

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

**AND**

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

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**SUBMISSIONS OF COUNSEL ASSISTING  
PART III: TERM OF REFERENCE 8  
20 SEPTEMBER 2000**

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**SUBMISSIONS OF COUNSEL ASSISTING**  
**PART III: TERM OF REFERENCE 8**

**Term of Reference 8:** *To make recommendations, consistent with section 4(a) of the Health and Disability Act 1993, as to any future action the Government or its agencies should consider taking.*

493. It is a sad fact that practically all of the most obvious recommendations that might be suggested have either already been made or have been generally recognised for years as being important features of cervical screening programmes. We refer, for example to:

- ?? the WHO Guidelines - see para 50 above; of note are the need for a central office or individual to have responsibility to plan, co-ordinate and evaluate the programme, quality control of smear takers and readers, agreed set of objectives against which the success of the programme can be assessed;
- ?? recommendations arising out of a meeting between the Cancer Society and the then Department of Health in April 1986 (**GRB/MOH/8/14**) – see para 51 above; note recommendations about training of cytologists, quality control, evaluation within three years;
- ?? the Cartwright report – see para 52 above and the reference to the main recommendations (**GRB/MOH/15**) including establishment of an expert group to advise on and implement the programme, revision of medical disciplinary procedures to ensure effective action against incompetent practitioners, requirement for training of cytologists and pathologists, centrally located national co-ordinator who could evaluate the NCSP and be answerable to the expert group, high priority on quality control and the surveillance of the programme;

?? the working papers from the Porirua Workshop in December 1988 – see para 54 above and **GRB/MOH/13/58** including executive group with decision making power to control the NCSP, accountability, appropriate safeguards such as quality control throughout the screening pathway, ongoing evaluation, national monitoring group to oversee quality control, clear guidelines in relation to access, quality control, training;

?? the work of the Ministerial Review Committee established in September 1989 – see para 58 above including the importance of not focussing on any particular aspect of the programme [eg, enrolment] but developing all aspects simultaneously, need for histology/cytology correlation, quality control, minimum standards for laboratories, performance indicators.

494. There are of course other examples. The point is that when it comes to the screening programme there seems to be a tendency for sensible (even obvious) recommendations to be ignored or to have their implementation delayed for unreasonable periods of time. At a very fundamental level, the screening programme seems never to have been a good ‘fit’ with a commercial model of health delivery, or with the desire of various administrations for decentralisation, or the initiatives to move the MOH towards becoming a policy (rather than operational) Ministry.

495. It is to be hoped that the recommendations of this Committee will not suffer the same fate as those that have gone before. In that respect the evidence given by the Director General of Health provides some reassurance. It is also the case that the recommendations now made will carry with them the weight of the knowledge that, had some of these things been done earlier, then lives would not have been lost.

496. Perhaps the most fundamental change that should take place after this Inquiry is that the NCSP should come to rest in an environment in which it is not subject to party political or departmental pressures. It should be done in such a way that those who are responsible for running the programme are able to do so (and can

discharge the responsibilities that are entailed) in a structure that reflects the fact that the programme is an essentially operational activity into which politics should not intrude.

497. We doubt that it would be helpful or appropriate to suggest recommendations in any purportedly final form. Instead we set out the various topics in respect of which we submit recommendations might be considered by the Committee.

### **Structural Aspects**

498. The responsibility for managing and seeing to the monitoring and evaluation of all aspects of the programme should be put into the hands of an executive committee. The committee should have the power to secure such changes as may be required from time to time, and to enforce compliance with standards as required.

499. The Committee should be made up of an appropriate mix of people with different skill sets, including skills in epidemiology, general medical practice, consumer representation, statistics, computing, financial management and so on. It should include appropriate Maori representation. It should not, however, be a large committee. Its principal role would be to act in a manner not dissimilar to the role of a Board of Directors in a private company.

500. Members of the Committee should be paid at an appropriate level for their work. It must be recognised that work on the Committee should be done on a proper professional basis and should not be left to depend for its outcomes on the support of volunteers (this is not intended as criticism of the work of volunteers in the past, but reflects the reality that there is great value to the programme in the work, and that it carries considerable responsibility with it).

501. There should be someone appointed in effect as a 'chief executive' for the programme. That might well be the person within the HFA presently responsible for the management of the programme. It should be someone who has medical

training and who could be expected to understand and deal with the very many (and often sophisticated) issues that will arise.

502. The Committee should report direct to the Minister of Health.
503. It should have and be expected to manage its own budget. It hardly needs be said that the budget should be large enough to ensure that all of the necessary activities of the programme – including for example monitoring and regular evaluation – can be attended to. It may well be that contracting for the provision of all services to the programme should be done through the Committee via its chief executive.
504. The ‘chief executive’ should have a brief to obtain appropriate external (ie., outside the Committee) advice as reasonably required. It might well be useful to establish a panel of advisers to assist from time to time. There needs to be an understanding of the need to balance requirements for external advice against the need to develop and maintain an adequate level of in – house expertise.
505. It is to be hoped that such a committee structure would provide an environment in which those who work for the programme are encouraged to stay in employment with the programme and thereby assist in the development and retention of ‘institutional memory’ within the programme.
506. In submissions for the Women Affected Mr. Corkill has drawn attention to the possibility of a wider cancer control agency. Evidence in support of such a suggestion was given by Professor Skegg (**DCS/CA/8; A 901 and A 979 – 982**), Dr Cox (**para 253-7; B 2551 – 2556**), Ms. Coney (**B 2744**) and Ms Marshall (**para 130 – 134**); on the other hand note some of the comments by Dr. Peters at **B 251/11** and following).
507. It may be that such an agency should be established, and that the structure for the cervical screening programme could then sensibly be made part of that agency. One danger in that, however, is that the restructuring of the programme may then be delayed until a wider Cancer Control strategy is developed to the

point of implementation. In our submission structural changes to the Screening Programme are required as a matter of urgency. Certainly there could be consideration in due course to bringing the cervical screening programme into a co-ordinated cancer control strategy, but that must not be allowed to delay the changes that are required for more effective delivery of the programme now – particularly given current restructuring of health sector which sees the HFA re-integrated with the MOH.

### **Monitoring/ Evaluation**

508. The standards and performance indicators suggested by Dr. Peters should be implemented forthwith. By this we mean to say that they should be implemented in a way in which they are capable of being enforced if that becomes necessary (it may be that this has been achieved since the hearings in July).

509. Within those standards, there should be a review of the proposed indicator for reporting of High Grade abnormalities (presently 0.5%).

510. The issue of a minimum (and maximum) number of smears that should be read by laboratories each year also needs to be resolved and implemented urgently. It is probably not appropriate for the Committee to specify a minimum/maximum number, but the evidence shows that the matter needs to be brought to finality soon. It may be that there is an answer to the question about the need to enable hospital laboratories to read smears in the model used in Australia where laboratories reading small numbers of smears obtain slides from other laboratories in such a way that the laboratories see an appropriate number of abnormalities to 'calibrate the eye'. But the principal concern is to set limits for community laboratories that read the majority of smears. Any residual issue about hospital laboratories must not be allowed to delay imposition of the important change required.

511. Meaningful statistical information should be generated on a regular basis. The European Guidelines provide a model that was the subject of discussion during the hearing. Certainly there needs to be a review of the types of information that

laboratories are required to keep and report. Attention must be paid not only to laboratory reporting rates but also to trends in the incidence of the disease, assessed by regions that are meaningful, ie that allow some correlation between reporting profiles of laboratories and the incidence of cancer. It is proper to recognise that this may be complicated by slides which are read outside the region in which the smear is taken. However it should be possible to devise a recording system to identify the region where smears are taken and to be able to identify reporting rates for regions even across different laboratories (indeed a comparison of reporting rates by different laboratories for smears taken in a given area might – if the numbers are large enough – in itself be a useful quality assurance tool. In any event the limitations of referring to laboratory reporting rates must be recognised.

512. The Cancer Register must be able to provide up to date incidence data. The evidence shows that before the enactment of the Cancer Registry Act 1993 the register was not robust. Even after 1993 there are reasons for concern that the data is not always accurate (see, eg the 7 September 2000 report by Professor Skegg after seeing the information that was made available to the Committee from the Cancer Register and the Screening register). The Register should be funded in a way that enables it to provide timely and accurate data that is meaningful.
513. A national audit/evaluation of the programme needs to be completed as a matter of urgency. Probably this will involve the Cox/ Richardson study or something very similar to that. However it proceeds, it should include a slide review - perhaps on the basis of all cases in which women on the programme with a diagnosis of cervical cancer have had one or more smears reported as normal within a period (say 5 years) of the cancer diagnosis. The details need to be resolved with the input of appropriate expertise such as that of an epidemiologist/statistician.
514. The entirety of the Cox/ Richardson evaluation proposal needs to be completed; it should not be limited to the three items that have thus far been contracted for.

515. There should be a regular programme of evaluation.
516. There should also be a system for automatic clinical review whenever there is a diagnosis of cervical cancer. This should be carried out routinely as an audit – type activity by those responsible for quality assurance in the Programme (as to issues of consent, see para **524** and **525** below).

### **Training and Qualifications**

517. The importance of properly trained cytopathologists is clear. In the end, all the best protocols and practices are of little comfort if the people who look at the slides are not adequately trained to do the work. This raises the question of whether the training course that was discontinued should be resurrected in some form. Certainly there should be an urgent review of the qualification requirements for those who are employed as cytoscreeners, and consideration of a system of registration of qualified technical assistants.
518. In addition the Inquiry has demonstrated that pathologists are not necessarily qualified by their general pathology training to screen cervical smears. Anyone who wishes to embark on a career in cervical screening should have specialist training in respect of cervical screening. That should apply whether the person concerned is already a trained pathologist or not.
519. The position in respect of the supervision of cytoscreeners is the same. Any laboratory that is to be engaged by the programme to read smears must be supervised by a pathologist or pathologists who have taken time to train in the particular discipline of cytopathology. Courses are available: see the evidence of .
520. We respectfully agree with the submissions on this subject made at paragraphs **388** to **391** of Mr. Corkill's submissions which suggest reconsideration in particular of the Medical Laboratories Technologists Regulations 1989 (SR 1989/282).

## Legal Issues

521. The status of legal issues - particularly those that involve section 74 A of the Health Act 1956 – may change. At the time of writing there is a very real possibility that matters identified in the Crown Law Office opinion dated 23 August 2000 will be submitted to the High Court for a conclusive opinion. However arrived at, we submit that in the end result (and whether by court decision or legislative change) matters need to be resolved in a manner that allows:

?? Linking of information on the cancer register with that which is on the screening register for the purpose of enabling those responsible for the programme to regularly correlate the data sets for the purposes of monitoring or evaluation of the programme;

?? Access to the information by persons such as Professor Skegg and Dr. Cox for the purposes of appropriate research (in this respect one approach that might be considered is to draw a ‘purpose’ provision such as section 4(2) of the Cancer Registry Act into the section).

522. We submit that, despite the view taken by the ethics committees, it is clear that the information on the Cancer Register is available to anyone who meets the purpose requirement in section 4(2). We doubt the basis on which the ethics committee asserted that privacy concerns prevent release of data to researchers such as Drs. Cox and Richardson for an evaluative audit of the programme. Nevertheless the position should be clear beyond any argument, and for that reason the Committee may wish to include recommendations to ensure that in future the issue does not delay the essential work of evaluating the programme.

523. Beyond that there is a more controversial issue as to whether access should be allowed to personal clinical medical records of women who suffer a diagnosis of cervical cancer despite being on the programme. Of course if in any given case the patient can be found and then consents to the use of data the obstacles are

removed. But in cases where it is impractical to find the woman concerned, or when consent is refused, then there is an issue as to whether the public interest in the effectiveness of the programme justifies access to the information in any event. One possible basis for such a provision should be that the fact of participation in the programme carries with it an implied consent. This was discussed with a number of the witnesses, none of whom expressed unequivocal support for the idea.

524. As suggested at para 475 above, we incline to the view that the effectiveness of the programme is sufficiently important to justify access even without consent to relevant personal medical records when that is necessary. We have emphasised that access should only be allowed on terms of confidentiality, and anonymity in the way the data is reported by the auditors.

525. It should also be emphasised that such access should only be allowed when it is necessary, ie. when the effectiveness of the programme would or might reasonably be thought to be jeopardised if the information is not available for the audit.

526. In this regard it should be recognised that the focus on the need for such access without consent arose out of the proposed Skegg study of cases of cervical cancer in the Tairāwhiti region. The circumstances of that were unusual, because the study was proposed to provide information about under-reporting for the Inquiry and as a result of that there were time constraints. In addition the nature of the exercise was such as to put a premium on the importance of having data from all cases. These factors may not be present in an audit for the programme of a greater number of cases, ie. across all regions. It may not be necessary once look back exercises are a regular and accepted part of the programme (so that, for example, consent from women is sought as a routine at, say, the time of diagnosis and sufficient consents are thus obtained to ensure that the outcome of the audit meets the objective of the audit). But if it should occur that a sufficient number of consents is not available for whatever reason (eg., women unable to be traced, deceased, refusal of consent) to achieve that then in the end the need to audit the

programme is such that it must be possible to do it. If that involves legislation to achieve that then such legislation should in our submission be recommended.

### **The Kaitiaki Regulations**

527. As submitted above (paras **485 – 460**), we consider that it would not be appropriate to recommend fundamental changes to the Kaitiaki Regulations. We have, however, suggested that the Committee might recommend that a process be put in place that would allow Maori women to review the effectiveness of the regulations in light of the experience of the Kaitiaki group to date. One possibility that might be considered by Maori women is that there be an exception to the Regulations, such that where research is being done under the auspices of the programme and for the benefit of the programme ( for example, the sort of evaluative research proposed in the Cox/ Richardson national study, or an audit of the type suggested by Professor Skegg, or even simply the compilation of statistical reports for the programme) then Kaitiaki Group approval would not be necessary.

### **Ethics Committees**

528. The experience of ethics committees in respect of the once proposed Tairawhiti audit (Professor Skegg) and the proposed national evaluation (Drs. Cox and Richardson) has highlighted the need for a review of the practice and composition of ethics committees – see paras **488** and **489 above**.

### **Miscellaneous matters**

529. There should be a protocol developed (perhaps as part of the Peters standards, or under the auspices of the Cervical Screening Committee we have suggested at para 498 above) to oblige a laboratory that becomes responsible for the slides of another laboratory to take steps to collect them and make them available in such a way that they can be referred to in any look back exercise that may be required.

530. We also agree with the submissions by Mr. Corkill (paras **336 – 339**) to the effect that those responsible for the programme should develop guidelines for managing incidents akin to the UK guidelines (EM/CA/2).
531. One matter arising out of the evidence concerns the medical disciplinary procedures even as now available under the 1995 Medical Practitioners Act. Consideration might be given to the addition of an express requirement in the provisions governing medical disciplinary proceedings which would oblige the body seized of the facts of any given case specifically to consider whether there are any grounds for concern that there may be a public health risk involved (see comment at B 1011 - 1013 by Medical Council/ Jones).
532. The Committee might consider recommending that a requirement for the ACC to report findings of medical error to the disciplinary body of the Medical Council be introduced.
533. There is also the position of the ACL cytology review panel to consider. If it should happen that the outcome of a slide review conducted by the Panel raises an issue about the competence of the laboratory in question (perhaps if there were several very clearly misread slides) then it might be suggested that the panel should also have an obligation to report to the disciplinary body of the Medical Council. On the other hand knowledge that such a report might occur could well dissuade laboratories from participating in what is, in the end, a voluntary procedure.

**Conclusion**

534. The ethical responsibilities involved in running a screening programme are such that the shortcomings that have been identified in this Inquiry must be rectified. If there is to be a screening programme at all, then it must be managed to be as effective as it can be. Anything less represents a failure to deliver to New Zealand women the benefits that are offered when they are encouraged to take part.

535. There must be no repeat of circumstances that have lead to this Inquiry.

Dated at Gisborne this 20<sup>th</sup> day of September 2000

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