

**BRIEF OF EVIDENCE OF:**

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**CHARLES WILLIAM CAMERON**

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**In the matter of the Ministerial Inquiry into the  
Under-Reporting of Cervical Smear Abnormalities**

**Gisborne, July 2000**

**WITNESS FOR THE WOMEN'S HEALTH RESOURCE  
AND INFORMATION TRUST**

## **I, Charles William Cameron, of Nelson say:**

### **Qualifications and Experience**

1. My name is Charles William Cameron. I am currently retired from medical practice since 1998.
2. I hold a Bachelor of Science degree from Canterbury University, an MB,ChB from Otago University and a Diploma of Obstetrics from Auckland University. I am a fellow of the Royal College of Pathologists of Australasia (FRCPA). I also hold a Certificate of Proficiency in Hospital Laboratory Practice (equivalent to ANZIMLT) the registrable qualification in medical laboratory technology.
3. I worked as a medical laboratory technologist and hospital scientific officer in the laboratories of the North Canterbury Hospital Board (1958-1963) and in the Dunedin laboratory of Dr N Fitzgerald (1963-1968). For some of that time I was a regional council member of the New Zealand Institute of Medical Laboratory Technology.
4. Following graduation in MB,ChB from Otago University in 1970 I worked as a house surgeon and obstetrics registrar at Nelson Hospital. I then worked as a GP/obstetrician/anaesthetist in Nelson until 1979. I then took up an appointment as a pathology registrar at Auckland Hospital. I completed my FRCPA in 1985.
5. From 1985-1989 I was head of the Auckland Area Health Board's School of Laboratory Technology, working as a hospital and forensic pathologist and a part time consultant for MedLab Auckland. I was also a member of the Medical Laboratory Technologists Board.
6. I resigned my positions in Auckland in late 1989. In 1990 I was appointed as a hospital pathologist in Nelson and also became a partner in the Nelson private diagnostic laboratory. I remained as principal of the laboratory until 1998. This laboratory was a participant in the National Cervical Screening Programme (NCSP). During that time I was certified as a TELARC assessor (New Zealand's laboratory accreditation agency). I was involved in the audit of small and medium sized laboratories both public and private until 1998.
7. Since my involvement as a council member of the NZIMLT in 1960 I have promoted issues relating to the education and training of medical and laboratory staff. I have been involved in establishing and the maintenance of systems of quality assurance, performance auditing, and quality control of medical laboratories.
8. In the period 1991-1994 I was chairman of the technology education sub-committee of the New Zealand Society of Pathologists. I was also a

member of the medical technical advisory committee of the medical technology advisory committee of the Central Institute of Technology (CIT) in Upper Hutt.

9. My evidence focuses on my experiences in the field of medical laboratory technologists training as it applies to staff undertaking cytoscreening. I will also provide evidence on the nature and purpose of quality assurance and audit of medical laboratory practice. I will also offer an assessment of quality control issues of the NCSP with reference to what might have gone wrong in Gisborne.

### **Education and Training of the Medical Laboratory Workforce**

10. This section of my evidence outlines the nature of education and training resources applied to medical laboratory technologists and screeners in the late 1980's and 1990's.
11. In 1985, I was appointed head of the Auckland Health Board's School of Medical Laboratory Technology. In consultation with Mike Churchouse, who was the charge technologist and tutor in the pathology unit at National Women's Hospital (NWH), we decided to do several things to try to improve the educational resources for cytodiagnostic laboratory workers. One of these things was to apply for assistance to review the educational processes around Australasia. We applied to the department of Health's Health Workforce Development Fund (HWDF) for funding of a review of the educational opportunities available at the RMIT Melbourne Victoria and the Victorian gynaecological cytology service.
12. In 1985, the education of medical laboratory technologists and laboratory assistants was and still is "Neanderthal" in education terms. This is especially evident in the non-mainstream sub-specialities of laboratory technologists (virology, histology, cyto-genetics).
13. Our report was forwarded to the HWDF in November 1987. The report recommended that an in-service training and retraining facility should be maintained and expanded within a teaching hospital. The recommendation was for the facility to be affiliated with a tertiary institution and its courses benchmarked against international standards. I have no idea what happened to this report and I am not aware of any of its recommendations being implemented.
14. At this time there were probably about 300,000 cytology examinations done annually in New Zealand, of which about 250,000 were cervical smears. There were about 90 persons employed in hospital and private laboratories to do this work, of whom 7 were qualified technologists, and about 40 had the QTA qualification issued by the NZIMLT. Some of the QTA staff and a few of the remainder of otherwise unqualified screeners had international certificates issued by bodies such as the International Academy of Cytology. About 28 laboratories examined and issued reports on cytology preparations. The bulk of cervical cytology screening was

done in the private laboratories. The (NWH) hospital cytology unit in Auckland was the only public institution with a significant enough cervical cytology workload to support a teaching programme.

15. Throughout the late 1980's and early 1990's, New Zealand's medical laboratories faced problems of compliance in quality assurance. It is generally accepted internationally that minimum protocols of quality control, data management, reporting formats and terminology, staff structure and supervisory mechanisms, together with specified performance criteria, should be met by laboratories registered or accredited to perform clinical tests. In other than third world countries, such accreditation requirements are mandatory. In New Zealand, they were voluntary.
16. This difficulty seems to arise because no statutory body is recognised as having authority to challenge the right of specialist medical practitioners to practise if they have the qualifications recognised by the Medical Council of New Zealand. The Medical & Dental Auxiliaries Act 1969, and the Medical Laboratory Technologists Regulations specify clearly and in the most liberal fashion, who may perform laboratory tests. It was to the credit of the Medical Laboratory Technologists Board that it attempted to alter the legislation in such a way as to require supervision of the work done by unqualified staff. For reasons that are obscure, the statutory changes proposed by the Board were not promoted through the Health Department.
17. It is thus possible for unqualified persons (say recent school leavers), supervised by a recent science graduate (called a scientific officer) to carry out laboratory procedures such as cytology screening and issue reports under the nominal control of a pathologist who is not required to have any specified post-graduate qualifications in cytodiagnosis. It would be naïve to assume that the integrity of the medical profession is such that this may not occur in New Zealand..
18. I was very concerned that the human resources needed to expand laboratory services were simply not available, and that despite constant and consistent reminders of this to the HWDF over a number of years and attempts to promote an effective tutorial resource at the NWH cytology department over the same time, there was no evidence that either the Health Department or the Auckland Hospital Board addressed this problem.
19. I believed at the time that no national promotion and expansion of a cervical screening service should have been initiated until a valid and accredited diagnostic and follow-up service had been established.
20. In 1989 an expert group considered setting up the national screening programme for cervical cytology which included advice on establishing a laboratory training facility. Although I had lobbied consistently through various channels for an improved educational resource for this purpose I was not invited to give advice on the programmes educational needs.

21. The subsequent history of resource management for education and training of cytoscreeners was that the resources at NWH were lost. The technical institutes were keen to use medical laboratory technology training as a lever to achieve a technological degree level programme and take some funding for this from the universities.
22. The technical institutes were unsuccessful as several universities were about to float "medical science" degrees by rehashing pre-medical subjects, avoiding the heavy technologic investment in staff and equipment required for a proper medical technical training programme. As cytology (and histology, virology & cytogenetics) were regarded as small-scale and peripheral in the mainstream of medical laboratory sciences, they were ignored by the tertiary institutions. The only recognised certification of cytoscreeners remains the educationally dubious "Qualified Technical Assistant Certificate" issued by the New Zealand Institute of Medical Laboratory Sciences.
23. The technical institutes, particularly the CIT in Hutt Valley tried to compete in provision of diploma level education for medical technologists, but in an environment of constraint and uncertainty, and fragmentation of coordination by service providers through the RHA system, there was resistance by employers to an industry-funded education programme.
24. As a member of the course advisory committee at CIT, and chair of the NZ Society of Pathologists technology education committee, I was quite unable to initiate an ITO (Industry Training Organisation) for medical technology, as there was no cooperation between the state employers (CHEs) and privately owned laboratories. These organisations were simply not adequately funded to maintain an ITO, and in any case, they said tertiary education was available through the universities, and was the responsibility of the individual students.
25. About this time in 1991, the CIT was funded by the Department of Health to set up a cytoscreener training resource, and offer short in-service block courses to the existing cytoscreening workforce, along the lines originally proposed for NWH in the mid 1980's. Despite a great deal of work and enthusiasm by the CIT (Harold Neal was the tutor) this programme was not funded further and closed in 1993. I believe employers did not support the service, and the course was insufficiently resourced to develop a diploma or certificate-level of training for new entrants.
26. I regret that we were unable to influence at least one centre in New Zealand to undertake a programme for cytoscreener training comparable in scope and quality to that in Melbourne, where that Victorian Gynaecological Cytology Service is an excellent model, serving a population similar to New Zealand. This training programme is accredited to a tertiary institution (RMIT), and uses a functioning in-service training resource.

27. There are many competent and dedicated cytoscreeners in New Zealand, but they are undervalued in the workforce, and lack an accreditable qualification in the education system. The scale of the cytoscreening service in New Zealand is such that competing tertiary providers, and industry-funded training programmes will continue to ignore this sector of the medical workforce. I believe it is the responsibility of the state, which sponsors essential population health screening programmes, to ensure adequate investment in the education and training of the screening workforce. The same principles apply in other screening programmes such as breast disease, metabolic and infectious diseases, and immunisation.

### **The Principles of Quality Assurance and Performance Audit in Medical Laboratory Practice**

28. In my opinion quality assurance, quality control and performance audit are critical components in laboratory service provision. The principles of quality control (QC) in medical laboratories have been recognised for decades, and are widely accepted internationally. Quantitative aspects of QC are statistically valid applications of data management to performance audit, using both internal controls and external sources of reference or unknown samples.

29. Compliance with internationally accepted protocols of both internal and external QC programmes is essential for accreditation of medical laboratories, and is now a prerequisite for registration as a contracted provider of medical laboratory services in this country.

30. Quantitative aspects of QC are not directly applicable to the morphologic areas of diagnostic and screening tests carried out in laboratories. In these tests the microscopic appearances of the test material are assessed by a trained observer and classified on the basis of a known and internationally accepted set of morphologic criteria. Such an assessment process has inevitable subjective and interpretive variation, both within and between observers, and other technical limitations (sampling and processing variations) which limit the duplication and hence the precision and predictive value of the observations.

31. The QC of these observational tests therefore comprises the use of internal (intra-laboratory) measures such as recycling test materials through the interpretive process, either with the same or a different observer, and comparing the findings. For example, many laboratories will recycle a proportion of cervical smears for reassessment, or may subject all smears to a brief reassessment by another observer.

32. External QC of cytologic or histologic materials comprises the examination and reporting of test materials supplied by a reference laboratory, or a professionally organised programme. Finding on these test materials is then correlated with the findings of reference material. Such programmes

have been available internationally for a decade or more for both histological and cytological services.

33. When population-based screening services are provided and coordinated on a large scale, with multiple laboratories participating in the screening service, there is an opportunity to apply another form of external QC. Analysis of inter- and intra- laboratory variation in rates of reporting abnormalities and in correlation of follow-up and diagnostic procedures with the screening data achieves this. This QC tool becomes progressively more powerful as data accumulates within the programme.
34. Accreditation of laboratories requires not only performance of internal and participation in external QC programmes, but also continuous audit and review of other aspects of laboratory organisation, staff development and skills maintenance, documentation and verification of procedures, equipment, the working environment, and data management.
35. Compliance with accreditation and audit processes is costly and demanding of time and resources, and may require installation and maintenance of software resources dedicated to QC processing.
36. A culture of dedication to quality maintenance and performance is also required, as some of the compliances can be seen as symbolic at best, or subversive of professional individualism at worst. In general, however, laboratory professionals regard QC compliance as a positive and empowering aspect of their work. In general, it is positive and empowering to have the feeling that a laboratory worker is doing a good job well, confirmed by both internal and external data sources and by performance audit.
37. It is an inherent requirement of a population-based screening programme that a data-management performance is included that has a quality assessment component. For cervical screening programmes, the requirements are not particularly complex or expensive.

### **What Might Have Gone Wrong in Gisborne?**

38. The failure of a Gisborne laboratory to detect significant numbers of abnormalities in routine cervical screening represents neglect of basic quality assurance principles by the director(s) and staff of that laboratory, by the Regional Health Authority, and by the National Cervical Screening Programme.
39. The pathologist involved, who owned and directed the laboratory until about 1994, is said to have been the only person involved in the screening of cervical smears. This gross misinterpretation of smears occurred. The laboratory was not accredited by TELARC, despite a requirement that all private laboratories should be at least provisionally registered with TELARC by December 1992. It is improbable that the laboratory

participated in any form of external quality assurance programmes applicable to cytoscreening.

40. It is not known if the pathologist concerned resisted audit and assessment for accreditation by TELARC on principle through an infallibility delusion, or because he knew that the laboratory performance was such that the laboratory would fail accreditation. In any case, the pathologist or laboratory manager must have made placatory signals to the RHA to whom it was contracted, in relation to the delays or postponement of the, by then, mandatory accreditation requirement.
41. It appears that the funder or contractee (the RHA) failed to write an accreditation requirement in their contract, or failed to enforce compliance in this case.
42. It is clear that such information as existed within the National Cervical Screening Programme database was either not analysed, or acted upon, when an atypical epidemiologic pattern of smear abnormalities was entered from the Gisborne region. If data from biopsy or surgical histology had been entered into the screening programme database, it would have been immediately obvious that an extremely high rate of false negativity was occurring.
43. The measures required protecting the public from non-performance and non-compliance in the provision of laboratory testing is simple and cheap. There is no way of preventing aberrant behaviour by individuals, but the application of compulsory QC protocols to laboratory provider accreditation can do much to minimise the adverse consequences of non-performance. Screening programme databases must be devised to allow monitoring and audit, not just of the programme as a whole, but of its component parts.

Charles Cameron