



Public Health
England



Protecting and improving the nation's health

Managing Safety Incidents in NHS Screening Programmes

Developed in collaboration by NHS Screening Programmes and NHS England

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.

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Preface

All providers of local NHS screening services in England should apply this guidance. This includes NHS trusts, NHS foundation trusts, general practitioners and private providers. It covers managing safety concerns, safety incidents and serious incidents in screening programmes and sets out accountabilities for reporting, investigation and management.

This guidance is for staff working in NHS funded local screening services, organisations that host these services, 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.

It should be read alongside NHS England's *Serious Incident Framework (updated 2015)*.

Development of the guidance

A PHE and NHS England working group developed this guidance in 2014/15. The group included patient safety, commissioning and screening specialists. It considered learning from 6 consultation workshops attended by over 150 professionals. There were also contributions from PHE regional and centre directors, screening and immunisation teams, directors of public health, the Trust Development Agency and the Care Quality Commission.

This document is an update of *Managing safety incident in NHS Screening Programmes* (October 2015). The update takes account of comments from 6 training sessions held in 2016, revised screening incident classifications and changes in organisations and practice.

1. Introduction

1.1 Incidents in NHS screening programmes

Safety concerns and incidents in screening services need special attention because of the characteristics of screening.

Screening is the process of identifying healthy people who may be at increased risk of disease or condition. Local screening services offer information, further tests and treatment. This is to reduce the risks or complications of the disease or condition.

Screening is a pathway not a test. Local screening services may span several clinical departments, organisations and geographical boundaries.

Screening rarely benefits all sections of the population and needs to be targeted. As some false positives and false negatives are unavoidable there is potential harm for an individual. There is an ethical responsibility to do as little harm as possible.

This means that:

- apparently minor local incidents can have a major service impact due to the large number of people screened
- if the problem is widespread in other local screening services there can be an impact on the population and screening can do more harm than good
- incidents often affect the whole screening service not just the local department or provider organisation in which the problem occurs
- incidents may involve several organisations across geographical boundaries
- local incidents can affect public confidence in screening services in other areas

PHE Screening gives advice on screening incidents and takes action to help prevent incidents elsewhere, including sharing lessons identified from incidents, developing new guidance and training.

1.2 Policy content

The NHS constitution emphasises the NHS's ethical responsibility to acknowledge and resolve failings. The *Francis Report* (2013) set out how important it is to have effective governance and investigate incidents.

Health care providers have a duty of candour. This is set out in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 .and in the NHS standard contract. The Care Quality Commission provides additional guidance. The legal duty applies if a safety incident is notifiable¹. Providers should inform and apologise to the service users harmed. This applies to local screening services but it is complex due to the characteristics of screening. In 2016 PHE Screening issued guidance on applying duty of candour and disclosing results of audits (see resources).

Health care providers should encourage their staff to report quality concerns so that action is taken to reduce risks and improve the service. Each year the Department of Health issues national service specifications to NHS England for each NHS screening programme. NHS England commissions local screening services from providers using these specifications. They set out that services are to comply with guidance issued by NHS screening programmes. This includes *Managing safety incidents in NHS Screening Programmes*.

1.3 Purpose

This guidance sets out the requirements for managing safety concerns, safety incidents and serious incidents in NHS Screening Programmes. It is important that actions are in proportion to the risk of harm and based on accurate investigation. It is relevant to healthcare staff that may identify or manage a screening incident including those who provide and commission NHS funded services. It is for staff of NHS Screening Programmes who advise on screening incidents.

1.4 Scope

The NHS Screening Programmes covered by this guidance are:

- NHS Breast Screening Programme
- NHS Cervical Screening Programme
- NHS Bowel Cancer Screening Programme
- NHS Diabetic Eye Screening 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

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

- NHS Newborn hearing screening programme
- NHS Newborn and Infant Physical Examination Programme

1.5 Screening safety incidents

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 Serious incidents

Some screening incidents require a heightened response. They are termed serious incidents. This is where the consequences or risks are so significant to individuals, carers and families; organisations and staff, populations, or represent significant potential learning for the NHS.

The heightened response means that formal governance is needed around reporting, investigating, action planning, implementation, closure and learning. Principles should be defined and consistent procedures followed,

It is a matter of professional judgement whether to declare a serious incident. Careful consideration of the definition is needed in each case.

In most instances, the provider of the local screening service declares the serious incident after deciding this with the commissioner and informed by QA advice.

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
- 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 serious incident definition. Characteristics that are applicable to screening are in the table below²

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.

Extract from NHS England Serious Incident Framework

- Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:
 - Unexpected or avoidable death³ of one or more people
 - Unexpected or avoidable injury to one or more people that has resulted in serious harm⁴
 - 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

The NHS England *Serious Incident Framework (updated 2015)* states that a suspected serious incident should be declared at the outset and scaled down where appropriate. Due to the characteristics of screening it is often difficult to judge severity at the outset.

Fact finding and assessment is used to decide whether to declare a serious incident (see Section 3). Its purpose is to understand and mitigate risk

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

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

All parties should agree accountability, responsibilities and governance. The RASCI model (responsible, accountable, supporting consulted, informed) is a method for doing this. Local differences in commissioning structures and ways of working can be accommodated. It is recommended in the NHS England *Serious Incident Framework (updated 2015)*.

2.1 Providers

All providers contributing to a local screening service have joint responsibility to ensure safe and coherent screening for the population in accordance with the national service specification.

Each provider is accountable for the safe and coherent delivery of their part of the screening pathway. There is joint accountability at the interface between providers.

Providers of screening services are responsible for operating within this guidance. It 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 organisation incident policies should reference both sets of guidance.

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

- notify SQAS (region) 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

If a serious incident is suspected or declared the provider provides reports to the commissioner of the service and, where this different, to the commissioner that leads on contracting with the provider organisation.

2.2 Commissioners

NHS England is responsible for commissioning local NHS screening services that deliver quality and outcomes in accordance with NHS Screening Programme requirements. Commissioners achieve this by monitoring and assessing the quality of services. They work in partnership with providers but challenge when needed.

PHE provide the public health expertise required to commission and oversee local NHS screening services. These screening and immunisations teams are embedded within the commissioning teams of NHS England at sub-regional level. A team with equal functions operates within NHS London⁵.

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

The NHS England Serious Incident Framework sets out the commissioner's involvement in a serious incident. 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 provides leadership and oversight where multiple commissioners are involved
- decide whether to discuss a screening serious incident at the local quality surveillance group

Providing leadership and oversight includes agreeing a RASCI model, where appropriate, so that all parties are clear about their responsibilities at the outset. It is clear which organisation is responsible for leading oversight of the investigation, where the accountability sits and who should be consulted and/or informed as part of the process. This allows the accountable commissioner that is the commissioner holding the contract, to delegate responsibility for managing the investigation of the incident to an alternative commissioning body. This does not remove the overall accountability of the commissioner who holds the contract.

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

If there are many providers involved or the screening incident occurs in primary care, the responsible commissioning organisation may need to take an active investigation and management role. To keep this separate from the commissioner's oversight and closure function, the PHE Screening and immunisation lead may undertake this role on their behalf.

PHE Screening's national programme team has a direct commissioning role in managing pilots, roll-out of new screening programmes or extensions to screening programmes. To carry this out, it collaborates with the commissioner associated with the local screening service.

If there is a screening safety incident, NHS Screening Programmes will oversee the provider's response along with the appropriate screening and immunisation lead. If there is a serious incident, NHS Screening Programmes will also work with the responsible commissioner to make sure the provider meets the requirements of NHS England's *Serious Incident Framework (updated 2015)*.

NHS Screening Programmes manage 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 screening and immunisation leads, oversee how provider organisations manage screening safety incidents and serious incidents, working with SQAS. They are embedded within NHS England, at sub-regional level and will use commissioning mechanisms to ensure that providers follow this guidance and act on QA advice.

If a screening safety incident or serious incident is suspected or declared, the screening and immunisation lead associated with the responsible commissioner will take a lead role using 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 screening and immunisation lead)

In serious incidents, the screening and immunisation lead 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. The screening and immunisation lead will notify the relevant PHE centre director and director of public health when a serious incident is declared.

2.4 PHE screening quality assurance service

SQAS (national) will:

- develop guidance and processes for managing and monitoring screening safety incidents and serious incidents
- develop resources and training packages to support the management of screening incidents
- collate and disseminate the learning from incidents at national, regional and local level

SQAS has a responsibility to ensure patient safety. It must have mechanisms to ensure swift action if patients are at risk. It will:

- provide expert advice to providers, screening and immunisation teams and commissioners of screening programmes so safety concerns, safety incidents and serious incidents are assessed, investigated and managed effectively. This includes advising providers to seek communications support from NHS England
- access specialist clinical and policy advice for specific incidents from PHE Screening's national programme team
- check that PHE regional communications are aware of incidents escalated to NHS England regional communications
- make sure that the relevant PHE centre director is informed when a serious incident is declared

2.5 PHE Centres

PHE centres want to be aware of all serious incidents in their area. The screening and immunisation lead will keep them informed supported by SQAS (region).

PHE centre directors provide professional support for screening and immunisation leads (SILs) and make sure that there is adequate public health support for screening incidents.

PHE centre directors may help resolve 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 national and regional levels must be informed and may work together to manage, co-ordinate or advise if:

- the suspension of screening 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 are not resolved locally
- there is a need to co-ordinate providing information to interested parties

2.7 Local Authority directors of public health

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

In the case of a serious incident the screening and immunisation lead should inform the director of public health in a timely way.

Directors of public health are responsible for independent scrutiny and assurance. They should be kept informed of serious incidents but consider potential conflicts of interest before joining a serious incident team

2.8 Care Quality Commission (CQC) and NHS Improvement

The NHS England Serious Incident Framework summarises the roles of the Care Quality Commission (CQC) and when the provider should notify them. 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.

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

NHS Improvement (NHS I) is the successor organisation to Monitor and the Trust Development Agency. It is responsible for overseeing NHS foundation trusts, NHS trusts and independent providers. NHS Improvement will provide national guidance for managing serious incidents. This guidance will provide the framework for the CQC and commissioners (including clinical commissioning groups and NHS England) to assess the quality of investigations undertaken across the NHS.

2.9 Resolving disagreements

Local discussion should resolve disagreements about the classification, handling and closure of a suspected or declared screening incident.

Where there is disagreement between the provider and PHE (SQAS and the screening and immunisation team), the responsible commissioner should mediate and use their contractual powers to resolve the issues.

Where there is disagreement between the provider and the responsible commissioner, SQAS will advise both parties but the commissioner is responsible for securing agreement (see above).

Where there is disagreement between the commissioner and PHE (either QA or the SIL) NHS England region will resolve this supported by 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 SQAS (regional) and the screening and immunisation team. The regional head of QA and PHE centre director will mediate.

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.

3. Assessing and managing screening safety incidents

3.1 Safety concerns

In most cases, safety concerns that maybe screening incidents are raised by staff of the local screening service or through internal quality monitoring. There may be a specific event, complaint, or media interest.

The screening and immunisation team and SQAS may identify safety concerns to investigate 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 incident

The organisation identifying the safety concern should consider whether it meets the definition of a screening safety incident or serious incident (see 1.5 and 1.6). If unsure the organisation should seek advice from SQAS (regional).

The problem must have occurred within the screening pathway.

Isolated minor events/errors with little or no safety risk which will not reoccur locally or in other screening services should not be managed as screening incidents. These issues should be resolved internally and reported at the next the screening programme board meeting.

Only performance failures that meet the screening safety incident or serious incident definitions should be dealt with using this guidance.

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

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

SQAS (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

SQAS (region) will assess the seriousness of the safety concern immediately. They will consider the scale, risk of harm and potential for recurrence and advise the provider whether to complete the screening incident assessment form (SIAF). The SIAF is used to inform a decision about how the safety concern should be classified and handled.

If an incident has occurred outside of the screening service pathway, for example within diagnostic or treatment services, SQAS (region) 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

SQAS (regional) will provide a summary of the facts to the screening and immunisation lead for them to hand over responsibility to the relevant commissioner.

3.4 Screening incident assessment: fact-finding

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

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

The **screening incident assessment form** (SIAF) should be completed so that key questions are addressed. Section 1 of the 3 part form is a summary of the facts and should be completed by the provider.

Quality problems in screening programmes tend to be complex and may need considerable resources to investigate. More time is allowed for fact finding and assessment compared with other incidents. The maximum period is 5 working days. The provider has 3 working days to establish the facts as far as possible. Then SQAS (regional) and the screening and immunisation team have 2 working days to assess, classify and agree the next steps.

A serious incident may be identified at any point during this 5 working day period. Where this is the case, NHS England's serious incident framework (updated 2015) applies. The provider must report the serious incident to the strategic executive information system (STEIS) (or its successor) and the responsible commissioner within 2 working days of the incident being identified as a serious incident.

The organisation where the incident occurred should lead the fact finding. The screening and immunisation lead, as part of the responsible commissioning organisation, may lead if the incident spans multiple providers or has occurred in primary care.

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

SQAS (regional) advice must be taken into account. SQAS may involve specialist clinical/screening programme/IT experts from NHS Screening Programmes or its professional and clinical advisors.

In provider-led fact finding, the provider must keep the screening and immunisation team and SQAS (region) informed.

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
- SQAS (region)
- risk manager representative drawn from provider organisations involved

3.5 Screening incident assessment: recommendations

The provider completes the fact finding section of the screening incident assessment form (SIAF) (section 1) and sends it to SQAS (region) and the screening and immunisation team. The SIAF should not contain any personal identifiable data (PID).

SQAS (region) will assess the implications for individuals, the population, the local screening service and NHS Screening Programmes and comment on the adequacy of actions taken or planned (section 2 of the screening incident assessment form). This may include making changes to the local screening service so that it can continue screening. If there is a significant safety risk SQAS will recommend restricting or suspending screening.

SQAS (region) will recommend one of the following classifications.

No concern – no further action required
Problem still suspected, cause not yet identified, further investigation required
Not a screening incident
Problem confirmed - This can be managed internally (No further QA action required)
Problem confirmed - This should be managed as a screening safety incident (internal investigation and incident report)
Problem confirmed - This should be managed as a screening safety incident (multi-disciplinary/multi-organisation investigation panel and incident report)
Problem confirmed - This should be managed as a serious incident (declaration, concise or comprehensive or independent investigation)

SQAS (region) completes section 2 of the screening incident assessment form and sends this to the provider organisation and the screening and immunisation team. If a serious incident classification is recommended, a copy should be sent to the chief executive of the provider and the responsible commissioner.

The provider, SQAS (region) and the screening and immunisation team should reach consensus on the classification of the problem, the follow up action required and the timescale. Differences of opinion should be resolved through local discussion. In exceptional circumstances further advice and mediation may be needed (see 2.9).

The screening and immunisation team record the decisions made in section 3 of the screening incident assessment form and send the completed form to the provider and SQAS (region).

Where further investigation is needed, the action required is recorded in section 3 of the screening incident assessment form. This should detail the actions, who will take them and the timescale. The screening and immunisation team should ensure that the investigation is timely.

In serious incidents the screening and immunisation team should liaise with the responsible commissioner. They may use RASCI to confirm roles and responsibilities and the distribution of the completed screening incident assessment form.

National discussion is needed before implementing a recommendation to suspend a local screening service (see 4.2).

The screening and immunisation team send copies of the screening incident assessment to the responsible commissioner, any co-commissioner(s), the PHE centre director and director of public health as detailed in the RASCI.

SQAS (region) distributes the completed assessment within SQAS and NHS Screening Programmes.

3.6 Managing a screening safety incident

The provider should register the safety incident on their organisation's local risk management system. In NHS trusts this will link to 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 to the NRLS via the e-form at [NRLS Reporting](#).

The provider organisation that led the fact finding will carry out any further investigation, and remedial actions. The screening and immunisation lead oversees this and SQAS (region) provides expert advice. The provider organisation must keep the screening and immunisation team and SQAS informed.

Screening safety incidents involving multiple professional areas or organisations may need a panel to investigate and take remedial action. The team assembled for fact finding may carry out this role until the incident closes. The panel should include SQAS (region) and the screening and immunisation team.

In these situations, the principles for managing serious incidents should be followed but scaled down so that the handling of the incident is proportionate to its severity (see section 4).

When investigations and remedial actions are complete the organisation should send its draft incident report to SQAS (region) and screening and immunisation team. This should be within 60 days of the incident being declared unless an alternative timescale is agreed. SQAS will advise if further work is needed. The screening and immunisation team may also comment on the report. The final incident report should be issued within 80 working days of the incident being declared unless an alternative timescale is agreed.

The provider organisation should submit the final incident report according to its governance structures. The commissioner-led screening programme board should also consider the report (see section 5). Closing safety incidents is the responsibility of the commissioner after taking SQAS advice.

The level of detail in the report should be proportionate to the severity of the incident. It should include what happened, the investigations carried out, the cause(s) and 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.

SQAS (regional) will identify lessons for wider dissemination and implications for national policy and guidance for consideration by PHE Screening.

4. Managing a serious incident

See flow chart at Appendix Figure 1.

4.1 Declaring and reporting a serious incident

Organisations are to declare and report a serious incident in a screening service in line with this guidance which is consistent with NHS England's *Incident Framework (updated 2015)*. This is in addition to local organisational requirements for reporting incidents.

Serious incidents are to be reported on STEIS or its successor serious incident management system. They are also reported to the NRLS and if appropriate to regulators such as the Care Quality Commission (CQC).

A serious incident can be declared at any stage. In the fact finding, assessment, investigation or handling process. The NHS England's *Incident Framework (updated 2015)* applies from this point. A number of organisations can call for a serious incident to be declared. (See 1.6).

A serious incident can be downgraded if during the investigation there is evidence that no serious incident has occurred. Similarly a safety incident may be escalated to a serious incident.

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.

Any organisation identifying an incident should inform:

- SQAS
- screening and immunisation lead (embedded within the responsible commissioner)
- accountable commissioner of the provider organisation (e.g. 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 SQAS (national) (to be informed by SQAS (regional))

The screening and immunisation team may develop a RASCI to decide the other interested parties to be notified.

4.2 Programme suspension or pause

This is where SQAS recommends that the local screening service is suspended or paused for patient safety reasons. SQAS (region) informs the provider and commissioner of the recommendation verbally and confirms this in the completed screening incident assessment form.

The recommendation is made to the provider, commissioner and PHE Screening (national). They will consider the recommendation and consult with the NHS England Public Health Commissioning Central Team and the regional director of public health.

If a commissioner wants to suspend a screening programme this must be discussed with SQAS (region), PHE Screening (national), the NHS England Public Health Commissioning Central Team and the regional director of public health.

The decision to suspend a screening programme is communicated by the commissioner of the service.

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 2 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 should 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 agreed between the organisation declaring the incident, the SIL and SQAS (region).

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 SQAS (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 involved the RASCI model should be used. In most cases the chief executive of the host organisation will identify an appropriate chair for the incident team, but this role may be carried out by the responsible commissioner. (See section 2.2).

Administration and documentation is essential. The chair of the incident team should identify adequate administrative and IT support.

Each team member will brief their own organisation about the incident and any actions taken. The PHE centre director will be kept informed by the screening and immunisation lead and may also 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 serious incident team should agree the role of external expert(s) at the start. They are to provide 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 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 local screening services.

SQAS (regional) member of the team will provide impartial expert advice on the 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. 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 and process for setting up an independent investigation.

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 apply, 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 show they have undertaken due diligence in assessing how the duty of candour applies 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 that is confirmed in writing.

Applying duty of candour to screening is complex due to the characteristics of screening. Further guidance on [applying the duty of candour to screening](#) is available.

Patient notification exercises

The National Patient Safety Agency's *Being Open Framework* (2009) provides detailed guidance on how to ensure good communications with patients, families and carers. The incident team should consider carefully how to contact members of the public.

Usually this will be through the clinical professionals that 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 extra information where needed.

The incident team should consider the communication needs of the individuals to be contacted and the level of support to minimise psychological harm. It is good practice to carry out 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 should 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 services beyond the area affected by the incident.

A communications lead 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 developing a communications strategy (proactive or reactive) and subsequent activity.

If media interest is likely, the provider communications lead should work with the regional communication teams of NHS England and PHE to agree a consistent message. The focus should be to coordinate communications activity. It should be

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 should lead and co-ordinate 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 public concern. They should share information with the provider chief executive, PHE's national lead of SQAS and the NHS England Public Health Commissioning Central Team.

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

NHS England may convene and lead a national and/or a regional serious incident team depending on the scale, size and complexity of the serious incident. The Public Health Commissioning Central team will identify a suitable director to lead the incident response.

NHS England's *Serious Incident Framework (updated 2015)* sets out that NHS England region typically commission and quality assure an independent investigation. For screening serious incidents this decision should be made in consultation with PHE's Director of Screening.

Informing the Department of Health about an incident should be agreed at a national director level of PHE and NHS England.

If the serious incident spans a number of screening services 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 to describe the issue, current position in terms of incident management and investigation should be produced. The 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 team should agree and produce a report on behalf of the chair.

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 (e.g. 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 using the agreed RASCI for reference. 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)
- SQAS (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 overseeing the serious incident. This follows a quality assurance review of the final report and action plan.

The provider should submit the final report to the responsible commissioner within 60 working days of the incident declaration 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. The provider should produce the report within six months if there has been an independent investigation.

The commissioner should acknowledge receipt of the final report 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 e.g. 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. SQAS (region) will review and may comment on the report. The commissioner will need to be satisfied that the report meets required standards and that satisfactory progress is being made to complete the action plan before closing the incident on STEIS. If a screening programme was suspended due to the incident, then routine screening will have been recommenced.

The screening programme board should review the action plan until completed.

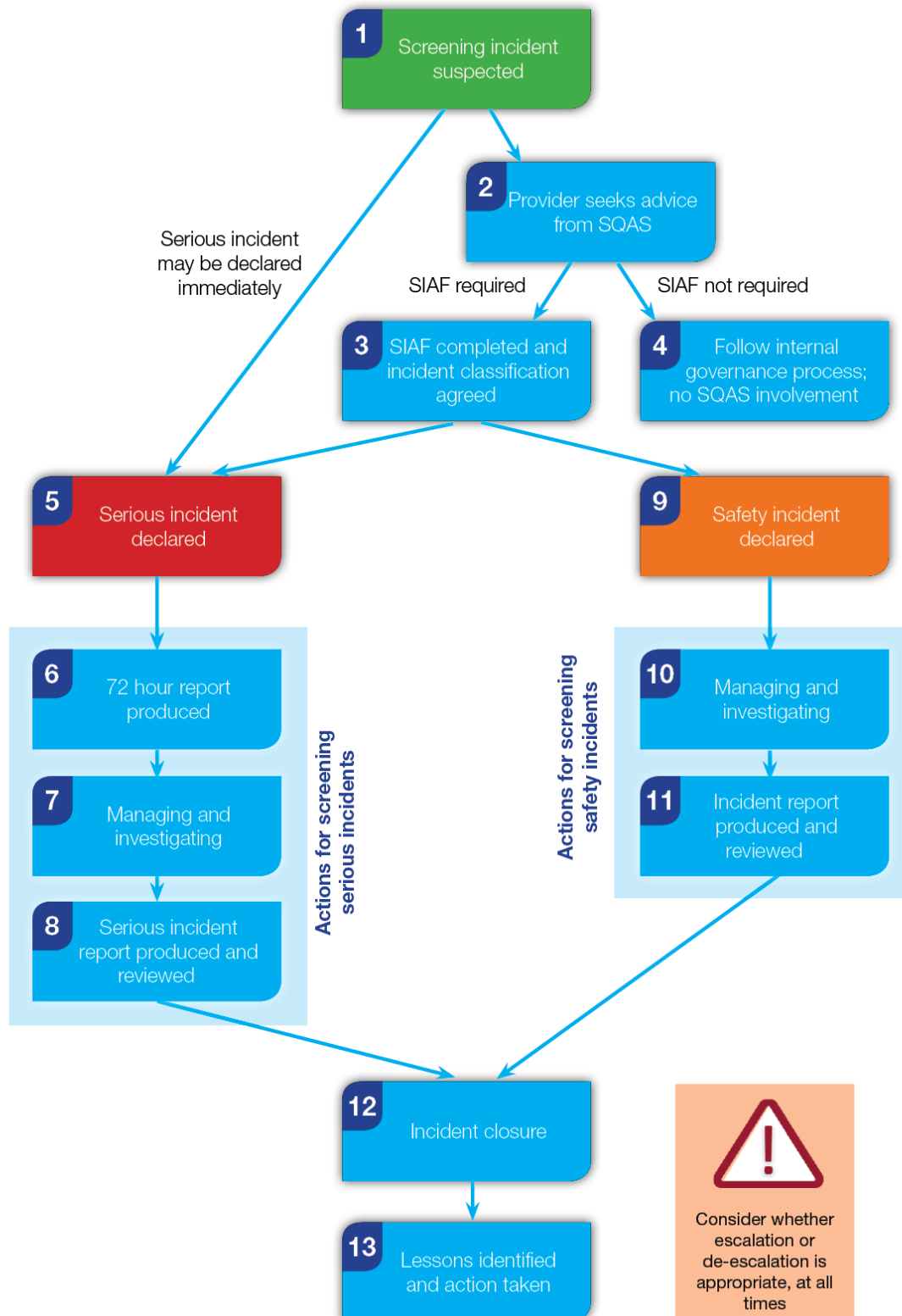
5.4 Identifying and sharing the lessons

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.

SQAS (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



Notes to accompany reporting and managing screening incidents flowchart:

1. Screening incident suspected

2. Provider seeks advice from SQAS

A serious incident may be suspected but if there is insufficient evidence or a risk to declare a serious incident then ensure advice is sought.

3. SIAF completed and incident classification agreed

Aim to complete within 5 working days.

- i. Provider details the facts in section 1 guided by SQAS (region).
- ii. Provider registers suspected incident on national reporting and learning system (NRLS) or replacement (reference provided on SIAF).
- iii. SQAS assesses and recommends a classification and handling to provider and SIT.
- iv. SIT confirms classification and handling to provider and SQAS.

4. Follow internal governance process; no further SQAS involvement

This will also apply if a SIAF is completed and the classification is 'not a screening incident'. If there is an incident but it is outside the screening pathway, the responsible commissioner is informed.

5. Serious incident declared

Provider reports serious incident on STEIS within 2 working days. Provider sets up incident panel (should include SIT and SQAS).

6. 72 hour report produced

7. Managing and investigating

Serious incident managed in accordance with agreed handling plan guided by SQAS (region). Changes to the handling plan and classification may be agreed by provider/SQAS (region) and SIT as more information is known.

8. Serious incident report produced and reviewed

Provider produces an incident report within 60 working days or alternative time period agreed with SQAS and SIT. SQAS and SIT comment on report. Aim is for all parties to agree the report within 20 working days.

9. Safety incident declared

If a final incident report is required then ensure the following actions are taken.

10. Managing and investigating

Safety incident managed in accordance with agreed handling plan guided by SQAS (region). Changes to the handling plan and classification may be agreed by provider/SQAS (region) and SIT as more information is known.

11. Incident report produced and reviewed

Provider produces an incident report within 60 working days or alternative time period agreed with SQAS and SIT. SQAS and SIT comment on report. Aim is for all parties to agree the report within 20 working days.

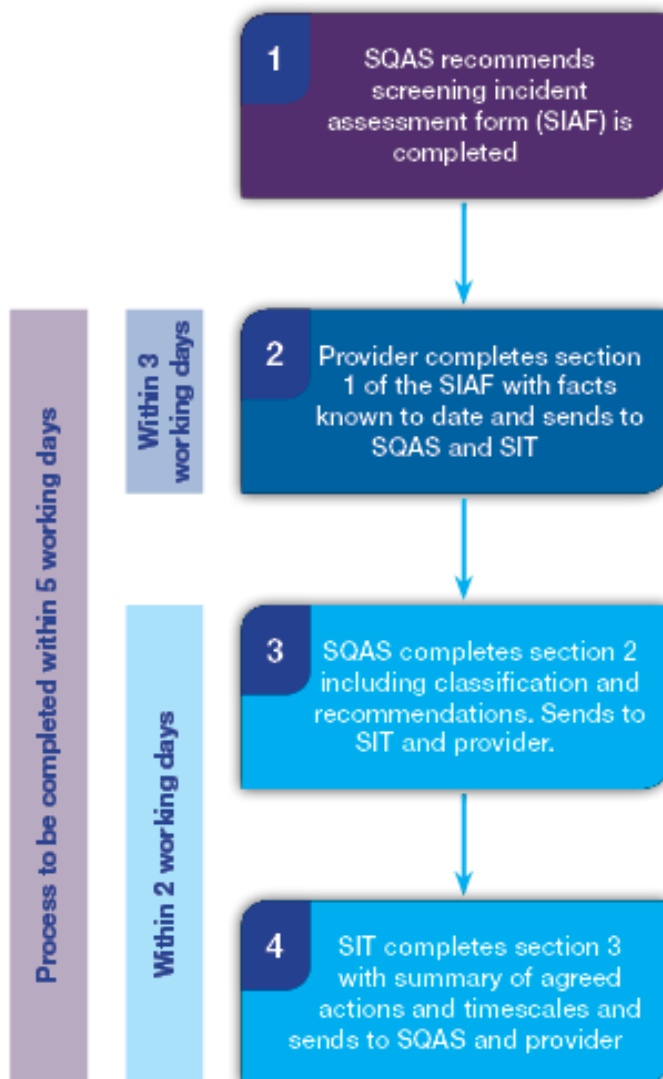
12. Incident closure

SQAS recommend incident for closure and responsible commissioner reviews and closes, governance for incomplete actions agreed, for example Programme Board monitoring.

13. Lessons identified and action taken

SQAS records (region) lessons identified and disseminates eg national policy or guidance may need review.

Appendix/Figure 2: 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 provide antenatal and 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.

Look back

A review of screening records to identify individuals harmed or at risk of harm as a result of a screening safety incident or serious incident. Look backs or case review may also be done as part of fact finding to establish whether there has been a screening incident. Look backs may result in a patient notification exercise/recall (see below).

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

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.

NHS Improvement will also seek to support implementation of this best practice through more direct engagement with Trusts and Foundation Trusts through its regional teams.

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.

Public health commissioning central team

This team is to be contacted by email if a screening incident needs need escalating to NHS England region/national level or if the suspension of screening is recommended (england.phs7apmo@nhs.net). The team has a protocol for regional and national incidents. It is led by the NHS England's director of commissioning system change and public health commissioning within the medical directorate.

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.

NHS Improvement (NHS I)

NHS Improvement (NHS I) is responsible for overseeing NHS foundation trusts, NHS trusts and independent providers. NHS I offer the support NHS trusts and NHS foundation trusts need to give patients consistently safe, high quality, compassionate care within local health systems that are financially sustainable.

NHS Improvement has taken over the responsibility from NHS England for providing national guidance for managing Serious Incidents. This guidance will provide the framework upon which CQC and commissioners (including CCGs and NHS England) will assess the quality of investigations undertaken across the NHS.

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). In some sub-regions the screening and immunisation lead carries out both roles.

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. Patient safety functions of NHS England were absorbed into NHS Improvement in 2017-18.

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 and are part of the screening division. 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).

Patient notification exercise

Members of the public identified as at potential risk of harm or harmed due to a screening incident are contacted by the screening service and informed of the quality problem. They can be offered repeat screening (recall to screening). Patient notification commonly occurs following a look back (see above).

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 SQAS. 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 Screening's 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. It is part of the screening division.

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.

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

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.

The SQAS regions can be contacted by email as follows:

PHE.Londonqa@nhs.net
PHE.MidsAndEastQA@nhs.net
PHE.NorthQA@nhs.net
PHE.SouthQA@nhs.net

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 SQAS (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

[National patient safety alerting system | NHS Improvement](#)

NHS England. National serious incident framework march 2015

[Serious incident framework | NHS Improvement](#)

National Patient Safety Agency. Comprehensive RCA investigation report template. 2009

www.nrls.npsa.nhs.uk/resources

National Patient Safety Agency. Seven Steps to Patient Safety. 2004

www.nrls.npsa.nhs.uk/resources/?entryid45=59787

National Patient Safety Agency. Route cause analysis (RCA) investigation guidance. 2010

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/

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

Public Health England. NHS Screening Programmes guidance on applying duty of candour and disclosing audit results. September 2016

[NHS screening programmes: duty of candour - GOV.UK](#)

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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

[Serious incident framework | NHS Improvement](#)

Public Health England (October 2015) *Managing Safety Incidents in NHS Screening Programmes*

www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes

Health Services Journal (5 December 2014) *Regulation: Duty of Candour What new regulations means for Trust*