

**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 CLINTON ADAM TEAGUE

**ROYAL COLLEGE OF PATHOLOGISTS
OF AUSTRALASIA**

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I, CLINTON ADAM TEAGUE, pathologist of Wellington say:

1. My full name is Clinton Adam Teague.

1. **QUALIFICATIONS AND EXPERIENCE**

2.1 **Curriculum Vitae**

My curriculum vitae is attached (see **CAT/RCPA/0001**).

2.2 **Qualifications**

My qualifications are MB ChB (1966) DCP (1972), PhD (1979),
FRCPA (1973).

2.3 My studies include six years full-time cancer research, in part for studies for my PhD and in part for post-doctoral work in New York. My full curriculum vitae is annexed.

2.4 I returned to New Zealand in December of 1987 wishing to pursue my career in pathology and my particular interest (first identified at age six) to reduce and prevent the incidence of cancer.

2.5 On my return to New Zealand I joined a private practice called "Medical Laboratory Wellington". As one of the partners of that firm I was responsible for histology, cytology and some forensic pathology, along with other pathologists in the practice.

2.6 I introduced the practice of running training sessions for pathology registrars, preparing material for them and going over cases with them on a weekly basis. This practice continues in various forms to the present day, and is one of a number of voluntary (unremunerated) initiatives I have taken in training and standards.

2.7 At the same time I had a clinical lectureship at the Wellington School of Medicine.

2.8 Shortly after returning to New Zealand I was offered the position of

Honorary Consultant to Hutt Hospital, which involved attending one morning per week, unpaid, for the purpose of reporting some cases and reviewing difficult cases with a panel of other pathologists from the region. This panel remains active to this day. For some of the period, I was paid by Hutt Hospital when I filled in for pathologists.

- 2.9 Also during the early part of the 1990's, I was appointed Honorary Consultant to Capital Coast Health. This also involved the reviewing of difficult cases, particularly when other specialists were on leave. This work was unpaid.
- 2.10 My current areas of special interest are cytology, gastro-intestinal and liver pathology.
- 2.11 I was the manager of the histology and cytology department until 1996, at which time I then became the overall manager of the laboratory. This is a demanding position in itself.
- 2.12 I describe my workload since the early 1990's as being very heavy. I have worked a minimum of 60 hours per week and been on call one week out of two. My on-call work includes forensic pathology and urgent surgical pathology.
- 2.13 My particular interests have resulted in my early and continued involvement in a voluntary capacity in a number of advisory groups established by the Minister, the Ministry, or by medical organisations including those referred to in evidence to the Inquiry.
- 2.14 The volunteer work I did in an advisory capacity was an addition to my full-time work as a partner in Medical Laboratory Wellington. Preparation for each meeting of an advisory group involves reading of articles, reading of background papers and, on occasion, further inquiries, research, or consultation with medical colleagues. Usually this work was carried out during weekends and evenings. In addition, there is the continued reading and other processes needed to maintain currency and competency in my specialist areas, with attendances at continuing education for those areas of pathology as well as cytology.

- 2.15 In the last few years my workload has remained the same, although for reasons of health and quality of life I am agreeing to less volunteer work.
- 2.16 In my evidence which follows I have included details of my remuneration, or lack of it, in the various positions I have held. I have done this to indicate the extent to which the NCSP and the Ministry was under-resourced and relied on volunteers. My own dedication was to achieve a successful programme and to save women from cancer. Frankly, I would have done all I did whether I was paid or not. In some instances where claims could be made, I did not. But the Ministry at times appeared to both exploit the goodwill of all of us, and then often disregard what we tried to achieve or alter it without consultation. I believe it was easy to do this when they treated us as well-intentioned volunteers.
- 2.17 **Committee Memberships:**

1998-present	Honorary Consultant to Cancer Registry
1998-present	Member, Advisory Group for Population Based Screening Programmes.
1997-98	Member National Health Committee Working Party on Colorectal Cancer Screening
1994-99	Member, RCPA Quality Assurance Cytopathology Programme Committee.
1994-96	Chairperson, Cervical Screening Liaison and Advisory Committee.
1992	Member, Committee for the Review of Treatment Protocols for Abnormal Cervical Smears
1991-94	Member, Cervical Screening Advisory Committee
1989-94	Chairperson, Cytology Advisory Liaison Committee
1989-91	President, New Zealand Society of Cytology
1989-91	Member, Expert Committee, National Cervical Screening Programme
1989	Member, Ministerial Review Committee on Implementation of a National Cervical Screening Programme.

2.18 Memberships and Positions in NCSP and RCPA:

- 1994-1995 Member Steering Group for Amalgamation of New Zealand Society of Pathologists and the Royal College of Pathologists of Australasia
- 1996-present Member New Zealand Committee RCPA
- 1996-present Member of Executive Committee of NZ Committee RCPA
- 1996-present Member of Standards and Information Technology Committee of NZ Committee RCPA
- 1996-present Elected member NZ Committee RCPA responsible for professional performance reviews
- 1996-present Laboratory Adviser to NCSP

2.19 My evidence is directed to Term of Reference 4.

3. **MAINTENANCE OF COMPETENCY**

- 3.1 All laboratories reporting cytology would be expected to have access to a range of modern textbooks on cytology and at least one international journal of cytology. In our laboratory we would have more than 20 reference texts on cytology and more than 100 reference texts on histology. We receive two international journals of cytology. Most pathologists would attend conferences relevant to cytology at least biannually.
- 3.2 In my own case I attend the New Zealand Society of Cytology Conference each year where I usually give a presentation and I attend at least one overseas conference annually.
- 3.3 I also attended annual Quality Assurance Meetings in Australia.
- 3.4 I attended the meeting and was a member of the Scientific Programme Committee of the 11th International Congress of Cytology in Melbourne 1992.
- 3.5 In 1991 and 1992 I was a part-time tutor in cytology at the Central Institute of Technology, Upper Hutt, New Zealand.
- 3.6 In 1993 I completed a two week post-graduate cytopathology tutorial at Westmead Hospital in Sydney.
- 3.7 In the subsequent two years I was a member of the faculty of that tutorial when it moved to Brisbane, Australia.
- 3.8 I have attended the International Academy of Pathology Meeting in Sydney on an annual basis.
- 3.9 In 1997 I attended an international conference on automation in cytology in Chicago, USA.

3. **ADVISORY GROUP FOR POPULATION BASED SCREENING PROGRAMME**

- 4.1 I was appointed as a nominee of the College and ACL. My position is as a nominee only. I am not representative of either organisation.
- 4.2 The committee is an HFA committee and has met on 7/12/98, 10/3/99, 9/6/99, 21/9/99, 3/3/2000 and 7.6.2000.
- 4.3 The meetings are held in Auckland.
- 4.4 Each meeting requires significant preparation. On one occasion I was required to travel up the day before in order to meet with HFA officials. The minimum preparation time is about 3 hours, and more usually 5-6 hours, including phone consultations. The day starts with a 7am plane to Auckland with the meeting commencing at 9am. The meeting usually finishes about 4pm in time to catch the 5pm plane to Wellington. Membership of this committee is remunerated by payment of \$750 for each meeting. In addition I am reimbursed for travel and accommodation costs.
- 4.5 At the time of appointment to this group, I indicated to my nominating organisations and to the Chair of the Group that I could only be a member for one year. For health, family and workload reasons it is my intention to withdraw from this Group this year.

3. **ROYAL COLLEGE OF PATHOLOGISTS OF AUSTRALASIA QUALITY ASSURANCE CYTOPATHOLOGY PROGRAMME COMMITTEE**

- 5.1 I was appointed to be a member of this Committee by invitation through the College.
- 5.2 In this role I represented New Zealand interests within the Australasian Programme. Most appointees to this Committee are from Australia. I was the first New Zealander appointed to this committee.
- 5.3 I received my air fares to and from meetings, accommodation and out-of-pocket expenses, but was otherwise an unpaid volunteer.
- 5.4 This committee is the board of management for the Royal College of Pathologists of Australasia's Quality Assurance Programme in Cytology. The Committee makes recommendations on the types of material that our members should examine, circulates slides within New Zealand, Australia, Malaysia and some other countries, and provides comments to laboratories who participate in the programme. The Committee reviews some of the slides that have caused debate during the year. The Committee also oversees surveys of laboratory practice and the written summaries of survey results.
- 5.5 The Committee publishes an annual report, a copy of which is produced (**CAT/RCPA/0002**). This report is sent to each of the laboratories which is enrolled in the programme. Copies are also sent to IANZ (formerly TELARC).
- 5.6 My own laboratory frequently donates material for inclusion in the survey.
- 5.7 This programme is a valuable quality assurance activity. Participation by laboratories in this programme (or an equivalent programme) is required by IANZ and will be required as part of a pathologist's vocational registration under the new Medical Practitioners Act 1995.

3. **CYTOLOGY ADVISORY LIAISON COMMITTEE (CALC) and its successor the CERVICAL SCREENING LIAISON AND ADVISORY COMMITTEE (CSLAC)**
- 6.1 The first laboratory advisory committee arose out of the National Cervical Screening Workshop held from the 6th to the 8th of December 1988 in Porirua under the auspices of the Ministry of Health.
- 6.2 Subsequent to the Workshop, the New Zealand Society of Pathologists, at its own expense, established a committee with two representatives from each of the following organisations: New Zealand Society of Pathologists, the New Zealand Society of Cytology, the Royal College of Pathologists of Australasia (New Zealand Committee) and the New Zealand Institute of Medical Laboratory Technologists. This Committee was independent of the Ministry of Health and the National Cervical Screening Programme. It was a committee of volunteers, each of whom had a special interest in the subject and in preventing cancer. In response to urgent needs arising from the recommendations of the Cartwright Inquiry, the Committee first met in 1989 at the Wellington Clinical School of Medicine. The Committee named itself “The Cytology Advisory and Liaison Committee (CALC)”. It had no formal terms of reference but saw itself as an advisory committee to facilitate the implementation of a National Cervical Screening Programme.
- 6.3 I was initially a member of CALC and then became Chairperson. The first meeting was held on 18 April 1989.
- 6.4 The Ministry of Health/National Cervical Screening Programme began to contribute to the Committee by providing secretarial support to the Committee from 1990 onwards.
- 6.5 Although I was initially appointed as a representative of the New Zealand Society of Pathologists, the evolution of the Committee was such that it became a committee to advise the Ministry rather than a committee set up under the umbrella of organisations including the

College.

- 6.6 When the Committee was called CALC it appears that I received no payments in 1989, 1991 or 1992 for any of the work or attendances at meetings. In 1993 I have a record of receiving the sum of \$250 including GST to attend a day-long meeting. I have also a record of receiving \$500 to attend two other day-long meetings.
- 6.7 When the Committee was constituted as CALC it was a very busy committee. We wrote to numerous organisations promoting the programme and the Bethesda System. This had to be put in place collaboratively as there was no statutory framework or power to require compliance with this system at the time. This is referred to later in my brief.
- 6.8 My work in CALC involved at least 100 hours per year in total. It was a particularly time consuming Committee, especially during the first few years.
- 6.9 In addition to attending meetings and promoting the screening programme around the country (unpaid), I also fielded numerous phone calls to provide advice to the Ministry, doctors and pathologists about subjects including the Bethesda System.
- 6.10 There were no terms of reference for the Committee until it became CSLAC.
- 6.11 However, the Committee did suggest, subject to consultation, that it could take on a monitoring role. At its meeting on 17 November 1993 the Committee, motivated by a concern about the lack of Quality Assurance Processes, agreed that data produced for quality assurance could easily be misused or misinterpreted. The meeting noted that there was no independent person with sufficient 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 discovered a possible indication of inadequate laboratory performance not apparently being addressed by TELARC the process for assessing these

problems should be as follows:

6.11.1 The NCSR identifies a potential problem with a laboratory's quality assurance data.

6.11.2 The issue should be presented to CALC and the laboratory concerned.

6.11.3 CALC will monitor the situation and review the issue after six 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.

6.11.4 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 six monthly if they are statistically significant. The meeting agreed that the process should be circulated to all laboratories for comment. (Some time later it was recommended that the statistics be revised six monthly but cover a 12 month period.)

6.12 It is notable that the monitoring function suggested was not incorporated, no doubt recognising that the Committee did not have the authority, nor the full range of expertise, to effectively perform this function. The Ministry of Health decided to reform the Committee to become an advisory committee to the Programme with specified terms of reference - see **GRB/MOH/18 July 1994**. This occurred in July 1994 and the Committee was renamed Cervical Screening Liaison and Advisory Committee (CSLAC).

6.13 The functions and role of the new Committee, by then called CSLAC, were defined as being:

6.13.1 The role of the Committee will be to:

6.13.1.1 provide technical medical advice relating to cervical cytology and histology; and

6.13.1.2 advise on the provision of quality laboratory services associated with the National Cervical Screening Programme.

6.13.2 Functions of the committee will be to:

6.13.2.1 Liaise with the National Coordinator who will inform the committee on the MOH work related to NCSP and laboratory issues requiring attention and advice.

6.13.2.2 Advise the National Coordinator of laboratory issues requiring attention and advice.

6.13.2.3 Assist the NCSP coordination team to effectively incorporate and correlate cervical histology results onto the NCSR.

6.13.2.4 Provide advice on quality assurance relating to laboratory cytology and cervical histology diagnostic services.

6.13.2.5 Advise the NCSP on appropriate training standards for cervical cytology.

6.13.2.6 Advise on the development of new technology and methods as appropriate.

6.14 Once the Committee became CSLAC my appointment could no longer be regarded as that of a nominee of the Society of Pathologists. I became a member of CSLAC by virtue of having been a member of CALC.

6.15 The first meeting of the Committee under this name was held on 15 February 1995 - see **GRB/MOH/18**. At that meeting I was nominated

Chairperson. I reluctantly accepted but agreed to the appointment for one year only. It was my hope in that year to see recommendations finally implemented so that I could hand over to someone else with a sense of completion.

- 6.16 The Committee was abolished by decision of the Ministry in 1996 despite reservations expressed by the Committee to the Minister of Health and the Director-General of Health. Those reservations were the failure of the training programme for the screeners of cytology slides and the lack of a single office for the NCSP. - **see letter 1 August 1996 to Dr Poutasi, Exhibit JMG/MOH/086.**
- 6.17 I have seen the service agreement for the Chairman (**GRB/MOH/18**). I do not recall having seen this previously, nor do I have a copy though I was given a copy of the terms of reference.

**COMMITTEE FOR THE REVIEW OF TREATMENT PROTOCOLS
FOR ABNORMAL CERVICAL SMEARS**

- 7.1 I can find no record of why it was that I was appointed to be on this Committee. My appointment probably arose because of my position on CALC.
- 7.2. This work involved attendance at numerous meetings. I have no record of receiving any specific payments for this work. The total sum that I received in the years 1991 to 1992 from the Ministry was \$1,729.30 which was the sole remuneration for what would have been at least 100 hours of work during the Committee's existence.
- 7.3 This Committee was formed to implement the recommendations of the Skegg Report and to produce revised protocols for the management of women with abnormal cervical smears. There were no terms of reference.

3. **OTHER APPOINTMENTS AND COMMITTEES**

- 8.1 Subsequent to the disbandment of CSLAC, I was approached by the then National Co-ordinator and invited to provide advice from time to time in relation to technical laboratory issues - **CAT/RCPA/003** is my letter of appointment. I agreed to do this on the understanding that issues of substance and policy would need to be considered by appropriate committees.
- 8.2 Such a committee was convened on 13 May 1998 to consider issues relating to implementation of new screening recommendations and other issues.
- 8.3 I have provided advice to the best of my ability on technical issues usually relating to coding issues on a number of occasions when contacted by the National Coordinator.
- 8.4 In this role I repeatedly advocated the implementation of histology/cytology correlation for evaluation by the programme and for inclusion with individual laboratory statistics.
- 8.5 I advocated that the programme look at the Australian Performance Standards as a potential model to be adapted for New Zealand.

3. **CERVICAL SCREENING ADVISORY COMMITTEE**

9.1 I was appointed to this Committee by the Minister of Health as a nominee of the New Zealand Society of Pathologists or the College or both (I have no record now). The appointment probably occurred as a result of an informal phone call.

9.2 I was not representative of any particular group. I put forward my own views but reported back to the Society annually, and reported from time to time to the Committee with the views of pathologists as I perceived them to be. In addition to reporting back annually to the Society, I also reported on the views of this Committee to other Committees on which I was a member.

9.3 My remuneration between 1993 and 1994 was \$591 for meetings which occurred three to four times per year. The meetings lasted all day, that is from 9 a.m. to 4 p.m. Preparation time for this committee was less arduous than for others, being approximately five hours preparation for each meeting. I have also found records of being paid \$190 on 29 July 1997 to attend the meeting which lasted from 9.30 a.m. to 4.30 p.m., receiving a further \$190 to attend a day-long meeting on 15 August 1997, receiving a sum of \$127.50 to attend a day-long meeting on 23 September 1997, receiving \$190 to attend a day-long meeting on 4 November 1997.

9.4 For each of these meetings I would have prepared for between four and five hours in reading background material. My position on this Committee also involved being phoned for advice on a regular basis by the Ministry.

9.5 The terms of reference for this committee are annexed to the brief of evidence of Ms Judy Glackin and are not repeated.

3. **PRESIDENT OF THE NEW ZEALAND SOCIETY OF CYTOLOGY**

10.1 I was a member of the Executive of the Society from 1989 to 1992, and President during the year of 1989 to 1991.

- 10.2 I was appointed by election of the members of the Society.
- 10.3 In this position I represented all practitioners in the field of cytopathology including pathologists, cytotechnicians and laboratory assistants.
- 10.4 This work was unpaid, involving approximately 40 hours per annum. The work involved attending meetings, reading background papers, preparing papers and liaising with the members of the Society.
- 10.5 A benefit of this Committee was to allow the networking of people in cytology. It prepared a newsletter and organised scientific meetings and workshops annually for the improvement of standards, exchange of information and teaching in this area.

3. **ROLE OF THE EXPERT GROUP**

- 11.1 I produce copies of the minutes and papers of the Committee still in my possession as **CAT/RCPA/0004**.
- 11.2 I was appointed to this Committee as a Ministerial Appointment.
- 11.3 I represented the New Zealand Society of Pathologists and the Royal College of Pathologists.
- 11.4 From my records it appears that I was paid approximately \$97 for each day long meeting that I attended. There was significant difficulty in obtaining any payments. To this end, I refer the Inquiry to Exhibit 1 (letter from P Koopman-Boyden).
- 11.5 Each meeting involved a minimum of three hours of preparation.
- 11.6 The Terms of Reference we worked to are at the back of our report (see **JMG/MOH/0005**, last page). These had specified a role for this Committee in implementation:
- “(ii) Oversee the implementation of the National Cervical Screening Programme ...”*
- which was defeated by the abolition of the Expert Group.
- 11.7 This Committee was set up as a result of a recommendation by the Ministerial Review Committee in 1989 which recommended the Ministry establish an expert group to advise on the implementation of the NCSP.
- 11.8 The workshop also recommended that an executive group, with decision-making powers, be formed to control the NCSP and to allocate funding for the programme to the Area Health Boards and that there be two National Coordinators, both women, at least one of whom would be a Maori woman.

- 11.9 I note from **GRB/MOH/0014** that it was decided on 15 December 1988 to appoint one coordinator and that the steering group “*would be advisory with no executive functions*”. The group would have a “time limited” role with advisory and monitoring functions. The ability to “go public” would be its final sanction.
- 11.10 The effectiveness of the group was hampered by a number of factors which were set out in a memorandum which I produce as **CAT/RCPA/0005** by the chairperson who eventually resigned.
- 11.11 The group made a number of recommendations, some of which are included in the attached letters numbered **CAT/RCPA/0006-0011** inclusive.
- 11.12 In February 1991 the group was abolished. In a letter dated 26 February 1991 the Associate Minister of Health stated:
- “I am writing to thank you for your contributions to the National Cervical Screening Programme Expert Group.*
- The Expert Group has played a valuable role in developing policy for the cervical screening programme. This policy represents a milestone for women’s health in New Zealand. The emphasis of the programme has now shifted to implementation and evaluation. To reflect this changed focus a smaller technical advisory group will be established to advise the Director-General of Health on implementation and evaluation.*
- Your commitment of time and contributions to the work of the Expert Group are greatly appreciated.”*
- 11.13 A relevant press release is produced marked **CAT/RCPA/0012**. The announcement that “*We need to shift from policy development to implementation and development and evaluation of the programme*” was most reassuring to me at the time.
- 11.14 At the time of the disbanding the group expressed concern that “*the new group established with a frame of reference which ensured a process by which the woman of New Zealand could continue to have*

input into the cervical screening programme ... the proposed technical group should be established as soon as possible”.

3. **MINISTERIAL REVIEW COMMITTEE**

- 12.1 I was also a member of a Ministerial Review Committee which was requested in November of 1989 to provide a report on the implementation of a national cervical screening programme. Also on that committee were Sandra Coney (representing Fertility Action), David Cook (Royal College of General Practitioners), Brian Cox (Department of Social and Preventative Medicine, Otago), Gillian Durham (Cervical Screening Implementation Unit), Marie Leonard (Programme Coordinator, Marlborough Area Health Board), Betsy Marshall (Cancer Society), Robyn McInley (Ministry of Women's Affairs), Neil Prentice (NZMA), Heather Simpson (Chairperson) and Waireti Walters (Maori Women's Welfare League).
- 12.2 The Ministerial Review Committee was "*set up as a result of widespread concern that the progress on implementation of a national cervical screening programme was unsatisfactory*" and the concern that the workshop that had occurred in 1988 also attended by myself had not been followed up and there had been no formal report.
- 12.3 My appointment to that Committee was made by the Minister.
- 12.4 I represented the New Zealand Society of Pathologists and the Royal College of Pathologists.
- 12.5 I have no record of receiving any payment for my work on that Committee.
- 12.6 I have been unable to find any Terms of Reference of that Committee.
- 12.7 The report of the Review Committee is in **JMG/MOH/1**.

3. **GENERAL COMMENT**

- 13.1 As will already be apparent from the evidence of the Ministry and Health Funding Authority, the evolution of the NCSP and, in particular, coordination, collation of data and the setting of minimum and consistent standards and practices, were at times frustratingly slow.

For those of us whose involvement extended over the decade there was on occasion a sense of the wheel constantly reinvented, with recommendations acknowledged yet again as a good idea but being slow in implementation.

- 13.2 My view was that despite frustrations with progress, it was better to work inside with people than outside with animosity. However, my frustration about the abolition of a cytologist training programme was so great that I made a statement to the media in August of 1993. This created difficulties for me in achieving change which is in part evidenced in Exhibit **JMG/MOH/087**. In July of 1994 the Ministry carried out reforms on the Committee.
- 13.3 This lack of progress reflected the high degree of consultation, on-going changes in health administration, and, I was advised, budgetary issues.
- 13.4 Although one of the options to me was to go public, when I did this it resulted in creating difficulties in working for progress.
- 13.5 At the meeting of CSAC on 11 March 1994 I am recorded as expressing concern *“about resource constraints nationally while local evaluations of varying quality are occurring on an ad hoc basis. Sue Dahl confirmed that funding at the local sites is devolved and that it is impossible to transfer or retrieve it. The meeting noted that it was a useful exercise to evaluate the evaluations that have been done by local programmes.”* It was agreed that a letter would be written to the Associate Minister of Health expressing *“concern that the Report’s recommendations have not been implemented, ... at the loss of 0.5 support/word processor person about national coordinator’s access to expertise and that there should be a person with permanent responsibility for evaluation of the NCSP ... The meeting noted that matters regarding routine monitoring are yet to be sorted out.”* (See **JMG/MOH/11**)
- 13.6 From time to time letters of concern were written. Examples are the letters produced as **CAT/RCPA/0005-0010**.

3. PROMOTING CERVICAL SCREENING

- 14.1 It is hard to believe now when the cervical screening programme is very much accepted within medical practice and patients' expectations that back in the beginnings of the programme there was resistance among both the provider and consumer groups. To address this, a promotional package was put together which is contained in **JMG/MOH/3**. I was actively involved in this programme, both in preparing the material, assisting with the art work and providing the figures for cervical smear results set out on page 55 in a pie diagram.
- 14.2 In December of 1991 a visit was arranged to the Manawatu where there was some considerable resistance. I went up to the Manawatu without pay with the Minister of Health to promote the programme. This is referred to in the Correlation of Quarterly Reports for Area Health Board Cervical Screening Programmes, December 1991, **JMG/MOH/75**.

ADOPTION OF THE BETHESDA SYSTEM

15.1 The first and most urgent task that CALC undertook and achieved by agreement (as we had no powers) was to establish a uniform reporting system for cervical cytology in New Zealand. Up until that time laboratories were using a number of different reporting systems and internationally there were diverse reporting systems in use.

15.2 The importance of this task was recognised at the Porirua Workshop. The laboratory group present at that Workshop made the following recommendation:

"Liaison should be established between the Society of Pathologists, the Society of Cytologists, the College of Pathologists and the New Zealand Institute of Medical Laboratory Technologists to continue discussion regarding a common terminology for reporting cervical cytology diagnoses." (Draft Report of the National Cervical Screening Workshop 6-8 December 1988 - **GRB/MOH/0013**).

15.3 The Ministerial Review Committee had noted in November 1989 that *"If the cervical screening register is to be used to make comparisons between different geographical regions and to compare the performance of different smear takers it is important that there is as high a degree of uniformity as possible in the reporting of smear results. Additionally, as considerable anxiety can be incurred by women waiting for smear results the time delay between smears being received by laboratories for analysis and results being reported back to the smear takers should be monitored."* (See **JMG/MOH/1**, page 124.)

15.4 By July of 1989 I was able to confirm to CALC *"that executives of all relevant bodies had been informed about the proposal to use the Bethesda system as a single national reporting system for cervical cytology"*. See **GRB/MOH/18**, minute of 18.7.89.

15.5 In the 1991 Policy Paper the role of laboratories and responsibilities for ensuring requirements were met were described as:

"4. LABORATORIES

4.1.1. The role of the laboratories in the implementation of the National Cervical Screening Programme will be to:

- *provide an efficient, timely, and accurate service for processing, examining and reporting cervical smears;*
- *report cervical smears according to the current or any approved, modified Bethesda Classification;*
- *communicate the reports on cervical smears to the appropriate area health board cytology registers in an agreed format suitable to both the laboratory and registers.*

15.6 Initially the decision was made that "The Bethesda System" should be adopted.

15.7 The Bethesda system was originally devised by a group of international experts meeting in Bethesda in December 1987.

15.8 At that time, Bethesda was published in bare bone detail in the literature. There was a lack of articles covering its detailed applications. However it was accepted in the international literature, and from that time, in order to publish in ACTA CYTOLOGICA and other journals, the Bethesda System was the only accepted classification system.

15.9 The first meeting of CALC was held on 18 April 1989. By 6 December 1989 we had achieved sufficient consensus to send out an agreed system to all laboratories through the project manager, Dr Durham.

15.10 After deciding on the Bethesda system, we consulted with, provided data for and promoted the system with all of the significant medical organisations in the area including the Royal College of Obstetricians and Gynaecologists, the New Zealand Medical Association, the Royal College of Pathologists of Australasia, the College of General Practitioners, the Institute of Medical Laboratory Technologists, the New Zealand Society of Pathologists, New Zealand Society of Cytology. We asked them to endorse the use of this system and all of their executives endorsed the use of this system in New Zealand.

15.11 The hundreds of hours of volunteer labour were rewarded by its acceptance as

a national reporting standard. This was despite some opposition and also a reluctance to accept this system in some other countries. It was important to win laboratories over collaboratively as I and the committee had no power or authority over any laboratory to enforce anything. What we did try to do was encourage laboratories to conform to the Bethesda classification. An example of this process is the minutes of the meeting at the Nelson Hospital Laboratory 19 September 1990, which I attended as a member of the Expert Group. This has already been produced as part of **CAT/RCPA/0004**. It is gratifying to note that we were one of the first countries in the world to adopt this as a uniform national reporting system, given that the Bethesda system has now become the international standard.

- 15.12 The original Bethesda classification used abbreviated descriptors attached to alphanumeric codes. The alphanumeric codes were for computerisation only and not for reporting. The report was to be made in normal English text, which however had to retain the meaning of the code to which it was attached.
- 15.13 Notably, the Bethesda system obliged laboratories to report on specimen adequacy, on the general categorisation of the smear (optional) including a recommendation for further patient evaluation and a description of any abnormality present.
- 15.14 In keeping with the concept of the Bethesda classification, although contrary to my personal preference, laboratories had the ability to use their own wording on reports, but the wording had to retain the meaning of the Bethesda category used.
- 15.15 This at times led to confusion because reports produced by the Programme did not match the precise wording used by the laboratories.
- 15.16 I think it is fair to say the laboratories accepted that that was going to be the reporting standard in New Zealand but had difficulties or differences with it in some areas. There were numerous occasions when laboratories wrote about various difficulties in individual codes and their application. These were dealt with as best we could during those years.
- 15.17 No programme statistics were available for some time. To display the benefits

of the system, we felt it important to get information out promptly. Hence six months into the system my laboratory published our first results - **CAT/RCPA/0013**. In the letter we sent out we stated: *“Please compare your own results with the laboratory average. If you have any problems related to these figures please feel free to discuss them with us at any time. We can produce your own smear statistics if you wish.”*

15.18 There were some initial difficulties in interpretation of some points of the use of that classification. Indeed that had led Bethesda itself in 1991 to slightly revise the classification.

15.19 Following the issue of the modifications to the original Bethesda system, and in an effort to achieve more uniform reporting, we organised, through CALC and the NCSP, a meeting in 1992 of all laboratories reporting cervical cytology (see **GRB/MOH/050**). The intent was to try and hammer out an agreed phraseology to be attached to all of the alphanumeric codes which are the computer side of this classification. By and large I think we obtained agreement from most laboratories. Further, we expanded the original codes in areas to accommodate various particular wishes and concerns of laboratories but only in a way which was compatible with the Bethesda classification. That is, the register could analyse data for statistical analysis purposes by The Bethesda System as published.

15.20 In response to international concerns with interpretation and application of The Bethesda System, a monograph entitled "The Bethesda System" by Kurman and Solomon (1994) was published and is used by most laboratories as a standard reference text for the use of the System.

15.21 Ongoing Concerns with the Bethesda System:

15.21.1 Precise definitions of the categories of specimen adequacy (satisfactory, satisfactory but limited, unsatisfactory) remain elusive. Although the concepts underlying these categories were defined in the original Bethesda communications, definitions, criteria and explanatory notes only became available with the publication of the Bethesda system by Kurman and Solomon in 1994. To this day the categorisation is

still somewhat subjective which results in variation of reporting of these categories. It is noteworthy that in Australia a system of reporting similar to the Bethesda system has been adopted but does not include the satisfactory but limited category.

15.21.2 The original Bethesda classification gave us, under "general classification" (which was optional), two categories, normal and abnormal. This at times led to confusion as abnormal smears encompassed those smears which were technically abnormal although the changes present had nothing to do with cervical cancer or precancer: for example, the findings of a candida infection. This issue was addressed in the revised version of Bethesda when the abnormal category got split into two divisions, one for benign cellular changes and the other for epithelial cell abnormality. This change was important because changes of inflammation or infection did not then generate the closer follow-up attached to the presence of epithelial abnormality.

15.21.3 The definition of what constitutes evidence of sampling of the transformation zone of the cervix and indeed the significance of this component in relationship to outcome measures, is still the subject of debate. The Cytology Advisory Liaison Committee in its initial recommendation for the use of the Bethesda system, emphasised the importance of endocervical cells as the critical component in assuming that the transformation zone had been sampled and therefore the smear was satisfactory. Since that time there has been a broadening of the definition to include squamous metaplastic cells and a lessening of its importance as a risk of concurrent or subsequent abnormalities. The current status is detailed in the Guidelines for the Management of Woman with Abnormal Cervical Smears, National Cervical Screening Programme 1999, **JMG/MOH/50**.

15.22 In the original Bethesda classification the concept of atypical squamous cells of uncertain significance embodied the concept of cellular changes that exceeded the features usually expected in a benign reactive process but were insufficient for the diagnosis of squamous intraepithelial lesions.

In a small number of smears there are cell changes that are suspicious of high grade squamous intraepithelial lesion although they are not diagnostic. In both the original and revised Bethesda systems these two types of atypical cells were not differentiated. Indeed they are still not differentiated in the Bethesda system but are separately categorised in the Australian reporting system. The need for these two types of atypical smears to be differentiated were recognised by the expert group meeting in 1998 and a Bethesda code was allocated for this purpose.

16. TELARC REGISTRATION

- 16.1 Compulsory registration by TELARC was recommended and seen as essential by all the committees involved in the NCSP.
- 16.2 Registration had been recommended as being compulsory as far back as the 1988 workshop.
- 16.3 On behalf of the College and in accordance with my strongly held personal views, I supported this recommendation.
- 16.4 The Straton Report (which I had some input into) commissioned in July of 1990 also recommended that TELARC registration should be compulsory. In order to ensure that all laboratories were TELARC registered it was recommended (**see PARAGRAPH 5.01**) that a system of accreditation of laboratories be established which is a requirement for reimbursement for reading smears. In July of 1990 the Straton Report (**see JMG/MOH/4**) recommended that Department of Health “*carry out a study of the laboratory workforce required to provide screening services for all women in the target population on a three yearly basis*”.
- 16.5 In its May/August 1990 report, the Expert Group recommended to the Minister that “*The Department of Health should be responsible for confirming that those laboratories carrying out cytology screening for the NCSP meet the recommendations set out in 12.2.2. Such confirmation should become a requirement for receiving the laboratory benefit for reading NCSP smears.*” (**See JMG/MOH/5**)
- 16.6 The 1991 Policy Paper of the Ministry stated:
- “4.1.1 *The role of the laboratories in the implementation of the NCSP will be to ...*
- 4.1.2 *All cytology laboratories servicing the National Cervical Screening Programme should be registered with the Testing Laboratory Registration Council of New Zealand (TELARC) or other recognised authority. It is expected that laboratories not so registered will apply*

and gain such registration. A reasonable period of time will be allowed for laboratories to obtain registration. This may take up to two years.

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

4.1.4 The criteria for registration by TELARC or other recognised authority will be established by the Cytology Advisory Liaison Committee. The Department of Health will be consulted. The criteria will include:

- reading of a minimum number of smears a year;*
- employment of adequate numbers of suitably qualified staff;*
- maximum workload for each cytoscreener;*
- adequate in-service education;*
- satisfactory participation in both internal and external quality assurance procedures;*
- provision of cytology reports to the cytology register.*

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

See **GRB/MOH/16..**

16.7 TELARC (subsequently IANZ) is an independent accrediting body which accredits on the basis of international standards and is itself subject to international audit. The initial standard which it audited against was ISO Guide 25 which incorporates elements of the international quality system standard ISO9002: 1987 as applied to the work of laboratories. I produce a letter from TELARC to Ms Sax marked **CAT/RCPA/0014** which provides information on TELARC.

16.8 In 1995 it changed from its then current practice of 4 yearly reassessments with an intermediate staff visit to a 4 yearly full reassessment with review visits conducted each year between reassessments. The purpose of the review visits was to review documented evidence of the implementation of laboratories' quality management systems. Items including quality manual amendments, equipment calibration records, staff training records, management review meeting minutes, internal audit reports, internal and external quality control programme records will be reviewed on site and a draft report will be presented to laboratory staff at the conclusion of each review visit.

16.9 Prior to the advent of the National Cervical Screening Programme, TELARC registration was not compulsory for laboratories in New Zealand. My own view was that this was an important quality control measure.

16.10 CALC recommended that TELARC registration became compulsory for laboratories reporting gynaecological cytology to the National Cervical Screening Programme. In 1990 we viewed TELARC registration as so fundamental and important that in due course it had to be made compulsory for laboratories. We took the same co-operative approach to start off with as with Bethesda. As well as adopting the approach towards compulsory TELARC registration, we encouraged organisations to encourage their members to become TELARC registered. At the same time we also advised the Programme that it should make that compulsory and that one of the ways they could do that would be through contractual arrangements. If this was not workable, the other way of doing it would be through regulation. It was the recommendation of the Expert Group in its report to the Minister of Health that by December 1991 all cytology laboratories servicing the NCSP should have applied for TELARC registration and should be TELARC registered by December 1993 unless TELARC couldn't meet these deadlines (**JMG/MOH/0005** at page 203, paragraph 12.2.2).

16.11 Under this stimulus and in 1993 the Association of Community Laboratories adopted the recommendation that TELARC registration for all medical laboratory testing be adopted as an ethical role of the Association. In September of 1993 the Phuah Report was released which recommended the monitoring of trends in the examination of histology and cytology.

- 16.12 I noted with interest when going through the Ministry documents **JMG/MOH/47**, that it was noted that in Britain in 1994: “*Attempts were made to increase quality assurance. Cytology quality standards and mechanisms for laboratories to participate in quality assurance were being developed (Slater 1994, Gifford and Colman 1994.)*.” The position does not seem to differ, at that time, from the position in New Zealand.
- 16.13 Similarly, I also note that in the same document it records that in 1993 Australia still had laboratories operating that were not on the National Register (see page 35).
- 16.14 My laboratory gained TELARC registration in 1989. In 1995 our laboratory, in its contract with the Regional Health Authority, was required to be TELARC registered and to inform the Health Authority if there was any suspension of that registration. I am not aware whether this was universal, though I note that the June 1996 National Cervical Screening Programme policy stated “*To be eligible for reimbursement for reading smears, laboratories providing services for cervical cytology and histology are required to be accredited with ... (TELARC) or an equivalent accreditation authority*”.
- 16.15 The details of the scope of TELARC registration is beyond this submission but will be covered, I am sure, by submission from TELARC/IANZ. It should however be pointed out that the obtaining of TELARC registration for the first time is a major undertaking for a laboratory. The process from application to requiring accreditation would normally take approximately one year, it may take up to two years to complete. Although there is a financial burden to this process, the major burden to the laboratory is in setting up the initial and comprehensive documentation associated with the process which consumes many hundreds of hours of laboratory personnel time.
- 16.16 The Committee recommended that the most effective way of ensuring that this happened was by way of contractual obligation to the purchaser of the laboratory services.

16.17 I was not provided with information about which laboratories were TELARC registered, but believe that at the commencement of the Programme the majority of smears were being read in TELARC registered laboratories although a number of laboratories were not TELARC registered.

16.18 CALC made two sets of recommendations to TELARC concerning quality standards in cervical cytology, the first on 15 August 1990 and the second in 1995. Recommendations included:

16.18.1 Rescreening of negative smears - the Committee is aware that various individuals and professional bodies are actively questioning the previously accepted views on this. However, the Committee has opted to stay (at least for the meantime) with a recommendation that laboratories should carry out random rescreening of at least 10% of negative cervical smears.

16.18.2 Maximum numbers of slides read by screeners - most professional organisations have recommendations relating to this but the figures recommended vary greatly (from 25 to more than 100 slides per day). The Committee recommends that the number of slides screened by a competent cytoscreener be limited to an average of 60 slides per day (or 14,400 slides per year) or 3000 non-gynaecological cases per year.

16.18.3 Checking of abnormal smears - the Committee noted that precise recommendations were hampered by a lack of acceptable definitions of abnormal smears and by the major influence of labour and economic factors as well as pathologist attitudes. The Committee however recommends that:

16.18.3.1 in any laboratory the pathologist(s) and technologist(s) must have a clear understanding of what is regarded as a significant abnormality, and

16.18.3.2 all significantly abnormal smears should be checked by a pathologist.

16.18.4 External quality control - the Committee acknowledges that there is no entirely satisfactory programme available in New Zealand.

Notwithstanding this, the Committee recommends that it is highly desirable that all cytology laboratories participate in an external quality control programme. Laboratories should be encouraged to participate in the RCPA Quality Assurance Programme.

16.19 The issue of minimum numbers of slides remained controversial. In its submissions (see **JMG/MOH/71, paragraph 1**) we submitted *“The reading of a minimum number of smears a year; this criteria has been the subject of considerable debate and no consensus in the world literature. Indeed the Committee is not aware of any scientific evaluation on which such a figure could be based. The Committee is aware that there have been recommendations in this area made by committees in various parts of the world but without hard documentary evidence to support the figures arrived at. The Committee feels that it may be more profitable to adopt a different approach along two lines. Firstly that regardless of sizes (and therefore number of smears a year), a laboratory should meet certain performance standards i.e. outcome measures which the programme will become well placed to measure, and would be in keeping with Australian initiatives in the area. The second approach may be to have criteria that would preclude ‘professional isolation’ which the Committee felt probably was more important than an arbitrarily defined number of smears read a year.”*

16.20 In 1995 CSLAC in its report on Standards for Laboratories recommended:

“1.1.4 If the number of abnormal cases reported by a pathologist is insufficient the pathologist shall take part in supplementary activities designed to maintain expertise.

Nata have recommended for gynaecological cytology as a preliminary figure the pathologist should see 20 abnormal slides per month. These will be derived from the work passing through the laboratory and supplementary educational material.”

and

“3.D. Pathologists whose laboratories are handling only small numbers of

cytological samples should seriously consider whether the numbers being seen are sufficient to maintain the appropriate technical and diagnostic skills of staff members. If not, it is in the patients' best interests for samples to be referred to institutions where the necessary skills are available."

16.21 In 1998 an expert group meeting convened by the NSCP (BS/CS/0042) recommended that:

"3a.1 In general laboratories should be reporting on a minimum of 10,000 cervical cytology specimens per annum unless they can make a special case for a lesser number, e.g. centres of gynaecological oncology and/or colposcopy."

16.22 Standards relating to minimum numbers of smears have to recognise the structure of the health care system in New Zealand. Currently public hospital laboratories process only relatively small numbers of cervical smears. Almost all would fail to reach the suggested minimum of 10,000 smears per annum. This includes hospitals with major training commitments and serving specialist gynaecological treatment facilities. Although some private laboratories such as my own provide training for registrars, this is not a universal practice.

16.23 In the very early 1990s, probably as a consequence of CALC and ACL initiatives, it was apparent that accreditation would become compulsory for laboratories, TELARC itself became overloaded with applications and I believe that there was up to a year's delay at times. It was for this reason that it was recommended that although TELARC registration become compulsory, a period of up to two years be given for that process to be completed. It was acknowledged that a reasonable period for accreditation would have to be made to enable new entrants into the scheme. In addition to normal laboratory accreditation, some laboratories, my own included, also obtained ISO9002 accreditation for some parts of the service not normally covered by laboratory accreditation.

16.24 In 1994 CALC was asked to make submissions on the Policy for National Cervical Screening. On the draft, we were shown it stated: *"the Ministry*

*of Health will be responsible for confirming that those laboratories carrying our cytology meet the requirement set out in 4.1.4.” - see **JMG/MOH/70**. CALC supported compulsory TELARC accreditation as a condition of funding and had consistently done so. I do not recall being aware of the change to “reasonable endeavours” as appears in the 1994/1995, 1995/1996 and 1996/1997 funding agreements.*

17. **TRAINING**

17.1 At the Porirua Workshop it was stated that the need for formal training of cytology screeners was recognised. Dr Boyd's evidence shows this had been identified in 1986 at a meeting between the Department of Health and the Cancer Society (**GRB/MOH/0008**).

17.2 In May/August 1990 the Expert Group had noted (**GMJ/MOH/20, page 204**) that *"The Department of Health is responsible for ensuring that there are sufficient training facilities to meet the cytology screening work force requirements of the NCSP"*.

17.3 CALC, in its volunteer capacity, had a role in obtaining funding and were pivotal in setting up such a training programme which was based, after national consultation, at the Central Institute of Technology in Wellington. This was funded through a development grant and ran for two years. The programme offered residential training in both the theory and practice of cytology and was supported by laboratories in most areas of New Zealand. The Committee acted as a curriculum advisory committee for the training programme.

17.4 Against the advice of the Committee, the programme lapsed after two years when funding was not renewed. This was on the grounds that the programme did not have enough student numbers to reach normal educational standard levels. The extreme concern of CALC was recorded in its minutes of 16 June 1993. The refusal to renew funding was, in my view, indefensible. It would take more than two years to build an ongoing training programme to the level where enough candidates would register for training. No alternative was put in place.

17.5 The lack of trained cytotechnicians continued to be an ongoing problem noted from time to time. Concern was formally put to the Minister of Education in June 1993 and noted in the Valerie Norton report of June 1993 where the laboratories had commented on issues which included: *"A lack of appropriately qualified staff"* and noted that *"In 1990 fewer than ten medical laboratory technologists in New Zealand were qualified in cytotechnology. Most screening and cytology is done by*

laboratory assistants of variable or unspecified background and training ... the national accreditation organisation (TELARC) has recognised a national deficit of qualified staff in this area of service. The failure to develop an educational and training programme for cytology screening technology staff. Laboratories supported the development of a course which was validated and accredited to a recognised educational institution. They argued that it was currently difficult to assess or audit the performance of cytoscreening services in New Zealand". (See JMG/MOH/25).

17.6 At CSLAC's 26 July 1995 meeting the minutes record concerns expressed about the training of technical staff and scientists in cytology - particularly gynaecological cytology. Training has a chequered history. Historically a number of qualifications have been offered but other than the MLT Board's examinations none were required for registration. A programme put in place some years ago for screeners at the laboratory assistant level ceased due to lack of adequate numbers. There are now three degree programmes for Medical Laboratory Science in place (Otago, Massey and AIT) but CSLAC expressed considerable doubt about the adequacy of the cytology component, both theoretical and practical.

17.7 Throughout my years associated with the Programme some pathologists such as myself have maintained an active role not only in promoting the Programme but also in promoting continuing education and quality assurance for cervical cytology. We have for many years contributed to training programmes and update programmes for smear takers run by the Family Planning Association. We have presented data from the National Cervical Screening Programme and from the RCPA Quality Assurance Programme regularly at meetings of the New Zealand Society of Cytology. I have used data from my own laboratory to compare and contrast with national statistics when relevant. On the occasions that I and other pathologists have been involved in TELARC inspections, we have promoted the objectives of the National Cervical Screening Programme and taken every opportunity to encourage laboratories to meet the Programme's objectives. When I have been involved as an examiner for the Royal College of Pathologists of Australasia I have actively promoted the importance of cervical cytology.

17.8 At the commencement of the NCSP it was a given that laboratory services would be performed by the existing laboratory providers. All existing providers would be providers under the new scheme. There was also an assumption that a shift to a standard pattern of three yearly smears would be a better use of resources given that many women were then being screened at lesser intervals of one year (and in some instances, six monthly).

17.9 The Ministry of Health did not carry out an effective work time survey, though on 4 May 1990 a letter from the Ministry of Health was sent to all Area Health Boards and to private medical diagnostic laboratories requesting the following information:

17.9.1 The number of cervical smears processed per year for the last two years (1988, 1989, Jan-April 1990);

17.9.2 If known, the number of women per year this total represented;

17.9.3 The number of women from whom cervical histopathology specimens were examined per year for the last two years, and

17.9.4 The percentage of unsatisfactory and abnormal smears.

I recall receiving a number of phone calls from laboratories around the country who were concerned because they did not have accurate figures to supply. I believe my advice to laboratories was that these were for workload projections and that laboratories should do their best to supply the figures but that they would not be held accountable for their accuracy.

17.10 In 1990 CALC attempted to carry out a manpower survey. The process was fraught with difficulty because the Committee had no status and indeed potential conflict of interest issues were raised in relation to the survey. In the end, it was agreed that results would be provided to myself on a confidential basis and that only a statistical analysis could be released. Despite our best efforts, the level of participation was not such that enabled completion. As a result no analysis was ever done and the

original returns were destroyed. Because of this, the exercise was not repeated.

17.10 Following the Cartwright report and up until the start of the Programme there is no doubt that laboratories in general were under pressure and in many instances were only just coping with increasing cytology workloads. Massive increases apparently occurred up to and including 1987. Concern was felt by the laboratory community that a sudden increase in workload could have the potential to add further pressures to laboratories reporting cytology and possibly result in unmanageable workloads. It was extraordinarily difficult to rationally predict workloads during the implementation of the Programme. This was because there was little information concerning the percentage of the relevant population already having smears. An Omnibus Survey was commissioned by the expert group. The percentage of unscreened women likely to join the Screening Programme and the effectiveness of recommendations which would have extended the screening interval to three years given that many women were currently being screened at lesser intervals of one year or occasionally six monthly was also hard to determine with any degree of accuracy. The number of smears also depends on recommendations relating to shorter interval follow up and the timing of referrals and these have changed from time to time during the Programme's history. It was suggested that an upper theoretical limit of approximately 600,000 smears per annum could have been projected although time has shown the actual number of smears has levelled out at just over 400,000 smears per annum.

17.12 I am not sure that our laboratory can be regarded as typical but our smears increased dramatically from approximately 17,000 smears per annum in 1983 through to 32,000 smears in 1988, 33,000 smears in 1989, 33,000 smears in 1990, 36,000 in 1991 and then back down to 34,000 smears in 1992 and thereafter a very slow decrease in smears to 33,000 in 1999.

17.13 In general terms many of the leading cytopathologists in Australasia have promoted the importance of cytopathology and particularly gynaecological cytopathology as a subspecialty in its own right and whilst this is, I believe, important I have over the years tried to concentrate my efforts more towards improving the ongoing education

of those involved in every day evaluation and reporting of the bulk of the cervical cytology. Whilst pathologists often have the means to attend major overseas conferences, workshops etc, these are not so readily available to screening staff. I have therefore over the years paid particular attention to trying to contribute to educational presentations at the New Zealand Society of Cytology where such screening staff regularly can and do attend. We have provided assistance for many of our screening staff to attend not only New Zealand conferences but also conferences overseas although this may not be typical.

17. **THE NATIONAL CERVICAL SCREENING PROGRAMME/ NATIONAL CORRELATION**
- 18.1 The November 1988 Azimuth report had recommended a centrally organised and monitored programme.
- 18.2 At the time the Programme was being set up a Government decision was made to use existing providers for the reading of cervical smears. At this time virtually all laboratory services were under pressure resulting from rapidly increased workloads generated in the wake of the publicity of the Cartwright inquiry and report. There was also a Government wish to implement the National Cervical Screening Programme with speed and it finally did so against the advice of its expert group - see minute of 18.12.89, p.18, regarding implementation guidelines for Area Health Board. Small pilot studies had been run in Nelson and Wanganui.
- 18.3 There was some concern that was is inappropriate to establish guidelines such as these without first developing a clear national policy for the national cervical screening programme.
- 18.4 This was in marked distinction to mammographic screening programmes in this country, the pilots for which were commenced at approximately the same time as the Cervical Screening Programme but which did not result in full national implementation until 1998.
- 18.5 In 1989 the Ministerial Review Committee noted resource issues, and made recommendations including the appointment of a single national coordinator.
- 18.6 The minutes of 29 March 1990 record our concern (p. 76) that *“it was impossible for [our committee] to adequately perform its task if the Cancer Registry was not adequately functional”*.
- 18.7 The Committee also recommended that the national coordinator should be responsible for ensuring *“that adequate monitoring and evaluation systems are established for all aspects of the programme”*.

18.8 In our 3 May 1990 Report to the Minister (p. 119) we stressed as our first recommendation “*A national population-based programme developed from three linked registers with initial focus on the centrally organised cytology register*”.

18.9 On 13 September 1990, steps were taken to bring the first Area Health Board (Christchurch) onto the programme - **see Minutes of Expert Group**.

18.10 The need for National Correlation of results was summarised in the Azimuth discussion paper in 1993 (**see GRB/MOH/20**) as being that:

“The short answer is Yes. In the absence of individual laboratory trends, the national average performance:

- ◆ *defines the average performance level that is achievable under current technology and knowledge*
- ◆ *defines the allowable performance band within New Zealand*
- ◆ *gives under-performing laboratories a target performance to aim towards*
- ◆ *assists the National Coordinator to identify reference laboratories*
- ◆ *assists the Programme in making global comparisons of laboratory performance.*

An impartial performance standard plus comparison against a national average identifies where each laboratory is placed at the start of the QA process, and provides the basis for later review.”

18.11 There were a number of corollaries associated with the introduction of a National Cervical Screening Programme using existing providers and implemented in a relatively short period. This meant that the Programme had to continue to evolve and that standards in parallel had to evolve in a way which enhanced and improved existing provider systems rather than precluding or destroying them.

18.12 There were, for instance, initial concerns that a sudden increase in smears could not be handled by the existing laboratory system and staff

available in New Zealand.

18.13 A system for laboratories to send smears to other laboratories should workload become too great was set up but to my knowledge was not formally implemented at any point. In fact, although there was a small increase in the number of smears being processed after the introduction of the Screening Programme, the bulk of the increase had already occurred in the lead up to Programme and post the Cartwright inquiry.

18.14 There were unfortunate delays arising from staff, resources and, I believe, lack of coordination in achieving a national register. The loss of Dr Gillian Durham and her medical position from the Cartwright Projects Unit was a significant backwards step (see p.82, minute of 29 March 1990). However significant progress was made after January 1994, following the Minister's approval of putting the 14 registers into one national register.

18.15 On 19 June 1996 Teenah Handiside, the National Coordinator, reported to CSLAC on the recommendations following review of the NCSP which included *“Ministry of Health no longer responsible for national coordination and review of location of NCSR”*.

18.16 CSLAC noted that the National Coordinator *“does not easily fit in this reformed environment”* but agreed that NCSP needs to *“be a centrally coordinated unit. CSLAC is concerned that the programme should not be devolved to individual RHAs given the size of New Zealand's population. There would still be a need for central co-ordination. There is still work to be done and it would be foolish to jeopardise its success so far especially in light of international evidence about the importance of a nationally coordinated programme. The NCSR is a unique reporting system, and is potentially one of the best research and monitoring facilities in the world. New Zealand's population size is too small for some key data to be meaningful at a CHE or RHA level.”*

18.17 On 1 August, 1996 I wrote to Karen Poutasi and the Minister of Health (JMG/MOH/83) noting, amongst other matters, *“It has long been acknowledged by those involved in the Programme that there was no obvious place for a single national programme to be sited in the*

reformed health environment. The committee however feels very strongly and is backed up by the overwhelming majority of International literature that an effective screening programme needs a single 'office' which is responsible for, and has accountability for, overall management of the programme."

19. **OPT-ON/OPT-OFF**

19.1 From at least 1990 programme enrolments were an issue of concern. It was the view of all the groups I was involved with that any system should capture as many women as possible to be on the programme.

19.2 In our report to the Minister of 29.5.90 (see page 98) we noted: *“As recommended in the Review Committee’s Report, entry into the Programme should be automatic. Participation should be considered routine although provision for women to opt out should be available. This will require legislation along the lines of the Victorian Cancer (Central Registers’) Act, 1989. Unfortunately, without this legislation, written consent would need to be obtained from every woman who enters the Programme in order to allow transfer of information from the National Cytology Register to Area Health Boards. We believe this to be cumbersome and likely to cause a barrier to women enrolling in the Programme. For the Programme to be successful, the registers must be as complete as possible.”*

19.3 In the early years of the Programme it also became apparent that using an opt-on system was providing relatively low numbers of smear results to fourteen different registries making statistical evaluation of laboratory performance extremely difficult given the relatively low incidence of significant abnormalities.

18.3 Under the opt-on system about 20% of women having smears were enrolling on the programme. This 20% could not reliably be taken as a representative sample of the population as a whole. Indeed, we knew that some groups of population were under-represented in having cervical smears and some groups were suspicious of the programme and/or the Registry. The latter groups would have smears taken but not go on to the programme. Some of these groups were at higher risk of cervical cancer. To compare laboratory reporting rates meaningfully, the analysis must include sufficient numbers in any category to provide a useful rate; that is, one that is not going to be materially altered by fluctuations which randomly occur from time to time. This means a minimal analysis of many thousands of smears or even tens of thousands

of smears for some very low reporting rate categories (e.g. squamous cell carcinoma, adenocarcinoma). Having obtained meaningful rates of reporting then inter-laboratory comparisons can be made and corrections for population differences can be examined.

- 19.5 By splitting the already small population base in New Zealand into 14 groups, both the number of laboratories and the number of smears being assessed becomes too small for meaningful analysis. Because of the relatively low incidence of cervical cancer (about 250 cases per year in New Zealand), even working out significant regional incidence becomes difficult. In some instances a difference of one or two cases in one area could significantly alter the apparent incidence rate.
- 19.6 It is only recently and under the opt-off system that about 90% of women having smears are now enrolled in the programme, allowing a more confident assessment of the data from a more representative sample. Because the programme now operates a single national database all laboratories can be compared.
- 19.7 I might add that this is only a small segment of the total monitoring and evaluation which also should include analysis of all cases of cervical cancer and which require sophisticated statistical and epidemiological expertise.
- 19.8 In 1993 the Ministry of Health investigated the possibility of RHA funding agreement having a performance indicator with the Committee being responsible for gathering this information.

19. **RECORDING OF CERVICAL HISTOLOGY ON THE REGISTER**

20.1 In 1989 the Ministerial Review Committee recorded (see **paragraph 2.23 JMG/MOH/1**) that *“committee members considered it essential that cytology and histology results should be recorded on the register”*.

20.2 The Register should include integration of cytology and histology reports and should link up with the National Registry.

20.3 CALC through its sponsoring organisations encouraged laboratories to supply histology in a timely fashion by electronic means. The Committee advised on the use of appropriate Snomed codes for this purpose. The Committee did all it could to facilitate the work of computer consultants employed by the Programme to advise on incorporation of histology into the database.

20.4 At page 124, **Appendix IV**, the Ministerial Review Committee also noted *“The accuracy of these [smear] results when compared with subsequent histological results should also be monitored as this is ultimately the determinant of the effectiveness of smear analysis.”*

20.5 In the November 1989 report (see **EXHIBIT JMG/MOH/1, paragraph 2.23**), the Ministerial Review Committee stated that *“Committee members considered it essential that cytology and histology results for women could be related to one another for two main reasons. The first and fundamental reason for doing this is to enable an assessment of the overall effectiveness of the programme to be conducted, and the second reason is to provide a means of assessing the quality and uniformity of smear reading throughout the country.”* At paragraph 2.24 we went on to comment *“As was the case with the development of a population register, committee members were concerned that requiring histology results to be incorporated onto the cytology register from the outset would delay the implementation of the overall cervical screening programme. It was recommended that development of the cytology register continue as planned, but that an investigation of methods by which histology results could be incorporated should begin immediately.”*

20.6 Recording histology data from cervical biopsies on the register was seen as being clearly needed by CALC as a form of quality control and also a back-up for ensuring adequate follow-up for women with abnormal smears. This was recorded in its minutes of 4 May 1990.

20.7 The Expert Committee also reported *“Developing a mechanism for linking histology results of cervical tissues submitted to laboratories for diagnosis to the cytology register is an urgent priority for the Department of Health. The Register will also be developed so that laboratory staff have direct access to a woman’s previous smear history when reading smears”*.

20.8 CALC had recommended that on 4 May 1990 cervical histology be recorded on the registry as a quality control measure enabling comparison of cytology and subsequent histology. It had also recommended to the programme that the reporting profiles of laboratories should be supplied to each laboratory on a regular basis (it was suggested that this be annual figures but produced six monthly) and be presented in such a way that the reporting profiles could be contrasted with both means and ranges for all laboratories in New Zealand and for community laboratories or hospital laboratories.

20.9 It was a disappointment to the Committee when this did not occur at the commencement of the Programme.

20.10 In April of 1993 Janet Phuah’s report recommended the following quality assurance process:

- “1. *The Programme will provide correlation reports for each participating laboratory. The reports will be provided at quarterly intervals and will cover the 12 months preceding the reporting date. The reports will be used to monitor trends in the examination of cytology and histology results.*
2. *Each laboratory will receive the following:*
 - *national correlation results*

- *histology correlation to the laboratory's cytology results*
 - *cytology correlation to the laboratory's histology results.*
3. *TELARC will be advised that the laboratories are provided with the correlation reports. TELARC will be asked to review those reports as part of its laboratory accreditation process and during its two-yearly review of the laboratory.*
 4. *The Programme will review the results and, upon detecting six continuous months of apparent discordant results when compared to the national results, discuss these discordances with the laboratory concerned. Should the apparent discordances prove to be actual discordant results, the laboratory will be given six months to change its processes and to correct any problems.*
 5. *If the discordant results continue, the National Coordinator will seek advice from CALC and nominate an independent authority to review the laboratory and to report back to the National Coordinator regarding the next actions."*

20.11 Ms Phuah and I spent many days working on a very sophisticated system to correlate the histology and cytology results. The tables we formulated are set out in **GRB/MOH/20**. This system required sophisticated computerisation but would have provided extremely valuable information, and I know of no reason, other than resources, why it could not be implemented.

20.12 The system has, to my knowledge, never been adopted. In the last year a system has been implemented.

20.13 In 1993 the Health Amendment Act was passed which required histology results to be sent to the Register. At the CSAC meeting on 5 November 1993 (see **JMG/MOH/11**) the National Coordinator advised us that *"The legislation is difficult to implement and an enormous amount of work has to be done in this area."* She advised us of a legal opinion. I had taken my own legal advice and questioned the opinion obtained by the Ministry of Health. By now, this issue was becoming rather tetchy

and the meeting records a suggestion that “*CALC and the Ministry of Health productively work together to seek a solution to the problem ... It was commented [that there] has been a measure of intolerance and non-constructive comment about this issue which has hindered progress.*”

20.14 When steps were finally taken to start loading the histology information onto the computer I expressed strong concern - not against the information but about the relevance. The programme was already under-resourced. I did not think it wise to overload it with results from hysterectomies for prolapsed fibroids or menorrhoea which are unrelated to cervical cancer.

20.15 This concern was summarised in a letter to the Minister of Health dated 8 December 1993 (see **JMG/MOH/11**). This letter was sent from CSAC where we stated: “*It was considered that the NCSP could be compromised if the current interpretation of the Act is followed. The intent of the legislation was to include the histology of women already enrolled on the register as a quality assurance measure. As currently interpreted, however, the Act requires all histology results to be entered on to the register. This includes results of women whose cytology results are not on the register or who have gynaecological surgery unrelated to cancer. As a result, time and resources are required to collect unnecessary information.*”

20.16 It was my view that this information should eventually come on, but we should concentrate on the most important and relevant information first.

20.17 As it transpired, the programme was overloaded and considerable delays occurred as a consequence. This was noted by the Minister of Health in her letter to CSAC dated 26 January 1994 (**JMG/MOH/11**), where she stated “*I acknowledge there have been some problems in the implementation phase of including histology results on the Register which has produced extra workloads.*”

related histology results have become available in the last six months. Cytology statistics by laboratory started to be produced on 7 August 1996. (**GRB/MOH/29**).

19. **EXTERNAL QUALITY CONTROL**

- 21.1 I have already referred to a number of requirements, most particularly recording of histology on the Register, seen as essential for quality control. Other factors are listed in this section.
- 21.2 Right from the start quality control was hampered by delays and, as recorded in the minutes of CALC 18 July 1989, **GRB/MOH/18**, *"Quality Control Financial restraints and the proposed time frame for starting the NCSP will allow only the cervical smear results and the patient the smear taker's registration numbers to be put on the register. Therefore, QC from the NCSP will only be available on the adequacy of smears and not of colposcopy histology/cytology results etc through the registry."*
- 21.3 In a report of the National Cervical Screening Programme's review of laboratory services June 1993 (Norton M.O.H. 1993), it was noted that 13 of 18 community laboratories participated in the RCPA Quality Assurance Programme and 4 of 12 hospital laboratories participated in this Programme. In addition, one community laboratory reviewed slides with pathologists and colposcopists at their regional or Area Health Board Hospital and another had a proportion of its work rechecked by two external screeners. In addition two hospital laboratories participated in the American Society of Cytopathology check path and check sample programmes.
- 21.4 It has been suggested that exchanging slides between laboratories is a means of external quality assurance. This was not seen as a reliable practice except as part of a properly organised quality assurance programme. The principal reason is that only a small percentage of slides will be abnormal, and as most of these will have been detected the percentage of slides reported as negative and which actually have abnormality present will be correspondingly even smaller, perhaps in the region of 0.1% or 1 in 1,000 slides for high grade abnormality. For the practice of swapping slides between laboratories to be useful as a quality control activity, laboratories would have to swap thousands of slides. This is the same problem as has been noted as a limitation of the rescreening of 10% of negative slides as an internal quality control measure.

- 21.5 In the National Cervical Screening Programme's review of laboratory services (June 1993, B Norton, Department of Health) it was noted that in 1992 9 out of 18 community laboratories and 5 of 12 hospital laboratories processing cervical cytology were TELARC registered for cytology testing; it was also noted that several other laboratories were in the process of obtaining accreditation.
- 21.6 In 1995 J Phuah, in her report, recommended that TELARC be advised of correlation reports for each laboratory as part of the accreditation process for laboratories.
- 21.7 In 1994 there was a change in management of the RCPA QA Programme and I was appointed as a New Zealand representative on the management committee. Since that time the reporting system used is compatible with the New Zealand Bethesda system and results are available as soon as the laboratory has submitted its appraisal of the slides sent for laboratories for assessment.
- 21.8 Since then, TELARC receives the annual report of the Programme detailing the exercises carried out and the overall performance of laboratories in the Programme.
- 21.9 Until I left that Committee last year I presented a summary of results from the Programme each year to the New Zealand Society of Cytology Annual General Meeting.
- 21.10 It is my understanding that all laboratories carrying out cervical cytology in New Zealand are now participating in the Programme.
- 21.11 On 19 June 1996, CSLAC was presented with the first national laboratory results analysis. The minutes record that "*Marianne Linton (Public Health Intelligence, Public Health Group, Ministry of Health) joined the meeting. Marianne presented a national statistical table of cytology results. It was reported that an individual breakdown for each laboratory together with a national analysis will be sent to laboratories. CSLAC agreed that this information was long overdue and very useful. Marianne asked for feedback on the usefulness of these statistics, format, etc. TELARC will be given the national analysis but not*

individual laboratory data. TELARC will be informed when the individual laboratory data has been sent out. The individual data will be reviewed by TELARC at the time of carrying out its site visit. This information will be useful to laboratories as an internal quality measure to TELARC as a registration body, and to the Ministry of Health to draw laboratory performance to the attention of the RHA as a purchasing body. This initial document can be used as a benchmark document. It analyses data from the first day to June 1994.”

21.12 The laboratory committees and other programme advisors had recommended that the reporting profiles of individual laboratories should be made available to individual laboratories on a regular basis (variable recommendations 6 to 12 monthly) together with the mean and range of reporting profiles for all laboratories and the mean and range for all hospital or all community laboratories as appropriate for the particular laboratories.

21.13 The laboratory committees had recommended that the data pertaining to all laboratories be simultaneously supplied to TELARC/IANZ so that inspection teams from these organisations would know when these reports were issued and could determine if laboratories who appeared to have deviant reporting profiles had investigated and taken appropriate action.

21.14 I did not prepare these reports although I believe I gave some advice about reporting hierarchies.

21.15 The first such report was issued in 1996 under Ms Glackin's signature. I understand that the delay in producing these reports was occasioned by the difficulty in merging divergent data from 14 separate registries. I believe the process of reformatting data so that it could be brought into a single database took approximately two years.

19. **STATISTICAL REPORTS**

- 22.1 It was expected that an annual report would be provided by the programme.
- 22.2 There were considerable delays in publishing the first report arising from factors which have been outlined earlier but having at their heart a lack of qualified senior staff.
- 22.3 Ideally the report would have been compiled by the programme using the expertise of an epidemiologist of significant standing, together with the assistance of statisticians, cytologists and other specialists. Employment of such people had been suggested from time to time.
- 22.4 Substantial and initial work on the first statistical report was carried out by Dr Cox and John Brackenbury with help from myself later in the process on laboratory issues and by others as acknowledged by Dr Cox in his brief of evidence.
- 22.5 The second statistical report was prepared by Marion Linton. I did have input into this report, particularly in providing advice relating to the definition of the hierarchies in the various cytological reporting codes. It was my understanding that epidemiological advice was also being obtained.
- 22.6 I was asked to peer review subsequent statistical reports which I did on the usual basis that my review could only be to the extent of my expertise as a pathologist.

19. CONSIDERATION OF FALSE NEGATIVE RATES

23.1 It was hoped that from approximately 1996 onwards the Programme could start to look at false-negative rates.

23.2 False-negative rates could be evaluated as part of an investigation of all cervical cancers occurring in New Zealand and submitted to the Cancer Registry. These have been registered by law since 1994 and an evaluation of the screening history together with re-evaluation of any relevant smears is an important "gold" standard by which the Programme could be evaluated. Such an evaluation essentially yields information on whether the screening programme is reaching the right people and if so whether there are inefficiencies in smear taking or in smear reading. This approach has been advocated to the programme by various committees. A second approach is to document the number of high grade or worse smears which have had a normal smear reported in the previous three to five years. This type of evaluation is similar to one of the recently adopted Australian standards and given the time frame of five years and that opt-off with its significant increase in smears for analysis commenced in 1994 this type of analysis will yield maximal information only from 1999-2000 onwards.

23.5 I have read the evidence of Dr McGoogan which helpfully sets out relevant matters.

19. CYTOLOGY SLIDE REVIEW PANEL

24.1 In 1994 the Association of Community Laboratories after consultation with the National Cervical Screening Programme, the New Zealand Society of Pathologists, the New Zealand Society of Cytology, CALC (see minute 29 June 1994) and the Royal College of Pathologists of Australasia instituted a system for review of cervical smear slides which are the subject of dispute. In brief, eight laboratories in New Zealand all with a particular interest or expertise in cervical cytology were nominated to become panel members.

24.2 A laboratory wishing to activate the review could contact one of the laboratories or the Executive Officer of the Association of Community Laboratories. If a laboratory was approached then that laboratory would co-ordinate the review but would play no part in the actual review process. The laboratory requesting the review was asked to submit the slide(s) in question together with other cervical smears to a total of ten slides together with relevant reports to the co-ordinating laboratory. The co-ordinating laboratory would then remove all identification from the relevant slides and number them. The numbered slides together with the following clinical information:- age (in years), pregnant (yes/no) and previous abnormal smear (yes/no) - were circulated to five panel member laboratories whose identity was confidential to the coordinator (this is an express promise) for assessment in their laboratory by their normal assessment process to report each slide using the Bethesda coding system. There is a provision for a worded comment. These results were received back by the co-ordinating laboratory who collated the results and then sent them back to the requesting laboratory.

24.3 If the case proceeded to formal inquiry, the requesting laboratory may be required to supply the results to the complainant.

24.4 The reason for setting this panel up was to get a fair assessment of what a normal laboratory would have reported on the relevant slides. It was hoped that this process would minimise review bias such as that reported by Boon and Suureijer 1993.

24.5 In her book on the Pap smear, Boon describes how known false-negative slides

were evaluated in the laboratory as a routine smear and only 4% were detected as positive compared with 87% which were detected as positive when the slide was examined as part of a known review. By using ten slides for the review, this bias is partially eliminated as the reviewing laboratory does not know which of the slides are the relevant ones although clearly there is still an element of review bias present.

24.6 This review process is unique and has been the subject of interest from the United Kingdom, the United States and Australia. The exercise is undertaken by the reviewing laboratories in good faith and the credibility of the process requires that the reviewing laboratories remain confidential. The process is slightly biased against the laboratory because of the relatively small number of slides but this was felt to be as fair and practical process as could be organised.

19. **INDIVIDUAL LABORATORIES**

25.1 From time to time CALC was asked to comment on the performance of individual laboratories.

25.2 The Committee did not have the power to investigate or assess the performance of any individual laboratory.

25.3 Issues of quality control in general were clearly of concern to the Committee and the Committee took the view that it had made substantive recommendations for standards in cytology to TELARC. It had recommended that TELARC accreditation be compulsory and that this be enforced by contractual obligation.

25.4 By setting qualification, systems standards and reviewing statistical data, TELARC was the important front line organisation for achieving minimum standards.

25.5 At its 17 November 1993 meeting CALC minutes record that the register would *“eventually provide information to detect laboratory under-reporting of inadequate or limited smears. This is part of the work that the technical group has been involved with. The National Coordinator agreed to document any cases that come to her attention and stated that the evidence presented to her so far has been anecdotal.”*

25.6 In 1991 I was requested to examine and report on a single case by the New Zealand Society of Pathologists. Essentially the case involved a smear which had been taken and spread onto two slides, one of which was submitted to one laboratory and the other to another laboratory. One of the slides had been reported as showing high grade abnormality and the other slide had been reported as normal, the normal report having been made by a Rotorua laboratory. I investigated the complaint. I examined the slides (and also had them examined by two of New Zealand's most senior cytopathologists). The results of this review showed clearly that there was one slide, probably the first taken from the smear, which contained large numbers of clearly identifiable abnormal cells. This was the slide that was reported as having high grade abnormality. The

second slide was technically more difficult to read with only sparse abnormal cells present. I concluded that although both slides showed abnormal cells, one of the slides was significantly easier to read than the other. The Rotorua laboratory had received the more difficult of the two slides to interpret.

25.7 I submitted this report to the New Zealand Society of Pathologists (see **GRB/MOH/43**). I understand that the New Zealand Society of Pathologists recommended that the laboratory become TELARC registered in cytology.

25.8 At the 12 December 1991 meeting of CSAC I reported back on the Rotorua Laboratory. The minutes record *“It was recognised that total smear reading accuracy could never be obtained. Even overseas programmes report that 15% of high grade lesions are missed. One third of these are missed in the taking of the smear; another third are due to laboratory error, and one third are cases which have not been followed up. To gauge the level of smear reading accuracy, there is a need to compare cytology with colposcopy and histology information and the number of women with invasive cancer. A laboratory should also be evaluated according to its total performance and not on the basis of one smear.*

The New Zealand Society of Pathologists have recommended the Rotorua Laboratory become TELARC registered. If the laboratory does not become registered, cervical smears taken as part of the National Cervical Screening Programme will not go on to the Rotorua Laboratory after 1993.”

25.9 Those minutes record my mistaken belief that earlier recommendations that TELARC registration be compulsory for funding to be obtained had been acted on.

25.10 In 1993 later the Cytology Advisory Liaison Committee was asked to comment on an issue raised by the same Cervical Screening Coordinator. The query raised concern about under-reporting of abnormalities by a Rotorua laboratory and was accompanied by some Area Health Board statistics relating to both that laboratory and the totals for the region. It did not appear to the Committee that the statistics supplied supported the

concern raised (shown in **GRB/MOH/32**). The numbers were too low for meaningful analysis although I note that the laboratory reporting rate for both High Grade lesions and for squamous cell carcinomas were more than double the rates for the Area Health Board combined statistics for the whole of that Board's area. CALC wondered why the coordinator had not in the first instance approached the laboratory. The issue was referred to NCSP for reply. I understand that the Programme offered to support the Area Health Coordinator in meeting with the laboratory concerned to discuss the concerns raised.

19. **GISBORNE**

- 26.1 I received a letter from Dr Bottrill dated 7 July 1995 requesting his laboratory statistics. As I had no access to the results of any individual laboratory, I handed this request on to the Cervical Screening Programme for action. When the information was not forthcoming after many months, I phoned again and was told that actioning this request would delay work on data for the whole programme.
- 26.2 On the 10th of July 1995 I received ten cervical smears from Dr M. Bottrill for review. These included four slides of a case in which there was medico-legal interest. I co-ordinated that review according to the protocol and the results of that review were sent to Dr Bottrill on the 14th of August 1995.
- 26.3 At the request of the complainant's counsel, I gave evidence for the complainant and presented the results of this review at a Medical Disciplinary Hearing in Auckland on the 20th of February 1997. At the request of the complainant's counsel I also took and produced photomicrographs of relevant slides.
- 26.4 Following the Disciplinary Hearing I was asked to provide opinion by counsel assisting Dr Bottrill. On the 8th of July 1997 I received by fax from Dr Bottrill's counsel a copy of a letter addressed to Mr K J Reeve, Gisborne Laboratories, giving the Gisborne laboratory's reporting statistics up to 30 June 1994.
- 26.5 In subsequent discussion with Dr Bottrill's counsel I indicated that I did not believe that these figures were indicative of systematic under-reporting as the percentages of abnormality fell well within the ranges reported by community laboratories and in particular the rate of high grade lesions (which, I believe is the critical abnormality in terms of safety) was well within the range identified for community laboratories (0.6% compared with a mean of 0.8% and a range of 0.4 to 2%).
- 26.6 This was also well within ranges reported for high grade lesions from other countries and registries (Working Party on Quality Assurance in Cervical

Cytology, 1994).

- 26.7 I was contacted by a general practitioner who reported having heard from Hamilton that a smear which had been reported in Gisborne was re-examined there. It showed malignant cells. The practitioner asked if there was a review process that I was involved in. I said there was a review process for when the slide was contentious but it was not a process used if the reporting laboratory accepted that the original report was in error. It was expected that the review process would be initiated by the reporting laboratory. I told the general practitioner that it was vital to bring this to the attention of the authorities (for example the Medical Council or the Health and Disability Commissioner), and it needed to be properly investigated. At the conclusion of the conversation, it became apparent that the patient may not want to do this. I stressed that the general practitioner should take some action. This was about two months prior to the Bottrill court case. The general practitioner then indicated that there were concerns in the past about another patient. I exhorted her to bring a complaint if she had concerns. My next move was to telephone the Hamilton laboratory. I spoke to the acting Clinical Director. He said he was unsure whether the slide had yet been examined by a cytopathologist, but didn't think it had. I said it should be reported in the usual terminology. If the slide reviewed was in doubt there was a review process which could be initiated through me. If not, then the results should be referred to the general practitioner.
- 26.8 I telephoned Dr Bottrill's counsel to inform them of this as it seemed to me that this information could be relevant to the case. Mr Hodson QC was not available but I was advised the information would be passed on to him. I telephoned later and was given a message that the information had been passed on. As a consequence of this, and my communication with the laboratory, I was reassured and saw no need to take the matter further.
- 26.9 At the request of Dr Bottrill's counsel I gave evidence in a High Court Hearing in March 1999. Again, I presented results of the review and reiterated my conclusion that there was not evidence of systematic under-reporting by Dr Bottrill.

- 26.10 At the High Court hearing, I was asked to comment on Dr Bottrill's practice. I have never visited Dr Bottrill's laboratory and have seen only the slides which were the subject of the review. However, those matters I was aware of caused me to express the opinion that I viewed his practice as sub-optimal.
- 26.11 Systematic under-reporting cannot be reliably assessed by examination of individual cases. This is because there is an inevitable false-negative rate for cervical screening.
- 26.12 My reasons for reaching this conclusion were as detailed as above. Also since that time the Australian standard had been finalised in relation to reporting rate for high grade squamous intraepithelial lesion. The standard states that a laboratory should not report less than .5% high grade squamous intraepithelial lesion.
- 26.13 The exact level of this false-negative rate is the subject of wide literature variation but there is universal agreement that there is a false-negative rate and cervical screening programmes cannot realistically aim to eliminate cervical cancer.
- 26.14 Indeed, a three yearly cervical screening programme should reduce the cumulative incidence of cervical cancer by nearly 91% (Eddy, 1990). Major reviews of the Pap smear yield false-negative rates from 5 to more than 50% and sensitivities of approximately 50 to more than 70%. A consensus developed from meetings of the New Zealand Society of Pathologists, New Zealand Society of Cytology and ACL stated that there was a 20% false-negative rate for high grade lesions on an individual smear. An Australian federal publication (Braggett et. al., 1993) noted evidence of a false-negative rate of 15 to 20% for CIN III. The same publication quoted a false-negative cytology rate (when compared with histology) of 3% for CIN III and 18% for CIN II.
- 26.15 A more recent consensus statement by the NCI/NIH in the United States stated "Pap smears are highly effective in screening for pre-invasive lesions, however a single test has a false-negative rate of approximately 20%. One-half of the false-negatives are due to inadequate specimen sampling and the other half are attributed to a failure to identify the abnormal cells

or to interpret them correctly". (FOCUS - Papanicolou Society of Cytopathology Vol 3 No.2, Dec 1996).

- 26.16 It is an unfortunate but inevitable that despite the Cervical Screening Programme cervical cancers will continue to occur and significant lesions will be missed, even by the best of laboratories.
- 26.17 The false-negative rates from a screening programme perspective include cases in which abnormal cells, although present in the woman are not present on the smear and these may represent between one-half and two-thirds of false-negatives, cases in which the abnormal cells are present on the smear but are not recognised by the laboratory and these also represent perhaps one-third to one-half of false-negatives and finally there are, from a screening programme perspective, a small number of cases where the abnormal cells are present on the slide the abnormal cells recognised by the laboratory but there is a failure to act appropriately on the report.
- 26.18 For these reasons individual cases of under-reporting do not of necessity indicate systematic under-reporting. Indeed, in any one area there will be a number of such cases attached to any laboratory.
- 26.19 I became aware that GIL was not TELARC registered at the time that Dr Bottrill contacted me in relation to setting up the slide review for the case that went to the Disciplinary Hearing. I advised him that he should become TELARC registered or send his cytology to a TELARC registered laboratory.
- 26.20 I had neither the power nor the authority to make laboratories become TELARC registered, or to make individuals participate in Quality Assurance Programmes. Despite my involvement in committees, neither I nor the College was provided with information, statistical or otherwise, that enabled me to state if an individual laboratory was not meeting an acceptable standard. However, from 1989 onwards, I actively strongly promoted and advocated for compulsory TELARC registration, which required as part of the registration criteria participation in Quality Assurance Programmes. Inclusion of histology in the programme statistics was also a quality assurance safeguard I advocated. Analysis of all invasive causes of cervical cancer should be carried out as a

fundamental quality assurance measure. All these measures should have been instituted with immediacy. I believe we would probably not have needed this Commission of Inquiry if these steps had been taken sooner.

19. **SUBSEQUENT EVENTS**

- 27.1 Following the High Court case in Auckland, there was a major public outcry and concern was expressed that there was indeed systematic under-reporting in Gisborne.
- 27.2 At that point I briefed the Royal College of Pathologists of Australasia's New Zealand Councillor, the HFA (Tracey Mellor) and the HFA's Public Screening Advisory Group of the above matters.
- 27.3 On the information available to me at the time, I believed that Dr Bottrill's results were within the expected range. The review findings have shown that the particular characteristics of the Gisborne cases would put Gisborne at the top of, or beyond, the top of, the range for community laboratories in New Zealand.
- 27.4 The results of the review of Dr Bottrill's reporting that I am aware of appear to indicate substantial under-reporting by that laboratory. I am personally and profoundly distressed by the findings as I have spent a significant portion of my life trying to improve the quality of cervical cytology and reduce the incidence of cancer in New Zealand.
- 27.5 I feel desperately sorry for those women who have been adversely affected by this situation. The fact that some cases were detected and some women saved is of little consolation. I believe that if all the measures for quality assurance and registration previously recommended that have been detailed in this submission are fully implemented, the chances of this event occurring again will be minimised. There are further improvements which would result in better outcomes.

19. **IMPROVEMENTS**

- 28.1 The reading of cervical smears is a subjective process. In my own teaching I frequently make the point that what is in the patient is fact, what is on the slide is artifact and what is on the report is an opinion on artifact.
- 28.2 The usefulness of the technique is dependent on the artifact being consistent and reproducible and on the training and diligence of the reporting person.
- 28.3 If the reading of smears could be reduced to a set of totally objective measures then image analysis linked to computer analysis would provide a totally accurate smear reading. This has however proved to be an elusive goal and despite many hundreds of millions of dollars spent worldwide, no such computer based system is yet available to eliminate the subjectivity of human interpretation.
- 28.4 A number of computer based systems have become available for use, particularly as rescreening devices, but all of these systems, whilst identifying those slides, cells or cell groups which are most likely to contain abnormality, still rely on the human observer for the final assessment.
- 28.5 Quite clearly there are major attempts throughout the world to increase the sensitivity and specificity of the cervical screening process and attention is currently focused on the areas of liquid based sampling systems, computer assisted image analysis systems and adjunctive human papilloma virus testing. Within the last two years there have been major Government sponsored reports on these techniques carried out overseas including Australian, United Kingdom and United States of America.
- 28.6 As yet there has been no unequivocal endorsement of these techniques in national screening programmes although there appears to be some increase in sensitivity associated with each technique in some situations.
- 28.7 Certainly the Australian review emphasised that the greatest benefit from cervical screening could be obtained by achieving full population

coverage using the conventional Pap smear technique. By international standards New Zealand has now achieved substantial population coverage. I therefore believe it is in New Zealand's interest to enhance its monitoring and evaluation of current strategy and to assess the possible future role, if any, of these newer techniques.

28.8 By law since 1994 all cancers of the cervix are registered on the New Zealand Cancer Registry. Amendments in the health legislation at the about that time also mandated that all histology reports relating to cervical tissues not accompanied by an indication that the women have had opted off be submitted to the National Cervical Screening Programme register. Therefore the most complete database in relation to the occurrence of invasive cervical cancer resides in the Cancer Registry.

28.9 There has been strong advocacy for a continuing evaluation of all cases of invasive cervical cancer occurring in New Zealand. This would require ethical approval and would require therefore consent of the women concerned. This process would then involve an assessment of the screening history and an appropriate review mechanism for previous cytology where relevant.

28.10 It is possible that the review mechanism related to previous cytology may involve two types of review - (1) aimed at determining how a competent laboratory would report the smears and (2) a more in-depth review aimed at trying to detect any possible clues which may be of a nature not readily picked up in the routine screening system. The mechanics of these two different types of reviews are different but both would probably require protection under peer review legislation.

28.11 In totality the evaluation of these cases should provide a "gold standard" for the screening programme. It potentially would identify whether the programme is reaching those who stand to benefit most by it and it could identify defects in the screening process in its totality from smear taker through laboratory services, diagnostic and therapeutic services.

28.12 Payment for smears has now been increased from \$15.00 to \$21.00 per smear. Laboratories must meet a new set of HFA laboratory quality standards to receive this payment.

28.13 There is concern about a shortage of pathologists in New Zealand. In my own laboratory we have actively contributed to the training of pathology registrars and the conducting of tutorials as part of clinical teaching. We conduct clinico-pathologic correlation sessions at the laboratory on a regular basis.

28.14 There should be active encouragement of all laboratories with sufficient expertise to become involved in training. We were among the first of the laboratories in New Zealand to introduce a system of double sign out for the initial diagnosis of malignancy and we have encouraged and participated in a weekly review session with pathologists from other laboratories where difficult slides are discussed and reviewed.

C.A. Teague

Date