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EDITORIALS

And now the failure of cervical screening

Everyone wants an excellent health service that is accessible and affordable. Theories on how to achieve this vary from universal insurance to payment by individuals in a free market. Traditionally, New Zealand lay in the middle of the spectrum with elements of both public and private provision and public and private funding. Over the last 10-15 years ideological swings by government have altered systems of funding and governance but on each occasion central control and the power of management has increased. Failures have been attributed, by proponents of the changes, to incomplete implementation or insufficient time. In the absence of careful, prospective collection of data, such contentions are not open to proof. We know that our current health rating by the World Health Organisation is disturbing.[1] Our performance is rated 80th in the world on level of health and 41st on overall health system performance.[1] Three recent 'studies', all retrospective, have provided some evidence about why this may have happened. These are the reports by the Health and Disability Commissioner into Christchurch Hospital[2] and Gisborne Hospital,[3] and that of the Committee of Inquiry into Cervical Screening at Gisborne.[4] Some general principles and underlying factors can be identified from them.

In Christchurch, the Commissioner found that "the Ministry of Health did not adequately meet its responsibilities ... it did not develop standards for effective monitoring," that Treasury and CCMAU set a business plan in which the "financial risks were high and the targets almost impossible."[2] This was known by the Ministers of Health and Crown Health Enterprises. Canterbury Health "focused predominantly on issues of efficiency, funding and financial performance. It is not evident ... that the issue of the adequacy of patient care was appropriately considered." "The lack of clinical involvement in high level policy planning and decision making was a major cause of the breakdown."[2]

In Gisborne "the key driver for the change was the financial imperative for Taraiwhiti Health Care to live within its budget." "Consensus processes ... did not extend into the organisation." "There was a level of consultation, but ... probably not a lot of cognisance was taken of concerns, because of the key driver to break even."[3] The Nursing staff in both Gisborne and Christchurch lost effective communication with management because of the loss of their independent professional organisations.

The saga of the Cervical Screening scandal is long and tortuous. Cervical screening received impetus from the inquiry at National Women's Hospital. That inquiry increased awareness of cervical cancer as a public health problem and it was decided in 1988 to set up a National Cervical Screening Programme. This was a high priority for then Minister of Health, Helen Clark. The National Advisory Committee on Cancer Treatment Services advised the Minister that given the current state of cytopathology and colposcopy facilities, implementation should be deferred. The Minister wished to proceed and meetings of the National Advisory Committee lapsed. Now, some 13 years later, the Gisborne committee of inquiry has found that: "There appears to have been a consistent failure to follow the advice of experts."[4]

"The Programme's design appears to have been influenced by lay persons, who seem not to have recognised that a screening programme has certain essential requirements."[4] "The expert advice at the time the Programme was being established was that all parts of a screening programme needed to be in place from the outset. This advice was not followed." On 25 August 1989, Helen Clark, Minister of Health sent a memorandum to the Director General of Health which stated: "There is widespread concern that there has been too much emphasis placed on the development of the national register and the computing system necessary to operate a register and recall system, at the expense of action on developing smear-taking programmes. I share this concern. My objective is to use the money available by Government to raise the awareness of the necessity of smears ... The importance of the register and ensuring all women are enrolled should probably be secondary to that ... I am not committed to launching a national register by the end of this year. I am committed to ensuring that the proportion of women having smears increases over the year."[4] This "imposed time pressures on officials which resulted in unrealistic deadlines and caused a shift in focus away from a balanced screening programme."[4]

The report goes on to say: "The Programme ... was originally shaped to fit and later forced to accommodate the prevailing ideologies on health delivery. This has created systemic problems in the Programme and has been at the expense of its effectiveness." The "failure to design and deliver a soundly based cervical screening programme" compounded by "no internal or external quality control at Gisborne Laboratories: ... "permitted Dr Bottrill to practise as he did."[4] The ethical issues involved are discussed in a Viewpoint article in this issue of the Journal.[5] Today we hear calls for the setting up of an independent cancer management authority. Clearly, national co-ordination and planning is required. It is a pity that the advice of the National Advisory Committee on Cancer Treatment Services was not heeded. It would have avoided a great deal of anguish.

The common factors uncovered by the inquiries into Gisborne and Christchurch Hospitals and cervical screening include breakdown in relationships between management and staff, authoritarian management, exclusion of qualified staff and their ideas from proper consideration in planning, and interference from the financial bureaucracy and politicians into detailed planning. Deaths occurred as a result of these factors. Although the hospital service is underfunded and an increased budget would be helpful, the issues of management, its relationships with staff, and planning are more important.

Who should be accountable? The Minister of Health who imposed a system of general management and insisted on setting up a cervical screening programme against health professional advice? Succeeding Ministers Simon Upton, Paul East, Bill Birch, Jenny Shipley and Bill English who accepted unrealistic budgets imposed on Health Boards and insisted on the acquiescence of Boards and health professionals? Medical advisors to these successive Health Ministers? The Director General of Health and her advisors who were willing to accept the strictures placed on them by Treasury and CCMAU? The Boards and Management of Crown Health Enterprises who restructured to meet unrealistic financial targets and were prepared to have their health professionals work with inadequate support? Those doctors who supported autocratic management in their positions on Health Boards or as medical advisors or clinical directors? The health professionals who provided inadequate services through the lack of adequate support or their own lack of knowledge? To be fair, many are at fault. Yet we have witnessed a desire to put the blame on one or two health professionals providing the service. In the cervical cancer inquiry, it seems that no one, other than the pathologist, really accepted responsibility.

The problems in the Health Service in New Zealand are endemic and serious. The relationships between Boards, Management and health professional staff are unsatisfactory in many hospitals. In a small country facing competitive economic pressures, we must make the best and most effective use of the resources at our disposal. To achieve this, we need strong collegial activity within health professional groups, between health professionals and management, and effective co-ordination of activities at a national level. This has not been the case for so long now that our Health Service puts people at unnecessary risk.

Many health professionals perceive that advice to government on matters of health has been ceded to those who support political initiatives-whatever they might be. There is little confidence in medical advice to Health Ministers or in the Ministry of Health who have become apologists for changing political theories. Planning has been dominated by short-term financial considerations. Instead of beginning with an assessment of health needs, followed by a plan to meet these within financial limitations, financial decisions came first. This has had serious consequences for the provision of effective services, for the morale of health professional staff and often also for the costs involved in the longer term. Removed from any ability to assist planning effectively, most medical staff became demoralised and retreated to concentrate on their individual clinical activities. This has had a profoundly damaging effect on the hospital as a community. Continued authoritarian administration, proliferation of protocols and insistence on petty documentation will not solve the issue.

We believe that clinical services will only be effectively planned when health professionals again participate. Sweeping central changes are high risk activities because medicine is complex and the needs of individuals vary so much. The direct interference by Treasury and CCMAU in health planning and delivery has been associated with many of the serious problems documented in the recent reports. The Ministry of Health has been found to have failed by each of the three investigations. Government should now consider where it might best seek advice in health matters. In hospitals, line management should be balanced by input from democratic health professional groups of doctors, nurses and allied health professionals. We urgently need to return to the professionalism that existed in health and education before the ‘reforms’ of the last 10-15 years and to remove Health from detailed control by Treasury and CCMAU, and domination by general management.

The Editors

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4. Duffy AP, Barrett DK, Duggan MA. Report of the ministerial inquiry into the under-reporting of cervical smear abnormalities in the Gisborne Region. Wellington: Ministry of Health; 2001 April.
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The Gisborne Inquiry - what can we learn?

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What can the Gisborne Inquiry teach us about population-based screening in New Zealand? The most important lesson is recognition of the ethical obligations that population-based screening entails.

Population-based screening, or mass screening, is a public health intervention. Public health practice and clinical practice share common ethical concerns, such as respect for autonomy, beneficence (doing good), non-maleficence (avoiding harm), and justice.[1] Because of their focus on the health of entire groups or populations, public health interventions must consider utility, or how to achieve the greatest good for the greatest number. Population-based screening raises particular ethical issues that make it unique even among public health interventions however:

> "*We believe that there is an ethical difference between everyday medical practice and screening. If a patient asks a medical practitioner for help, the doctor does the best he [or she] can. He [or she] is not responsible for defects in medical knowledge. If, however, the practitioner initiates screening procedures he [or she] is in a very different situation. He [or she] should, in our view, have conclusive evidence that screening can alter the natural history of the disease in a significant proportion of those screened*".[2]

Those who seek advice and help from the health system, usually do so because they are unwell. Aside from the usual commitment of health professionals to do their best for an individual patient, no prediction of a good outcome can be given in advance. In contrast, those who take part in population-based screening programmes are well, and participate because they have been invited to, on the understanding that the programme can offer a benefit. Clearly, once this invitation is issued, there is an ethical obligation for those who establish and maintain the programme to ensure that it can deliver the benefit claimed. This benefit cannot be assumed, as a poorly run programme may not deliver the expected benefit. Thus, it is unethical to offer screening if the screening programme is not appropriately organised and monitored.

By the time implementation of the New Zealand national cervical screening programme was announced in 1988, organised cervical screening programmes had existed in some countries for 20 years.[3] By 1988 it had been recognised and reported that properly organised screening programmes have the greatest impact on cervical cancer incidence and mortality.[4-8] Criteria for successful cervical screening programmes had been published in 1985 (Table 1). In 1988 the World Health Organisation (WHO) published technical guidelines for cytological screening in the control of cervical cancer which emphasised that screening should be seen as a public health intervention, and for it to be effective, programmes should be well organised.[9] The WHO guidelines included specifications for the collection, processing, and interpretation of smears, along with recommendations for diagnosis, treatment and follow-up, and the associated workforce requirements. Common faults in screening programmes were identified once again, and included unclear goals, lack of adequate long-term commitment and financial support, inadequate long-term integrated planning and organisation, and lack of clear assignment of responsibility.[9]

Table 1. The essential elements for a successful screening programme.[19]

1. The target population has been identified.
2. The individual women are identifiable.
3. Measures are available to guarantee high coverage and attendance, such as a personal letter of invitation.
4. There are adequate facilities for taking the smears and adequate laboratory facilities to examine them.
5. There is an organised quality control programme on taking of the smears and on interpreting them.
6. Adequate facilities must exist for diagnosis and for appropriate treatment of confirmed neoplastic lesions.
7. There is a carefully designed and agreed referral system, an agreed link between the woman, the laboratory and the clinical facility for diagnosis of an abnormal screening test, for management of any abnormalities found and for providing information about normal screening tests.
8. Evaluation and monitoring of the total programme is organised in terms of incidence and mortality rates among those attending, among those not attending, at the level of the total target population. Quality control of the epidemiological data should be established.

Despite the wealth of information available about the features required for successful cervical screening, the programme established in New Zealand did not meet published criteria. This was recognised at the time. In October 1989 in a leading article in this Journal, **How not to organise a cervical screening programme,** Professor David Skegg warned that “What we cannot afford is an expensive charade that ignores the lessons learned in other countries.”[10] Shortly after this the British cervical screening programme came under scrutiny because, despite the introduction of screening in the 1960s, there had not been an appreciable effect on cervical cancer incidence and mortality, in contrast to countries with well organised screening programmes.[11,12] The lack of benefit was attributed to deficiencies in the organisation of the British programme, and it was recommended that the cervical screening programme adopt clear guidelines supported by quantified standards and appropriate evaluation.[12]

What were the ethical implications of inviting New Zealand women to participate in a programme that did not meet the criteria for a successful cervical screening programme? The principle of non-maleficence or avoiding harm, is relevant. Unfortunately, all population-based screening programmes have the potential to do harm, as well as to provide benefit. Screening tests are not perfect. A screening test is used to divide people into two groups; those likely to have the disease being screened for (a positive screening result), and those unlikely to have the disease (negative screening result). Further investigations are required for those with positive screening tests, to find out whether they have the disease or not. Some people with positive tests are then found not to have disease (false positive). Sometimes people with negative tests may actually have the disease (false negative).

Although women with true positive results can benefit from the screening programme, the women with false positive or false negative tests may be harmed. Those with false positive smears experience anxiety and sometimes further investigations, and those with false negative smears may be falsely reassured. The problem, and relevance of non-maleficence, is that only a small proportion of the thousands of women who take part in screening will actually benefit from screening (because most women screened do not have the disease). But any harm associated with screening has the potential to affect a larger number of women.

Screening tests such as cervical cytology and mammography are difficult to interpret. It is often difficult to identify abnormalities, and if the threshold for calling a test positive is lowered in an effort to miss fewer abnormalities, this is often at the expense of many more women receiving false positive results. Although it is impossible to completely avoid false positive and negative tests, given the subjective nature of interpreting these screening tests and the possibility of human error, appropriate training and quality control can minimise the number of false positive and negative tests.[9,13,14]

Population-based cervical screening is more than just a screening test though. For the programme to be successful, every aspect of the programme, from identification and invitation of eligible women, through taking smears, preparing cytology slides, interpreting the slides, reporting the results, referral for assessment and treatment where required, to recall for re-screening must be performed to the highest standard. The best way to ensure that a screening programme is beneficial and minimise the risks of harm from screening is to ensure that the programme is properly organised and appropriately monitored.[3-14]

One of the accepted ways to monitor the programme is to examine the screening histories of women who have developed invasive cervical cancer. It may then be possible to identify deficiencies in the screening programme. By remedying these deficiencies, the programme can be improved, and the risk of subsequent harm to women taking part can be reduced. In countries where this type of monitoring has been undertaken, the largest category of women to be diagnosed with invasive or fatal cervical cancer is those who have never been screened. The next largest category is women whose abnormal smears were not adequately followed up, then women with a long interval between smears, and finally women with false negative smears.[15] As a result of such monitoring of screening programmes in other countries, efforts have been directed to improving identification and invitation processes, creating fail-safe follow-up and recall systems, and implementing quality control in laboratories.

To monitor the cervical screening programme properly, it is important to review the screening histories of all women who developed invasive cervical cancer. In order to respect the autonomy of these women, it may seem imperative to seek their informed consent to review their medical records. It may appear unethical not to seek informed consent from all the women, however requiring their informed consent may not be in the best interests of the thousands of other women participating in the cervical screening programme. There are many reasons that informed consent might be unobtainable. It may not be possible to trace some women, others might not reply to letters or telephone calls, and some may have decided not to be screened (or declined follow-up when it was offered) and may fear that they will be 'blamed' for their subsequent illness. If the screening histories of these women are not included, only a partial understanding of the reasons contributing to the development of invasive cervical cancer in the population will be possible. The group of women from whom it is possible to obtain informed consent may not be representative of the group. Thus the review of screening histories could be biased, and the relative importance of deficiencies in the screening programme may be obscured. It should be emphasised that a review of screening histories does not imply any loss of confidentiality. Such reviews are carried out by health professionals with due regard to confidentiality, and individual women are not identified in any reports arising from the audit.

In New Zealand, concerns on the part of ethics committees, and the interpretation of privacy legislation by the Ministry of Health prevented a national audit of this type in relation to the national cervical screening programme. Similarly, considerations of privacy mean that there is no record of women who decline an invitation to participate in the national breast screening programme, BreastScreen Aotearoa. Where participation rates in BreastScreen Aotearoa are lower than expected it will be impossible to determine whether this is because women have declined to take part, or because the programme has failed to identify and invite eligible women. The latter possibility has ethical implications, not only with respect to monitoring the programme, but also in relation to equity of access. Reports from the BreastScreen Aotearoa Independent Monitoring Group have already shown lower participation rates among Maori and Pacific women.[16] Thus, one of the most important criteria for population-based screening has not been met, despite several letters to the previous and present Ministers of Health.

In must be recognised that in order to protect and promote the health of those who participate, screening programmes will have an impact on individual autonomy. In this respect, screening is similar to other public health practices that aim to protect and promote the health of populations. For example, in communicable disease control, it is accepted that details about people with infectious diseases are notified to the Medical Officer of Health, in order to protect the population from epidemics. It is even accepted that an individual's autonomy can be restricted to the extent that the person's liberty is curtailed (for instance an HIV positive individual who is unable or unwilling to practice safe sex, or a patient with tuberculosis who refuses medication) in order to protect the wider population.

In New Zealand, there is considerable inconsistency in the requirement (or otherwise) for consent to disclose information. For example, information about individuals is transferred between the Inland Revenue Department and Work and Income New Zealand, without consent, in order to protect the New Zealand taxpayer from misuse of public funds. Information held on owners of registered motor vehicles can be accessed by the police, without consent for disclosure, in order to maintain law and order. Interestingly, private individuals may also access information on vehicle ownership, without the knowledge or consent of the owner of the vehicle. Information held by credit agencies about individuals is also routinely disclosed without their consent, in order to protect commercial interests. In none of these examples are the stakes necessarily as great as the potential for harm resulting from a poorly monitored screening programme, but disclosure of information without consent is accepted.

Disclosure of medical information without consent also occurs already in New Zealand. Hospitals are allowed to review patients' medical records without obtaining informed consent, if this is for the purpose of audit.

Normally, ethics committee approval is not required for the use of health information for monitoring or internal audit undertaken by staff involved in the institution or service.[17]

Population-based screening programmes must be audited in order to protect those who participate. These programmes should not be undertaken unless there is acceptance of the ethical obligation to monitor them appropriately. Perhaps this is a choice to be made; if we wish to have population-based screening, we accept the ethical obligation to monitor screening properly, including appropriate disclosure of information, or if considerations of privacy are paramount, we accept that this precludes the establishment of screening programmes in New Zealand.

Finally, the report of the ministerial inquiry states that recommending compensation for the women affected by the unacceptable level of under-reporting at Gisborne "would mean that the women affected were treated differently from other persons who have suffered a personal injury either by accident or by medical misadventure ..." and that "It is difficult to see any reason why in principle the women affected by the unacceptable level of under-reporting at Gisborne should be treated differently ...".[18] This is difficult to understand; these women are in a different situation already, since in a population-based screening programme the initial contact is made by the health system, not the women, on the understanding that screening is beneficial. These women were invited to participate in a screening programme that did not meet internationally accepted criteria for success. But only programmes that meet accepted standards can be expected to deliver the anticipated benefit. No amount of money can restore the health of these women or their trust, but compensation is important because it is a public acknowledgement that a wrong has been done. We have seen that there is a price to pay for screening programmes that do not meet internationally accepted criteria for success. Compensation would ensure that the women involved do not pay this price alone.

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