provided met their specific needs.

Overall, women reported that the services provided by the HFA were useful and met their needs. Comments indicated women would have liked services to be available sooner and some women reported they did not know of the specific services available to them. In particular, a number of women reported they had had to pay for their smear despite free smears being offered by the HFA.

Providers in Tairawhiti reported that they were well informed throughout the investigation and that overall the number of women requiring smears and referral for further assessment had been managed as efficiently as possible. Services such as providing a mobile colposcopy clinic to women on the East Coast were valued.

Appendices

Appendix 1: Cervical Screening in New Zealand

Structure of the New Zealand health service 1999–2000

The New Zealand health services have undergone key structural changes since 1993, when a purchaser–provider split was introduced. The Health and Disability Services Act 1993 established the roles of the key agencies and provided a framework for funding and purchasing in the health sector.

The Department of Health shed the majority of its operational functions. It then focused on developing policy, monitoring performance, providing Ministerial support services, and administering legislation and regulation.

Four Regional Health Authorities replaced the 14 Area Health Boards. They purchased all personal health and disability support services and 23 Crown Health Enterprises (later to become Hospital and Health Services), each of which centred on a public hospital, as the new publicly owned providers of health care services. From 1 July 1997 the four Regional Health Authorities were amalgamated into one health authority (the Transitional Health Authority), which operated as the Health Funding Authority (HFA) from 1 August 1998 to 31 December 2000.

The passage of the New Zealand Public Health and Disability Act 2000 significantly changed the structure of the health section. From 1 January 2001 the HFA was disestablished. Its activities were absorbed into the Ministry of Health and 21 newly established District Health Boards.

The New Zealand health system is predominantly publicly funded. Health services are provided by a mix of:

- publicly owned providers – publicly owned hospitals provide most secondary medical and surgical care
- private providers – most primary care is provided by publicly subsidised but privately run general practices; the private hospital sector specialises mainly in elective surgery and long-term geriatric hospital services
- a wide range of not-for-profit providers – particularly involved in disability support and mental health services.

Most women are required to pay at least part of the cost of GP consultations, including those consultations where a smear is taken. Following an abnormal smear result, diagnosis and treatment are normally fully subsidised for all women.

Health Funding Authority

The functions of the HFA were to:

- fund health and disability services for the people of New Zealand
- allocate resources, taking into consideration effectiveness, cost, equity, Māori health and acceptability
- deliver on the Government's medium-term strategy for disability and support services.

The HFA had five operating groups: Personal Health, Public Health, Māori Health, Mental Health and Disability Support Services. Three corporate groups were responsible for maintaining the HFA infrastructure including financial systems, as well as for strategic planning at a corporate level, servicing the operating groups, and carrying out other statutory functions. Each operating group and corporate group had a general manager, who reported to the chief executive officer. The chief executive officer reported to the chairperson of the HFA Board.

In general, each operating group had a similar structure, although there was some variability. The basic structure included four locality teams, situated in Auckland, Hamilton, Wellington and Christchurch or Dunedin, responsible for developing regional plans and purchasing services within their localities. Other components were a change-management team, service strategy team and support staff for the general manager.

Management of the National Cervical Screening Programme within the HFA

Within the HFA, the Public Health operating group and the Personal Health operating group had major roles and responsibilities in regard to the National Cervical Screening Programme.

The *Public Health operating group* had overall responsibility for the National Cervical Screening Programme. It had particular responsibility for programme and policy development, data management, programme monitoring and evaluation, and national provider co-ordination. It also funded national activities (such as health promotion and media recruitment campaigns) and local co-ordination and register entry sites.

Within the Public Health operating group, locality teams were responsible for purchasing regional co-ordination services (in the same 14 regions covered by the previous area health boards).

Many of the services provided were personal health services purchased through the *Personal Health operating group*. For the National Cervical Screening Programme, the locality teams purchased smear taking (mostly as part of General Medical Services subsidies or capitated contracts for primary care), smear reading services from community and hospital laboratories, and colposcopy and treatment services from hospitals.

The Personal Health operating group was responsible for developing laboratory services and primary care purchasing strategies that affected or interfaced with the National Cervical Screening Programme. In addition, it was responsible for the review and/or audit activities in relation to laboratory services in general.

The role of the Accident Compensation Corporation

Through the Accident Compensation Corporation (ACC), New Zealand maintains a no-fault, comprehensive 24-hour personal accident insurance scheme. ACC is a Crown-owned entity. It is the sole New Zealand provider of personal accident insurance cover for people who suffer a personal injury as a result of an accident in either a work or a non-work environment. Accident, work-related process, disease or infection, medical mishap or error, sexual assault and abuse may cause personal injuries. A personal injury may be physical or mental. Medical misadventure is a personal injury resulting from treatment by a registered health professional.

ACC's responsibilities include delivering, establishing and operating an insurance-based scheme to rehabilitate and compensate persons who suffer personal injury (as defined in the Accident Insurance Act 1998). ACC also has a role in reducing the social, economic and physical impact of personal injury on individuals and the community.

Examples of assistance include treatment costs, travel, compensation for wages, child care, special equipment and education support.

Principles of population-based screening programmes

Population-based screening programmes aim to reduce the incidence and mortality of disease (in this case, cervical cancer) by routinely screening an entire defined population at regular intervals. The screening test is intended to detect the disease or its precursors at a very early stage, enabling early diagnosis and treatment when it is likely to be most successful.

Population-based screening programmes specifically target and invite an asymptomatic population to be tested for the presence or precursors of a disease. The health sector takes these initiatives, so it has an ethical responsibility to ensure that overall the benefits of screening outweigh the risks. Hence, services for screening, diagnosis and treatment must be of very high quality and provided in a timely manner. In addition, it is necessary to inform the eligible population of both the benefits and risks of screening so individuals are able to make an informed decision regarding their own participation.

To succeed in reducing the incidence and mortality from a particular condition, a screening programme depends on high levels of enrolment and coverage, and high-quality screening and follow-up services. It must also be properly organised and co-ordinated.

The WHO has promulgated guidelines that identify the key organisational requirements of an effective cervical screening programme. These requirements include:

- a central office or individual responsible for planning, co-ordinating, monitoring and evaluating the programme
- computer-based information systems
- extensive coverage of the eligible population
- quality control for both smear taking and smear reading
- measures to ensure that women with abnormal smears are followed up and treated.

The National Cervical Screening Programme

The need for a New Zealand population-based cervical screening programme was first identified in 1984. A working group was then formed in 1985 to make recommendations on routine cervical screening for New Zealand. In August 1988 Dame Silvia Cartwright released *The Report of the Committee of Inquiry into Allegations Concerning the Treatment of Cervical Cancer at National Women's Hospital and into Other Related Matters*, recommending as a matter of urgency that a national population-based cervical screening programme be established. The National Cervical Screening Programme was launched nationally in 1990 as the first national cancer screening programme in New Zealand. A unit within the Ministry of Health provided national co-ordination and leadership, along with management of the register.

Initially, to enrol in the programme women were required to complete an application form in writing stating they wanted to be a part of the programme. Since 1993 a legislative change allowed for the inclusion of all women who did not object, and for the recording of cervical histology test results as well as cytology.

Incidence of cervical cancer

It is estimated that about one in every 97 women in New Zealand can expect to develop cancer of the cervix before the age of 75 years. The rates for incidence and mortality increase with age, as cervical cancer usually takes about 10 to 15 years to develop. Cox and Skegg (1992) have estimated that without an organised screening programme there would be about 340 new cases and 116 deaths per year.

Since the programme began the rates of both disease and deaths from cervical cancer have fallen significantly. From 1987 to 1996 cervical cancer incidence rates decreased by 22 per cent. Over the same 10-year period the death rate for cervical cancer dropped by 43 percent. Age-standardised incidence rates for cervical cancer have declined from 13 per 100,000 in 1988 to 9.2 per 100,000 in 1998. Age-standardised mortality rates for cervical cancer have declined from 4.9 per 100,000 in 1988 to 2.9 per 100,000 in 1997.

At the beginning of December 2000 there were 978,586 New Zealand women aged 20 to 69 years enrolled on the National Cervical Screening Programme. This number represents some 90.17 percent of eligible women.

Appendix 2: Terms of Reference for the Investigation Advisory Group

The advisory group consists of a multidisciplinary team of recognised experts and consumer representative to assist the HFA's investigation of cervical screening – pathology in the Gisborne area. The role of the investigation advisory group is:

1. To provide overall guidance aimed at ensuring that women are provided with the right advice and support to maintain confidence in the cervical screening programme.

2. To provide expert advice to the HFA on the detailed design and priorities of the investigation, and on the methodologies and implementation processes. This advice may include, but is not limited to:

    - whether any cervical smear specimens should be re-read, and if so, which specimens should be reviewed and the methods for reviewing specimens. Review may be required for treatment reasons and/or to enable the HFA to assess the extent of inaccurate reporting
    - whether women should be advised to have additional smear tests, and if so which woman and how they are contacted
    - what clinical follow-up and support women should be offered
    - the priority in which different elements of the investigation should be undertaken
    - the communication strategy, including methods for communicating with women and GPs / smear takers

3. To provide expert advice to enable the HFA to provide the best possible advice and information to GPs, smear takers and other health professionals. This advice and information would be provided both to those health professionals currently working in the area, and to at least some of those treating women who had smears read in Gisborne prior to 1996.

4. To provide expert advice to the HFA on whether there is any basis for further investigation of other pathology reporting from the laboratory.

5. To make recommendations to the HFA to identify any issues or areas of concern in relation to the Gisborne case. These could have implications for national monitoring, evaluation and quality assurance processes.

6. To provide expert advice and comment on the final report, which will be a public document.

Appendix 3: Rationale and Criteria for Laboratory Selection

At its meeting on 26 May 1999, the investigation advisory group recommended the following.

> *The investigation of cervical screening pathology in Gisborne/Tairawhiti involves the re-reading of approximately 30,000 cervical smears from the period 1991 – 3 March 1996. The preferred option is to have the slides re-read by a large, reputable overseas laboratory. The next option would be to go outside NZ with more than one lab. If either of these cannot be arranged then we would consider suitable New Zealand laboratories, as they would also meet the necessary quality requirements. The preference is to have this work performed outside New Zealand due to the following rationale.*

The rationale for an overseas re-reading laboratory included:

- to maintain total independence from the issue in New Zealand
- to keep the re-reading of the Gisborne slides independent of the ongoing laboratory requirements for cervical screening in New Zealand, including the National Cervical Screening Programme. This will ensure that impact from re-reading of approximately 30,000 slides is fully minimised with respect to the programme and its current initiatives.

Criteria for laboratory selection

1 No demonstrable conflict of interest from previous involvement in either Dr Michael Bottrill's High Court case or the Medical Council's disciplinary hearing.

2 All slides to be re-read at one laboratory site; or if at several sites, then to have the same or substantially similar quality assurance processes.

3 If possible, to complete all by 30 November 1999.

4 Fully accredited by IANZ (International Accreditation New Zealand) or equivalent. Note that Australian labs are accredited by a similar organisation known as NATA, the National Association of Testing Authorities.

5 Perform adequate throughput of cervical cytology smears per year.

6 Have qualified cytopathologist to oversee the re-reading exercise. Senior cyto-technologists to undertake all re-reading.

7 Price is fair and reasonable.

Appendix 4: Reading the Slides – Report from Douglass Hanly Moir Pathology (DHM), Sydney

Background

After an initial approach by the investigation team and following due discussion, we decided to explore the feasibility of this large and complex exercise, using the multilaboratory capacity within the Sonic Healthcare group and our prior experience with shipments of Pap smears to and from Hong Kong. An additional consideration for our company was the feasibility of expeditious completion of the project (as requested by the HFA) within the constraints of routine cytology workloads within each participating laboratory within the Sonic group.

Developing the project

The project details were developed conjointly by the HFA and Sonic Healthcare. These details have been published elsewhere but, in brief, they included the weekly transhipment of Pap smear slides in batches of 1200 from Gisborne to Sonic's Sydney-based laboratory, Douglass Hanly Moir Pathology (DHM). A request form accompanied each slide and a computer disc with patient details accompanied each batch. Upon receipt of each batch, DHM generated a unique identification number for each patient and the patient details were then entered into the DHM mainframe computer system.

The slides were then distributed amongst the five Sonic Healthcare laboratories:

- Douglass Hanly Moir Pathology (Sydney)
- Capital Pathology (Canberra)
- Southern Pathology (Wollongong, NSW)
- Clinpath Laboratories (Adelaide)
- Barratt and Smith Pathology (Penrith, NSW).

More than half of the slides were screened at DHM. Despite the multicentric nature of the project, a uniform reporting system and format were adopted for all smears across all participating laboratories. Results were electronically downloaded into a discrete and unique database.

The smears were reported using the conventional Australian modified Bethesda terminology but were then translated into the modified Bethesda system used routinely by NZ laboratories. Software to facilitate this translation was developed by Sonic especially for this project. In addition, customised software was written to enable the direct electronic transfer of smear results from our database into the NZ Pap test register for further analysis.

Undertaking the project

The project was substantial and challenging, in terms of volumes, logistics and required expediency. The process may be elucidated under the following headings.

The logistics

A staff member was employed by DHM to co-ordinate the receipt of slides, to enter patient details and histories from the request forms into the system, to generate ID numbers and to manage the transhipment of slides to the other participating Sonic laboratories.

This person also co-ordinated the return receipt of slides from the other Sonic laboratories, the packaging of slides for transhipment back to Gisborne, the generation of reports in hard and soft copy formats and the dispatch of a disk with completed results to the Pap test register in Wellington.

Three slides were broken in an initial test package of 100 slides. They were able to be put back together and read. Other than this minor incident, no slides were broken or lost during the entire project.[4]

The slides

The condition of the slides was remarkably good. The overall staining quality was satisfactory for accurate cytological assessment and no slides required re-staining. Approximately 50 percent of the slides did however require re-coverslipping, as up to 20 percent of the material in these cases was not captured by the original coverslip. Of note was the number of slides requiring re-coverslipping because the original coverslip had been applied on the wrong side of the slide.

The reports

The standard method of reporting Pap smears was adopted in all cases. Reporting Pap smears is a two-step process:

1 Firstly, the slide must be screened. This is a well-described process whereby a specially trained person examines every cell on the slide by moving from one end of the slide to the other, in a grid-like manner, using a light microscope. This is a skill that needs to be developed over considerable time. This task is usually carried out by a specially trained scientist/technician. The process of screening may be carried out by a pathologist but there are very few who have taken the time to develop this skill. During the screening process, any abnormal cells are identified and marked on the slide itself. If no abnormal cells are detected, it is standard practice for the initial screener to issue a negative/normal report.

[4] Note that three further slides were also broken in a later batch on their return to Gisborne.

2 The second part of the process is the classification of any abnormality found. In our laboratory, where any deviation from normal is detected, the slide in question is then re-screened by another senior scientist. If the appearances are still considered abnormal, the slide is then examined by a cytopathologist who will be responsible for issuing the final report.

It is well to note that cytology remains a qualitative rather than a quantitative test and that opinions between cytologists may vary somewhat.

The standard procedure described above was adopted in all participating laboratories for all slides in the Gisborne project. Standard quality assurance measures were also adopted throughout the project. Rapid rescreening was not performed and targeted rescreening was used as per our routine protocols.

The Gisborne slides could be identified by our screeners as different from their routine work. However, reporting was performed by our usual screeners, in our usual laboratories, at our usual workbenches, using our usual microscopes.

The criteria used to make the cytopredictions were the conventional appearances described initially by Papanicolaou, Koss and others in the 1940s and 1950s. The terminology has changed somewhat since then but the appearances are essentially the same.

The results

The increased incidence of high-grade abnormalities in the slides was readily apparent. Re-screening smears previously reported as negative from women who present within two years with a high-grade abnormality is a standard practice in our laboratory. We had presumed that if we were to find any extra abnormalities that they would have these particular appearances.

We also presumed that the overall rate of high-grade abnormalities would approximate the rate normally detected in our laboratories (0.7–1.0 percent).

It was quite apparent from the first batch that both the numbers of abnormalities and the detected appearances were very different from those which we normally encounter. All laboratories participating in the project made this observation. The incidence of abnormalities found is now documented, as is the poor correlation between the original Gisborne reports and those issued by our laboratories.

The project was remarkable for the unusual cytopathological changes detected in the cohort of abnormal slides. The *number* of abnormal cells per slide was remarkably high. The remarkably severe nuclear and cytoplasmic changes were also notable, with large keratinising cells and tumour diathesis, more akin to the changes originally described by George Papanicolaou than those normally seen in routine cytological practice. The relatively large number of unsatisfactory slides was due to scanty material, blood and inflammation.

The unexpectedly large number of high-grade abnormalities may be explained on the basis that the pathology had remained undetected for long periods of time, perhaps well in excess of the normal screening interval. The burden of disease in this population would therefore not have been reduced as would normally be expected in a screened population of women.

Conclusion

- The project has now been completed successfully. More than 20,000 slides have been transhipped, screened and reported, without significant incident.
- The detected abnormalities have been remarkable. We did not anticipate the unusual nature of the cytopathology uncovered in the re-screening project, or the high incidence of abnormalities detected. We look forward to the final correlation and follow-up of results. The information generated by this project is of great importance and it is hoped that the outcomes are used constructively in the greater public interest.
- Although the demands on Sonic's laboratories and cytology staff have been considerable, the project has been professionally satisfying. We certainly hope that our efforts will provide assistance to the HFA in its endeavour to rectify a specific health care problem.

Appendix 5: Comparing Original and Re-reading Results (Slides)

This appendix is based on tables in the interim report. It:

- distinguishes between cancer and high-grade results, and between low-grade and ASCUS results
- provides a comparison of only those slides that both the original and re-reading laboratories reported as fully adequate (A1)
- provides a breakdown of the nature of comments made in results that the Gisborne laboratory reported as C6 (outside normal limits).

The tables included refer to results; reported for each smear. Note that where more than one result was reported for smears taken on the same day, the most severe result has been included in the data.

All results reported are cytology results, that is, they are the results reported by the laboratory reading the cervical smear. Data has been coded according to the Bethesda system used by the National Cervical Screening Programme. For the purposes of the investigation and this report, codes have been aggregated into categories (high-grade, low-grade, etc). Appendix 7 describes how both original and re-reading laboratories used the codes.

Comparison of all results reported by the original and re-reading laboratories

Table A5.1 compares all cytology results as originally reported with the results of the re-reading. It includes all smears reported by either laboratory, and therefore includes smears that one or both laboratories considered were unsatisfactory for reporting, as well as those considered less than satisfactory but for which a result was reported. Table A5.2 reports on only those slides that both laboratories considered to be fully adequate for reporting.

Table A5.1: Summary of the grade differences reported on all smears

Original results	Results reported by re-reading laboratory							Total original results
	Cancer	High	ASCUSH	Low	ASCUS	Normal	Unsatisfactory	
Cancer	9		2			1		12
High	7	81	2	11		9	1	111
Low	2	93	8	50	30	69	2	254
ASCUS	1	63	13	15	30	94	2	218
Outside normal limits[1]		6	2		6	49	8	71
Normal	10	297	255	481	1201	18,751	1101	22,096
Unsatisfactory[2]		1	1	2	7	58	86	155
Missing[3]		3	1	1	3	45	6	59
Total re-read	29	544	284	560	1277	19,076	1206	22,976

Notes:

1 Outside normal limits refers to Code C6 'other'. In New Zealand this code could be used for free text comment from the pathologist to the smear taker. Although it is currently recognised as a high grade code under the Bethesda system, it was not necessarily viewed in the same way in the early 1990s. The content of these results is analysed in further detail below.

2 For unsatisfactory slides, the laboratory was unable to report a result. Slides reported as limited, but where the laboratory has reported a result, have not been separately identified in this table.

3 For slides reported as 'missing', the original report was not available but the slide was re-read. Hence the original result cannot be compared with the re-read result.

Comparison of all results reported as adequate (A1) by both laboratories

This section compares those slides that both laboratories considered fully adequate for reporting. The total number of smears reported is therefore 19,989, that is, 2987 fewer than the 22,976 included in Table A5.1. One or both laboratories reported 5.5 percent of the smears (1275) as *unsatisfactory for evaluation* (A3) and 13 percent (1712) as *satisfactory although evaluation is limited* (A2).

Table A5.2: Comparison of slides that both laboratories reported as adequate (A1)

Results originally reported	Results reported by re-reading laboratory						Total results
	Cancer	High	ASCUSH	Low	ASCUS	Normal	
Cancer	5		1			1	7
High	6	78	2	10		9	105
Low	2	89	8	49	29	67	244
ASCUS	1	49	8	15	26	78	177
Normal	8	284	210	450	1101	17,371	19,424
Outside normal limits		4	2		4	22	32
Total re-read	22	504	231	524	1160	17,548	19,989

Analysis of smears coded as 'outside normal limits' (C6) by the original laboratory

In the early 1990s the C6 code could be used in New Zealand for any comment regarding the smear result. Since the introduction of the revised Bethesda code (from 1994) it has been used to further describe an abnormal result. If this code is used without an abnormal result, it alters a woman's status on the National Cervical Screening Register from 'normal' to 'abnormal' smear history and alters her schedule of recall.

The original laboratory reported 71 slides with a C6 result only. The results of 65 of these slides have been reviewed. Of these, 16 have been reported with a description concerning the appearance of the smear and five have a recommendation for referral. The re-reading laboratory reported 14 of the smears as abnormal, of which nine were high grade and five low grade.

Appendix 6: Written Communication with Individual Women

Letter and information sheet sent to all women in the Tairawhiti region to inform them of the re-reading project

June 1999

Greetings, Tena koe, Talofa lava

Cervical Screening in Gisborne

The Health Funding Authority is carrying out an investigation into the accuracy of the reporting of cervical smear tests by a pathologist in Gisborne, who retired in February 1996. This investigation concerns cervical smear tests that were read by the Gisborne community laboratory prior to this date. This involves most of the smears taken in the Gisborne area.

We are sending this letter to all households in the Gisborne area in order to help ensure that all women are given advice about what they should do. The most common questions and answers are given in the attached sheet. We have also enclosed a form which you should complete and return if you do not want your slides (from between 1991 and February 1996) to be re-read.

We feel this letter is the most effective way of reaching all women in the area. However, we do not want to cause unnecessary distress, especially to those people and their families who may have been affected already. We apologise if it does cause any upset.

Please contact the 0800 number – 0800 444 633 – if you have any questions or concerns about this letter.

Tracy Mellor

Team Leader, Quality Improvement and Audit
Personal Health

Cervical Screening Advice for women who had smears taken in the Gisborne area, prior to February 1996

Do I need to have another smear?

- If you have already had two smears since February 1996 you do not need to take any further action.
- If you have had one smear since February 1996, you should have another smear approximately one year after that smear. If it is now longer than one year since that smear you should have another smear within the next few weeks.
- If you have not had a smear since February 1996, you should have one in the next few weeks and another in approximately one year's time.
- If you have had an abnormal smear test result at any time, your smear taker/GP should have advised you as to how often you should have smears. If you are unsure, please contact your smear taker/GP.
- If you are over 70 (and therefore no longer on the programme) and have concerns, please discuss these with your smear taker. You are welcome to have a free smear if you wish.

How can I find out when I had my last smear?

If you are not sure whether your test was read by the community laboratory, or you are not sure of the dates of your last smears, please contact your smear taker or the Cervical Screening Co-ordinator (Public Health Unit, Tairawhiti Healthcare, 06 867 9119) for advice.

Will I have to pay for the smear?

The HFA agreed with all general practices and other smear takers in the Gisborne area that all smears would be provided free of charge, until the end of June.

This period has now been extended, and smears will be free until the end of August 1999.

Should I have my smear immediately?

Smear takers will try to give you an appointment as soon as possible, but you may have to wait a little while. Cervical cancer takes a long time to develop, and a delay of a few weeks is unlikely to have any effect on your health.

Smear takers are being asked to give priority to those women who have not had any smears since the end of February 1996. If this affects you, you should have recently received a letter to remind you to have a smear. Please let your smear taker know if you have had one of these letters.

Who will read my slide?

Unless your smear is taken in the hospital, it will be sent to MedLab Gisborne. From here it will be sent to a larger laboratory, usually Hamilton, where it will be read.

All laboratories who process the smears obtained by Gisborne women are now accredited. All normal smears are double checked by a second technician. Whenever an abnormality is seen, a senior technician or a pathologist reviews the smear.

Why should I continue to have smears?

For women aged 20–70, having regular smears remains your best protection against developing cervical cancer. Even if you have a history of normal smears, never ignore any symptoms such as bleeding after sex, between periods, or after menopause; abnormal discharge or pain. If you do have any of these symptoms, see your GP as soon as possible.

What else can I do?

Make sure you are registered on the National Cervical Screening Register, and that your details are up to date. This makes it easy for us to contact you if we need to – such as in situations like this.

Who can I talk to if I have more concerns?

Talk to your smear taker or general practitioner if you wish to discuss your concerns, and your individual screening decisions, in more detail.

We have also set up an 0800 number – 0800 444 633. This is being run by Tairawhiti Health Care, and they can answer general queries.

What else is the HFA doing?

We are making arrangements to re-read all cervical smear tests between 1991 and 1996. This will help us to identify any other mis-read slides. It is likely to take several months to complete this work. If you do not wish to have your slides re-read, please complete and return the enclosed form. Otherwise any slides from these dates will be re-read.

We will also be investigating the circumstances surrounding this case, in order to identify other issues or areas of concern and to make recommendations for the future.

Who will re-read the slides?

We do not yet know which laboratory will re-read the slides, and will announce the decision publicly as soon as it is made. We are hoping to have all the slides re-read by a single laboratory, and our preferred option is that this will be a laboratory outside New Zealand.

When will the slides be re-read?

We are hoping that all slides will have been re-read by the end of December 1999, but until we have finalised details with a laboratory we cannot confirm this. Details will be announced publicly as soon as possible.

What will happen when my slide(s) have been re-read?

We expect that most slides, when re-read, will have the same result as the result you have already been given. Where this is the case, you will receive a letter to tell you this. These letters will be sent out once all slides have been re-read, so that we can make sure we have re-read all slides belonging to any individual woman.

However, if one of your slides is found to have been mis-read and a high-grade abnormality is detected, we will advise your GP/normal smear taker immediately and ask them to contact you to discuss the results. This will be at no cost to you. We are taking steps to ensure that any necessary treatment and support services (including counselling where necessary) will be available. In most cases your GP or normal smear taker will be able to provide counselling, and this will be available free of charge.

If any of your slides are found to be have been mis-read, but high-grade abnormalities are not detected, we will advise your GP/smear taker once all slides have been re-read. They will be asked to contact you to discuss the results. This will be at no cost to you.

Request not to participate in the re-reading of Cervical Smear Tests taken in the Gisborne/Tairawhiti area between 1991 and February 1996

Unless we receive instructions not to have slide(s) re-read, we will be re-reading all cervical smear slides taken between 1991 and the end of February 1996. **If you do not want to have slide(s) re-read**, please complete and return this form.

Name: .....

Address: .....

.....

.....

Please include any names you have used previously, and any other addresses between 1991 and 1996, so we can ensure we find all slides which belong to you.

If you are completing this form on behalf of someone else, please state below your relationship to that person and the reason why you are completing the form.

.....

.....

I do not wish my cervical smear tests to be re-read.

Signature: .....

Date: .....

Please complete and return this form by Friday 11 June, to:

Tracy Mellor
Personal Health
Health Funding Authority
PO Box 10 097
Wellington

Example of letter sent to women enrolled in the National Cervical Screening Programme with normal results from both original reading and re-reading

1 March 2000

Dear

As you may be aware, the Health Funding Authority has recently completed an exercise in which all cervical smear slides, read by Dr Michael Bottrill (Gisborne community laboratory) between 1991 and 4 March 1996, have been re-read by an Australian laboratory.

One or more slides from cervical smear tests you had during this period was included in this re-reading. All your results, both those reported originally by the Gisborne laboratory and those subsequently reported by the Australian laboratory, were normal. I have enclosed with this letter a summary which confirms this for each slide that has been re-read.

As you are enrolled on the National Cervical Screening Register, your smear results are normally recorded on the register. However, our records from the early days of the register (the early 1990s) are not always complete. In order to ensure we have the fullest possible record of your smear history, we intend to put all your re-reading results onto the register. If you do not wish us to do this, please write to Justine Kenderdine at the above address by 31 March 2000.

We have developed a comprehensive database of all information related to this investigation. This includes all results reported originally by the Gisborne laboratory and those subsequently reported by the Australian laboratory. This information will be used to enable us to develop an understanding of the implications of this exercise.

It is also intended that the information will be available, in a way which does **not** allow identification of individuals, to government agencies (including the Health Funding Authority and the Ministry of Health), and health researchers (university departments, individual health professionals and research staff) in order to allow the health sector to research and understand the wider implications of the investigation. Access to this database will be subject to protocols, which will ensure the information is only used in appropriate ways.

On behalf of the Health Funding Authority, I acknowledge that this investigation may have caused concern to you and your family and hope that this letter provides you with some reassurance.

Yours sincerely

Tracy Mellor
Team Leader – Quality & Audit

Letter to general practitioner or smear taker for woman with high-grade results from the re-reading

13 March 2000

Smear taker/general practitioner

Dear Dr

Re-reading of cervical smear slides taken in Gisborne

As you are aware, the HFA is currently having all cervical smear slides, read by Dr Michael Bottrill between 1991 and 4 March 1996, re-read by an Australian laboratory.

As discussed, the HFA have just received notification that a slide belonging to the above has been re-read, and that the re-reading has detected a high-grade abnormality. Please find attached copy of the cytology report from this re-reading.

Unfortunately this re-read result is different to the original screening of *date* which was reported as high grade. Therefore the HFA would appreciate if you could immediately arrange a consultation to advise of this result, and of its implications in terms of initial or further treatment that may be required.

The HFA has made arrangements for experienced colposcopists[5] to provide colposcopy services for women affected by this investigation who no longer reside in Gisborne/ Tairawhiti. This service is primarily for any woman who, based on the investigation's re-reading, has had a slide mis-read by Dr Bottrill and has not previously received treatment.

Please refer to the below list of names, addresses and telephone numbers. If the above woman has not had previous treatment then please try to establish **direct contact** with the experienced colposcopist that is most appropriate to her location and family circumstances. Following your telephone contact, please ensure that this referral is marked **URGENT – Gisborne investigation**. Any other referrals for women who have had previous treatment should be done as per normal and it would be useful to state that it is in respect of the Gisborne investigation.

Details of six experienced gynaecologists across New Zealand who had agreed to provide colposcopy services for the women.

[5] As defined in *Cervical Screening – Guidelines for the Management of Women with Abnormal Cervical Smears 1998*, p.19.

The following guidelines have been suggested to the above colposcopists for these colposcopy services outside of Gisborne.

- Primarily intended for any woman who, based on the investigation's re-reading, has had a slide mis-read by Dr Bottrill and has not previously received treatment.
- HFA would prefer that these women be seen within one week of referral with a maximum waiting time of two weeks.
- The HFA's preference would be this service to be provided in their hospital clinic. However, if there will be any undue delay or interruption to the usual hospital patients then they are welcome to make other arrangements on where a particular woman is seen. (The HFA is specifically funding this arrangement regardless of where the treatment is provided.)
- The HFA will fund a minimum of two such consultations (diagnosis and initial treatment) with each woman.
- Ongoing management of an established treatment programme could then be managed by the local hospital. The option of them continuing with treatment may be possible but if so it is expected this would be done within the public hospital system.

This should help facilitate immediate access to this service. It is understood that some smear takers may not have a full history in relation to the women they are taking smears for, and if this is the case, it is appreciated if you could confirm any previous treatment history with the woman's general practitioner before making referral decisions.

An action plan for the management of women referred to you with two low-grade abnormalities has also been developed, and a copy is attached for your attention. It will also be most helpful if a copy of all previous smear reports is provided to the colposcopist when making a referral.

The HFA will meet reasonable costs for this consultation; please do not charge the woman, but invoice the HFA. The invoice should include details of the service provided, the net cost of providing the service (please indicate whether GMS has already been claimed), NHI and/or name and address of the woman. The invoice should be sent to Tane Cassidy, Business Support Manager, PO Box 10-097, Wellington.

Some additional support services may also be available. Please note that the HFA has agreed to meet the cost of additional consultations/counselling required by women as a result of the re-reading.

I would also appreciate if you could contact me to confirm that you have been able to make contact with the above. The HFA will then send her a confirmation letter regarding this matter. The HFA may also contact you at a later date to follow-up on the outcome of any treatment.

Thank you very much for your co-operation.

Yours sincerely

Tracy Mellor
Team Leader – Quality & Audit

cc: Regional Site for National Cervical Screening Programme

Appendix 7: Definitions

In this report, cytology (smear) results and histology (biopsy) results are reported in accordance with the classifications below. Unless otherwise specified, women are categorised by the most abnormal result reported.

Classifying women by the most abnormal cytology (smear) result reported

Unless otherwise stated, results reported for cytology refer to the cytology results reported by the re-reading laboratory. In a few tables, the results refer to smears taken at colposcopy – as is clearly specified in relation to each table concerned. The most abnormal smear result is classified according to the following definitions.

Table A7.1: Definitions of cytology result categories

Result category	Definition
Cancer	Includes all women for whom one or more smears have been reported as cancer.
High grade	Includes all women for whom one or more smears have been reported as high grade *except* those women who have already been included in the cancer category.
ASCUSH (high grade cannot be excluded)	Includes all women whom the re-reading laboratory reported as having ASCUSH abnormalities, *except* those women who have already been included in the high grade category.
Low grade	Includes all women for whom one or more smears have been reported as low grade *except* those women who have already been included in one of the categories above.
ASCUS	Includes all women for whom one or more smears have been reported as ASCUS *except* those women who have already been included in one of the categories above.
Outside normal limits	Includes women whom Dr Bottrill's laboratory reported as being outside normal limits *except* those women who have already been included in one of the categories above.
Normal	Includes women for whom normal results have been reported, *except* those women who have already been included in one of the categories above.
Unsatisfactory	Includes women for whom a smear has been reported as unsatisfactory (ie, unable to report whether normal or not) *except* those women who have already been included in one of the categories above.
No result available	Includes women for whom we have been unable to locate any record of the result reported by Dr Bottrill *except* those women who have already been included in one of the categories above.

Classifying women by the most abnormal histology result reported

The details of the codes included within each category are given below. Unless otherwise stated, women are classified by the most abnormal histology result reported as a result of their first colposcopy. The most abnormal histology result is classified according to the following definitions.

Table A7.2: Definitions of histology result categories

Result category	Definition
Cancer	Includes all women for whom one or more histology results have been reported as cancer.
CIN2/3	Includes all women for whom one or more histology results have been reported as high grade *except* those women who have already been included in the cancer category.
AIS/glandular	Includes all women for whom one or more histology results have been reported as having AIS or glandular abnormalities, *except* those women who have already been included in the categories above (CIN2/3 or cancer).
CIN1/HPV	Includes all women for whom one or more histology have been reported as low grade *except* those women who have already been included in one of the categories above. This category includes any histology reported as atypia.
Normal	Includes all women for whom normal histology results have been reported, *except* those women who have already been included in one of the categories above.
Unsatisfactory	Includes all women for whom a histology has been reported as unsatisfactory (ie, unable to report whether normal or not) *except* those women who have already been included in one of the categories above.
No result available	Includes all women for whom a record of the histology result reported has not been found, but understand a biopsy was taken.

Cytology codes

Table A7.3: Cytology code classification and mapping of Australian results

Classification of codes	Australian result	Mapped to NZ Bethesda codes
Normal	Normal	None
Low grade	Low grade/atypia	
Atypia		
Squamous	ASCUSL	C3A1; C3A1A/B/C/D; C3A1F/G
Glandular	AGUSR	C3B2; C3B2A/B; C3B2B1; 3B2C/E
HPV	HPV	C3A2A1
CIN1	CIN1	C3A2A; C3A2A2
CIN1/HPV	CIN1+ HPV	C3A2A3
High grade	High grade	
Atypia		
Squamous	ASCUSH*	C3A1E*
Glandular	AGUSD	C3B2A1; C3B1B2; C3B2D
CIN2	CIN2	C3A2B1
CIN2/3		C3A2B
CIN3	CIN3	C3A2B3/5/6
CIN2 or3 +HPV	CIN2 or 3+ HPV	C3A2B2/4
CIS	CIS	C3A2B5
CIS+HPV	CIS+ HPV	C3A2B6
AIS	AIS	C3B3D/E/F
SCC	SCC	C3A3
Adenocarcinoma	ADENO	C3B3; C3B3A/B/C
Tumour	Tumour	C3C; C4
Endometrial cells	Endome	C3B1A-C3B1C
Other abnormality		C6

Note:

* ASCUSH/C3A1E are the codes used for abnormalities where high grade cannot be excluded. These have been classified as high grade for the purposes of following up women, but are separately identified in this report. C3A1E was not in general use in New Zealand until 1998.

Histology codes

Table A7.4: Histology code classification and NZ SNOMED codes

Classification of codes	NZ SNOMED codes
Normal	
Negative result – normal tissue	M60000
Polyp	M76800
Squamous metaplasia	M73000
Microglandular hyperplasia	M72480
Other	M01000
Inflammation	M40000
Low grade	
Atypia	M67000
Glandular atypia	M67030
Dysplasia	M67015
Condyloma, HPV, Koilocytosis	M76700
CIN1	M67016
AIS/glandular	
Adenocarcinoma in situ	M81402
Glandular dysplasia	M67031
High grade	
CIN2/3	M67017
Carcinoma in situ	
Cancer	
Adenosquamous carcinoma	M85603
Invasive squamous carcinoma	M80703
Invasive adenocarcinoma	M81403
Microinvasive squamous cell	M80763
Carcinoma	
Unsatisfactory	M09010

Appendix 8: The Most Abnormal Cytology Result Recorded for Each Woman

This appendix summarises the most abnormal cytology result (as defined in Appendix 7) reported for each woman by both laboratories, broken down by ethnicity (Māori, non-Māori and unknown). Ethnicity has been reported according to the information already recorded for that woman. Where the woman is on the National Cervical Screening Programme, the ethnicity data recorded there has been used, and we are grateful to the National Kaitiaki Group for their permission to do this. Where no ethnicity record was available from the National Cervical Screening Programme, but the woman's National Health Index number was available, the ethnicity recorded against the National Health Index number has been used.

It should be noted that the definitions and processes used for recording ethnicity on the National Cervical Screening Programme are not identical to those used on the National Health Index; it is also likely that both approaches have changed over time. Both rely on self-reporting of ethnicity. In addition, it should be noted that there are concerns about the accuracy of ethnicity information recorded in both systems. This data is, however, the closest to a complete set that could be obtained. As it was considered important to record the impact of this investigation on Māori women in some way, a number of tables using ethnicity data have been included. Nevertheless, caution is recommended in all analyses and interpretation of such information.

Based on the definitions of the National Cervical Screening Programme and National Health Index, the data show that 56 percent (6802) of women whose smears were re-read were non-Māori and 38 percent (4555) were Māori. For 6 percent (742) of women, ethnicity was not recorded. According to the 1996 Census, among the women aged 20 to 69 years in the Tairawhiti region 54 percent were non-Māori, 40 percent were Māori, and ethnicity was not recorded for 6 percent.

Results for all women by ethnicity

Table A8.1 presents the results that the original laboratory reported, while Table A8.2 presents the results that the re-reading laboratory reported. In both cases, data are broken down by the ethnicity of the women as recorded in the re-read database.

Table A8.1: Number of women in each original result category, by ethnicity

Original result reported	No. of women whose slides were reported			
	Māori	Non-Māori	Unknown	Total
Cancer	6	4		10
High grade	52	54		106
Low grade	94	117	4	215
ASCUS	78	105	3	186

Normal	4284	6479	707	11,470
Outside normal limits	24	29	5	58
No result available	3	3	21	27
Unsatisfactory smears	14	11	2	27
Total	**4555**	**6802**	**742**	**12,099**

Table A8.2: Number of women in each re-read result category by ethnicity

Re-read result category (ie, the result reported by the re-reading laboratory)	**No. of women whose slides were reported in the re-read**			
	Māori	**Non-Māori**	**Unknown**	**Total**
Cancer	16	10		26
High grade	206	188	2	396
ASCUSH	80	118	2	200
Low grade	219	203	13	435
ASCUS	381	554	21	956
Normal	3533	5581	674	9,788
Unsatisfactory smears	120	148	30	298
Total	**4555**	**6802**	**742**	**12,099**

Appendix 9: Number of Smears Under-reported for Each Woman

This appendix details the total number of smears reported for each woman, and the number of these that were under-reported by one of the laboratories.

Total number of smears re-read for each woman

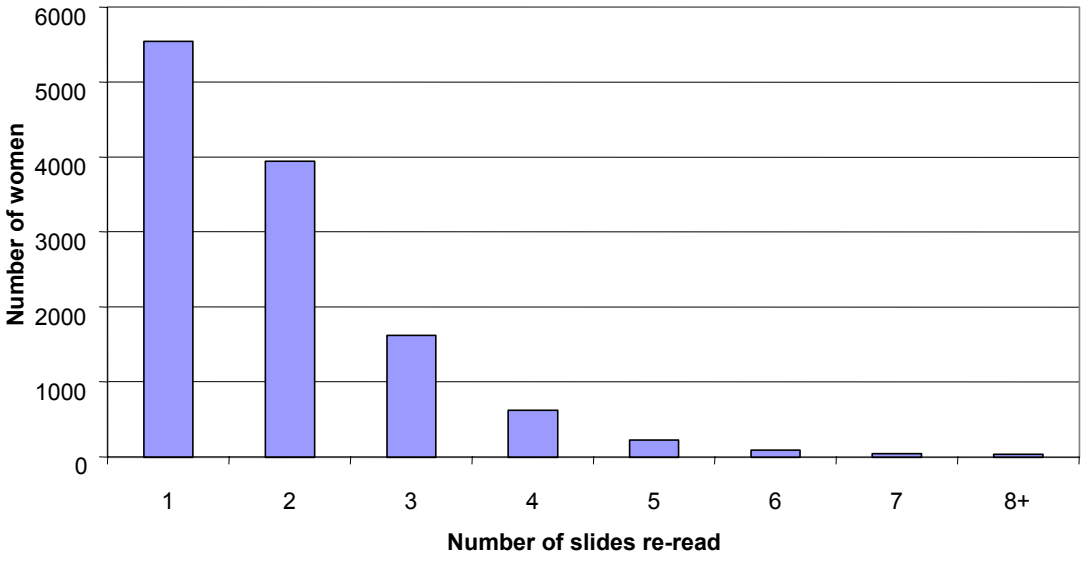
All smears re-read as part of the investigation were originally read during the five years between January 1991 and 6 March 1996. At the time the National Cervical Screening Programme recommended that women should have a routine smear every three years, unless specifically advised otherwise. Annual smears were recommended for women with a previously reported high-grade abnormality.

Therefore it can be expected that most women would have had two or possibly three routine smears, and those with previous abnormalities up to six smears, during the period. Some women may have more smears taken if, for example, they had a significant number reported as unsatisfactory. These women would have been advised to have another smear within three or six months.

From Figure A9.1 (refer tables A9.1 and A9.2):

- 78 percent of women (9475) had one or two smears re-read
- 21 percent of women (2553) had three to six smears re-read
- approximately 0.6 percent of all women (71) had more than six smears re-read.

Figure A9.1: The number of smears re-read for each woman



Number of smears where the two laboratories reported different results

Tables A9.1 and A9.2 show the number of slides re-read for all women, and indicate the number of women who had slides where the two laboratories differed in the results reported. Table A9.1 reports the re-read results for which the degree of abnormality reported was higher than for the original results. Table A9.2 reports the original results for which the degree of abnormality reported was higher than the re-read results.

Women with slides where the original result recorded a lower grade of abnormality than the re-reading

Of the 1883 women for whom one or more smears were originally reported with a lower grade of abnormality:

- 1793 women had either one or two smears originally reported with a lower grade of abnormality
- 90 women had three or more smears originally reported with a lower grade of abnormality.

Note that the individual women's complete smear histories as they were originally reported are not recorded here. For example, a woman who had three smears re-read may have had two smears originally reported with a lower grade of abnormality than the re-read result, but for the third smear the Gisborne laboratory may have identified a higher grade of abnormality.

Women with slides where the re-read result recorded a lower grade of abnormality than the original reading

For 175 women, the re-reading laboratory reported one or two smears with a lower grade of abnormality than the original laboratory reported.

Table A9.1: Comparison of the number of slides where the re-read result indicated a higher degree of abnormality than the original result for all women

No. of slides re-read	No. of re-read results with a higher degree of abnormality than the original result							
	0	1	2	3	4	5	6	Total
1	5026	502						5528
2	3308	512	127					3947
3	1243	269	94	16				1622
4	426	109	50	23	11			619
5	137	41	23	12	7	3		223
6	43	25	11	1	5	3	1	89
7	18	8	6	3	2			37
8	9	5	1	1	1			17
9	4	2	3					9
10	2	1	1		1			5
11			1					1
12			1					1
14			1					1
Total	**10,216**	**1474**	**319**	**56**	**27**	**6**	**1**	**12,099**

Table A9.2: Comparison of the number of slides where the original result indicated a higher degree of abnormality than the re-read result for all women

No. of slides re-read	No. of original results with a higher degree of abnormality than the re-read result			
	0	1	2	Total
1	5503	25		5528
2	3905	41	1	3947
3	1580	42		1622
4	595	20	4	619
5	204	17	2	223
6	76	13		89
7	36	1		37
8	12	4	1	17
9	6	2	1	9
10	4	1		5
11	1			1
12	1			1
14	1			1
Total	**11,924**	**166**	**9**	**12,099**

Women with slides originally read as normal and re-read as high grade

Differences in reporting are likely to have had the most impact on women whose slides have been originally reported as normal, and re-read as high grade (cancer, high grade or ASCUSH).

Table A9.3 details the number of women for whom the original smears reported a result that was normal and the re-read result was high grade. Note that, following the approach above, each woman is included only once.

For a further three women, the Gisborne laboratory reported one of their results as low grade, and the Sydney laboratory reported the same result as cancer.

Table A9.3: Results reported as normal originally and in 'high grade' categories on re-reading, by number of women involved

Number of smears originally reported as normal	Number of women involved		
	Re-read as cancer	Re-read as high grade	Re-read as ASCUSH
1	8	221	172
2	1	35	25
3	0	2	9
4	0	0	0
5	0	0	1
Total	**9**	**258**	**207**

As Table A9.3 shows, a total of 474 women had one or more smears originally read as normal and re-read as high grade (including cancer and ASCUSH). The majority (85 percent) had only one smear in this category.

Appendix 10: Colposcopies

This appendix describes colposcopy results, histology results, and treatment related to the first time period in which each woman entered assessment and/or treatment services. Time is recorded in three periods. First, from 1991 to February 1996 Gisborne Laboratories Limited initially read the slides that have now been re-read. Secondly, March 1996 to April 1999 spans the time after Dr Bottrill retired and before the investigation began. The third period is from May 1999, when the investigation began.

Histology is recorded where it was reported within two months of the first colposcopy result, and treatment is recorded where it was reported within 12 months of the recorded histology result. This information has been taken from the National Cervical Screening Programme register and from colposcopy records. Note, however, that this information is somewhat incomplete. In particular, early records are incomplete because histology has only been reported to the National Cervical Screening Programme since 1994; recent records are incomplete because there remain a small number of women still to have colposcopy. For example, Table A10.5 indicates there are 45 women identified who have been diagnosed with cancer, but Tables A10.3 and A10.4 show histology results for only 24 women. Tables A10.3 and A10.4 are based on histology taken at first colposcopy, whereas Table A10.5 is derived from data recorded by the Cancer Registry.

Table A10.1: Period in which all women underwent their first colposcopy for assessment and/or treatment, by the original result category

Highest abnormality reported on original results	First colposcopy						
	January 1991– February 1996		March 1996 – April 1999		May 1999–		
	No further action	Histology taken	No further action	Histology taken	No further action	Histology not known	Histology taken
Cancer		7					
High grade	15	57		6	4		3
Low grade	15	54	1	14	13	1	21
ASCUSL	1	24	3	12	18		17
Normal	9	32	3	120	180	4	314
Outside normal limits		5		1	2		
Total	**40**	**179**	**7**	**153**	**217**	**5**	**355**

Table 10.2: Period in which all women underwent their first colposcopy for assessment and/or treatment, by highest abnormality reported by the re-reading laboratory

Re-read results category	First colposcopy						
	Up to February 1996		March 1996 – April 1999		May 1999–		
	No further action	Histology taken	No further action	Histology taken	No further action	Histology not known	Histology taken
Cancer	3	16					1
High grade	23	97	2	48	43		114
ASCUSH	4	13	1	22	59	1	59
Low grade	5	28	2	38	38	3	58
ASCUS	5	25	2	41	71	1	104
Normal				4	6		18
Unsatisfactory							1
Total	**40**	**179**	**7**	**153**	**217**	**5**	**355**

Table 10.3: Histology results from initial colposcopy for all women, by highest original smear result over three periods

A10.3a: First colposcopy between 1991 and February 1996

Original result	Cancer	CIN2/3	CIN1/HPV	Normal	Unsatisfactory	No result	Total
Cancer	2		1			4	7
High grade	4	31	6	2	1	13	57
Low grade		17	18	7	1	11	54
ASCUS	1	4	9	3	1	6	24
Normal	2	11	7	4		8	32
Outside normal limits	1	2				2	5
Total	**10**	**65**	**41**	**16**	**3**	**44**	**179**

A10.3b: First colposcopy between March 1996 and April 1999

Original result	Cancer	CIN2/3	CIN1/HPV	Normal	Unsatisfactory	No result	Total
Cancer							
High grade		3	3				6
Low grade	1	6	6	1			14
ASCUS	1	4	6	1			12
Normal	4	56	41	16	1	2	120
Outside normal limits			1				1
Total	**6**	**69**	**57**	**18**	**1**	**2**	**153**

A10.3c: First colposcopy in the period May 1999 to the present

Original result	Cancer	CIN2/3	AIS/ glandular	CIN1/ HPV	Normal	No result	Unsatis-factory	Total
Cancer								
High grade				2	1			3
Low grade		6		11	4			21
ASCUS	1	5		9	2			17
Normal	7	91	1	161	47	5	2	314
Total	**8**	**102**	**1**	**183**	**54**	**5**	**2**	**355**

Table A10.4: Histology results from initial colposcopy for all women, by highest re-read smear result over three periods

A10.4a: Period of first recorded colposcopy 1991 to February 1996

Re-read result	Cancer	CIN2/3	CIN1/HPV	Normal	Unsatisfactory	No result	Total
Cancer	4	3	2		1	6	16
High grade	5	46	14	4	1	27	97
ASCUSH	1	2	3	4		3	13
Low grade		9	12	3		4	28
ASCUS		5	10	5	1	4	25
Normal							0
Total	**10**	**65**	**41**	**16**	**3**	**44**	**179**

A10.4b: Period of first recorded colposcopy March 1996 to April 1999

Re-read result	Cancer	CIN2/3	CIN1/HPV	Normal	Unsatisfactory	No result	Total
Cancer							
High grade	6	30	12				48
ASCUSH		14	4	2	1	1	22
Low grade		11	20	7			38
ASCUS		12	20	8		1	41
Normal		2	1	1			4
Total	**6**	**69**	**57**	**18**	**1**	**2**	**153**

A10.4c: Period of first recorded colposcopy May 1999 to present

Re-read result	Cancer	CIN2/3	AIS/ glandular	CIN1/ HPV	Normal	Unsatis-factory	No result	Total
Cancer				1				1
High grade	6	42	1	47	18			114
ASCUSH	2	12		32	11		2	59
Low grade		15		34	9			58
ASCUS		23		64	14	2	1	104
Normal		9		5	2		2	18
Unsatisfactory		1						1
Total	**8**	**102**	**1**	**183**	**54**	**2**	**5**	**355**

Table A10.5: Number of women diagnosed with cervical cancer, by the period of their first cancer diagnosis (cancer diagnosis confirmed by cancer registry)

A10.5a: Period of first diagnosis of cancer by original result category

Original result	1991 – February 1996	March 1996 – April 1999	May 1999–
Cancer	6		
High grade	5		
Low grade	2	3	1
ASCUS	3	1	2
Normal	5	5	10
Outside normal limits	1		1
Total	**22**	**9**	**14**

A10.5b: Period of first diagnosis of cancer by re-read result category

Re-read result category	1991 – February 1996	March 1996 – April 1999	May 1999–
Cancer	11		
High grade	9	7	9
ASCUSH			4
Low grade			
ASCUS	1	1	
Normal	1	1	1
Total	**22**	**9**	**14**

Appendix 11: The Ministerial Inquiry into the Under-reporting of Cervical Smear Abnormalities in the Gisborne Region

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 HFA reviews of cervical cytology and histology samples. The specific terms were:

i To determine whether there has been an unacceptable level of under-reporting in consequence of mis-reading 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.

Summary of conclusions of inquiry

Term of reference one

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

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.

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.

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

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.

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 property exercised.

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

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 practise medicine. The new Act introduces measures which ensure that medical practitioners are, and remain, competent to practise 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

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

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

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.

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

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.

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 Māori 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 Māori women's data on the register for the purposes of monitoring and evaluating the programme.

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.

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