

UNDER THE HEALTH AND DISABILITY
SERVICES ACT 1993

IN THE MATTER OF THE MINISTERIAL
INQUIRY INTO THE UNDER-
REPORTING OF CERVICAL SMEAR
ABNORMALITIES

EVIDENCE OF JIM DUROSE

HEALTH FUNDING AUTHORITY

DATED JULY 2000

INCLUDING EXHIBIT JD/HFA/001 – THE FINAL REPORT

HEALTH FUNDING AUTHORITY

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Jim DuRose – Background and Qualifications

1. My name is James (Jim) Patrick DuRose II. I am currently a Quality Improvement & Audit Coordinator in the Personal Health operating group of the Health Funding Authority.
2. My role is to work with health and disability providers and associated professional organisations with respect to the delivery of services to agreed requirements and / or specific quality improvement initiatives. I have fulfilled this role since the then Southern Regional Health Authority initially employed me in June 1995.
3. I have been responsible for the management and facilitation of the Health Funding Authority's "Review of Cervical Cytology Practice in New Zealand Community Laboratories 1990 - 1999." I was also a member of the Health Funding Authority's investigation team into the allegations of misreading of cervical smears in Gisborne.
4. My qualifications include a Bachelor of Arts Degree (major in chemistry). I have post graduate diplomas from Massey University in Rehabilitation (with distinction) and Business Administration. I am one paper away from completing a Masters in Business Studies from Massey University. In 1995 I completed the SGS (ISO) Lead Assessor Training Certificate for Quality Systems.

The Final Report

5. Attached as **Exhibit JD/HFA/001** is a copy of the Final Report of the Health Funding Authority's "Review of Cervical Cytology Practice in New Zealand Community Laboratories 1990 - 1999" (the Final Report).
6. I will begin my evidence by referring to the key outcomes of the review as described in this Final Report followed by a chronological description of the process and work undertaken to complete the review.
7. As a result of the early results from the re-reading of cervical slides for the HFA's investigation into cervical pathology in Gisborne / Tairāwhiti the HFA began to consider whether a similar situation could have occurred elsewhere.

8. The overall objective of the practice review has been to gather enough evidence to establish whether community laboratories in New Zealand were practising within acceptable standards in their reporting of cervical cytology during the period 1990-1999.

Summary of Outcomes (refer Part One of Final Report)

9. Based on the information considered by the review the cervical cytology practice review process undertaken with community laboratories has found the following outcomes:

- No major concerns with respect to the health and well being of women have been identified.
- The review has identified a number of situations in which smear result codes have been inaccurately reported to the National Cervical Screening Register (NCSR). The laboratories concerned are working actively with the National Cervical Screening Programme (NCSP) to rectify this and ensure it does not continue.
- In general, the appropriate current practices in cervical cytology identified from the review align reasonably well with the NCSP's draft policy and quality standards.
- It is also considered that the review has provided a foundation to support the implementation of impending quality standards and monitoring with respect to the NCSP.

10. Refer to Part Two of the Final Report for the overall results and practices identified from this review. Key results from the questionnaire responses about the standard of cervical cytology in New Zealand community laboratories during 1990 –99 include:

- All of these laboratories had screener(s) in place and there is no indication of any pathologist routinely performing primary screening.
- All have been using some form of rescreening since 1992 and all attempt to feedback to screeners identified errors on individual cases.

- As of 1999 all but one laboratory was undertaking 100% rapid review rescreening for internal quality control.
- The pathologists in all laboratories are reviewing the majority of abnormal smears.
- All laboratories have been registered as accredited by TELARC (IANZ) since 1995 and all have participated in the Royal College of Pathologists of Australasia (RCPA) Cytology Quality Control Programme since 1995.

Process Followed in the Practice Review

11. The first step was to analyse the cervical cytology abnormality reporting rates for all laboratories, from the records held on the NCSR. In late October 1999 the HFA considered that it was necessary to consider these laboratories in more detail and that it would be preferable to implement a staged review. This review was to commence only with community laboratories as they report 94% of cervical cytology in New Zealand. Data for hospital laboratory abnormality reporting rates essentially reflected expected trends. Note that the Gisborne Laboratory was not included in this review though available data was prepared for this laboratory during the period 1991 – 95.
12. The approach taken by the practice review needed to recognise the absence of any specific standards or targets in New Zealand and thus focused on the assessment of risk to women by examining markers of possible under-reporting of abnormalities. As such, this review does not represent a thorough assessment and evaluation of the quality of cervical cytology services. Also, whilst it is recognised that over-reporting of abnormalities is an important outcome issue within a screening programme it was not the perceived brief of this review to consider this matter.
13. The cervical cytology practice review has involved the following steps:
 - HFA completed a preliminary analysis of abnormality reporting rates and a potential action plan on 27 October 1999.

- In early November the results of the analysis and the proposed plan were presented to the Royal College of Pathologists of Australasia (New Zealand Committee) (RCPA) and the Association of Community Laboratories (ACL).
- As a result of advice from the RCPA's Cytology Focus Group a questionnaire approach was adopted for all 17 community laboratories rather than targeted onsite reviews with some laboratories as originally proposed by the HFA.
- On 7 December 1999 all community laboratories received a detailed questionnaire about their cervical cytology practices 1990 –1999.
- By 21 January this year all laboratories returned their completed questionnaires.
- The HFA then arranged for the questionnaire responses to be independently assessed by five pathologists from New Zealand and three from overseas. The assessments were returned to the HFA by 10 February 2000.
- On 15 / 16 February 2000, an HFA Evaluation Panel reached preliminary conclusions. The Evaluation Panel included an overseas pathologist, two RCPA-nominated pathologists, and two HFA representatives, including myself. The Evaluation Panel considered the following information.
 - The questionnaire assessment profiles completed from collated comments from all eight assessors.
 - The analysis of abnormality reporting rates completed for the period 1991 – 1999.
 - The histology / cytology correlation analysis completed from the Register for 1996 -98.
 - Age adjusted rates for incidence of cervical cancer 1990 – 95 from the HFA's analysis of 7 February 2000.

- From 27 March 2000 a multidisciplinary Advisory Group met on several occasions to consider the results of the practice review and provided recommendations to the HFA with respect to some laboratories.
- On 10 April 2000 each laboratory received an individual feedback report and the summary report (Part Two of the Final Report).

Factors affecting interpretation of results

13. To help reach preliminary conclusions about laboratory practices in cervical cytology the Evaluation Panel had to set benchmarks for abnormality reporting rates and they were set at:

- Greater than 0.5% High Grade abnormality
- Greater than 5 % Total Abnormality: “high grade” + “low grade”(ASCUS included)

14. These benchmarks were developed from data obtained across New Zealand community laboratories to form one basis of assessment of comparative risk. The levels were not specifically taken from any particular programme, although the 0.5% high grade corresponded to the benchmarks of the Australian Performance Standards and also to the NCSP’s first draft of proposed national indicators for laboratories.

15. It was noted that there are several factors that may influence reporting rates. These include:

- Demographics and estimates of cancer incidence rates
- The proportion of Maori women in a population
- Coding issues
- Enrolment rates
- Historical issues (National Register opt on/opt off; previous screening activity, coverage rates etc)
- Liaison with smertakers and clinicians

Further clarification required from some Laboratories

16. A decision was made by the Evaluation Panel to obtain further clarification from six laboratories. This decision relied considerably on the analysis of rates of abnormalities reported to the NCSP. This was not necessarily an indication of inadequate performance with respect to any particular laboratory.
17. The next step required with regard to these laboratories was to gather the necessary information to further consider practice at that laboratory.
18. As a result of the preliminary conclusions reached by the Evaluation Panel, the multidisciplinary Advisory Group considered the available information from six laboratories in total, three with respect to current practice (1999) and three with respect to past practice. The main issue with all of these laboratories was that the rate of reporting abnormalities during some period had been outside either of the benchmarks set by the Panel. Some of these laboratories were also asked to give further clarification to their previous response to the questionnaire in addition to being invited explain the situation when a benchmark has not been met.
19. There were other laboratories whose reporting rates were above the benchmark and in which the Evaluation Panel identified practices from the questionnaire that could be considered for improvement. These laboratories received specific suggestions in their individual feedback report and all laboratories received detailed comments on their questionnaire response in this report (refer Part Three of the Final Report, appendix 1).
20. Following several meetings and an ongoing process of clarification the Advisory Group has gained the necessary assurance that, based on the available evidence, there are no major concerns with respect to any laboratory's practice. With respect to past practice, two laboratories explained that due to their own internal quality control systems they had identified the need for changes in their reporting practice of better defining some categories of high grade abnormalities. At that time these cases had been reported as abnormalities with follow-up recommendations considered appropriate by the laboratory. These recommendations were either for a repeat smear in 3 - 6

months or referral for colposcopy. As a precautionary measure these laboratories are working with the HFA to ensure that all of these women have subsequently received the appropriate management for their situation. It should be noted that a recommendation for a low grade abnormality had been reported to the smear taker at that time.

Part Two of the Final Report

21. The Summary Report: Overall Results and Practices (Part Two of the Final Report) provides much of the data used by the Evaluation Panel in reaching its preliminary conclusions. Refer to Exhibit JD/HFA/ 001 page 012 for the table of *Incidence of Cervical Cancer by NSCP Region 1990 - 95* and refer to the supplementary data (refer Exhibit JD/HFA/001 pages 024 to 033) that provides time series and ranking graphs for community laboratory abnormality reporting rates 1991 - June 99.
22. The table on page 014 of Exhibit JD/HFA/001 summarises the results across all 17 community laboratories involved in the review based on their questionnaire responses, and the analysis of data from the National Cervical Screening Register. This table and the graphs were provided so that the laboratories could compare their results (as provided in the individual feedback reports) with these overall trends.
23. In consideration of all the questionnaire assessment profiles the Evaluation Panel was able to put together what we identified as “appropriate current cervical cytology practice from the review.” This summary report gave the Evaluation Panel the opportunity to link these appropriate practices identified from the review with the first draft of the NCSP’s Policy and Quality Standards for providing a laboratory service. This comparison starts on page 015 of Exhibit JD/HFA/001.
24. Accompanying the Summary Report (Part Two) each laboratory was provided an individual feedback report that included:
 - the data provided in Part Three of the Final Report.
 - the generic and in some cases more specific suggestions.

- detailed comment on their response to the questionnaire prepared by Dr Gabriele Medley and in recognition of the collated comments from all the assessors.

Part Three of the Final Report

25. Part Three of this Final Report presents the results of the practice of each community laboratory and includes the decisions reached by the Advisory Group for the six laboratories they considered in further detail. These individual results should also be considered in the context of the overall results and practices provided in Part Two of this report. To support improvements to the NCSP this Summary Report was provided to all community laboratories on 10 April with an accompanying individual feedback report (for the generic example refer to Exhibit JD/HFA/001 pages 063 to 071).

26. As previously indicated the Gisborne Laboratory was not included in this review. However, the key indicators used in this review for the Gisborne Laboratory (1991 – 95) were prepared and included in the supplementary data graphs in Part Two of the Final Report (Exhibit JD/HFA/001, pages 024 to 033).

27. Part Three of this Final Report begins by presenting further details with respect to the Gisborne Laboratory. Indicators used in the practice review with respect to the Gisborne Laboratory (1991 – 1995) are as follows.

- Abnormality Reporting Rates 1991 – 93 from the Register (from NCSR cytology pattern reports dated 5 December 1999):
 - High Grade = 0.67%
 - Total Abnormalities = 3.0%
 - B2B8 referral recommendation = 1.21%
- Abnormality Reporting Rates 1994 – 95 (from NCSR cytology pattern reports dated 2 December 1999):

- High Grade = 0.49%
- Total Abnormality = 3.0%
- B2B8 referral recommendation = 0.99%

28. Incidence of cervical cancer 1990 - 95 for the Tairāwhiti region = 30.0 per 100,000 (2nd highest in NZ)

29. Tairāwhiti has the highest proportion of Māori women aged 20-69 at 39.5% (1996 Census Statistics).

30. In summary, the Gisborne Laboratory was below the practice review's high grade benchmark in 1994 / 95 and below the total abnormality benchmark throughout 1991 – 95. This is in an area of incidence of cancer that was above the national average during this period and is an area of the highest proportion of Māori women in New Zealand.

31. There is some data that was able to be considered in the practice review that is not available for the Gisborne Laboratory (1991 –95) such as the cytology / histology correlation data for 1996 –98. Correlation of cytology reporting with subsequent histology is an important indicator in considering the performance of a cytology laboratory.

32. Also, an understanding of all the other community laboratories' practice in cervical cytology has been obtained via the questionnaire. It is understood that a feature of the Gisborne Laboratory during the period 1991 - 1995 was that a sole pathology practitioner was "primary screening" the smears and that there was minimal internal quality control.

33. Part Three of the Final Report goes on to provide a coded summary for every laboratory involved in review.

How the review began – Preliminary Analysis

34. Due to the early results from the Gisborne Investigation's rereading of Dr Bottrill's cervical cytology slides the HFA began to consider whether it should have concerns about the cervical cytology performance of other laboratories.

Between 27 – 31 August 1999 cytology reporting pattern reports for all laboratories were obtained from the NCSR for the period 1994 / 95 and January – June 1999. In recent years these reports have been periodically provided by the NCSR to individual laboratories. They provide a laboratory's volumes and percentages for each Bethesda Code versus the national average.

35. The subsequent analysis of these reports for 1994 /95 showed four community laboratories with a high grade reporting rate similar to the Gisborne Laboratory (Dr Bottrill). Two of these laboratories had a high grade reporting rate slightly less than the Gisborne Laboratory's rate of 0.46 % for this two year period. As has been outlined by a number of witnesses to this Inquiry, it is not possible to assess the performance of a laboratory on the basis of a single indicator such as this one. This early analysis provided an indication that the laboratories should be considered in more detail if the HFA was to be assured that the situation in Gisborne was an isolated case.
36. On 25 September 1999 cytology reporting pattern reports for all laboratories were obtained from the National Cervical Screening Register (NCSR) for the three year period 1996 – 98.
37. On 28 September 1999, agreement was reached with David Moore, General Manager Personal Health, that an HFA Research Analyst, and I would prepare a report to consider this issue as soon as possible. This approach was discussed and confirmed with the HFA's Chief Executive Officer and General Manager of the Public Health operating group. The Director General of Health and other Ministry of Health officials were also informed that work was underway to consider the performance of other laboratories. On 12 October 1999 Tracy Mellor informed the HFA Board that this analysis was underway as part of her update on the Gisborne Cervical Screening Investigation.
38. In completing this work, we were supported by HFA staff from the NCSR, the public health change management team responsible for the NCSP and the Team Leader Quality and Audit in Personal Health (Tracy Mellor). The outcome of this collaborative effort is the report dated 27 October 1999 titled *Cervical Cytology New Zealand Laboratories Risk Review Preliminary Analysis and Action Plan*. A copy appears as **Exhibit JD/HFA/002**.

39. The analysis of abnormality reporting rates from Register data for this preliminary analysis included categories of “high grade”, “high grade & other” and “low grade”. Abnormality reporting rate percentages were presented for the time periods of 1994 / 95, 1996 - 98, January - June 1999 and 1994 - June 1999 (refer data sets 1 and 2 at pages 015 to 020 of Exhibit JD/HFA/002). A special run of the 1996 -98 data was conducted by the HFA Research Analyst that was based on using only one diagnosis per smear, either highest smear only or the last smear only (refer data set 3: at page 021 of Exhibit JD/HFA/002). These categories represented an adjustment to minimise the potential effect of screening interval / recall rates. The findings of these special runs generally aligned well with the other analysis presented in datasets 1 and 2.
40. As a result of the preliminary analysis a potential action plan was proposed that selected nine laboratories to proceed further with an onsite / audit review process - refer to page 009 of Exhibit JD/HFA/002 for the reasons for selecting these nine laboratories. Note that one laboratory was selected that consistently had the greatest reporting rate of high grade abnormalities. The reason for this was to help gain a broader perspective in understanding overall laboratory performance.
41. On 27 October 1999, Tracy Mellor, Team Leader Quality and Audit, and I made a verbal presentation to the Personal Health Purchase Board based on the report appearing as Exhibit JD/HFA/002. The Personal Health Purchase Board is the mechanism through which substantial funding decisions are made within the Personal Health operating group. The Board sought assurance that there was not sufficient evidence to justify more immediate action in relation to any of the laboratories. It was agreed the proposed review should proceed as quickly as possible and expenditure of \$150,000 - \$300,000 was authorised to cover the proposed on-site laboratory audits.
42. On 29 October 1999, David Moore, General Manager Personal Health, Tracy Mellor, Team Leader Quality and Audit, and I made a verbal presentation to the HFA Board. The Board asked similar questions to those raised by the

Purchase Board, noted the significance of the review and appreciated being kept informed of the issue.

43. On 1 November 1999 the Minister of Health received a written briefing about the proposed review from the HFA's Chief Executive Officer.

Key Stakeholder Engagement and Questionnaire Development

RCPA - Cytology Focus Group

44. On 2 November 1999, Tracy Mellor and I met with representatives from the RCPA and presented the preliminary analysis and proposed review. The College had in place a Cytology Focus Group that consisted of 5 members. Two of those members were at this meeting, Dr Andrew Tie and Dr Karen Wood. We agreed it was an important matter to work together on and they suggested I make contact with the other members of the focus group. On 9 November 1999 I met with two other members of the Cytology Focus Group, Dr Tony Bierre and Dr Margaret Sage. On 11 November I had a phone discussion with the remaining member of the focus group, Dr Peter Fitzgerald and discussed the copy of the written presentation I had provided beforehand.
45. As a result of this engagement and suggestions from the Focus Group it was agreed that the review would proceed by way of a questionnaire approach to all community laboratories rather than an onsite audit visit to nine laboratories as initially proposed by the HFA. The reason for this change was that it was considered to be a fairer approach to include all laboratories and that more information about individual practices could provide a better understanding of the reporting rates identified in the preliminary analysis. The approach would still enable the HFA to meet its timeframes for the review. The HFA confirmed that it would also seek to obtain the services of an overseas pathologist to assist with the review. A letter confirming these details dated 11 November 1999 was sent to the Cytology Focus Group and copied to the Association of Community Laboratories (ACL).

Association of Community Laboratories

46. On 9 November 1999 Tracy Mellor and I met with Mike Fitzgerald of ACL who agreed that ACL would consider what it could do to support the review

and appreciated being kept informed. On 30 November 1999 I met again with Mike Fitzgerald and on 1 December 1999 I met with the ACL Management Committee who gave their support in principle to the review and indicated that they would like to be engaged in how it was to be implemented.

Design of Questionnaire

47. From 25 November through early December I engaged with the Cytology Focus Group and ACL Management Committee on the design of a questionnaire that could be used with all community laboratories.
48. On 7 December 1999 I sent a cover letter and final questionnaire to all community laboratories – reference **Exhibit JD/HFA/003**. This was sent after I confirmed with Mike Fitzgerald of ACL that he had made contact with all the laboratories informing them that they would be receiving some important information from the HFA.
49. This letter explained the review, defined timeframes and confirmed that it was conducted under an obligation of confidence.
50. On 10 December 1999 I provided an update report to Tracy Mellor who used it to give the Personal Health Purchase Board a verbal update.
51. Between 13 December 1999 and 6 January 2000 I visited all the community laboratories to discuss the review and present some of the preliminary analysis. A copy of the agenda and presentation for these visits is attached as **Exhibit JD/HFA/004**. On 20 December 1999 I met with Dr Llewellyn Richards, Chief Executive Officer of International Accreditation New Zealand (IANZ), to advise that the HFA was conducting this review with all community laboratories.

Assessment of Questionnaire Process

52. As a result of ongoing discussions with the RCPA Cytology Focus Group and my visits to laboratories a process for how all the information was to be considered was under development. This would be based on the principle that the questionnaire should be considered independently of the analysis of reporting rates.

53. I had previously obtained a list of international cytopathologists from Dr Tie of the RCPA.
54. I made contact with Dr Gabriele Medley, Director of the Victorian Cytology Service, in Melbourne who expressed interest in assisting with the project. A letter and an information package were sent to Dr Medley on 24 December 1999. I also wrote to eleven other international pathologists seeking interest from those who may be available to assist with the review.
55. On 11 January 2000 I completed a first draft for the questionnaire assessment methodology. This was discussed via teleconference with the Cytology Focus Group on 12 January. I then put together a paper dated 14 January 2000 that defined the Assessment / Evaluation model for the review. On 18 January I circulated this model and a timeframe to complete the review in letters to both the Cytology Focus Group and ACL.

Assessors

56. During this period, eight assessors were engaged for assessment of the questionnaire. This included the five RCPA focus group members and three pathologists from overseas; Dr Medley, Dr Alexander Meisels, Emeritus Professor of Pathology, Laval University, Quebec City, Canada and Dr Grace McKee Associate Pathologist Massachusetts General Hospital and Associate Professor, Harvard Medical School.

Completion of Questionnaires

57. Completed questionnaires were received by the HFA from the all community laboratories by 21 January 2000. An acknowledgement letter was sent to all of the laboratories on 27 January 2000 thanking them, advising of the assessors and providing them a copy of the assessment / evaluation model (dated 14 January). A copy of this correspondence is attached as **Exhibit JD/HFA/005**.

Instruction of assessors

58. Instructions and information was sent to all 8 assessors on 24 January 2000. By 10 February 2000, each assessor completed and returned a laboratory

profile for each laboratory. The HFA then collated comments from all assessors and prepared a summary profile for each community laboratory.

Evaluation Panel Preparation and Process

59. Also during January and early February, further analysis was completed that could be considered in the evaluation phase of the review. This analysis was conducted on cervical cytology reporting pattern reports for community laboratories dated 2 – 7 December 1999 obtained from the NCSR for each year 1991 – 1995 and the three year period 1991 – 93. This analysis added to the preliminary analysis that had been completed in the report of 27 October 1999.

60. As a result of the engagement to date with the Cytology Focus Group and the laboratories, some changes were made in putting this analysis together. These changes included a focus on “high grade”, “total abnormalities” (high + low grade), and noting the ASCUS rates within these categories.

61. On 7 February 2000 Dr Barry Borman, HFA Public Health epidemiologist, provided an analysis of incidence of cervical cancer by National Cervical Screening Programme Region 1990 - 95. On 14 February 2000 cytology / histology correlation reports for 1996 –98 for each community laboratory was obtained from the NCSR.

62. The HFA had now gathered the information that was to be considered by the Evaluation Panel and this consisted of:

- assessment questionnaire profiles of each laboratory,
- analysis of reporting rates from NCSR data 1991 – June 1999,
- cytology / histology correlation data for 1996 –98 and
- estimates of incidence of cervical cancer by NCSP region 1990 – 95.

Evaluation Panel

63. During January - February 2000 an Evaluation Panel had been formed that consisted of Dr Gabriele Medley, two RCPA nominated representatives (Dr Sage and Dr Peter Fitzgerald) and two HFA representatives (Tracy Mellor and myself).
64. The Panel met on 15 / 16 February 2000 and considered all of the available information in reaching preliminary conclusions. Conclusions reached by the Evaluation Panel are discussed further below.
65. During this meeting further analysis was done to summarise unsatisfactory rates for 1996 – 98. Also, abnormality reporting rates were calculated for January – October 1999 from cytology reporting pattern reports obtained from the Register on 16 February.
66. Letters dated 17 February 2000 were sent to the RCPA and ACL advising them of the principles and process followed by the Evaluation Panel in reaching its preliminary conclusions.
67. As a result of the Evaluation Panel meeting, interim reports were provided on 18 February to four laboratories. These reports requested clarification of why an abnormality reporting rate may have been under the benchmarks set by the Panel for a specific period and / or further information relating to their practices as identified in the questionnaire response. The reports also outlined a process in which the Panel would discuss this with the laboratory if necessary.
68. Further interim reports were provided to a fifth and sixth laboratory on 28 February 2000. Although this sixth laboratory had a satisfactory questionnaire assessment and its reporting rates had improved significantly since 1996, it was decided that further clarification was required due to its abnormality reporting rate being below the benchmarks during 1991 to 1995.
69. A progress report / update was prepared by Tracy Mellor and I on 21 February and on 28 February 2000 a more comprehensive paper from Tracy Mellor and myself was presented to the Personal Health Purchase Board. The Board

approved the recommendation to form a multidisciplinary Advisory Group to consider the results of the practice review from the wider perspective of cervical screening. The paper also confirmed that if this Advisory Group considered further action was necessary with any laboratory then the likely options were

- 1) to rescreen a representative sample to identify whether a laboratory is reporting within acceptable standards or if there is evidence of significant under-reporting of high grade abnormalities,
- 2) an intensive campaign covering a particular region to encourage women to have another smear within the next six to twelve months,
- 3) full rescreening of smears to identify any woman at risk of previously misread smears,
- 4) scope to consider a national campaign to support women and the screening programme.

These options can be found in **Exhibit JD/HFA/006** at pages 074, 075, 153 and 154 - *Background and Preparation for Multidisciplinary Advisory Group 17 March 2000*.

70. On 29 February 2000 Tracy Mellor gave a verbal update to the new Health Funding Authority Board. The Board noted that the potential cost could be substantial should additional action be required and confirmed that work should continue on the basis that the full range of options might be necessary. This was on the understanding that resources would of course have to be identified before such costs are incurred.
71. A Health Funding Authority Report was completed dated 2 March 2000 that documented the "*Decision Making Processes and Conclusions Reached by the Evaluation Panel*" - refer to Exhibit JD/HFA/006 page 068. This now forms Part One of the document titled *Background and Preparation for the Multidisciplinary Advisory Group (17 March 2000* – refer to Exhibit JD/HFA/006). On 3 March a copy of this report was provided to the RCPA and ACL.

72. Also, on 3 March 2000 a letter was sent to each community laboratory informing them of the principles, processes and conclusions reached by the Evaluation Panel, that these results would be considered by a multidisciplinary Advisory Group and that confidential documentation would need to be prepared for the Gisborne Ministerial Inquiry.

Multidisciplinary Advisory Group Formation and Process

73. The multidisciplinary Advisory Group was formed and included the following members: Sandra Coney (Consumer Representation), Dr Jo Baxter (Maori Representation), Dr Peter Jennings (Gynaecologist), Dr Mary Jane Sneyd (Cancer Epidemiologist), Dr Peter Fitzgerald and Dr Margaret Sage (RCPA Pathologists). HFA and Ministry of Health officials, including Dr Colin Feek (Ministry of Health), Tracy Mellor, Dr Julia Peters and myself supported the Advisory Group.

74. On 15 March 2000 the HFA provided a verbal update to the Minister of Health.

75. On 16 March 2000 a briefing meeting was held with senior management and communication staff from the Personal Health and Public Health operating groups and the HFA's Chief Executive Officer.

76. The attached Exhibit JD/HFA/006 is a copy of the background paper dated 17 March 2000 that was provided to the Advisory Group to prepare for its first meeting.

77. As a result of the clarification process undertaken by the Evaluation Panel with some laboratories, I completed further analysis for the review. Bethesda B2B8 recommendation codes for referral for assessment / colposcopy were summarised for all community laboratories across the time periods. Abnormality reporting rates were calculated for 1998 for all community laboratories from cytology reporting pattern reports obtained from the NCSR on 9 March. Also, abnormality reporting rates were calculated from reports obtained from the NCSR on 14 March 2000 for the entire 1999 year for the three laboratories to be considered by the Advisory Group with respect to current practice.

78. The first meeting of the Advisory Group was held on 27 March 2000. A copy of the terms of reference and the minutes of the first meeting are attached as **Exhibit JD/HFA/007** with the background preparation document as Exhibit JD/HFA/006.
79. On 28 March 2000 a meeting was held with senior management and communication staff from the Personal Health and Public Health operating groups, Dr Colin Feek (MoH) and the HFA's Chief Executive Officer. The HFA accepted all recommendations from the Advisory Group except one for laboratory (e, K) for which the HFA considered further work was needed in order to fully consider the recommendation.
80. A meeting was held on 3 April 2000 to discuss possible options for this laboratory. This was attended by Dr Colin Feek (MoH), Dr Mary Jane Sneyd (epidemiologist), Dr Win Bennett (HFA), Dr Barry Borman (HFA epidemiologist) and myself. It was agreed that Dr Sneyd and I would develop a paper that gave an epidemiological perspective to the issue and outlined sample slide re-reading options. This paper would be prepared for consideration by the Advisory Group (see Exhibit JD/HFA008).
81. On 10 April I sent each laboratory an Individual Feedback Report with *The Summary Report: Overall Results and Practices* discussed earlier in this brief (refer to Exhibit JD/HFA/001 – page 007).
82. The Advisory Group's next meeting was held on 19 April 2000. The preparation document for this meeting consisted of a three part paper as follows:
- Introduction to the Epidemiology of Screening for Cancer - by Dr Mary Jane Sneyd
 - Cervical Smear Sample Rereading: Possible Alternatives and Options - by myself
 - Inquiries into cervical screening at Inverclyde, Scotland and Kent and Canterbury Hospitals, England - by Dr Mary Jane Sneyd

83. A copy of this paper, the agenda and minutes of this meeting and the proposed “*Practice Assessment, Monitoring & Improvement Plan*” are attached as **Exhibit JD/HFA/008**. Senior management and communication staff from the Personal Health and Public Health operating groups and the HFA’s Chief Executive Officer were briefed that afternoon about the results of this meeting
84. On 11 and 12 May I visited the Victorian Cytology Service in Melbourne. The purpose of this visit was to further discuss details of the review with Dr Medley. Information was also obtained about how laboratories are monitored in Victoria and how performance standards are reported. VCS’s internal monitoring of screening performance and training was also discussed. Some information about the Victorian Cervical Cytology Register was obtained. This information has been shared with the NSCP staff within the HFA.
85. The Advisory Group’s next meeting was held on 24 May 2000. The agenda, Update Confidential Report and the minutes of this meeting are attached as **Exhibit JD/HFA/009**.
86. The next day senior management and communication staff from the Personal Health and Public Health operating groups and the HFA’s Chief Executive Officer were updated on the results of this meeting. On 26 May 2000 Tracy Mellor gave a verbal update on the results of this meeting to the HFA Board.
87. The Advisory Group’s next meeting was held on 28 June 2000. The updated reports and agenda are attached as **Exhibit JD/HFA/010**.

Confidential information

88. The practice review was conducted under an obligation of confidence and all information relating to the laboratories has been coded and is non-identifiable to maintain confidentiality. It is not necessary to identify who the laboratories are to see how conclusions were reached for the review.
89. We made a commitment to the laboratories that the review would be undertaken under an obligation of confidence and that it was the HFA’s intention to maintain the non-identifiable nature of the review.

90. The obligation of confidence was considered appropriate for a number of reasons and these reasons can be summarised as follows:

- It is normal audit practice to work with providers in this manner and then to provide a public summary of results, but not to make public individual provider information on which the results are based.
- In order to undertake the review in a thorough way, it was necessary to have a considerable amount of information about each laboratory. This has been provided with the full co-operation of all the community laboratories and in recognition of the obligation of confidence.
- There is considerable international debate about the extent to which performance monitoring information should be made public. It is generally acknowledged that, if such information is to be made public, this should be agreed, or at least made clear, in advance of the provision of the information. As far as we are aware, the routine monitoring of laboratories in cervical screening programmes in other countries is done in a non-identifiable manner.
- There were minimal standards against which performance could be monitored. Work is currently underway to implement such standards for the National Cervical Screening Programme to be supported with a monitoring and evaluation plan for the programme.
- The review has been carefully designed and implemented, with the input of a range of expertise at appropriate points. The HFA is therefore confident that, based on the information considered by the review, the results can be relied upon by the public.

Acknowledgements

91. In summary, this review of cervical cytology practices has been a major undertaking completed within very demanding timeframes. This type of retrospective review was made even more challenging by the need to look back over the previous 10 year period and in the absence of agreed specific laboratory standards in gynaecological cytology.

92. The Health Funding Authority wishes to thank the following for their contribution to the practice review.

- The Royal College of Pathologists, and the Association of Community Laboratories.
- The Assessors, Evaluation Panel and multi-disciplinary Advisory Group.
- All of the community laboratories for their support and co-operation in the review.

93. In closing, I wish to acknowledge the support and advice received from Dr Gabriele Medley as her contributions have been significant in both the overall quality of reports and the outcomes related to this review. Please refer to **Exhibit JD/HFA/011** for a copy of Dr Medley's curriculum vitae and to the attached schedule for a summary of Dr Medley's curriculum vitae.

J. DuRose

SCHEDULE

SUMMARY OF THE CURRICULUM VITAE OF DR GABRIELE MEDLEY

I graduated in Medicine (MB.BS.) from the University of Melbourne in 1959 being awarded the Exhibition in Medicine (Levy Prize) in the Final Examination.

After a two year residency and one year as a research scholar at the Alfred Hospital in Medicine, I did part time clinical work whilst I was establishing my family of three children. I then commenced my pathology training at the Alfred Hospital and was granted the Fellowship of the Royal College of Pathologists of Australasia in 1973 (Anatomical Pathology Special). I was the first person to be granted the opportunity by the College to pursue this training on a part time basis, spanning seven years instead of the full-time requisite of five years.

After a short period of further part time pathology practice and a lectureship in the Department of Medicine of Monash University organising a clinico-pathological correlation curriculum for medical students, I accepted a position as a full-time pathologist at Prince Henry's Hospital, Melbourne, in 1975.

During the next three years I added training in cytopathology to my routine duties in surgical pathology, utilising the training programme of the Victorian Cytology Service (VCS) which was co-located with the Department of Anatomical Pathology. From this period my duties included routine cytopathology.

In 1987 I was appointed Director of the Victorian Cytology Service and the Department of Cytopathology of the hospital. In 1991 the Victorian Cytology Service moved from Prince Henry's Hospital (which was closed and demolished) to the campus of the Royal Women's Hospital, where it remains to this day. I have remained as Director and also hold consultant positions at the Royal Women's and Mercy Hospital for Women, and am a Senior Associate in the Department of Obstetrics and Gynaecology, and the Department of Pathology of the University of Melbourne.

Victorian Cytology Service is an independent public sector laboratory which reports around 280,000 Pap smears per year and some non-gynaecological cytology and cervical histopathology. It is the largest laboratory devoted to cervical pathology in Australia and is considered an industry leader in quality assurance in the field. I am a co-author of many often cited publications from the laboratory in the international scientific literature.

I have served on a number of government committees relating to cervical screening in Australia and currently remain a member of some. I have been President of the Australian Society of Cytology and am currently Victorian State Councillor to the Society. I am currently Chair of the General Policy and Long Range Planning Committee of the International Academy of Cytology and I retain membership of a number of Australian and international bodies relating to pathology in general and cervical screening in particular.

I have participated in many meetings as an invited speaker and panellist in Australia and overseas and continue to be an Assessor for NATA, the organisation which is responsible for inspecting, and approving for accreditation, pathology laboratories in Australia.

I will retire from my Directorship of VCS on June 30 2000 but have accepted a three year appointment as Director Emeritus, working three fifths of full time to continue my involvement as a practising cytopathologist with a particular interest in quality management.