

**GUIDELINES FOR MANAGING INCIDENTS
IN THE CERVICAL SCREENING PROGRAMME**

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PREFACE

These guidelines have been developed by a working group set up following the recommendations of the review of cervical screening services at Kent and Canterbury Hospitals NHS Trust.

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Guidelines on Managing Incidents in the Cervical Screening Programme

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*Problems in cervical cytology? The IBMS guide to the process of investigating performance outside the expected norm in cervical cytology. *Biomedical Scientist*, 1997: 452–453.

1. INTRODUCTION

1.1 Purpose of the guidelines

The purpose of this document is to provide guidance for managers in health authorities, trusts and the cervical screening programme on the steps to be taken if a serious incident in cervical screening is confirmed.

The guidelines:

- outline the means by which a **suspected problem** may be identified
- describe the stages in the **investigation** of a suspected problem and **diagnosis** of its cause
- recommend the sequence of steps to be taken if a problem is confirmed which has consequences for the clinical management of women (what we have termed an **incident**)
- set out the factors to be taken into account when considering rescreening of smears or recalling women for additional investigation or treatment (what we have called **retrospective action**)
- provide guidance on **closure** of an incident.
- A flow chart that summarises the stages in the identification and investigation of a problem, and in solving the problem, managing the consequences and taking retrospective action if the problem becomes an incident is shown in Figure 1.

1.2 Background

The NHSCSP is a population-based screening programme for the detection of changes in cervical cells, some of which, if left untreated, may develop into cervical cancer.

There are four main elements to the programme:

- computerised call and recall
- smear taking and follow-up of smear results
- smear reading and reporting
- colposcopy – investigation and treatment of abnormal smear results.

In the last 10 years or so there have been a number of widely publicised incidents in the cervical screening programme. Most of these have involved problems with the reporting of smears by cervical cytology laboratories. However, there have been examples of problems with other stages of the programme, for example the quality of smear taking, reporting of results to smear takers, the transfer of results from laboratories and problems with the quality of colposcopy.

1.3 Clinical governance and quality assurance

The new and developing requirements for clinical governance apply to the cervical screening programme as much as to other clinical services provided by the NHS. Arrangements for quality assurance for the cervical screening programme are being developed within the framework of clinical governance, and this protocol is designed to reflect the principles of clinical governance.

The implementation of quality assurance in the cervical screening programme has included the development and implementation of

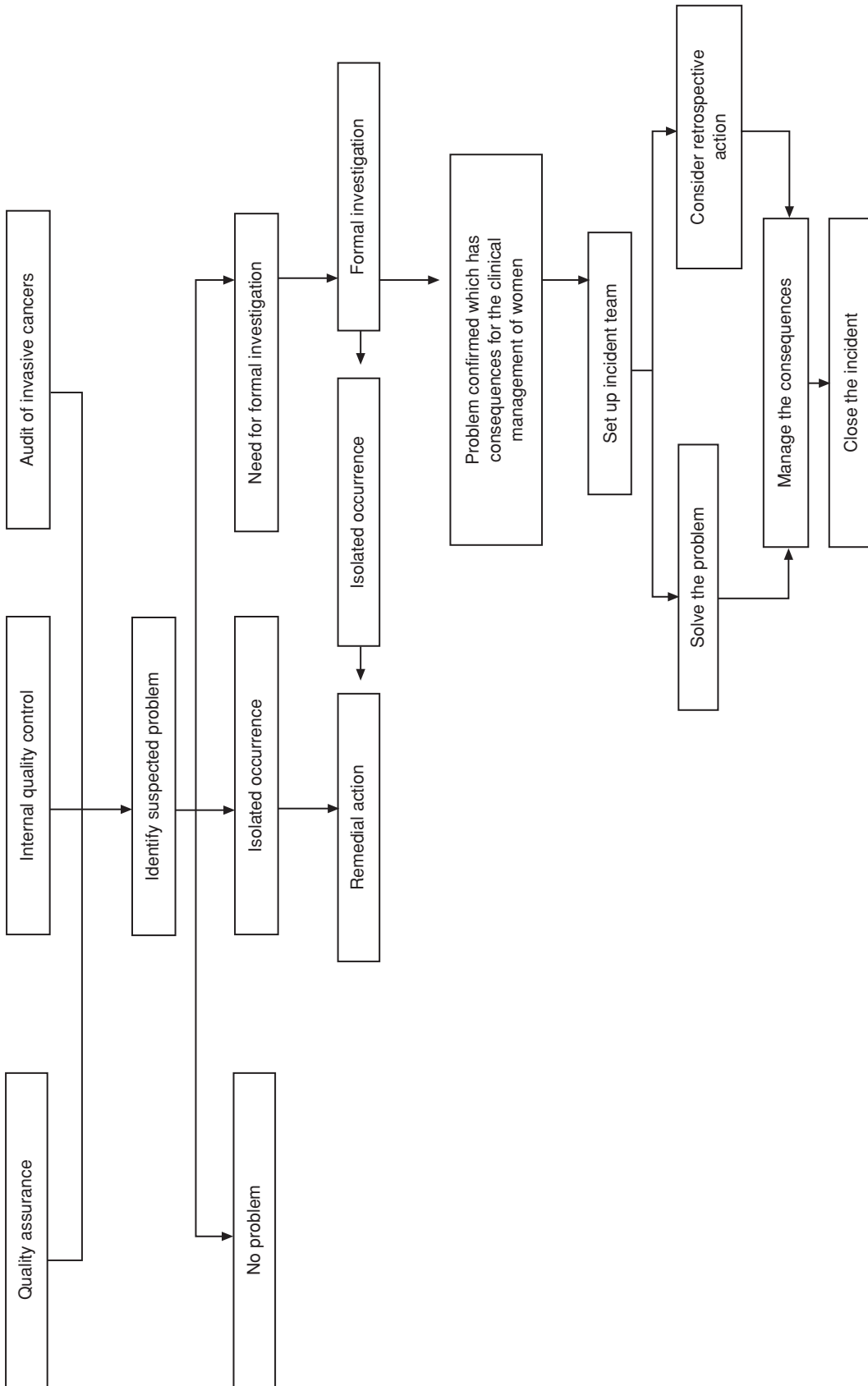


Figure 1 Identifying and investigating a suspected problem, and managing an incident.

standards for cervical cytology and other aspects of the programme.¹⁻³ Regional quality assurance teams have been set up to monitor and review performance against the standards, and national coordinating committees are being set up to further the development of quality assurance.

The introduction of quality assurance means that potential problems are identified, investigated and remedied at an early stage as part of the normal routine of quality assurance, and they should not become incidents. In the meantime, quality assurance may identify some existing deficiencies which were not previously apparent and which may need retrospective action.

2. IDENTIFYING PROBLEMS IN CERVICAL CYTOLOGY

2.1 Background

The cervical smear is a screening test, not a diagnostic test. False-negative smear test results are inevitable in screening, even in the best laboratories. In the last 10 years or so, a number of major incidents have occurred in cervical cytology laboratories as a result of false-negative reports. The three main incidents of this type, namely in Liverpool in 1987, Inverclyde in 1992 and Kent and Canterbury in 1996, were all the subject of health authority or external inquiries resulting in published reports.⁴⁻⁶ All of these incidents occurred when one or more new members of senior medical or technical staff were appointed from outside the laboratory concerned, and perceived quality problems, the likely seriousness of which became apparent from observations during their routine duties in the laboratory.

2.2 Performance indicators

The publication in 1995 of *Achievable Standards, Benchmarks for Reporting and Criteria for Evaluating Cervical Cytopathology (ABC)* introduced, for the first time, performance indicators for cervical cytology laboratories.² The issue for the programme is whether or not laboratory performance lying outside the target ranges is necessarily an indicator of substandard performance. The ABC document was a first attempt to establish standard ranges for laboratory performance, and experience and continued evaluation of new data will result in adjustment of the ranges in due course. The occurrence of laboratory performance outside the standard target ranges should primarily be considered as a quality assurance issue. The importance of individual indicators must be judged in the context of the overall performance of the laboratory.

Potentially the most serious indicators of possible substandard performance are pick-up rates for high-grade abnormalities falling below the target range, or sensitivity of primary screening falling below the target range. However, it is unlikely that the target ranges are yet robust enough for outlying performance necessarily to be substandard, particularly where only a single indicator is concerned. Little is known about the relationship between the coverage by screening, incidence and prevalence of cervical intraepithelial neoplasia (CIN) and the incidence of invasive carcinoma. It is possible that there are well-screened, stable populations with an inherently low occurrence of CIN and that this results in some laboratories failing to reach screening targets, despite adequate laboratory performance. This should not, however, be accepted as an explanation for such failure without thorough justification. Performance falling outside more than one target range, or marked fluctuations in performance from year to year, should always be investigated.

Substandard performance may manifest itself in other ways, such as through internal quality control (rapid review), from false-negative smears discovered on review when women are found to have high-grade abnormalities, or from review of the smears of women developing

invasive cervical cancer. It is important to remember that single errors, or small numbers of errors, are inevitable in screening and inappropriate over-reaction should be avoided. Nevertheless, if such errors form part of a pattern, for example in smears reported by a particular individual, or during a particular period of time, then they should be investigated. Unless a problem is very obvious (such as occurred in previous major incidents), statistical analysis of screening performance is likely to prove the best indicator of substandard performance.

2.3 Reviewing a sample of smears

If statistical analysis of performance indicators or an unexpected pattern of false negatives leads to the suspicion of an underlying problem in a laboratory, then further investigation is warranted. This will normally take the form of a review of a sample of smears selected from those reported by a particular individual, or from a particular period of time. A review of a sample of 500–1000 smears is usually sufficient to reveal a problem if one exists. Such a review may form part of a formal investigation of a suspected problem as described in Chapter 3. The large-scale re-examination of slides to identify other false-negative slides is described in Chapter 5.

3. INVESTIGATING A SUSPECTED PROBLEM IN CERVICAL CYTOLOGY

3.1 Initial investigation

If there is cause for concern about the performance of a cervical cytology laboratory, then the first step is for an initial investigation to **review the evidence** and **establish the facts**.

The clinical head of the cytology laboratory will normally lead the initial investigation. The trust management must be informed, as well as the regional quality assurance team and the director of public health of the commissioning health authority. Membership of the team should include:

- clinical head of the cytology laboratory
- scientific head of the cytology laboratory
- (hospital-based) programme coordinator
- regional quality assurance director and/or quality assurance team member for the appropriate profession
- senior member of trust management.

The aim of the initial investigation is to establish as quickly as possible one of the following outcomes:

- there is no problem
- there is substandard performance that needs to be remedied by the laboratory
- there is the possibility of a major problem, which needs further investigation.

It is important to be clear that this is all that the initial investigation is trying to achieve. Although staff directly involved need to be informed that an investigation is taking place, communication should be limited to those who need to know, and the investigation should not be referred to as ‘an incident’.

The initial investigation team should also consider what additional safeguards or quality assurance checks should be introduced on a temporary basis to prevent continuation or repetition of the suspected problem. These temporary measures should remain in place until the suspected problem is confirmed or the team is satisfied that the suspicion has not been substantiated.

The initial investigation will reach one of the following conclusions and take the corresponding action (Table 1).

In the case of a suspected problem where the competence of the clinical and/or scientific head of the laboratory has been called into question, it may be appropriate to move directly to a formal investigation.

Table 1 Outcomes and actions of the initial investigation

Outcome	Action
1. The initial suspicions have not been confirmed, i.e. there is no evidence of any systematic errors in cytology reporting	Record the methodology and the basis for the conclusion reached Reassure the staff concerned Report the outcome to trust management and the director of public health
2. There is substandard performance by the laboratory which needs to be remedied, but which does not have consequences for the clinical management of women	Record the methodology and the basis for the conclusion reached Make recommendations for remedial action to remedy weaknesses within the laboratory Reassure the staff concerned Report the outcome to the trust management and the director of public health
3. There is a problem: the possibility of clinical under-performance or failure of laboratory systems which have consequences for the clinical management of women cannot be excluded	Inform the trust chief executive Trust chief executive sets up a formal investigation team

3.2 Formal investigation

A formal investigation must be set up if there is a lack of confidence in any or all of the following:

- the clinical competence of one or more individual members of the laboratory staff
- laboratory procedures for handling smears and reporting smear results
- the management and accountability of the laboratory.

A senior manager nominated by the trust chief executive should lead the formal investigation team. Membership of the team should normally include:

- clinical head of the cytology laboratory
- scientific head of the cytology laboratory
- (hospital-based) programme coordinator
- regional quality assurance director
- quality assurance team member for the appropriate profession.

If the performance of the clinical head or scientific head is under scrutiny, he or she should not be included in the investigation team. Depending on the nature of the problem, consideration should be given to including one or more members from outside the trust with the appropriate professional expertise.

The formal investigation team should:

- inform in writing anyone whose performance may be under review
- ensure that correct lines of accountability are followed within the laboratory
- inform the director of public health, regional director of public health and national coordinator about the investigation
- keep full records of the investigation.

The formal investigation team should:

- review the evidence from the initial investigation
- determine the scope and the timescale of further investigations
- identify the nature and causes of the failure to provide an acceptable standard of service
- assess the likely effects and implications of the failure and forecast the likely consequences
- recommend actions to prevent the continuation or recurrence of the failure
- recommend actions to manage the consequences including consideration of retrospective action (rescreening).

At this stage, it is the responsibility of the trust chief executive, in consultation with the director of public health and regional director of public health, to make a judgement as to whether the problem and the consequences of the failure are sufficiently serious to warrant setting up an incident team.

The possible consequences of the problem include:

- preventable deaths and cancers among women screened
- misdiagnosis leading to inappropriate treatment of women screened
- litigation arising from deaths or misdiagnosis
- adverse publicity and loss of confidence in the trust and the screening programme
- disciplinary action against one or more individual members of staff.

Other factors that need to be taken into account are:

- the size of the problem – how many women are likely to have been adversely affected
- the timing of the problem – over what period of time was there a problem, and how long ago was it?
- the costs of retrospective action and the availability of resources to undertake such action.

The costs and outcomes of retrospective action are discussed further in Chapter 5.

If the consequences of the problem include any of the above, then it is likely that a formal incident team will need to be convened. This should be based on the investigation team but may need strengthening and additional membership.

4. MANAGING AN INCIDENT IN CERVICAL CYTOLOGY

4.1 Setting up an incident team

Within 48 hours of an incident being confirmed, the trust chief executive should set up an incident team. Membership of the team should be agreed between the trust and the regional office in accordance with the regional protocol for serious untoward incidents. Membership should include:

- trust chief executive (or nominated senior manager)
- trust medical director
- clinical head of the cytology laboratory
- scientific head of the cytology laboratory
- (hospital-based) programme coordinator
- regional quality assurance director and/or quality assurance team member for the appropriate profession
- director of public health of the commissioning health authority.

An incident room should be set up in accordance with local protocols and the team will need appropriate administrative and clerical support.

The incident team must inform the regional director of public health and the national coordination team that an incident has occurred. Close liaison is required, particularly in responding to media enquiries.

The incident team should consider what additional expertise and help it may require:

- external expertise in cervical cytology
- designated press officer (who should liaise with the national coordination team, be trained in dealing with the press and be the one point of contact with the media)
- legal adviser
- adviser on patient counselling
- adviser on personnel issues.

Consideration should also be given to liaison with primary care groups and general practitioners, for example by including a general practitioner on the team.

4.2 Actions for the incident team

Guidance is given sequentially, but many of the actions described below will need to be taken simultaneously.

1. Define the objectives for the incident team.
2. Decide whether any further investigation or actions to deal with the problem are necessary.
3. Decide how to deal with the following aspects:
 - women who may have received substandard screening

- other women whose smears may have been reported by the laboratory
- staff working in the laboratory
- GPs who may have sent smears for reporting by the laboratory
- staff working in colposcopy services
- wider cervical screening programme
- media (local and national).

Consider carefully the detail of the wording to be used in any communications. The wording should be informative and clear as to what will happen, and when. It must put the incident into the context of the NHSCSP as a whole. It must be understandable to the audience(s) and provide information about access to further information and support. The aim should be to inform women directly affected and their GPs before they hear of the incident from the media. (See Appendix 1: Key messages and Appendix 2: Dealing with the media.)

4. Identify the women directly affected, that is those who will require further treatment or a repeat smear.
 - consider the likely numbers involved
 - set up a database of all women affected (names, addresses and GPs)
 - check for accuracy against health authority general practice database and against death records and hospital records.
 - search for women who have moved using the NHS Central Registry.

It is essential to keep information on the database up to date.

5. Decide what action needs to be taken for women who have been affected. This may include:
 - informing all women directly affected
 - setting up a telephone helpline (see Appendix 3)
 - providing access to counselling
 - providing access to further investigation and treatment (colposcopy).

If the media become aware of the incident before all women directly affected have been contacted, then the media should be advised of a date by which the investigations are expected to be completed and all affected women contacted. Reports on the findings should not be released until that date and all women have been contacted.

6. Inform general practitioners:
 - the letter should be drafted by the incident team for signature by the director of public health
 - the letter should include general advice about the problem, the steps being taken to deal with it and the likely timescale

- the letter should be sent to all GPs in the locality
 - copies should be sent to practice managers and practice nurses, and the local community health council (CHC)
 - copies should be sent to neighbouring labs, private labs and other hospitals who may use the same laboratory, and to community health clinics including family planning clinics
 - consider using fax or E-mail as well as or instead of letter post (though confidentiality and data protection rules must be observed for information about named individuals)
 - further briefing for GPs on the progress of the incident may be necessary.
7. Write to women directly affected:
- the letter should be drafted by the incident team and signed by the trust chief executive or medical director
 - enclose a pre-paid, self-addressed envelope and return slip (or ask the woman to telephone a special number) to confirm that she has received the letter
 - a form to notify any change of address or personal details may be included
 - send the letter by first-class post
 - avoid posting letters that will be delivered on a Saturday, when support from health professionals may be difficult to access
 - it may be helpful to include leaflets, e.g. about colposcopy.
8. Brief the staff groups involved:
- face-to-face briefings by the incident team leader of those staff whose performance is under scrutiny
 - if necessary, offer access to counselling or support from occupational health or personnel staff
 - face-to-face briefing by the incident team leader of those staff in the laboratory or in colposcopy who will have to deal with urgent and perhaps increased workload: they will need to know the size of the problem, the workplan, the timescale and their role
 - other staff in the trust should have access to a general briefing note drafted by the incident team outlining the problem and the action being taken.
9. Prepare a press briefing. This should follow the principles set out in 3 above and should say:
- what the nature of the problem is
 - when the problem occurred
 - how the problem was identified
 - how many women are affected
 - if all the women have been told, and when
 - what advice, investigation or treatment has been offered to the women

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- when the follow-up will be complete
- what is being done to stop the problem happening again
- the name of the press contact at the trust and health authority.

The trust should be prepared to provide a local spokesperson for press interview if necessary. This may be the trust chief executive or medical director, or the clinical head of the laboratory. Local issues are best dealt with locally, and it may cause unnecessary friction with the local media if no local spokesperson is available.

10. Report to the health authority, regional office and national coordination team on:
 - setting up of an incident team
 - agreed actions to solve the problem
 - the strategy for managing the consequences
 - how this is being communicated
 - what is being said.
- 4.3 **Actions for the health authority**
 11. Consider whether to issue its own press statement or a joint press statement with the trust.
 12. Decide how and who should respond to any queries which it may receive from the public, worried women, the media or professionals.
 13. Monitor the effectiveness of the processes involved in handling the incident.
 14. Liaise as necessary with the local community health councils.
- 4.4 **Actions for the regional office**
 15. Consider whether to issue its own press statement or a joint press statement with the trust or health authority.
 16. Decide how and who shall respond to any queries that it may receive from the public, the media or professionals.
 17. Provide information and advice to the trust and the health authority, with the regional director of public health taking the lead role.
 18. Notify the cancer team at the Department of Health and be prepared to provide a full briefing for ministers if the incident is likely to generate national media interest.
- 4.5 **Actions for national coordination team**
 19. Decide how and who shall respond to any queries that it may receive from the public, the media or others in the screening programme.
 20. Provide to the trust, the health authority and the regional office:
 - information and advice based on experience gained from other incidents

- access to professional public relations advice through its contract with a company familiar with the cervical screening programme
- established links with the national media
- access to national expertise across the professional disciplines in the programme.

21. The national coordination team will:

- monitor the process of managing the incident against national guidance and draw lessons accordingly
- advise on the wording of any letters to women
- address any implications for the wider screening programme.

If appropriate, the national coordination team will also:

- inform the wider screening programme about the incident
- advise the wider screening programme on how to respond to any queries from worried women and the media
- act as spokesperson for the national programme
- put out any press release on national issues
- advise the Department of Health on national issues.

4.6 Actions for the Department of Health

22. Provide advice to regional offices on briefing for ministers about the incident.
23. Consider its response to any media enquiries that it may receive.
24. Inform regional directors of public health, regional screening teams and health authorities about the circumstances and any national implications of the incident.

5. RETROSPECTIVE ACTION

5.1 Previous incidents

Two of the three previous major incidents in cervical cytology led to large-scale rescreening exercises to determine the number of slides that had been misdiagnosed and to offer appropriate remedial action to the women concerned. There are two consequences of a large-scale screening exercise. Firstly, for a small number of women, there are significant effects on their clinical management, leading to recall for colposcopy and possible treatment. At worst, there is the knowledge that they could have been treated at an earlier stage. Secondly, for a much larger number of women, there is little or no effect on their clinical management, but the rescreening exercise subjects them to a period of anxiety until their personal outcome is known. More generally, the exercise undermines public confidence in the cervical screening programme.

5.2 Rescreening exercises

The purpose of a rescreening exercise is to re-examine slides in order to identify those which have previously been misdiagnosed as a result of a problem in the cervical cytology laboratory. The decision about whether or not to undertake such an exercise depends on the nature and timescale of the problem, and the costs and likely outcomes of the rescreening exercise. A mathematical model has been developed by the Sheffield School of Health and Related Research (ScHARR)⁷ to help the decision-making process. The model can be used to estimate the expected numbers of additional abnormal cases that would be detected by a rescreening exercise and the likely cost per case. Copies of the model (on disk) and user instructions are available from the national coordination team or from regional quality assurance teams.⁸

The advantages and disadvantages of a rescreening exercise are summarised in Table 2.

5.3 Other retrospective action

The aims of any retrospective action are to put right for women affected what was done wrong in the past and to restore confidence in the cervical screening programme. Rescreening exercises may not achieve either goal, and other forms of retrospective action should also be considered. These include the early recall of women for a routine smear or no action at all other than to remedy the underlying problem. Whatever decision is made about retrospective action, the incident team must be prepared to justify the action, and to manage the consequences.

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Table 2 Benefits and disadvantages of a rescreening exercise

Benefits	Disadvantages
<i>Public perceptions</i>	
Seen to be dealing with the problem	Increased anxiety about cervical screening
Increased awareness of cervical screening	Loss of confidence in the programme
Opportunity to re-educate public expectations	
<i>Standards and protocols</i>	
Provide reassurance that quality assurance is in place	
<i>Programme performance</i>	
Short-term increase in detection rate for high-grade abnormalities	Delay to routine screening
	Distortion of laboratory data
	Discovery of some false negatives
	Overcalling of smear abnormalities
<i>Staff issues</i>	
	Reduced staff morale
	Pressure on laboratory staff
	Pressure on clinical staff
<i>Trust issues</i>	
May lead to improved resources	May lead to recruitment problems
May lead to improved management arrangements	Financial costs of exercise
	Potential medico-legal issues
<i>National programme</i>	
Alert other units to potential problems	Adverse publicity for programme

6. CLOSING AN INCIDENT

6.1 Closure

The leader of the incident team will decide at what stage the incident has come to an end and communicate the outcome(s) in accordance with guidance in Chapter 3 to:

- GPs
- staff
- trust chief executive
- director of public health
- regional director of public health (who, in turn, informs the Department of Health)
- national coordination team.

The team should consider informing the media, taking account of specialist public relations advice in order to avoid rekindling inappropriate media interest in the issue. The incident team and its facilities should be formally brought to a close. The incident team leader should ensure that the work of the incident team members is acknowledged.

6.2 Reporting

The incident team should produce a brief report which covers:

- causes of the problem
- identification of the problem
- investigation of the problem
- solution of the problem
- management of the consequences
- the lessons learned locally
- any implications for the wider screening programme.

A copy of the report should go to:

- trust chief executive
- director of public health
- regional director of public health
- national coordination team.

6.3 Evaluation

The incident team should also evaluate the process of managing the incident against the objectives set for the exercise and report to the trust chief executive on the lessons learnt and recommendations for changes in the procedures for managing any such incidents in the future. This evaluation of process will include:

- effectiveness of the incident team
- the contribution of its specialist membership
- how the helpline worked
- effectiveness of communications with women, GPs and practices
- media coverage
- usefulness of these guidelines.

A copy of this report should be sent to:

- trust chief executive
- director of public health
- regional director of public health
- national coordination team.

7. OTHER INCIDENTS IN CERVICAL SCREENING

7.1 Problems in other areas of cervical screening

Previous chapters have focused on problems in cervical cytology because this is where previous major incidents in the screening programme have occurred. There have, however, been instances of problems with smear taking, with transfer of results from laboratories to smear takers, and with colposcopy. The principles set out in earlier chapters still apply, and the stages in managing an incident remain the same. These are:

- initial investigation
- formal investigation
- set up an incident team
- consider retrospective action
- close the incident.

The only significant difference will be in the personnel involved in the investigation and in the incident teams, whose membership will depend on the nature of the problem.

7.2 Problems with call and recall

The effectiveness of the cervical screening programme depends not only on the quality of clinical performance, but also on administrative systems which ensure that the right results are sent to the right woman, and that she is recalled at the right time for routine screening, for a repeat smear, or for further investigation and treatment. The call and recall system depends on the accurate reporting of smear test results from the laboratory to the health authority and to the smear taker. There has been at least one instance of results reported to the health authority not being reported to the smear taker, with the consequence that some women did not receive appropriate follow-up. Regular audit by smear takers of smears taken and the results are a means of identifying any discrepancies. Moreover, health authorities should undertake regular audits of the call and recall system.⁹ The initial investigation team for suspected problems with call and recall should include the (hospital-based) programme coordinator as well as the manager of the health authority call and recall system.

7.3 Problems in smear taking

Previous problems in smear taking have been caused by the use of inappropriate techniques for taking smears. The publication of the *NHSCSP Resource Pack for Training Smear Takers* should lead to improved training and a more consistent standard of smear taking, and should also encourage smear takers to monitor their own rates of inadequate smears.¹⁰ Quality assurance teams are also monitoring inadequate smear rates as a means of improving consistency both of smear taking and of laboratory performance. Suspected problems in smear taking should be investigated initially by a team that includes a general practitioner or practice nurse with extensive and recent experience of smear taking.

7.4 Problems in colposcopy

Quality assurance guidelines for colposcopy were published in 1996, and work in monitoring performance against national standards is in

progress.³ Nevertheless, there has been one recent incident in which concerns about the quality of colposcopy were raised by a new member of staff. As a result, a number of women were recalled for further investigation and treatment.¹¹ The initial investigation team for suspected problems in colposcopy should include the clinical head of the colposcopy service. Consideration should be given to involving external experts in colposcopy on the investigation and incident teams, particularly if the performance of an individual clinician is in question.

The decision whether or not to recall women for further investigation requires very careful consideration. The review of the management of the recent incident concluded ‘recall exercises for cervical screening programmes are traumatic for the women involved, difficult to manage and handle, and resource intensive, and should be used only as a last resort when there are strong reasons to believe that women are at significant risk’.

7.5 Problems in histopathology

Guidance on histopathology reporting in cervical screening has recently been published by the NHSCSP.¹² This includes advice on audit and quality assurance. The routine audit of histology provides a means of identifying suspected problems. The initial investigation team for any such problem should include the clinical head of the histopathology service, and consideration should be given to seeking expert advice from outside the laboratory if appropriate.

APPENDIX 1: KEY MESSAGES

About the incident

What is the nature of the incident?	(e.g. possible misreporting of abnormal smears)
When did the problem occur?	(e.g. smears read by one screener between April 1996 and January 1997)
How was the problem identified?	(e.g. problems picked up by regional quality assurance programme and a rapid review of 1000 smears)
How many women are affected?	(e.g. 20 women being referred for colposcopy, 80 women need repeat smears)
Have all the women been told?	(e.g. the trust has written on 6 December 1997 to all the women affected)
When will follow-up be complete?	(e.g. all women will have had treatment or results of repeat smears within two months)
What is being done to stop it happening again?	(e.g. screener concerned no longer working in cervical screening/receiving further training)
What is being done to deal with media enquiries?	(e.g. trust issuing a press release on date X and setting up helpline to deal with enquiries from media and concerned women)
What is the (sympathetic) line to take?	(e.g. problems with the quality of a small number of smears were identified quickly by the quality assurance programme in place. In the light of this, we have taken swift action in ordering a rapid review of 1000 smears. As a result, a small number of women are being asked to have repeat smears as a precautionary measure. They should have their results within the next two months).

About the cervical screening programme

- Cervical screening works. The number of cases of cervical cancer is dropping fast. Deaths from cervical cancer are falling by 7% a year.
- According to the Imperial Cancer Research Fund, cervical screening prevents up to 3900 cases of cervical cancer every year.
- Cervical screening is screening not for cancer, but for abnormalities, some of which may develop into cervical cancer.
- A cervical smear test is not 100% accurate. If you have any symptoms such as abnormal bleeding, you should consult your GP straight away.

APPENDIX 2: DEALING WITH THE MEDIA

- A nominated press officer should be part of the incident team from the start of the exercise.
- The press officer should have experience of dealing with the national as well as the local media.
- There must be close liaison within the regional press office, the NHSCSP public relations team and the Department of Health press office.
- The press officer should have access to all briefing material used locally and nationally to ensure a consistent message.
- A press release should be prepared as soon as possible, though every effort should be made to identify and contact affected women before informing the press.
- Advice from the public relations advisers to the national coordination team should be sought at an early stage on the wording and timing of press releases and on liaison with the national media.
- A press conference can be an effective way of dealing with a large number of media enquiries but may also generate substantial knock-on interest.
- A medically qualified person (the director of public health, the trust medical director or clinician) should be present at a press conference.
- Press releases should not be delayed if it proves difficult to convene a press conference.
- A controlled release of information is preferable to a 'leak'.

APPENDIX 3: TELEPHONE HELPLINES

1. Women may be concerned about how an incident in the cervical screening programme might affect them. They will often want immediate access to information and advice about their concerns, and need reassurance about their risk of developing cervical cancer. Local telephone helplines can meet this need by:

- helping allay immediate concerns
- providing a valuable first step in the counselling process
- offering patients personal and private advice
- providing information on the procedures in place to recall women who have been identified as needing a repeat smear or further investigation.

A distinction should be made between **general** helplines, which provide information and reassurance to all women, and **specific** helplines set up to provide more detailed information and advice to women who have been notified individually that they have been affected by an incident.

2. In establishing local helplines it is useful to bear the following in mind:

- the telephone company should be contacted immediately the decision to set up a helpline has been made
- the number of lines needed will be dictated to some extent by the scale of the problem and whether a general or specific helpline is to be set up
- a large number of helplines can take 24–48 hours to establish. If necessary, start with as many lines as can be made available at the time and then introduce more as soon as possible. Some lines can always be decommissioned as demand subsides.
- widespread publicity regarding general helpline numbers is essential
- lines should ideally operate from 8 a.m. to midnight in the first instance, and over the weekend. An answerphone with a reassuring message should be in operation overnight
- helplines should not be routed through the main hospital switchboard otherwise it will become jammed
- staff manning the helpline should ideally have experience of telephone helplines and counselling rather than knowledge of cervical screening
- staff manning the helpline will need to discuss with the incident team the issues likely to be raised and will need to be briefed on the local protocol for arranging further screening and for treatment
- briefing for helpline staff should include advice on how to handle complaints from callers

- helpline staff need frequent breaks and easy access to refreshments
- helplines should take account of the particular needs of women whose first language is not English, or who have hearing difficulties.

All staff operating a helpline should attend regular debriefing sessions. This should not be optional.

3. Depending on the number of women likely to phone in and the staff available it may be helpful to establish a system of triage, i.e.:
 - first calls to the helpline should be screened by the operator to ascertain if the caller has been notified in writing and, if not, to be counselled and reassured
 - women who have been notified should be transferred to more highly skilled counsellors, who can then offer more detailed advice and reassurance. These counsellors will need a second bank of phone lines
 - when case finding is not complete then the first-line operator should tell callers that they will be phoned back once their records have been checked. This must be done as soon as possible
 - it is helpful to give a different helpline number in the letter to women who have been notified so that they can immediately call a second-line counsellor
 - when helplines are continually blocked, experience has shown some people phone or come directly to the hospital. Switchboard and reception staff require briefing and should know where to refer them.
4. It is absolutely essential to have one overall manager who takes control and who is able to co-opt the help that is needed. The manager in charge of the operation should set up rotas and ensure that operators have a day off every three or four days.
5. When a helpline is set up, the operators must have up-to-date briefing materials, which should be revised whenever press releases go out. Particularly at the outset when the initial media briefing takes place, operators must be informed of what is being said on both television or radio. It is useful to have access to a television and radio so that information that is broadcast is available to operators. A single senior manager should take responsibility for the updating of briefing materials.
6. Records of all helpline calls should be filed alphabetically so that they are easily accessible when callers ring again. A simple ring binder system would ensure that operators could check earlier information that had been given. A computer operator should be available to input information onto the database of women affected as required.

7. Contingency plans should be made for those women wishing to continue seeking support and reassurance after the main helpline has stopped.

Adapted from *AIDS–HIV Infected Healthcare Workers: Practical Guidance on Notifying Patients*. Department of Health 1993.

REFERENCES

1. Pritchard J. *Quality Assurance Guidelines for the Cervical Screening Programme*. Sheffield, NHS Cervical Screening Programme, 1996 (NHSCSP Publication No. 3).
2. Herbert A. *Achievable Standards, Benchmarks for Reporting and Criteria for Evaluating Cervical Cytopathology*. Sheffield, NHS Cervical Screening Programme, 1995 (NHSCSP Publication No. 1).
3. Luesley D. *Standards and Quality in Colposcopy*. Sheffield, NHS Cervical Screening Programme, 1996 (NHSCSP Publication No. 2).
4. *Internal Review into the Laboratory at the Women's Hospital, Liverpool*. Liverpool Health Authority, 1987.
5. Scottish Office. *Report of the Inquiry into Cervical Cytopathology at Inverclyde Royal Hospital, Greenock*. Edinburgh, HMSO, 1993.
6. Wells W. *Review of Cervical Screening Services at Kent and Canterbury Hospitals NHS Trust*. NHS Executive South Thames 1997.
7. Turner J, Brennan A, Dixon S. *The Costs and Outcomes of Cervical Re-screening*. University of Sheffield School of Health and Related Research (SchARR), 1999. Available from NHSCSP Publications.
8. *Mathematical Model for Cervical Re-screening* (Excel disk with user instructions). Available from NHSCSP Publications.
9. *Practical Guide for Health Authorities*. Sheffield, NHS Cervical Screening Programme, 1997 (NHSCSP Publication No. 7).
10. *Resource Pack for Training Smear Takers*. Sheffield, NHS Cervical Screening Programme, 1998 (NHSCSP Publication No. 9).
11. *Colposcopy Review*. St George's Healthcare NHS Trust, 1999.
12. *Histopathology Reporting in Cervical Cytology*. Sheffield, NHS Cervical Screening Programme, 1998 (NHSCSP Publication No. 10).