
under the Health and Disabilities Services Act 1993

in the matter of The Ministerial Inquiry into the Under-Reporting of Cervical
Smear Abnormalities

STATEMENT OF EVIDENCE OF DIANE VAN DE MARK

Dated

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STATEMENT OF EVIDENCE OF DIANE VAN DE MARK

- 1 My name is Diane Van de Mark. I am a Specialist Obstetrician and Gynaecologist practising in Gisborne, a town where five generations of my family have lived. I am a Fellow of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and the American College of Obstetricians and Gynaecologists.
- 2 After growing up in Wairoa, I attended Auckland University where I earned B.A. and M.A. degrees. Subsequently, I married and moved to the United States. I earned my pre-medical qualifications at the University of Pittsburgh. I then sat the National Medical College Admissions Test and after undergoing the written and oral application process was accepted by several medical schools. I chose Brown University, an old and prestigious University in the Eastern United States, where I earned my M.D. degree.
- 3 In 1984 I began a rigorous specialist-training programme in Obstetrics and Gynaecology at the University of New Mexico in Albuquerque. This training included four years of gynaecologic oncology and colposcopy. I was thoroughly instructed not only in detection of cervical precancer and cancer, but also in all the treatment modalities, including cautery, cryotherapy, laser therapy and excisional surgery. I became a fellow of the American College of Obstetricians and Gynaecologists in 1993.
- 4 Prior to returning to New Zealand in September 1997, I worked for more than nine years in Boston, Massachusetts as a Specialist Obstetrician/ Gynaecologist. I was a Clinical Instructor for Harvard University Medical School throughout that time.
- 5 I was also appointed Chief of Obstetrics and Gynaecology for the Medical Centre at which I worked and was a preceptor, instructing other Gynaecologists in a number of surgical techniques, including Laser treatment and the LEEP or LLETZ procedure for removing pre-cancerous cervical cells. I also served on several Hospital committees, including the Quality Assurance and Medical Records Committee.
- 6 I became a member of the North American Menopause Society, the Society of Laparoendoscopic Surgeons and the Massachusetts Medical Society. I attended continuing Medical Education conferences at Harvard and other Universities to update my clinical knowledge, surgical skills and understanding of quality assurance and liability issues.
- 7 In 1997, I returned to New Zealand and was employed as a Specialist Obstetrician and Gynaecologist by Tairāwhiti Healthcare at Gisborne Hospital. I fully expected to provide the same high quality of care, and achieve the same good outcomes which I was accustomed to.

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- 8 The comments that follow are not specifically directed to the principal question being addressed by the inquiry, namely the incidence (if any) of misreading or misreporting of cervical smear abnormalities in the Gisborne region. That issue is perhaps best addressed by pathologists and cytologists. Rather, they relate to my experience as a Gynaecologist in Gisborne. I believe that there is a completely unacceptable level of invasive cervical cancer, and probably also of high-grade cervical intraepithelial neoplasia ("pre-cancer") in this region. I do not have a clear answer as to why these numbers are high, but believe several questions need to be explored, in addition to the possible misreading or misreporting of cervical smears by any individual.
- 9 When I began working under supervision as a specialist in New Zealand I knew there would be differences between my practices in Boston and in Gisborne. But one difference was alarming, namely the amount of high grade cervical disease and even invasive cancer I encountered. It seemed that before long I was caring for as many women with cervical cancer as I remembered seeing in my entire nine years of practice in Boston.
- 10 I tried to define the extent of the problem and was amazed at how difficult it was to get statistics. The Cancer Register would provide information only if I paid for it, charging nearly \$800.00 per request. The Hospital I worked in, the Cervical Smear Program, the Cancer Society and Midland Health were all unable to give me figures for the Gisborne area. Some time in mid 1988 Midland Health sent me a booklet, which seemed to confirm what I had noticed clinically.
- 11 The publication was entitled "Sexual and Reproductive Health in the Midland Health Region (Volume 2, Part 3, August 1997). In it read that:
- "The incidence of invasive cervical cancer within the region is significantly higher than that for New Zealand as a whole, with consequent higher levels of death."
 - "For all age groups within the Midland Health region, Maori women were at least twice as likely to die from cervical cancer as non-Maori women."
 - "Between 1989 and 1993 an average of 59 women per year living in the Midland Health Region were diagnosed with (invasive) cervical cancer."
 - "For the five year period 1990-1994, an average of 24 women died from cervical cancer each year in the Midland Health Region."
- 12 Since cervical cancer is considered to be a largely preventable disease, I felt those statistics were completely unacceptable. I decided to start speaking out on the issue believing this would stimulate discussion and that if a problem was recognized, steps would be taken to solve it.

- 13 Several times when addressing public meetings of women I voiced my concern, saying that I did not know why there appeared to be so much cervical disease in the area but I felt it needed investigating.
- 14 In August 1998, I was interviewed for the Gisborne Herald's Daffodil Day Supplement and talked about cervical and uterine cancer in our area. It is important to note that I was not given the chance to proof-read this article before it went to press and would certainly have made some corrections if I had had that opportunity. However, I was grateful for the opportunity to express my concerns in print, especially regarding the "high incidence of cervical disease" and the belief that it constituted "an epidemic."
- 15 The article evoked several responses from health professionals, both to the newspaper and to me personally. However, the general tenor of the comments was that I was being unnecessarily alarmist and that statistics had not demonstrated a particular problem in our area. It was suggested that my remarks would serve only to make women lose faith in the NCSP. No one proposed that an investigation might be in order to find out if there was a real cause for my concern. No hard questions were asked.
- 16 I began to suspect that no accurate statistics were available. If they were, I had not been able to access them. I needed data to back up my clinical impressions.
- 17 I bought a notebook and my Clinic Nurse and I started entering in it the names of all patients diagnosed with invasive cancer from the time I started work in Gisborne. Most were my patients, a few were women whose disease was diagnosed during that time by other Specialists (for example by locum Gynaecologists).
- 18 In 30 months I collected 17 names. These were all women newly diagnosed with invasive cervical carcinoma. I did not include patients with carcinoma or adenocarcinoma in-situ (non-invasive cancer). I did not count another woman whose cancer might or might not have started to become invasive. (The Pathologists were not in agreement on this issue).
- 19 Of the 17 women in my notebook, 11 had had screening smears at least every three years.
- 20 Three more had had smears within the preceding five years. Nine were Maori, eight were non-Maori. They were young women, most still in their childbearing years. Overall, their average age was 43. The oldest was 58 at the time of diagnosis. The youngest was only 28 when she lost her uterus to cervical cancer.

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- 21 Many of the women on the list were later identified during the HFA re-read program as having had a (possibly) misread smear. However, the majority had had subsequent smears (sometimes three or more) read by other pathologists/cytologists as normal.
- 22 Only one of these women was diagnosed as a directed result of this inquiry and the HFA re-read programme. I know other invasive cancers have been identified during the re-read programme but they are patients with whom I have not been involved so they are not included on the list.
- 23 There may also have been others whose names were inadvertently not entered in the notebook. I do not claim it was an infallible system.
- 24 Clearly then, this is not a complete list, and does not fully represent the number of cervical cancers in our area. But it is an attempt to establish a relatively accurate database, something which I believe is crucial to assessing whether or not we are delivering good medical care.
- 25 I did not keep statistics on the number of high-grade pre-cancerous lesions of the cervix, which I diagnosed and treated. However, the number of LLETZ procedures performed probably gives a loose approximation. In 1998 there were about 80 patients treated with LLETZ procedures, in 1999 there were 110 and through April of this year, 62. Most of these procedures would have been performed for treatment of high-grade lesions.
- 26 These are important numbers, since many gynaecologic-oncologists believe that 30-70 percent of high-grade lesions, if left untreated, will progress to carcinoma. Many also believe that almost all cases of CIN III will eventually become invasive cancer if not treated. There is disagreement regarding the time-span required for this progression. It was once believed that dysplasia took 10-15 years to become cancer. According to the oncogenic model, this is probably not true. Instead, it is thought that a woman infected with a high risk HPV type will probably progress very quickly to a high-grade dysplasia and then to cervical cancer.
- 27 I have been struck by the size and depth of many of the pre-cancerous cervical lesions I have treated here. Years ago, when I was being trained in removal of cervical lesions using a CO₂ laser, we were taught that a laser excision or ablation should reach a depth of seven millimeters. This was thought to be deep enough to destroy CIN in the transformation zone. I have found as a Specialist in Gisborne that it is by no means unusual to remove tissue to three times that depth and still find that some of the disease has been left behind. This may represent long-standing but undiagnosed disease. It could also mean a high incidence of rapidly progressive lesions.

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- 28 It is important to try to put the numbers from my notebook into prospective. According to New Zealand Health Information Service (NZHIS) figures brought before the inquiry, 2313 New Zealand women were diagnosed with cervical cancer over the 10 year period from 1988 to 1997. Using the NZHIS female population base of 1,384,377, that would give an approximate incidence of 16.5/100,000.
- 29 It is difficult to feel confidence about the accuracy of this conclusion, however, because it supposes a New Zealand female population of only 1,384,377 females. Census and de facto data suggest this number should probably be closer to 1,800,000, which would obviously change incidence rates considerably.
- 30 If we use instead the data put before the inquiry by Professor Skegg, 1877 New Zealand females aged 15-85+ developed malignant neoplasms of the cervix between 1990-1997. This would be an incidence of roughly 234 per 1,800,000 annually or about 13 per 100,000 females.
- 31 Recent census figures for Tairāwhiti show a female population of 23,229. Using my list of 17 women over 30 months, we would have an incidence rate of 24/100,000 females. (The actual number is higher than my figures suggest, for reasons previously stated).
- 32 For comparison, U.S. National Cancer Institute figures for that country show a 1990-1996 incidence rate of 9/100,000.
- 33 Since it is possible that some "malignant neoplasm" figures could have included in-situ lesions, it might perhaps be more accurate to compare death rates.
- 34 Professor Skegg's figures show that for the seven years 1990-1997 (figures for 1995 were apparently not available). 607 New Zealand females aged 15-85+ died of cervical cancer. Using 1994 New Zealand de facto estimated population figures, this would give a death rate of roughly 5/100,000.
- 35 For Tairāwhiti, there were 12 deaths during that period, giving a death rate of roughly 7/100,000. The U.S. death rate from 1990-1996 was 2.8/100,000.
- 36 It may seem inappropriate to compare our figures with the U.S., which has had a screening programme in place longer than we have, recommends annual smears for women and has a different population base. However, a comparison which includes Australia does not put us in a much better light. Recent age-adjusted death rates per 100,000 over 1994-1997 indicate that for the USA it is 2.4, Australia is 2.6 and New Zealand as a whole is 3.4.

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- 37 I am not a statistician. My figures are approximate and I am basing conclusions on small numbers. But I believe my findings are cause for concern, and worthy of investigation.
- 38 If we decide after investigation that the numbers of women with cervical cancer are unacceptably high in Tairawhiti (and perhaps New Zealand) how should the problem be attacked?
- 39 It is important to keep in mind that there is a chain of responsibility involved. Women are responsible for getting routine smears, general practitioners/smear takers are responsible for obtaining adequate samples, being alert for suspicious signs and symptoms and referring appropriately. Cytologists/pathologists must read smears as accurately as possible, specialists diagnose and treat appropriately. Hospitals need to maintain appropriate outpatient and surgical waiting times. Also we must have easily accessible accurate statistics if we are to know the extent of the problem and attempt to improve outcomes. If any link in the chain is weak, the system fails.
- 40 At Gisborne Hospital we started working on several fronts. Suspecting a problem, I started collecting data. I spoke unofficially on several occasions with Rosanna Lapham, a locum pathologist formerly from M.D. Anderson Hospital in Houston, Texas.
- 41 Dr Lapham was also concerned about the number of high-grade cervical biopsies she was seeing and felt that a recently introduced liquid medium for collecting cervical samples might improve the accuracy of cytology. This method was approved for use by the hospital despite the extra cost involved, and we have been using it exclusively since 1998.
- 42 At the end of 1998 I also increased my number of colposcopy clinics to two weekly to decrease outpatient waiting times. I achieved my goal of seeing women with high-grade lesions within about two weeks of referral. I also added extra theatre sessions, starting early in 1998, so that by the end of the year I had virtually no surgical waiting list and LLETZ procedures were performed promptly after diagnosis of high grade CIN.
- 43 I also spoke with the hospital's Group Manager, Rachel Haggerty, about how we could assess and improve women's health outcomes. In 1998 Ms Haggerty proposed to the HFA a demonstration project to integrate and manage women's reproductive healthcare in Tairawhiti. Some features of her proposal were a computerized clinical record, a standardized screening tool and development and implementation of clinical pathways. Identified as a key issue was "higher incidence of invasive cervical cancer within the Midland region as a whole with a consequent higher death rate."

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- 44 Last year I approached local foundations and received a generous grant to buy a new colposcope and a treatment unit. This has been used at Gisborne Hospital and has also been transported to clinics in rural areas.
- 45 These were all attempts to improve quality of care within a small region. But this inquiry has made it clear that many far-reaching issues remain.
- 46 New Zealand needs a screening programme with a single identifiable person or office in charge, empowered and funded to provide strong central leadership.
- 47 We need reliable statistics.
- 48 There must be quality controls at all levels within the programme.
- 49 I believe there are also important clinical issues to be addressed.
- Are routine smears every three years adequate? In the United States women have smears every year. In Australia, I believe the recommendation is every two years. We know that the smear test is to be regarded as a screen and not as an accurate diagnostic tool and that there will be false negatives. If a woman has one false negative smear, then potentially she may have had CIN for almost six years before she has her next smear. With increasing evidence that some HPV viral strains progress very rapidly the three year screening interval may no longer be appropriate.
 - Should we recommend PAP smears starting at an earlier age? We know that many women are becoming sexually active in their teens and evidence suggests that a young cervix is most susceptible to HPV infection.
 - Would it be appropriate to institute a pilot viral typing programme in one or more regions? This would be relatively expensive but might provide useful information. If for example we found a high prevalence of oncogenic HPV types this might modify clinical practice. Overseas studies suggest that the sensitivity for detecting high-grade disease by means of identifying HPV ranges from 81 to 97%. In a population where annual screening is the rule this method is probably inappropriate but might be useful in a situation where women are being screened every three years or less frequently than that. Cervical cancer is supposed to be a disease of elderly women, but my experience in New Zealand has not borne that out. I believe it is something that needs to be investigated and maybe viral typing would contribute to our knowledge.

- Overseas there seems to be a growing body of evidence that the use of liquid base cytology decreases the false negative rate. How could we evaluate that method and also perhaps the computerized analysis of cervical smears and decide whether those technologies would be appropriate in our country?
 - I would like to see all women with a single CIN I smear or two atypical smears referred to a Gynaecologist. It is not at all unusual to find that a patient and her physician have been falsely reassured by a negative smear following up a positive smear, allowing her disease to progress undetected.
 - How do we reach women who have a high incidence of not being screened?
 - Should it be recommended that a cervical smear be included as part of every woman's antenatal screen? Since this is a time when most women see a health professional, it is a good opportunity to make sure they have a smear test and this is routine in some parts of the world. Two of the women I know with invasive cervical cancer had it diagnosed within two weeks of delivering their child.
 - Should follow-up after a LLETZ procedure be extended to one year, especially if histology does not demonstrate clear margins? Several studies have shown that residual disease may not be apparent before that time.
- 50 At several times during this inquiry, I have heard the phrase that something "should have been reported" to those in a position to act. This is much easier said than done. Issues of privacy and liability make it extremely difficult to report sub-standard clinical practice. Can this issue be constructively addressed? I would like to see an independent review of the notes of all the Gisborne women diagnosed with cervical cancer within the past three years, including a reread of all their smear tests.
- 51 I have seen far too much cervical cancer since I came back to New Zealand. I have also seen the extraordinary courage of women facing up to their diagnosis and treatment, and it has been impossible to remain unmoved. I mourn three beautiful, brave women I knew, who died in Gisborne of their disease. And I challenge all those who can play a part, the politicians, health administrators and clinicians of our country to bring about change so that this sad story is not retold.

Diane Van de Mark
Specialist Obstetrician and Gynaecologist

Dated: