

**UNDER THE HEALTH AND DISABILITY  
SERVICES ACT 1993**

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

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**EVIDENCE OF GEORGE ROBERT BOYD**

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**MINISTRY OF HEALTH**

## **PART TWO : QUALITY ASSURANCE IN THE NCSP**

### **Introduction**

1. This section of the Ministry's evidence should be read in the context of the more general evidence relating to the chronology of the NCSP to be presented by Judy Glackin. This section relates to the policy issues relating to the quality and safety of the health care services utilised by the NCSP. It is important to note that there were no new clinical services developed for the NCSP. All the clinical elements were already in place and operating when the Minister announced in 1988 that there would be a nationally co-ordinated service. The section will cover:

1.1 competent personnel;

1.2 laboratory internal quality control procedure; and

1.3 laboratory external quality control processes.

### **COMPETENT PERSONNEL**

#### **Smear takers**

2. One difficulty in obtaining quality results from laboratories reading smears has been problems with the original smear. Problems can include:

2.1 insufficient cells for examination;

2.2 the absence of endocervical cells (suggesting incomplete sampling from the cervix);

2.3 the presence of foreign material (such as lubricant used in the examination);

2.4 poor fixation or preservation of the cells on the slide; and

- 2.5 the presence of blood or inflammatory material obscuring the squamous cells.
3. The NSCP has received advice on improving the quality of smear taking and taken the following steps:

3.1 *Training and competence of non-medical smear takers:*

Non-medical smear takers are usually registered nurses who have completed an NZQA accredited smear takers course. This course is based on *National Standards for Non-medical Smear Taker Training and Continuing Competency* developed by the NSCP. On satisfactory completion of the course, an identification number is given to the nurse to enable the authorisation of their client's laboratory tests. Some practice nurses also take smears which can be submitted to the laboratories under the registration numbers of the general practitioners with whom they work or under the smear taker's own number.

There is a very small number of lay smear takers. These women are not registered nurses but complete the same smear takers' course and often have additional training to provide a thorough health context for the work they do. Lay smear takers usually work in areas where there are no medical or nurse smear takers or where they fulfil the cultural needs of the local population, for example, Maori and Pacific Island groups. Clinical support from a local general practitioner or a suitably qualified person is usually arranged by the local co-ordinator of the NCSP.

3.2 *Feedback to the smear taker on the quality of the specimen:*

The Bethesda reporting system used in the NCSP includes fields for the laboratory to comment on the quality of the specimen received. This information is provided to the smear taker by the Register operated as part of the NCSP at 6 monthly intervals and is available to the programme for use in quality audits.

## **Medical practitioners**

4. Until the legislative changes to the Medical Practitioners Act 1995, in force from 1 July 1996, the medical profession, including pathologists, were self-regulating. Monitoring the professional competence of an individual practitioner, so far as the Department/Ministry was concerned, relied largely on appropriate entry standards into the profession, and the sanctions applied by the disciplinary bodies established under the Act to any doctor found guilty of professional misconduct or disgraceful conduct. As I have said, the Department's primary method of influence until 1993 was through the payment of benefits and the threat of non-payment. This was relevant only to private laboratories as laboratories in public hospitals were bulk-funded through the hospital. Thus there was not even this level of influence over hospital pathologists.

### *Entry standard for medical practitioners*

5. Before registering a person as a medical practitioner pursuant to the Medical Practitioners Act 1995, the Medical Council of New Zealand has to be satisfied that the person has met the Council's entry requirements for registration and has satisfied the Council that he or she has the adequate skill and knowledge to practise medicine. All pathologists are medical practitioners.
6. The standards for entry into what has been called, since 1996, the vocational register (formerly the specialist register under the Medical Practitioners (Registration of Specialists) Regulations 1971), are determined by the Council in consultation with the appropriate medical college. To obtain vocational registration (including registration as a pathologist) a practitioner must:
- 6.1 hold general registration; and
  - 6.2 hold such qualifications as the Council determines are appropriate for vocational registration in respect of that branch or sub-branch of medicine; and

- 6.3 possess such training and experience as the Council determines are appropriate for vocational registration in respect of that branch or sub-branch of medicine; and
  - 6.4 be considered to be competent to practise that branch or sub-branch of medicine.
7. General practitioners were not classed as a specialist under the Medical Practitioners Act 1968. With the coming into force of the Medical Practitioners Act 1995, general practice became a registerable vocation on an equal footing with other medical specialities. The legislation requires that general practitioners have to be either vocationally registered or work under the oversight of a practitioner who is vocationally registered as a general practitioner. Transitional provisions apply until 2001 for doctors who were registered under the previous 1968 Act.
  8. The purpose of oversight is to assist the Medical Council in determining that the doctor is practising competently. There is a system of random audit by the Medical Council to see that the oversight requirements are being met.
  9. To be entitled to vocational registration, a doctor in general practice must submit to re-certification, the criteria for which are presently being worked out by the Medical Council and the specialist medical colleges. The College for general practice is the Royal New Zealand College of General Practitioners. For Obstetricians and Gynaecologists the relevant organisation is the Royal New Zealand College of Obstetricians and Gynaecologists.

## **Midwives**

10. Midwives are registered by the Nursing Council of New Zealand pursuant to the Nurses Act 1997, either as nurses who have undertaken relevant post-graduate training or following a course of training leading to direct-

entry into the profession of midwifery. There are no continuing competency requirements for midwives in the present legislation.

## **Pathologists**

### *Entry standards for pathologists*

11. Prior to the coming to force of the Medical Practitioners Act 1995 Act on 1 July 1996, pathology was recognised as a speciality branch of medicine and pathologists who had obtained training acceptable to the Medical Council could apply to have their names included on the specialist register under the Registration of Specialists Regulations 1971. There was no requirement for maintaining competency and names were maintained on the register until the practitioners asked to have their name removed, died, were not able to be contacted by the Medical Council or were struck off as a result of disciplinary action by the Council.
12. Under the 1995 Act, to practise independently as a pathologist (i.e. without oversight), a medical practitioner must hold vocational registration as a pathologist. One must first obtain registration as a medical practitioner; then complete a five-year training programme to become vocationally registered as a pathologist. The training programme in New Zealand is run by the Royal College of Pathologists of Australasia and I understand that completion of the five year training programme is a requirement for Fellowship of the Royal College.
13. The Medical Council then decides whether Fellowship of the Australasian Royal College is a necessary prerequisite for admission onto the vocational register and whether any other qualification is also acceptable.
14. Pathologists who were registered under the 1971 Regulations retained their vocational registration with the coming into force of the Medical Practitioners Act 1995. They are subject to transitional provisions until the year 2001 when they will have to satisfy the Medical Council of their competence to continue in independent practice.

*Cytology and cytopathology training*

15. Cytopathology (the study of cells) became a regular part of the examination requirements for the Fellowship of the Royal College of Pathologists of Australasia examinations in the mid 1980s. Doctors training to be anatomic pathologists are also able to sit an examination in cytopathology. In addition a post Fellowship Diploma in Cytopathology is also available.
16. There is an international Academy of Cytology which is US-based. It runs examinations that are recognised worldwide. There are examinations for laboratory assistants and medical laboratory technologists as well as a separate examination in cytopathology for medical practitioners.

*Recognition of supervising pathologists*

17. As a separate process, the Department/Ministry of Health maintained and published a list of specialists eligible to claim specialist benefits under the Social Security Act 1964.
18. As I have said, the LSAC dealt with applications for recognition as specialists in pathology for the purposes of the Social Security (Laboratory Diagnostic Services) Regulations 1971. Until 1980 its membership comprised five pathologists and a Department of Health chairperson.
19. In 1980 the Committee was reconstituted with a wider membership and revised terms of reference, but it continued to consider applications for recognition as a specialist in pathology for the purposes of the 1971 Regulations.
20. Pathologists seeking recognition were required to describe the laboratory services that would be provided, the laboratory equipment and staffing and their qualifications which would make them suitable for supervising the laboratory service to be provided. A recommendation went from the Committee to the Minister of Health when the Committee considered a pathologist suitable to claim benefits.

*Registration of Dr Bottrill*

21. The name of Michael Bernard Bottrill appeared in 1969 under the speciality of Pathology, published in the Clinical Services Letter No.93 of 12 December 1969. A copy is produced as **GRB/MOH/0017**. He remained on the list until that part of the Social Security Act was repealed in 1993. The regional health authorities then became responsible for paying the government subsidies through a contracting arrangement.
22. The LSAC met annually, mainly to consider new tests to be added to the schedule of subsidised laboratory tests. It also provided advice on matters brought to it by the Department of Health concerning private laboratory services. One example of advice being given where quality concerns had been raised is the October 1987 example concerning a laboratory in Christchurch, referred to later in this evidence. I can find no reference in the minutes of the Committee to any issue arising concerning the Gisborne laboratory supervised by Dr Bottrill, which I understand was established in 1967.

**Cytologists**

23. Cervical smear reading is a regulated practice under the Medical Laboratory Technologists Regulations 1989. Regulation 9 of these Regulations states that it can only be carried out by a registered medical practitioner, a registered medical technologist or someone working under the supervision of either of the above.

*Medical practitioners*

24. Note that the Regulation does not require the medical practitioner to be a pathologist and on the vocational register, but from 2001 any medical practitioner carrying out this task would need to be subject to the oversight of a vocationally registered pathologist.

*Registered medical laboratory technologists*

25. Medical laboratory technologists are registered by the Medical Laboratory Technologists Board, established under the Medical Laboratory

Technologists Regulations 1989. The Board has disciplinary powers but does not have powers to require evidence of ongoing competence.

26. The course of training to become a medical laboratory technologist is a four-year training programme, resulting in the award of a Bachelor of Medical Laboratory Science, which has compulsory components of cytology. The degree course started in 1992 and is offered through Massey and Otago Universities and the Auckland University of Technology.
27. In the fourth year of the degree course students take two preferred options in medical laboratory science. If cytology is one to the preferred options then they are required to spend one semester working in a laboratory.
28. Prior to the introduction of the degree course the training programme in cytology was hospital and technical institute based. In addition the Laboratory Technologists Board conducted examinations and awarded the Diploma in Medical Laboratory Technology up until 1997. This training programme was equivalent to the New Zealand certificate level and as part of the qualification, candidates must have had practical experience in cytology.
29. In July 1995 the Cervical Screening Laboratory Advisory Committee (CSLAC) met with NCSP staff and representatives of the Medical Laboratory Technologists Board and the New Zealand Institute of Medical Laboratory Science. At the meeting it was noted that the phasing out of the old course, and the phasing in of the degree courses had created a “gap” in training numbers, leading to a shortage of skilled cyto-technologists, which had led to active recruitment of staff from Canada and Australia.

#### *Laboratory assistants*

30. Laboratory assistants work under supervision of a medical laboratory technologist, scientific officer, or registered medical practitioner. Most laboratory assistants will have completed a two-year correspondence course run by the National Women’s Hospital. On completion of the

course, and after having had at least two and a half years experience in a laboratory, a laboratory assistant is eligible to sit the Qualified Technical Assistant examination conducted by the New Zealand Institute of Medical Laboratory Science.

### **Shortage of trained laboratory staff: 1987-1992**

31. In 1985 the Department of Health was advised of an impending shortage of cervical smear readers in laboratories performing cervical cytology, which would be exacerbated if a national screening programme were introduced.
32. The Department allocated funds for additional training to be purchased from the National Women's Hospital. Negotiations fell through. Then as a consequence of the publicity surrounding the Cartwright Inquiry, there was a 10 percent to 25 percent increase in cervical smears for reading.
33. The issue of training cytology screeners was very concerning for those involved in providing cytology services for the proposed National Cervical Screening Programme. Issues regarding the training of cytology screeners were raised at the first meeting of a committee formed by interested professional groups, the Cytology Advisory Liaison Committee (CALC), on 18 April 1989. The representatives at the meeting comprised two members from the Royal College of Pathologists of Australasia, two members representing the New Zealand Institute of Medical Laboratory Technologists, two members representing the New Zealand Society of Cytology and two members from the New Zealand Society of Pathologists. This committee was initially neither a formal Ministerial nor a Departmental advisory committee, but did receive some financial support through the Department. The relationship was subsequently formalised. At this point I produce as document **GRB/MOH/0018**, a bundle of documents which contains the terms of reference and those minutes of the CALC and its successor the Cervical Screening Laboratory Advisory Committee (CSLAC), plus some relevant agenda papers, which are available from Ministry files.

34. The minutes of the first meeting on 18 April 1989 disclose that points raised at that first meeting included the following:
- 34.1 the need for a formal training course for ...;
  - 34.2 the strong recommendation that pathologists enter new staff in such a course;
  - 34.3 the need for a proper career structure;
  - 34.4 that any course should be under the auspices of a tertiary institute, for administrative and funding reasons;
  - 34.5 that any course should be a national programme and therefore not funded by area health boards;
  - 34.6 that a full-time appointee run the course. A senior graded tutor cytotechnologist was required; and
  - 34.7 that the course should have a strong hospital association.
35. The minutes of the second meeting on 18 July 1989 disclose that the Committee recommended that the Department of Health speed up the process to get a cytology course up and running. Further discussions had been regarding proposals received from the Auckland Technical Institute and the Central Institute of Technology (CIT).
36. As part of the November 1989 Ministerial Review Committee Report (**JMG/MOH/0001**), standards of competency for smear readers were considered. The importance of the role to be played by laboratories and their staff was well understood as it would be through them that cytological information would be collected and assessed and recall dates established. Therefore, the need for consistency between the approach of laboratories to smear analysis, reporting and meeting minimum standards of competency was specifically recorded in the report.
37. The Review Committee noted that the Department, CALC and the Testing Laboratory Registration Council of New Zealand (TELARC) would set

standards for training of cytology laboratory assistants. The Department would then be responsible for ensuring there were sufficient training facilities to meet the workforce requirements of the NCSP.

38. In 1990 the cytopathology course was begun at the CIT with seeding funding from the Department of Health's Health Workforce Development Fund. The arrangement was that \$160,000 per year for three years would be provided to the CIT to run the course. After this, the understanding was that ongoing funding for the course would come out of the CIT's bulk grants from the Ministry of Education. The course was run in three six-week blocks per year.
39. The Government's Cervical Screening policy issued in 1991 (JMG/MOH/0015) provided, in clause 4.1.5, that:

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

40. The minutes of its meeting on 10 April 1992 disclose that the CALC noted that trainees in the cytology course at the CIT were halfway through the three-year course with an 80 percent pass rate expected. A major problem was maintaining sufficient enrolment numbers to ensure government funding. A minimum of ten full-time students were needed. It was noted that within the last five years the employment situation had changed for laboratory assistants from a situation of there being a shortage to the current situation to one where laboratory assistants were having trouble finding work.
41. At a meeting of CALC on 16 June 1993 it was reported that the CIT training course was in abeyance. The course was unable to attract funding from the Ministry of Education and did not resume.
42. On the subject of ensuring competent laboratory staff, I note that on 19 August 1994, CALC was presented with a discussion paper on quality control and cytotechnicians in the NCSP prepared by the Ministry of Health to meet NZQA requirements following the closure of the training

course. These included draft competencies for cytotechnicians. These competencies had been developed by the Ministry for in-house training in laboratories. The Committee considered that the paper overlapped with the work that it was doing in preparing standards for TELARC and was not in favour of it going out without considerable amendment. The document was discussed by the Committee, now renamed the Cervical Screening Laboratory Advisory Committee (CSLAC), again on 15 February 1995 when it was still not accepted as suitable for publication.

43. I am not aware from seeing documents or from any other source that there have been any significant concerns about shortages of laboratory assistants after 1994.

#### **LABORATORY INTERNAL QUALITY CONTROL PROCEDURES**

44. Laboratories, like most organisations, have introduced processes of checking their own work to varying degrees. The ways in which this quality assurance activity is carried out is at the discretion of the laboratory itself, except where standards are mandated by the purchaser of their service or by the professional bodies to which the laboratory staff belong.
45. In its 1994 advice to the Minister of Health on cervical screening, previously produced in Judy Glackin's evidence (**JMG/MOH/0031**), the Public Health Commission noted that ongoing monitoring of cytology screening staff was being performed by the individual laboratories or crown health enterprise laboratories and that "the quality of smear-reading, the turn-around time for smears and the correlation between cytology and histology results all require on-going monitoring and evaluation".
46. The Public Health Commission went on to recommend to the Minister that regional health authorities continue to purchase, for the 1994/95 and succeeding financial years, cervical screening services which maintain ongoing monitoring and evaluation of the laboratories' performance to ensure the accuracy of screening and diagnosis of abnormal cytology.

47. An early example of voluntary quality assurance standards applicable to reading cervical smears was presented to the New Zealand Society of Cytology and the New Zealand Society of Pathologists by a subcommittee formed by the Societies in 1986. I produce this document as **GRB/MOH/0019**.
48. These standards focused on facilities, personnel recording and reporting, processes and proficiency testing of the laboratory as a whole and staff members individually, and clinical correlation to follow up on abnormal findings.
49. The three most significant areas of internal quality control identified during the discussions at meetings of CALC were the re-reading of cervical cytology slides, correlation of cytology results with subsequent histology findings and throughput and workload.

#### **Re-reading of cervical cytology slides**

50. In 1985 the meeting on cervical screening convened by the Cancer Society and the Department of Health was told by Dr Stewart Alexander, a Hutt Valley pathologist (and Chair of the Medical Council), that in his laboratory up to 50 percent of the slides were looked at by more than one person. Those for re-reading were selected because they were reported initially as abnormal, the women had previously had an abnormal smear result, or there was a relevant clinical history provided. However the meeting recommended rather that laboratories should have all abnormal smears read by two people of different levels of seniority.
51. At the third meeting of the CALC on 4 May 1990 members agreed to recommend that 10 percent of smears reported as normal should be re-read randomly.
52. Regarding re-screening of abnormal smears, the Committee considered that it was up to the pathologist and technologist to define what was an abnormal smear for their particular laboratory. The Committee

recommended that all significantly abnormal smears should be seen by the pathologist.

53. A review of laboratory services prepared for the NCSP in 1993 reported that internal quality control procedures used in hospital and community laboratories included random re-screening of 10 percent of negative smears, routine rescreening and checking of specific categories or smears, correlation of cytology and histology results and review of previous negative smears of women whose current smears were abnormal. (See the NCSP's Review of Laboratory Services, (V Norton) which is **JMG/MOH/0025**.) However, the report did not quantify how many laboratories were carrying out which procedures. The Ministry's files do not contain the raw data upon which this report was based. It was considered by the CALC at its meeting of 28 April 1993.
54. In 1994 the CALC was invited to draft revised standards for laboratories to be used by TELARC when auditing laboratories providing cytology services for the NCSP. There was considerable discussion about the level of re-reading of smears for quality assurance purposes. Some local laboratories had introduced rapid rereading of 100 percent of smears by another staff member. This usually meant that the slide is rapidly passed through the microscope in a Z-wise fashion, so that the second reader gets an impression of the cellular elements and can put any suspicious slides aside for a more thorough re-read.
55. In the minutes of 19 June 1996 the Committee, now named Cervical Screening Laboratory Advisory Committee (CSLAC), referred to the NCSP standards (already with TELARC) and confirmed that they would be circulated to all laboratories. There was no specific reference to the proportion of slides which should be re-read in the final document. Those standards are produced later in my evidence (**GRB/MOH/0025**).

### **Correlation of cytology results with subsequent histology**

56. The meeting convened in 1985 by the Cancer Society and the Department of Health recommended that cytology laboratories develop a relationship

with those treating cervical disease, so that specimens taken during colposcopy examinations (histology specimens) could be examined in the same laboratory where the previous cervical smear had been read (**GRB/MOH/0008**). This was to enable correlation of the two results to occur, providing an internal quality assurance check on the original cytology.

57. The Ministerial Review Committee into the NCSP in 1989 recommended that urgent attention be given to including histology on the NCSP Register (**JMG/MOH/0001**).
58. This type of feedback, providing a trigger to go back and examine all of that woman's previous cervical smears, was discussed from the early days of the NSCP. In 1993 the programme commissioned Azimuth Consulting Limited to define the requirements for adding histology results to the Register. This report, completed in April 1993, has already been produced in Judy Glackin's evidence (**JMG/MOH/0023**).
59. The advantages of adding histology results to the Register listed by the consultants included:
  - 59.1 the ability to compare and correlate cytology results with histology results; and
  - 59.2 the ability to detect discordant results and make appropriate decisions regarding quality assurance.
60. The minutes disclose that the CALC considered this report at its meeting on 28 April 1993 and recommended a technical group be set up to make recommendations on matters relating to histology data including quality assurance.
61. In September 1993 the NCSP wrote to four members of the CALC providing them with a paper apparently prepared by Azimuth Consulting Limited as a result of work by the technical group. It set out a draft quality

assurance process related to implementation of histology in the Register. I produce a copy of this letter and the report as **GRB/MOH/0020**.

62. The report proposed that the NCSP provide correlation reports for each participating laboratory at quarterly intervals to be used to monitor trends in the examination of cytology and histology results. Each laboratory would be provided with:

62.1 national correlation results;

62.2 histology correlation to the laboratory's cytology results; and

62.3 cytology correlation to the laboratory's histology results.

The report also proposed that TELARC would be advised that laboratories would be receiving these results so that they could be reviewed as part of the laboratory's accreditation process (which will be described more fully later in the evidence under "Laboratory External Quality Assurance Processes"). It also suggested ways that the NCSP itself could detect and manage discordances detected in laboratory results.

63. These proposals were further elaborated in a discussion paper prepared following a meeting between the consultant and the National Co-ordinator of the NCSP on 8 September 1993. I produce the report as document **GRB/MOH/0021**. An important point to note from this document is the suggestion that a trend in discrepancy between cytology and histology results may not appear until two years after histology had been added to the Register.

64. As Judy Glackin says in her evidence, the NCSP was unable to start providing laboratories with feedback from the histological examination of specimens taken at subsequent colposcopy examinations until histology results were routinely entered into the Register in 1996.

65. It appears from the minutes that the CALC considered the proposed quality assurance processes at its meeting of 17 November 1993 and rejected it in

favour of a different process for dealing with possible indications of inadequate laboratory performance. The minutes record the following:

**“The meeting discussed Janet Phuah’s paper.**

**The meeting agreed that data produced for quality assurance could easily be misused or misinterpreted. The meeting noted that there is no independent person with enough expertise to assess potential histology/cytology correlation problems within New Zealand. The meeting discussed the process for assessing problems of quality assurance at length.**

**The meeting agreed that if the NCSP discovers a possible indication of inadequate laboratory performance the process for assessing these problems should be as follows:**

- **The NCSR identifies a potential problem with a laboratories quality assurance data**
- **The issue should be presented to CALC and the laboratory concerned**
- **CALC will monitor the situation and review the issue after 6 months at which stage CALC may visit the laboratory in question, present the problem and check to see if there is a simple explanation or suggest remedial action**
- **if no improvement then CALC would present the issue to TELARC and/or the New Zealand Society of Cytology and/or the New Zealand Society of Pathologists**

**The meeting agreed that the statistics should be generated by the Register every 12 months. If there is a discrepancy then the statistics may be generated 6 monthly if they are statistically significant.**

**The meeting agreed that the process should be circulated to all laboratories for comment.” (para.10.2)**

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

### **Throughput and workload**

67. The report of the National Cervical Screening Workshop of 1988 refers to a minimum number of smears per annum for any laboratory to maintain quality. A figure of 1000 smears per annum was suggested as the

minimum, and for a training laboratory the suggested figure was 25,000. It is my understanding that Dr Bottrill's laboratory was processing approximately 5000 slides per annum at the inception of the NCSP. Health Benefits Limited, which paid laboratories the Laboratory Services Benefit after 1993 has advised that payments were made through a manual system until February 1997 and they are unable to confirm the number of claims for cervical smears from Dr Bottrill's laboratory.

68. Subsequently, when discussing standards for laboratories, CALC members were divided about whether the standards should set minimum numbers per cytology reader (to maintain competence) or set maximum numbers, (per day per cytology reader), to prevent stress and fatigue reducing their accuracy. In the end the standard distributed in 1996 contained a provision that there should be sufficient staff to ensure that any individual involved in primary screening is normally not required to consistently examine more than sixty (60) slides per normal working day, with an absolute maximum of eighty slides per day.

#### **LABORATORY EXTERNAL QUALITY ASSURANCE PROCESSES**

69. Until TELARC accreditation was mandated by the purchaser for laboratories providing cervical smear reading services for the NCSP, there were several ways in which laboratories and their staff could voluntarily compare the quality of their work with that being done in other laboratories. These included:
- 69.1 attendance at professional meetings;
  - 69.2 exchange visits to other laboratories;
  - 69.3 exchanging collections of slides with other laboratories and comparing the reading results;
  - 69.4 inviting an external accreditation or registration body to audit the laboratory against accepted standards;

- 69.5 comparing cervical smear reading results with subsequent histology results; and
  - 69.6 participating in a programme to compare the results of cervical smear reading from individual laboratories with the national average.
70. The last four of these will now be discussed in greater detail.

### **Exchange of slides**

- 71. Public and private laboratories have had voluntary arrangements to share slides and compare results for many years.
- 72. The Royal College of Pathologists of Australasia runs a Cytology Quality Assurance programme which uses a standard protocol for sharing slides amongst participating laboratories and has done so since before 1990. This scheme is voluntary. It covers all cytology, not just cervical smears.

### **Comparison of histology results with previous cervical smears**

- 73. Correlation of histology and cytology results can be considered both an external and an internal quality assurance activity. As an external check on a laboratory's performance the Register can provide statistics to show the proportion of women having colposcopy whose histology results:
  - 73.1 confirm the result of a previous smear reading;
  - 73.2 do not confirm previous smear readings. In this case the histology may show no abnormality when one had been indicated, or a lesser degree of abnormality. There is also a possibility that a woman may have a colposcopy examination, although not as a result of a recommendation from the smear reader, and the histology results shown an abnormality when none had been predicted by the smear reader.
- 74. These data require analysis before they can be used as an indicator of the quality of the previous smear reading. I understand that each case may

have several factors which could contribute towards a discrepancy between the histology and the reported result of the cervical smear. These include:

- 74.1 an incomplete sampling of the cervix by the smear taker;
  - 74.2 poor fixation of the slide;
  - 74.3 failure to identify abnormal cells on the slide;
  - 74.4 classifying normal cells as abnormal;
  - 74.5 incorrect coding, leading to an incorrect report being sent out;
  - 74.6 development of abnormal cells in the time since the previous smear.
75. I am not an expert in either cytology or statistics and expect the Inquiry will hear from experts at a future time who can describe more fully the different interpretations that can be put upon the seemingly simple concept of false-negative and false-positive reporting of cervical smears.
76. In 1990, Judith Straton of Western Australia was invited to review the NCSP. Her report criticised the absence of histology reports on the NCSP register. A copy is **JMG/MOH/0004**. In the same year, the NCSP Expert Group had recommended that the NCSP be linked to the Cancer Registry to provide correlation of smear reading results with proven cancer, even though the specimen may have been reported by another laboratory at a later date. A copy is **JMG/MOH/0005**.
77. The difficulties that the NCSP encountered in including these data onto the Register is described elsewhere in the Ministry's evidence relating to the Register. It was finally achieved in 1996 and results have been sent out from the Register to laboratories regularly since then for use in quality assurance activities monitored through TELARC accreditation.

### **Accreditation**

78. The Testing Laboratory Registration Council of New Zealand (TELARC) is a user-funded statutory body, established in 1972 with a primary

function of formally recognising laboratory expertise and competence through its Registered Laboratory Programme, which later became known as its Medical Laboratory Accreditation Programme.

79. TELARC itself has undergone a name change to International Accreditation New Zealand (IANZ).
80. In 1990 few medical laboratories were accredited with TELARC. The Straton Report recommended that laboratory reimbursement for cervical cytology should be linked to accreditation. In May 1990 CALC noted that, in due course, all laboratories would need to be TELARC registered. At the same meeting CALC was discussing accreditation standards to be used by TELARC for cytology services.
81. TELARC issued an advisory notice in May 1991 to members of its Medical Laboratory Accreditation Programme concerning quality assurance, based on the recommendations of CALC. I produce a copy as document **GRB/MOH/0022**.
82. In 1992 the Department of Health received legal advice that it would be doubtful if the Department had the authority to demand that laboratories already claiming laboratory benefits under the Social Security Act 1964 must seek TELARC accreditation.
83. In November 1993, following the repeal of the Social Security Act and the transfer of laboratory funding to regional health authorities, the issue was reviewed by CALC. The representative of the NCSP at the meeting advised that she would be seeking to have it included in RHA funding agreements. She subsequently wrote to the Central RHA asking that her letter be discussed at the next joint RHA meeting to consider laboratory services. The letter set out the NCSP's expectation that all laboratories be TELARC registered (or equivalent) within a reasonable time and that the laboratories provide services with the NCSP national policy. I produce a copy of the letter dated 3 November 1993 as document **GRB/MOH/0023**.

84. The Women's Health Action Group wrote on 24 November 1994 to the Minister of Health regarding a woman's false-negative smear result and asked, amongst other things, about what structures were in place for monitoring laboratory quality. This letter will be dealt with in greater detail later in this evidence. The Ministry sought assistance from the Cervical Screening Laboratory Advisory Committee (CSLAC) in drafting a reply for the Associate Minister, Hon Katherine O'Regan.
85. In response, the Associate Minister advised that, in accordance with 1995/96 Policy Guidelines, the RHAs must ensure that all laboratories providing cervical cytology and histology services were registered with TELARC. Furthermore, work was under way to reconfigure the Register from 14 stand-alone registers into one central database. The members of the CSLAC believed that the reconfigured Register would have the strongest national monitoring capabilities in the world.
86. The Associate Minister noted that laboratories themselves should be documenting their own false-negative rates, however there was nothing in place to enforce this. It was acknowledged that some laboratories had better systems than others. The current protocol for handling cases such as this is that there is a revision of all disputed slides. She noted also that the current NSCP protocol for the management of abnormal smears was due to be reviewed in the next financial year 1995/96. I produce copies of the Women's Health Action Group's letter of 24 November 1994 and associated documents ending with a copy of the Associate Minister's response of February 1995 as a bundle, **GRB/MOH/0024**.
87. The members of the CSLAC agreed that a rapid re-screening of all slides in a Z-wise fashion would pick up some abnormalities and be probably more effective than the 10 percent random re-read which was occurring at that time.
88. Various draft standards for TELARC were circulated and discussed among CALC/CSLAC members during 1994. They were referred to TELARC for discussion at the end of 1994 (see minutes of CSLAC meeting of 15

February 1995, item 7). There is a gap in the minutes but it appears that the standards were implemented by TELARC in 1995. A copy of the CSLAC report entitled “National Cervical Screening Programme Standards for Laboratories” (1995) is produced as **GRB/MOH/0025**). In brief, the standards recorded:

- 88.1 that laboratories must employ at least one pathologist, one technologist/scientist, and as well, must have sufficient staff to ensure optimal examination of no more than 60-80 slides per day per screener;
- 88.2 that as a minimum requirement for continuing education, laboratories must hold all current editions relating to cytology, documented internal/external teaching programmes and staff must attend an external relevant professional meeting every two years;
- 88.3 that there must be a pathologist readily available to advise the clinicians on: the suitability/adequacy of the requested procedure; the clinical significance of laboratory results; further procedure which may be helpful;
- 88.4 that for laboratory facilities, all processing, evaluation and reporting of cytology slides must be performed on accredited laboratory premises;
- 88.5 that standard current practice regarding the accurate, detailed, written documentation of all methods should be followed;
- 88.6 that, for External Quality Assurance, it was mandatory for laboratories to be enrolled in, participate in and remain in an external quality assurance programme complying with Royal College of Pathologists of Australasia criteria.;
- 88.7 that, for Internal Quality Control, each laboratory must possess documentation of its internal quality control which covers all of its activities;

88.8 that all cytological reports of significant abnormality must be confirmed by a pathologist and the definition of “significant abnormality” must be documented in the laboratory.

89. The Ministry does not have any additional material on its files about TELARC (or any equivalent) accreditation standards for cytology laboratories after 1996, when accreditation became mandatory.

### **Comparison of laboratory smear results against the national average**

90. In 1990, in an attempt to develop a baseline set of national records of the number of women having cervical smears and the number reported on, the Department of Health sent out a memorandum to Area Health Boards and private medical diagnostic laboratories which included a questionnaire. I understand that because laboratories were manually recording their results at that time there was difficulty completing the questionnaire, especially where it asked for the number of women being referred for cervical histopathology and the percentage of results being reported as abnormal. I produce the memorandum and examples of replies as **GRB/ MOH/0026**.

91. From this material the Department completed a set of tables which appear to me to have been totally inadequate for making valid comparisons. I produce these as **GRB/MOH/27**.

92. There is no evidence in the files that the results of the questionnaire were ever collated and sent out to the laboratories, perhaps because they contain commercially sensitive information, but no information suitable for quality assurance purposes.

93. For completeness, I also produce as **GRB/MOH/0028** a copy of a letter from Dr Bottrill to Dr Teague seeking a comparison of his laboratory results with national results. There are no further relevant records that can be located on Ministry files concerning this request.

94. In association with the production of the second statistical report on the NSCP in 1996, the Register was able to provide each laboratory providing cytology services with a comparison of its results up to June 1994 against

the national average. The results and the process were discussed by the CALC at its meeting of 19 June 1996. Individual results were mailed to laboratories on 7 August 1996, and covered all results recorded on the register up until June 1994. As an example I produce the result for Dr Bottrill's laboratory as **GRB/MOH/0029**. Since then I understand the Register has sent out a number of similar reports to laboratories. By the August 1999 report, there was a significant catch-up so the period being reported on was 1 January 1999 to 30 June 1999 (i.e. only a three month delay in receiving the information). The intent of the reports is to provide the laboratory with information for use in its own quality assurance programme and a stated aim is to reduce the number of false-negative reports.

#### **INVESTIGATIONS INTO CONCERNS ABOUT THE QUALITY OF LABORATORY CYTOLOGY SERVICES**

95. A search of Ministry files revealed four allegations or comments about the quality of reporting by individual laboratories.

##### **October 1987: Christchurch**

96. Ex-employees of a Christchurch laboratory wrote to the Department of Health concerned about the standards at the laboratory, which was TELARC registered. They alleged that three unqualified trainees were responsible for all cytological screening and were inadequately supervised.
97. As Manager of the Primary Healthcare Programme, I took advice from the Laboratory Services Advisory Committee and then visited the laboratory with another officer of the Department. The laboratory explained its procedures and allowed us to see a recent report prepared by the Testing TELARC as part of a registration audit.
98. My recollection is that I reported back to LSAC, which recommended no further action. However, the relevant documents cannot be located. I

produce as document **GRB/MOH/0030** a bundle of letters relevant to this Inquiry.

**May 1989: Tairawhiti**

99. One of the Department of Health's Visiting Medical Practitioner reported to me as Manager of the Primary Health Care Programme about his visits to general practitioners and specialists in the Tairawhiti area. One general practitioner, who was running a cervical screening programme in his practice, expressed concern that he had never received an "abnormal" report from the private laboratory in Gisborne (Dr Bottrill's laboratory). The Visiting Practitioner asked the general practitioners he visited subsequently in the area and the two specialist gynaecologists in Gisborne if they had similar concerns. They did not. One specialist said that of the four most recent cervical cancer cases he had dealt with, none had had a cervical smear taken prior to presenting with the disease, which I took to mean that his concern was with women not presenting for smears, rather than false-negative reporting. I reviewed the information and concluded that the Visiting Practitioner had done the correct thing by seeking evidence to corroborate the concerns expressed by one doctor and had not found any support amongst general practitioners and appropriate specialists. I referred the report to the Cervical Screening Implementation Unit.
100. At that time the Primary Health Care Programme of the Department of Health employed two medical practitioners and a pharmacist as Visiting Practitioners. Their role was to visit general practitioners and specialists throughout the country, to maintain liaison between the Department and those in practice, to explain changes in health benefits, to promote rational prescribing and appropriate use of laboratory services and to feed back to the Department Head Office intelligence about major issues affecting practitioners, the effects of current health policy and any other information they felt was relevant. In 1989 cervical screening was an issue and the Visiting Practitioners would have had it on their list of topics for

discussion with general practitioners and appropriate specialists, whenever they visited.

101. The Visiting Practitioners did not have a disciplinary function and were not auditors of quality or safety. I do not recall any other instances of concern about accuracy of laboratory cytology, but I do recall being advised about concerns over delays of up to twelve weeks in receiving back reports of cervical smear reading. I produce as document **GRB/MOH/0031** the information from this report relevant to this issue.

### **March 1993: Rotorua**

102. A cervical screening Area Manager reported that she was receiving expressions of concern about the quality of smear reporting at one laboratory in Rotorua. The Co-ordinator of the National Cervical Screening Programme referred the letter and some comparative results from this laboratory and two others to the CALC.
103. The Committee determined that, considering the small number of cases involved, there was nothing to suggest that there was a problem with that laboratory. I produce **GRB/MOH/0032**, a bundle of documents from the Ministry's files relevant to this matter.

### **November 1994: Auckland**

104. The Minister of Health received a letter from the Women's Health Action Group regarding false-negative cervical smear results. This letter has been referred to earlier in this evidence (refer document **GRB/MOH/0024**). An individual's case of cervical cancer had come to the attention of the Group where the person concerned had had two smear tests. One, taken in 1993, was a false-negative whilst a previous smear test taken in 1990 (but not part of the NSCP) had contained some abnormal cells which according to the pathologist who originally reported on the smear, "should have been followed up". The Group therefore put a number of questions to the Minister who took advice from the CALC and replied to the questions asked. She summarised the policy as it existed at that time and pointed out that international literature records false-negative rates of between 7 and

25 percent for individual smears. She also noted her expectation that all laboratories involved in the NCSP would have TELARC (or equivalent) accreditation by 1996 year end.

## **PROPOSED LEGISLATIVE CHANGES TO PROTECT A DOCTOR'S PATIENTS**

105. As a consequence of a report prepared by the Ministry into issues arising from the legal proceedings involving Dr Bottrill (**JMG/MOH/0058**), the Ministry identified a number of areas where the health and safety of the public may not be adequately served through the complaints processes. The Ministry recommended amendments to the Medical Practitioners Act 1995 and the Health and Disability Commissioner Act 1994 covering:

105.1 the suspension of medical practitioners;

105.2 investigation of complaints; and

105.3 competence and fitness to practice.

I produce a copy of that recommendation to the Minister as **GBM/MOH/0033**.

106. The Minister of Health asked the Ministry to proceed with the consultation necessary to prepare policy decisions for Cabinet on legislative changes. A consultation document on the changes to the Medical Practitioners Act 1995, the Health and Disability Commissioner Act 1994 and the Health Act 1956 was sent out to key stakeholders in November 1999. Forty nine replies were received and there was general support for the proposed changes. A copy of the consultation document is produced as **GRB/MOH/0034**.

107. I also produce as **GRB/MOH/0035** the proposed legislative bid to include a Medical Practitioners Amendment Bill on the year 2000 legislative

programme. As yet there is no definitive place for this proposed legislation on the Government's legislative programme.

.....  
**George Robert Boyd**

**Date:**.....

## Exhibits Produced by Dr George Robert Boyd

### VOLUME 1

<b>Ref No.</b>	<b>Exhibit</b>
1	<i>National Cervical Screening Programme Policy.</i> Wellington: Ministry of Health, 1996.
2	Illustration: <i>Stages in the development of invasive cervical cancer.</i>
3	<i>Quality Assurance in Cervical Cytology.</i> Council on Scientific Affairs, American Medical Association. JAMA, 1989.
4	Bethesda code development (bundle).

### VOLUME 2

<b>Ref No.</b>	<b>Exhibit</b>
5	<i>Clinical Services Letter 106.</i> Wellington: Department of Health, 7 April 1971.
6	<i>Clinical Services Letter 163,</i> Wellington Department of Health, 14 January 1977.
7	<i>The Skegg Report.</i> New Zealand Medical Journal, 1985.
8	<i>Screening for Cervical Cancer.</i> The Proceedings of a meeting called by the Department of Health and the Cancer Society of New Zealand (Inc), November 1986.
9	<i>A Pilot Study for a Cervical Screening Service,</i> Otago, 1988.
10	<i>Towards a More Effective Cervical Screening Service for Women in New Zealand,</i> Wellington: Department of Health, September 1988.
11	<i>Notes of a Meeting Between Department of Health and Chairpeople of Hospital and Area Health Boards,</i> September 1988.

**VOLUME 3**

<b>Ref No.</b>	<b>Exhibit</b>
12	<i>Proposal for a Nationally Co-ordinated New Zealand Cervical Screening Programme</i> , Azimuth Systems Limited for the Department of Health. November 1988.
13	<i>Draft Report of the National Cervical Screening Workshop</i> . Department of Health. 6-8 December 1988.
14	Memorandum to Minister of Health, re recommendations of National Cervical Screening Workshop 20 December 1988.
15	<i>Women's Health, What Needs to Change: A Summary of the recommendations of the Cervical Cancer Inquiry and a Practical Guide to Action</i> . Ministry of Women's Affairs.
16	Letter re functions of Laboratory Services Advisory Committee. 1967.
17	<i>Clinical Services Letter 93</i> . Department of Health. 12 December 1969.

**VOLUME 4**

<b>Ref No.</b>	<b>Exhibit</b>
18	Terms of Reference, Agendas, Minutes and Papers from the Cytology Advisory Liaison Committee (CALC) and Cervical Screening Laboratory Advisory Committee (CSLAC). Bundle.

**VOLUME 5**

<b>Ref No.</b>	<b>Exhibit</b>
19	Report of the New Zealand Society of Cytology and the New Zealand Society of Pathologists, Cytology Standards Subcommittee. 1986.
20	<i>Draft Quality Assurance Process</i> . Azimuth/Ministry of Health(J Phuah, September 1993) and cover letter to Dr C Teague dated 10 September.
21	Azimuth National Cervical Screening Programme <i>Discussion Paper</i> . 20 September 1993.

- 22        *Cytology Advisory Liaison Committee Recommendations*, Testing Laboratory Registration Council of New Zealand Medical Laboratory Accrediation Programme. 1991.
- 23        Letter from T Handiside to regional health authorities. 4 November 1993.
- 24        Women's Health Action letter and replies. 1994/95. Bundle.
- 25        National Cervical Screening Programme Standards for Laboratories. 1995.
- 26        Department of Health memorandum and examples of replies to laboratories questionnaire. 1990.
- 27        Regional laboratory comparison tables for cervical smears: 1986-1990.
- 28        Letter from Dr Bottrill to Dr Teague dated 14 July 1995.
- 29        Form letter to laboratories attaching Gisborne Laboratory's smear results and national comparisons. 1996.
- 30        Correspondence relating to concerns of the quality of cervical cytology services in Christchurch. 1987. Bundle.
- 31        Visiting Medical Practitioner Report for Tairāwhiti. 1989.
- 32        Correspondence and reports into laboratory reporting cervical cytology, Rotorua. 1993. Bundle.
- 33        Ministry of Health report to the Minister on possible changes to legislation. 1999.
- 34        Form letter to key stakeholders requesting comments on changes to Medical Practitioners Act. 1999.
- 35        Legislative bid for changes to Medical Practitioners Act. (1999)