Law, Ethics and Epidemiology: The Case of the Cervical Screening Audit

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Abstract

This paper provides a legal and ethical analysis of some controversial aspects of a recent proposal for an independent audit of New Zealand's National Cervical Screening Programme. The analysis reveals the difficulties likely to arise between investigators and ethics committees when the interests served by important public health research compete with the rigorous protection of patients' privacy.

New Zealand's National Cervical Screening Programme (NCSP) was established in the early 1990s, on the recommendation of Judge Cartwright, following the Inquiry into events at National Women's Hospital. An unfortunate aspect of the NCSP has been the lack of a formal evaluation of the screening process and its outcomes. Despite repeated calls for an evaluation of the programme, it was not until May 1999 that the Ministry of Health (MoH) entered a contract for its evaluation with epidemiologists at the University of Otago.

The proposed evaluation included an audit of the screening histories and management of those women who had subsequently been diagnosed with invasive cervical cancer. This would have involved the researchers obtaining access to the names of women held on the national Cancer Registry (CR) without their prior consent, and the matching of those names with data from the National Cervical Screening Register (NCSR), followed by an approach, after consultation with their medical advisers, to the women concerned. A controversy soon emerged over the ethics and the legality of some aspects of the audit protocol; and the ethics committees to which the protocol was submitted recommended significant changes to the proposed access and consent procedures.

This article will use this example to investigate the relationship between public registers, epidemiological researchers, ethics committees and patients. Two of the central issues considered are when, if ever, an individual's interest in their privacy must yield to the public good, and the question of the processes which should be followed when direct access by a researcher to a patient's identifying health information is proposed.

Epidemiological and Public Health Research

Epidemiology is the study of the distribution and determinants of health-related states or events in specified populations, and its application to the control of health problems (Last, 1998, p.42). It involves investigation into the surveillance of disease, causes of disease and increased health risk, and investigations into the efficacy or safety of preventive, diagnostic or therapeutic regimes.

Epidemiology has greatly improved the human condition, clarifying our understanding of many physical, biological and behavioural dangers to health. Two examples include the discovery of the relationship between cigarette smoking and lung cancer, coronary heart disease and stroke, and the link between oral contraceptives and thromboembolism (Keppel, 1992, p.6).
Most epidemiological research is observational and requires no intervention other than asking questions, inspecting medical files, and conducting laboratory tests or medical examinations. Observational methods of study often make use of existing medical records or national databases, which can include sensitive and personally identifying information. Access to such information may be essential to evaluate data, to identify individuals for interview or to link records to compare those who have a certain disease with those who do not (Last, 1998). In most cases, ethical standards require the informed consent of the research subject in order for researchers to access personal information. But, with large population-based studies this ideal may be very difficult or even impossible to achieve. The validity of population-based research depends on high levels of inclusiveness. The sheer number of individuals involved in a study may prevent informed consent being obtained from every individual, particularly where the research uses huge quantities of previously collected data and researchers would encounter extreme difficulties in tracing past patients. If people cannot be traced or refuse to participate, the sample may be skewed, producing a biased study with invalid results.

So the use of information contained in medical records or databases, for research, without the consent of the individual concerned, raises important ethical and legal concerns.

**Research and Ethics**

When a research proposal is submitted to an ethics committee for review the aim is to ensure that the research takes place under proper ethical constraints. The committee is to consider the features of the proposed study in light of ethical principles, with a view both to the protection of subjects against the risks of harm, and to facilitating the ethical conduct of beneficial studies.

In considering an application, several documents are available to guide an ethics committee in New Zealand. These include:

- *The Declaration of Helsinki* 1964
- The New Zealand National Standard for Ethics Committees 1996 (National Standard)
- The Health Research Council *Health Research and Privacy Guidance Notes for Health Researchers and Ethics Committees (HRC Guidelines)*.

These documents all uphold the ethical principle of autonomy, by directing attention to the importance of informed consent and its role in the protection of research subjects. Informed consent serves to minimise harm, protect privacy and improve research (Dickens, Gostin and Levine, 1991). Generally speaking, these documents charge ethics committees with the responsibility of weighing potential benefits against risks of harm when deciding whether to approve research that seeks to use personally identifying information without consent; and to consider whether any risks to the subject can be justified by the expected benefits. In their decision-making the committees may have to balance the conflicting ethical obligations, such as those of autonomy, beneficence, non-maleficence and justice (Beauchamp and Childress, 1994). On some occasions, the relevant ethical principles may conflict, but they still provide a useful framework through which moral problems surrounding epidemiology may be understood and evaluated (Coughlin, 1996, p.145).

Respect for autonomy requires respect for individuals’ right to control access to private health information about them. When researchers view private information from the medical records of a person without their consent, they harm that person’s autonomy interests. But the investigators might then invoke the principle of beneficence to justify this (Dickens, Gostin and Levine, 1991, p.176). They may argue, for instance, that the public interest in conducting research into diseases where little information is available, or the need for proper audit of medical services that may be functioning inadequately, is of overriding importance. Data linked to personal identifiers are valuable sources of new knowledge about the causes and control of many diseases. So access without consent may be justified on occasion by the potential value of the research.

**The Law on Requests by Researchers for Personal Health Information**

The law governing health research also places considerable importance on patients’ privacy, permitting access to personally identifying health information, without patients’ consent, only in limited situations. One difficult issue in this complex field of law arises in precisely the circumstances...
presented by the proposed national audit: i.e., when researchers seek access to other people's personally identifying health information and that information is held by a public sector organisation.

The difficulty arises because this kind of information is both ‘health information’ within the meaning of the Health Information Privacy Code 1994 (HIPC) (issued under the Privacy Act 1993), and it is ‘official information’ within the meaning of the Official Information Act 1982 (OI Act). Both legal regimes may therefore apply, but the former is mainly concerned with the protection of personal privacy, the latter with promoting the availability, on request, of official information.

The two regimes apply similar rules to the disclosure of private material, and privacy considerations may strongly influence the decision to withhold access to official information, but there are still significant differences between the two schemes. In particular, the OI regime requires disclosure to be made when the principle of availability applies, whereas the HIPC merely permits disclosure, leaving the final decision with the information holder.

One might think that NZ law would provide a clear rule as to which statute would prevail, and that the HIPC, being aimed at health information, would be the one preferred; and many organisations and commentators have proceeded on this basis. But these assumptions do not seem to hold. The rules governing the respective spheres of the two regimes in this research context are not so clear; and, when they are unravelled, it seems that the more general OI regime will sometimes take precedence when a researcher seeks access to data covered by both regimes: i.e., access to what might be called ‘official personal health information’.

The nub of the controversy concerns the interpretation of the so-called ‘savings’ clauses found in both the Privacy and the OI Acts. Both clauses state that when some other enactment regulates disclosure of information, that other enactment’s rules will take precedence: i.e., there seems to be a system of mutual deference between the two regimes. This apparent impasse may be resolved, however, by giving priority to the later statute in time, here the Privacy Act, which was enacted after the OI Act and with knowledge of its terms. On that view, the somewhat ironic conclusion is reached that the rule of deference found in the Privacy Act is the more authoritative, so the OI Act would then apply in any case where there is a complete conflict between them.

The Ombudsmen have taken steps to clarify the situation, issuing a practice note (Practice Guidelines No. 6, 1994) in which they state their position: that the OI Act is the controlling statute when a request is made by a third party — such as a researcher — for access to any personally identifying information held by a public sector organisation, such as the MoH or a public health provider, which is covered by the official information regime. This view has been endorsed by Longworth and McBride (1994, pp.180-183), and by Roth, in their texts on NZ privacy law; and it was advocated by the Crown and the Health Funding Authority at the Gisborne inquiry. In the absence of any authoritative judicial determination to the contrary, this seems the best approach to follow. On this view, the general legislative structure would be as follows.

**The General Structure of the Legislative Regime**

When a request is made by a third party for access to official information the position is directly governed by the OI Act, whose general policy is that the information should be made available unless there are good reasons, stated in the statute, to withhold it (s 5). One good reason to withhold it is to protect personal privacy (s 9(2)(a)). But the privacy concerns are not determinative, because s 9(1) of the Act explicitly requires the information holder, in responding to such a request, to go on to consider whether ‘in the circumstances of the particular case’, the privacy interests which support ‘the withholding of that information [are] outweighed by other considerations which render it desirable, in the public interest, to make that information available’.

So a two-stage legal test is applied. The privacy concerns must be identified; and then they must be weighed against any public interests which nevertheless favour the information’s disclosure to the person who has requested it. Only if the privacy concerns are found to predominate may the information be withheld.

A wide range of factors may be relevant to this balancing calculus. The person making the assessment should consider...
carefully the extent of the intrusion on personal privacy involved, and should consult with the person concerned if practical. But the views of the person whose privacy is threatened are not determinative either, because the competing public interests in favour of disclosure must still be taken into account.

In assessing the strength of the interests for and against disclosure, the rest of the law concerning privacy and disclosure of information will still be very important, because the law constitutes an authoritative statement of what the public interest requires. And the privacy concerns are not to be narrowly distinguished from the public interest, because there are strong public interests in protecting personal privacy and in maintaining the confidentiality of certain kinds of relationships: e.g., between doctors and patients.

When no third party request for access to official information has been made, however, the legal situation is different: i.e., when either no third party request has been made at all, or where the request does not relate to 'official information'. In those circumstances, when the information is held in the private sector, for instance, or where the information holder wishes to disclose the information of their own volition, or where an identifiable person makes a request for information held by others about them, it is the Privacy regime that will generally apply, not the OI Act.

The main focus of this Privacy legislation is to empower individuals to exercise control over information about them held by others. It establishes a number of general principles, which are then subject to exceptions. These include the principles that:
- individuals are entitled to obtain access to information collected by agencies about them and to know the purposes for which it is collected and used
- information collected for one purpose is not to be used for another purpose without the further consent of the person to whom it relates
- information about identifiable individuals will not be disclosed, without their consent, to third parties, except in accordance with the purposes for which it was collected, unless an exception exists.

The list of exceptional situations is still lengthy; and there is no limitation placed on the disclosure of anonymous, or non-identifying information, which remains freely available.

A particular feature of the privacy regime is the promulgation of the HIPC. It replaces the general Privacy Principles in the parent Act with more specific principles tailored to the special sensitivities of health information (Stewart, 1996).

As mentioned, the third main feature of this area of law is that both the OI and the Privacy regimes are subservient to more particular statutory rules which either prohibit or require the disclosure of information, or which impose a particular scheme which regulates disclosure. The two general statutes therefore provide many background principles in the field, but they are displaced by more specific legislation.

In the health information area, many statutes require the disclosure of patient information for public health and accountability purposes; and disclosure is permitted to many public officials, and for other bona fide purposes, under ss 22B-22H Health Act 1956. These provisions supersede the more general statutory rules (Roth).

The Research Exception in the Privacy Regime
One of the exceptional situations covered by the Privacy regime, in which health information may be disclosed without the person’s consent, is disclosure for the purposes of research. Rule 11 HIPC permits such disclosure when three criteria are all met; i.e., when:
- those holding the information ‘believe on reasonable grounds that it is either not desirable or not practicable to obtain authorisation [to disclose] from the individual concerned’ (Rule 11(2))
- the information is ‘to be used for research purposes (for which approval by an ethics committee, if required, has been given)’ (Rule 11 (2)(c)(iii))
- the information ‘will not be published in a form which could reasonably be expected to identify the individual concerned’ (Rule 11 (2)(c)(iii)).

Ethical Approval and the Distinction between Audit and Research
In the second leg of this research exception, it is said that approval by an ethics committee must be given ‘if required’.
But the Code does not state when such approval is required, nor that ethics committee approval is always required for this purpose. Indeed, the implication is that there are some situations in which such approval would not be required, even to obtain the benefit of this rule.

In particular, it is not clear whether use of the word ‘required’ means here that ethical approval must be obtained only when it is required as a matter of law, or whether it must be obtained whenever needed to comply with the principles of research ethics. If the former is the case, then the class of research protocols needing ethical review for this purpose would be more narrowly drawn, as there is no general rule in NZ law which requires ethical approval for all research involving human subjects, even if such approval may always be required as a matter of research ethics.

Some epidemiological research conducted within the MoH, for instance, using data already collected and lodged on its patient registries, which is funded by the MoH and does not involve registered health professionals or direct service provision, may not be subject to any of the specific legal rules in NZ which require ethical approval to be obtained in particular circumstances. This is the kind of case in which the ambiguous language of the research exception to Rule 11 HIPC needs a definitive interpretation.

The requirement of ethical review may also be affected by the distinction between audit and research. The National Standard, for instance, in addition to requiring ethical scrutiny for research, lists some matters that do not require ethical scrutiny. These include audit and the monitoring of the quality of care (Clause 3.3 and Appendix 5). It is said that an audit is only excused from ethical review, however, when it is undertaken by, or under the supervision of, senior members of the health care team directly responsible for the care of that group of patients, and where there is no access to confidential medical information by persons who do not owe a professional duty of confidence to those patients. It is therefore doubtful whether this exemption from ethical review would cover an independent audit of a screening programme conducted by university epidemiologists who are not involved in the clinical care of the patients concerned.

In any case, those involved in an audit may still approach an ethics committee for advice, if they wish, as noted in Appendix 5 of the National Standard. It might even be considered necessary, as an ethical matter, to seek such advice. The CIOMS Guidelines (CIOMS, 1991) state at paragraph 52, for instance, that although ethical review is not required for ‘programme evaluation’, ‘it could be considered poor practice to forego this type of quality assurance’; and that where there is ‘uncertainty as to whether a research proposal amounts to an epidemiological study or is a routine practice’, the protocol should be submitted to an ethics committee ‘for its opinion on whether the proposal falls within its mandate’.

We therefore do not accept the suggestion in the recent report of the Gisborne inquiry that ethics committees should refuse to give ethical advice on audit protocols (Gisborne, 2001, paras 9.26-9.28). It cannot be right that such ethical advice should be refused, or jurisdiction declined, when the potential auditors seek an opinion on their proposed investigation from an ethics committee. To the contrary, the ethics committee would be failing in its obligations to the investigators if it did not respond. To refuse might obstruct the investigators’ adherence to the ethical principles of their profession, which may require them to obtain ethical clearance, and it would deny the investigators an important source of advice. In our view, any study that proposes non-consensual investigator access to individuals’ identifying health details raises important ethical issues, on which advice might be sought, irrespective of whether the study is an instance of audit, evaluation, research, or monitoring.

The Audit of the Screening Histories and Management of Women with Cervical Cancer

Cervical cancer is the third most common cancer in women in the world, with lifetime incidence rates in NZ of over one in one hundred women. Cytological screening provides an effective control for cervical cancer, by urging apparently healthy women with no symptoms to undergo a test to detect pre-invasive lesions. Screening women between the ages of 20 and 64 every three years is estimated to reduce the incidence of cervical cancer by 91 percent.

The NCSR (National Cervical Screening Register) is managed within the MoH. Women who are screened are listed on the Register, unless they choose to ‘opt-off’ the programme. The Register provides a back-up recall system
for women with normal smears, and it can be used to ensure that women with abnormal smears are followed up and reports not overlooked (Straton, 1994).

A cancer registry collects, stores, analyses and interprets data on people with cancer. The CR (Cancer Registry), also managed within the MoH, was first established in 1948. With the early Registry, registration was compulsory for public hospital patients under the Hospitals Act, but voluntary for patients in the private sector. This changed in 1993 when, under the Cancer Registry Act 1993 (CR Act), it became compulsory for pathologists to report all cases of cancer. The CR Act makes provision for the compilation of a statistical record on the incidence of cancer in its various forms, and provides a basis for the direction of programmes for research and cancer prevention. Where the presence of cancer is identified in a person, the laboratory must report the results to the Director-General of Health to go on the CR; and the details of women who have cancer are forwarded from the NCSR to the CR. Personal identifying information is essential for the CR, otherwise duplicates could not be eliminated and the incidence data would be worthless (Keppel, 1992). There is no legal requirement that the patient’s consent be obtained before this information is sent to the registry.

Improvements in cervical screening since the establishment of the NCSP appear already to be saving many women from serious illness and premature death. However, the full potential of cervical screening can only be realised if the systems for screening are effective and if appropriate action is taken on positive results. When healthy people are encouraged to undergo screening, there is an obligation to monitor the quality of the process and the outcomes it achieves (Richardson, 2001).

In response to a growing demand for an evaluation of the NCSP, an evaluation contract between the MoH and a group of epidemiologists was signed in May 1999. The researchers proposed to evaluate the NCSP by:

• Assessing whether the NCSR provides appropriate data for evaluating the NCSP (completed)
• Assessing the appropriateness of follow up and treatment of women with abnormal smears (due for completion in June 2001)
• Auditing the screening histories and management of women with invasive cervical cancer.

The final part of this programme would involve obtaining access to some personal health information without the women’s prior consent.

In more detail, this aspect of the audit proposed:

1. To access the CR details of women diagnosed with cervical cancer, including the name, address and date of birth for each woman and the name of the clinician responsible for her cancer treatment.

2. To approach the managers of the NCSP for details of cervical smear results, from the NCSR, of women with cervical cancer identified from the CR.

3. To send a letter, concerning each woman, to her clinician and to her general practitioner, seeking approval to approach her. If both doctors thought it appropriate, the researchers would then approach the woman directly, by sending her a letter inviting her to participate in the study. Women who agreed to participate would then be interviewed. The research purpose of the interview would be to investigate the accessibility and acceptability of that woman’s health care.

4. Then to seek consent from the woman, and, if given, to access her records, held by her general practitioner and her gynaecologist, to establish her screening history.

The National Audit and the Ethical Review Process

The above proposal was submitted by the researchers for multi-centre ethical review. It was thus sent to a primary or lead ethics committee, in the area in which the principal investigator was based (the Otago Ethics Committee in this instance), which sent copies of the protocol for review to the other relevant regional committees. The overall decision in a multi-centre review process is based on consensus between all the committees involved, with the lead committee coordinating the review process and handling communications with the researchers. We shall, for this reason, refer hereafter to the ‘committees’ opinion’ when commenting on the ethics committees’ responses to the proposal.

The thrust of the ensuing arguments for and against ethical approval, as expressed by the protagonists at various points...
(but not necessarily expressed to one another), can be knitted together from a range of sources and summarised for our purposes as follows.

For both legal and ethical reasons, the committees' opinion was that the protocol should not be approved unless significant changes were made to the proposed access and consent procedures. In the committees' opinion the proposal did not sufficiently protect the interests of the women participants. They were concerned about the initial data access without consent, and about the direct approach to the women without their having been asked first whether they would be willing to be contacted by a researcher.

Given the events leading up to the Cartwright inquiry, and the subsequent breakdowns in care, attended by much publicity, the committees' opinion was that women on the NCSR were a special group of participants requiring extra caution (Evans, 2001). Further, some of the women to be included in the study were the subjects of another inquiry at Gisborne concerned with the under-reporting of cervical smear abnormalities and the possibility of sub-optimal treatment in some cases. In the view of the committees, these women constituted an especially vulnerable sub-group of potential participants, who were already in a situation in which they felt many things crucial in their lives were beyond their control. The committees considered it unethical to override their autonomy further and to risk causing them additional psychological harm by allowing non-carers access to personal information about them without their consent. Authorising such access might also cause feelings of anxiety, stress and grief and could contribute to a loss of self-esteem.

In the committees' opinion, the risks of harm to the participants would be minimized if the women were given an opportunity to consent to researcher access to their data. They suggested that the CR undertake the initial approach to the women by sending a letter on the CR letterhead directly to the women seeking their consent, the committees believing that the women would already know that the CR held the information that they were diagnosed with cancer. Following responses to that letter, the researchers could be provided by the CR with the name and contact details of the women who consented to further contact. The researchers could then approach these women through their medical practitioner with details of the study, and with their requests to obtain access to further information and to interview the women. Keeping in mind their obligation to protect research subjects, and the central role informed consent plays in research ethics, the committees' view was that these alternative procedures would improve the study's consent procedures and its overall ethics.

The researchers saw several scientific, practical and ethical obstacles to the committees' suggested amendments. Accurate results depend upon complete data. The researchers considered that it would be unrealistic to expect the Registry to contact all the necessary patients, as it lacked the staff to make direct contact with the women and to follow up non-responses from those who may have changed their address or died. Overall, the researchers believed that there would be a low response rate if the first approach were from the Registry, and the data would therefore be incomplete and the results biased.

Even if it were feasible for the CR to make the initial approach to the women, the researchers did not consider that it would be ethically desirable for them to do so. As noted by the Privacy Commissioner at the Gisborne Inquiry, extensive efforts to obtain informed consent may, in themselves, involve a considerable breach of privacy, for example, where locating individuals requires considerable contact with relatives or others. In addition, although it may be less private for women with a diagnosis of cancer to be approached by an unknown researcher, it would be more personal than receiving a letter from an official registry. Also, as misclassification can occur, some women whose names appear on the CR may not have cancer. Unlike the managers of the Registry, the researchers would check the diagnosis before approaching the women and would check with the women's general practitioners for reasons why it might not be appropriate to contact the women directly. In this way the methods the researchers originally proposed would better safeguard the interests of the women, and prevent anxiety and distress to sick or dying people, and to those who were mentally disturbed or recently bereaved.

In short, the researchers expressed scepticism about both the desirability and the practicality of the ethics committees' suggested amendments to their study design. In so doing,
their response on ethical issues closely paralleled the requirement specified in the HIPC that access without consent should only occur when it is neither desirable nor practicable to obtain the patients’ prior authorisation.

This is where the matter came to rest, because the audit protocol was subsequently withdrawn by the investigators from the process of ethical review before the issues were finally resolved. As the matter rested, the committees had neither approved nor declined the original protocol. They had suggested amendments to it, and received comments in reply, but they had never gone on to reach a final decision to approve the audit or not, in light of the responses the epidemiologists had made.

Our main approach, in the discussion which follows, is not so much to judge the positions actually taken by the committees or the investigators (although some judgments are made); it is to work through the principal legal and ethical issues as best we see them ourselves, aware that we are doing so with all of the advantages of time, hindsight and further research.

Is Consent Legally Required?

The Cancer Registry

The CR is maintained by staff of the National Health Information Service, within the MoH. It is therefore a holder of ‘official information’, although it is not involved in direct clinical care. The CR Act, under which the Registry now operates, states in its long title that it is ‘to provide a basis for the better direction of programmes for research and for cancer prevention’. Section 4(2) reinforces this point, stating that the purposes of the CR are:

(a) To provide information on the incidence of, and mortality from, cancer; and
(b) To provide a basis for cancer survival studies and research programmes.

The Act requires laboratories to send cancer-related data to the Registry, with no reference made to any requirement of patient consent, or to any need to inform patients that the information is being sent. It therefore appears that the general statutory intent of the Act is to ensure the availability of data from the CR for the purposes of cancer research, regardless of patients’ views.

Another feature of the Act is that it contains no express provisions concerning disclosure of information from the CR, nor have Regulations been issued on this subject, nor is there any reference to use of information for the purposes of auditing or for improving screening services, unless these are considered ‘research programmes’, as they might be. There is therefore no specific privacy or disclosure code provided in the Act which would supersede the general rules on these subjects found in the OI and Privacy regimes.

So, in accordance with this legal analysis, and as the MoH and the Health Funding Authority (2000) argued at the Gisborne inquiry, a request by outside researchers for identifiable patient information from the CR should be viewed as a request made under the OI Act. To apply that Act in such circumstances, one must balance the public interests in the free availability of the information requested against any relevant privacy concerns.

To give detailed content to the privacy concerns, one may then usefully turn to the HIPC. The CR is a ‘health agency’ in terms of the HIPC, as it supplies services with regard to health information (clause 4(2)(i)); it holds data about identifiable individuals; and this is ‘collected ... in the course of, and incidental to, the provision of [a] health service’ (as broadly defined) to those persons (clause 4(1)(e)).

Significantly, in this context, the guidance to be derived from Rule 11 HIPC, concerning public policies on disclosure of personal health information to third parties, suggests that privacy concerns are not compromised unnecessarily by non-consensual disclosure when this ‘is one of the purposes in connection with which the information was obtained’ (Rule 11(1)(c)). Further, where it is not ‘practicable or desirable’ for the consent of the person (or their agent) to be obtained, disclosure is still justified without consent under Rule 11(2), for: directly related purposes; in accordance with the research exception discussed earlier; to lessen serious and imminent threats to public health (e.g., by reducing mortality from cancer); and when disclosure ‘is required for a professionally recognised external quality assurance programme’.

If one knits together all these recognised exceptions, in which the usual privacy concerns are said to be abated, and
applies their general tenor to a national cancer registry for which the data are collected under statutory authority without patients' consent; and the investigators, in addition, give an undertaking not to publish any identifying particulars; one might well conclude that not even the first leg of the legal test for holding back information under the OI Act is met: that it would be ‘necessary to protect the privacy’ of individuals. That conclusion would be end of the legal analysis and the information sought by the researchers should then be disclosed.

If, on the other hand, the staff of the Registry did consider the personal privacy concerns sufficiently weighty here to constitute a good reason to withhold the data from third party researchers, in principle, all the public interests in favour of disclosure would then have to be weighed in the balance to reach the final decision.

Here, in our view, the stated statutory purposes of the CR would comprehensively tip the balance in favour of disclosure of the information sought for the purposes of the audit, because the stated public policies behind the operation of the CR include providing a basis for cancer survival studies and research programmes. Or, to put this in terms of the HIPC, because the information is initially collected for those purposes, under statutory authority and without patients’ consent, it may later be disclosed to researchers for those purposes as well.

In short, putting the provisions of the CR Act, the OI Act and the HIPC together, it can be argued convincingly either that the privacy concerns are abated in these circumstances; or that the public interest in freedom of access by cancer researchers to this kind of information is bound to prevail, at least as long as the researchers do not publish any details that would identify individual patients. This now seems to be the general legal consensus.

**The National Cervical Screening Register**

Section 74A Health Act 1956 regulates the NCSR and disclosure of the information it contains. This section was enacted by an amendment in 1993, in the same year as the CR and Privacy Acts.

Section 74A(5) provides: ‘No person may disclose information on the register that identifies a woman, except on one of the following grounds’:
- ‘with the consent of the woman’: s 74A(5)(a)
- for the purposes of further diagnosis, treatment, follow up or testing of the woman: s 74A(5)(b),(c) and (d)
- ‘for the purpose of enabling the compilation of statistics that do not enable the identification of the women’: s 74A(5)(f);\(^{10}\) and, notably,
- to provide access ‘to persons studying cancer’: s 74A(5)(e).

But access is permitted under this final rationale only in accordance with Regulations made under s 74A(7); and at the time of this controversy no such Regulations permitting access for cancer studies had been made.

There are a number of initial points to make about these provisions. The first is that they appear to constitute a complete code on the subject of ‘disclosure’ to third parties. They prohibit any such ‘disclosure’ of data from the NCSR ‘that identifies a woman’, without that woman’s consent, except in specified circumstances. The disclosure rules in both the OI Act and the HIPC are therefore displaced by these more specific rules.

A second point, however, is that these disclosure provisions in s 74A(5) may not apply to use of the data by the MoH staff who maintain the Registry, because such uses may not involve any ‘disclosure’ in the necessary sense. Indeed, such internal uses do not seem to be directly covered by s 74A at all. This does not mean such internal uses are not controlled by law. It means they are controlled by the general background rules, here by Rule 5 of the HIPC, governing unauthorised access to data, and by Rule 10, which specifies certain permitted uses of previously collected health information.

A third and very significant point is that the exceptional disclosure rule in s 74A(5)(e) expressly covers ‘persons studying cancer’. So it was within Parliament’s contemplation that this kind of study, even when conducted by third parties, could be authorised. But it would have to be authorised by Regulations, and that further law-making process would provide another opportunity to set the criteria, and the process, under which disclosure of data for such purposes could proceed. In our view, the deliberate
creation by Parliament of such a key to the ‘front door’ of the
NCSR counts heavily against other legal arguments which
would permit access by third parties through a ‘side door’,
and which would not involve Regulations being made.

We can see three additional legal arguments which might be
used to justify entry by independent auditors through a side
door, not under Regulations. These arguments would be that:
• the audit involves no more than the ‘compilation of
statistics’, so disclosure would be authorised under s
74A(5)(f)
• that the implied ‘consent’ of the women has been
obtained, and this is sufficient
• that in the conduct of the audit the epidemiologists
would act only as ‘agents’ of the NCSR, or would only
be ‘processing the information on behalf of’ the NCSR,
so no ‘disclosure’ of data would occur.

For the reasons to be given below, we do not find any of
these arguments sufficiently convincing, however, to
displace the principle just expounded: that where Parliament
expressly authorises something to be done, but only under
Regulations, those Regulations should be made for that
conduct to be lawful.

The first of these additional arguments, that the national
audit would involve no more than the ‘compilation of
statistics’, is less than convincing on the facts. That phrase
does not seem sufficient to describe the work of expert
epidemiologists, even in the initial stages of such a complex
audit. Before the women were approached, for instance, it
appears that access would be sought, via the NSCR, to the
cervical screening histories of identifiable women. This
seems to go somewhat beyond the purely statistical domain.

As to implied consent, it might well be argued that women
do give their implied consent to disclosure of identifying
data for audit purposes, simply by accepting their enrolment
on the screening programme; and this possibility is
considered further in the ethical discussion below. Implied
consent may be obtained where a person is assumed to be
aware of the connection between two circumstances. That is,
perhaps women who accept their enrolment on the
programme would expect that it would be audited so that it
functions well; and they would not want to participate if it
were not monitored or not effective. So women will
recognise the connection between programme participation
and its evaluation; and they therefore give their implied
consent to the information being used for audit purposes.

The report of the Gisborne inquiry makes a similar point in
its assertion that consent to audit might be covered in these
circumstances by the women’s consent to undergo treatment;
i.e., when they permit cervical smears to be taken and the
results sent to the NCSR (Gisborne, 2001, paras 6.98, 9.6.
9.11, 9.28).

Nevertheless, we do not think such notions can be brought
easily within the legal concept of consent when this term is
used in this statute. No express consent to any such
disclosure is given, nor could such a consent be considered
even minimally informed, when, at present, the women are
not advised that the data collected may be disclosed for audit
or research purposes. Further, if implied consent were
sufficient to bring studies of cancer under s 74A(5)(a), it is
hard to see why another rule would provide separately for
disclosure of data to ‘persons studying cancer’, through an
additional regulation-making process. Overall, while we
have some sympathy for this argument, we are not
convinced that we should stretch the legal concept of
consent in this manner, to obtain access to the data through
a side door, when the key to the front door is already in
responsible hands.

The third additional legal argument, about actions taken by
agents, and the processing of information on behalf of
others, also has some weight. The suggestion here would be
that, provided the staff of the NCSR are themselves entitled
to use the data they have collected for audit purposes, they
could lawfully employ, or contract, or appoint agents to do
this work on their behalf, or could contract out this
‘processing of data’. This would be one implication, it may
be argued, of s 3(4) Privacy Act, which states that where
someone:

holds information—
(a) Solely as an agent; or ...
(c) For the sole purpose of processing the information
on behalf of another agency, —
and does not use or disclose the information for its own
purposes, the information shall be deemed to be held by
the agency on whose behalf that information is so held,
or, as the case may be, is so processed.
We might call these the ‘use through an agent’ and ‘information processing’ exceptions to the usual principle that handling the data in this way would involve its ‘disclosure’. If such a handling of the data involves no disclosure at all, because the information is deemed to remain in the hands of the first agency, the tight code of rules governing ‘disclosure’, provided by s 74A(5), would not come into play.

This line of argument will succeed only if the audit would be a use of data already collected by the NCSR which is permitted by law on the part of its own staff; and the contracted epidemiologists engaged in the audit would be acting solely as agents or solely as processors of information on behalf of the NCSR; and they would not use the information for their own purposes.

The first of these requirements may be satisfied, because the additional use of the screening data for audit purposes by the staff of the NCSR arguably falls within a number of the additional use exceptions provided by Rule 10 HIPC, even when these additional uses do not have the consent of the patients concerned. The audit could be considered a purpose directly related to that for which the data was first collected; or it could be considered necessary to reduce a serious threat to public health; or a use for research purposes for which the approval of an ethics committee is not at present strictly required by law — and no identifying details need be published. On this basis the audit might lawfully be undertaken by the staff of the NCSR, given the urgency of the situation, and there would seem to be no legal objection to outside experts providing them with advice.

But to consider expert epidemiologists, employed separately by a university, to be engaged solely in the ‘processing of data’, or to consider them to be acting solely as agents of the NCSR, if they were to conduct an independent audit, does not seem very convincing, because to take that approach would be to view the epidemiologists as both expert and non-expert at the same time, and as both independent of, and internal to the Ministry. We do not think, in either case, one can have it both ways. This is especially so if the epidemiologists, to protect their academic freedom, would wish to reserve their right to publish an independent account of their results, or would wish to use their findings to make a wider contribution to medical knowledge: i.e., if their investigations might be properly characterised as both audit and academic research at the same time. In our view, it is precisely their independence and their expertise — the reasons for which they are most valuable to the audit process — which prevents the epidemiologists being viewed solely as agents or as data processors for the NCSR.

Conclusion on Lawfulness of Access without Patients’ Consent

Our conclusions on the law are therefore as follows. It would be lawful for data from the CR to be disclosed to the epidemiologists without the women’s prior consent. It would also be lawful for the staff of the MoH who manage the NCSR to use data already collected for the further purposes of an audit without the women’s consent, although this has the disadvantage that it may compromise the audit’s independence and therefore its credibility. But if experts are to be used to conduct an independent audit, as arguably they should be, the consent of the women should be obtained before any identifying information can be disclosed to those experts from the NCSR, unless the necessary Regulations are issued, or the legislation is changed.

Is Consent Ethically Required?

Ethical issues regarding the national audit remain to be discussed. The central points of initial disagreement between the ethics committees and the investigators concern: (a) the best way to approach the women; and (b) the acceptability of researcher access to the women’s identifying personal details without their consent.

In our discussion of these issues, we start by considering the potential harms which may flow to the women participants if the proposed audit were to proceed. In particular, we focus on potential harms to the autonomy interests of the women, and on whether we should consider such interests to have been served if the women have given their implicit or hypothetical consent to investigators’ access to their data. In passing, we compare, with respect to these autonomy interests, the study as initially proposed (the National Study), with the study as it would have been amended by the ethics committees’ initial recommendations (the Amended National Study). To make this comparison fair, we assume that the researchers would have pursued either study with full conscientiousness and vigour. And we keep in reserve the possibility that both versions of the study might be unethical, with the result that neither should be approved.
The discussion of potential harms from the audit is then balanced with some discussion of its potential benefits, though some of these potential benefits, such as reducing mortality from cancer, are so obvious they need little emphasis here.

This will put us in a position to weigh the likely harms from the audit against the potential benefits. In this part of the analysis we will concentrate on how this balancing of interests should be conducted. In particular, we will consider the matter of acceptable levels of harm in non-consensual research, and whether it should be harm to each individual participant, or averaged harm across all potential participants, that is the focus of concern. Finally, we reach a positive overall judgment as to the ethics of the National Study.

**Harms and Benefits**

First, we assume that the crucial ethical issues can be satisfactorily addressed in terms of the interests of affected parties, and especially in terms of harm and benefit to those interests (Feinberg, 1984). The study’s participants, and also wider communities, are the affected parties. We also assume that persons have many interests. These include ‘autonomy interests’ in making their own choices from among a number of worthwhile options. Persons also have interests in having their reasonable expectations met, or at least not frustrated, and in avoiding feelings or experiences of pain, exclusion, discomfort, humiliation, loss of self-esteem, and so forth. Our discussion of individuals’ ‘overall interests’ aims to take all these into account.

Second, the level of harm or benefit to a person we take to be one thing, and its probability another.

Third, we distinguish the total from the incremental harm or benefit to a person. Consider a woman who has advanced cervical cancer. Due to this illness, the total harm to her might be great, whether or not she faces any small additional burden or benefit of participation in research. But the incremental or extra harm or benefit of research participation might be small. Only the incremental harm can fairly be attributed to the research in such cases, and it alone should here be the focus of research ethics. Consistent with this ‘incremental’ approach, one might also believe that, even among individuals or groups who would be equally harmed by some activity, some additional weight should be given to avoiding harm to any who are already in a harmed state, or who are particularly vulnerable.

Finally, assessment of the incremental harm or benefit to a person involves many considerations that are hard to specify fully, let alone quantify. In judgments of overall harm and benefit, there is inevitably some room for reasonable persons to disagree.

In light of those assumptions, we propose now to blend further discussion of the autonomy interests of the women participants with a discussion of how those interests would be differently affected by the methods of access suggested by the investigators and the ethics committees. That is, we will start with the question: would the National Study’s no-consent approach harm participants’ autonomy interests more than the Amended National Study’s consent-based approach?

**Participants’ Autonomy Interests**

We focus first on participants’ autonomy interests in determining for themselves who has access, and for what purposes, to health information about them. We consider that persons have such autonomy interests, and that any potential participant in either national study would have such interests in her health information. In our view, participants have a separate autonomy interest in determining for themselves whether the investigators will gain initial access to their personal health details, held on the registries, and they have such interests regardless of whether there would be other harmful consequences for them after such access is gained. That is, we consider that there is an independent autonomy interest in controlling initial access by others to one’s personally identifying health data.

On the face of it, a different view on this aspect of autonomy has been advanced by a working group of the Royal College of Physicians. Their view of researcher access to medical records, even without participant consent, was that, provided confidentiality and anonymity are preserved:

... the review of medical records is, by nature, not intrusive and will neither harm nor subordinate the interest of the individual to that [of the] community. It
therefore satisfy[s] the criterion of ‘no detriment’ (College of Physicians, 1994, p.439).

The nature of the claim here is not entirely clear. Perhaps the claim being made is simply that access without consent to medical records involves no net harm to the individual. It would seem very hard to justify the stronger claim that it involves no harm at all. It would ignore the separate interest people have, regardless of other consequences, in controlling access to their personal information. If the working group of the College is taking this ‘no harm’ view, we disagree. This independent autonomy interest may not be of the most important kind, and often it may be outweighed by other considerations. But we think it should not be discounted altogether. We think people have an interest in being asked about access to their personal health data, even if they would agree, if asked, and even if they might indeed benefit overall if non-consensual access were obtained.

Implicit Consent
There would be no compromise to such autonomy interests, however, if the individual had consented to others’ obtaining access to their information. Those with personally identifying data recorded on the CR and NCSR typically do not explicitly consent to having this included in any study. Do they implicitly consent?

The Gisborne report comments that programme evaluations such as the National Study are, should be, or ‘can be seen as’ part of the treatment to which the women consent (Gisborne, 2001). To determine whether all these women have actually consented to inclusion in such an evaluation, however, the relevant question is whether they all actually had, or can reasonably be supposed to have had, this very broad understanding of the treatment proposed.

Perhaps the only thing that would make it reasonable for all the affected women to expect that such study inclusion might occur, and that would make it reasonable for others to suppose they had this expectation, would be a pervasively shared cultural understanding that important personally identifying health data is to be shared, not just within the healthcare teams of particular health service organizations, but also with those who collect data on adverse reactions, with qualified persons who conduct service audits, and with registered medical practitioner epidemiologists whose profession is to evaluate the safety and effectiveness of health services and programmes for the sake of the public health. This shared public understanding would bring with it the relevant implicit consents.

Something like that understanding did exist until recently, led by the ethos of the medical professions. It persists to some extent. Many women with details on the CR and NCSR may well believe these data will be used in research, and will have been pointless collected if this is not so. For it to be reasonable for every such woman to have these beliefs and expectations, however, this shared understanding would have to be very clearly and widely shared. With the emergence in NZ and elsewhere in the late 1980s and early 1990s of a greatly increased cultural and legal emphasis on individual privacy interests, our view is that the required ethos is no longer widely enough shared to underwrite the required implicit consents from all women involved. The Gisborne report firmly expresses the view that we should have this ethos, but even if this is granted, one cannot conclude that we now do have this ethos (Gisborne 2001). And the question whether we now do have this ethos is the relevant one, when we are asking what people have implicitly consented to.

So far, then, our view is that the Amended National Study would better serve the autonomy interests of significant numbers of participants in determining for themselves access to their personal data.

Hypothetical Consent
If considerations of explicit or implicit consent cannot support the National Study, however, one might appeal instead to hypothetical consent. Respect for hypothetical consent can serve a person’s actual autonomy interests. We serve the actual autonomy of the unconscious Jehovah’s Witness, for example, if, despite a blood transfusion’s being clinically indicated for her, we do not give her one. We do so by not giving her a treatment that she would autonomously opt not to have. Hypothetical consent is relevant to our case because there is evidence about what participants in non-consensual studies would autonomously prefer. In a recent NZ study of 891 women with breast cancer, which required the names of potential participants to be released to researchers from the
CR, only 2 women were unhappy that this release occurred, and 1 made a complaint about the matter. In another recent NZ study of 951 men with prostate cancer, where the same methods were used, it was found that only 3 men were unhappy that their names were released to researchers from the CR, and none made a complaint about this. In an earlier and relevantly similar UK case-control study of the aetiology of cervical cancer, only 2 of the 226 participants regretted taking part (Taylor, Trowbridge and Chilvers, 1991). From the fact that hardly any participants in these studies disapproved of unconsented researcher access to data about them, it is reasonable to conjecture that nearly all National Study participants would have given their informed consent to such researcher access.

Considerations of hypothetical consent therefore offer good evidence that the National Study would serve the actual autonomy interests of nearly all its participants regarding initial researcher access to health information about them. But this does not affect our conclusion that the Amended National Study’s requirement of actual consent would respect these autonomy interests to an even greater degree. Hypothetical consent may be good; actual consent is even better.

The Autonomy Interests of Vulnerable Participants
One additional aspect of participants’ autonomy interests of special relevance here, in light of the ethics committees’ views, concerns the position of some specially vulnerable women who might be included in the study. Some potential National Study participants were also the subjects of an inquiry in Gisborne into under-reporting of cervical smear abnormalities. Some of these women may already have felt that important aspects of their health and healthcare were beyond their control. Perhaps special weight should therefore be given to their autonomy interests in determining for themselves who has access to their details. Any such weighting would increase the advantages of the Amended National Study regarding these autonomy interests.

We accept this argument, in principle, but what does it show? In any sufficiently large non-consensual epidemiological study, there will be potential participants who enter it with important existing harms or vulnerabilities that justify giving particular weight to their autonomy interests. If the presence of such persons is enough to strike out a study as unethical, then all large-scale non-consensual epidemiological research, audit, and health surveillance would be unethical. This conclusion seems very implausible, and NZ ethics committees explicitly reject it. We therefore do not think this ‘special vulnerability’ line of argument on its own should lead to rejection of the National Study. It remains, however, a factor to consider in assessing the potential harm to the participants in this study that might actually arise.

One possible response would be to exclude the vulnerable Gisborne women from the National Study, if this could be done without severely compromising the study’s scientific validity or its fairness between participants. But there would be a serious downside. The National Study would then be well designed to answer crucial questions about cervical cancers, smears, and screening for every NZ region except Gisborne, and since the exceptional public interest in these issues has centred on the Gisborne situation, this would be an unfortunate result.

Overall Conclusion Regarding Autonomy Interests
Our overall conclusion on this dimension therefore is this: that actual consent serves autonomy better than does hypothetical consent; and that even with hypothetical consent inferred for the National Study, the Amended National Study would still better serve participants’ autonomy interests in determining access to their health information.

But this is not an overall ethical judgment in favour of the Amended National Study. The claim is only that the amended study design would be preferable in this one respect. This modest ethical advantage for the Amended National Study is consequently not decisive. We must go on to consider other relevant interests as well. And we note the significance for any overall balancing of these interests, which must still be conducted, of the evidence cited above, that most of those very few participants who are initially distressed to have been included in a study of this sort without their consent are well satisfied later when the reasons for this practice are carefully explained. We maintain our position that actual consent is preferable to hypothetical consent, but this does not preclude the latter having advantages which still count, in an overall balancing exercise, in favour of the National Study as originally proposed.
Potential Benefits from the Study

We turn now to consider briefly some corresponding benefits which may flow from the study. These benefits may accrue either to the individual participants, or to the wider community, or to both.

First, consider the interests of the women concerned in participation in worthwhile research. We consider they have such interests, but they will not be served if the audit cannot adequately answer the research questions posed. Thus any general support for the Amended National Study must be conditional upon its being able to answer satisfactorily the relevant research questions. The researchers’ strong scientific, practical, and ethical objections to the suggested amendments to the study design which were proposed by the ethics committees, invite the conclusion that there was no reasonable chance that the Amended National Study could answer the questions the epidemiologists had sought to ask, or that it would do so less well. We are not competent to judge the merits of the methodological arguments, but we feel bound to say that we know of no reason to think that, in their views on this matter, the researchers were mistaken. Further, we consider that such issues, concerning studies’ ability to achieve their stated research goals, are central to the deliberations of ethics committees (see CIOMS, 1991, clause 40). A study is less likely to be ethical if it is less capable of generating important knowledge.

If either version of the proposed audit would secure credible answers to its study questions, then this would offer several sorts of significant benefit to participants. One sort of benefit would be enhanced understanding of their own previous health and healthcare. Another would be satisfaction of the reasonable expectation that if they were to participate in this sort of study, then it should be a worthwhile study that is clearly capable of answering the questions it sets itself. Further, if such benefits were available only from the National Study, then those would be genuine incremental benefits from that study’s design.

Any such valid study would also strengthen public and policy-maker understanding of many very important matters concerning cervical screening and cervical cancer. Those would be general social benefits of the study, and there are also important individual interests closely related to these public concerns. Many individuals care deeply about making a contribution to the interests of current and future others, about uncovering any serious failings within the health services, about getting these publicly acknowledged, about having the matter of how those failings arose investigated in a maximally informed way, about ensuring that improvements are worked out and implemented, and so forth.

Serving these interests would all be corresponding benefits flowing from the conduct of the audit.

A ‘Threshold-Plus-Balancing’ Approach to Non-Consensual Studies

We now put aside comparison of the two proposed study designs, to address ourselves squarely to the study originally proposed by the epidemiologists, and to consider how we should assess the respective harms and benefits it might confer. Should its proposal, for non-consensual access to the women’s data, be considered unethical?

Current research guidelines typically state that where researchers seek access to information without participant consent, ethics committees must balance the relevant ethical obligations. These guidelines, and especially the CIOMS International Guidelines for Ethical Review of Epidemiological Studies, are some help in spelling out these obligations. But no guideline is precise about when proposed non-consensual research is ethically justified. To offer further guidance, we propose a ‘threshold-plus-balancing’ approach. Its lead idea is that there is a threshold of maximum permissible harm to participants, beyond which any non-consensual study is unethical, no matter how much public good it promises. On this approach, the ethical issues arise as follows:

1. Does the expected incremental harm that the study would generate for participants breach the threshold level (i.e., does it exceed the maximum permissible level)?

2. If the study does breach the harm threshold, then it is ethically unacceptable as proposed, and should be referred back to the researchers to determine whether appropriate research design changes can reduce its expected harm to participants.

3. If the study does not breach the harm threshold, then is
its potential public benefit important enough to justify its expected harm to participants?

4. If the study is not important enough, then it is ethically unacceptable.

5. If the study is important enough, then can its expected public good be secured at any lesser expected harm to participants?

6. If it can, then the study as proposed is ethically unacceptable, and should be referred back to the researchers to make the relevant changes.

7. If it cannot, then in this respect, the study is ethically acceptable, assuming that the researchers also fully protect participant confidentiality.

This threshold-plus-balancing approach to non-consensual studies sympathetically extends the main current research ethics guidelines. If ethics committees were to take this approach, then a key issue is where to set the threshold of maximum permissible harm.

Some might argue that the threshold should be zero. This would collapse the threshold-plus-balancing approach into the view that no harm to any participant can ever be ethically justified for the sake of any non-consensual study. No health research ethics guideline known to us sets this very stringent ‘no-harm’ standard for non-consensual studies. But this is not decisive. Let us consider the arguments.

Suppose that swift completion of some particular non-consensual study is our only serious hope of averting a pandemic. The no-harm standard seems to imply that this study would be unethical. This is an implausible implication to be committed to. But proponents of the no-harm standard can reply that this is only for the ethics committee consideration of cases. Where public interests are gravely at risk, there are compelling ethical reasons to ensure that public bodies other than ethics committees decide the case. The no-harm standard is silent on how these larger public or political decisions should be grounded.

Consider another case. Suppose that a crisis has arisen with our safety and record systems for injury or poisoning, with perhaps 50 lives at stake over an extended period. The crisis is not grave enough to justify taking the matter out of ethics committee hands, but a non-consensual study is part of the best way to protect these lives. Recalling the distinction between a harm’s level and its probability, suppose also that, among the hundreds of potential study participants, it is reasonable to expect that just one or two will be harmed by their participation. The harm is as mild and short-term as annoyance or inconvenience can be. Its probability of occurrence is greater than zero, but only barely. The no-harm standard implies that this study would be unethical. In our view, this implication is unacceptable. In our view, to try to prevent this kind of harm it clearly would be worth risking a very low probability of a very minor harm to a few people. We take this to be a persuasive criticism of the no-harm standard.

We doubt that there is any plausible rival to the claim that, in the ethics of non-consensual research, minor participant harms should be balanced against any serious considerations of public good with which they conflict. On occasion, the public good at stake will be ethically more significant than the conflicting individual interests. The threshold-plus-balancing view is a very cautious way for ethics committees to conduct such balancing.

Again, then, where should we set the threshold of permissible harm? The guidelines typically state a criterion, for non-consensual studies which cannot be conducted adequately in any other way, of no more than minimal harm (e.g. CIOMS, 1991 clause 4). We doubt there is much value in trying to make this criterion more detailed, given the many situations which arise. But there is one important issue that we do wish to consider further, which such a criterion does not adequately clarify. This is whether the harm threshold relates to the position of every individual in the study; or whether it relates to total likely harm averaged across the members of the participant group as a whole.

The individualised approach to harm would imply that when we can reasonably expect that even one participant would be more than minimally harmed, then the harm threshold is breached, and the study is unethical, no matter how much public good is promised. The problem is that for a great many large population-based studies, it is reasonable to expect that there would be some participant who would take major exception to the study’s non-consensual approach.
Plausibly, this would count as more than minimal harm to that individual. But this would rule out as unethical a great many important non-consensual population-based studies. We reject this conclusion, and must consequently refine our view to avoid it.

The obvious alternative approach is to make the harm threshold refer to the average level of harm across all study participants, or to the expected harm for an individual chosen at random from among them. But suppose we know that one potential participant would be very seriously harmed by inclusion in a non-consensual study, and nearly all of the hundreds or thousands of others would not be at all harmed. Averaging across persons would dilute this very serious harm to one individual, perhaps even making the average harm fall far below the threshold. This would allow non-consensual studies to inflict unacceptably serious harm on particular individuals.

In the face of these difficulties, we stand by the threshold-plus-balancing approach to the ethics of non-consensual studies; but we add to it the following dual threshold of harm. The harm threshold is breached here if and only if it is reasonable to expect that the study would cause: (a) serious physical or psychological harm to any individual; or (b) more than minimal average harm across the participant group as a whole. And in more than minimal harm we include significant humiliation, loss of dignity, or injury to feelings.17

This rules out as unethical any non-consensual study that would seriously harm any individual. Equally importantly, it does not strike out every large non-consensual study. It also embodies the important fact that in health research and ethics, we should care about each individual participant, and about the whole participant group, and indeed the wider community.

The Ethics and Legality of the National Study: an Overall Assessment

We now apply that modified threshold-plus-balancing analysis to the National Study.

The first question is whether it would cause any participant serious overall harm, beyond the harm she already faced, or whether it would cause more than minimal incremental harm averaged across all participants. We believe the answer to this complex question is ‘no’. The National Study consequently does not breach the harm threshold. So it is not ruled out on this ground alone and the balancing of the interests must proceed.

Is the expected public good of the National Study then enough to justify the sub-threshold harm that it might cause participants? We think the answer here is ‘yes’. This study could offer considerable benefits to women throughout NZ. The independent autonomy harm likely to be suffered by a few women is relatively minor. There is considerable merit in the argument from hypothetical consent. Historically, cervical screening has been less than fully effective, due to the frequency of false negative results, a failure to act on abnormalities detected at screening, and a failure to treat pre-invasive abnormalities. A high quality, genuinely independent evaluation could identify any major tendency for a laboratory to issue false-negative reports that may lead to undetected cases of invasive cancer. It might ultimately prevent the deaths of significant numbers of women. It is therefore imperative that the programme be independently evaluated and any weaknesses detected and remedied.

From this overall assessment of the interests at stake, we conclude that, provided the researchers do not themselves publish any identifying particulars and maintain confidentiality, the National Study is ethically acceptable. A similar conclusion was reached when we undertook a balancing of the interests for the purposes of our legal analysis, when applying the OI Act.

We emphasize, however, that this is not a final judgment on the position taken by the ethics committee, because they did not ultimately reach any equivalent decision on the overall ethics of the audit, before the protocol was withdrawn.

Further, this conclusion does not avoid the one remaining legal barrier to the study that we have identified, which stands in the way of independent epidemiologists obtaining access without the women's consent to identifying health information held on the NCSR. In our view, there was a genuine privacy law concern. The way forward on this count is for the necessary Regulations to be made; or, as the Gisborne inquiry has recommended, for the legislation to be changed.
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Notes
1. The declaration was last revised in October 2000. Controversy has erupted over this revision of the Declaration, on just the sorts of issues we canvass in the present paper. See, for example, Sanilka et al (2001).

2. Privacy Act 1993 s 7; OIA Act 1982 s 52(3); see also s 18(c)(f) OIA Act


4. The Ombudsmen emphasize the significance of s 29A OIA Act, which requires them to consult with the Privacy Commissioner before deciding whether to uphold a complaint by a third party concerning a refusal on personal grounds to make official information available. This requirement indicates that the primary jurisdiction in the area lies with the Ombudsmen, which in turn indicates that the matter is one of ‘official information’, as that is the area within the Ombudsmen’s jurisdiction lies.

5. Under s 46 Privacy Act 1993, the Privacy Commissioner may issue codes of practice to modify the application of the Information Privacy Principles for a particular sector or industry. It was under this power that the Privacy Commissioner released the HIPC in 1994.

6. See also paras 9.16, 9.22 and 11.18.


8. In 1997 there were only 73 deaths from cervical cancer, the lowest mortality rate for half a century. See Skegg (2000).

9. Clause 3(b)(ii) of the HRC Guidance Notes states that the reasons for not seeking consent for the use of individual health records should be justified to an ethics committee: reasons being scientific, practical, or ethical.

10. A National Kaitiaki Group must also approve the release of any statistical information which ‘identifies the woman or women to whom the information relates as being Maori’: see Health (Cervical Screening (Kaitiaki)) Regulation 1995. In effect this imposes an additional process of approval when it has first been established that ‘disclosure’ of such data would be otherwise authorised by s 74A(5). We reach the conclusion below, however, that ‘disclosure’ for the purposes of an independent audit would not even clear that first hurdle.


12. See, for example, Medical Research Council of New Zealand, 1986, especially pp.39-41. For discussion see Buchan and Paul (1992).

13. We thank Martin Wilkinson for this point and this example.


15. Donald Evans, personal communication. See also the report of Dr E Dryson’s relevantly similar study, Otago Daily Times, Dunedin, 20.12.2000.

16. Let us emphasize that we intend no parallel here with the National Study. We take no view here about how many lives, if any, the National Study might save, and we believe that some of the harms it might cause would be more significant that the almost negligible ones we imagine in our hypothetical case.

17. We draw here on the s 66(1) Privacy Act 1993, which includes an overlooked provision, the effect of which is to require that before a remedy may be granted for a breach of privacy, it must be shown that the breach caused or may cause significant harm to the individual.

References


Practice Guidelines No. 6 (1994), Current Approaches of the Ombudsmen to the Interface between Sections 9(2)(a) and 27(1)(b) of the Official Information Act/Sections 7(2)(a) and 26(1)(b) of the Local Government Official Information and Meetings Act and the Privacy Act, July. In Roth.


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