

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

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

**STATEMENT OF EVIDENCE OF
RONALD WILLIAM JONES**

HEALTH FUNDING AUTHORITY

I, RONALD WILLIAM JONES, Registered Medical Practitioner, state:

1. I have the following qualifications: M.B., Ch.B, F.R.C.S., F.R.C.O.G., F.R.A.N.Z.C.O.G. I am a Past President of the New Zealand Society for Cervical Pathology and Colposcopy and currently a member of the Executive of the International Federation for Cervical Pathology and Colposcopy. I am a member of the consulting gynaecological staff at the National Women's Hospital and Clinical Reader in Gynaecological Oncology at the University of Auckland. I am a member of the HFA Advisory Group on the Gisborne Cervical Cytology Inquiry.
2. My principal responsibilities are to care for women with cervical smear and lower genital tract disorders and I will restrict my comments to the clinical aspects related to this inquiry.
3. Cervical cancer is a theoretically preventable disease. To date this Inquiry has focussed mainly on the mechanics of the failure of one facet of a screening programme and the resultant distress caused to a group of women.
4. The success of any cervical screening programme is not limited to the efficiency of a cytology screening programme alone, but is dependent on a high quality colposcopy service, histopathology service and national public health and epidemiological strategies. The outcome in relation to cervical cancer prevention relates to the weakest component of the triage process. If the benefits of this inquiry are to extend to all New Zealand women, the Inquiry must recognise that the alleged failures in Gisborne are only one part of a much broader prevention programme. The Inquiry must also understand that all facets of the screening programme are dependent on the interpretation (which is to some extent subjective) of the microscopic appearance of cells seen through a microscope (cytology, colposcopy and histopathology). Cervical cancer prevention strategies are by their very nature imperfect.

5. Clinical

In order to correctly address the Terms of Reference of this Inquiry, the clinical histories of the women known to present with cervical cancer during and subsequent to the years of the Inquiry need to be established. Cytology alone is of restricted value if there are deficiencies in the clinical assessment of these women. Clinical details relating to cases of cervical cancer have not been available for evaluation.

6. Colposcopy examination has been central to the assessment of those Gisborne women who have been found to have cytological abnormalities as a result of the smear re-reading process. Colposcopy involves the examination of the cervix with a microscope and this aims to identify the possible site, extent and severity of any potential lesion. Tiny tissue samples (biopsies) can be taken under colposcopic guidance for histological examination and diagnosis.
7. Colposcopy, like cytology, is a subjective procedure which requires considerable training and experience. I was Chairman of the 1998 Ministry of Health/Health Funding Authority Working Party (“Guidelines for the Management of Women with Abnormal Cervical Smears”) which introduced minimum standards for those practising colposcopy in New Zealand. Eight New Zealand gynaecologists considered to be experienced in the field have seen the majority of women requiring this examination as part of the review process.
8. Only interim evaluation of early data from the time of the colposcopy examinations is available. The numbers in many of the analyses are small and it would be unwise to draw firm conclusions.

(a) Table 1 - Adequacy of Colposcopy Examination

In approximately 14% (70/475) of cases, the colposcopist was unable to visualise the entire transformation zone – the region considered to be at risk of developing cervical cancer. While additional techniques, e.g. endocervical curettage, may assist in the colposcopic evaluation of the cervix, the above findings do point to some of the limitations of colposcopic examination.

Table 1 - Adequacy and reason for colposcopy

	Satisfactory	Unsatisfactory	Total
Diagnostic	405	70	475
Follow-up	2		2
TOTAL	475	70	477

(b) Table 2 - Comparison of Colposcopy Assessment with the Histology Results

- 75% (31/41) of lesions assessed colposcopically to be high grade or cancer were confirmed by biopsy.
- 26% (10/38) of lesions considered colposcopically to be low grade or normal, had a high grade histological lesion.

Table 2 - Comparison of Histology Taken at the Time of Colposcopy with the Findings of the Colposcopy Based on Visual Examination

Histology result on colposcopy	Colposcopy Grade (visual)					Total
	Cancer	CIN 2/3	CIN1/HPV	Normal	Not known	
Cancer	3					3
AIS /Glandular					1	1
CIN 2/3	1	27	8	2	24	62
CIN 1/HPV		11	46	16	45	118
Normal		2	15	8	16	41
Not taken	1	4	15	128	59	207
No result		3	16	19	7	45
Total	5	47	100	173	152	477

(d)

Table 3

- 72% (77/106) of re-read CIN 2/3 lesions had normal cytology at the time of the colposcopy examination.
- In 17% (18/106) the re-read high grade cytology was persistent high grade cytology at the time of the colposcopy examination.

Table 3 - Comparison of Cytology Taken at the Time of Colposcopy with the Re-read Results

Re-read result category	Cytology taken at time of colposcopy								
	High Grade	ASCUS H	Low grade	ASCUS	Normal	Unsatis	No result	Not taken	Total
Cancer					2				2
High Grade	18		4	7	77		12	28	146
ASCUS H	5	1	7	8	68	2	7	16	113
Low Grade	2		6	4	44		4	11	71
ASCUS	5		9	13	81		5	27	140
Normal	2			1	2				5
Total	32	1	26	33	274	2	28	82	477

(e)

Table 4

This shows only a 60% correlation between the colposcopy assessment of the high grade abnormalities with the cytology at the same time.

Table 4 -Comparison of Cytology Taken at the Time of Colposcopy with the Findings of the Colposcopy Based on Visual Examination

Cytology result on colposcopy	Colposcopy Grade (visual)					Total
	Cancer	CIN 2/3	CIN1/HPV	Normal	Not known	
Cancer						
High grade	2	10	3	5	13	33
Low Grade		4	6	4	12	26
ASCUS L		2	10	7	13	32
Normal		12	60	122	80	274

Not taken	3	16	12	26	25	82
Unsatisfactory			1	1		2
No result		3	8	8	9	28
Total	5	47	100	173	152	477

(f) **Table 5**

This shows a 90% (19/21) correlation between high grade cytology and the histology taken at the time of the colposcopy.

Table 5 - Comparison of the Cytology and Histology Results Taken at the Time of Colposcopy

Cytology taken at colposcopy	Histology taken at colposcopy							
	Cancer	AIS/ Glandular	CIN 2 / 3	CIN 1 / HPV	Normal	Not taken	No result	Total
Cancer								
High Grade	1		18	2		7	5	33
Low Grade			4	10	1	8	3	26
ASCUS		1		17	1	9	4	32
Normal			9	66	26	159	14	274
Unsatisfactory					1	1		2
No result			7	5	2	8	6	28
Not taken	2		24	18	10	15	13	82
Total	3	1	62	118	41	207	45	477

Comments

- (1) Colposcopy has limitations as an investigative technique particularly if the lesion is not visible or is small. The technique is subjective and depends not only on the experience of the observer, but the physiological state of the cervix at the time of the examination. For example, a high proportion of the women assessed in the colposcopy clinics in Gisborne were on Depo Provera, amenorrhoeic and had thick, opaque cervical mucus.
- (2) Variable cytology reporting standards between different laboratories.

- (3) Spontaneous regression of the epithelial abnormality in the 4-9 year interval between the original smear and the evaluation in 1999-2000. Ostor's paper highlights the wide divergence of reported rates of spontaneous progression and regression.
- (4) Cytology is a predictor and is not diagnostic of epithelial abnormalities of the cervix. Diagnosis can only be established with histopathology examination of representative tissue samples. Cytology/histopathology correlation has been reported at approximately 65% in New Zealand. (This was 75% in the Gisborne review (see above)). I believe the issues of false positive and false negative cervical cytology have been dealt with elsewhere in the inquiry.
- (5) On occasions, cervical smears can detect "precancerous" cells which have originated elsewhere in the genital tract. It should be noted that the cervical smear is more efficient in the detection of squamous, compared with glandular abnormalities of the cervix. (Approximately 20% of cervical cancers are glandular in origin).
- (6) The colposcopist may fail to recognise an abnormality (possibly because it is a very small lesion) or to site the biopsy correctly.
- (7) There may be a failure of the pathologist to recognise a "true" abnormality – which may relate to tissue sampling.

Histopathology is without question the "gold standard" of assessing tissue abnormalities. Nonetheless, it is a subjective process, requiring considerable training and experience. Both inter and intra observer variations in reporting cervical tissue pathology are well documented – particularly with low grade abnormalities. I am aware of at least one tissue specimen taken at colposcopy during the Gisborne review process which was assessed at one laboratory as being normal and in another reviewing laboratory as high grade.

9. I have presented the above data in order to demonstrate the inherent limitations of both colposcopy and histopathology, and the difficulties in reaching meaningful conclusions (let alone scientific evaluation) from this unfortunate incident. However, high quality cytology, colposcopy and histopathology can be very effective diagnostic procedures. At best, only broad generalisations can be made from the available results. Nonetheless, health authorities have a responsibility to ensure that the data from this investigation is properly evaluated in order to further our knowledge and benefit all New Zealand women.
10. For some years a number of us have promoted the importance of establishing a mandatory prospective audit (with appropriate legal protection for all parties) of cases of cervical cancer. (see Guidelines for the Management of the Abnormal Cervical Smear 1998). This would involve:
- (i) establishing whether women presenting with cervical cancer have previously had cervical smears according to the National Guidelines (i.e. whether there has been a failure of the NCSP)
 - (ii) whether there has been a failure in the process of interpreting the cervical smear (as is alleged to have occurred in this case)
 - (iii) whether there has been a failure to properly manage the known cytological abnormality (i.e. a failure of colposcopy, histopathology, surgery etc.).

If such a process had been in place, this inquiry would not be taking place. New Zealand has had two high profile cervical cancer disasters in 12 years. Improved management of smear abnormalities was the inevitable outcome of the Cervical Cancer Inquiry (Cartwright 1988). Improved quality control and audit procedures in cervical cytology are an inevitable outcome to the present inquiry. A legacy for which this inquiry would be remembered is a strong recommendation for the introduction of a system of mandatory prospective audit of all new

cases of cervical cancer. This will not be easy to achieve and some will resist the necessary legislative measures. Such unique legislation would not only improve New Zealand's cervical cancer prevention strategies, but (for once!) provide a positive international image in this field.

A retrospective audit of cases of cervical cancer in Gisborne (as suggested by Professor Skegg) will increase our knowledge of past systems failures, but a prospective audit has the advantage of allowing a more immediate response to current or perceived defects in the system.

- 11 Those of us involved in the clinical assessment of the 500 women with re-read cervical smear abnormalities have been impressed by their positive approach to this unfortunate event.

I would like to take this opportunity to thank three Gisborne women – Goldie Proffit, Shona Teaho and Missie Winiata – who have done so much to help the women involved and to facilitate the process of clinical evaluation.

12. I have already pointed out that all of the triage procedures employed in cervical cancer prevention are imperfect. I would like to finish by quoting from a paper by the doyen of cervical pathology, Leopold Koss, written in 1989:

“Although the cancer detection system (cytology) has been shown to be effective in reducing the rate of morbidity and mortality from cervical cancer in appropriately screened populations, there is no evidence that the Papanicolaou test has succeeded anywhere in the complete eradication of this theoretically preventable disease. It is important to inform the public about the potential failures of the system and the reasons for them”.

R W JONES

25 June 2000