



NSW
CERVICAL
SCREENING
PROGRAM

CERVICAL SCREENING IN NSW:
LEGAL ISSUES

A Joint Commonwealth/State Initiative
Managed by the Western Area Health Service

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This Paper identifies, describes and analyses legal issues that arise from or are related to cervical cancer screening, including those arising from the establishment and operation of the New South Wales Pap Test Register. The law that has been researched has been confined to Australia. In completing this task, I have had the benefit of consultations with the members of the Medico-Legal Reference Group and with the coordinator of the Pap Test Register. The Pap Test Register and the NSW Cervical Screening Program provided extensive and valuable documentation. The task would not have been completed without the assistance of Melanie Turner and Lynda Lee. However, errors and omissions remain my own.



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PART A INTRODUCTION

Chapter One: Structure and Sequence

1.1 Structure and Sequence

The discussion is arranged by reference to the five stages of the screening pathway identified in the National Policy. In this paper, these are called (the language differs from that used in the National Policy):

- recruitment
- conduct of Pap smears
- tests of Pap smear slides
- notification of test results
- management of women with abnormal tests results

A section has been added covering a range of issues arising from the on-going use of information on the Pap Test Register. For the purpose of this paper “test” and “smear” are used interchangeably in reference to the Pap test although the legislation which established the Pap Test Register distinguishes between “tests for cervical cancer ,” and the specific test, a “Pap smear”.

In each of the first five stages, the discussion is arranged in the same sequence. Issues related to health practitioners are addressed first, those arising from the common law followed by those arising from statute. In some sections related to health practitioners, some typical questions asked by practitioners that were provided by the Medico-Legal Reference Group have been added, together with suggested answers. Then follow issues related to laboratories, first arising from the common law and then from statute. There is separate chapter that provides an account of the principles of negligence and of civil procedure.

The paper can therefore readily be broken up into separate papers relating to health practitioners, to laboratories or in relation to the use of information on the Pap Test Register. The chapter on negligence and civil procedure can be used or not as the audience demands.

Practitioners recurrently ask questions such as:

How is the standard of care established?

Could you clarify the underlying principles of the law in relation to medico-legal issues, for example, what is the connection between negligence, causation and damages?

Can I be sued for a mistake which is negligent, but causes no harm to the patient?

How useful are clinical notes these days?

This chapter responds to these.

Chapter Two: Establishing Liability: Principles, Procedures and Adversarial Systems

2.1 Principles

Claims against health practitioners and laboratories for compensation in relation to cervical cancer have relied on the principles of negligence. To succeed in such a claim, the claimant (or plaintiff) must establish all of the following:

- that the defendant, whether practitioner or laboratory, owed a duty of care to the plaintiff
- that in acting to meet that duty, the defendant's conduct had fallen below the relevant standard of care
- that the plaintiff had suffered harm, and
- that the harm was caused by that conduct of the defendant that had fallen below the standard of care.

Most lawyers use the expression "negligence" to mean the cumulative effect of these elements. Others who are not lawyers will often use the expression "negligence" or "negligent" to refer to conduct that is careless or that fails to measure up to professional standards. Confusion can result. Negligent conduct, in this popular sense, will not automatically lead to legal liability. It may be the subject of professional discipline.

These elements are cumulative: all are necessary. Failure to establish any one of them will result in an outcome in the defendant's favour. Therefore, if a practitioner is careless in failing to provide adequate information or failing to conduct a Pap smear correctly, but no harm results to the patient, no liability will arise. Equally, if the patient suffers harm, for instance, contracts cancer, but the practitioner's conduct has met the relevant standard of care, no liability will follow. Further, even if the patient suffers such harm and the practitioner's conduct *did* fall below the relevant standard of care, but that conduct *did not cause* the harm (which was due to some other cause), no liability will follow.

The elements mix matters of fact and matters of legal inference. For instance, to establish that a health practitioner owed a patient a duty of care, it would be sufficient to show that there had been a professional consultation between the patient and the practitioner. That there was a duty of care is a legal conclusion derived from the fact that a patient-professional relationship existed.

So, facts are essential. In establishing whether the defendant's conduct did or did not fall below a standard of care, the facts of the particular situation are most important. Facts are established by evidence. In medical negligence cases, evidence will usually include:

- **verbal evidence** given by people who, in answering questions, tell of what they saw, said or heard and
- **documentary evidence** in the form of notes, records, x-rays, test results, and
- **expert evidence** given by people who are shown to be recognised as expert in a field of professional practice and who answer questions about what, in their opinion, was the state of knowledge and appropriate conduct at the time of the events being examined.

In these cases, establishing a fact means showing, by reliance on evidence, that fact is more likely than not to have happened. For instance, whether a particular conversation took place in the course of consultation between a patient and practitioner is often highly important. Verbal evidence will usually be given by the patient and the practitioner together with documentary evidence of the practitioner's notes. These accounts will often differ. The judge will reach a conclusion that the conversation did or did not take place and, if it did, contained certain exchanges by deciding, from what is presented, which is more likely to have been the case. Lawyers refer to this as proving that something happened "on the balance of probabilities".

It cannot be emphasised enough that the detailed facts of each situation are critical. When lawyers respond to the question "Would I be liable if . . ." with the answer "Well, it depends . . .", all they mean is that the legal conclusion of liability has to be inferred from an established set of facts. Until a judgement is made as to which of several accounts of those facts is the more probable, the factual basis for the legal conclusion is uncertain.

Duty of Care

A person owes another a duty of care when, in contemplating a course of conduct, that person can reasonably foresee that the other could suffer harm if reasonable care was not exercised and knows that the other person is or will be in proximity to the conduct. It is well established that health practitioners owe to their patients a duty of care. The duty is the legal inference from the fact of a patient-practitioner relationship. That relationship can be established by one consultation, e.g. between a patient and a locum general practitioner, whom the patient sees only once, or between a patient and a specialist whom the patient sees on referral or by many consultations.

The content of the duty can be described as being to exercise reasonable care and skill in the provision of professional advice and treatment.

The Standard of Care

In relation to any person with some special skill, the applicable standard of care means conduct in the particular circumstances that would be followed by an ordinary skilled person exercising and professing

to have that skill. Another common expression is conduct that a reasonable and competent practitioner would have followed. The factual context is important. Although the standard is an objective one (i.e., it is a measure of what a reasonable practitioner would do, not what this particular practitioner would do), it will be adjusted to the exigencies of the relationship being examined. The standard will be that degree of care and skill reasonably to be expected of the hypothetical reasonable practitioner projected into the more precisely confined case.

This is usually the major area of contest in a medical negligence claim. It will usually be contested in two stages. The first is to establish what happened: what the patient and practitioner said or did. There will commonly be verbal and documentary evidence of these events and there may be differences in the memories of witnesses.

The second stage is the evaluation of whether what the practitioner said met or failed to meet the applicable standard of care. Often this will involve evidence of experts and expert opinion will usually differ. Reference to relevant guidelines is also likely. Compliance with them will be argued to be evidence that the relevant standard of care has been met and failure to comply will be argued to be evidence that it has not. (See Section 3.3 for further discussion on the use and status of guidelines)

Harm

The plaintiff must establish that she or he suffered harm. Further, that harm must be shown to be of a kind that a person could reasonably foresee would follow from careless conduct that is being examined in the claim. Evidence will need to be provided of that harm and this will usually be in the form of verbal accounts from the claimant and documents in the form of medical reports.

The measure of the compensation for that harm will include the out-of-pocket expenses for medical treatment, compensation for the pain and suffering experienced and often a component for both past loss of earnings and the loss of the future capacity to earn. Where a patient who has commenced a claim dies, the legal system permits the patient's estate to maintain that claim but only in a limited way. For instance, if a person whose claim arises from failure to diagnose cancer dies before judgment, the claim for general damages and for loss of future earnings cannot be maintained. The system also provides for claims to be made by close relatives of a patient for the loss that they have suffered because of the death of a patient.

In medical negligence cases, harm will usually be physical harm: physical injury to parts of the body or the onset of a preventable illness. In some situations, another form of loss has been claimed, usually referred to as the loss of a chance. There is some criticism of the result in the *O'Shea* case (Gerber, *Journal of Law and Medicine*, 2(4) May 1995 327-334) that all she lost was the chance of earlier treatment, a loss usually measured in lower damages than those she was in fact awarded. Dr. Gerber's

argument is that evidence in the case showed that the only harm that Dr. Sullivan's negligent conduct caused was that treatment was delayed by five months. However, the judge held that, had Dr. Sullivan not been negligent, Ms. O'Shea could have been completely cured. This meant that Dr. Sullivan (and Macquarie Pathology) were liable for all of Ms. O'Shea's damages. If, on the other hand, all she had lost because of their conduct was the chance of an earlier intervention which may or may not have resulted in a cure, then the defendants would be liable only for the extent to which she was worse off because of the delay. The court would have to hear evidence as to the statistical probability that such earlier treatment would have changed the outcome. This will be a complex calculation and one on which expert evidence will be necessary.

Where all that has been lost (as a result of the defendant's practitioners' conduct) is a chance of a better medical outcome, the court must calculate a degree of probability that such a better outcome would have been obtained and then discount an award of damages by that degree of probability.

Causation

The patient must establish that the conduct that fell below the applicable standard of care caused the harm for which she or he are claiming compensation. In simple terms, this will involve assessing whether that harm would have occurred but for the conduct in question and, as noted above, whether the harm is of a kind that a reasonable person who followed that conduct would have foreseen. Issues of causation in medical negligence cases can be complex and often depend on expert opinion.

In *O'Shea*, causation was established by proving that the condition that led to the patient's harm and death would not have done so had the defendant acted reasonably to undertake further treatment. By contrast, in *Anasson*, it was argued by the defendant that even if a Pap smear had been advised when the patient consulted the defendant, the hysterectomy she underwent and for which she sought compensation would still have been necessary and therefore the defendant's unreasonable conduct had not caused this loss. For the patient, it was argued that this loss of the child she was carrying when the hysterectomy had to be conducted could have been avoided if the defendant had acted with reasonable care and advised the patient in time for her to avoid conception. On appeal, the Federal Court decided that the defendant practitioner had not been negligent so, because one of the essential elements was not present, there was no liability and no need to resolve the dispute about causation.

The cases involving breast cancer show a similar range of outcomes as to causation. Even where a defendant doctor has been found not to have acted with reasonable care, as in *Stacey v Chiddy*, if the condition that the defendant failed to diagnose was not what caused the harm of which the patient complained, no liability will follow. In other cases, *Putnam v Huber* and *Talbot v Lusby*, liability was found because the condition that caused the patient's harm was not diagnosed due to the defendant's lack of skill.

2.2 Procedures

The procedures followed in medical negligence claims follow a course largely determined by the rules of the court in which the claim is commenced. The first formal step is the filing and service of a statement of claim. There will have been much previous activity by the patient and her or his representatives. Before taking this first formal step, the patient's lawyers will need to have satisfied themselves that there is sufficient evidence to support their client's case. This will be a judgement reached after reviewing such material as is available and this will usually not include material from the defendant practitioner or institution. That judgement is not that the case will certainly succeed, but only that there exists evidence that would, unless outweighed by other evidence, sustain the claim.

There will usually have been some exchange of correspondence between the patient and practitioner or institution or their respective legal representatives.

The statement of claim is a series of assertions of facts. In effect, the patient's lawyers are saying: if we establish that these facts occurred, a legal inference will follow that the defendant is liable for the damages claimed. In reply to this statement, the practitioners' lawyers usually request more details of the facts set out: what are usually called further and better particulars. The answers given are critical: the claimant can later be held to these answers and not permitted to go back on them.

The next formal step is the filing and serving of a defence by the practitioner's lawyers. This will usually be in the form of set of statements. Some of these will precisely deny statements made in the statement of claim and others will precisely admit other statements made there. Other parts of the defence will assert matters of fact that, if established, will show that some or all of the facts necessary for the patient to succeed cannot be established. In the majority of cases, no further formal documents are filed and it is accepted that the plaintiff "joins issue" with everything in the defence. This means that, between them, the statement of claim and the defence set out all of the questions of fact that the court is asked to decide.

These documents are usually referred to as the pleadings. They are crucial because by their exchange of assertion and denial, they set up the questions of fact that will be the focus of evidence at a court hearing. They are the first expression of the goal of the procedural rules: to define what the parties in the case will be arguing about. There are other procedures that assist this.

Of these, the most important are discovery of documents and interrogatories. Each party will commonly be requested by each other party to "discover" all documents relevant to the issues in the case that are in their power or control. Lists of documents are exchanged and then the documents on these lists made available for inspection. Some documents that appear on these lists can be withheld from inspection on grounds of what is called privilege. A common ground is legal professional privilege: that

is, documents brought into existence in client-lawyer interaction or for the dominant purpose of the litigation can be withheld. In simple terms, the idea is that justice is more likely to be served if clients are fully candid with their legal advisers and they will be so if they can be assured that what they provide will be kept for the purpose of advice.

Interrogatories are written questions directed at specific individuals that relate to the issues set up by the pleadings. Answers are on oath and become available as evidence. Their aims are to more closely define the issues in question and to save time in a court hearing.

Before a trial, the court will usually conduct a series of checks with the parties to monitor their progress toward a hearing, including the possibility of a settlement.

If the claim is not settled and a hearing commences, it will usually be before a single judge. The patient's case will be presented first by giving evidence that is designed to establish the statements of fact in the statement of claim. Evidence from individuals is given by their answers to questions, first by the lawyer for the side who called them as witnesses (called evidence in chief), then by the lawyer(s) for the other party(ies) (called cross examination) and often again by the lawyer who called them (called re-examination).

Sometimes documents are used in the course of these processes as a base for asking questions. Where these documents were made at the time of the events to which they relate, they will have considerable weight in supporting the version of facts that they record. Where they are cryptic or ambiguous, they will serve this purpose less well: their ambiguity may be a way of casting doubt on the accuracy of verbal evidence given by the person who made the document, whether clinical notes or some other document.

Documents, particularly hospital and medical records, can usually be accepted as business records without further verification through questions, particularly helpful where the maker of hospital records cannot be found. Not only the contents but the omissions from such documents can be important. It is commonly argued that the omission of an event from a record indicates that it did not happen.

There are many more detailed rules and practices concerning these procedures than can be usefully summarised here. There is one important observation that can be made. This is that the purpose of questions is to elicit answers that, being on oath, are evidence supporting facts. It may be sufficient to have a witness give an answer that casts doubt on a statement that they have previously made: it may not be necessary to compel them to decide which of two statements they think is true. Later, it will be possible to refer to such an answer as casting doubt on and so making less probable one aspect of

the facts. The test is which version of the facts is more probable: evidence that tends to the preferred version is useful.

Expert witnesses are the only witnesses permitted to express an opinion and indeed it is their opinion that is sought. They must be accepted as expert and this can be a source of contest if qualifications are challenged. A common example in medical negligence claims that relate to events that occurred in Australian cities many years ago is whether an expert witness (especially one from overseas) can speak as to the professional standards applicable in that city at that time. In questioning experts, all parties will be seeking to elicit answers that tend to support the version of facts that best advances their case or that cast doubt on the version that supports the other party. However, questions of experts are confined to issues that are addressed in the written report that is usually prepared by that expert and provided to the parties before the hearing.

The final stages of a trial involve each side summing up their case. These addresses are designed to persuade the judge to accept that the evidence, with all of its uncertainty, will best bear a meaning that supports that party's legal claim. It is in these addresses that the legal inferences are drawn from the facts established by the evidence. The addresses can take the form of providing the judge with a set of legal reasons, inferred from the evidence, which can be used to justify deciding the case in that party's favour.

2.3 Adversary System

Australian courts generally speaking operate under what is called the adversary system of dispute resolution. This is an historical adoption of the system developed over centuries in courts in England. There are some assumptions that mark that system that have significant effects on the roles of the parties and the courts.

The adversary system places the control of the proceeding in the hands of the participants. It is the parties who, by the drafting and exchange of pleadings, define what issues they wish to have the court decide. A defendant practitioner can choose to leave some elements relatively unexamined, preferring to rest her or his case on showing that one essential element, for instance, causation, cannot be established.

Consistent with this, it is for the parties and not the court to decide what evidence to bring. It is for the parties and, generally speaking, not the court, to challenge evidence or questions brought or asked by other parties. Such a challenge is an appeal to the judge to apply the rules, for instance to rule out irrelevant matter. The judge usually does not take on the role of intervening to enforce the rules or to keep proceedings on track.

These features means that there will constantly be a strategic element to how a claim is carried forward and defended. Often, pursuing a difference in accounts of a central fact (to find the best version) will not be as important as leaving a doubt that can be used to advantage.

PART B RECRUITMENT

Chapter Three: Common Law Responsibilities of Health Practitioners

3.1 Obligations of Health Practitioners in Relation to Tests for Screening Purposes

In 1991, a National Policy on Screening to Prevent Cervical Cancer was published by the Commonwealth Department of Health, Housing, Local Government and Community Services (now Health and Family Services) in association with a wide range of relevant organisations. The Policy states that routine screening with Pap smears should be carried out every two years for women who have no symptoms or history suggestive of cervical pathology. All women who have ever been sexually active should commence having Pap smears between the ages of 18 to 20 years, or one to two years after first sexual intercourse, whichever is the later. In some cases, it may be appropriate to start screening before 18 years of age. Pap smears may cease at the age of 70 years for women who have had two normal Pap smears within the last five years. Women over 70 years who have never had a Pap smear, or who request a Pap smear, should be screened.

Although the decision to undergo a Pap smear is the patient's, an important legal issue for health practitioners is whether there are circumstances in which they, in order to meet the relevant standard of reasonable care, should recommend or conduct a Pap smear. Some case law in Australia assists in answering this question.

In *Anasson v Koziol* (Supreme Court, ACT, 1996 and, on appeal, Federal Court 1997 unreported), the plaintiff patient consulted the defendant doctor for the first time and described to her the cessation of taking the contraceptive pill, not having had a period for a couple of months, two pregnancy tests that were negative, nausea and sore nipples. She said that she was concerned about these symptoms and that she wished to be pregnant. The defendant made a provisional diagnosis of post pill amenorrhoea and advised the plaintiff that if she had no further periods in the next two months, she should return for a referral to a specialist gynaecologist. The court also accepted that in 1987, when these events occurred, general practitioners knew that all women who were sexually active were at risk of cervical cancer, that the risk was at its peak between the ages of 40 and 50 years, that a Pap test was a useful method for preliminary testing for cervical cancer and that regular Pap tests every 18 months to two years were an appropriate way to guard against the risk. This was reinforced by published material in the Medical Journal of Australia in 1985 in which a Pap smear was recommended for all sexually active women. In this context, the trial judge said:

"In other words, I think that from what the plaintiff told her, the defendant should have been on notice that the plaintiff's problems might not have been as simple as post pill amenorrhoea, and a few more questions on the defendant's part would have then put the defendant on further notice that a full gynaecological history was required and that a recommendation for a Pap

smear was advisable. In this respect I conclude that the defendant failed to reach the standards appropriate to the ordinary and reasonable general practitioner in Canberra in 1987."

This conclusion of liability was reversed on appeal to the Federal Court. That court noted that the doctor was found negligent on the basis of expert evidence that, in the circumstances, she should have taken a full history that would have indicated that the patient was likely to contract cancer. The court analysed the conflicting expert evidence and concluded that, as a whole, it did not support the opinion on which the trial judge relied, and that that opinion was logically flawed. The patient was asymptomatic for cancer, so that the only basis for recommending a Pap smear would have been screening practice (and not diagnosis), having regard to the length of time since her last test. It was not necessary to take a full history from the patient to determine that. Further, the evidence was that opportunistic Pap smears were not taken by reference to the history of a patient.

The court concluded that the doctor had fulfilled her legal responsibility to the patient in relation to the problem for which the patient sought treatment. The court continued:

"That would not conclude that matter had it been recognised in the medical profession in 1987 that, when a woman presented with a gynaecological problem, a general practitioner should make an inquiry as to when a Pap smear had last been taken, and, if a smear had not been taken within the last 12 months or so, should recommend that one be obtained. In 1987, that was not the case. Whether it is presently the situation is not a matter which the Court is called upon to determine. The trial judge accepted that opportunistic Pap smears were not commonly practised by general practitioners in 1987."

The court also said:

"In rejecting the claim for negligence, we deal solely with the circumstance where the patient attended a general medical practitioner for the first time and did so for advice and treatment in relation to a specific condition. We have not considered what might have been the duty of Mrs. Anasson's regular general practitioners, the Scullin Medical Centre. Those practitioners had dealt with Mrs. Anasson for many years and knew her history. Because they were Mrs. Anasson's medical practitioners, their duty of care necessarily had a somewhat wider ambit than the duty imposed on a medical practitioner who saw the patient for the first time and in respect of a specific complaint."

These paragraphs underline the importance in all medical negligence cases of the court's focus on all the relevant presenting circumstances. Two important aspects are singled out. First, what is the state of general knowledge expected of the medical profession and second, the amount of knowledge a medical practitioner has of a patient. The first of those matters will usually be the subject of competing

evidence, as it was in this case. In relation to 1987, most of that evidence was from expert witnesses, both general practitioners and specialists. There was little evidence of published material indicating a state of awareness or practice. Now, in relation to cervical cancer screening, the existence of the National Policy, the extent of professional publications about cervical cancer, the degree of publicity on the matter and, indeed, the existence of Pap test registers, like the Pap Test Register, in most Australian states would be likely to make a significant difference. The existence of this material is one thing: its legal significance and weight relative to other evidence is another. The status of Guidelines is taken up in section 3.3 below.

The second matter underlines the importance of establishing precisely what is the relationship between a patient and medical practitioner. It is from relationships that duties of care arise and from which their scope is defined. The *Anasson* case makes it clear that what will be expected of a locum to discharge the duty of care to a patient may be less than what may be expected of that patient's regular doctor.

Some things have been clarified. The relevant obligation of a health practitioner is that of providing advice and information. In the *Anasson* case, the judge also observed that the question was whether the defendant should have tendered advice to the plaintiff in order that the possibility of cervical cancer might be investigated and early intervention initiated.

The judge in *Anasson* held that an aspect of *Rogers v Whitaker* (1992 175 CLR 479) applied to this question. By this he meant that medical practice alone would not establish negligence in providing advice or information. The High Court in *Rogers v Whitaker* said:

" . . . while evidence of acceptable medical practice is a useful guide for the courts, it is for the courts to adjudicate on what is the appropriate standard of care after giving weight to the paramount consideration that a person is entitled to make his own decisions about his life."

"whether a patient has been given all the relevant information to choose between undergoing and not undergoing the treatment is a . . . not a question ...the answer to which depends upon medical standards or practices. Except in those cases where there is a particular danger that the provision of all relevant information will harm an unusually nervous, disturbed or volatile patient, no special medical skill is involved in disclosing information, including the risks attending the proposed treatment. Rather, the skill is in communicating the relevant information to the patient in terms which are reasonably adequate for that purpose given the patient's apprehended capacity to understand that information." (175 CLR 479 at 489-490)

When does the obligation to advise or inform a woman about a Pap smear arise? None of the cases answer this question. However, the emphasis on the need to act so as to exclude the possibility, remote but even if at all possible, of cervical cancer (emphasised in the *O'Shea* case), and to act in the

knowledge of those women who are at risk and of the efficacy of regular Pap smears as a prevention (left undecided in *Anasson*, but of more force in 1997 because of the greater publicity of the National Policy) together suggest that the obligation to raise the issue of a Pap smear could arise as soon as a history indicates that a woman is sexually active and within the age of risk. Further, once a woman is in that risk group, it may be prudent for any health practitioner whom she consults to ask her about her Pap smear history and advise her accordingly if, according to the National Policy, a fresh test is or might be due. (It is here that a health practitioner's access to the Pap Test Register could be valuable in confirming a woman's test history).

Practitioners Questions

What obligations do I have in offering Pap smear screening to women who present to my practice?

As indicated in the previous section, the prudent approach is to give that advice to any patient whose history indicates she is sexually active and within the age of risk.

If I don't like doing Pap smears and recommend to my patients that they go elsewhere, for example, to another doctor, does this discharge my responsibility for making sure these women are screened?

The last part of the question overstates the responsibility of a practitioner. There is no authority that a practitioner has a responsibility to make sure that female patients are screened. The duty of care is to act as an ordinary skilled practitioner would in the situation. The Anasson case makes it fairly clear that the practitioner's obligation in issue is to advise and provide information about Pap smears. Provided that is done and, prudently, is in conformity with the National Policy, that obligation has been fulfilled.

3.2 Obligations in Relation to Tests for Diagnostic Purposes

Some cases have addressed the obligations of health practitioners in relation to Pap smears for patients who present with symptoms. In these situations, it has been clear that the purpose of a Pap test was diagnostic, usually to assist in determining whether the patient has cancer.

In *O'Shea v Sullivan* (Supreme Court NSW 1994), the question of the failure of Dr. Sullivan turned on what she did or did not do in the light of the symptoms, including the results of Pap smears. Some comments were made about the legal significance of Pap smears. After commenting on some of the expert evidence the judge said:

"In my opinion, in view of the false negatives, the mistakes which can be made in interpretation and the preponderance of eminent medical evidence it is not a test on which too much reliance should be placed if the diagnosis of cancer is under consideration."

The interpretation of test results and the consequent diagnosis and treatment of women at risk was the focus of *O'Shea's* case. There, the continuing symptoms of irregular menstrual cycles and post coital bleeding together with an abnormal Pap test result were said to put the doctor on notice that some further treatment was needed. Her failure to do this and, instead, maintain her alternative diagnosis and her view that cancer in a young woman was not a real possibility was a failure to reach the relevant standard of care.

In *Burnett v Kalokerinos*, (Supreme Court NSW 1995) no finding of failure to reach those standards was made in respect of the defendant doctor's failure to take a Pap smear when consulted by the plaintiff at a time when she was suffering vaginal bleeding. The court held that the doctor's decision not to take a Pap smear at a time when the patient was experiencing heavy bleeding was not a breach of his duty of care. (A finding of a failure to reach the relevant standard of care was made in relation to other conduct of the doctor).

The circumstances of the diagnosis and treatment of cervical cancer will vary infinitely. It will be necessary to assess that diagnosis and treatment against the relevant standard of care. It is clear from the decision in *Rogers v Whitaker* that the standard of care to be observed by a person with some special skill or competence is that of the ordinary skilled person exercising and professing to have that skill. In that case, the court addressed the question of how that standard is to be decided. The court recognised that, as a matter of general principle, it should not always be determined solely or even primarily by reference to the practice followed or supported by a responsible body of professional opinion. This was so even in the sphere of diagnosis and treatment, "the heartland of the skilled medical practitioner" where the patient's contribution was limited to the narration of symptoms and relevant history and the medical practitioner provides diagnosis and treatment according to his or her level of skill. However, the court said that whether a medical practitioner carries out a particular form of treatment in accordance with the appropriate standard of care *in any particular case* is a question to which responsible professional opinion will be influential, and could be decisive.

3.3 Conformity to Guidelines

The cases relating to cervical cancer screening and to breast cancer screening have arisen from periods of practice in the late 1980's when there were fewer (if any) published or definitive guidelines for practice. Those cases do not offer adequate guidance on whether such guidelines are measures of standards of care. Some, albeit slender, guidance can be found in decisions in other contexts.

In two cases that involved judgements about an impairment level and the safety of a procedure, courts have referred to relevant guidelines. In the first case, (*Bowles v Coles-Myer* 1995 1 VR 480) one question was whether a determination had been made under the Accident Compensation Act 1985, which limited recovery of compensation for injuries that were not "serious injuries." It was held that to decide whether an injury was serious, the decision maker would need to show a familiarity with a relevant guide, here, the Australian Medical Association Guide to the Evaluation of Permanent Impairment. In the second case (*Bacha v P and M Quality Smallgoods Pty Ltd*, Supreme Court NSW, unreported 1992) it was said that an application of the standard contained in Lifting Guidelines published by the National Health and Medical Research Council "...was indicative of the work being of an acceptable safety standard." The court later said:

"The issue to be determined is whether the defendant, as the employer of the plaintiff, was in breach of the duty of care it owed to him concerning the safety of the system of work which it provided. However, in determining this issue it is appropriate to have regard to guidelines such as those considered by the experts in this case."

In *Maiolo v Read* (Supreme Court NSW unreported 1997), in finding that the defendant doctor had not failed to meet a relevant standard of care, reference was made to guidelines. These were those published in October 1995 by the Australian Gastroenterology Institute to the effect that a biopsy was not indicated in a patient with dyspepsia but in whom no evidence of an ulcer was found on endoscopy.

There are clear statements that professional guidelines can be valuable in determining relevant professional standards of care in cases from the United Kingdom and New Zealand. In *W. v Egdell*, the United Kingdom Court of Chancery needed to determine the scope of a medical practitioner's duty to maintain confidentiality. The judge considered publications of the General Medical Council and said:

"These rules do not provide a definite answer to the questions raised in the present case as to the breadth of the duty of confidence owed by Dr. Egdell. They seem to me valuable, however, in showing the approach of the General Medical Council to the breadth of the doctor/patient duty of confidence."

The judge found that there was an exception to the general duty, that is, that confidential information could, in some circumstances, be disclosed in the public interest. This had been recognised in the General Medical Council's guide and was accepted as a defence in the case.

In *Furniss v Fitchett*, the New Zealand Supreme Court said that although the ethical code of the British Medical Association could not create new common law duties, that code was evidence of the general professional standards to which a reasonably careful, skilled, and informed practitioner would conform.

Although there is no definitive finding of the weight of practice guidelines, it seems plainly arguable that their existence will be relied upon in any contest about the conduct of a health practitioner and their content is likely to be weighty evidence of what is considered prudent practice. Opposing sides will seek to interpret guidelines so as to support their arguments, of either compliance or breach, and it will be the nature of those documents that they will not provide definitive conclusions in all cases. Further, where those guidelines relate to matters of the provision of advice or warnings, it will be always arguable that the guidelines should not be the sole determinant of what is reasonable care, but have only a relative weight to other circumstances.

Chapter Four: The New South Wales Pap Test Register

4.1 Outline of Operation of the Pap Test Register

In NSW, health practitioners providing Pap smears have certain obligations related to the NSW Pap Test Register. This is a brief note on the establishment and operation of the Pap Test Register. More detailed discussion of these provisions appears where relevant in the following sections. Reference there to statutory sections are to sections of the Public Health Act 1991 (NSW), unless otherwise indicated.

The Pap Test Register commenced operation on 29 July 1996 and is authorised by amendments to the Public Health Act 1991 (NSW), sections 42E to 42P. The legislation plainly authorises the establishment of the Pap Test Register, either by the Director-General or by virtue of a contract or arrangement with another person (section 42F).

The object of the Pap Test Register is to reduce the incidence of, and mortality from, preventable cervical cancer. In simplified terms, the Register operates by receiving and recording the results of laboratories' examination of specimens. The specimens are provided by health practitioners who have conducted a test that is commonly known as a Pap smear. The results of the test, identifying information of the laboratory that conducted it, the health practitioner who provided the specimen, and certain other specified data, are also recorded on the Register. Identifying particulars, defined as a woman's full name, any previous name and residential or postal address are also recorded unless a woman elects not to have these recorded.

This information on the Pap Test Register is then to be used to provide reminders to women who do not have another test within a reasonable time, to assist in linking all test results for each woman, to monitor test rates, to provide information (not including identifying particulars) to the public, health practitioners and laboratories, the State Department of Health and the Commonwealth. These uses are designed to fulfil the statutory object of the Pap Test Register, namely, to reduce the incidence of and mortality from preventable cervical cancer. The information will include identifying particulars only

where it is provided to the woman concerned, to her health practitioner, to the person in charge of the laboratory engaged to examine a specimen taken from her or with her consent. To ensure that the data is received by the Pap Test Register, there are obligations on laboratories and health practitioners who carry out tests to report in a specified manner. Health practitioners are also required, before either taking a specimen from a woman or conducting a test, to provide certain information about the Pap Test Register to the woman. After they take specimens from a woman for the purpose of a test, health practitioners must include certain information on a test request form.

4.2 Implications of Statutory Obligations for the National Policy

The objects of the National Policy and of the Pap Test Register are similar: to reduce the incidence of and mortality from preventable cervical cancer. Central to their achievement is the regular undergoing of Pap smears and tests by women in the risk group. If the legislation contains any disincentives for women or health practitioners to undertake Pap smears, the objectives will be obstructed rather than fostered.

The present legislation was preceded by a different proposal in which health practitioners were to be subject to a significant penalty for failing to inform women of the Register as part of the then policy of an opt-on register. There remain penalties for health practitioners in the current legislation, but these are for failing to report a test or failing to convey advice of a woman's election to withhold her identifying particulars. There remains a duty on health practitioners to inform women of the Register, but failure to do this does not result in a penalty. There may continue to be some confusion about the obligations of health practitioners in relation to the Pap Test Register and the consequences of not fulfilling them. To the extent that this is an obstacle to timely Pap smears and tests, clear advice on the obligations of health practitioners needs to be provided.

Chapter Five: Statutory Duties of Health Practitioners

5.1 Duty To Inform Women of Pap Test Register

Health practitioners, before they take a specimen or conduct a test, are required (by section 42P) to "provide the woman concerned with details of:

- (a) the object of the Register, and
- (b) the information that is recorded on the Register, and
- (c) the purposes for which that information may be used, and
- (d) the way in which the confidentiality of the register is protected."

This obligation is related to the recognition of a woman's right to opt off the Pap Test Register and also

to the recruitment of women to use the Pap Test Register. There is no definition of what would constitute sufficient “details” for the purpose of section 42P. However the object of the Pap Test Register can be stated simply and unequivocally as it is in section 42G; that is to reduce the incidence of, and mortality from, preventable cervical cancer.

Practitioners Questions

How can I be penalised in relation to the Pap Test Register? How are these penalties enforced?

Practitioners can be penalised for three matters:

1. *failure to report a cervical cancer test for inclusion on the Register*
2. *failure to note on a pathology request form that a woman has elected to withhold her identifying particulars from the Register or*
3. *providing those particulars to anyone for inclusion on the Register.*

The Public Health Act provides that offences are prosecuted in a Local Court. Accordingly, penalties would be imposed following a formal proceeding alleging a breach of the Act.

Does the Pap Test Register absolve me responsibility for following up patients with abnormalities?

No. The Pap Test Register provides reminders to women that their next test is overdue... In response to a request in writing, the Pap Test Register will advise a woman who has not elected to withhold her identifying particulars of her test result.. Health practitioners retain a duty of care to advise and treat their patients, including advising of test results, follow-up and the management of abnormalities.

Information recorded on the Pap Test Register can be set out in the following list as it is in section 42H(1), with some minor simplification of sub-paragraphs (e), (g) and (h). For instance, the pamphlet used by the Pap Test Register does this reasonably well, but omits the content of sub-paragraph (e) and (f). Section 42H specifies that the Pap Test Register is to contain the following information in relation to a cervical cancer test:

- (a) the identifying particulars of the woman who had the test,
- (b) her date of birth
- (c) the date of the test
- (d) the result of the test
- (e) an indication of whether the test was carried out:
 - (i) because the woman had symptoms that warranted investigation, or
 - (ii) as a routine measure only,
- (f) the identification number of the test,
- (g) if the test consisted of a pathological examination of a specimen taken from a woman:

- (i) the name, address and identification code of the health practitioner by or on whose behalf the relevant pathology request form was submitted, and
- (ii) the identification code of the laboratory that examined the specimen,
- (h) if the test was a test, or a test of a class, prescribed by the regulations:
 - (i) the name, address and identification code of the health practitioner who carried out the test, and
 - (ii) such clinical information as the regulations may prescribe

The uses to which the information can be put can also be listed, with some simplification of the language used in section 42I(1): a reminder service, a record of past tests, to monitor rates and patterns of cervical screening, and to provide information for public awareness, quality control and research.

The final requirement is complex: providing details of the way that confidentiality of the Pap Test Register is protected is not a simple task. This is the first use of the word "confidentiality" in this Part of the Act. It is a term of legal significance that relates to contractual or fiduciary relationships in which certain obligations arise as to use of information provided in the course of those relationships arise. Here, it would be simpler and legally more accurate to speak of the ways in which a woman's information privacy is protected. This would begin with notice of a woman's right to elect to withhold her identifying particulars: an important element of privacy protection. There would need to follow information about how information on the Pap Test Register, excluding identifying particulars, can be used. Thereafter, the protection of privacy depends upon statutory controls on government employees and common law obligations on employees of other organisations which maintain the Pap Test Register. This is not simple. If compliance with this present notification obligation is a disincentive for health practitioners, it risks a lower rate of Pap smears and prejudices the achievement of the object of the Pap Test Register.

The importance given to respecting a woman's choice to withhold her identifying particulars (by the imposition of statutory offences for failing to respect that choice) would be more clearly reflected if subparagraph (d) referred to a woman's right to elect to withhold her identifying particulars.

Further, it needs to be made clear to women and, according to section 42P, probably by health practitioners, that it is only their names and addresses that can be withheld from the Pap Test Register: everything else is recorded whatever the women's opinions. Using the word "confidentiality" in this context risks significant misunderstanding and consequent risk of incompletely informed decisions by women as well as statutory offences by health practitioners who act on advice, given under section 42M, that is confused.

Legislation in other Australian jurisdictions varies markedly from that in NSW. In only the Northern

Territory and Victoria is there an obligation similar to that in section 42P. In the Northern Territory, a health practitioner is required, at the time of taking a specimen, to

"inform the woman

- (a) about the existence of the Register, the purpose of the Register and the nature of the details that are to be recorded in the Register;
- (b) that she may refuse to consent to the details in respect of her being recorded in the Register;
- (c) that the details in respect of her will be provided to the Chief Medical Officer so that they may be recorded in the register unless she refuses to consent to the recording of the details in the Register, and the woman shall consent, or refuse to consent, to the recording of the details in respect of her in the Register."

(Public Health (Cervical Cytology Register) Regulations, reg. 6(1))

In Victoria, section 62 (4) of the Cancer Act 1958 provides that a person who makes an examination or takes a specimen from a person to determine whether that person is suffering from cancer, before a report is forwarded

- (a) must ensure that that other person has been informed of the right to object to the report being forwarded; and
- (b) if aware of an objection by that other person, must ensure -
 - (i) that the report includes notice of the making of that objection, and
 - (ii) that the written acknowledgment of the objection is given to the other person."

In all other jurisdictions, a woman has the right to withhold information from a register (usually ALL information relative to her, not merely identifying particulars) but health practitioners have no statutory duties to inform women about the register. If these provisions achieve satisfactory levels of use of registers and the New South Wales provisions create difficulties for health practitioners, some process of clarifying that obligation needs to be set up.

Where a health practitioner fails to comply with section 42P, a woman's right to elect whether or not to withhold her identifying particulars will be less informed than it should be. If, as a result, more women withhold their identifying particulars because they are concerned about or confused by the health practitioner's explanation, the object of the Pap Test Register will be compromised and it will be less comprehensive as a reminder. Further, where a health practitioner finds it difficult to comply with the disclosure obligation, this may be detrimental to the level of trust in the relationship between practitioner and patient. In relation to a condition as sensitive and serious as cervical cancer, such an outcome should be avoided.

The development of a simplified statement of these matters and an understanding that use of that

statement would satisfy the statutory duty may be an appropriate step. Reaching that understanding may be complicated by need for health practitioners to recognise the difference between conduct that satisfies the statutory obligation and conduct that fulfils a common law duty of care. It would need to be clear to them that using an agreed statement was to meet the former obligation.

Where the practitioner's records show that a woman has previously been provided with details of the Register, all that is required to be disclosed is to remind the woman of her right to have her identifying particulars removed from the Register. (section 42P(2)). There is no penalty for failing to fulfil this obligation.

Where those records do not indicate that information has been previously provided, the practitioner is required to also inform the woman

- (a) that she may elect to have her identifying particulars withheld from the Register, and
- (b) that is she does so elect, she may have those particulars removed from the Register at any time later (Section 42P(3)).

It seems that in this situation, all the details have to be provided as well as these reminders about identifying particulars. There is no penalty for failing to fulfil this obligation.

Practitioners Questions

When I am taking a Pap smear, what happens if I forget to mention the Pap Test Register?

There is a statutory duty to tell a woman about the Register but no penalty for failing to do so.

What do I tell women about the Pap Test Register? In what form (verbal, written, posters in my waiting room, etc.) do I have to give this information?

As set out above, the Act requires practitioners to "provide details" about the object of the Register, what is recorded on it, for what that information can be used and how its confidentiality is protected. There is no specification of how this is to be done. While written material may be adequate, a prudent practice would be to check verbally if the woman has seen and read that information and note this in her records. This is because of the different requirements of disclosure where practitioner's records show that a woman has previously been provided with details (see above).

Do I have to talk about the Pap Test Register before every Pap smear?

Not at any length. After you have provided the details about the Register once and recorded this in your records, all that is required is to remind the woman of her right to have identifying particulars removed from the register.

PART C THE TAKING OF PAP SMEARS

Chapter Six: Common Law Responsibilities of Health Practitioners

6.1 Duty of Care in Advising About Pap Smears

The duty of care of health practitioners includes a duty to inform patients of material risks of procedures or treatments. Any health practitioner, in taking a Pap smear, will be subject to a legal duty of care to inform the patient of the nature of the procedure and of its material risks and to conduct that procedure with reasonable care and skill. (Health practitioners must, in addition to their common law duty, disclose the information required by section 42P. This was discussed above in section 5.1.)

Material risks are of two kinds: those that a reasonable patient would consider important and those which a practitioner knows or ought to know a particular patient would consider important. Often, a patient will show, by their questions or conduct that certain risks are significant for them. The obligation is applicable to the conduct of Pap smears.

The case law in relation to cervical screening does not offer precise guidance as to what would be material risks in relation to a Pap smear for screening purposes. The test itself would appear to carry few risks. The consequences of declining to undergo the procedure will be more important, even where it is for screening purposes only. Health practitioners would be expected to be familiar with at least the National Policy and its justifications.

One of the risks of a Pap smear is that it may be unsuccessful in that the smear will be unsatisfactory, due to inadequate appropriate cells. Although there is no specific authority for a practitioner to disclose this, it seems clear such a well recognised risk should be disclosed. It is essential to explain whether the test is a screening test or related to symptoms. This will have to be passed on to the laboratory in compliance with sections 42K(4) and 42H. Information about the full range of test results could be offered and reliance on the National policy or the related Pap Smear Test Results: A Guide for Women with An Abnormal Pap Result (1995, DHFS) would be prudent.

It is well established that in 10% of women with the disease, the Pap test will be incorrectly reported as negative. The presence of this risk could be disclosed before the Pap smear is undertaken (although it is strictly not a risk of the smear procedure) and should be if a question is asked about it. The risk of such inaccurate results should preferably be disclosed at the time that the test results are notified together with appropriate advice about particular symptoms that might warrant further investigation.

Practitioners' Questions

I know that Pap smears are not perfect, but how much do I have to explain this to the woman?
As indicated above, the risks of unreliability and the need for repeat smears ought to be disclosed.

I know that the Government recommends two yearly smears, but some people tell me that women should have them every year. Whose advice is safest?

The answer rests on the basic legal duty to provide such advice as a reasonable competent practitioner would. The National Policy provides a ground for that reasonable advice and one that has greater weight than less formal opinion. Circumstances in a particular woman's history may be other reasonable grounds for advising a greater frequency of smears.

6.2 Duty of Care in The Taking of Pap Smears

The taking of the Pap smear itself is a procedure to which the standards of an ordinary competent practitioner apply. The discussion of the establishment of standards of care in chapter 2 is relevant here, as is the discussion of guidelines in section 3.3. The National Policy contains what appears to be a clear and specific guide to taking a Pap smear and a prudent practitioner would be aware of and be guided by that document.

Practitioners' Questions

I don't take Pap smears very often, do I have any obligations for learning or improving my techniques?

As indicated above, the normal standard of the ordinary competent practitioner would be applicable to any practitioner professing the capacity to take a Pap smear. To the extent that training is necessary to meet that standard, it would be prudent.

My laboratory tell me that smears have to show endocervical cells to be adequate and recommend repeating the smear if they are not present. I know that it is difficult to get endocervical cells in all women. Will I be found negligent for not giving the laboratory a good sample?

An appropriate response to a test report of absence of endocervical cells but otherwise negative is to advise repetition of the smear in two years. Liability for negligence will only follow when all the elements of negligence are established. Obtaining a smear that lacks endocervical cells may occur even where reasonable care has been taken. Further, liability would not arise unless such a smear was shown to be causally related to later harm. Trials have failed to show that increasing the proportion of smears with an endocervical component is associated with an increase in the detection of high grade abnormalities. (NHMRC Guidelines for the Management of Women with Screen Detected Abnormalities, pp 14-15)

Chapter Seven: Statutory Duties of Health Practitioners

7.1 Duty to Convey Information to Laboratories

Section 42K(4) requires a health practitioner who takes a specimen from a woman to ensure that a pathology request form in relation to that specimen has adequate information. That amount of information is defined as being as much of what is required by the section to be included in a report from a laboratory as it is in the power of the health practitioner to provide.

The information that could be conveyed includes all that listed in section 42H because a report is required to include this. A health practitioner will not have in her or his power information as to the date of the test, (i.e.. the date of examination of the sample by the laboratory to which the sample is being provided), the result of the test, the identification number of the test or of the laboratory. However, the health practitioner will usually know a woman's name (and previous names), address, date of birth and whether the test is to be done because symptoms warranted it or only as a routine measure.

A pathology request form that complies with the Act by stating the purpose of the test will commonly confirm what has already been recorded in the health practitioner's notes.

7.2 Withholding of Identifying Particulars: Notification Duties of Practitioners

Section 42O(1) requires a health practitioner, to whom a woman has made an election to withhold her identifying particulars from the Pap Test Register, to note the pathology request form accordingly and not to provide those particulars to any person for inclusion in the Pap Test Register. In simple words, the laboratory must know that the identifying particulars are not to be passed on to the Pap Test Register. The section is subject to a penalty for breach. The Pap Test Register kit provided to health practitioners contains a supply of notification stickers to be attached to request forms.

If a woman so elects, this does not relieve a health practitioner from providing those particulars to the laboratory as required by section 42K(4). This will of course enable the test result to be linked to the woman when it is provided to the health practitioner by the laboratory. Section 42J authorises the disclosure of that result and the identifying particulars to the woman concerned or to her health practitioner or, with the woman's consent, to someone else. The section authorises disclosure by "a person", so permitting disclosure by a health practitioner, a laboratory or, when the woman has not elected to withhold her identifying particulars, the Pap Test Register. This appears to be a straight forward set of legal controls. However, if, as a result of the change in legislative policy from an opt-on to an opt-off register, there remains confusion among health practitioners about their statutory obligations, this needs to be clarified. It will be particularly important to clarify that there is no penalty for not informing a woman of the existence of the Pap Test Register (although there is a duty to do so), but there are penalties for not reporting a test and for not reporting a woman's election to withhold her identifying particulars.

Practitioners Questions

If a woman does not consent to being recorded on the Pap Test Register, how should I record this in my notes and do I need her to sign anything? What are my obligations and are there any penalties for not doing this?

As indicated above you will need to record this on the pathology request form. It would also be prudent to make the same note in your records. Although there is no statutory requirement for the woman to sign a form, the Pap Test Register kit provided to practitioners contains a useful form to be signed by the woman recording her election to withhold her particulars. Part of the form is designed to be retained by the practitioner and part by the woman.

Chapter Eight: Quality Assurance

8.1 Use of Data for Quality Assurance Purposes

Section 42I provides that information on the Pap Test Register is to be used to monitor rates and patterns of cervical cancer tests to assist in planning and evaluation of test programs and to assist health practitioners and laboratories to monitor their quality control procedures in relation to cervical cancer tests.

The use of this information seems capable of identifying the frequency of Pap smears conducted by a practitioner, the percentage of Pap smears that are reported to be unsatisfactory or other indications of ineffective conduct of tests. There is no provision in this part of the Act preventing disclosure of information in such a way as to identify any practitioner without her/his consent (as there is in the ACT regulations).

Laboratories are likely to choose to conform to the National Standards. These include a provision (paragraph 4.2) that laboratories provide smear takers with a summary of smear results at least annually, including the number and proportion of unsatisfactory smears and those with an insufficient endocervical content. The rate of unsatisfactory smears or those lacking sufficient endocervical cells will be a typical quality assurance outcome and, properly used, may lead to improvement in practice where the rates indicate an unsatisfactory level of performance in taking smears.

Release of information by the Pap Test Register for quality assurance activities by health practitioners or laboratories may also risk disclosure of information detrimental to their reputation or to their conduct in particular situations. Where such quality assurance activities are conducted by approved committees by a prescribed establishment, then section 20D of the Health Administration Act (NSW) will protect such disclosure.

PART D TESTS OF PAP SMEAR SLIDES

Chapter Nine: Common Law Responsibilities of Health Practitioners

9.1 Advice About Automated Cytology

The cases concerning cervical screening relate to standards of practice in Australia in the late 1980's, a time before there were nationally published standards for screening for cervical cancer. In the absence of those standards, it was argued and accepted that medical practitioners were expected to be aware of professional teaching and discussion concerning the desirability of mass screening for the purpose of detecting cancer early enough to lower mortality rates. With such awareness and presented with the pattern of symptoms, practitioners were found to have an obligation to take steps to confirm or exclude cancer.

Since 1991, there have been nationally published policies on screening to prevent cancer of the cervix. It would seem to be clearly arguable, on the basis of the decided cases, that an awareness of these policies would now be expected and, further, that conduct not in conformity with them would arguably fail to meet the relevant standard of care.

The published policies (and later documentation) do not distinguish between conventional and automated cervical cytology. Would a practitioner increase her or his risk of not meeting the requisite standard of care if, knowing it was available, they chose not to recommend automated cytology? Generally, a practitioner would discharge his or her duty of care by sending samples to a laboratory that was accredited to examine Pap smears by a recognised method.

However, the decided cases show that it is difficult and probably unwise to answer such a question outside the context of a patient's symptoms. However, it is important to explain why this is so. The issues in the decided cases have been whether, in the light of the pattern of symptoms, a Pap test should have been recommended or whether, in the light of either a normal or an abnormal Pap test result *together with a pattern of other symptoms*, some further tests should have been recommended. The reliability of Pap tests has not, of itself, been a decisive issue and the fact of false negative results has been recognised. What was legally significant was the recommendation by a medical practitioner of steps, if any, to be taken by a patient in the light of all the symptoms including the test result, whether negative, abnormal or positive. Accordingly, whether a test is conducted by automated or conventional methods, the result is not an isolated fact on which alone a determination of conformity with legal standards will be made. There will be a medically relevant context. The nature of a practitioner's judgement as to further steps, if any, to be taken in that context (including the test result), measured by the standard of care expected of the reasonable, competent practitioner, will remain an important legal issue in claims that negligence in treatment by a medical practitioner has caused harm in the form of the development of cervical cancer.

Practitioners Questions

There is a lot of publicity about automated cytology. I have heard that I am obliged to offer this technology to my patients when they are having Pap smears. Can I be sued for not mentioning/suggesting/offering/recommending this technology?

Failing to do so would lead to liability only if all the elements of negligence were otherwise made out. One of these would be a failure to meet the applicable standard of care as to advice about cytology. That obligation is to provide such advice as a reasonable, competent practitioner would do. There is currently no ground for regarding advice about automated cytology as part of that reasonable standard.

Does it matter which laboratory I send my smears to? How much effort do I have to put in to assessing the quality of a laboratory. Can I rely on Government inspections to tell me a laboratory is competent or registered?

A practitioner would be wise to ensure that Pap smears were sent to a laboratory that was registered with the National Association of Testing Authorities and that participates in accreditation with the Royal College of Pathologists, Australia. As regular procedures of quality assurance and inspection develop, laboratories will be provided with annual reports of their performance measured against national standards.

Chapter Ten: Statutory Duties of Health Practitioners

10.1 Statutory Duty to Report on Tests

Health practitioners who carry out a cervical cancer test are required to provide a report to the Director-General of Health (or the person with whom the Director-General has arranged to maintain the Pap Test Register) within 30 days, incorporating defined information in an approved form (section 42K(3)(5)). The information to be included in the report is listed in section 42H. Where a woman has elected to withhold her identifying particulars (defined as her full name and any previous name and residential or postal address), that information must not be disclosed in the report (section 42O(1)(b)). Both the requirement to provide a report and the prohibition on including identifying particulars where a woman has elected to withhold them carry statutory penalties.

The prohibition on disclosing identifying particulars arises from a woman "advising" the health practitioner that she does not want to be identified in the Pap Test Register. (Section 42M) No formal mechanism is provided for this advice. By contrast, if a woman at a later time requires her identifying particulars to be removed from the Pap Test Register, this must be done in writing. Because a statutory liability will follow the failure of a health practitioner to act on a woman "advising" her or him, it may be prudent to record a woman's election to withhold her identifying details in writing. The Pap Test Register kit sent to

health practitioners contains a two part form to be used to record a woman's election to withhold her identifying particulars.

Chapter Eleven: Common Law Duties of Laboratories

11.1 The Standards of Care in Conducting Tests

There is now no doubt that there exists a sufficient relationship between a woman who provides a specimen and a laboratory who examines that specimen to found a duty on the part of the laboratory to exercise reasonable care and skill in examining and reporting on that specimen. (*O'Shea*)

The definition of what is a reasonable standard of care and skill would be approached through the conventional principles of the law of negligence. These require conformity to a standard of a reasonable and competent member of that class of person or, in this case, laboratories. The decided cases in which the conduct of laboratories has been questioned have occurred when no published standards for laboratories existed, as they do now. In those cases, it was necessary to rely upon expert evidence as to what a reasonable laboratory would have done. However, in *O'Shea*, the conduct of the laboratory fell so clearly below a relevant standard of care that there was little need for definition and little discussion of such a standard.

The current existence of the accreditation Requirements and the National Performance Standards offers a source of definition of a reasonable standard of care. The status of such standards cannot be stated unequivocally, but can be inferred from the status accorded to other guidelines and standards. The matter of the status and weight of guidelines is discussed in paragraph 2.3 above. It follows that a prudent laboratory will be aware of these standards and establish systems to demonstrate that the laboratory is being conducted in conformity with them.

The issues that arise here also affect the quality and accuracy of the report that the laboratory provides to a woman's health practitioner and the report required to be submitted to the Pap Test Register.

11.2 Automated Cytology

Expertise in medical science continues to develop and so, in response, do relevant standards of care to be expected of practitioners. However, whether a new practice is the measure of a relevant standard of care will be matter of evidence and acceptance within the relevant professional group. The legal standard remains that of the ordinary competent laboratory. It would follow that until the standard for an ordinary competent laboratory was the use of automated cytology and the professionals who are expert in testing acknowledged that new standard, automation would not be mandatory.

However, in relation to two computerised, automated devices approved by the Food and Drug Authority, the American Society of Cytopathology has stated recently that "additional studies to determine the effectiveness and cost of these devices are essential. Presently, computer-based automated screening devices should not be considered proven standards or practice in cervicovaginal cytology." This is of course not presented as definitive. However, to the extent that a standard of practice can be relied upon, some more positive support for automation would be necessary before it becomes the required standard of care.

Chapter Twelve: Statutory Duties of Laboratories

12.1 Duty to Report on Tests

Persons in charge of laboratories which carry out a cervical cancer test are required to provide a report to the Director-General of Health (or the person with whom the Director-General has arranged to maintain the Pap Test Register) within 30 days, incorporating defined information in an approved form (section 42K(3)(5)). The information to be included in the report is listed in section 42H. Where a woman has elected to withhold her identifying particulars (defined as her full name and any previous name and residential or postal address), that information must not be disclosed in the report (section 42O(1)(b)). Both the requirement to provide a report and the prohibition on including identifying particulars where a woman has elected to withhold them carry statutory penalties.

12.2 Duties in Relation to Identifying Particulars

Section 42O(2) requires a person in charge of a laboratory who receives a pathology request that bears a note that the woman concerned has elected to withhold her identifying particulars to ensure that the laboratory does not provide those particulars to any person for the purpose of their inclusion in the Pap Test Register. Consistent with the importance accorded to the protection of this right to opt-off, there is a penalty attached for failure to conform to this obligation.

As noted above, laboratories will be informed of the identifying particulars of all women who have provided specimens for testing. Those details would have been provided to a health practitioner on the basis that the relationship between the woman providing them and the practitioner imposes a duty of confidentiality on the practitioner in relation to that information. It would be clear to a laboratory that, on receipt of the information, it is similarly subject to duty of confidentiality and to use that information only for the purpose for which it was provided. Those purposes include conducting a test of the specimen and reporting the result of that test to the health practitioner. If a woman withholds her consent to be included on the Register she does not necessarily preclude the laboratory from conducting its own follow-up procedure by communicating with her. She may still receive reminders from that source. As noted below in section 13.1, the accreditation requirements for laboratories could be read

to require such a system. However, if laboratories began the practice of such follow up it may lead to an increase in the number of women who withhold identifying particulars from the Pap Test Register, on the basis that they can be followed up (in relation to abnormal test results) without having to further disclose identifying particulars.

Chapter Thirteen: Quality Assurance by Laboratories

13.1 Use of Pap Test Register Information for Quality Assurance Purposes

One of the uses of information on the Pap Test Register is to provide it to laboratories to assist them to monitor their quality control procedures. The national Performance Standards for Australian Laboratories (the "Standards") and Requirements for Gynaecological (Cervical) Cytology published by the National Pathology Accreditation Advisory Council (the "Requirements") both refer to the need for constant quality control procedures. Laboratories will already have data provided from health practitioners, including identifying particulars, which will be necessary for some of these procedures, especially checking accuracy of negative cytology reports. Additional information can be provided to laboratories by the Pap Test Register for these purposes, but cannot contain identifying particulars.

Conduct of quality assurance procedures may disclose practices that are defective and are in need of improvement. Because of the perceived risk of this disclosure, there is legislative provision under section 20D of the Health Administration Act 1982 for limitation of compulsion of disclosure for approved quality assurance committees set up by, generally speaking, hospitals, area health services and establishments prescribed by regulation. If laboratories are to be similarly protected, they would need to be part of a prescribed establishment and to have set up a quality assurance committee that conforms to the statutory provisions. Prescribed establishments are listed in a schedule to the regulations under the Health Administration Act. Among the prescribed establishments is the Australian Institute of Medical Laboratory Scientists, which may be a body that could attract the protection of the legislation for relevant laboratory quality assurance procedures.

It appears that laboratories, in order to comply with the Requirements and the Standards, need to conduct quality assurance procedures. Compliance will be a prudent course of conduct on the basis that the Requirements and the Standards are likely to be evidence of the relevant standard of care and should reduce the risk of adverse events occurring. However, in the absence of statutory protection from disclosure, this may lead to the production of reports and evaluations of performance that would be available for production in court proceedings.

The Requirements include at 9.4.1 a requirement that laboratories have a follow-up system or use a cytology registration follow-up system for all patients with an abnormality which is mild dysplasia (CIN 1) or worse. Laboratories which do not establish a follow-up system for such patients risk allegations

that they have not conformed to an appropriate standard of care as evidenced by the Requirements. It is not clear whether a follow-up system that relies upon advice to health practitioners will conform with the Requirements. If not, laboratories may consider that they need to conduct their own follow-up system. Women who have not elected to withhold their identifying particulars from the Pap Test Register whose test result falls into this category would receive both a reminder from the Pap Test Register and a follow up from a laboratory. It would be highly important for these to be consistent in their advice. Women who elected to withhold their identifying particulars from the Pap Test Register and whose test results fall into this category may only receive a follow up from a laboratory. The protocol on Reminder and Follow-up adopted by the Pap Test Register provides reminders to women outside the time periods recommended in the National Policy, in order not to duplicate, but to complement, other reminder systems.

PART E NOTIFICATION OF RESULTS

Chapter Fourteen: Common Law Duties of Health Practitioners

14.1 Notification of Results

It is clear from Australian cases on cervical cancer that a failure to notify a woman of abnormal Pap test result is actionable (*Morton v Jools* 1991 Australian Torts Reporter 69150), (*Sharples v Northern Territory*, Supreme Court, Northern Territory unreported 1988) and can lead to professional discipline (*Ison v Northern Rivers Area Health Service*, Industrial Relations Court, unreported, 1997). However, the reports of the first two of these cases show only that a cause of action was available. Their outcomes have not been reported.

This obligation would be part of the general duty of care of a health practitioner to a patient. As part of the practitioner's relationship with a patient whose Pap smear the practitioner had submitted to a laboratory, there would be a duty to inform her of the result. Fulfillment of that duty would require a practitioner to take reasonable steps to inform a woman of her test results. The issue is similar to that discussed in section 17.2. Although prescriptive guidelines cannot be laid down, actually advising all test results, whether negative, abnormal or positive (and not only when abnormal) is prudent. Where advice is verbal, some recording of the content of that advice would also be good practice. Reasonable steps would include at least telephone or postal advice to the last known number or address.

The majority of the High Court in *Rogers v Whitaker* stated that the aspect of the duty that related to providing information about material risks was subject to a therapeutic privilege, that is, a privilege to withhold information on therapeutic grounds. The court did not explain or give examples of what circumstances would merit withholding information. On existing Australian authority (*Battersby v Tottman* (1985) 37 SASR 524), it would only be where the harm resulting from disclosure was clearly greater than the harm from non-disclosure that such a privilege might be available. The risk of harm to a woman of being informed of a positive Pap smear test result is, by contrast, clearly far less than the risk of harm to her of not being informed of such a result.

14.2 Abnormal Test Results and False Negatives

There are now recommended Guidelines For The Management of Women With Screen Detected Abnormalities (Department of Health and Family Services, 1995). Section 3 of those Guidelines contains recommendations as to the evaluation of the different categories of test reports. The Guidelines acknowledge that there will be some test results that are inconclusive and further investigation is recommended unless there is an obvious reason for the diagnostic difficulty. Equally, there will be reports that the smear was technically unsatisfactory and repeat of the smear is recommended in 6 to 12 weeks. The Guidelines provide a sound basis for addressing most test results, assuming that laboratories follow the recommendations.

It is clear from *O'Shea's* case that health practitioners will be expected to be aware of the fact of false negative results. Accordingly, in determining what advice to give or what course of treatment to implement, Smart J said, in that case, that a Pap smear

"is not a test on which too much reliance should be placed if the diagnosis of cancer is under consideration"

The last clause in this sentence is perhaps the most important. Where, as in that case, there were symptoms for which cancer might have been a cause, reliance on a Pap test result would probably not be sufficient to establish that a health practitioner had acted with reasonable care.

In cases involving breast cancer, there has been some discussion of false negatives from mammography. There, additional and more reliable tests in the form of ultrasound, fine needle biopsy and open biopsy are available. The cases involved reliance on mammography for diagnostic and not screening purposes and make clear that practitioners are expected to be aware of and take into account in their decision making the likelihood of false negatives. Nonetheless, the possibility of false negative mammograms does not automatically mean that an ultrasound needs to be arranged. In *Talbot v Lusby*, it was noted that although the defendant doctor knew that, in circumstances like those of the patient, false negative rates for mammography were as high as 10-15%, there was no expert evidence that suggested

"...that the known false negative rate of mammograms ought to lead to the automatic use of ultrasonic scans whenever a negative result was reported in a woman with dense breasts."

In *Stacey v Chiddy* (Supreme Court NSW, unreported 1993), it was noted that the defendant was aware of high rates of false negative test results for mammography and did not attach much weight to that test. The defendant doctor did arrange an ultrasound which was also negative. However, where, within a week of the mammography test results, a breast lump remained palpable, the court said that

'..a significant degree of suspicion should have remained regarding the issue of the breast lump.'

The correct course of action was to review the lump during the next month and, if it remained, refer the patient to a surgeon. Instead, the defendant doctor told the patient to return in about three months: too long a period in the light of the persistent lump but despite the negative test results.

It therefore seems clear that false negative tests results are a known risk of Pap tests. This would be a material risk in the sense outlined in section 6.1 above and so should be disclosed either at the time of the Pap smear or when the test result is notified. However, the presence of that risk alone does not warrant advice that the test should be immediately repeated. If there are other symptoms that, taken together with the negative tests result, might tend to suggest that the test result was in fact inaccurate, prudence would suggest advising a repeat smear within a short time.

A health practitioner's knowledge of the possibility that a negative test result is false is one factor to be taken into account in assessing whether, in all the circumstances and particularly all the patient's symptoms, the practitioner acted with reasonable care. Where cancer is a possible diagnosis for those symptoms, reliance on a negative Pap smear result alone would not meet the applicable standard of reasonable care (on the basis of *O'Shea's* case). In these circumstances, advising some further investigation, including a repeat Pap smear test, would be needed to meet that standard of care.

Chapter Fifteen: Common Law Obligations of Laboratories

Practitioners' Questions

If I forget to pass on a Pap smear result to a woman, can I be sued?

Such conduct would fail to meet the applicable standard of care, but liability would only follow if all the other elements of negligence were established. For instance, the woman would have to show that she had suffered harm because of your oversight.

I insist that all of my patients come back to me to discuss their results whether they are normal or abnormal. I am worried however about the Health Insurance Commission saying that I am overservicing but I am more worried about patients not getting their results. Is this overservicing? *The Guidelines for Management of Women With Screen Detected Abnormalities emphasise that a woman must be informed of options and should be involved in decision making. Where test results are abnormal, such recommended conduct would not be overservicing. Where the test results are normal, their two yearly frequency and any other aspects of the patients condition may also justify a conclusion of not overservicing.*

15.1 Standards of Care in Reporting

There are now national standards for reporting of these tests. Conformity with these standards is likely to be important for laboratories to the extent that the standards are a measure of a relevant standard of care. It will be important to ensure that the Pap Test Register's requirements for reporting do not conflict with the national reporting standards. From discussion with the administrator of the Pap Test Register it is understood that standard reporting arrangements are in place for laboratories to provide reports to the Pap Test Register.

Of more importance is whether there is a duty in law on laboratories to so report. *O'Shea's* case provides an example of assessment of the duty of care of laboratories. In that case, it was alleged and found that Macquarie Pathology had failed to exercise reasonable care in examining and reporting on the slide. As a result, Ms. O'Shea's treatment was delayed, a delay that led to her not being cured. The

allegation was that the laboratory had failed to observe that the relevant slide contained atypical cells and failed to so report and advise that the plaintiff should seek further medical investigation. The negligence was in the defective examination and resulting erroneous report, not in failing to report.

It is clear that there is a duty to report any test results. From the way in which *O'Shea's* case was argued, however, it seems that a laboratory can fulfil this duty by informing the health practitioner of the test result and that once this is done, there is no longer any duty to report to the woman concerned. The report that will fulfil that duty need not only to be accurate but also clear and not misleading as to the opinion of the cytologist. Against this is the ground contained in the National Requirements (discussed in section 13.1) for an obligation, as part of a quality assurance process, to follow up women who have some categories of abnormal test results.

15.2 Abnormal Test Results and False Negatives

Research and practice reveals that a percentage of false negative results are, in the nature of the procedures, unavoidable. (Mitchell, Diagnostic Accuracy of Community Cytology Screening Programs, *Journal of Law and Medicine*, 1(3) Feb 1994 156-160) On this basis, it has been recommended that the law in Victoria be amended to provide that a false negative result will not of itself be evidence of negligence. (Legal Liability of Health Service Providers, Law Reform Committee, Parliament of Victoria, May 1997 at 28-38 Parliamentary Committee Report). Even without such a legal change, an argument that one false negative result was, of itself, evidence of negligence would be challenged by expert evidence that these results can occur even with all reasonable care and skill. In order to establish a failure to exercise reasonable care because of false negative test results, more evidence as to the manner in which the laboratory conducted its testing would be needed. Here, the extent to which that conduct did or did not conform to national standards would be important.

The "Standards" contain recommended performance measures, including a measure of accuracy of negative reports. The measure would involve re-screening of specimens originally reported, within the previous 24 months, as negative from women with a histological report of CIN 3. Assistance of a cytology register is accepted as necessary and it is acknowledged that no external validation is provided. There seems good legal reason to support the regular adoption of such a measure. It would provide a laboratory with evidence it has taken all recommended steps to reduce the incidence of inaccurate test results (especially those that were negative) so that, in the face of an allegation that a test was inaccurate, there will be a basis to argue that this did not result from negligence.

If a test result is wrong, causing the Pap Test Register to provide an untimely reminder, there is a statutory provision that protects the individual adviser from liability in the event that a woman suffers harm, e.g. by delaying further tests and losing the chance of preventive treatment. It follows that a

failure by the Pap Test Register to notify or advise a woman appropriately, a failure which arises from an incorrect test report, will not lead to liability for the Pap Test Register. Therefore claims by the Pap Test Register against laboratories to recover loss suffered by the Pap Test Register's liability to a woman will not follow. However, a woman might seek compensation from a laboratory that provided that incorrect or misleading information to the Pap Test Register which led in turn to a late Pap Test Register reminder whose timing was such that she suffered harm in not being put on notice early enough to take preventative or therapeutic action.

Chapter Sixteen: Statutory Duties of Laboratories

16.1 Duty to Disclose Test Results

Section 42K(1) requires a laboratory to provide a report containing the prescribed material when it carries out a cervical cancer test. The test is defined in section 42E to be a test carried out to determine whether or not a woman has cervical cancer or any of its precursors and consists of a pathological examination of a specimen of any kind taken from a woman. It is clear that laboratory examination of Pap smear slides falls within this definition.

The report is to be provided within 30 days of the conduct of the test, must contain prescribed information and must be in an approved form. There is a penalty for not complying with this obligation. Subsection (2) contains a defence to a prosecution that a report did not contain information which it was not within the power of the laboratory to provide. The information to be included is that listed in section 42H. It is clear that some of this information can only be provided by a laboratory if it has been provided by a health practitioner. This would include the purpose of the tests, whether on specimens from a symptomatic woman or as a routine measure and the identification code of the health practitioner. There is a corresponding duty in section 42K(4) for health practitioners who take specimens to provide in a pathology request form such of the information required for a report as it is in their power to give.

There is a second statutory obligation that underlines the importance of a woman's election to withhold her identifying particulars from the Pap Test Register. In section 42 (2), a person in charge of a laboratory who receives a pathology request noted that identifying particulars are to be withheld from the Pap Test Register must ensure that those particulars are not provided to anyone for inclusion on the Pap Test Register. A penalty is prescribed.

There are some laboratories which provide reports to the Pap Test Register on a voluntary basis as they are situated outside NSW and are thus not technically bound by the provisions of the Act. It may be prudent to enter into formal arrangements with these laboratories subjecting them to contractual obligations in the same form as those in the Act. This would protect those New South Wales women on whose behalf the non-resident laboratories conduct tests.

16.2 Misleading and Deceptive Conduct

One of the arguments between the health practitioner and the laboratory involved in *O'Shea's* case was that the inaccurate report provided by the laboratory amounted to false and misleading conduct which had led in turn to a loss by the practitioner. The outcome of the argument was that the loss that the practitioner had suffered had been caused by her own negligence and not by any conduct on the part of the laboratory. As this causative link was essential to the success of the claim under the Trade Practices Act, this claim failed. However, it was acknowledged in the appeal court that the question of whether a false test report was misleading and deceptive conduct was a "lively question". Further, there was discussion on the relevance in such a claim of the plaintiff's conduct. The argument merits discussion.

Section 52 of the Trade Practices Act 1974 (Cth) provides that a corporation shall not in trade or commerce engage in conduct that is misleading or deceptive or is likely to mislead or deceive. Section 82 of that Act provides that a person who suffers loss or damage by conduct of another person that was done in contravention of a provision of Part IV or V may recover the amount of the loss or damage by action against that other person or against any person involved in the contravention. There is a three year limitation period on the commencement of such an action.

The discussion in *O'Shea's* case would support the possibility that a false report of a test would be misleading or deceptive conduct or conduct likely to mislead or deceive. This cannot be taken to have been decided conclusively, for the reasons noted. The critical question will be whether a woman can establish that she suffered her loss "by" that conduct. In *O'Shea's* case it was noted that a claimant's own negligence or unreasonable behaviour may be relevant to showing whether conduct did in fact mislead or deceive. It needs to be shown that the conduct complained of operated in some way as an inducement or influence on the conduct of the claimant: that she had relied on a false report from a laboratory and this misled her into not taking any further action for such a period that she lost the chance of preventing cancer or some other loss. The full medical spectrum of symptoms would also need to be examined, as these would all be relevant to her decision to rely on the test result. Despite these uncertainties, it must be accepted that this basis of liability for a laboratory is tenable.

Further, it would seem not to matter whether the false report was provided to the woman via the Pap Test Register, direct from the laboratory or through the woman's health practitioner, provided that she relied on the test result and not, for instance, on advice from her health practitioner. For liability to be established under the Act, the false report would need to be shown to have been the factor influencing her action.

PART F MANAGEMENT OF WOMEN WITH ABNORMAL TEST RESULTS

Chapter Seventeen: Common Law Obligations of Health Practitioners

17.1 Standards of Care

There would be no question that addressing the appropriate treatment for a woman whose test results were abnormal would be part of a health practitioners' general duty of care as described above. The standard of care would be that of the reasonable competent practitioner. The standard would be different for a specialist gynaecologist or oncologist than for a general practitioner because of the different levels of skill that each professes.

The *O'Shea* case did involve considerations of appropriate professional conduct. The important conclusion was that Dr. Sullivan should have taken full account of all of Ms. O'Shea's symptoms and not placed too much reliance on a test result. The cases have not addressed circumstances where there has been a failure to respond appropriately to an abnormal Pap test result (other than failure to inform the results in *Ison v Northern Rivers Area Health Service*). Nor have the cases addressed the question of the extent of follow up that would be expected.

17.2 Guidelines

With regard to deciding and advising on a course of conduct in response to an abnormal test result, the Guidelines for the Management of Women With Screen Detected Abnormalities will be important because of their status, their publication and their prescription. Health practitioners should be familiar with what these guidelines recommend in two areas. First, practitioners need to know the standards for test reporting and what each test report means. Secondly, the course of advice and treatment recommended in response to each of the categories of test report. These are clearly set out in Parts 2 and 3 of the Guidelines.

The Guidelines recognise that general principles of evaluation and management require that:

- the woman must be informed of the options for evaluation
- the woman should be able to participate in decision making
- treatment methods will depend on expertise and modalities available to the clinician as well as the attitudes and preferences of the woman.

The emphasis on practitioner discretion is a recognition that the features of each individual case will vary and should be decisive and that no guidelines can ever cover all the possibilities. However, to have given consideration to the Guidelines as the first stage in approaching advice and treatment will be a sound step in meeting an applicable standard of care. Though the Guidelines cannot be a complete recipe for all clinical decisions, they provide a recognised set of initial considerations. To have given

them consideration before reaching a decision about advice and treatment (and maybe to have recorded that fact) will be, legally speaking, good practice.

The Guidelines recognise that adequate follow up is essential and that both women and practitioners should accept responsibility for follow up. However, there is no specific prescription of what is required. A legal assessment begins with the basic principle that in this, as in all other professional conduct, the applicable standard is that of the reasonable competent practitioner. Notification of the test result is necessary and, in conformity with the Guidelines' recommendations about consultation, advice about options and involvement in decision making, a face to face consultation seems clearly warranted.

Practical difficulties will arise where patients have moved or no longer consult the practitioner who now has the test result. Reasonable steps would need to be taken to communicate that test result. These should, for caution, involve more than sending a letter to a last known address. The resolution of these difficulties lies however in preparing for the possibility and acting on the recommendation in the guidelines that part of the responsibility for follow up remains that of the woman. Establishing a procedure for contact at the time that each Pap smear is conducted would be a prudent start. No recipes can be definitively given. The significance for the woman of knowing that a test result is not negative will be a factor in determining what amounts to reasonable care. A test result of CIN II or CIN III merits prompt advice and decision and extensive efforts to make contact. A laboratory report of abnormality of uncertain significance and recommendation for retesting in three months probably requires the same response. On the other hand, in response to a report of a low grade abnormality, less urgency may still be reasonable conduct.

In on-going follow-up treatment, involving referral to specialist care and recommendations for periodical review or testing, the Guidelines again emphasise that both the woman and the practitioner should accept responsibility. There are reasonably specific recommendations in Part 4 that would serve as a first guide to sound professional conduct. For the practitioner, careful documentation of the stages of recommended care, the advice to the woman, particularly that concerning the implications of not having the abnormality treated and of her decision will be important.

Practitioners Questions

The Pap Test Register recently sent me a reminder about a patient I saw last year who needs a repeat Pap smear. I don't see this patient any more. Whose responsibility is it to follow her up now?

The Guidelines referred to above suggest that some responsibility remains with you to take reasonable steps to see that the reminder reaches her. What will be reasonable steps will depend on what you know of her condition as well as her whereabouts.

I am aware of the NHMRC Guidelines about management of women with abnormal Pap smears. Sometimes my laboratory tells me one thing, for example, they recommend a repeat smear for an inflammatory smear in three months, whereas the Guidelines say 12 months. Whose advice should I follow?

The Guidelines, although having a national status, make it clear that they cannot prescribe for every situation. They also make it clear that it is your discretion and judgement that should be decisive, while informing the patient. All that is clinically relevant about that patient should be considered before reaching your decision on the advice to give and treatment to recommend. Caution in the face of uncertainty or competing advice, in favour of earlier retesting is probably legally prudent.

How much effort do I need to go to in tracking down a woman with a normal/abnormal result?

The discussion above has attempted to respond to this question.

I am aware of the NHMRC Guidelines about management of women with abnormal Pap smears. The Guidelines tell me that all women with any grade of CIN should be referred for colposcopy and biopsy. In my town, there is only one gynaecologist who does not believe in colposcopy. What obligations do I have to ensure that my patients get managed according to NHMRC Guidelines?

The Guidelines make it clear that the responsibility for advice and treatment is a matter of practitioner's discretion and emphasise the importance of informing the woman concerned of all the options and involving her in a decision. A full discussion of these matters, including whether the local specialist offers colposcopy, with the patient and reaching a decision on treatment would be an appropriate response to the Guidelines. They are a guide to approaching treatment

After treatment, the gynaecologist that I refer patients to usually advises patients to come back to me for repeat follow up Pap smears. I worry that I may lose track of these patients. Am I responsible for their follow up? If they get lost to follow up, am I responsible or is the gynaecologist? *Section 4 of the Guidelines for Management of Women With Screen Detected Abnormalities set out a useful statement of the respective responsibilities of specialists, referring practitioners and women. They recommend that the specialist inform the referring doctor of follow up procedures and the woman of the importance of follow up. The referring doctor should then be aware of what is expected of the woman and, in the event that she does not conform, contact her to make her aware of the implications of no treatment. Specification, explanation and information about follow up are thus the responsibility of the specialist; attending to that follow up of those woman is shared, to the extent of alerting the woman of the implications, by the referring practitioner.*

I have received follow up letters from the Pap Test Register. One states that the last cytology report for a patient of mine recommended that she have a further Pap test and that the Pap Test Register has not recorded another test for her. The letter says that a reminder will be sent to that woman if a Pap test has not been received within three months. Another states that the Pap Test Register records show that a patient of mine should have attended for further investigation and possibly treatment after her last Pap test and that the Register has not received a cervical histology result for her. The letter says that a follow up letter will be sent to the woman within four weeks unless I advise the Register that such a reminder will be unnecessary or inappropriate. A questionnaire is attached for me to complete. What should I do? Can I ignore the letters?

Both letters serve as reminders that patients of yours were recommended to undertake either a further Pap test or further investigation. The responsibility to ensure that the need for further testing or investigation is known to your patients rests with you, as the Guidelines referred to above make clear. Prudent practice will involve recording the steps that have been taken to fulfil those responsibilities. Your records will probably record what steps you have taken in relation to women about whom the Pap Test Register sends you letters. Retaining those letters and your response to them, which will confirm the steps you have taken, will assist you to demonstrate that you have fulfilled your responsibilities to your patients..

17.3 Laboratories

The Guidelines do not recommend that laboratories have a role in the follow up of women who have screen detected abnormalities, beyond recommending that a uniform set of test results is adopted.

Where laboratories implement quality assurance measures as part maintaining their relevant standards of conduct, they may contribute to a follow up process. However, the scope of the a laboratory's duty of care to women whose specimens they test is essentially to use their reasonable care and skill in examining that specimen and providing a report. It seems unlikely that this duty would include a follow up obligation.

PART G OPERATION OF THE PAP TEST REGISTER

Chapter Eighteen: Provision of Information to Women

18.1 Reminders to Women About Tests

Section 42I provides that information in the register is to be used, among other things, to remind any woman who does not have a further cervical cancer test (or other appropriate investigation or treatment) within a reasonable time after a cervical cancer test that a further test (or investigation or treatment) is recommended.

There is no definition of a reasonable time. The importance of this lies in the conjunction of the object of the Part as set out in section 42G with the language of 42I, particularly the verb "is", rather than "may". That is, the object of the Pap Test Register is to reduce the incidence of and mortality from preventable cervical cancer. One of the uses of information on the Pap Test Register that will assist in achieving this object is to provide reminders to women, hence this is a use in 42I. But those reminders will only contribute to achieving the object if they are timely. The timeliness of a reminder will vary according to the result of the previous test: if that test result was normal, then reliance on the National Policy would support a reminder shortly after two years have passed since the previous test. Where that earlier test is not normal, then a reasonable time may be significantly shorter, as short as six months.

Section 42I(2) protects the Pap Test Register and the people responsible for it from any liability that they might otherwise have for failing to provide appropriate reminders or advice to women in relation to any matter concerning the Register. The statutory immunity provided by section 42I(2) is a broad one, and legal liability will exist only if it can be shown that the people concerned were not acting "in good faith." In other words, it would be necessary to establish not merely negligent conduct in the management of the Pap Test Register and the reminder system, but a deliberate and wilful disregard for appropriate procedures.

The immunity in section 42I(2) is consistent with the overall purpose of the Pap Test Register to act as a back-up or safety net, and not as a substitute for the obligations of health practitioners to ensure that their patients receive appropriate follow-up. The practical effect is that any legal liability for a failure to provide appropriate reminders and follow-up for women undergoing cervical screening will rest primarily with the treating health practitioners, and possibly also the laboratories, rather than with the Pap Test Register.

18.2 Access By Women to Information on The Register:

Although the conventional fulfillment of the notification of results stage of the screening pathway will be filled by the report from a laboratory to a health practitioner and from her to her patient, some attention is appropriate to the right of access available to a woman in relation to her test results.

(a) Under the Public Health Act

Information about women is recorded on the register through reports either by laboratories (section 42K(1)) or health practitioners (section 42K(3)), whether with or without identifying particulars.

Section 42J authorises a person to disclose test results and identifying particulars to the woman concerned, to her health practitioner, to the laboratory engaged on her behalf to examine a specimen taken from her, for the purpose of a reminder to her or to link her tests with her health practitioner and laboratory. The details may also be disclosed if permitted or required under a court order or in accordance with regulations (which have at this stage not been made). The practice has developed of responding in writing to a woman's written request for her test results.

However, this Act does not grant a woman a right of access to the entry of her cervical test results on the Pap Test Register, but only authorises the disclosure of the information to her.

(b) Under the Freedom of Information Act

The Pap Test Register probably falls within the definition of a public authority under the Freedom of Information Act 1989 (NSW) so that a right of access to documents held by it is granted (s.16). This is subject to the authority being exempt from the operation of the Act where it is specified in Schedule 2 (which the Pap Test Register is not) and to the document being exempt, where specified in Schedule 1. Documents are exempt (except to the person they concern) because they contain "matters the disclosure of which would involve the unreasonable disclosure of information concerning the personal affairs of any person (whether living or deceased)". The Pap Test Register would not be exempt on this ground because it contains information concerning the person by or on whose behalf an application for access to the document is being made. The Pap Test Register may however be a document that is exempt because it contains matter "the disclosure of which would found an action for breach of confidence or which would otherwise disclose information obtained in confidence and could reasonably be expected to prejudice the future supply of such information to the Government or to an agency, and would on balance be contrary to the public interest."

It appears that, under this Act, a woman has a right of access to her test results on the Pap Test Register but that no-one else has.

18.3 Information and Advice Provided to Women by Those Conducting the Register

Those maintaining the Pap Test Register are frequently asked for advice on matters, e.g. whether a woman over 70 or one who has had a hysterectomy should continue having Pap smears or what a Pap test report means.

Providing a copy of the data on the Pap Test Register to a woman to whom that data relates conforms to the Act and provides the same degree of access as would be available under the Freedom of Information Act, but more informally. There seems no legal reason to alter this practice. There are risks of providing incorrect information or mismatching test results, laboratories or health practitioners, but these are no different from those attending the identification of women for reminders. Under the present arrangements for the Pap Test Register, section 42I(2) would be a defence to claims for compensation arising from such errors.

Providing advice in addition to data does raise further considerations. There is no doubt that the general principles of negligence regarding advice apply to private as well as to government instrumentalities (*Shaddock & Associates v. Parramatta City Council* 1980-1981 150 CLR 225). Those principles can be summarised in the words of Mason J (as he then was) from p. 250 of that report:

"...whenever a person gives information or advice to another upon a serious matter in circumstances where the speaker realises or ought to realise that he is being trusted to give the best of his information or advice as a basis for action on the part of the other party and it is reasonable in the circumstances for the other party to act on that information or advice, the speaker comes under a duty to exercise reasonable care in the provision of the information or advice he chooses to give."

Of these criteria, it would be strongly arguable that advice of the kind that is sought is on a serious matter and that the speaker would know that they are being trusted to give their best information or advice for action by the inquirer. However, there may be some doubt as to whether in the circumstances it is reasonable for the inquirer to act on the advice. Where the advice is provided by a person who is not a health practitioner and the advice involves more than repeating the content of national guidelines on Pap smears, then it may well not be reasonable for the inquirer to act on the advice. If so, no duty of care would result so that even if the advice was careless and wrong and harm resulted from reliance on it, no liability would follow. The provisions of section 42I(2) may also be a defence, although there could be argument as to whether giving advice is "acting for the purposes of this Division".

Prudence suggests a more cautious policy requiring those maintaining the Pap Test Register to provide women only the information relating to them that is on the Pap Test Register together with what is contained in published guidelines about test results or the management of women with abnormal results. Although it has been argued that there may be no duty of care in relation to advice on the part of those maintaining the Pap Test Register, it would be prudent to confine advice narrowly. Advice should be

confined to the recommendation that women seek advice from a health practitioner on the interpretation of her test results or whether she should continue having Pap smears.

18.4 Access by Health Practitioners to the Pap Test Register

Section 42J authorises disclosure of tests results and identifying particulars to, among others, a woman's health practitioner. Access to a patient's test history as recorded on the Pap Test Register is likely to be valuable, not only to remedy any failure in a patient's memory but to inform a practitioner's judgement. At least a practice of releasing information to health practitioners in response to their requests, accompanied by a woman's consent to identify her to be a patient of that practitioner, should be implemented.

A further step that might give to the Pap Test Register additional value for health practitioners would be to grant them a right of access to the information on the Pap Test Register that relates to their patients, subject to obtaining a patient's consent. A patient with an abnormal test result can present a health practitioner with difficult medico-legal choices about advice and treatment. One of the causes of these difficulties is uncertainty as to a patient's history of Pap test results. The Pap Test Register could provide a reliable history, especially in relation to a new patient. At present, health practitioners face a legal obligation to provide advice and treatment with reasonable care and depend for the information on which they must exercise this judgement on their patient's memory. While this is the situation in ordinary health care practice, the availability of reliable information on the Pap Test Register could reduce the risk of reaching an unformed judgement. A right of access could be presented as a positive contribution to the medico-legal climate in which health practitioners now practice

18.5 The Use of the Information on the Pap Test Register and Public Health

The language of section 42I may be such as to mandate the use of information on the Pap Test Register to achieve the object set out in section 42G. Identifying particulars on the register can be used for:

- providing reminders
- linking results of tests, health practitioners and laboratories
- monitoring rates and patterns of tests to assist in planning and evaluation of test programs

There is no specification as to who can so use the data, but the sense of the legislation is that the State can do so. Reference is made to the provision of data to the Department of Health (section 42I(1)(d)(iii)), but this would be necessary where, as now, the Pap Test Register is being maintained under an arrangement. Where data is used for the third of these purposes, there is uncertainty as to whether identifying particulars can be used (see 19.1 and 19.2).

If use of Pap Test Register information for any of the first three uses is mandatory, it may be that the

other uses that must not involve identifying particulars are similarly mandated. While this may be an unwarranted interpretation, it appears to be a result of the importance of mandating reminders as one use of the Pap Test Register data and including all other uses in the same section. This is avoided in some other jurisdictions, of which the clearest example is the ACT (see Public Health (Cervical Cytology) Regulations ACT reg 7(1), (2) & (3)).

18.6 Access by the Pap Test Register to Laboratory Records

The Act does not contain a reference to the right of the Pap Test Register or of the NSW government to access to the records of a laboratory. The practice by which laboratories provide reports pursuant to section 42K(1) is electronic via an access computer on which are placed test reports. The Pap Test Register then accesses these computers and down loads the reports to the register.

The emphasis given in the Act to ensuring that a woman's election to withhold her identifying particulars from the Pap Test Register makes it appropriate that the Pap Test Register have no other access to a laboratory's records.

Chapter Nineteen: Regulation of Information Privacy

19.1 Information Privacy

The legislation permits information on the Pap Test Register to be used for five specified purposes. Of these three purposes (to monitor rates and patterns of cervical cancer tests; to assist in planning and evaluation and to provide information about screening for reasearch) the disclosure of identifying information is either expressly prohibited or is otherwise not permitted under the Act. It is taken that these uses would not impinge on a woman's information privacy.

The remaining uses, in which a woman's privacy could be said to be at risk are:

- to remind a woman about her next test
- to link a woman with her test results and health practitioner(s), and
- to monitor rates and patterns of tests to assist in planning and evaluation of test programs

These uses appear not to risk an infringement of a woman's information privacy in that they do not involve disclosure of her identifying particulars beyond those responsible for maintaining the records to produce reminders and record links. Further, section 42O(3) prohibits a person who has reason to believe that a woman has elected to withhold her identifying particulars from including them on the Pap Test Register.

The statutory prohibitions on government employees disclosing any personal information acquired in the course of their employment would be applicable, where relevant, and the common law obligations of employees not to disclose information that they know to be confidential would apply where the Pap Test Register is being maintained by another organisation. Privacy protocols have been implemented by the present organisation responsible for the Pap Test Register.

Section 42J authorises disclosure of test results and of identifying particulars with the written consent of the woman. This disclosure is presumably limited by the uses of the information of the register in section 42I. These include some uses of information not including identifying particulars, namely, provision of information to the public, to health practitioners and laboratories, to the Department of Health and to the Commonwealth and for use in a database for research. It is not clear whether it is intended that a woman's consent can override these restrictions. For instance, can a woman consent to her personal details being used for research or does the form of the legislation limit research to a database of unidentified information? Other states contain clearer provisions regarding the use of information from the register, including identifying particulars, for research. Some provide that agency approval of research is a condition precedent to such use of data. (Public Health (Cervical Cytology) Regulations (ACT) reg 7(4), Public Health (Cervical Cytology Register) Regulations (NT) reg 4(e)(iii); health Act 1937 (QLD) section 154M).

19.2 Identifying Particulars

These are defined as a woman's name and any previous name and her post and or residential address. A woman's election to withhold these only means that this information is not recorded on the Pap Test Register. Unlike some other jurisdictions, she cannot refuse to have her age, her test results, with linked data of her medical practitioner, laboratory and reason for test recorded.

Even if women exercise their right to elect to have these identifying particulars withheld, there may be sufficient data on the record to identify groups according to demographic, socioeconomic or cultural factors. These may well be valuable data for research that would form the base for programs that would promote the object of the Pap Test Register. If such group identification is possible without individual identifying particulars, should this be disclosed to women?

The election to withhold identifying particulars is assumed to be made in the course of a consultation with a health practitioner (section 42M) in which a woman will be provided with information about the Pap Test Register (section 42P). The means of establishing that such a choice has been made is not well defined. This may be a response to the preceding legislation in which a written election to opt-on was required and this was subject to some criticism. However, there is a lack of definition in both the information to be provided and the manner in which an election is to be exercised. The Pap Test Register kits supplied to health practitioners contain a form in two parts: one that is signed by the

woman and retained on the health practitioners records, the other provided to the woman. Such a procedure does clarify that the election has been made and assist in establishing this fact in the event of a dispute.

19.3 NSW Information Privacy Code of Practice

The NSW Health Department Privacy of Information Committee published the first edition of this code in 1996. The Code is consistent with the approach taken under the Commonwealth Privacy Act which encourages the development of guidelines to cover specific areas of practice. One of the key objectives of the Code is to protect the privacy of patients by ensuring that only information which is necessary to provide care or services is collected (2.2). It also contains provisions dealing with the use, disclosure and storage of personal health information.

The Code applies to all employees and other health workers in the public health system who, in the course of their work, have access to personal health information. This includes doctors, nurses and allied health staff (including visiting service providers); administrators, clerical and service staff; and technical, scientific and laboratory staff. (3.1).

The Code covers personal health information which is in the possession of the Department of Health, or any public hospital, Area Health Service or associated organisation (3.2). Personal health information is defined in the Code as “information which concerns a person’s health, medical history or past or future medical treatment and is in a form that enables or could enable the person to be identified”. (1)

To this extent, the Code provides guidance on the appropriate standard of privacy governing activities in the public health sector. It is detailed and fairly comprehensive in its application, and provides a useful addition to the provision of the Public Health Act. (NSW) relating to confidentiality.

Chapter Twenty: Access to information Held by Health Practitioners

20.1 Access by Patients

Section 42J(1) permits a person to disclose, in conjunction with the result of a cervical cancer test, the identifying particulars of a woman to the woman concerned. The section thus authorises the Pap Test Register to fulfil the reminder function referred to in section 42I(1)(a). The section also permits a health practitioner to inform a woman of her results. However, the section does not give to a woman a right of access to information held by a health practitioner.

Patients have limited legal rights of access to medical information about their treatment. The *Freedom of Information Act* gives patients a right to information held by public hospitals. The records of private

doctors, private hospitals or pathology laboratories, on the other hand, are not subject to the *Freedom of Information Act*.

It is NSW Health Department policy that patients be given access to their medical records. As a result very few patients need apply for access under the Freedom of Information Act within the public health system. The Private Hospitals and Day Procedure Centers Act and regulations contain mechanisms for patients to obtain copies of their medical record in the private sector. Where a hospital refuses to give access there is a right of appeal to the Director-General.

A patient's common law right of access to medical information from a private doctor was considered in the High Court of Australia's decision in *Breen v Williams* (25/1996, September 1996) where it was held that a patient had no proprietary right in her medical practitioner's records. It was considered that records created by a doctor remained his or her private property. An interesting question arises as to whether diagnostic or screening test results sent to a doctor form part of the doctor's property. There is a strong argument that a doctor cannot prevent a patient from gaining access to these test results.

Whatever the uncertainties of the common law may be, it is clear that a practitioner has a duty to inform a patient of an abnormal Pap smear result. Failure to take reasonable steps to ensure that an abnormal Pap smear result is brought to the attention of a patient is negligent. Whether the negligence supports a claim in damages, however, depends on whether the information, had it been known, would have probably resulted in a course of action which would avert injury. The practitioner should be left in no doubt, however, that an abnormal Pap smear result needs to be acted upon. A practitioner has a common law duty - and the patient has a corresponding common law right - to information regarding her abnormal Pap smear result.

Chapter Twenty One: Other Issues

21.1 Categories of Practitioners

Health practitioners relevant to this paper are those who take specimens from women for the purpose of cancer tests or who conduct those tests. These include medical practitioners and some nurses, particularly women's health nurses. In the course of preparation of the paper, it became apparent that the context in which some of these professionals worked differed in relevant ways from registered medical practitioners. This section notes these differences.

Most women's health nurses are qualified by training to provide Pap smears. However, because they cannot be reimbursed for their services through the Medicare arrangements, this being available only to medical practitioners who hold provider numbers, these nurses provide their professional services in clinics funded by the State. The standards of accreditation that determine which nurses can provide

certain services vary so that in some clinics or centres, women's health nurses cannot conduct Pap smears but they can in others. Further, there are other related procedures that these nurses are qualified to perform, for example pelvic examinations. Where cervical cancer is advanced, a Pap test result is often negative so that a pelvic examination or other procedure is needed to exclude cancer.

Women's health nurses frequently provide women's health services, including Pap smears, to populations of women who strongly resist any form of identification, for personal, family or cultural reasons. The need to clarify and simplify the health practitioner's duty of disclosure, both at common law and in relation to the Pap Test Register, is important for these women. Although one purpose of the disclosure is to clarify their right to withhold their identifying particulars, an unduly complex presentation may operate as a disincentive to undertake a Pap smear at all. Further, these populations often include women who are itinerant or who deliberately give false names and addresses. Where a Pap smear test for such a woman is returned with an abnormal result, women's health nurses experience difficulty in fulfilling their professional (and probably legal) obligation to inform these patients.

To the extent that accreditation of health practitioners, other than medical practitioners, especially women's health nurses, to perform Pap smears is a matter of State law, it is a relevant legal issue. The extent to which the services of such practitioners are available for conducting Pap smears is a matter of State provision of health services.

TABLES

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