Screening Programmes

Managing Safety Incidents in NHS Screening Programmes

Developed in collaboration by NHS Screening Programmes and NHS England

October 2015

About NHS Screening Programmes and Screening Quality Assurance

Quality assurance (QA) is the process of checking that national standards are met (ensuring that screening programmes are safe and effective) and encouraging continuous improvement.

Public Health England (PHE) is responsible for the NHS Screening Programmes and the Screening Quality Assurance Service (SQAS). PHE is an executive agency of the Department of Health and works to protect and improve the nation's health and wellbeing, and reduce health inequalities.

Screening Quality Assurance Service (national)
Zone B, 2nd Floor
Skipton House,
80 London Road,
London, SE1 6LH
T +44 4 (0)207 654 8429
Twitter: @PHE Screening
www.screening.nhs.uk/quality-assurance
www.gov.uk/phe

Prepared by: Jane Woodland
For queries relating to this document, please contact: PHE.screeninghelpdesk@nhs.net

Published October 2015
PHE publications gateway number: 2015442

Contents

Preface

This guidance on screening incidents applies to all organisations that provide NHS screening programmes in England whether an NHS trust, NHS foundation trust, general practitioner or private provider.

The guidance details the accountabilities for reporting, investigating and managing NHS screening programme safety incidents. It covers the management of safety concerns, safety incidents and serious incidents in screening programmes. It is written for staff working in local NHS funded screening programmes, organisations that host screening programmes, commissioners of screening, Public Health England (PHE) screening and immunisation teams, the screening quality assurance service (SQAS), national screening programme teams, PHE regions and centres and local authority directors of public health.

This guidance replaces *Managing Safety Incidents in NHS Screening Programmes – updated interim guidance issued in March 2015*. It should be read alongside NHS England's *Serious Incident Framework (updated 2015).*

Development of the guidance

The guidance was drawn up by a PHE and NHS England working group involving patient safety, commissioning and screening specialists. The learning from 6 consultation workshops involving over 150 professionals was considered. The draft guidance was consulted upon and piloted. Contributions were made by PHE regional and centre directors, screening and immunisation teams, directors of public health, the Trust Development Agency and the Care Quality Commission.

These contributions are gratefully acknowledged.

1. Introduction

1.1 Incidents in NHS screening programmes

Screening is a process of identifying apparently healthy people who may be at increased risk of a disease or condition. They can then be offered information, further tests and appropriate treatment to reduce their risk and/or any complications arising from the disease or condition.

The characteristics specific to screening programmes mean that safety concerns and incidents require special attention and management. This is because:

- there is potential for safety incidents in screening programmes to affect a large number of individuals/users of the service. This means that seemingly minor local incidents can have a major service and population impact
- as asymptomatic people are invited to participate in screening there is an ethical responsibility to do as little harm as possible. It is imperative to prevent and respond effectively to quality concerns
- poor quality screening can do more harm than good – it can harm individuals and have no benefit to the population
- incidents often affect the whole screening pathway not just the local department or provider organisation in which the problem occurred
- incidents may involve several organisations across geographical boundaries
- local incidents can affect public confidence in a screening programme beyond the immediate area involved
- investigation and dissemination of learning from safety incidents, ‘potential’ incidents and near misses should be shared with NHS screening programmes to help prevent incidents elsewhere and to inform guidance and training

1.2 Policy context

The ethical responsibility of the NHS to acknowledge failings and resolve them openly is emphasised in the NHS constitution. The NHS standard contract includes a duty of

candour. The *Francis Report* (2013) emphasised the need to put patients at the centre of services, have effective governance and investigate safety incidents rigorously. The *Health and Social Care Act 2008 (Regulated Activities) Regulations 2014* sets out the legal duties of providers with this elaborated upon in *Care Quality Commission guidance for providers*. Users of NHS services should be informed and receive an apology if they have been harmed and there is a statutory duty if the safety incident is notifiable[1]. Staff should be encouraged and supported to report quality concerns as opportunities to improve the quality of services and reduce risk. This applies to NHS screening programmes.

National service specifications for each NHS screening programme are issued annually as part of an agreement between the Department of Health and NHS England. These include the requirement for providers of screening programmes to comply with the guidance from NHS screening programmes.

This guidance on screening incidents applies to all organisations that provide NHS screening programmes whether a NHS trust, NHS foundation trust, general practitioner or private provider.

1.3 Purpose

This guidance sets out the requirements for managing safety concerns, safety incidents and serious incidents in NHS screening programmes. It provides clarity for staff providing and commissioning NHS funded services who may be involved in identifying or managing a screening incident.

It is important to ensure that there is a proportionate response based on an accurate investigation and assessment of the risk of harm.

1.4 Scope

The NHS screening programmes which are covered by this guidance are:

- NHS breast screening programme
- NHS cervical screening programme
- NHS bowel cancer screening programme

[1] 'A notifiable safety incident is where death, severe and moderate harm or prolonged psychological harm has occurred.

- NHS diabetic eye screening programme programme
- NHS abdominal aortic aneurysm screening programme
- NHS fetal anomaly screening programme
- NHS infectious diseases in pregnancy programme
- NHS sickle cell and thalassaemia programme
- NHS newborn blood spot programme
- NHS Newborn hearing screening programme
- NHS newborn and infant physical examination programme

1.5 Definition of a screening safety incident

Screening safety incidents include:

- any unintended or unexpected incident(s), acts of commission or acts of omission that occur in the delivery of an NHS screening programme that could have or did lead to harm to one or more persons participating in the screening programme, or to staff working in the screening programme
- harm or a risk of harm because one or more persons eligible for screening are not offered screening.

Characteristics are:

- they occur at a particular point of the screening pathway, at the interfaces between parts of the pathway or between screening and the next stage of care
- they can affect populations as well as individuals. Although the level of risk to an individual may be low, because of the large numbers of people offered screening, this may equate to a high population risk
- the root cause can be an individual error or a failure of a system(s), or equipment or IT

- there is a systematic failure to comply with national guidelines or local screening protocols that has an adverse impact on screening quality or outcome

- due to the public interest in screening, the likelihood of adverse media coverage with resulting public concern is potentially high even if no harm occurs. Examples include breach of patient confidentiality or data security

1.6 Definition of a serious incident

Some incidents have consequences that are so significant to individuals, families and carers, populations, staff or organisations, or represent such significant potential learning for the NHS, that a heightened level of response is warranted. This means following consistent and clearly defined principles and procedures, with a significant management focus and formal governance arrangements around reporting, investigation, learning, action planning, implementation and closure.

Incidents identified as requiring this heightened response are termed ‘serious incidents’. Whether a serious incident should be declared is a matter of professional judgement on a case by case basis and after careful consideration of the definition. It is important to ensure that the response is proportionate to the risk.

The stimulus to declare a serious incident can come from a number of organisations but in most cases the decision to declare a serious incident is made by the provider of the screening programme and the responsible commissioner informed by QA advice.

The NHS England *Serious Incident Framework (updated 2015)* states that a serious incident must be declared at the outset and can be scaled down as appropriate. In screening incidents it is often difficult to judge severity at the outset and there is a fact finding and assessment process that can be used to determine whether a serious incident should be declared (see Section 3). Its purpose is to understand and mitigate risk.

In distinguishing between a screening safety incident and a serious incident, consideration should be given to whether individuals, the public or staff would suffer avoidable severe harm or death if the root cause is unresolved; or the likelihood of significant damage to the reputation of the organisations involved. This means that a “near miss” can be a serious incident where there is a significant existing risk of a system failing.

Reference should be made to NHS England's *Serious Incident Framework (updated 2015)* and its definition of a serious incident. Characteristics that may be applicable to screening are as follows[2]:

- *acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:*
    - *Unexpected or avoidable death[3] of one or more people*
    - *Unexpected or avoidable injury to one or more people that has resulted in serious harm[4]*
    - *Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent*
        - *the death of the service user*
        - *serious harm*
- *an incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:*
    - *serious data loss/information governance related incident*
    - *serious property damage*
    - *serious security breach/concern*
    - *incidents in population-wide healthcare activities like screening and immunisation programmes where the potential for harm may extend to a large population*
    - *systematic failure to provide acceptable standard of safe care*
- *major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or organisation*

[2] Extract from NHS England Serious Incident Framework March 15). Elements of the definition not applicable to screening are excluded eg reference to never events, mental health, safeguarding, emergency preparedness.
[3] Caused or contributed to by weaknesses in care/service delivery (including lapses/acts and/or omission) as opposed to a death which occurs as a direct result of the natural course of the patient's illness or underlying condition where this was managed in accordance with best practice.
[4] Serious harm: severe harm (patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care), chronic pain (continuous, long-term pain of more than 12 weeks or after the time that healing would have been thought to have occurred in pain after trauma or surgery) or psychological harm, impairment to sensory, motor or intellectual function or impairment to normal working or personal life which is not likely to be temporary (ie has lasted, or is likely to last for a continuous period of at least 28 days).

2. Accountability, roles and responsibilities for managing screening safety incidents and serious incidents

This section describes core roles and functions, how parts of the system should collaborate and how disagreements should be resolved.

In each incident it is important that accountability, responsibilities and governance is agreed by all parties. The RASCI model (responsible, accountable, supporting consulted, informed) provides a method for doing this and is recommended in the NHS England *Serious Incident Framework (updated 2015)*. It enables local differences in commissioning structures and ways of working to be accommodated.

2.1 Providers of NHS screening programmes

All providers contributing to a screening pathway have a joint accountability to ensure safe and coherent screening for the population screened in accordance with national service specifications.

Each provider is accountable for the safe and coherent delivery of their part of the screening pathway and has joint accountability at the interface with another provider.

Providers of screening services have a responsibility to operate within this guidance. This guidance applies to safety concerns, screening safety incidents and serious incidents. The NHS England *Serious Incident Framework (updated 2015)* applies to serious incidents in screening programmes. Provider incident policies should reference both sets of guidance.

When a screening safety incident is suspected or declared, the provider will:

- notify the screening QA service (regional) service and the PHE screening and immunisation team embedded in/associated with the commissioner of the service
- fact find, manage and investigate the safety issue taking account of QA advice and reporting to the screening and immunisation team
- collaborate effectively with other providers and, where agreed, assume a “lead provider” role

When a serious incident is suspected or declared, in addition to the above, the provider will provide reports to the commissioner of the screening service and, if this is different, to the commissioner that leads on contracting with the provider. Commissioners should work with providers to ensure this is the case.

2.2 Commissioners of NHS Screening Programmes

NHS England is responsible for commissioning NHS screening programmes. Commissioners are accountable for securing services that will deliver quality and outcomes in accordance with NHS Screening Programme requirements. They achieve this by monitoring, assessing, working in partnership with providers and, where necessary, challenging the quality of services that they commission.

The public health expertise required to commission and oversee local screening programmes is provided by PHE. These screening and immunisations teams are embedded within the commissioning teams of NHS England at sub-regional level. A team with equivalent functions operates within NHS London[5].

The commissioning organisation's role in screening safety incidents varies across the country but as a minimum includes reviewing trend data and discussion as part of general quality reviews.

The commissioner will have direct involvement in a serious incident in accordance with the NHS England Serious Incident Framework. It will:

- hold the provider(s) to account for their response(s) to a serious incident occurring in services it commissions

- be responsible for ensuring that there are clear governance arrangements for managing the serious incident, for quality assurance and formal closure

- ensure a responsible commissioner is agreed to provide leadership and oversight where multiple commissioners are involved. A RASCI model should be agreed at the outset so that all parties are clear about their responsibilities. This will clarify the organisation responsible for leading oversight of the investigation, where the accountability ultimately resides and who should be consulted and/or informed as part of the process. This allows the 'accountable commissioner', that is the

[5] References to the functions carried out by screening and immunisation teams throughout this guidance are applicable to the public health screening team embedded within NHS London

commissioner holding the contract, to clearly delegate responsibility for managing the serious incident investigations to an alternative commissioning body. This does not remove the overall accountability of the commissioner who holds the contract

- decide whether to discuss a screening serious incident at the local Quality Surveillance Group

If multiple providers are involved or the serious incident has occurred in primary care, the responsible commissioning organisation may need to take an active investigation and management role. To ensure that this is kept completely separate from the commissioner's oversight and closure function, the PHE screening and immunisation lead (SIL) would typically undertake this role on their behalf.

PHE's national team of NHS screening programmes has a direct commissioning role in managing pilots, roll out of new screening programmes or extensions to screening programmes. Where this occurs it will commission providers directly in collaboration with the commissioner associated with the screening programme. In the event of a screening safety incident, NHS screening programmes will collaborate with the screening and immunisation lead in overseeing the provider's response. In a serious incident, NHS screening programmes will also collaborate with the responsible commissioner in meeting the requirements of NHS England's *Serious Incident Framework (updated 2015).* NHS screening programmes will lead the management of screening safety incidents and serious incidents occurring in IT software or equipment that it commissions.

2.3 PHE Screening and immunisation teams

Screening and immunisation teams, led by SILs, will work closely with providers and the screening quality assurance service to oversee the management of screening safety incidents and serious incidents. Embedded within NHS England at sub-regional level they will utilise commissioning mechanisms to ensure that providers follow this guidance and QA advice is acted upon.

If a screening safety incident or serious incident is suspected or declared, the SIL associated with the responsible commissioner will undertake a lead role utilising their public health expertise. This includes ensuring that:

- there is an appropriate RASCI model, particularly where:

  - there are multiple providers and commissioners contributing to the screening pathway
  - the incident has occurred in primary care or involves independent sector providers
  - the incident has occurred at the interface between screening and the next stage of care

- management and investigation of the screening safety incident or serious incident is appropriate, including assuming the lead role if necessary
- all screening safety incidents and serious incidents are reviewed by the local screening programme board (usually chaired by the SIL)

In serious incidents, the SIL will work closely with the commissioning and patient safety functions of the lead commissioner to ensure that the requirements of NHS England's *Serious Incident Framework (updated 2015)* are met.

2.4 PHE Screening quality assurance service

The screening QA service (national) will:

- develop guidance and processes for managing and monitoring screening safety incidents and serious incidents for agreement with NHS England
- develop resources and training packages to support screening incident management supported by the national team of NHS screening programmes
- collate and disseminate the learning from incidents at national, regional and local level

The screening QA service (regional) will:

- provide expert advice to providers, screening and immunisation teams and commissioners of screening programmes so that the assessment, investigation and management of safety concerns, screening safety incidents and serious incidents are effective and timely. This includes advising providers to seek external communications support from NHS England. The screening QA service has a responsibility to ensure patient safety and must have mechanisms to ensure swift action if patients are at risk

- access specialist clinical and policy advice for specific incidents from the national team of NHS screening programmes

- ensure that PHE regional communications are aware of incidents escalated to NHS England regional communications.

- notify the relevant PHE centre director when a serious incident is declared

2.5 PHE Centres

PHE centres will want to be aware of all serious incidents in their area and need to be kept informed via SILs with support from the screening QA service (regional).

PHE centre directors will provide professional support for SILs and ensure that there is adequate public health support for all screening safety incidents and serious incidents.

PHE centre directors may be asked to support the resolution of disagreements about the classification and handling of a screening safety or serious incident (see 2.9).

2.6 Involvement of regional and national tiers

PHE and NHS England region and or national level must be informed and may need to provide collaborative management, advice and co-ordination if:-

- the suspension of a programme is recommended (see 4.1)

- the scale and complexity of the problem requires cross boundary leadership, support and communications (see 4.5)

- disagreements about classification and handling cannot be resolved locally

Ensuring a coordinated approach is taken to providing information about an incident to interested parties is particularly important.

2.7 Local Authority directors of public health

Directors of public health working within local authority health and wellbeing boards will want to be assured that screening services provided for their resident population meet national standards and can deliver the public health outcomes framework.

In the case of a serious incident the SIL should inform the director of public health in a timely way.

Reflecting the responsibility of directors of public health for independent scrutiny and assurance, they should be kept informed but consider potential conflicts of interest before becoming involved in a serious incident team.

2.8 Care Quality Commission (CQC), Monitor and the NHS Trust Development Authority (TDA)

The role of these organisations and when they should be notified by a provider is summarised in the NHS England Serious Incident Framework. (See the resources section for guidance on CQC notifications).

The duty to inform CQC of serious incidents is discharged for NHS secondary care providers by reports made to the National Reporting and Learning System (NRLS). All other providers must notify CQC directly and without delay.

The TDA's remit is for NHS trusts only. The TDA regional care director should be informed by NHS trusts about all serious incidents in screening programmes. The TDA will want to establish if the provider has broader quality or performance or cultural issues. It will work with the commissioner to address concerns about the services provided by an NHS trust.

There may be circumstances where the commissioner of the provider notifies CQC or Monitor directly, for example if there is concern about governance or a culture of bullying and harassment.

2.9 Resolving disagreements

Occasionally there may be disagreement about the classification, handling and closure of a suspected or declared safety incident or serious incident. These should be resolved through local discussion. If this cannot be achieved, then the guidance below applies.

Where there is disagreement between the provider and PHE (SQAS and screening and immunisation lead), the responsible commissioner will act as an intermediary and may use commissioning levers to resolve such issues. Although the provider could ask the TDA for support, it does not have a decision making role.

Where there is disagreement between the provider and the responsible commissioner, QA will provide advice to both parties, but the responsibility for resolving the disagreement remains with the commissioner (see above).

Where there is disagreement between the commissioner and PHE (either QA or the SIL) this should be escalated to NHS England region, which will support the resolution and engage the PHE centre director or the regional director of public health. Who this will be depends on availability and a judgement by the parties about who will be best placed to assist.

Where there is disagreement between screening QA service (regional) and the screening and immunisation team, the regional head of QA and PHE centre director will be engaged.

In rare cases, NHS England or PHE Region may involve national directors to support resolution.

If individuals or groups have concerns about progress or inaction in relation to a screening incident, they should take these concerns to the responsible commissioner. They should escalate any concerns that are not resolved following this through the management chain of the responsible commissioner.

3. Investigating a screening safety incident

3.1 Identifying a screening safety incident

In most cases, concerns that there may be a safety incident within a screening programme are raised via staff or internal quality monitoring. There may be a specific event, complaint, or media interest.

The screening and immunisation team and QA may identify issues for investigation through routine monitoring or other activities such as a formal QA visit. A local authority may raise concerns arising from its scrutiny activities.

3.2 Assessing a suspected screening safety incident

The organisation identifying the safety concern must consider whether it meets or could meet the definition of a screening safety incident or serious incident (see 1.5 and 1.6). The problem must have occurred within the screening pathway.

It is important to distinguish between safety incidents and isolated, minor events/errors with little or no safety risk which will not reoccur locally or in other screening services. These issues should normally be resolved internally and reported to the next meeting of the screening programme board.

A distinction should also be made between poor performance and concerns about quality and safety. This guidance should only be applied if the performance failure meets the screening safety incident definition or the serious incident definition.

The organisation should seek advice from screening QA service (regional) if they are unsure.

If there is a potential screening safety incident or serious incident the provider must inform screening QA service (regional) and the screening and immunisation team. The responsible commissioner must be informed if there is a potential serious incident.

Screening QA service (regional) and the screening and immunisation team must ensure that the other party is notified.

Screening QA service (regional) and the screening and immunisation team must be informed immediately if there is:

- actual harm or risk of harm to individuals eligible for screening
- actual harm or risk of harm to staff
- concern about competence of a member of staff or team that meets the safety incident or serious incident definitions.
- failure or misuse of equipment
- failure or malfunction of the IT system
- breach of patient confidentiality or data security
- systematic failure to comply with national guidelines or local screening protocols that has an adverse impact on screening quality or outcome

This immediate verbal notification should be confirmed in writing.

3.3 Initial quality assurance assessment

Screening QA service (regional) will make an immediate assessment of the seriousness of the safety concern in terms of scale and risk of harm and potential for recurrence. They will advise the provider whether the screening incident assessment form (SIAF) should be completed to inform a decision about how the safety concern should be classified and handled.

If an incident is reported which has occurred outside of the screening programmes, for example within diagnostic or treatment services, screening QA service (regional) will advise the provider that:

- it is a non-screening incident and outside the remit of the screening programme
- the organisation’s normal governance processes should be followed
- the responsible commissioner should be informed

Screening QA service (regional) will provide a summary of the facts to the SIL for them to hand over responsibility to the relevant commissioner.

3.4 Screening incident assessment: Fact-finding stage

See flow chart of the screening incident assessment process at appendix figure 2.

Establishing the facts is the first stage. This should ensure that a measured assessment is made of the seriousness of the problem and the immediate actions required.

To ensure that key questions are addressed, a screening incident assessment form (SIAF) should be completed. The form can be downloaded from www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes. Section one of the three part form should be completed by the provider and is a summary of the facts.

As quality problems in screening programmes tend to be complex and may require considerable resources to investigate, more time is allowed for fact finding and assessment compared with other incidents. The maximum period for fact-finding is five working days. The provider has three working days to establish the facts as far as possible. Following this screening QA service (regional) and the screening and immunisation team have two working days to assess, classify and agree the next steps.

A serious incident may be identified at any point during this five working day period. Where this is the case, NHS England's serious incident framework (updated 2015) applies. The serious incident must be reported to the strategic executive information system (STEIS) (or its successor) and the responsible commissioner within two working days of the incident being identified as a serious incident.

Fact-finding should normally be led by the organisation in which the incident has occurred. The SIL, working within the responsible commissioner, may lead if the incident spans multiple providers or has occurred in primary care.

The investigating methodology will vary depending on the incident and is the responsibility of the organisation leading the fact finding.

Screening QA service (regional) advice must be taken into account and they may involve specialist clinical/screening programme/IT experts from NHS screening programmes or other members of the screening QA service (region).

In provider-led fact finding, the screening and immunisation team must be kept informed and is responsible for ensuring that the fact finding accords with national guidance and screening QA service (regional) advice.

Whether a fact finding team is needed and its membership will depend on the nature and scale of the incident. As it is important to establish the facts quickly, the team should be small but have access to the necessary skills/expertise.

In a screening safety incident the fact-finding team is likely to include:

- screening and immunisation lead or manager
- lead professional from screening service in each provider organisation
- senior manager from each provider organisation
- screening QA service (region)
- risk manager representative drawn from provider organisations involved

3.5 Screening incident assessment: Recommendations for action

The completed fact finding section of the screening incident assessment form (SIAF) (section 1) should be sent, with relevant evidence, to screening QA service (regional) and copied to the screening and immunisation team. This should not contain any personal identifiable data (PID). The screening QA service (regional) will assess the implications for individuals, the population, the local screening programme and NHS screening programmes (section 2 of the screening incident assessment form). Screening QA service (regional) will comment on the adequacy of actions taken or planned. This may include changing the operation of the screening programme in order to continue screening. A recommendation to restrict or suspend screening will be made if the screening QA service (regional) concludes that there is a significant safety risk.

Screening QA service (regional) will recommend one of the following classifications:

1. no concern – no further action required
2. problem still suspected, cause not identified, further investigation required
3. problem confirmed. It could be managed in several ways:
    - internally (no further QA action required)
    - screening safety incident (internal investigation/root cause analysis)
    - screening safety incident (multi-disciplinary/organisational team/panel investigation/root cause analysis)

- serious incident (declaration if not yet declared, concise or comprehensive or independent investigation to be decided)

A copy of the screening incident assessment form including conclusions and recommendations will be sent by screening QA service (regional) to the host provider organisation and the screening and immunisation team. If a serious incident classification is recommended the report should be sent to the chief executive of the host provider, the SIL and the responsible commissioner.

A consensus decision should be reached by the provider, screening QA service (regional) and the screening and immunisation team on the classification of the problem, the follow up action required and the dissemination of the report.

It is expected that where there is a difference of opinion between the parties this will be resolved through local discussion. In exceptional circumstances, further advice and mediation will be needed before agreement is reached (see 2.9).

The SIL is responsible for recording the decisions made in section three of the screening incident assessment form and for sending this to the provider and the screening QA service (regional).

Where further investigation is required to classify the safety concern, the action required should be documented in the screening incident assessment form. This should include the further work required, justification, roles and responsibilities, and likely timescale for completion. The SIL should ensure further investigation happens in a timely way.

If a serious incident is declared, the screening and immunisation lead should develop a RASCI and liaise with the responsible commissioner.

If suspension of screening is recommended, consultation at national level is required before a decision is implemented (see 4.2).

The SIL is responsible for distributing the report to the responsible commissioner and any co-commissioner(s), the PHE centre director and director of public health as detailed in the RASCI.

Screening QA service (regional) will disseminate the report within QA and NHS screening programmes.

3.6 Managing a screening safety incident

If a screening safety incident has occurred but it does not meet the serious incident threshold, it should be registered on the provider organisation's local risk management system. In NHS trusts this will link directly with the National Reporting and Learning System (NRLS). All patient safety incidents must be reported to the NRLS.

Providers without a local risk management system linked to the NRLS should report all screening safety incidents directly to the NRLS via the e-form.

All incidents should be recorded on local risk management systems (LRMS) and, where the incident is a patient safety incident, it must be reported to the (NRLS) (see resources section).

The provider organisation, or the organisation that has led the fact finding, will set up arrangements for further investigation, and implementation of remedial actions. These will be in accordance with internal incident management policy that should be consistent with this guidance. Screening QA service (regional) will provide expert advice and must be kept informed. The SIL is responsible for ensuring that the incident is managed in accordance with this guidance and must be kept informed.

Screening safety incidents which involve multiple professional areas or a number of organisations typically need a panel to investigate and take remedial action. It may be decided that the team assembled for fact finding continues to operate until the incident is closed. Screening QA service (regional) and the screening and immunisation team should be represented.

In these situations, the principles applied to managing serious incidents outlined later in this guidance should be followed, adjusted to ensure a proportionate response.

When investigations and remedial actions are complete, an incident report will be submitted to the provider organisation's governance structures and the local commissioner-led screening programme board (see Section 5).

The level of detail should be proportionate to the severity of the incident. All reports should include what happened, the investigations carried out, the cause(s), the actions taken or required to mitigate harms and prevent the incident happening again.
The completed screening incident assessment report should be part of the incident report.

Screening QA service (regional) will identify any lessons for wider dissemination and implications for national policy and guidance for consideration by NHS screening programmes.

4. Managing a serious incident

See flow chart at Appendix Figure 1

4.1 Declaring and reporting a serious incident

The requirements regarding notification of serious incidents as described in this document are in addition to local organisational requirements for reporting incidents and consistent with NHS England's *Serious Incident Framework (updated 2015).* All reporting must be in line with this framework. Particular note should be taken of the requirement to report serious incidents on STEIS or its successor serious incident management system and to the NRLS and regulators, including the Care Quality Commission (CQC), as appropriate.

A serious incident can be declared at the outset of a problem being identified or at any stage in the processes of 'fact-finding', investigation and handling, and by any of a number of organisations (see 1.6). The *Serious Incident Framework (updated 2015)* applies from the point the serious incident is declared. A serious incident declared at the outset of the assessment process can be downgraded if the evidence shows no serious incident has occurred.

In accordance with the *Serious Incident Framework (updated 2015)* the chief executive of the organisation declaring the serious incident, or the officer with relevant delegated authority, is responsible for ensuring that it is reported formally to appropriate bodies including the responsible commissioner within two working days of identification.

A RASCI should be developed by the screening and immunisation lead to determine who should be informed. In a serious incident this should include:

- screening QA service
- screening and immunisation lead (embedded within the responsible commissioner)
- accountable commissioner of the provider organisation (eg CCG)
- PHE centre director (to be informed by the screening and immunisation lead and SQAS (region)
- director of public health (to be informed by the screening and immunisation lead)

- NHS screening programmes and screening QA service (national) (to be informed by screening QA service (regional))

- regional care quality director, TDA (NHS trusts only)

4.2 Programme suspension or pause

In cases where QA, for reasons of patient safety, recommend that the programme should be suspended or paused:

The screening QA service (regional) will inform the provider and commissioner that they are concerned about patient safety and are recommending to the provider, PHE's national head of screening quality assurance and director of screening and quality assurance that the screening programme should be paused or suspended until an incident team can be put in place and concerns investigated. The recommendation will be made verbally and confirmed in the completed screening incident assessment form.

The recommendation will be escalated and a final decision will be made following consultation with directors of PHE and regional directors of NHS England.

The final decision to suspend a screening programme rests with the responsible commissioner of the service and will be communicated by them.

4.3 Setting up a serious incident team

The chief executive of the organisation declaring the incident (or the senior officer with delegated responsibility) should set up a serious incident team within two working days of the serious incident being declared. If the management of the serious incident is being led by the responsible commissioner, the screening and immunisation lead (SIL) will usually undertake this role. This will prevent a conflict of interest with the commissioning organisation's responsibility for quality assurance and closure of serious incidents. Membership of the team should be explicit and defined according to the RASCI. It should be agreed between the organisation declaring the incident, the SIL and screening QA service (regional).

Membership will depend on the nature and scale of the serious incident but is likely to include:

- the chief executive of the organisation declaring the serious incident (or senior officer with delegated authority) (chair)

- the manager and clinical lead of the screening service (unless the performance of the individual(s) has been identified as part of the serious incident)
- the screening and immunisation lead working within the responsible commissioner
- the senior manager from the provider organisation's accountable commissioner (if different from above)
- a representative from screening QA service (region)
- a patient safety/risk manager/clinical governance lead with expertise in root cause analysis
- a communications expert

If there are multiple providers and commissioners the RASCI model should be used to agree who is responsible for oversight of the investigation, where accountability ultimately resides, the support functions needed and who should be consulted and/or kept informed.

In most cases the chief executive of the host organisation is responsible for identifying an appropriate chair for an incident team, but there may be circumstances when this role is be undertaken by the responsible commissioner.

It is essential to identify a team member with responsibility for administration and documentation and for there to be adequate administrative and IT support.

It is the responsibility of all team members to keep their own organisation fully briefed about the incident and actions being taken. The PHE centre director should be kept informed by the screening and immunisation lead and may provide professional support.

Depending on the incident the team may need ready access to:

- external clinical expertise in the screening programme
- legal advice
- human resources advice
- counselling advice

- IT system or equipment commissioner and/or supplier
- specialist communications advice NHS England and PHE region

The role of external expert(s) should be agreed by the serious incident team at the start. Normally, they should be asked for advice on specific issues but are not part of the decision-making process.

4.4 Role and actions of the serious incident team

The serious incident team should have clear objectives formalised in terms of reference reflecting its responsibility to:

- take immediate action to make the screening service safe
- produce/implement an action plan to manage the consequences of the problem, including its impact on members of the public, services and staff
- establish the root cause(s) of the incident
- oversee the progress of the recovery actions
- agree timescales for closure of the incident
- identify lessons to be learnt from the incident and its handling

The following checklist provides a guide to the action plan of the serious incident team:

1. define the cohort of people at risk of being harmed (case definition)
2. identify the individuals directly affected and at risk of being harmed
3. set up a secure database of the individuals affected (names, addresses, date of birth and general practitioners) and use data bases such as Open Exeter to confirm current details
4. decide the action to take for individuals who have been affected by the incident. A key decision is whether to recall the individuals for a repeat screening. However, the options and need for recall will vary by screening programme

5. develop/implement a communications strategy

6. brief the staff groups involved and arrange any necessary support

7. agree/implement recovery actions with timescales to make the screening service safe and any follow up audit

8. commission/agree a root cause analysis of the incident as part of an incident report, with timescales

9. decide whether immediate notification is needed to other screening programmes

The screening QA service (regional) member of the team will provide expert impartial advice on any required investigation either in person or through a delegated expert. This includes:

- the format and methodology for any further investigation into the causes and extent of the incident

- whether routine screening should be suspended/restricted for the period of the incident

- whether individuals screened should be re-offered screening and how this should be done

- how the problem should be resolved to minimise risks

- when it is safe to resume routine screening, if routine screening has been suspended

NHS England's *Serious Incident Framework (updated 2015)* defines 3 levels of investigation in order that the investigation is proportionate to the serious incident. These are concise, comprehensive and independent investigations. The serious incident team should agree the scale of the investigation and include this in the 72 hour report required by the *Serious Incident Framework (updated 2015).* The completed screening incident assessment form should provide the information on which to base this decision.

Due to the nature and complexity of screening serious incidents, it is likely that a level 2 comprehensive investigation will be needed. The NHS England's *Serious Incident*

Framework (updated 2015) details the criteria for setting up an independent investigation and the process.

The following aspects of managing a serious incident need particular focus:

Duty of candour

The statutory duty of openness and transparency applies to notifiable screening incidents where death, severe and moderate harm or prolonged psychological harm has occurred or could occur.

The expectation that providers are open and transparent when things go wrong is not new and it should be noted that the duty of candour has been included in NHS contracts since April 2013.

For the duty of candour to be applicable, the incident investigation will have reached a point where the individuals affected are known.

It does not apply where no harm has resulted but the provider(s) may decide to disclose.

Providers should be able to demonstrate they have undertaken due diligence in assessing how the duty of candour is applicable to each serious incident and seek legal advice where necessary.

Individuals affected should be told the facts; the further enquires being carried out and receive an apology in person which is confirmed in writing.

Need for and management of a patient notification exercise

The National Patient Safety Agency's *Being Open Framework* (2009) provides detailed guidance on how to ensure good communications with patients, families and carers.

How to contact individuals should be considered carefully. Usually this will be through clinical professionals who are the normal first point of contact for patients. These clinical professionals should be briefed in advance so they are able to respond to questions, concerns and access additional information where needed. Communications should be tailored to the needs of the individuals to be contacted. Consideration should be given to equity implications and the level of support required minimising psychological harm. It is good practice to undertake an equity impact assessment and "test out" planned

communications with patient experience experts, and staff with no knowledge of screening.

Communications strategy

The aim of the communications strategy is to support the effective management of the incident. It needs to be tailored to the incident.

It should distinguish between operational communications to manage the incident, communications to professionals and communications to those affected and the wider public.

The goals are to minimise anxiety and maintain confidence in the screening programme as a whole.

Communications should initially focus on those directly affected.

Staff working in the programme and primary care professionals must be kept informed and supported so they are able to answer questions from their patients.

Arrangements must be in place for answering queries from the media and general public where the scale and severity of the incident warrants this.

The local organisation to provide communications input to the serious incident team should be agreed at the outset. This will normally be the organisation in which the incident has occurred, but this depends on the severity of the incident, provider size/capacity and whether there are implications for screening programmes beyond the area affected by the incident.

A communications lead, ideally with experience of handling incidents and dealing with national and local media, should be part of the incident team from the start. The communications lead should advise on the development of a communications strategy (proactive or reactive) and subsequent activity.

If it is likely that there will be media interest, the provider communications lead should work with the regional communication teams of NHS England and PHE so that a consistent message is agreed. The focus should be to ensure that communications activity is coordinated and transparent, so that patients and the public receive timely and accurate information as soon as possible.

For incidents requiring NHS England and PHE communications input, NHS England is responsible for leading and co-ordinating communications, in conjunction with the provider.

PHE will provide expert advice on the specific screening programme to support the communications plan.

4.5 National and regional level serious incidents

Providers, commissioners and quality assurance staff should remain vigilant for serious incidents which may have widespread implications or raise widespread public concern. They should share information with the provider chief executive, NHS England region and PHE's national head of screening QA, who can then decide whether to inform a directorate lead within the NHS England central team, the director of PHE's screening division and PHE national directors.

NHS England and PHE will work together in national/regional level serious incidents so that there is a coordinated and common approach. There should be early dialogue with the CQC as it may decide to carry out a section 48 investigation.

NHS England directors may convene and lead a national and/or a regional serious incident team depending on the scale, size and complexity of the serious incident.

NHS England's *Serious Incident Framework (updated 2015)* sets out that an independent investigation of the role of the commissioning system or where there is significant public concern would typically be commissioned and quality assured by NHS England region. In respect of a screening serious incident this decision should be made in consultation with PHE national directors.

A decision to inform the Department of Health (DH) should be agreed at a national director level by PHE and NHS England.

If the serious incident spans a number of screening or public health programmes, PHE may set up a national expert reference group to co-ordinate its advice to NHS England.

A communications strategy should be agreed with local, regional and national stakeholders to ensure that all communications are consistent. NHS England and PHE communications teams should agree the content, the dissemination plan, and which agency is the most appropriate to lead on communications activity including DH counterparts where appropriate.

A briefing which describes the issue, current position in terms of incident management and investigation should be produced. Briefing should be reported up through each agency and the joint national governance structures that oversee screening. Information should be disseminated through the appropriate professional accountability and commissioning routes including nursing, medical, operational and commissioning teams.

5. Closing the serious incident

5.1 Final report and action plan

The serious incident report should be produced on behalf of the chair of the serious incident team and agreed by the serious incident team.

The report should cover:

- the root causes of the serious incident
- identification and investigation of the problem, including the methodology used for the root cause analysis
- findings of the investigation and outcome of any look back/recall (eg positive cases found)
- contributory factors including service delivery problems
- lessons learned
- recommendations directly in response to the incident
- recommendations for improvements to existing systems
- an evaluation of the process of managing the incident
- recovery actions for the future, including clear timescales and leads – the NPSA action plan template should be followed (see NHS England *Serious Incident Framework (updated 2015)*

5.2 Submission and distribution of final report

The chair of the serious incident team should decide on a distribution list for copies of the report with reference to the RASCI agreed for the incident. However the list should include:

- chief executive of the provider organisation(s)

- director/clinical lead and programme manager of the screening service
- screening and immunisation lead, who will distribute the fact finding report within the commissioning organisation in which they are based and to the PHE centre director and director of public health as appropriate
- members of the serious incident team
- accountable commissioner of the provider organisation(s)
- screening QA service (regional), who are responsible for dissemination within QA and NHS screening programmes
- NHS trust development authority (NHS trusts only)

The screening and immunisation lead should ensure the report is submitted to the local screening programme board.

5.3 Closure of the serious incident

This is the responsibility of the commissioner who has overseen the serious incident following a quality assurance review of the final report and action plan.

The final report should be submitted by the provider to the responsible commissioner within 60 working days to comply with NHS England's *Serious Incident Framework (updated 2015)*. If the incident is particularly complex, a longer time frame may be agreed with the commissioner in advance of the deadline. If an independent investigation is required the final report must be produced within six months. Receipt of the final report must be acknowledged by the commissioner in writing.

The responsible commissioner should complete its quality assurance review of the final report within 20 calendar days. Reference should be made to the closure checklist included as an appendix in NHS England's *serious incident framework (updated 2015).* The report should evidence:

- an appropriate investigation that identifies findings, based on root causes and recommendations
- a satisfactory action plan with action points to address each root cause recommendation(s) and with a named lead and timescale for implementation

- that actions are either implemented or that local monitoring arrangements are in place to ensure action points will be implemented

- lessons learned, including partners or stakeholders with whom the learning has been shared

- full completion of the STEIS record covering the above points eg date investigation completed and population of root cause analysis (RCA) /lessons learned section

The responsible commissioner may involve other commissioning organisations, such as the accountable commissioner of the provider organisation in the assurance and closure process, for example where there is a risk of conflict of interest. The screening QA service (regional) will review and may comment on the report. Before the commissioner closes the incident on STEIS, there must be assurance that the report meets the required standards and that the action plan is completed or satisfactory progress is being made. Where this is considered acceptable, the screening programme board should ensure the action plan is reviewed regularly until it is implemented.

If a screening programme was suspended due to the incident, then routine screening will have been recommenced.

5.4 Identifying and sharing the lessons

It is important that lessons for other screening services and NHS screening programmes are identified, alongside learning about managing the incident and dealing with the consequences. It maybe that changes to screening protocols and guidance would minimise the risk of a similar incident occurring.

Screening QA service (national) is responsible for ensuring that:

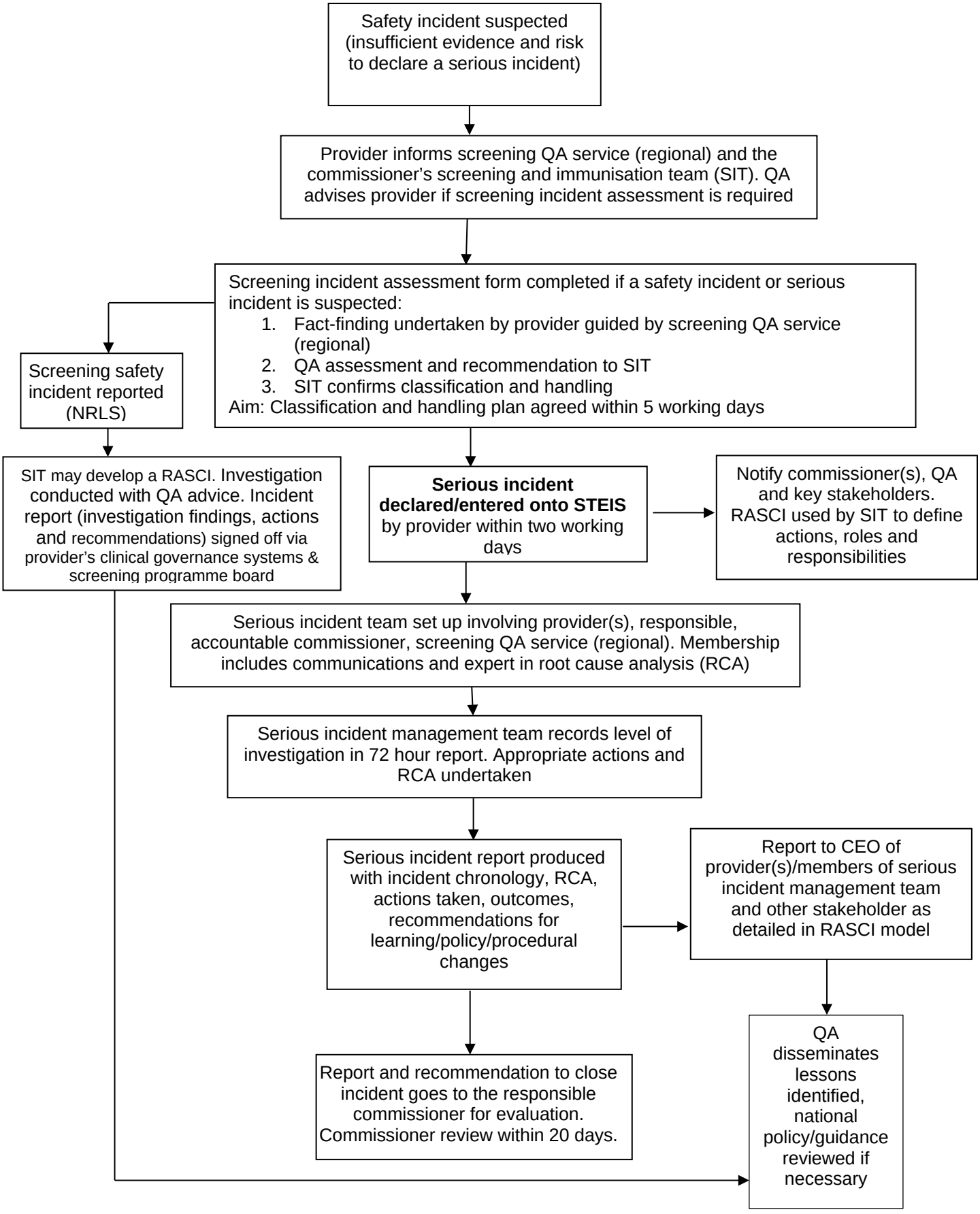
- screening safety incidents and serious incidents are recorded, monitored and analysed systematically

- recommendations for changes in screening guidance are considered and changes enacted where appropriate

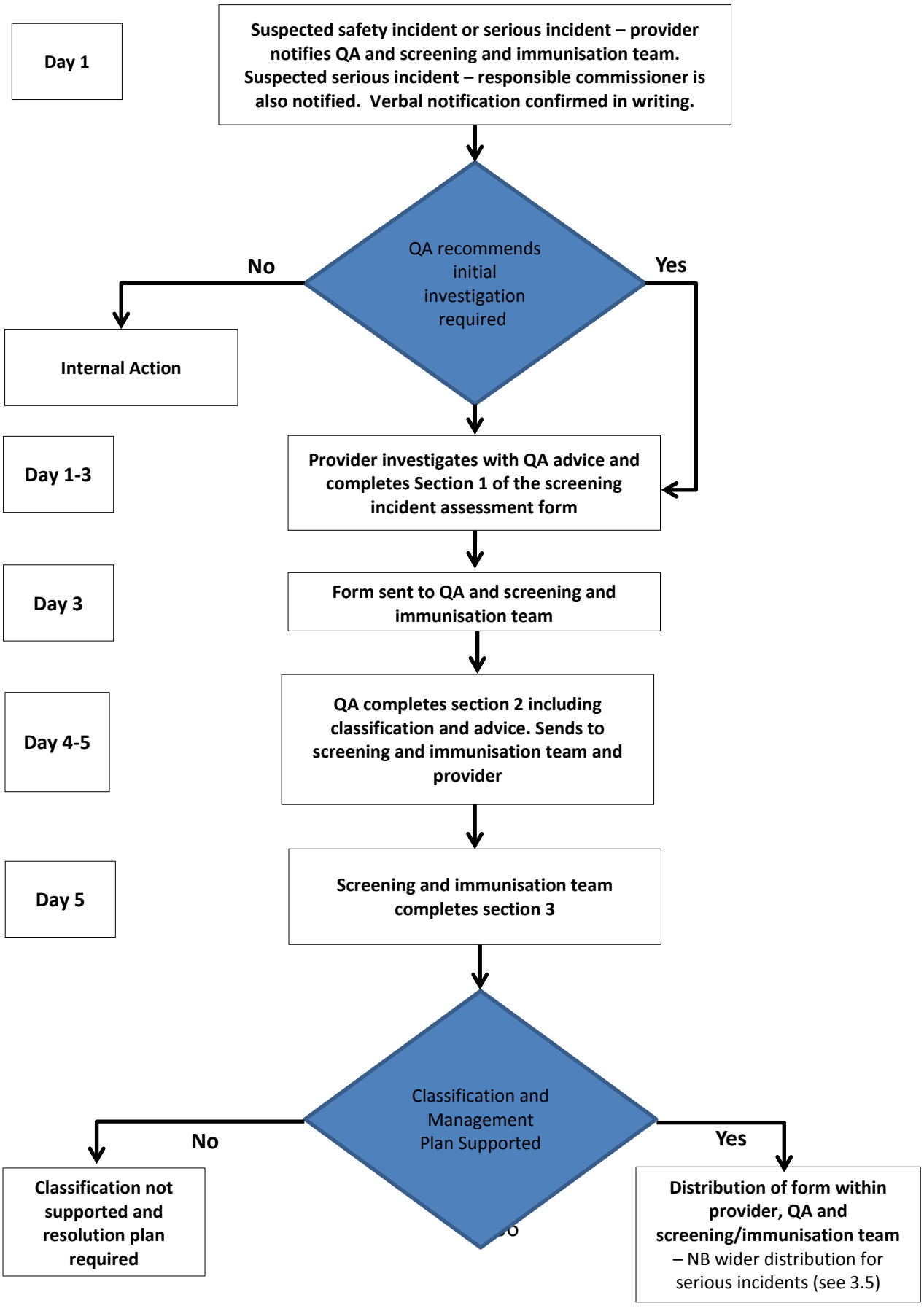
- learning identified from incidents is disseminated to all local screening services and commissioners via briefings, meetings and reports.

- all screening incidents are reviewed to ensure that lessons are disseminated across screening programmes and geographical areas.

Appendix/Figure 1: Reporting and managing screening incidents



Appendix Figure 2: Flowchart of Screening Incident Assessment Process



Glossary

Adverse event

An event or omission arising during clinical care and causing physical or psychological injury to a patient.

Child Health Records Departments (CHRDs)

CHRDs provide a clinical record for all 0-19 year olds within a defined geographical area. They are the “administrative hub” supporting the flow of information at an individual and population level. This supports the delivery of universal population health services such as health visiting, screening and immunisations and statutory functions such as safeguarding.

To carry out these functions, CHRDs maintain a child health information system (CHIS).

Clinical Commissioning Groups (CCGs)

Clinically-led organisations that commission most NHS-funded healthcare services on behalf of the population registered with GPs operating within the CCG. These include services that interface with screening. CCGs:

- hold the contracts for maternity services, which are providers of antenatal a newborn screening
- are responsible for commissioning pathways of care and services to treat screen positive patients
- have a quality improvement duty; this extends to primary medical care services delivered by GP practices such as immunisation and screening services.

Clinical governance

A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.

Commissioner

An organisation with responsibility for assessing the needs of service users, arranging or buying services to meet those needs from service providers either in public, private or voluntary sectors, and assuring itself as to the quality of those services.

Care Quality Commission (CQC)

The CQC is the independent regulator of all health and social care services in England and must be notified by providers of some care quality issues/safety incidents. (See Resources section for further information on CQC notifications).

Datix

A web-based system for incident reporting widely used by providers of NHS healthcare as part of local incident management arrangements. In NHS trusts this system links to the National Reporting and Learning System (NRLS).

Duty of candour

The *Health and Social Care Act 2008 (Regulated Activities) Regulations 2014* imposed this duty on NHS bodies which supplements professional duties of individual clinical staff.

Health service bodies must act in an open and transparent way in relation to the care and treatment provided to service users. The duty criminalises NHS bodies that fail to notify and apologise to their patients for incidents that have caused them harm.

Incidents are anything unintended or unexpected if it causes or is expected to cause death, severe harm, moderate harm or prolonged psychological harm, as follows:

1. harm caused by the incident rather than the disease/condition

2. severe harm – permanent lessening of bodily, sensory, motor, physiological or intellectual functions.

3. moderate harm – harm that is significant so that it requires a moderate increase in treatment and harm that is significant but not necessarily permanent

4. prolonged psychological harm – a minimum of 28 continuous days

Regulation: Duty of Candour What new regulations means for Trusts. Health Services Journal, 5 December 2014.

Local Authority

Provides local government and services for a defined geographical area. Since April 2013, authorities have had responsibility for commissioning/provision of some public health services, health improvement and oversight/scrutiny of NHS services for their resident population.

Health and wellbeing board

Each local authority has a health and wellbeing board, a statutory committee that leads and advises on work to improve health, wellbeing and reduce health inequalities for the population served. Membership includes the director of public health, councillors, commissioners across the NHS, public health and social care; and representatives of patients and the public, including the local Health Watch.

Director of public health (DPH)

Public health functions are led by the director of public health. There is a director of public health for each upper tier local authority, although a DPH may cover more than one local authority. They are appointed jointly by the Local Authority and Public Health England.

Medical Device

Medical devices and equipment are items used for the diagnosis and/or treatment of disease, for monitoring patients, and as assistive technology. This does not include general purpose laboratory equipment. Any incidents involving medical devices should be reported using the online form.

www.gov.uk/report-problem-medicine-medical-device

Monitor

Monitor is the regulator of NHS Foundation Trusts in England. Its role is to protect and promote the interests of patients by ensuring that the whole sector and that these provider organisations meet performance and financial targets.

NHS England (NHSE)

NHSE provides strategic direction and oversight of the NHS. Its vision is that everyone has greater control of their health and their wellbeing, supported to live longer healthier lives by high quality health and care services that are compassionate, inclusive and constantly-improving.

Regions

NHSE is organised into 4 regions – North, Midlands and East, South and London. NHS England regions are the organisational level used to escalate concerns around quality in local screening programmes. Each region has a number of local offices.

Local offices of NHS England regions

NHS screening and immunisation services are commissioned by staff working in local offices. They ensure that service providers deliver against the national service specifications and meet agreed quality standards. They ensure adequate responses are made to QA recommendations and use commissioning levers to implement change where necessary.

Public health commissioning in NHS England

Each sub-region's public health commissioning team comprise NHS England's own staff (led by the head of public health/public health commissioning lead) and also 'embedded' PHE staff, (led by screening and immunisation leads).

National Patient Safety Agency (NPSA)

The NPSA was set up in July 2001 following recommendations from the Chief Medical Officer in his report on patient safety, *An Organisation with a Memory*. Its role was to improve the safety of patients by promoting a culture of reporting and learning from patient safety incidents. Its guidance and resources to manage and investigate serious incidents are still applicable (see resources section). NPSA functions were absorbed into NHS England in April 2013.

National reporting and learning systems (NRLS)

A confidential and anonymous electronic reporting system developed by the NPSA for the collection and analysis of patient safety incident information. It receives incident reports from NHS organisations, staff and contractor professions and, in time, patients and carers.

UK National Screening Committee (UK NSC)

The UK National Screening Committee (UK NSC) advises Ministers and the NHS in the four UK countries about all aspects of screening. The UK NSC is hosted by Public Health England.

NHS screening programmes

The NHS screening programmes are led by Public Health England. The national teams set and review standards, develop information materials for the public and education and training strategies for screening staff. They also provide operational support to local screening services.

Near miss

Situations that could have resulted in an accident, injury or illness for a patient but were avoided by chance or by intervention.

Never event

A list of serious, largely preventable patient safety incidents that would not have occurred if the available preventative measures have been implemented. There are no screening incidents in this list.

NHS standard contract

The NHS standard contract is mandated by NHS England for use by commissioners for all contracts for healthcare services other than primary care.

Patient safety

The process by which a provider of health care improves the safety of patient care. This should involve risk assessment, the identification and management of patient-related risks, the reporting and analysis of incidents, and the capacity to learn from and follow-up on incidents and implement solutions to minimise the risk of them recurring.

Patient safety incidents, screening safety concerns, safety incidents and serious incidents

Patient safety incidents are incidents that could have or did harm a patient receiving NHS funded care.

A safety concern in a screening programme is where an event or set of circumstances is reported that may meet the definition of a screening safety incident or serious incident.

Screening safety incidents are incidents that could have or did harm to one or more persons participating in the screening programme, or to staff working in the screening programme; or because one or more people eligible for screening were not offered screening.

Serious incidents in screening programmes are of greater severity than screening safety incidents in that individuals, the public or staff would suffer avoidable severe harm or death if the root cause is unresolved. (See 1.6 for full definition).

Public Health England (PHE)

An executive agency of the Department of Health that began operating on 1 April 2013. It is a national organisation with a remit to protect and improve the nation’s health and wellbeing, and reduce health inequalities. It provides expert public health advice, support and services, tailored to local needs. It is responsible for NHS screening programmes and the screening quality assurance service. These functions are managed by the Screening Division of PHE’s health and wellbeing directorate.

PHE Regions

There are 4 PHE regions with the same boundaries as NHS England regions. Each is headed by a Regional Director of Public Health. They provide evidence based public health and population healthcare advice and focus on supporting localities and linking with NHS England.

PHE Centres and centre directors

There are 8 PHE centres that are the front door for most of PHE's local services across health improvement, public health and health protection. They support the challenge and scrutiny role of Local Authority directors of public health (DsPH) through the dissemination of evidence and intelligence.

Each PHE Centre is led by a PHE centre director. They provide professional support to the PHE staff embedded in the NHS England sub-regional teams. PHE Centres lead the response to outbreaks of vaccine preventable disease and provide expert advice to screening and immunisation teams in cases of immunisation incidents.

PHE Screening quality assurance service (SQAS)

PHE's Screening quality assurance service (SQAS) has a quality assurance remit for all NHS screening programmes in England. It was formed in April 2015 from cancer screening QA reference centres and the regional screening QA teams for antenatal and new born screening, diabetic eye screening and abdominal aortic aneurysm screening.

Its purpose is to ensure local screening programmes operate within national standards and guidance - from identification of the cohort eligible for screening to referral out of screening into treatment or intervention services.

These functions are carried out through a programme of QA activities by a national team and 4 regional teams, one for each PHE and NHS England region.

SQAS has an advisory role in screening incident management and leads on monitoring and sharing lessons identified from incidents and developing incident management guidance.

Quality surveillance groups (QSGs)

These NHS England-led virtual teams operate at a regional or sub-regional level bringing together organisations across the health economy. Each QSG works to safeguard the quality of care that people receive by collectively considering and triangulating information gathered through performance monitoring, commissioning, and regulatory activities and intelligence sharing intelligence and information.

Risk

The likelihood of something happening that will harm individuals, the public and/or organisations. It is assessed in terms of likelihood and severity of the consequences.

Risk management

Identifying, assessing, analysing, understanding and acting on risk issues in order to reach an optimal balance of risk, benefit and cost.

Root cause analysis (RCA)

A systematic process whereby the factors that contributed to an incident are identified.

As an investigation technique for patient safety incidents, it looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which an incident happened.

Screening and immunisation lead (SIL)

Consultant in public health who leads a Screening and Immunisation team. Employed by Public Health England but line managed and works within NHS England at sub-regional level. Professionally accountable to a PHE Centre Director.

Screening and immunisation team (SIT)

Embedded within local offices of the 4 NHS England regions, these teams provide local system leadership and commissioning of screening and immunisation services. Each team comprises:

- screening and immunisation lead(s) (public health consultant)
- screening and immunisation managers
- screening and immunisation coordinators.

Screening programme board

Provides governance and oversight of a local screening programme. Typically chaired by a screening and immunisation lead with representation from all providers and staff groups that contribute to the screening programme and screening QA service (regional).

Strategic executive information systems (STEIS)

The national information system which enables the electronic logging, tracking and reporting of serious incidents.

Systems failure

A fault, breakdown or dysfunction within operational methods, processes or infrastructure

Resources

Care Quality Commission
www.cqc.org.uk/

Care Quality Commission Notifications
www.cqc.org.uk/content/notifications

Department of Health. The never events policy framework. October 2012
www.gov.uk/government/news/never-events-list-update-for-2012-13

NHS England. National Reporting and Learning System
www.england.nhs.uk/ourwork/patientsafety/report-patient-safety/

NHS England. National Serious Incident Framework March 2015
www.england.nhs.uk/ourwork/patientsafety/

NHS England. National Safety Standards for Invasive Procedures (NatSSIPs). 2015
www.england.nhs.uk/patientsafety/never-events/natssips/

National Patient Safety Agency. Comprehensive RCA Investigation Report Templat. 2009
www.nrls.npsa.nhs.uk/resources

National Patient Safety Agency. National Framework for Reporting and Learning from SIRIs. 2010
www.nrls.npsa.nhs.uk/resources/?entryid45=75173

National Patient Safety Agency. Seven Steps to Patient Safety. 2004
www.nrls.npsa.nhs.uk/resources/?entryid45=59787

National Patient Safety Agency. Three Levels of RCA Investigation - Guidance. 2008
www.npsa.nhs.uk/rca

National Patient Safety Agency. Tools and training resources to support robust systems investigation in the NHS
www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/

Further information for multi-incident investigations, examples of concise report and
www.nrls.npsa.nhs.uk/resources/?entryid45=75355

Public Health England. Managing safety incidents in NHS Screening Programmes. 2015
www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes

Public Health England. Screening Incident Assessment Form
www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes

References

Care Quality Commission Guidance for Providers. *Guidance for NHS providers on the fit and proper persons requirement for directors and duty of candour*
www.cqc.org.uk/content/fit-and-proper-persons-requirement-and-duty-candour-nhs-bodies

Francis Report. Mid Staffordshire NHS Foundation Trust Public Inquiry (2013). *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, HC 947*. The Stationery Office: London
www.midstaffspublicinquiry.com/report

Health and Social Care Act 2008 (Regulated Activities) Regulations (2014)
www.legislation.gov.uk/uksi/2014/2936/regulation/20/made

National Patient Safety Agency. *Being Open: communicating patient safety incidents with patients, their families and carers* (2009)
www.nrls.npsa.nhs.uk/resources/?EntryId45=83726

NHS England (2015) *Serious Incident Framework*
www.england.nhs.uk/ourwork/patientsafety/

Managing Safety Incidents in NHS Screening Programmes – updated interim guidance issued in March 2015