

**DISCLOSURE OF AUDIT RESULTS IN CANCER SCREENING
ADVICE ON BEST PRACTICE**

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1. INTRODUCTION

1.1 Aim of the publication

The aim of this publication is to advise on the best practice for passing on information about the results of audit of an individual case to the individual concerned and how to deal with any related medicolegal aspects.

The advice in this document is directed towards cases of cancer diagnosed symptomatically in the interval between routine screening after being previously screened by the national screening programmes and given a normal result. However, there are similar situations in which this advice would also be a useful description of best practice. This may include local family history surveillance programmes and those patients with cancer who were diagnosed within the national programmes but whose cancers were, with hindsight, probably present at the previous screening examination.

1.2 Background

The objective of cancer screening is to reduce the incidence of, or mortality from, malignant neoplasia. In order to ascertain whether a cancer screening programme is achieving its objectives, various evaluations are carried out. In particular, the incidence and mortality rates are monitored closely.¹⁻³ Incidence and mortality alone, however, do not give the complete picture about the effectiveness of the programme. They depict how effective the programme is, not how effective it could be if its activities were all optimised. Audit of a programme can help generate this further information. Moreover, as cancer screening moves from the tightly controlled arena of the randomised controlled trials which usually determine the standards for each programme to actual practice in the NHS, there are many questions about the effectiveness of the screening programmes that can be answered only by auditing the operational programmes.

In England, there are currently two major cancer screening programmes: the NHS Cervical Screening Programme (NHSCSP) and the NHS Breast Screening Programme (NHSBSP).

In the NHSCSP, women aged 25–64 are offered cervical screening by cytology every 3–5 years, depending on their age. It is estimated that cervical screening prevents 75% of invasive cervical cancers by detecting and treating cervical abnormalities that, if left, would place patients at high risk of developing invasive cervical cancer. About 80% of women accept their invitation to screening.

The NHSBSP offers women aged 50–70 breast screening by mammography every three years. It aims to prevent 25% of breast cancer deaths in patients in this age group by detecting and treating breast cancers at an early stage before symptoms are apparent. About 75% of women accept their invitation to screening.

A new cancer screening programme, the NHS Bowel Cancer Screening Programme (NHS BCSP), is to begin during 2006. The NHS BCSP will for the first time offer cancer screening to men as well as to women. The

programme will offer people aged 60–69 colorectal cancer screening initially using the guaiac faecal occult blood test every two years. It is expected that around 55–60% of people invited will participate in this screening programme.

The purpose of audit in a cancer screening programme is to monitor the effectiveness of the programme and to identify both areas of good practice and areas where improvements can be made. Audits yield information at a national, local and individual level, and the findings consist of the patterns that emerge when the results of the audits of individual cases are analysed together. In addition, the review of events and specimens from previous years can highlight valuable learning points for health professionals which can lead to improvements in the effectiveness of cancer screening. Separate publications exist for the breast and cervical screening programmes on how audit should be carried out.^{4,5} A publication will be produced for the bowel cancer screening programme when sufficient experience has been gained.

Beyond the population and operational aspects of audit, people who are diagnosed with an invasive cancer outside a screening programme, despite having participated in the programme, often wish to know why this has happened. Audit of their personal screening history, including a review of events and specimens from previous years, can yield this information.

2. PSYCHOLOGICAL ASPECTS

2.1 Background

The outcome of clinical audit is not always bad news. However, if the results indicate that there was possibly or probably an abnormality present at the last screening episode which may not have been managed appropriately, then doctors and others involved in the cancer screening programmes have expressed concerns about disclosing the results to patients. These concerns centre on:

- giving information to people who may not want it
- the timing of the disclosure, ie finding the appropriate moment to discuss the results of a clinical audit
- selecting the appropriate person to give the information to the patient
- the psychological distress of doctors and other health professionals dealing with patients in this situation.

2.2 Ascertaining what information patients want

Offering the suggestion that an abnormality or cancer may have been missed previously should be handled in a flexible manner suited to the needs of the individual patient. Some patients will not want to know the results of any audit. It should be noted that, although voicing concerns may be considered cathartic, some patients may genuinely not have any concerns or at least not any that they wish to discuss and, in this respect, the individual's choice should be respected. Importantly from a clinical perspective, undisclosed worry may cause anxiety and depressive disorders later. Research suggests that those who have been given too little or too much information are at greater risk of suffering such disorders, and that up to 50% of patients would not be diagnosed or treated later for anxiety or depressive disorders had the focus been on bringing their concerns into the open at an early stage. Whilst this may be an oversimplistic assessment, it is still worth bearing in mind. Patients respond to receiving information about their health differently and may conceal their psychological and physical distress. The more anxious and depressed patients are, the less likely they are to disclose their concerns.

Rather than allowing patients to carry a psychological burden of unexpressed concerns, early discussion with them is recommended. If they are harbouring any doubt as to their screening results, a review to address this should be offered. Doctors might invite patients to express their concerns and ask them what they want to know. This should be done before the doctor moves into the information and reassurance phase that often follows giving bad news. Empathetic guesses as to the patient's concern and open, directed, questions can be extremely important in this area as ways of eliciting disclosure of anxiety.

2.3 Minimising distress for health professionals

In the context of a possible or probable false negative screening result, the results of audit are being given to a previously screened patient who now has cancer. This will always be bad news because the patient is being told that he or she has, or may have had, cancer or a precancerous abnormality for a longer period than he or she was previously aware. Improving the experience of imparting bad news may be facilitated

for doctors and others by specific training on handling such a situation according to protocols.

The results of audit and review of individual screening histories must always be given carefully to ensure good understanding. It is important, nevertheless, that health professionals elicit and address individuals' information needs and do not adopt a formulaic approach to giving or withholding information. This is a difficult area for all those involved. Effort is obviously required to deal with each patient according to his or her particular information needs. Significantly, Ramirez et al⁶ found that 25% of cancer clinicians were high on the scale for emotional exhaustion, leading to patients being treated in a depersonalised manner, and Wilkinson⁷ suggested that cancer nurses were as poor as doctors at assessing psychosocial concerns. Alleged lack of empathy in the behaviour of doctors and nurses involved in disclosing health information is often stated to be a major source of complaints and claims.

With training and better support for those involved in discussing with patients their information needs, many complaints and claims may be avoided, and patients susceptible to increased anxiety can be identified from the outset. Levinson et al⁸ found that transparency reduces the number of complaints and/or claims, which is a view supported by the reported experience of many clinical negligence lawyers.⁹

It is intended that the advice given below will help to address the concerns of doctors and other health professionals who have to deal with the disclosure of audit results in this situation.

2.4 When to inform patients about audit

The process of imparting information to a patient in accordance with her or her needs begins at the initial consultation when the news of the diagnosis is given. It is important to develop appropriate strategies to deal with imparting information because an unexpected diagnosis could lead to an inappropriate context for breaking bad news. An example might be a telephone conversation giving the results of a pathology test that everyone involved had expected to be normal but that now requires a patient to be contacted to attend clinic urgently.

The attitude of the original clinician also influences a patient's view of the rest of the care team. Patients do not start afresh, for example, with the nurse who follows the consultation with the doctor.

It is inappropriate to introduce audit and review in the initial consultation when the diagnosis is given, unless the patient initiates questions about history. At this time, patients are likely to be focused on the implications of their illness and on treatment considerations. Talking about the review when the patient has other priorities could be seen as irrelevant and an unwelcome distraction; therefore, it could be difficult to introduce with any empathy or clarity. In addition, patients generally find that they already have too much information to take in.

The conversation about the review of previous screening history should take place after treatment has concluded, unless patients themselves

introduce the subject. Patients will do this when they are ready to consider the information and when they have established a satisfactory relationship with the person to whom the question is addressed. Patients do, however, often ask during a consultation about their previous tests and examinations. The advice in this document should not prohibit or inhibit the natural discussion between the patient and the clinician or nursing team at the time of diagnosis about previous history. The advice is offered in addition to current practice protocols, and does not stand instead of them.

A phrase such as ‘we always review previous screening history and if you want the results of that review let us know’ might be used. The patient’s response to this question would indicate whether he or she wished to take the matter further. Patients may express refusal of the offer in a number of different ways. For example, the patient might argue that the original result was negative and that he or she is happy to accept this result. Any such refusal should be respected.

A written leaflet might be given to the patient at diagnosis, which can be used later as a means to raise the issue if the patient so wishes at a time and place of his or her choosing. The leaflet should present the audit of the individual’s case in the context of general cancer screening programme audit. It should include positive information about the cancer screening programme and general information about why screening might fail. The risk of a false negative result should be included in the leaflet. The leaflet should include space for notes. The offer of information should be along the lines of ‘the screening histories of all patients with interval cancers are regularly reviewed to improve the service. Would you like the result of the review of your case?’ The appendix gives general advice on the content of such a leaflet for use by local screening programmes.

The nurse on the multidisciplinary team treating the patient should ensure that he or she understands the information that has been given, including that contained in the leaflet. However, the patient should not be asked about any screening history in order to avoid inducing guilt in non-participants and adding to their distress. Nurses could tell patients when the audit results would be likely to be available if asked and assure them that they will be given the results if they so desire.

2.5 How to communicate the results of audit

2.5.1 Who should speak to the patient?

The clinician treating the patient should handle this interview. Evidence suggests that if others, such as a nurse, deal with this interview it may be interpreted as avoidance on the part of the clinician. Such a strategy can increase the risk of complaints or claims. Patients should be helped to understand, as best they can, the reason for any missed abnormality, and they should be offered the opportunity to discuss their case with the appropriate lead clinician from the cancer screening programme. This might be, for example, the head of the laboratory cytology service which reported the relevant cytology in the case of cervical screening, the lead radiologist in breast screening or the lead colonoscopist for

bowel screening. The written report of the review should form the basis of the discussion.

2.5.2 *How to conduct the interview*

If the review of an individual's screening history finds that there has been a possible or probable false negative mammography report, an under-reported cervical cytology or histology report or a similar occurrence in colposcopy or colonoscopy or breast assessment, the conversation giving the patient that information should be treated as a bad news interview. The protocols designed for giving bad news should be followed. In other words, not only should patients be given the information but also the doctor should ask patients what their concerns are and invite them to disclose these concerns before moving on to provide reassurance. Patients should be encouraged to disclose any feelings of anxiety in order to minimise poor psychological outcomes. This approach has been shown to reduce the risk of complaints or claims. An uncertain result should also be reported to the patient. This can be difficult to explain if the patient's previous understanding of screening is that it always produced clear answers. This outcome should therefore also be treated as leading to a bad news interview.

Patients may ask whether a potential false negative (or uncertain) result had lessened their chances of survival, or had reduced their options as regards surgery or chemotherapy. If this is a possibility, then the clinician treating the patient should acknowledge it. If the person conducting the interview is not the clinician treating the patient, it may be best to suggest that the patient would do better to discuss this with him/her.

The interview should follow the steps below:

- **check** the patient's understanding of why he or she has asked for the information
- **ascertain** how much the patient wishes to know
- **discuss** the relevant reports and implications
- **invite** the patient to voice his or her comments and concerns.

It is important at this stage to keep explanations short and simple with little or no background information. At all times, the person carrying out the interview should endeavour to elicit the patient's feelings and concerns and to respond appropriately, avoiding defensiveness. Background information can be supplied later if the patient or circumstances so require.

Whilst a prepared script may inhibit the natural flow of the conversation, the person carrying out the interview should have already determined in advance what information ought to be communicated and be prepared to deal with the likely concerns the patient may have. It may be helpful to have notes prepared in advance on these issues.

Following the interview, a note of the discussion should be written up by the clinician who has conducted the interview. The clinician should also write to the patient's GP outlining what has been discussed. This should include use of the appropriate terms, as used in the interview,

because patients often consult their GP after a bad news interview and it is essential that the GP understands what has been said and can interpret it correctly. Furthermore, patients are entitled to receive copies of letters written about them by one healthcare professional to another, and may receive a copy of the letter if they have made such a request at some point in their treatment.¹⁰

3. MEDICOLEGAL ISSUES

3.1 Introduction

Complaints or claims are less likely if patients perceive that the process which has led to these interviews is transparent, and also if they receive an apology or expression of sympathy for their present position. In addition, the fact that audit of patients' cancers may improve things for other patients may appeal to their sense of altruism and reduce the risk of complaints or claims.

Doctors cannot be expected to act as lawyers in a bad news interview or undertake to do more than give the facts. However, questions about compensation need not be stonewalled; rather, patients (or their relatives) who say they wish to complain or seek legal redress should be given first step information as to how they may proceed. Apologies and explanations, as opposed to admissions of liability, are to be encouraged. The NHS Litigation Authority (NHSLA) Circular 02/02 *Apologies and Explanations* provides guidance on this issue.¹¹

If they are concerned to establish for themselves their rights of redress, patients may be given the contact details for the Patient Advisory Liaison Service (PALS) and informed about the trust's complaint procedure that may ultimately involve investigation by the Health Ombudsman. Mention may also be made of the assistance to complainants provided by the Community Health Council, the Citizen's Advice Bureau and the AVMA (Association for the Victims of Medical Accidents). The alternative is to seek legal advice directly from a solicitor whom the Law Society recommends as a specialist in medical claims. Doctors and trusts should not recommend or refer patients to particular solicitors or firms but may assist by providing contact details for the Law Society, the AVMA and the other external bodies as well as the trust's complaints/claims manager.

3.2 Background

The focus of this advice is upon communicating the results of audit undertaken for education and improvement of the service rather than the prevention of claims for damages. However, as part of the process of audit, steps can be taken to reduce the risk of complaints and claims. As discussed above, understanding the likely issues and dealing with them sensitively is key.

A common reaction to the receipt of bad news is to look for ways to blame the person imparting it. This may take the form of arguing that the information disclosed was obtained in an underhand way without the patient's authority. Therefore, issues of consent to audit and confidentiality in respect of patient data need to be addressed in the course of the interview.

Most obviously, one of the risks associated with being open and transparent about communicating news of a reporting discrepancy is that patients may regard the disclosure as an admission of error. It may be seen as an error responsible for the development of their cancer which otherwise would have been avoided. However, from a medicolegal perspective, such conclusions may not be justified.

Damage to the doctor–patient relationship and wasted expenditure of time and costs on legal fees can arise from poor communication, giving rise to false impressions about liability and expectations of compensation. Flat denials of liability are as unhelpful as admissions of liability, whilst lack of definite advice may give rise to allegations of stalling for time or fudging the issue. A consistent approach is required which sets out the issues objectively.

3.3 Consent to use of information for audit

Information about a patient is generally held on a confidential basis and may be imparted between trust staff only in relation to management of a patient's treatment. Accordingly, use of confidential information for audit purposes has depended upon the patient's consent being implied when entering into a screening programme that his or her results would be subject to audit. Such knowledge has been generated through a screening programme's invitation to screening and through leaflets, notices and posters about a screening programme. There is overwhelming benefit of audit in terms of assisting to improve public health and patient care. The detriment from potential skewing of results if patients were given the opportunity to opt out means it is necessary to over-ride individual consent for use of screening data. This approach is subject to regulation by the Secretary of State for Health. In respect of these audits of national cancer screening programmes, exemption has been obtained. Therefore, individual consent is not required from patients to use information about their test results or to undertake review of such results. Participation in the screening programme includes implied consent for data to be audited, and the information that the programmes are subject to extensive quality assurance and audit procedures is included in information leaflets and on the programmes' website and in other general information about the programmes. This does not mean that the review results may be broadcast or published in an identifiable manner. For this step to be taken, the patient's consent would have to be sought directly in the usual way.

3.4 Consent to being informed about the results of audit

Consent to being informed about the results of the audit and how fully is another matter. Whatever the outcome of discussions with clinicians, the point to be respected is that the patient has a right to refuse information as matter of choice. He or she also has a right to be given information concerning personal health. There may be cases in which clinicians consider the patient is in denial about his or her condition and is refusing information as a result. In this situation, it may be appropriate to explore further, perhaps at a later date, the issue of disclosure of review result information. However, the offer and rejection of review information should be recorded in the notes as evidence of the attempts made to provide disclosure. In these circumstances, the main difficulty is one of safeguarding the patient against inadvertent disclosure against his or her wishes. This requires that the staff involved in the patient's care are made aware of his or her decision not to know the results of any review. In addition, a note should be made on the front of the medical records file containing details of any discussion about the audit result. It should also be entered in the patient administration system (PAS) to alert those that may be involved in a subsequent request for disclosure of medical records by the patient. Whilst application for sight of his or her own record suggests that the patient has changed his or her mind it may be

as well in these circumstances to write and ask if this is the case before providing copies of the notes in their entirety.

3.5 Access to records by relatives of patients living and deceased

Whilst the patient is alive and competent to refuse consent to disclosure of his/her medical record, an 'interested' party (wife or husband, partner, sibling or child) cannot be given access to medical information about the patient even if this may seem to be in the patient's best interests. Should a patient become incompetent then access may be obtained by the patient's receiver acting as litigation friend or by the official solicitor appointed to act on behalf of the patient. The position is more complicated under the Access to Health Records Act 1990 in respect of dealing with requests for disclosure made following a patient's death. Each case needs to be considered carefully and, if in doubt, legal advice obtained.

However, it should be noted that if a patient's record before death states that his or her notes are not to be disclosed then (with reference to Section 4(3) of the above Act) access shall not be given. Alternatively, access may be denied under Section 5(3) if the holder of the record reasonably believes that the information contained in the record was provided by the patient in expectation that it would not be disclosed. Access may also be denied on the grounds that information within the record may cause serious harm to the applicant or, if related, to another individual.

Otherwise, under Section 3(1)(f), the patient's personal representative (and any person who may have a claim arising out of the patient's death) may apply for access. Significantly, Section 5(4) provides that records not relevant to the claim arising out of the patient's death are not accessible, and therefore it will not generally be necessary to disclose the whole of the patient's records extending possibly over many years.

The main difficulty lies in ensuring that the recipient of any medical record has a legal entitlement to see it given that the duty of confidentiality in the record extends after the patient's death. Confusingly, a patient's personal representative may not be the patient's next of kin and, although less likely, a person having a claim arising out of the patient's death may not be the next of kin either. However, to serve as a personal representative requires taking out 'letters of administration' authorising handling of the deceased's estate. Where the deceased made a will, the personal representative appointed is known as an executor or executrix and will have obtained a 'grant of probate' authorising handling of the deceased's estate. Sometimes, a bank or a firm of solicitors will be appointed under a will and more than one person may be entitled to act as the deceased's personal representative/executor. However, in common, the personal representative/executor will be able to produce on request an official copy of the letter of administration/grant of probate whereupon (subject to the considerations above) records may be disclosed.

The position is rather more difficult if a relative, friend or apparent stranger not acting as the deceased's personal representative or executor seeks access to the records, suggesting that they may have a claim arising from the deceased's death. Whether or not such a request for access should be granted in most cases will be a matter requiring legal advice.

Whilst there is no obligation upon the trust to review test or examination results and volunteer medical information to the relatives of a deceased patient should a relative give intention of pursuing a claim, then it is likely that a solicitor will advise review of the deceased's records (including any specimens or images) and disclosure of the results to the claimant's legal advisors.

It remains the case that openness and transparency are required as, in many cases, a bereaved relative is not so much concerned to bring a claim but is seeking reassurance that all that could have been done was done to avoid the death of a loved one. Accordingly, handling requests for access to medical records made by the deceased's relatives or close friends requires sensitivity to the applicants' grief. They might need to maintain some connection with the deceased if only through sight of the records. Overall, when results are reviewed on a case by case basis around the time of a patient's diagnosis, disclosure considerations are less complicated than those that arise in situations involving retrospective group audits in which patients may have died or become difficult to trace because of changes of address.

3.6 Complaints and claims

Whether or not reclassifying test or examination results in the course of audit has caused the patient a loss attracting compensation as a matter of law is an issue that requires investigation by lawyers with the assistance of medical experts. Therefore, at the time of disclosing review results, patients should not be assured of a right to compensation but rather of the right to have the issue investigated further.

Generally, the complaints procedure does not provide a means by which patients can obtain compensation. However, patients with the assistance of PALS may seek to have their allegations of substandard care investigated in house by trust complaints staff.

Failing resolution of the patient's concerns through the complaints procedure (or immediately if the patient is determined upon securing financial compensation), the patient may be directed to the charity Action for Victims of Medical Negligence or to the Law Society. Either organisation will assist a patient in finding a solicitor to represent them in investigating a claim.

In the event that a formal claim for compensation is lodged, and the trust wishes to seek an indemnity from the Clinical Negligence Scheme for Trusts, the matter should be reported to the NHSLA, which will appoint a panel solicitor to deal with the case. Consideration will be given to resolution of the claim without litigation, if possible, by way of early admissions of breach of duty where appropriate and joint instruction of experts on causation. The NHSLA can also offer assistance at an early stage if audit indicates a particular problem, which might lead to claims against the trust by a number of patients. In these circumstances, efforts will be made to agree a claims handling protocol to avoid the delay and expense of litigation.

Where patients are confident that doctors are doing their best to look after

their needs, it is to be hoped that most will be dissuaded from pursuit of legal remedy since the mistake will be seen for what it is in most cases, namely a much regretted non-negligent error.

Crucially, most complaints and claims are capable of being resolved or avoided through sensitive discussion with patients. Generally, patients need to be made aware that reporting discrepancies found on review do not imply that the same findings should have been made under routine conditions and, importantly, why this is the position. The quality of the explanation is key and must be detailed if it is not to be seen as a self-protective attempt to avoid blame.

Patients should be reminded that the benefit of hindsight cannot be underestimated. No matter how closely the review panel tries to reproduce the original screening conditions, in truth the conditions of a review are inescapably different. The fact that a review includes records of a patient known to have cancer cannot fail but to heighten vigilance and increase reports of abnormality. However, under normal conditions, those caring for a patient are not expected to be hypervigilant or to have a sixth sense or perfect visual acuity. Rather, the law expects no more of them than that they perform as may be reasonably expected of members of their profession.

3.6.1 *Cervical screening*

The cervical screening process involves many steps aiming to identify and treat cervical intraepithelial neoplasia in order to prevent cancer. The steps involved range from invitation, cytology sample taking and reporting, result issue and failsafe, colposcopy and diagnosis. It is possible that at any one or more of these steps there may have been suboptimal provision, or it may be that they have all worked efficiently and that a cervical cancer has developed despite an efficient programme. Audit will help to identify if there are potential problems at any one or more of these steps, and improve the whole process for women in the future. There is also the issue of ownership by the woman herself – regular attendance is essential for the screening process to achieve optimal effectiveness.

When they are made aware of the standards expected of the profession, of the low sensitivity associated with the cytology test and its inherent fallibility as a diagnostic tool, patients may be less inclined to regard a discrepant review result as an error revealing want of care. Colposcopy (the diagnostic and treatment part of the programme) also has a recognised failure rate.^{12–16}

Examples may be given of slides failing to reveal any abnormality. This could be the case despite repeated scrutiny by experts and despite a consensus that, given the size of the tumour found at diagnosis, abnormal cells must have been present in the cervix when the sample was taken. In such cases, and without anyone being at fault, experts will accept that the sample simply did not contain cells that would have prompted a referral for colposcopy.

Essentially, cytology is based upon interpretation of appearances on a slide in a situation where the boundary between normality and abnor-

mality is not firmly drawn. This may result in debate between experts as to the appropriate classification of some samples. Indeed, it is accepted that erring too far on the side of caution in every such situation would result in an unacceptably high level of false positive results. If this were the case, many patients would be recalled unnecessarily, leading to overtreatment.

Patients need to be aware too that the law judges standards according to the year in which the sample was taken. Therefore, improvements over the years in screening technique, the influence of training and experience altering a screener's ability to see what was 'missed' before will not result in a retrospective finding of liability. It would be inappropriate to judge yesterday's performance by the improved standards and knowledge of today. On a positive note, although perhaps of small consolation to a patient informed of a discrepant result, audit has played a fundamental role in providing feedback enabling improvements to the service that have saved lives. Without audit, the opportunity to learn vital lessons from individual cases would have been lost. Therefore, each patient's results may be regarded as making a positive contribution to knowledge of cervical abnormalities, the timeframe over which cancers develop, which lesions may regress and the most effective treatment to increase survival.

3.6.2 *Breast screening*

The breast screening programme operates through local breast screening services that invite women for screening using the local NHS database. Women are called either to mobile mammography vans or to static services generally located in NHS premises. The images are then reported by the service, and around 5% of the women are called back to the service because they have been identified as needing further investigation. The programme was set up in 1988 with quality assurance as an integral part of the service, and this initiative has continued to develop as the service has grown since its inception.

Examples may be given of mammograms failing to reveal any abnormality. This is the case despite repeated scrutiny by experts and despite a consensus that, given the size of the tumour found at the time of the diagnosis, an abnormality would most likely have been present in the breast at the time the mammogram was taken. In such cases, and without anyone being at fault, experts will accept that the mammogram simply did not demonstrate the abnormality.

Essentially, mammography screening is based upon interpretation of appearances on a mammogram in a situation where the boundary between normality and abnormality is not firmly drawn. There may be genuine debate between experts as to the appropriate classification of some films. Indeed, it is accepted that erring too far on the side of caution in every such situation would result in an unacceptably high level of false positive results. If this were the case, many women would be recalled for unnecessary investigations.

When women are made aware of the standards expected of the profession, of the specificity issues associated with screening tests and their inher-

ent fallibility as a diagnostic tool, they may be less inclined to regard a discrepant review result as an error revealing want of care.

Patients need to be aware too that the law judges standards according to the year in which the mammogram was taken. Therefore, improvements over the years in screening technique, the influence of training and experience on a film reader's ability to see what was 'missed' before will not result in a retrospective finding of liability. Plainly, it would be inappropriate to judge yesterday's performance by the improved standards and knowledge existing today. On a positive note, although perhaps of small consolation to a patient informed of a discrepant result, audit has played a fundamental role in providing feedback enabling improvements to the service that have saved lives. Without audit, the opportunity to learn vital lessons from individual cases would have been lost. Therefore, each woman's results may be regarded as making a positive contribution to the field of knowledge concerning the nature and variety of breast abnormalities.

3.6.3 *Bowel cancer screening*

This service has operated in pilot form since 2000 and is now being rolled out across the country. It will operate through a small number of programme hubs which invite men and women to participate. These hubs develop and report the test kits, which participants return through the post to the hub. They will also book patients in to their local screening centre if colonoscopy is indicated.

The initial test being used for the new screening programme is the guaiac faecal occult blood (FOB) test. This test has been shown in trials to be effective in reducing colorectal cancer mortality in the population offered screening, but it is known to have limited sensitivity.¹⁷ FOB tests must be read within 30 seconds of having developer applied, and thus there is no opportunity for review of the actual test itself. In addition, it is generally accepted that many polyps and cancers bleed only intermittently, and thus blood may not actually have been present in the specimen sent for testing. However, the screening history can be reviewed to ensure that the patient was managed appropriately and records of colonoscopy examinations can be examined. Even this examination is known to have a false negative rate.¹⁸⁻²⁰

When they are made aware of the low sensitivity associated with the FOB test and its inherent fallibility as a diagnostic tool, patients may be less inclined to regard a discrepant review result as an error revealing want of care. They should also be made aware of the standards expected of the colonoscopist and of the quality assurance and training that underpins colonoscopy in the context of the screening programme.

Patients need to be aware too that the law judges standards according to the year in which the examination was performed. Therefore, improvements over the years in technology and technique, the influence of training and experience altering a colonoscopist's ability to see what was 'missed' before will not result in a retrospective finding of liability. It would be inappropriate to judge yesterday's performance by the improved standards and knowledge of today. On a positive note, although perhaps of small

consolation to a patient informed of a discrepant result, audit has played a fundamental role in providing feedback enabling improvements to the service that have saved lives. Without audit, the opportunity to learn vital lessons from individual cases would have been lost. Therefore, each patient's results may be regarded as making a positive contribution to the knowledge of colorectal abnormalities, the timeframe over which cancers develop, which lesions may regress and the most effective treatment to increase survival.

3.7 Causation

3.7.1 *Cervical screening*

When discussing issues of clinical misreporting of cytology or of problems with the diagnostic or treatment elements of the programme, it needs to be appreciated that, even if a judge finds that the screener/pathologist/colposcopist has been negligent in failing to detect an obvious abnormality, liability for such error is not automatic. In other words, admitting an error or offering an apology in respect of a discrepant review result does not necessarily mean the patient will receive a compensation payment.

This is because, in addition to the error being judged blameworthy by the standards of the profession pertaining at the time, compensation is payable only where on balance, and as a result of the screening error, the patient is found to have suffered a measurable harm. Such harm may be proved in cases where the patient has undergone more radical treatment than might otherwise have been the case. Alternatively, where she is able to prove on balance that she has lost the opportunity of a better outcome or significant damage has resulted from treatment that could have been avoided.

Clinical negligence claims often fail because the claimant is unable to establish that as a result of the reporting error she has suffered any damage. It is fair to say, for example, that even though the cervical screening programme aims to prevent cancers developing very small invasive cancers may be detected through the screening programme and treated as an outpatient procedure. It is often argued that such cases represent a success of the programme.

This is not because the burden of proof is set too high. On the contrary, the claimant has to prove her loss only on a balance of probabilities. That is to say, for example, that a better outcome would have been more likely than not but for the misreported sample. Rather, her difficulty lies with the fact that in many cases it is simply not possible to say that the outcome would have been any better had the abnormality been found sooner.

The likely outcome for patients in many cases suggests that similar treatment would have been required in any event. The time for development of invasive cervical cancer, although variable, is generally considered to be long, and a discrepant cytology result may document only an increased risk of developing a more severe lesion rather than the materialisation of that risk. This is particularly the case where the misdiagnosis involves an upgrading from normal to borderline as many minor abnormalities regress in any event without treatment.

In relation to cervical cancer, the extent of the treatment undergone may not be entirely the result of the cervical lesion but of other pre-existing pathology. For example, a patient may have been recommended to undergo a salpingectomy or hysterectomy because of a non-cancer related problem; indeed, although rare, the cervical disease found may have arisen from a primary lesion elsewhere. In addition, secondary consequences of surgery, such as urinary problems following hysterectomy, may be found to be a consequence of the patient's age. Taking account of the size and type of tumour found at diagnosis, experts will attempt to decide the stage of the cancer or precancer at the time treatment would have started but for the misreported sample. Using a variety of growth models, it may be argued that had the tumour been detected sooner then the treatment options would have been different and the outcome for the patient better.

However, such models are in themselves hypothetical, and are by no means conclusive as to the behaviour of a tumour in any individual case. Some tumours are known to be aggressive, such that earlier intervention, even years earlier, may not on balance have made any real difference to the patient's survival or the need for radical treatment. In some cases, working backwards will indicate the absence of even a microscopic tumour capable of being seen on colposcopy but which the sample review result nevertheless indicates must have been present.

A clinical staging difference between, say, FIGO 1b1 and 1b2 may have no bearing on the treatment recommendations. Indeed, if as a result of the pathological findings the tumour was in fact less advanced, the lymph nodes were clear and the patient has already survived five years without any signs of recurrence, the patient is unlikely to prove a loss attributable to the misreporting of her sample.

In the case of cervical cancers, some experts will argue that a delay of six months is likely to be significant in terms of treatment. However, there is no hard line that can be drawn for all tumour types. If the patient had a less than 50% chance of a successful treatment in any event, or it cannot be said on a balance of probabilities that she would have fared better as a result of earlier or different treatment, then the claim will fail. The complexity of the medicolegal issues arising in the context of disclosing audit results means that a patient is not often entitled to compensation. Assisting patients with clear explanations and providing the contact details of external bodies to help will go a long way to preventing unnecessary claims and will reassure patients that health service professionals care about their welfare.

3.7.2 Breast and bowel cancer screening programmes

The breast and bowel cancer screening programmes aim to prevent deaths from the cancers in question by finding invasive disease at a stage earlier than it would normally present clinically. However, it will also find disease at a stage where it has the potential to become invasive but has not yet done so. This is in situ carcinoma of the breast and adenomatous polyps in the bowel.

In the context of discussing issues of clinical misreporting of mammo-

grams or a colonoscopy examination, it needs to be appreciated that, even if a judge finds that the radiologist has been negligent in failing to detect an obvious abnormality, liability for such an error is not automatic. In other words, admitting an error or offering an apology in respect of a discrepant review result should not be construed as providing an admission bound to result in the patient receiving a compensation payment.

This is because in addition to the error being judged blameworthy, by the standards of the profession pertaining at the time, compensation is payable only where on balance, and as a result of the screening error, the patient is found to have suffered a measurable harm. Such harm may be proved in cases where the patient has undergone more radical treatment than might otherwise have been the case. Alternatively, where the patient is able to prove on balance that he or she has lost the opportunity of a better outcome or significant damage has resulted from treatment that could have been avoided.

Clinical negligence claims often fail because the claimant is unable to establish that as a result of the reporting error he or she has suffered any damage.

This is not because the burden of proof is set too high. On the contrary, the claimant has to prove loss only on a balance of probabilities, that is to say that a better outcome would be more likely than not but for the misreported mammogram or colonoscopy examination. Rather, the difficulty lies with the fact that in many cases it is simply not possible to say that the outcome would have been any better had the abnormality been found sooner.

The likely outcome for patients in many cases suggests that similar treatment would have been required in any event. Taking account of the size and type of tumour found at the time of diagnosis, experts will attempt to indicate the stage of the cancer, carcinoma in situ or polyp at the time treatment would have been started had the mammogram or colonoscopy not been misreported. Using a variety of growth models, in some cases involving long periods of delay, it may be argued that had the tumour been detected sooner then the treatment options would have been different and the outcome for the patient better.

However, such models are in themselves hypothetical and are by no means conclusive as to the behaviour of a tumour in any individual case. Some tumours are known to be aggressive, such that earlier intervention, even years earlier, may not on balance have made any real difference to the patient's survival or the need for radical treatment.

In the case of breast or bowel cancers, some experts argue that a delay of three months is likely to be significant, resulting in more extensive or invasive treatment or excluding a possible treatment option. However, there is no definite timescale for all tumour types that can be applied in individual cases. If the patient had a less than 50% chance of a successful outcome to treatment in any event, or it cannot be said that he or she would have fared better as a result of earlier or different treatment, then

the claim will fail. Whether or not the treatment options change from conservative to radical or dictate a significant difference in condition and prognosis has to be considered in each case. The complexity of the medicolegal issues arising in the context of disclosing audit results means that a patient is not often entitled to compensation. Assisting patients with clear explanations and providing the contact details of external bodies to help will go a long way to preventing unnecessary claims and will reassure patients that health service professionals care about their welfare.

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APPENDIX: ADVICE ON CONTENT OF LEAFLET TO ADVISE PATIENT ABOUT AUDIT AND RESULTS

Trusts may wish to produce a leaflet to be given to patients at the time of their diagnosis concerning the fact that an audit of their screening history will be carried out and that the results will be made available to them if they so wish.

The leaflet should include the following points:

- audit is essential to the running of high quality screening programmes and as such is a routine part of their workings
- information gained from audit of individual cases helps to improve the systems of the programme and also to develop scientific knowledge about the development of cancers and their diagnosis
- the cancer screening programme is estimated to save x lives per year nationally and y lives locally/prevent x cancers per year nationally and y cancers per year locally
- screening does not always identify every cancer/cervical abnormality/polyp because ... (items can be repeated from the national invitation leaflet)
as appropriate:
 - colonoscopy will miss around 10% of cancers
 - the FOB test kit will pick up only around half of bowel cancers
 - breast screening will identify around two-thirds of the cancers that will occur in the three year screening period
 - around 10% of breast cancers do not show up on mammograms
 - cervical cytology will prevent about 75% of cervical cancers
- when results of the audit will be available (eg about six months after your diagnosis)
- how the patient can find out the results of audit (eg ask the doctor to give you the results of the audit when you are at the clinic)
- include space for the patient to write notes
- include the offer to the patient of the information, eg ‘the screening histories of all patients with interval cancers are regularly reviewed to improve the service. Would you like the result of the review of your case?’.