

## **INTERIM** Guidelines for Managing Incidents in the NHS Bowel Cancer Screening Programme

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## *Cancer Screening Programmes.*

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## PREFACE

Handling and learning from adverse incidents plays a crucial role in ensuring robust quality assurance within the NHS Bowel Cancer Screening Programme (NHS BCSP). With national rollout now complete, and QA processes in place, we are now able to produce interim guidance for health professionals involved in the NHS BCSP on managing such incidents.

Underpinning this guidance is an awareness of the need for a professional approach to communications when incidents occur. The document has also been informed by the NHS clinical and information governance frameworks, and the National Patient Safety Agency's nationwide system for reporting and learning from patient safety incidents.<sup>1</sup>

The objective of this document is to provide interim incident management guidelines for the BCSP that:

- are effective, clear, workable and easily understood by users.
- cover staffing, strategic, operational, IM&T, and finance-related incidents, as well as clinical events.
- will justify and sustain continued public confidence in the BCSP.
- will reassure commissioners and stakeholders.

The authors gratefully acknowledge the contributions of colleagues who participated in the workshops on adverse incidents (held in Sept 2010 and March 2011) and of the editorial group responsible for producing adverse incident guidelines for the Cervical Screening Programme,<sup>2</sup> who laid out many of the generic principles outlined here.

# 1 INTRODUCTION

## 1.1 Background

The NHS BCSP offers a two yearly screening test, known as the Faecal Occult Blood test (FOBT), to individuals in England aged 60–74. An abnormal test result means that the individual is offered endoscopic assessment of the large bowel with colonoscopy.

These interim guidelines set out advice on best practice for incident management within the NHSBCSP. They are based on experience gained from a number of bowel cancer screening incidents that have occurred since the programme began in 2006, and on knowledge gleaned from other screening programmes (published in the *Guidelines for Managing Incidents in the Breast Screening Programme*<sup>3</sup> and *Interim Guidelines for Managing Incidents in the Cervical Screening Programme*).<sup>2</sup>

The NHS BCSP is complex, with multiple agencies involved along the patient pathway (Figure 1). The result is that problems are not always easy to identify. While not all such problems constitute incidents, failures to identify and manage problematic situations can transform them into incidents. Where these adversely affect a large number of screened individuals, they can lead to high profile complaints about the screening centre, which can impact in a negative way on screening uptake. These facts make rigorous quality assurance (QA) essential.

There are numerous systems for reporting problems and incidents in the NHS, some of which overlap with one another. Each Trust and Primary Care Trust (PCT) will have local protocols for managing adverse events, and each bowel cancer screening centre or hub must operate in accordance with these protocols when managing risk and reporting/managing incidents. These guidelines represent an addition to these local protocols, not a replacement for them.

The requirements set out in these guidelines for reporting incidents in the NHS BCSP do not replace the reporting requirements of the Department of Health (DH), or of the Trust or local PCT.

Instead, they are a mandatory addition to existing incident handling requirements.

They apply to **any** organisation providing NHS BCSP services, including NHS Trusts, Foundation Trusts, PCTs, private providers, or other commissioning organisations.





## 1.2 Incidents in the NHS BCSP

### 1.2.1 Definition

The term 'incident' in the NHS BCSP refers to any failure by a bowel cancer screening centre or programme hub that:

- puts individuals at risk of inadequate screening, assessment, or treatment; or
- puts staff at risk; or
- leads to adverse public or media interest.

**The magnitude of any incident, and the final risk categorisation, will be based on the outcome of subsequent investigation.**

Appendix 1 gives some examples of incidents that have occurred within the BCSP. This list is not exhaustive and is intended as guidance only. It is based on the risk categorisation (RAG system) familiar to clinical teams.

### 1.2.2 Identifying an Incident: Roles and Responsibilities

The Director of Public Health (DPH) for each Strategic Health Authority (SHA) appoints a regional QA Director. An important part of the QA Director's role is to identify, support, and respond to problems in a bowel cancer screening centre and/or programme hub. He or she should advise the screening centre on how to solve these problems, and should also help to ensure that prompt resolution takes place.

The QA Director may judge a problem to have serious consequences for the individuals screened, or may come to the conclusion that an issue is long-standing and has not been adequately resolved. In such cases, he or she will advise the Chief Executive of the relevant organisation and the Chief Executive(s) of the commissioning Primary Care Trusts (PCTs) that the problem should be declared an incident. The SHA screening lead will also be informed of this decision.

There are likely to be some potential incidents that the QA Director judges to be of insufficient scale to warrant the full involvement of every individual listed above. However, it is essential that the principles of this guidance are applied in the first instance, irrespective of the magnitude of the (potential or declared) incident.

**A cautionary approach to incidents should always be taken until the facts are fully available.**

### *1.2.3 Managing an Incident: Roles and Responsibilities*

Once a problem is declared an incident, then its subsequent management should be led by the Chief Executive of the organisation in which the incident has originated/occurred. Where multiple organisations are involved, agreement must be reached between these parties about their roles and responsibilities during the investigation.

The QA Director will provide expert advice about bowel cancer screening, and impartial, objective leadership of the investigation into the causes and extent of an incident. This advice can be given in person, or through a delegated expert. The QA Director will advise on achieving a resolution to the incident that minimises the risk both to individuals who have already been screened, and to those who may be screened in future.

### *1.2.4 Stages in Identifying, Investigating, and Managing an Incident*

The main stages involved in identifying, investigating, and managing an incident in the NHS BCSP are outlined in Figure 2. These are:

- identifying a suspected problem.
- investigating the problem (led by the QA Director).
- managing the incident (led by the Chief Executive of the organisation in which the issue has arisen).
- managing the consequences of the incident (including recalling subjects where necessary).
- closing the incident and monitoring actions.
- learning lessons.

### 1.3 Other incident reporting systems

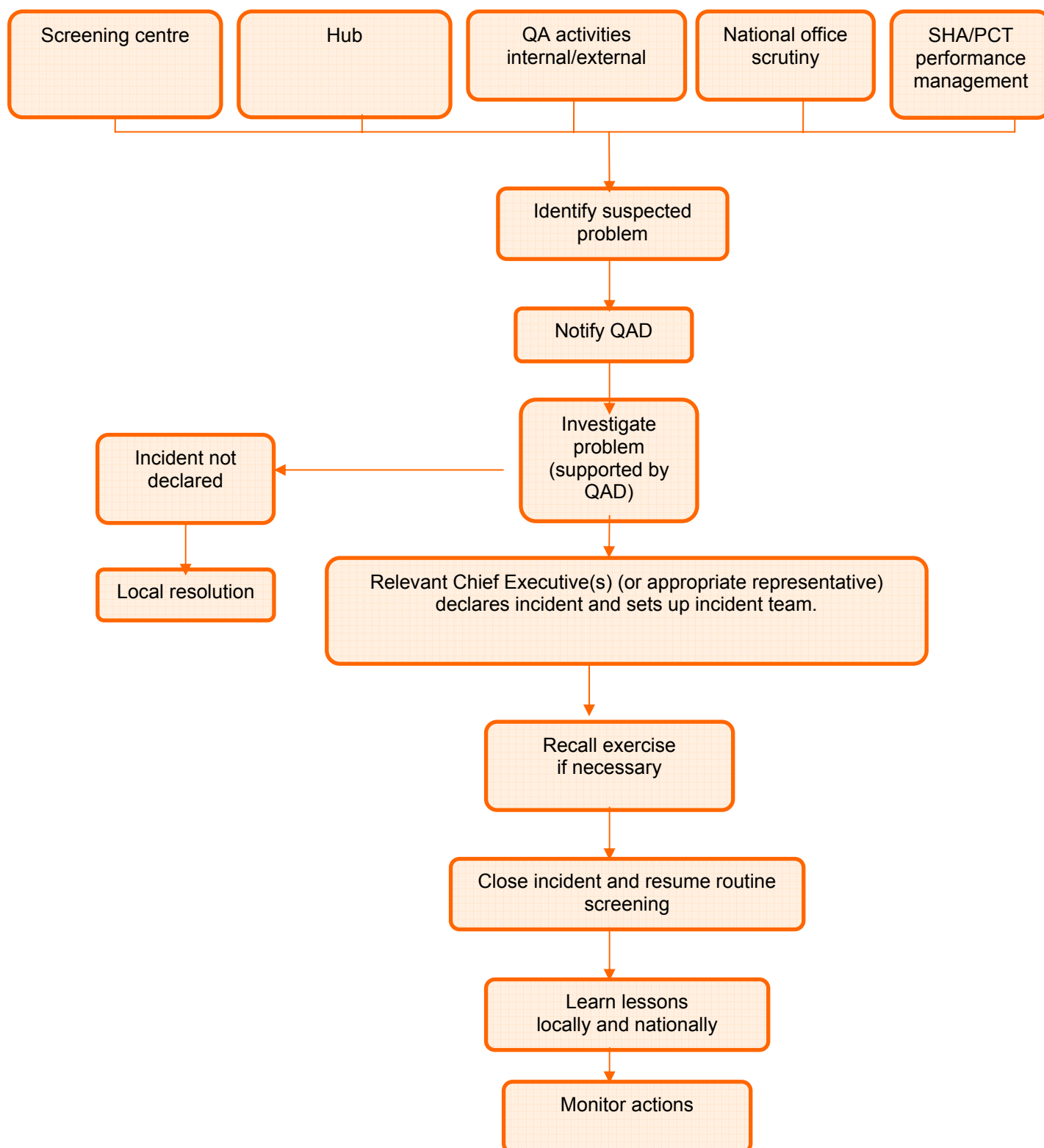
The Patient Safety Division of the National Patient Safety Agency (NPSA, [www.npsa.nhs.uk](http://www.npsa.nhs.uk)) helps the NHS in England and Wales to learn from patient safety incidents. It collects information on incidents from patients and staff via the National Reporting and Learning System (NRLS). The NPSA defines patient safety incidents as 'any unintended or unexpected incident which could have, or did lead to harm for one or more patients receiving NHS-funded healthcare'.<sup>1</sup>

If an incident has serious implications for organisation(s) involved in any aspect of the bowel cancer screening programme, the relevant Chief Executive may declare it to be a serious incident (SI). Examples of SIs include:

- unexpected death or serious injury to patients.
- serious breaches of confidentiality.
- serious disruption to services.

Trusts are required to notify the SHA and DH of SIs, using the SI reporting system. This obligation also extends to Foundation Trusts.<sup>4</sup>

If there has been a serious service failure, the SHA DPH and the Chief Executive of the commissioning PCT or the Trust may need to involve an appropriate body, e.g. Monitor, or the Care Quality Commission (CQC). A serious service failure in bowel cancer screening is defined as an ongoing failure of one or more individuals or systems, which the screening centre and its host Trust have been unable to correct. An investigation into a failure at a bowel cancer screening centre or programme hub may include scrutiny of the role played by PCT Commissioners, SHAs, the regional QA team, and the national office of the NHS Cancer Screening Programmes.



**Figure 2** Outline of the incident management process

## 2 INVESTIGATING A PROBLEM

### 2.1 Identifying a problem

Most problems in the BCSP are identified by the screening centre or hub concerned. They may become aware of a problem by a number of means, including:

- a specific event gives rise to concern.
- a routine quality assessment or control activities.
- routine reporting of equipment and/or technical faults.
- quality assurance activities by the BCSP.
- monitoring by the host Trust as part of its clinical governance activities.
- staff concerns.
- a complaint or litigation.
- media interest.

Many of the problems identified are isolated, non-systemic events of a clinical or administrative nature. They are resolved by the screening centre/hub concerned and there is little or no risk of the problem recurring.

Equipment-related issues may also fall into this category. Equipment faults encountered in the course of routine use are usually repaired promptly by the supplier's service engineers. However, any fault, which may have compromised either the quality of screening, or patient or staff safety, should be reported immediately to the QA Director. In addition, a serious equipment fault which has, or could have, led to death or life-threatening injury should be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA, [www.mhra.gov.uk](http://www.mhra.gov.uk)).

The regional QA Reference Centre (QARC) must be notified as soon as possible of a suspected problem (whether clinical, administrative, or equipment-related) if it compromises the quality of the screening service. Such problems include situations involving:

- actual harm, or risk of harm, to individuals eligible for, or participating in, bowel cancer screening.
- actual harm, or risk of harm, to staff.
- concern about the professional competence of an individual.
- concern about the competence of the screening centre and/or hub.
- failure or misuse of equipment.
- failure or malfunction of the bowel cancer screening call and recall system (BCSS) (or of any other computer system used for patient management within the programme).
- breach of patient confidentiality or data security.
- systemic failure to comply with national guidelines or local bowel screening protocols.

Notification of the QARC should be by telephone, accompanied by a written copy of the completed BCSP incident form and Trust incident form (where appropriate). Confirmation of any further details should be sent to the QARC in writing within seven days. The QARC will then notify the QA Director. In cases where patient confidentiality or data security have been breached, local advice should be sought on whether the Information Commissioner should also be notified.

## **2.2 Other mechanisms for identifying a problem**

### *2.2.1 Endoscopy team*

The risks associated with colonoscopy mean that bowel cancer screening has the potential to cause serious harm or even death. The endoscopy community has evaluated these risks and adopted a stratified approach to reporting all clinical incidents in screening centres and host organisations. To facilitate incident reporting in screening centres, the relationship between this approach and the RAG risk scoring system used in most host organisations has been mapped (see Appendix 1).

### *2.2.2 Regional QA team*

The regional QA team can identify potential problems occurring at a bowel cancer screening centre or hub. The monitoring of routine statistics by QARCs may highlight certain issues, while formal, three-yearly, multidisciplinary QA visits offer an opportunity to review performance and identify problems in key areas (such as working relationships) that may affect the quality of the BCSP.

As part of their performance management activities, PCT commissioners, SHA DsPH, and SHA screening leads may also identify potential problems. The national office of NHS Cancer Screening Programmes can also detect potential issues via scrutiny of programme performance and review of QA visit reports.

## **2.3 Initial assessment by the QA Director**

As soon as the QA Director becomes aware of a suspected problem at a bowel cancer screening centre or hub\*, he/she should assess the potential seriousness of the problem. This assessment should take into account the context in which the suspected problem has arisen, whether there are issues of governance or individual performance that may require further investigation, and whether the incident is likely to be isolated or systemic. The QA Director may need to seek advice from members of the QA team, from other specialists, and from the national office while undertaking this process. A written record of the sequence of events, and the available evidence, must be kept. Figure 3, on the next page, lists some questions that the QA director may wish to ask.

If the initial assessment by the QA Director reveals a possible failure of the bowel cancer screening centre or hub, he/she should notify the following parties with immediate effect:

- the Chief Executive of the Trust/s.
- the Chief Executive(s) and D(s)PH at the commissioning PCT(s).
- the Regional DPH and SHA screening lead.
- the Director of the NHS Cancer Screening Programmes.

\* Programme hubs may need to report to several QARCs, SHAs, and PCTs.

**Initial assessment of a suspected problem**

What is the problem?

Is it an isolated event or has it happened before?

Has it the potential to happen again, or to affect a greater number of individuals than those impacted previously?

How was the problem identified?

What evidence is available to support the notion that a problem exists?

What is the scale of the problem?

When was the problem first identified?

How long has it been going on?

Are any individuals directly affected? (If so, estimate how many.)

Does it affect any staff?

What are the possible causes of the problem? Is there a failure of equipment, procedures, or IT systems? Is an individual at fault?

Is it still a problem?

If yes, is it safe to continue the screening programme?

Are there any immediate implications for other bowel cancer screening centres or hubs?

Are any other agencies involved?

What has the BCSP done about the problem so far?

Has an initial investigation been conducted by the local screening centre or hub, and reported to the QAD?

Has the local service or Trust investigated the practice of any individuals in the screening centre?

Is the problem public knowledge? If so, how has it become so?

What actions are being taken to inform/support staff?

What does the bowel screening service plan to do next?

**Figure 3 Assessment checklist**

Problems should not be allowed to compromise the quality of the BCSP and/or put additional people at risk whilst an investigation is conducted. Therefore, the QA Director should consult with other key people (the Trust's Chief Executive or commissioning PCT's lead) to determine whether it is safe to continue with bowel cancer screening. However, as the impartial expert, the QA Director should take the lead on this decision.

If the decision is made to suspend a screening centre or hub while an investigation takes place, then the Trust must ensure that appropriate arrangements are made to manage subjects who are part-way through the screening process.

The national office may also make recommendations about whether or not elements of the BCSP should be suspended, and will decide whether other regions potentially affected by the problem should be informed. It must therefore be kept informed of events as they unfold.

## 2.4 Investigation team

Membership of the investigation team depends on the nature of the problem under scrutiny, but is likely to include as a minimum:

- senior representation from the organisations involved, e.g. a Director of Public Health or Medical Director, or a nominated member of staff who is at director level.
- the screening centre Director, and lead professionals from those elements of the screening centre or hub under examination. If the local lead professional(s) are, or could be, directly involved in the potential incident, consideration should be given to including a suitable alternative, e.g. a member of the regional QA team.
- the QA Director.
- the QA lead for the relevant profession. A suitable professional alternative should be considered if the problem has occurred in the screening centre of the QA lead.
- risk management staff.
- staff with media communication skills (if individuals may need to be contacted, or where there may be media interest in the incident).

In the early stages of the investigation, when it is important to establish the facts quickly, a small team is often more easily convened than a larger team. As the investigation progresses, the QA Director may recommend the inclusion of additional professional expertise (the national office can offer advice on potential sources).

The role of the QA Director is to provide expert advice about bowel cancer screening, and objective scrutiny of the findings of the investigation. Costs of the investigation must be borne locally.

## 2.5 Investigation process

The format of the investigation will depend on the nature of the suspected problem, but may include the following

- review of administrative activities, including processes, procedures, and protocols.
- review of training records.
- review of FOBt kit testing.
- review of 'right result to right individual' procedures.
- visit(s) to the screening centre and/or hub by the relevant professional QA coordinator or QA team.
- review of selected case notes.
- review of pathology procedures and cases/samples.
- review of equipment quality control records.
- verification of performance data by the bowel cancer screening centre and the QARC.
- further statistical analysis of performance data by the QARC.

It is possible that individuals may need to be contacted, or that media interest in the investigation requires a response. A holding press statement should therefore be prepared to cover the eventuality that enquiries are received before the investigation is concluded.



Checklists for the investigation of problems in call and recall (Appendix 3), pathology (Appendix 4), and imaging radiology (Appendix 5), appear at the end of this document.

## **2.6 Progress of the investigation**

During the course of the investigation, the QA Director should continuously evaluate:

- whether it is safe to allow the invitation process, testing of FOBt kits, SSP clinic, or screening colonoscopy service to continue (or, alternatively, whether it is safe for them to operate at a reduced rate).
- whether the invitation process, SSP clinic, or screening colonoscopy service should be suspended for a period or stopped altogether; and/or
- whether urgent action is needed to remove an individual or a piece of equipment from the process.

If the QA Director recommends the suspension of the whole, or elements of, an unsafe screening centre/hub, and this is not acted upon, the QA Director should immediately set out his/her concerns to the Chief Executive of the relevant organisation. The SHA DPH and Director of the NHS Cancer Screening Programmes should also be informed.

If there is a possibility that disciplinary action will be taken against an individual by the host Trust or a professional body, then the QA Director should be careful not to prejudice any such proceedings. The QA Director should also advise on the appropriateness of reporting the incident through other incident reporting systems.

If either the SHA DPH or the Director of the NHS Cancer Screening Programmes has concerns about governance within the host Trust itself, then they, or their authorized representatives, may refer the matter to an appropriate body (e.g. Monitor and/or the CQC).

## **2.7 Findings of the investigation**

The QA Director is responsible for ensuring that a report detailing the initial findings of the investigation is available within 7 working days. This must reach one of three conclusions:

- initial suspicions have not been confirmed and there is no problem.
- a problem is still suspected, the cause has not yet been identified, so the investigation is ongoing.
- the problem has been confirmed and the cause identified.

The report must:

- set out the reasons for investigating the matter.
- record the methodology already used in the investigation.
- set the objectives for any further investigation, establish a realistic timescale for their achievement, and advise on the methodology to be employed.
- recommend whether screening should continue while further investigations take place.

Full details of the investigation should form part of the report (see section 4.2). A copy of the report should be sent to:

- the Chief Executive of the commissioning PCT(s) or Trust(s) involved.
- the SHA DPH and screening lead.
- Director of the NHS Cancer Screening Programmes.

## 3. MANAGING AN INCIDENT

### 3.1 Declaring an incident

At any stage during the investigation of a problem, a formal incident may be declared. In this case, the Trust Chief Executive will need to set up an incident team. The role of the incident team is to:

- establish the cause(s) of the incident.
- agree an action plan to resolve the problem and manage its consequences.
- monitor the progress of the action plan.
- agree timescales for closure of the incident.
- identify lessons to be learnt.

The role of the QA Director is to provide expert, impartial advice during an investigation, either in person or through a delegated expert. In particular he/she will advise on:

- the format and methodology for any further investigation into the causes and extent of the incident.
- whether any part of the bowel cancer screening service should be suspended for the duration of the investigation.
- whether a recall exercise is necessary for individuals who have undergone screening colonoscopy.
- the way in which the problem should be resolved, to minimise risks to individuals screened in future.
- whether hub activities need be moved, partially or totally, to an alternative hub.
- the timescale for safe resumption of both call and recall and screening colonoscopy.

### 3.2 Setting up an incident team

The Chief Executive of the host Trust should set up an incident team within 48 hours of the decision to declare an incident. The incident team should have clear terms of reference.

Membership of the team should be explicit and be agreed between the host Trust, the commissioning PCT(s), the SHA, and the regional QA Director. Membership will depend on the nature of the problem but is likely to include:

- the Chief Executive of the host Trust organisation.
- the Medical Director of the host Trust organisation.
- the Director of Public Health, or a nominated deputy from the commissioning PCT(s).
- the SHA DPH or nominated deputy,
- the QA Director (or nominated representative).
- the relevant professional QA team members (a suitable professional alternative should be considered if the problem is in the screening centre of the QA team member).
- hub Director/s.

- screening centre Directors.
- a designated communications officer (where individuals will be contacted or where media interest is likely or expected; this person should be trained in dealing with the local and national press and must be the sole point of contact with the media).

If more than one Trust, PCT, or SHA is involved in the incident, then all parties should be represented on the incident team. The team should be chaired by the Chief Executive of the host Trust or their representative, or by the senior officer from the commissioning PCT(s). It is essential to identify a team member with responsibility for administration and documentation, and there must be adequate administrative and IT support. It is also useful for the team to have access to the following:

- external expertise in the relevant aspect of bowel cancer screening.
- legal advice.
- human resources advice.
- counselling advice.

It is the responsibility of each team member to keep their own organisations fully briefed about the incident and remedial actions being taken.

### **3.3 Actions for the incident team**

1. Define the objectives of the incident team and draw up an action plan. This should be agreed with the SHA, in accordance with the local incident protocol.
2. Estimate the probable number of individuals affected (this may involve the QARC and staff from the screening centre/hub).
3. Confirm the identity of the individuals directly affected by the incident.
4. Where patients are involved, set up a secure database of all affected individuals (names, addresses, date of birth, and GP), and check it for accuracy. BCSS should then be used to confirm current details and to search for individuals who have moved away (arrangements for the latter group can be made in conjunction with hub staff, who can liaise directly with colleagues in other areas of the country).
5. Decide what action to take where individuals have been affected by the incident. This may include:
  - re-inviting individuals for bowel cancer screening and/or colonoscopy.
  - reviewing screening colonoscopy records.
  - providing access to support and advice from specialist doctors or nurses.

Careful thought should be given to the desirability and likely consequences of inviting individuals to undertake repeat FOBt or repeat colonoscopy before the incident team has agreed a course of action. The NHS strongly encourages a culture of openness and shared learning where incident reporting is concerned; however, public concern should not be raised prematurely or speculatively.

6. Prepare for the consequences of any action taken:

- consider setting up a rapid-response helpline.
- make arrangements to deal with enquiries from the media and the general public.
- brief any staff who are likely to receive an increased number of queries from worried individuals (chiefly local hub staff and SSPs).

If the host Trust is confident that all the individuals directly affected have been contacted and have been offered the opportunity to discuss their concerns with an appropriate health professional, then setting up a general helpline may not be necessary, and may cause unnecessary anxiety among unaffected individuals. People with general queries about bowel cancer screening should be advised to contact the hub via the freephone telephone number.

Wherever possible, phone lines should be staffed by appropriately qualified people (SSPs, nurse endoscopists, or counsellors) who are familiar with the situation. If numbers permit, it may be preferable for the first contact to be via telephone by appropriate qualified staff.

7. Consider carefully the wording to be used in any communications, including any legal implications and issues of confidentiality:

- be informative about what has happened and why.
- describe what will happen next and the probable timescale.
- put the incident into the context of the BCSP as a whole.
- consider responses to probable questions.
- provide information on sources of further information and advice.
- be accurate, truthful, and consistent.
- offer an apology, where appropriate.

The NHS Cancer Screening Programmes' press office will advise on the wording of press releases and should be consulted before such documents are finalised. Local QA teams can also provide useful assistance and may liaise with the national press office if required. Details of the communications strategy are given in Appendix 9. The incident team should also liaise with the host Trust's communications team.

8. Specific proposals about the actions to be taken regarding individual patients should be drafted by the incident team. These should be signed by the Director of Public Health/ Medical Director (or equivalent) of the host Trust, before being sent to the GPs of affected individuals. This ensures that GPs are informed of the problem before the individuals themselves.

9. A letter to directly affected individuals should be drafted by the incident team for signature by the Chief Executive or Director of Public Health/Medical Director of the host Trust.

- The letter should be sent by first class post (or by recorded delivery or courier if numbers allow).
- The individuals should be asked to confirm receipt of the letter either by telephone, or via a prepaid, self-addressed envelope and return slip.

- It may be useful to include the relevant national information leaflet, or advise individuals to look for further information on the website of the NHS Cancer Screening Programmes.

Ensure appropriate planning so that letters do not arrive on a Saturday or public holiday, when support from health professionals and the individuals' GPs may be difficult to access.

10. Brief the staff groups involved:

- the incident team leader must conduct face-to-face briefings with staff from the bowel cancer screening programme who are directly involved.
- the incident team leader should also conduct face-to-face briefing sessions for SSPs, screening colonoscopists, administrative staff at the screening centre, pathologists, bowel cancer screening laboratory staff, colonoscopists, and nurse endoscopists, all of whom may have to deal with an urgent and increased workload as a result of the incident.
- other staff in the screening centre and in the hub should have access to a general briefing note drafted by the incident team, which outlines the problem and the action being taken.

The incident team should aim to inform all those affected before they hear of the incident through the media.

11. Prepare a statement in case a press briefing is needed.

The key organisation(s) involved should be prepared to provide a local spokesperson for press interview if necessary. This may be the organisation's Chief Executive, the DPH/Medical Director, or the Chief Executive of the lead commissioning PCT.

Local issues are best dealt with locally. It may cause unnecessary friction with the media if no local spokesperson is available.

12. Document the actions taken, and suggest timescales for these. This information should form the basis of the incident report (see section 4.2)

### 3.4 Actions for the commissioning PCT(s)

The role of the commissioning PCT(s) is to work with the Trust to investigate and resolve the incident, and deal with its consequences. The PCT(s) should:

- work with the SHA and key organisation(s) to prepare material for a joint press briefing (separate press briefings may cause confusion, and encourage the perception that antagonism exists between various involved parties).
- decide how, and who, should respond to any queries that may be received from the public, the media, or those working in the programme.

- monitor the effectiveness of the incident management strategy (where the PCT is itself not a party to the incident).

### **3.5 Actions for the SHA**

The role of the SHA is to scrutinise the management of the incident in order to ensure due process. The SHA should:

- consider whether to prepare a separate press briefing, or joint press briefing, with the key organisation(s) involved and PCT commissioner(s) (bearing in mind the advice in 3.4, above).
- decide how to respond to any queries that be may received from the public, the media, or those working in the programme.
- provide advice to the key organisation(s) involved and the PCT commissioner(s).
- notify the cancer policy team at the Department of Health of the incident and of the action(s) being taken.
- be prepared to provide a full briefing for Ministers if the incident is likely to generate national media interest.
- consider how to respond to queries from local MPs/Councillors.
- assess the effectiveness of incident monitoring.

### **3.6 Actions for the national office**

The role of the national office is to ensure that confidence in the BCSP is maintained, and that the risks to individuals, and the anxiety caused by the incident, are kept to a minimum. The national office will:

- provide advice, based on experience of previous incidents, to the key organisation(s) involved, PCT commissioner(s), QA team, and SHA.
- facilitate access to national expertise in bowel cancer screening.
- advise on the way in which communications with affected individuals are handled.
- provide access to the national media through the NHS Cancer Screening Programmes website.
- decide, in consultation with the key organisation(s) involved (commissioning PCT(s), QA teams, and SHAs), how to respond to queries that may be received from those working in the screening programme, the public, or the media.
- after consultation with the key organisation(s) (commissioning PCT(s), QA team, and SHA), advise the wider screening programme of the circumstances and implications of the incident.
- if the incident is equipment-related, ensure that screening centres with similar equipment and the relevant regulatory authorities are informed.

## 4. CLOSING THE INCIDENT

### 4.1 Defining an end point

It is important that the key organisation(s) involved in an incident's management work towards a defined end point for its closure, which is formally recognized by all concerned. Closure generally occurs once all the consequences of the incident have been identified, and arrangements for dealing with those consequences have been put in place, and are operating effectively. Some consequences can be dealt with in a short timescale before the closure of the incident. Other consequences may take a longer time to resolve, and may continue to be handled after closure of the incident, provided that the incident team have developed appropriate reporting arrangements.

The incident team decides when to close the incident. After closure is achieved, the team can be disbanded. Where screening services have been suspended, the screening centre or hub may be able to resume work. The decision about the resumption of screening remains the responsibility of the incident team, who must take QA guidance on this matter into account.

### 4.2 Incident report

The incident report should be written by the chair of the incident team. The report should cover:

- the identification of the problem.
- procedures for investigating the problem.
- the findings of the investigation.
- recommendations made in response to the incident.
- other recommendations for improvements to existing systems.
- an evaluation of the process of managing the incident.
- an action plan for the future (many of the actions will already have been taken).

The chair of the incident team should send a copy to:

- the Chief Executive(s) of the key organisation(s) involved.
- the Director of Public Health at the commissioning PCT(s).
- the SHA DPH and screening lead.
- the regional QA Director.
- the Director of the NHS Cancer Screening Programmes.



### 4.3 Learning the lessons

The QA Director should provide the SHA DPH and the director of the NHS Cancer Screening Programmes with an objective report on the incident and the problem(s) that gave rise to it. This may include any ongoing concerns about, or issues with, the local health economy as a whole. Any findings relevant to the wider BCSP should be highlighted, alongside general lessons on managing such types of incident and dealing with their consequences.

Where there are implications for other screening centres, the QA Director should ensure that the main learning points are disseminated through routine QA activities and communication networks.

A copy of the report should also be sent to

- the Chief Executive(s) of the key organisation(s) involved.
- the Chief Executive of the commissioning PCT(s).
- the Director of the NHS Cancer Screening Programmes.

The report from the QA Director should be considered by the relevant national QA professional coordinating group and by the QA Directors' group. The timing of this process may depend on whether there are disciplinary or legal issues outstanding after formal closure of the incident.

The relevant professional coordinating group within QA should make recommendations regarding necessary changes to national policies and procedures that will minimise the risk of a similar incident occurring in the future. Agreed changes should be monitored as part of routine QA activities. The QA Directors' group should evaluate the progress that has been made in managing the incident against this national guidance, and should also recommend changes to policy and national guidance where appropriate.

The national office of NHS Cancer Screening Programmes should ensure that any recommendations are disseminated to the BCSP and implemented as soon as possible.

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# APPENDICES

## APPENDIX 1 Examples of Risk Categories

| Category of Risk | Clinical/ participants<br>(See also Appendices 3 (a-c) below from <i>QA Colonoscopy Guidelines</i> )   | Operational/ equipment   | Information governance  | Staff   | Strategic/external  | Financial   |
|------------------|--|--|---|---|---|---|
| <b>FATAL</b>     | <b>Clinical incident resulting in death.</b>   |  |   |   |   |   |
| <b>MAJOR</b>     | <b>Major clinical harm</b><br><br>Clinical incident resulting in: <ul style="list-style-type: none"> <li>o unplanned surgery.</li> <li>o perforation.</li> <li>o ITU admission &gt;1 night.</li> <li>o unplanned admission or prolongation for &gt;10 nights.</li> </ul> Pathology clinical error resulting in inappropriate surgery or missed cancer diagnosis. | Failure to offer assessment/ diagnosis to screen-positive people, leading to delay or serious harm to a single patient, or potential harm to a group of patients.<br><br>Wrong result to patient, leading to actual harm. Patient lost to follow-up, resulting in avoidable disease progression.<br><br>Equipment not serviced, maintained, or used correctly, leading to actual harm to individuals<br><br>Hub FOBt interpretation error, leading to serious harm to individuals. | Inappropriate access to BCSS at local screening level.<br><br>Inaccurate/ incomplete data entry on BCSS, resulting in avoidable disease progression in individual(s).<br><br>Breached confidentiality of significant number of patients, or a smaller number of sensitive cases. Examples include: leaks to media, loss/theft of mail, loss/theft of laptop, loss/theft of memory stick or other removable device which has unencrypted, patient identifiable data.<br><br>Loss of hard copies of patient data (medical records, personal notebooks). | Staff not trained to BCSP standards participate in the screening programme, leading to known serious harm to a single individual or group of patients.<br><br>Sustained loss of key groups of staff, leading to known serious harm to patients. | Failure to offer screening to eligible population, with substantial inappropriate exclusion/ceasing.<br><br>Failure to identify eligible population<br><br>Highly damaging national or international publicity and loss of reputation | Impact on service owing to financial constraints, resulting in a failure to offer screening or subsequent investigation (within the scope of the programme) to the eligible population. |

|                     |   |  |   |   |   |   |
|---------------------|---|--|---|---|---|---|
| <b>INTERMEDIATE</b> | <p>Clinical harm</p> <p>Bleed with:</p> <ul style="list-style-type: none"> <li>• Hb drop of <math>\geq 2</math> g/dL</li> <li>• Transfusion.</li> <li>• Unplanned admission or prolongation for 4–10 nights.</li> <li>• ITU admission for 1 night. Interventional procedure (endoscopic or radiological).</li> </ul> <p>Other</p> <ul style="list-style-type: none"> <li>• Unplanned admission or prolongation for 4–10 nights.</li> <li>• ITU admission for 1 night.</li> <li>• Interventional procedure (endoscopic or radiological).</li> <li>• Interventional treatment for skin or other tissue injuries.</li> <li>• Unplanned ventilatory support during conscious sedation.</li> </ul> <p>Pathology clinical error resulting in incorrect pathway (e.g. attending at wrong surveillance interval).</p> <p>Hub FOBt interpretation error.</p> | <p>Failure to offer assessment/diagnosis to screen-positive people, leading to delay and potential harm to a single patient.</p> <p>IT failure leading to a delay in screening for a group of patients</p> <p>Wrong result: patient lost to follow-up, with potential for disease progression.</p> <p>Equipment not serviced, maintained, or used correctly, leading to potential harm to individuals.</p> <p>Hub FOBt interpretation error, leading to potential harm to a group of individuals</p> | <p>Inaccurate/incomplete data entry on BCSS, resulting in potential disease progression in a group of patients</p> <p>Potential breach in confidentiality involving a significant number of patients or a smaller number of sensitive cases (e.g. loss/theft of laptop, memory stick, or other removable device that has been encrypted or contains anonymised personal data).</p> <p>Loss/theft of hard copies of anonymised/ pseudonymised personal information i.e. medical records, personal diaries/notebooks.</p> | <p>Sustained loss of key groups of staff, leading to potential harm to a group of patients.</p> <p>Issues regarding the competence of individuals within BCSP, affecting the functioning and/or reputation of the programme at a national or local level.</p> | <p>Unplanned delays in the invitation or recall of individuals for routine screening or follow-up surveillance.</p> <p>Highly damaging local publicity and loss of reputation</p> | <p>Impact on service of financial constraints, resulting in serious delays to screening or subsequent investigation (within the scope of the programme), adversely affecting the eligible population.</p> |
|---------------------|---|--|---|---|---|---|

|              |   |   |  |   |   |   |
|--------------|---|---|--|---|---|---|
| <b>MINOR</b> | <p><b>No clinical harm</b></p> <p>Bleeding:</p> <ul style="list-style-type: none"> <li>• Procedure aborted.</li> <li>• Unplanned post-procedure medical consultation.</li> <li>• Unplanned hospital admission, or prolongation of hospital stay for <math>\leq 3</math> nights.</li> </ul> <p>Other</p> <ul style="list-style-type: none"> <li>• Procedure aborted (or not started) owing to adverse incident.</li> <li>• Unplanned post-procedure medical consultation.</li> <li>• Unplanned hospital admission, or prolonged hospital stay, for <math>\leq 3</math> nights.</li> <li>• Use of reversal agent.</li> <li>• Hypoxia (<math>O_2</math> saturations <math>&lt; 85\%</math>).</li> <li>• Hypotension (<math>&lt; 90/50</math> mmHg).</li> </ul> <p>Pathology clinical error that does not result in patient harm.</p> | <p>Wrong result: patient given incorrect follow-up interval, with potential for disease progression.</p> <p>Equipment not serviced, maintained, or used correctly, leading to delays in the patient pathway.</p> <p>Hub FOBt interpretation error leading to potential harm to an individual.</p> | <p>Potential to breach the confidentiality of a significant number of individuals, or a smaller number of sensitive cases. Examples include: two FOBt kits sent in one envelope, FOBt kit sent to wrong subject.</p> <p>Inappropriate information given to a subject/ participant/ patient by telephone or letter, leading to potential harm to an individual.</p> | <p>Sustained loss of key groups of staff, leading to delays in the patient pathway for a group of patients.</p> | <p>Delays in inviting or recalling individuals for routine screening or follow-up surveillance.</p> <p>Inappropriate ceasing of individuals from the programme</p> <p>Damaging local publicity and potential loss of reputation</p> | <p>Impact on service owing to financial constraints resulting in disruption to the screening service.</p> |
|              |   |   |  |   |   |   |

**APPENDIX 2a Reporting of Bleeding\***(from NHS BCSP *Quality Assurance Guidelines for Colonoscopy*<sup>5</sup>)

| Criteria  | Severity     | Action   |
|---|--------------|--|
| Rectal bleeding within 30 days of procedure resulting in any of the following   |              |  |
| <ul style="list-style-type: none"> <li>• Procedure aborted.</li> <li>• Unplanned post-procedure medical consultation.</li> <li>• Unplanned hospital admission, or prolongation of hospital stay for ≤3 nights.</li> </ul>   | Minor        | <ul style="list-style-type: none"> <li>• Record on BCSS as adverse event.</li> <li>• Report to QARC.</li> <li>• Record timing post-procedure.</li> <li>• Record site in colorectum.</li> <li>• Record cause of bleeding, equipment used, diathermy settings, additional factors etc.</li> <li>• Record haemoglobin drop.</li> <li>• Record number of units transfused.</li> <li>• Record interventional procedure(s) &amp; surgery.</li> <li>• Record length of stay.</li> </ul> |
| <ul style="list-style-type: none"> <li>• Hb drop of ≥2g.</li> <li>• Transfusion.</li> <li>• Unplanned admission or prolongation for 4-10 nights.</li> <li>• ITU admission for 1 night.</li> <li>• Interventional procedure (endoscopic or radiological).</li> </ul> | Intermediate | As above, plus <ul style="list-style-type: none"> <li>• Root cause analysis</li> </ul>   |
| <ul style="list-style-type: none"> <li>• Surgery.</li> <li>• Unplanned admission or prolongation for &gt;10 nights.</li> <li>• ITU admission &gt;1 night.</li> </ul>  | Major        |  |
| <ul style="list-style-type: none"> <li>• Death.</li> </ul>  | Fatal        | As above, plus <ul style="list-style-type: none"> <li>• Record cause and time of death</li> </ul>  |

Adapted from Cotton PB *et al.*<sup>6</sup>

**APPENDIX 2b Reporting of Perforation\****(from NHS BCSP Quality Assurance Guidelines for Colonoscopy<sup>5</sup>)*

| Criteria  | Severity | Action  |
|---|----------|---|
| Any perforation within 30 days of procedure should be recorded. Perforation is defined as evidence of air, luminal contents, or instrumentation outside the GI tract. |          |   |
| <ul style="list-style-type: none"> <li>Managed conservatively (no endoscopy/surgery).</li> <li>Endoscopic management.</li> <li>Surgery.</li> </ul>                    | Major    | <ul style="list-style-type: none"> <li>Record on BCSS as adverse event.</li> <li>Report to QARC.</li> <li>Root cause analysis.</li> <li>Record timing post-procedure.</li> <li>Record site in colorectum.</li> <li>Record cause of perforation, whether diagnostic or at site of therapy/instrumentation, equipment used, diathermy settings, additional factors etc.</li> <li>Record interventional procedure(s) and surgery.</li> <li>Record length of stay.</li> </ul> |
| <ul style="list-style-type: none"> <li>Death.</li> </ul>  | Fatal    | <p>As above, plus</p> <ul style="list-style-type: none"> <li>Record cause and time of death.</li> </ul>   |

\*Adapted from Cotton PB *et al.*<sup>6</sup>

## APPENDIX 2c Reporting of other Adverse Events

(from *NHS BCSP Quality Assurance Guidelines for Colonoscopy*<sup>5</sup>)

| Criteria   | Severity     | Action  |
|--|--------------|---|
| <p>Various other unplanned events may occur as a result of a BCSP colonoscopy. These should be recorded, with appropriate details.</p> <p>Categorisation of the severity of an adverse event (AE) is given below. Note that bleeding and perforation have their own categorisation (see separate tables).</p> <p>Every event should be recorded, even if it is deemed unlikely to have been caused by the procedure (see 'Attribution of event').</p> <p>Excludes admissions for social reasons.</p> |              | <ul style="list-style-type: none"> <li>Record on BCSS as adverse event.</li> <li>Report to QARC.</li> <li>Record whether pre-, during or post-procedure; record timing if post-procedure.</li> <li>Record details of event.</li> <li>Record any procedures required.</li> <li>Record length of stay.</li> </ul>                                       |
| <ul style="list-style-type: none"> <li>Procedure aborted (or not started) due to AE.</li> <li>Unplanned post-procedure medical consultation.</li> <li>Unplanned hospital admission, or prolonged hospital stay, for <math>\leq 3</math> nights.</li> <li>Use of reversal agent.</li> <li>Hypoxia (O<sub>2</sub> saturations <math>&lt;85\%</math>).</li> <li>Hypotension (<math>&lt;90/50</math>).</li> </ul>  | Minor        | <p>Attribution of event</p> <p>It is not always clear whether an adverse event relates to the procedure. After root cause analysis, attribution of AEs should be recorded by the appropriate QA reference centre as follows:</p> <ul style="list-style-type: none"> <li>Definite.</li> <li>Probable.</li> <li>Possible.</li> <li>Unlikely.</li> </ul> |
| <ul style="list-style-type: none"> <li>Unplanned admission or prolongation for 4-10 nights.</li> <li>ITU admission for 1 night.</li> <li>Interventional procedure (endoscopic or radiological).</li> <li>Interventional treatment for skin or other tissue injuries.</li> <li>Unplanned ventilatory support during conscious sedation.</li> </ul>  | Intermediate | <p>As above, plus</p> <ul style="list-style-type: none"> <li>Root cause analysis.</li> </ul>  |
| <ul style="list-style-type: none"> <li>Surgery for adverse event/ sequelae.</li> <li>Permanent disability.</li> <li>Unplanned admission or prolongation for <math>&gt;10</math> nights.</li> <li>ITU admission <math>&gt;1</math> night.</li> </ul>  | Major        |   |
| <ul style="list-style-type: none"> <li>Death.</li> </ul>   | Fatal        | <p>As above, plus:</p> <ul style="list-style-type: none"> <li>Record cause and time of death.</li> </ul>  |

Adapted from Cotton PB *et al.*<sup>6</sup>



### APPENDIX 3 Hub Call and Recall and Laboratory Analysis

The effectiveness of the NHS Bowel Cancer Screening Programme depends not only on the quality of clinical performance, but also on:

- Inviting the eligible population for screening in a timely manner.
- the accurate and timely transfer of test results from the hub to:
  - the individual.
  - the individual's GP.
  - the appropriate screening centre (for individuals with an abnormal result).

Problems in these areas can lead to failures to invite individuals, failures to inform individuals of their result, and failures in follow-up.

Examples of problems include:

- Lack of access to BCSS for significant periods of time (>24h) due to loss of Trust N3 connection.
- Failure to invite eligible subjects, due to exclusion of their GP Practice from the BCSS download.
- Failure to invite eligible subjects, due to an incorrect or incomplete registration by the GP Practice.
- Invitations being sent to the wrong subjects.
- Poor quality kits being sent to subjects.
- Two kits being sent in one letter.
- Discrepancies between the name on the letter and the name on the kit.
- Errors in the contents of letters sent to subjects.
- Loss of kit on receipt by the hub.
- Kits being logged, but not read.
- Entry of the incorrect participant ID onto BCSS.
- Entry of incorrect results onto BCSS.
- Failure to enter result of kit reading.
- Failure to enter correct sampling date.
- Reading errors, leading to an avoidable false positive or false negative result.
- Inappropriate assignment of a kit as 'spoilt' or 'technically failed'.
- Failure to notice a kit that is out of date (past its expiry date).
- Incorrect NHS number on BCSS, due to NHAIS / CfH error.
- Failure to send the result to the correct participant(s).
- Postal delivery problems of various sorts (to and from subjects).
- Bulk loss of mail.
- Late receipt by participant of an invitation for SSP appointment.
- Failure to provide the correct clinical location/ map to participant.
- Failure to book/rebook appointment correctly.
- Failure to book surveillance colonoscopy.
- Inappropriate ceasing of patients.
- Providing inappropriate information to individuals or organisations e.g. researchers, PCTs or QARCs.

Owing to the nature of laboratory and call and recall processes, problems with the transfer or communication of invitations and results may affect large numbers of individuals. Examples include:

- Screening letters that are held on the system and not printed or issued to subjects / participants or patients in a timely manner.
- Problems with the printing and/ or packing of letters that result in confidentiality breaches (e.g. result letters for more than one individual posted in a single envelope).

Where problems are suspected with call/recall or mailing, the initial investigation team should include the hub Director, hub Manager and the hub Laboratory Lead. Consideration should be given to involving expertise from the national office or Connecting for Health.

When managing incidents associated with call and recall, the communication under scrutiny may have occurred some time earlier. In such cases, some of the individuals involved may have since been retested, either locally or by another hub. Careful consideration should be given to the appropriate course of action in such cases, based on an assessment of the likely risks to the individuals concerned.

Particular attention should be given to ensuring that individuals requiring colonoscopy or early repeat testing have received appropriate information.

In situations where individuals need to be contacted, or where there has been a confidentiality breach, communications advice should be sought at a very early stage. In cases where confidentiality has been breached, local advice should be sought as to whether the Information Commissioner should also be notified.

#### Investigation of Errors:

When an error is reported/discovered:

- Assess the scale of the problem and isolate it.
- Identify all of the potential affected participants, and begin the process of informing them.
- Put in place procedures to prevent further errors (*these may change once the cause has been identified*).
- Once the scale of the problem has been assessed, begin the process of identifying its cause.
- Once the cause is identified, develop sustainable procedures to prevent future problems.
- If the error has the potential to occur at other hubs, report via the formal channels, and communicate with the other hubs.
- Once the revised procedures are in place, perform audits to demonstrate that the changes are having the desired effect.

## APPENDIX 4 Pathology

Guidance on histopathology reporting in bowel screening, including advice on audit and quality assurance, has been published by the NHS BCSP.<sup>7</sup>

The routine audit of histology provides a means of identifying problems. The initial investigation team for any such problem should include the clinical head of the histopathology service. Consideration should also be given to seeking expert advice from outside the laboratory, particularly where the performance of an individual clinician is in question, or where there are potential issues with the overall management of the service.

### The areas in which problems could arise include:

- Timeliness in reporting lesions.
- Dissection of lesions submitted.
- Interpretation and reporting of lesions submitted.
- Communication of results to relevant individuals.

### Review of pathology procedures

#### *Define the problem*

- Has the exact nature of the problem been identified?
- What are the possible consequences for the individuals involved?
- How long has the issue been a problem?
- Has this issue been raised as a result of previous reviews?
- Have concerns been raised from previous screening audits?
- Does the problem relate to the handling of specimens in endoscopy or in the laboratory (e.g. mixing up individual data/biopsy specimens)?
- Does the problem relate to pathology examination and/or assessment?
- Does the problem lie in a process, with an individual clinician(s), or with the local multidisciplinary team meeting (MDT)?

#### *Is there a continuing risk to patients?*

- Have all the patients who may have been affected been identified?
- Have they been informed?
- Does the problem relate only to screening patients, or are there wider implications for other endoscopy specimens?
- Have measures been taken to prevent further risk to patients while the problem is investigated? (If not, immediate action should be taken to prevent further risk to patients).
- Is it safe for the laboratory to continue screening or reporting specimens?

#### *Establish process of assessment and pathology involvement*

- What is the usual process of tissue diagnosis?
- Was this process followed?
- How are samples transferred to the pathology laboratory?
- Was adequate information provided to the receiving pathology laboratory?
- Have the pathology staff received adequate training in the management of screening-generated cases?
- Have trained staff reported sufficient numbers of screening-generated cases annually?
- Are there written protocols for handling and reporting these specimens?

- Were these followed?

*Multidisciplinary discussion (if appropriate)*

- According to national guidance and local protocols, should the case(s) have been discussed at MDT?
- Did MDT discussions take place?
- If so, when, and at what stage?
- Are there written records?
- Was all previous history reviewed?
- Who was present? Were all core members present for the whole meeting(s)?
- What final decision(s) were reached?
- Were the treatment decision(s) appropriate and do they comply with national guidelines?
- Were the decision(s) followed in each case?
- If not, were any reasons given?
- Has there been an audit of the implementation of MDT decisions?

*Possible methods of investigation*

- Establish timeline and progress for each affected patient(s).
- Review pathology policies, and standard operating procedures (SOPs).
- Review training policies and records.
- Review pathology records and case notes.
- Review record of MDT discussions/attendance at MDT.
- Talk to all members of MDT. Is there effective communication within the team?
- Review QARC data for the screening centre.
- Review previous QA reports.

*Reporting the outcome of the investigation*

- Report in writing to the QA Director.

*Feedback and lessons learnt*

- What lessons can be learnt?
- Who will benefit from learning the lessons?
- Send feedback to NHS BCSP national office.

## APPENDIX 5 Imaging Radiology

**This is a provisional appendix, subject to review, modification, and approval by the newly-formed National Coordinating Group for QA of Radiology in the BCSP.**

### Investigation of problems

Many radiology services currently provide CT colonography. However, where good quality CT colonography is not available locally, or where patients are unsuitable for screening colonoscopy, or have undergone an incomplete colonoscopic examination, double-contrast barium enema is provided.

The *Guidelines for the Use of Imaging in the NHS Bowel Cancer Screening Programme*<sup>8</sup> include advice on audit, quality assurance, and performance measures. The routine audit of imaging and performance measures provides a means of identifying suspected problems. The initial investigation team for any such problem should include the clinical lead of the imaging service. Consideration should be given to seeking expert advice from outside the local service, particularly where the performance of an individual clinician is in question, or where there are potential issues with the overall management of the service.

### The areas in which problems could occur include:

- a patient's eligibility for imaging.
- information and consent processes.
- reactions to spasmolytics, bowel preparations, or intravenous contrasts.
- radiation dose.
- safety of patients during the procedure.
- quality of examination technique.
- referral of patients for investigations outside imaging (e.g. endoscopy).
- interpretation and recording of results.
- communication of results to individuals.
- audit and performance monitoring.
- staff induction and training procedures.

### Review of imaging procedures

#### *Define the problem*

- Has the exact nature of the problem been identified?
- What are the possible consequences for the individuals involved?
- How long has the issue been a problem?
- Has the issue been identified following previous reviews?
- Have concerns been raised following previous screening audits?
- Does the problem relate to the imaging procedure, its interpretation, or the reporting of the procedure?
- Does the problem lie with the process, individual clinician(s), or the local multidisciplinary team?

#### *Is there a risk to patients?*

- Have all the patients who may have been affected been identified?
- Have they been informed (where necessary)?

- Does the problem relate only to screening patients, or are there wider implications for other patients undergoing imaging?
- Have measures been taken to prevent further risk to patients while the problem is being investigated?
- Is it safe for imaging to continue? (Or for any individual involved in the imaging process to continue?)

*Establish imaging processes*

- What are the usual parameters and protocols for screening-related imaging?
- Are these in line with national guidance?
- Were they followed?
- Was adequate information provided prior to imaging?
- Were the radiology staff adequately trained to perform screening-related imaging?

*Multidisciplinary discussion (if appropriate)*

- According to national guidance and local protocols, should the case(s) have been discussed at MDT?
- Did MDT discussions take place?
- If so, when, and at what stage?
- Are there written records?
- Was all previous history reviewed?
- Who was present, and were all core members present for the whole meeting(s)?
- What were the final decision(s)?
- Were the treatment decision(s) appropriate, and do they comply with national guidelines?
- Were the decision(s) followed in each case?
- If not, were any reasons given?
- Has there been an audit of the implementation of MDT decisions?

*Possible methods of investigation*

- Establish timeline and progress for each affected patient(s).
- Review local policies and procedures.
- Review case notes.
- Review training policies and records.
- Review records of MDT discussions/attendance at MDT.
- Talk to members of the MDT. Is there effective communication within the team?
- Where available, review QARC data for the service.
- Where available, review previous QA reports.

*Reporting the outcome of the investigation*

- Report in writing to the QA director.

*Feedback and lessons learnt*

- What lessons can be learnt?
- Who will benefit from the lessons learnt?
- Feedback to the NHS BCSP national office.

## APPENDIX 6 Colonoscopy

In bowel cancer screening, the ratio of benefit to harm is finely balanced. It is recognised that some incidents, in particular colonic perforation, may be categorised as a major risk, and that this complication occurs in 1:1000 patients undergoing the procedure (rising to 1:500 patients undergoing polypectomy).

Rigorous monitoring and quality assurance of colonoscopy performance against national standards are therefore essential. Whilst not all problems are incidents, a problem can become an incident if it is not managed appropriately. Where a risk affects a large number of screened individuals, complaints about the screening centre may gain a high profile, which may impact on the national uptake of screening invitations.

The initial investigation team for suspected problems in colonoscopy should include the screening centre Director (unless she/he is personally involved). Consideration should be given to involving external experts in colonoscopy on the investigation and incident teams, particularly if the performance of an individual clinician is in question, or where there are potential issues with the overall management of the screening centre.

### The areas in which problems could arise include:

- assessment of a patient's suitability for colonoscopy.
- information and consent processes.
- clinical competence of screening colonoscopists and endoscopy unit staff
- the experience and safety of the patient during the procedure.
- diagnostic and therapeutic procedures for the investigation and treatment of individuals (including infection control, specimen handling, missed pathology).
- administrative procedures and IT systems within the colonoscopy service, including communications with MDTs (e.g. other hospitals).
- referral of individuals for specific (e.g. difficult) procedures outside the screening centre.
- communication of results to individuals.
- staff induction and training procedures in the endoscopy environment, as part of the BCSP.
- Breaches of confidentiality (e.g. data security, loss or theft of patient identifiable records).

### Review of colonoscopy procedures

#### *Define the problem*

- Has the exact nature of the problem been identified?
  - What are the possible consequences for the individuals involved?
  - How long has the issue been a problem?
  - Does the problem relate to the clinical examination, patient care, or the recording or communication of results?
  - Does the problem lie in a process, with an individual, or with the local multidisciplinary team?
- 
- *Is there a continuing risk to patients?*
  - Have all the patients who may have been affected been identified?
  - Have they been informed?

- Does the problem relate only to screening colonoscopy patients, or are there wider implications for other patients?
- Have measures been taken to prevent further risk to patients while the problem is investigated? (If not, immediate action should be taken to prevent further risk to patients.)
- Is it safe for screening colonoscopy to continue (or any individuals involved to continue scoping), while the investigation is under way?

*Establish the colonoscopy processes in place*

- What do the local clinical guidelines cover? Are they in line with national guidance?
- Were local and national guidelines implemented, followed and monitored?
- Are QA guidelines (GRS) for endoscopy monitored?

*Multidisciplinary discussion (if appropriate)*

- According to national guidance and local protocols, should the case(s) have been discussed at MDT?
- Did MDT discussions take place?
- If so, when, and at what stage?
- Are there written records?
- Was all previous history reviewed?
- Who was present? Were all core members present for the whole meeting(s)?
- What were the final decision(s)?
- Were the treatment decision(s) appropriate and do they comply with national guidelines?
- Were the decision(s) followed in each case?
- If not, were any reasons given?
- Has there been an audit of the implementation of MDT decisions?

*Possible methods of investigation*

- Establish timeline and progress for each affected patient(s).
- Review local policies.
- Review case notes.
- Review training policies and records.
- Review record of MDT discussions/attendance at MDT.
- Talk to all members of MDT. Is there effective communication within the team?
- Review QARC data for the service, or request specific colonoscopy audits to be performed.
- Review previous QA reports.
- Review previous patient survey results.

*Recording and reporting the outcome of the investigation*

- Report in writing to the QA Director.
- Record attribution of events as definite, probable, possible, or unlikely.

*Feedback and lessons learnt*

- What lessons can be learnt?
- Who will benefit from learning the lessons?
- Feedback via the NHS BCSP national office.



**Recall exercises**

The decision whether or not to recall individuals for further investigation requires careful consideration. Recall exercises for the BCSP may be traumatic for the individuals involved, difficult to manage, and resource intensive. They should be used only as a last resort when there are strong reasons to believe that individuals are at significant risk.

## APPENDIX 7 Surveillance

Guidance on adenoma surveillance in the BCSP has already been produced.<sup>9-10</sup> The routine audit of both surveillance and the Quality Assurance guidelines for colonoscopy provides a means of identifying suspected problems.

The initial investigation team for any such problem should include the local screening service Director (unless he or she is personally involved). Consideration should be given to seeking expert advice from outside of the local service, particularly if the performance of an individual clinician is in question, or where there are potential issues with the overall management of surveillance.

### The areas in which problems could occur include:

- surveillance planning.
- histological identification of adenomas.
- entry of adenoma data onto BCSS.
- administrative procedures and IT systems within the surveillance pathway.
- communications with multidisciplinary teams (e.g. other hospitals).
- referral of individuals for specific (e.g. difficult) procedures outside the screening centre.
- communication of results to individuals.
- discharge from surveillance.

### Review of surveillance procedures

#### *Define the problem*

- Has the exact nature of the problem been identified?
- What are the possible consequences for the individuals involved?
- How long has the issue been going on?
- To what aspect of the surveillance pathway does the issue relate?
- Does the problem lie in the process, with individual clinician(s), or with the local multidisciplinary team?

#### *Is there a continuing risk to patients?*

- Have all the patients who may have been affected been identified?
- Have they been informed?
- Does the problem relate only to surveillance patients or are there wider implications for other patients?
- Have measures been taken to prevent further risk to patients while the problem is investigated?
- Is it safe for the service (or any individuals involved) to continue whilst the investigation is undertaken?

#### *Establish the processes in place*

- What do local clinical guidelines cover? Are they in line with national guidance on adenoma surveillance?
- Has local and national guidance been implemented, followed, and monitored?

#### *Multidisciplinary discussion (if appropriate)*

- According to national guidance and local protocols, should the case(s) have been discussed at MDT?

- Did MDT discussions take place?
- If so, when, and at what stage?
- Are there written records?
- Was all previous history reviewed?
- Who was present? Were all core members present for the whole meeting(s)?
- What were the final decision(s)?
- Were the treatment decision(s) appropriate and do they comply with national guidelines?
- Were the decision(s) followed in each case?
- If not, were any reasons given?
- Has there been an audit of the implementation of MDT decisions?

#### *Possible methods of investigation*

- Establish timeline and progress for each affected patient(s).
- Review local policies.
- Review case notes.
- Review BCSS data.
- Review training policies and records.
- Review records of MDT discussions/attendance at MDT.
- Talk to all members of the MDT. Is there effective communication within the team?
- Review QARC data for the service, or request specific surveillance audits to be carried out.
- Review previous QA reports.
- Review previous patient survey results.

#### *Reporting the outcome of the investigation*

- Report in writing to the QA Director.

#### *Feedback and lessons learnt*

- What lessons can be learnt?
- Who will benefit from learning the lessons?
- Feedback via the NHS BCSP national office.

### **Recall exercises**

The decision whether or not to recall individuals for further investigation requires careful consideration. Recall exercises for the BCSP may be traumatic for the individuals involved, difficult to manage, and resource intensive. They should be used only as a last resort, when there are strong reasons to believe that individuals are at significant risk.

## APPENDIX 8 Communications Strategies

The focus of the communications strategy is to care for individuals who are directly affected by the incident. The aim is to minimise anxiety and maintain confidence in the screening programme as a whole. GPs and staff working in the programme must be kept informed and adequately supported so that they are able to answer questions from individuals. There must also be arrangements for answering queries from the press and the general public.

### Key principles

Every incident is different; the following points should be used as a guide only:

- Include a nominated communications lead as part of the incident team from the start. Ideally this individual should have experience of handling incidents and dealing with the national and local press.
- The communications lead should consider setting up a communications group to work alongside the incident team. (This will depend on the size and nature of the incident).
- If a communications group is set up, a clear mechanism should be put in place to ensure that the incident team and the communications group are kept up-to-date.
- The communications lead should advise on the development of a communications strategy, and outline an agreed approach (e.g. proactive or reactive) for subsequent activity.
- Ensure that all communications are as consistent as possible. Agree the communications strategy with all interested parties, including the PCT commissioner(s), the SHA DPH, and the NHS Cancer Screening Programmes press office.
- Establish close working relationships between the communications lead/group and all other interested parties (e.g. ensure that an agreed approval procedure is in place for all materials).
- Consider using the NHS Cancer Screening Programmes press office to provide advice and support (this is also available to local QA teams requiring support). The NHSCSP press office can:
  - advise on the development of an communications strategy.
  - identify spokespeople, and advise on media training.
  - provide recommendations on materials developed for the media.
  - advise on communicating with individuals, staff, and other parties.
- The communications lead should oversee the development of all communications material, to ensure that a consistent message is delivered to individuals, staff, stakeholders, and the media.
- The wording used in any communications with individuals, staff, GPs, media, and stakeholders should be chosen with care.
- Legal implications and confidentiality issues should be given careful thought.
- Materials should be informative, accurate, truthful, and consistent about what has happened, and why

- Communications must be clear and sensitive, use appropriate phrasing and terminology, and avoid medical/technical jargon.
- Materials should outline what will happen next and give a realistic timescale, recognising that failure to meet such deadlines could further damage reputation and undermine confidence.
- Responses to probable questions should be drafted.
- Sources of further information and advice should be provided.
- Where screening has been suspended, a clear message should be delivered regarding alternative arrangements. A timescale for the recommencement of the service should be provided.

### **Communicating with individuals**

- The interests of the individuals affected should be the priority in developing a communications strategy and producing all materials.
- The incident team should aim to inform all those involved or affected by the incident of developments before the media is given this information.
- Where individuals need to be recalled for additional tests or assessments:
  - avoid contacting them close to a weekend or a bank holiday, when support from health professionals is not available.
  - notify their GPs in advance (if they are not already involved).
  - check their contact details, recent medical history, language, and any other special needs in advance and put appropriate provisions in place.
  - consider contacting individuals by telephone in advance of sending a letter (wherever possible, the call should be made by a suitably qualified member of staff).
  - where telephone contact is not made, consider putting in place a mechanism to confirm receipt of a letter.
  - where possible, letters should be signed by the host Trust's Chief Executive or Director of Public Health/Medical Director. They should be posted first class.
  - consideration should be given to providing affected individuals with additional support and advice, e.g. providing contact details for a named health professional or providing a rapid response helpline (possibly through NHS Direct) to enable individuals to discuss the matter further, should they wish.
  - develop briefing materials for the health professionals who will support the recalled individuals.
  - develop a comprehensive list of frequently-asked questions and answers for helpline staff.
  - develop a clear protocol for responding to queries from the public that cannot be answered immediately. Individuals should be given a clear idea about when to expect an answer, and these deadlines should be met.
  - as the review progresses, consider writing to reassure individuals who may be aware that they are included in a review of screening tests or colonoscopy cases, but who are not required to attend for additional assessment.

- allocate responsibility for answering queries from unaffected but interested groups (e.g. staff, other health professionals, GPs, MPs, and patient groups) and for keeping them informed.

### **Communicating with staff**

- It is important that staff in the local bowel cancer screening centre are kept well informed; where there are already regular staff meetings, these may provide an effective forum for communications.
- Local bowel screening staff involved in a patient recall or review will need the following information to ensure that they are adequately supported and able to answer queries from the public:
  - an overview of what has occurred, the measures being put in place to remedy the situation, an idea of what will happen next, and the timescales involved.
  - a list of frequently-asked questions and answers. These are particularly important where staff are required to act as a helpline, and where the media publicise an incident before those involved or affected have been informed.
  - the name of a nominated lead, who will answer professional questions or queries from the public that are not included among the frequently-asked questions
- Other staff in the host Trust, commissioning PCT(s), and SHA should have access to a general briefing note that outlines the problem and the action being taken. This document should also include details of the staff leads to whom any calls should be referred.

### **Communicating with GPs (if not directly involved)**

- GPs are often the first port of call for individuals concerned about their health, so it is important to keep them informed.
- All local GPs must receive regular updates so that messages being relayed to individuals are consistent.
- Information for GPs should include:
  - an overview of what has occurred.
  - the measures in place to remedy the situation.
  - an outline of what will happen next.
  - a clear indication of the messages to be delivered to the public.
  - a date and time for the next update.
- If individuals are identified for recall, their GPs should be notified in advance.


### **Communicating with the media**

- A reactive statement should be prepared as soon as possible, for use in the event of queries/enquiries (although every effort should be made to inform all those involved or affected by the incident before they hear of it through the media). The statement should explain:
  - the nature of the problem.

- how the problem was identified.
  - how many individuals are affected.
  - what is being done to stop the problem recurring.
  - whether all involved individuals have been informed, and when they were informed.
  - the advice, investigation, or treatment that has been offered to affected individuals.
  - any next steps.
  - a timescale outlining when the review, recall, or follow-up will be complete. (It is likely that journalists will phone back to check on progress, so publicised timelines should be realistic).
  - contact details for the press officer for the host Trust, commissioning PCT(s), and SHA. In the event that the incident has occurred in a general practice, the commissioning PCT will usually handle all media enquiries and will take the lead, in conjunction with the NHS Cancer Screening Programmes' press office, on the development of communication and information materials for individuals and staff involved.
- Frequently-asked questions may also need to be drafted to support the reactive statement.
- Media statements and frequently-asked questions should be shared with all interested parties, to ensure that messages are consistent.
- A local spokesperson should be made available, as local issues often generate local press and media attention.

### **Communicating with others**

- Consideration should be given to informing others (e.g. MPs and local patient groups) immediately before those involved or affected by the incident are told. The information provided may include
  - an overview of what has occurred.
  - the measures being put in place.
  - what will happen next.
  - an indication of when they will receive a further update.
- A mechanism should be put in place to enable other parties to air any concerns they have with the incident team. This will allow the team to provide reassurance before other parties feel they need to air their concerns in public.



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