



*UK National
Screening Committee*



Screening Programmes

Managing Serious Incidents in the English NHS National Screening Programmes

Guidance on behalf of the UK National Screening
Committee (UK NSC)

Version: 4.0

June 2010

CONTENTS

Acknowledgements

1. Introduction
 - 1.1 Background
 - 1.2 Purpose
 - 1.3 National patient safety context
 - 1.4 Scope
 - 1.5 Programme-specific Guidelines for Handling Incidents
 - 1.6 Training for Handling Serious Incidents in Screening
 - 1.7 Terminology
2. Responsibilities for Screening Programmes
3. Why Is the Robust Management of Serious Incidents Important?
 - 3.1 Key Principles of New NPSA Guidance
 - 3.2 Media
 - 3.3 Robust Management
4. What Constitutes a Serious Incident?
 - 4.1 Definition
 - 4.2 Overall definition of Serious Incidents for screening programmes
 - 4.3 Potential Serious Incidents or Near Misses
5. Responsibility for Handling Serious Incidents
 - 5.1 Staff
 - 5.2 Regional Lead Expert in each Screening Programme
 - 5.3 Responsibility
6. Investigating and Managing Serious Incidents
 - 6.1 Root Cause Analysis
 - 6.2 Screening Expertise
 - 6.3 Cost and Proportionality
7. Route of Reporting for Serious Incidents in National Screening Programmes
 - 7.1 Reporting
 - 7.2 Recommendations from Serious Incident Reports
 - 7.3 Serious Incident Policies
 - 7.4 Central Alerting System
 - 7.5 NPSA Recommended Timescales for Investigating and Handling
8. Key Principles on Programme Suspension
 - 8.1 Suspension
 - 8.2 Look-back or Recall Exercise
9. Resources to Support the Handling of Serious Incidents in Screening within each Region
 - 9.1 Dedicated Resource
 - 9.2 Communications

- 9.3 Communications Scenarios and Strategies
- 9.4 Communications Responsibilities
- 10. Closure of Serious Incidents
- 11. Sharing Learning
- Appendix 1 – Suggested Programme of Training
- Appendix 2 – Communications Strategies
- Appendix 3 – Examples of Serious Incidents in each Screening Programme
- References
- Endorsements

ACKNOWLEDGEMENTS

This draft guidance was commissioned by the Cross Programme Quality Assurance Group which is accountable to the Regional Directors of Public Health and the UK National Screening Committee (UKNSC). A working group of the Cross Programme Quality Assurance Group was formed to provide this draft guidance. The members of this working group were as follows:

Fergus Neilson SHA Screening Lead, NHS North East (Chair),

Dr. Andrew Clark, Deputy Regional Director of Public Health, NHS Yorkshire and the Humber

Dr. Ellis Friedman, Director of Public Health and Medical Director for Secondary and Tertiary Care, East Lancashire PCT and North West Regional QA Director for Breast Screening

Jeanette Bowes, Breast Screening Programme Manager, Gateshead NHS Foundation Trust

Elizabeth Graham, Head of Clinical Governance, County Durham PCT

Carrie Stone, Serious Incident Reporting and Learning Lead, Patient Safety Direct, National Patient Safety Agency

David Woodthorpe, Deputy Director of Communications, NHS East Midlands

Joanne Lacey, Clinical Governance Workstream Lead, NHS East Midlands

Sally Wood, Clinical Lead, NHSP Programme Centre

Steve Page, Strategic Head of Patient Safety, NHS North East

Yvonne Evans, Portfolio Manager for Patient Safety, NHS North East

Kylie Murrell, Project Manager, NHS North East

Consultation

The following groups were involved in the consultation on draft 3 of this document:

Director of Programmes of the UK National Screening Committee

The NHS Cancer Screening Programmes

Regional (SHA) Patient Safety Leads (**cascaded to local PCT and Trust Clinical Governance Leads, Chief Executives and Risk Managers**)

SHA Screening Leads - (**cascaded to PCT Screening Leads, Directors of local screening programmes, Directors of Public Health and a local GP**)

Directors of each national screening programme (**cascaded to local programme leads**)

Managers / Directors of each national screening programme
Communications Lead for each SHA - (**cascaded to local PCT and Trust Communications Leads and AN and NB Screening Co-ordinators**)

Regional Quality Assurance Directors for Breast Screening (**cascaded to local breast screening programme leads**)

Regional Quality Assurance Co-ordinators for Breast Screening

Regional Quality Assurance Directors for Cervical Screening (**cascaded to local cervical screening programme leads**)

Regional Quality Assurance Co-ordinators for Cervical Screening

1. INTRODUCTION

1.1 Background

National screening programmes are public health interventions, which aim to identify disease or conditions in defined populations in order to either reduce morbidity or mortality from that disease or condition, or to provide improved choice and information to patients. Regional Directors of Public Health have a special responsibility to oversee screening programmes, which often involve a range of commissioning and provider organisations. The UK National Screening Committee and the Directors of each of the national Programme Centres each have a responsibility of oversight, co-ordination and development of the relevant screening programmes.

In the summer of 2008, the Director of the UK National Screening Committee (UKNSC) and the Regional Directors of Public Health commissioned a national working group to provide advice on the principles and structures which can be applied to all national screening programmes. This is to ensure that quality assurance arrangements for these are robust and that accountabilities for screening and quality assurance are clear. One aspect of ensuring robust quality assurance in screening is the effective handling and learning from serious incidents.

Management of serious incidents in screening programmes is complicated because the screening programme often has a pathway across several organisations. In addition there are often a wider range of organisations nationally, which need to be informed and involved, to ensure that lessons from a local serious incident are appropriately disseminated and addressed accordingly. In addition, there are external quality assurance organisations for some screening programmes which have a role in investigating and managing incidents. The number of these external quality assurance organisations for screening programmes is likely to increase.

In the past, due to the multi-organisation and national aspects of serious incidents in screening, standard NHS processes for managing and reporting serious incidents have not fitted easily with the necessary consideration for national screening programmes. There is a potential for this to cause delay or confusion in the process of managing a serious incident in screening.

It is important that this new guidance sets the handling of

serious incidents in screening firmly within the policy and mechanisms for handling incidents which is applied within the wider NHS, whilst recognising those aspects which are relevant to screening.

1.2 Purpose

The purpose of this guidance is to make explicit the requirements for national screening programme related serious incidents and to provide clarity and understanding for all staff providing NHS funded care. This guidance, as part of the National Framework for Reporting and Learning from Serious Incidents requiring Investigation ¹, which was published by the National Patient Safety Agency, it is intended to build on and align existing policies at local, regional and national level. Local, regional and national policies should be revised in light of this guidance.

1.3 National patient safety context

This guidance for screening aligns with new National Framework for Reporting and Learning from Serious Incidents requiring Investigation ¹ for the NHS developed by the National Patient Safety Agency (NPSA). The National Framework provides definitions, standards and consistency in the identification, notification, investigation, action plan implementation, closure and communication of all serious incidents occurring in NHS funded care in England.

The National Framework for Reporting and Learning from Serious Incidents requiring Investigation ¹ was launched in March 2010.

1.4 Scope

This guidance is aimed at all staff working in NHS - funded screening programmes who may be involved in identifying and / or managing serious incidents. This includes NHS organisations, independent practitioners and independent service providers.

The national screening programmes which are covered by this policy are:

- Diabetic Retinopathy
- Abdominal Aortic Aneurysm
- Fetal Anomaly
- Infectious Diseases in Pregnancy
- Sickle Cell and Thalassaemia

- Newborn Blood Spot
- Newborn Hearing
- Newborn and Infant Physical Examination

The NHS Cancer Screening Programmes currently have their own national guidelines. Many of the principles of these new guidelines reflect those in the NHS cancer Screening Programmes. These new guidelines also provide an up to date reflection of current NHS structures.

(Whilst not a screening programme under the responsibility of the UK National Screening Committee the principles in this document could equally be applied to the Chlamydia Screening Programme and the new NHS Health Checks Programme).

1.5 Programme - specific guidelines for handling serious incidents

Some national screening programmes may elect to develop comprehensive guidance for investigating and handling serious incidents. These are valuable resources which give more detailed advice on the nature and methods of investigation for serious incidents in that Programme. These should be seen as supplementary to this generic national guidance for managing serious incidents in screening programmes.

1.6 Training for Handling Serious Incidents in Screening

In the formation of these guidelines, many consultees have commented that the publication of the document will not in itself improve the investigation, handling and learning for serious incidents in screening programmes. The UKNSC Director will commission a long-term, comprehensive programme of training for those involved in the investigation and handling of serious incidents in screening programmes. This training programme should include: training in the specific processes comprising the NPSA's Framework for Reporting and Learning from Serious Incident requiring Investigation; training in the processes as set out in this document; and workshops and role playing based on programme specific guidance and on programme - based scenarios for real incidents.

In order to facilitate this, each of the national screening programme centres will provide the following:

- A list of criteria or indicators which would trigger investigation into an incident in their programme.
- A list of known or likely incidents in their screening programme.

- A suite of example scenarios describing real incidents in their screening programme, which could be used for training purposes.
- Criteria that would indicate the need for a “look back” exercise, a recall to screening exercise and the circumstances in which screening should be suspended.
- Examples of the approaches a national programme would recommend are used in specific scenarios

See appendix 1 for suggested national programme of training in serious incident identification, handling and learning for screening programmes

1.7 Terminology

The NPSA’s agreed term to be used is “**Serious Incidents**”. This replaces “Serious Untoward Incidents”.

Locally, organisations have used the term “**Incident**” or “**Adverse Event**” to describe an occurrence where something in the management of one or more patients has gone wrong. This will, in some cases, be escalated to be described as a “Serious Incident”.

The **NPSA’s Data Quality Standards identify a “Patient Safety Incident” rather than “Adverse Event”**, however, local screening programmes should understand this, but work within the policy and current terminology of their own host Trust.

“**Potential Serious Incidents**” are those occurrences which have not yet been confirmed to be either a serious incident, but which are of sufficient concern to be thoroughly investigated in the manner of a serious incident until they can be defined as a serious incident or the investigation can be stood down, where no serious incident is confirmed.

“**Investigation Team**” is the term given to the group gathered to consider and take responsibility for investigating, managing and reporting on a potential or actual Serious Incident. It should follow guidance and agreed timescales as stated in the National Framework for Reporting and Learning from Serious Incidents requiring Investigations. The main three members of this group are: Chief Executive (or nominated representative) of the organisation in which the Serious Incident occurred, Director of Public Health of the lead commissioning PCT (or nominated representative) and a “lead expert”. Further

stakeholders and experts such as the Communications Lead may also be asked to be members of this group.

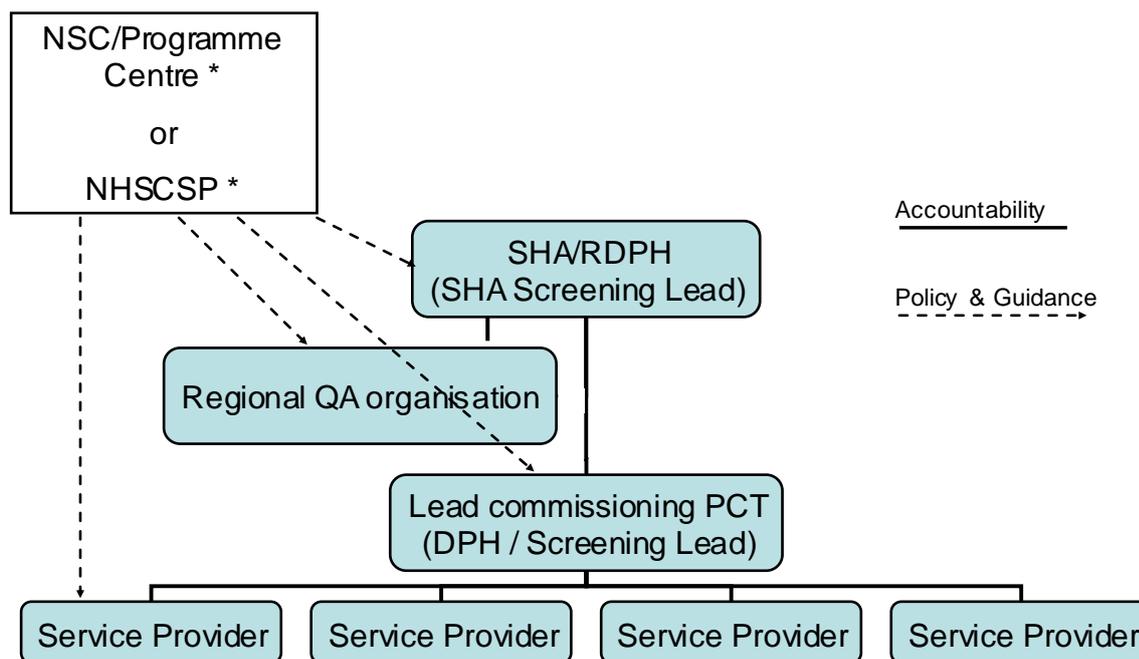
“Lead Expert” - this person will have expert, knowledge of the national screening programme in question. To support local PCTs, each region (SHA) should give some advance consideration to who these people might be for any of the screening programmes in their region.

See Section 5

2. RESPONSIBILITIES FOR SCREENING PROGRAMMES

Responsibilities for screening programmes are shown in Figure 1 and described in Table 1.

Figure 1: Responsibilities for a national screening programme



* NSC = National Screening Committee, NHSCSP = NHS Cancer Screening Programmes

Table 1 – Responsibilities for Screening Programmes

RDPH (supported by SHA Screening Lead)

- Commission QA programme(s) for screening
- Advise PCTs on appropriate structures for commissioning and monitoring screening programmes
- Commission regional structures to enable the measurement and monitoring of the long-term outcomes of the screening programmes (for example national/regional disease registries and public health observatories)
- Advise on and performance manage the arrangements for serious incident investigations by PCTs (this role is currently in transition and differs in each SHA area)

External quality assurance programmes

- Provide a QA service to the RDPH, which monitors and works with the component organisations of the screening programme to ensure that minimum standards are met and that continuous improvement is sought.
- Inform national screening programme centre on incident investigations (ongoing and outcomes of investigations)
- Be a centre of reference and expertise for all components of the programme including:
 - Trusts
 - PCTs
 - National Programme Centres
 - UK National Screening Committee
 - Other Clinical networks

Primary Care Trusts

(These are public health screening programmes and the Director of Public Health has a lead role for this within a PCT. The DPH is often supported by a “PCT Screening Lead”)

- Commission the entire pathway for each screening programme, on behalf of the PCT’s population
- If appropriate, to form “lead” or collaborative commissioning arrangements in accordance with NHS Guidance.
- Commission appropriate screening services, taking into account the advice of the UK National Screening Committee, National Programme Centres, RDPH and external quality assurance programme.
- Performance manage the provider organisations which contribute to the screening programme pathway

Provider Host Trusts

- Provide services in accordance with the agreements specified by the commissioning PCT
- Participate in internal and external quality assurance and monitoring arrangements as specified by the PCT and in national guidance for the screening programme
- Work with the provider Trusts in the other parts of the screening pathway to ensure safe and coherent screening for the individual client

UK National Screening Committee

(The UKNSC has appointed a “National Programme Centre” to lead each of its screening programmes)

- Set out national guidance and standards, information and advice for the use of all interested parties within the relevant screening programmes.
- Provide national information and advice for the public and patient representatives
- Develop guidance for programme of QA which can be applied in each SHA area
- Assist the Department of Health with the development of policy in respect of screening programmes
- Monitor the functioning of the regional external quality assurance services to provide comment to the RDPH on the quality of the service that these provide.
- Commission some nationally relevant services to support the local screening programmes, such as: external quality assurance; national software systems; components of screening programmes which operate at a national or super-regional level; training programmes
- Commission national media management services to represent the screening programmes at a national level and to provide advice to regional and local services on appropriate communications in respect of the national screening programmes
- Conduct or commission specific national audits and reports
- Contribute with advice and oversight to the management of screening incidents
- Commission work to monitor the overall effectiveness and long term outcomes of national screening programmes against their stated aims
- Dissemination of findings following incidents
- Lead on introducing new national screening programmes

3. WHY IS THE ROBUST MANAGEMENT OF SERIOUS INCIDENTS IMPORTANT?

3.1 Key Principles for serious incidents

There are four key principles underpinning the investigation, handling and learning from serious incidents

- i. To provide assurance of governance and safety for the most serious incidents
- ii. To facilitate the sharing of learning arising from serious incidents, locally, regionally, nationally and, where appropriate, internationally
- iii. To help prevent reoccurrence where a serious incident has occurred and reduce the chance of the same serious incident happening elsewhere
- iv. To support service improvement by providing information, guidance and recommendations which support managers in directing resources where they are most needed in order to improve quality and safety, including engagement with relevant bodies for full investigation and identification of learning from a serious incident

3.2 Specific issues affecting screening programmes

- Screening pathways cross several provider organisations and so accountabilities and responsibilities can sometimes be unclear.
- Serious incidents affect the whole pathway and not just the local department or provider organisation in which the serious incident occurred or was identified.
- The volumes involved in screening can give seemingly minor local incidents a major service and reputational population impact. There is potential for incidents in screening programmes to affect a large number of individuals / users of the service.
- There is an added ethical imperative for screening programmes to ensure that the benefits significantly outweigh the harms because individuals are invited to be screened rather than referring themselves.
- Local serious incidents can affect the national reputation and public participation in the Programme more widely than the area involved in the incident.
- Local “Potential” serious incidents or near misses are

relevant to the rest of a national programme for which it may highlight actual serious incidents elsewhere.

- Lessons need to be learned in the rest of the National Programme, which has large networks and numbers with an interest and responsibility.

4. DEFINITION OF A SERIOUS INCIDENT IN SCREENING PROGRAMMES?

4.1 Overarching Definition in accordance with NPSA guidance

A serious incident requiring investigation is defined as an **incident** that occurred in relation to **NHS-funded services and care** resulting in one of the following:

- **Unexpected or avoidable** death of one or more patients, staff, visitors or members of the public.
- **Serious harm** to one or more patients, staff, visitors or members of the public or where the outcome requires life-saving intervention, **major surgical/medical** intervention, **permanent harm** or will shorten life expectancy or result in **prolonged pain or psychological harm** (this includes incidents graded under the NPSA definition of severe harm).
- A scenario that prevents or threatens to prevent a provider organisation's ability to continue to deliver healthcare services, for example, actual or potential loss of personal/organisational information, damage to property, reputation or the environment, or IT failure.
- Allegations of **abuse**.
- Adverse media coverage or public concern about the organisation or the wider NHS.
- One of the core set of 'Never Events' as updated on an annual basis

4.2 Definition of Serious Incidents in screening programmes

For screening programmes this definition can be clarified further as follows:

An actual or possible failure at any stage in the pathway of the screening service, which exposes the programme to unknown levels of risk that screening, assessment or treatment have been inadequate, and hence there are possible serious consequences for the clinical management of patients. The level of risk to an individual may be low, but because of the large numbers involved the corporate risk may be very high. Complex screening pathways often involve multidisciplinary teams working across several NHS organisations in both primary and secondary care, and inappropriate actions within one area, or communication failures between providers, can result in serious incidents.

4.3 Potential Serious Incidents or Near

Potential serious incidents or serious near misses in screening programmes should be investigated with the same level of priority as for actual serious incidents. The

Misses

reason for this is that whilst the local provider organisation may have been fortunate enough to have avoided a serious incident, it may be that their local procedures need to be tightened to avoid an actual serious incident occurring in the future. In addition to this, there may be lessons which other screening programmes need to learn.

4.4 Preventing screening incidents

It is important to note that the following are most likely to prevent incidents in screening programmes:

- Allocation of clear accountabilities;
- Clear oversight of the entire screening pathway by the lead commissioning PCT;
- Existence of a robust comprehensive quality assurance programme;
- Putting into place fail-safe mechanisms or checks at strategic points in the patient / client pathway;
- Systematic open sharing and learning from Incidents and Serious Incidents.

5. RESPONSIBILITY FOR HANDLING SERIOUS INCIDENTS

Figure 2 shows the pathway for identifying, investigating, managing and reporting on a serious incident or potential serious incident. *(Figure 2 is based on the original work of the NHS Cancer Screening Programmes)*

Key roles and responsibilities are set out in the National Framework for Reporting and Learning from Serious Incidents requiring Investigation¹. However responsibility for the oversight and performance management of the handling of serious incidents is in the process of transferring from Strategic Health Authorities to Primary Care Trusts. Each SHA area is at a different stage of transition and reporting arrangements vary from region to region. Therefore all parties must ensure they are familiar with the Serious Incident Policy and procedures that apply to their SHA area, in order to provide consistent advice.

Due to the multi-organisational nature of screening programmes, past experience has shown that the issue of quickly identifying and assigning responsibilities is a major problem, causing delay, confusion and anxiety. Close attention needs to be paid to this.

In anticipation of serious incidents occurring in any screening programme, SHA Screening Leads should ensure that arrangements and responsibilities are clearly understood in their SHA area.

5.1 Responsibility

Prime responsibility for the identification and notification of serious incidents lies with the **Chief Executive (or equivalent) of the provider organisation in which the serious incident occurred.**

For screening programmes, the **Director of Public Health of the commissioning PCT** has an **equal responsibility** to be assured that the incident has been suitably escalated, notified and managed. Therefore, they must work closely with the Chief Executive of the provider organisation to ensure that this is the case.

For each screening programme in each SHA area there should be a nominated **“lead expert”** who should support the Chief Executive and the Director of Public Health. It is the responsibility of the SHA Screening Lead to ensure that suitable people are identified for this role in

anticipation that they may be needed to support Serious Incidents. For other screening programmes, this person may need to come from outside the SHA area – possibly from the National Programme Centre.

The **SHA Screening Lead** has a responsibility on behalf of the **RDPH**, to be notified of potential or actual serious incidents and to be assured by the commissioning Director of Public Health that the serious incident is being appropriately investigated and managed. The SHA Screening Lead will work closely with their SHA's Patient Safety Team to maintain this oversight.

5.2 Other participants The key people listed above are not necessarily a complete list of members of an Investigation Team.. Further stakeholders and further experts may be involved as necessary.

5.3 Assigning responsibilities at the start of each Serious Incident The responsibility for investigating, managing and reporting on screening Serious Incidents can sometimes be unclear and fall between organisations. This is why it is very important for the Chief Executive and DPH of the lead commissioning PCT to rapidly agree relative responsibilities and to assign the Investigation Team. If agreement cannot be reached, the SHA Screening Lead on behalf of the RDPH, will recommend responsibilities. .

5.4 Staff Every member of staff within the NHS and provider organisations should know who to contact with concerns or information regarding an incident or potential incident. Provider organisations must, as part of their NHS Litigation Authority compliance with Health Care Commission care standards, encourage the reporting of serious incidents by their staff. From April 1 2010, as part of the new registration requirements arising from the *Health and Social Care Act 2008*⁸, organisations are required to notify the CQC about events that indicate or may indicate risks to ongoing compliance with registration requirements, or that lead or may lead to changes in the details about the organisation in the CQC's register. Reports about serious incidents and deaths are defined in the CQC's guidance, *Essential Standards of Quality and Safety*⁴. For English NHS trusts most of these requirements are met by reporting via the NPSA, and the NPSA will forward relevant information to the CQC.

This should be embedded into induction and update training. Commissioning PCTs should ensure that this is a specific requirement

This should be supported by detailed requirements in

service specifications provided by commissioning PCTs.

When human resources or disciplinary processes are brought into play, those managing the handling of the serious incidents should separate these issues from the rapid investigation and reporting as far as possible. A useful tool to support this is the NPSA's incident decision tree. For information on action and support for staff see the NPSA's Incident Decision Tree: www.nrls.npsa.nhs.uk/resources

5.5 Commissioning PCT

The commissioning PCT has the responsibility for making sure that all provider and commissioning organisations understand their responsibilities in the event of a serious incident in a screening programme.

5.6 Delegated responsibilities

It is possible for any of these responsibilities to be delegated. Delegated responsibilities should be actively communicated.

5.7 Serious Incidents occurring across SHA boundaries

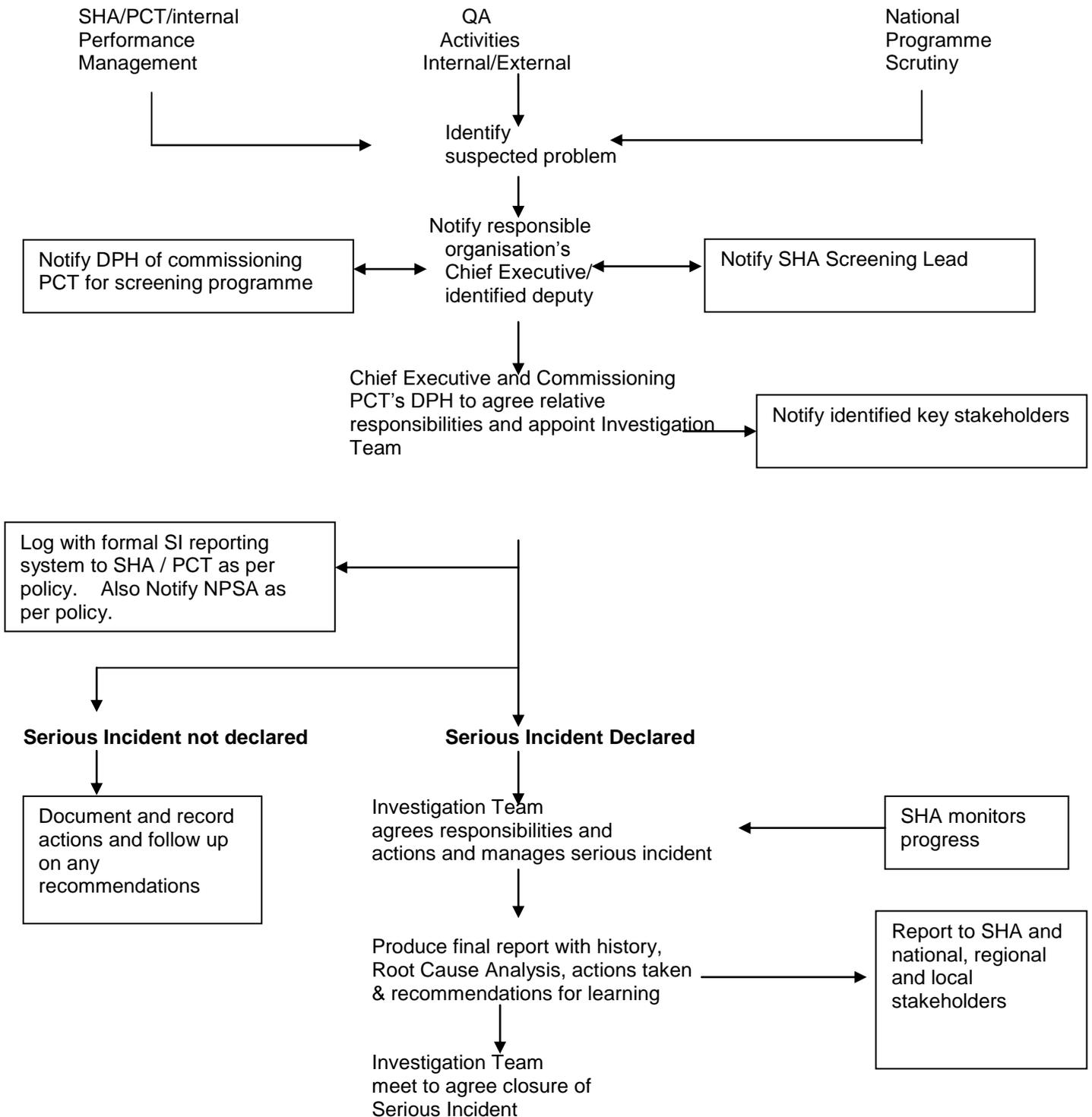
Where this occurs, the SHA Screening Leads are responsible for agreeing and assigning responsibility for leadership and oversight between them for the purposes of the investigation and management. This should be clearly communicated to all relevant stakeholders.

Where the SHA Screening Leads cannot reach agreement, this will be escalated via the RDsPH to the Chief Medical Officer for decision and include input from the National Programme Director.

FIGURE 2:

Identifying, investigating, managing and reporting a serious incident (or potential serious incident)

(This process should be undertaken in accordance with NPSA and local serious incident reporting and handling timescales)



6. INVESTIGATING AND MANAGING SERIOUS INCIDENTS

6.1 Programme Specific Guidance

Each national Programme Centre should provide their own published guidance with specific examples of:

- triggers which indicate that a Serious Incident may be occurring
- tools to assist assessment and investigation of common incidents
- example materials for communicating to patient, professionals and the public during the course of a Serious Incident

6.2 Root Cause Analysis

The NHS best practice standard for investigating serious incidents is to utilise Root Cause Analysis methodology. Templates and guidance are available on the NPSA website www.nrls.npsa.nhs.uk/rca. Standards and guidance for conducting investigations into serious incidents, including timescales for their completion, are included in the National Framework for Reporting and Learning from Serious Incidents requiring Investigation.

Those with responsibility for leading and / or providing expert advice should be trained and familiar with these.

6.3 Cost and Proportionality

Managing a serious incident can be expensive in terms of both finance and staff time. The response to an incident should therefore be proportionate to its significance. This is a judgement to be made by the Investigation Team

6.4 Open fair and just culture

It is essential for the learning and thorough handling of serious incidents that the “**open, fair and just culture**” be emphasised. Experience in the investigation of serious incidents in screening programmes has shown that serious incidents are rarely the result of one person’s failure, but usually arise from a systemic deficit.

However, one cannot exclude the possibility of the blame of individuals for their actions, where the actions are against professional codes of conduct or are illegal. The NHS emphasises the need for openness and to seek to learn from errors and encourages the concept of “**open, fair and just culture**”.

7. ROUTE OF REPORTING FOR SERIOUS INCIDENTS IN NATIONAL SCREENING PROGRAMMES

Reports for Serious Incidents for national screening programmes should be written up in sufficient detail to cover:

- Background and nature of the Serious Incident
- Investigation method and findings
- Management of clients/patients/media and relevant stakeholders
- Root Cause Analysis
- Recommendations with identified responsibilities
- Points of learning

7.1 Reporting

The formal route for reporting of serious incidents in national screening programmes is exactly the same as it would be for any other serious incident.

The responsibility for receiving and monitoring Serious Incident reports currently sits with the SHA in each region but is being devolved to PCTs in some regions. Wherever this responsibility sits, the SHA (or PCT) should routinely alert the SHA Screening Lead and the QA organisation. This is a backup mechanism only to ensure that the Serious Incident for a screening programme is being appropriately investigated, managed and reported.

Serious Incidents should also be reported to the National Reporting and Learning Service (NRLS) and currently on Strategic Executive Information System (STEIS). More information can be found at <http://www.npsa.nhs.uk/nrls/reporting/>.

In addition to this, there are a number of key stakeholders who need to be informed. The Investigation Team is responsible for ensuring these stakeholders are informed. The key stakeholders are as follows:

- Director of the UK National Screening Committee
- Director of the relevant national screening programme

- Regional/National Quality Assurance Director for the relevant screening programme
- The Regional Director of Public Health
- Relevant Directors of Public Health of local PCTs who are responsible for populations covered by the local screening programme in question
- Relevant PCT Screening Lead(s), who are responsible for the screening programme in question
- UKNSC Head of Communications
- Relevant, local, regional and national communications teams
- Trust Chief Executives of provider services for related parts of the screening pathway

The SHA Screening Lead should provide a reference list of an up to date register of relevant contacts for each of the screening programmes as described above. These should be published on the SHA's website with links from each PCT website.

7.2 Recommendations from Serious Incident Reports

These should be timetabled, feasible and monitorable with assigned responsibilities for action and monitoring. The incident report and recommendations should be copied to all relevant parties with consideration of the same list as in section 6.1 of this document. The aim of the report and recommendations is to ensure that learning is achieved and assurance of safety given. The NPSA has developed an action plan template to standardise serious incident action plans and provide quality assurance.

Tools and resources

www.nrls.npsa.nhs.uk/rca

7.3 Serious Incident Policies

Each SHA's and PCT's Serious Incident policy should include reference to these guidelines and to Screening Programme specific guidance.

Each SHA, PCT and provider should ensure that relevant staff are trained in the specific aspects of investigating and managing screening incidents.

Each SHA, PCT and provider is also responsible for creating the underlying conditions which reduce the risk of

Serious Incidents occurring.

PCTs should build this guidance into service specifications or other service quality/performance arrangements and with their provider services for screening.

7.4 NPSA Recommended Timescales for Investigating and Handling

The NPSA has outlined its recommended timescales for the investigation and management of Serious Incidents in the **National Framework for Reporting and Learning from Serious Incidents requiring Investigation**¹, which was launched in March 2010

8. KEY PRINCIPLES ON PROGRAMME SUSPENSION AND LOOK-BACK

8.1 Suspension

A programme should be considered for **suspension** when there is:

- serious concern about the competence of the screening team in either identifying and calling the right people to be screened, sampling, analysing the tests, or assessing those referred on;
- failure or misuse of equipment so it is unsafe to those being screened or staff operators, or the results of tests are unreliable (it is advisable to consult with a health and safety executive when there has been an equipment failure and inform Medicines & Healthcare Products Regulatory Agency);
- failure, misuse or malfunction of the screening IT system such that there is no certainty about who has been invited and screened;
- a backlog of unanalysed / unreported test results equivalent to significantly more than the acceptable turnaround time for results in that programme.

Each of these examples should be treated with considerable judgement about the benefit of suspending against the harm and disruption caused.

Often, when a programme is suspended, an alternative provider is not available and therefore the risks to the target clients of not having the benefit of being screened at all must be compared with the risks of continuing with a service with sub optimal performance.

8.2 Look-back or Recall Exercise

A look-back or recall exercise is required if the service can no longer be confident that certain negative / normal screening results are reliable and significant disease may have been missed. Proportionality is important here, as it is recognised that no screening programme identifies 100% of disease, but a systematic failure which has led to performance well below published standards or norms warrants a review of work. If this is not possible, because there is no image, sample or copy which can be revisited, then there does need to be a recall of the affected group for retesting.

Each national screening programme should publish a more detailed and programme specific guide in respect of look-back or recall exercises. This would provide both the criteria, which would determine the need for and the issues to consider in the management of such exercises.

9. RESOURCES TO SUPPORT THE HANDLING OF SERIOUS INCIDENTS IN SCREENING WITHIN EACH REGION

9.1 Communications Communications responsibilities lie at a local, regional and national level and, once again, the requirements of the national Serious Incident Reporting and Learning Policy should be followed.

9.3 Communications Scenarios and Strategies Generally there are three communications categories that will determine how a serious incident may be handled:

- the media is unaware of a serious incident,
- the media is unaware of a serious incident but the media should be informed so it can help with the handling of the incident by notifying the general public and/or section of the public of, for example, the need to come forward for re-testing following a screening programme incident, or

the media is aware of an incident first and in this case the SHA/PCT/provider organisation may have only learned of a problem because it has been publicised by the media or the handling of an ongoing serious incident has 'leaked' into the public domain

Please see Appendix 2 for further guidance on media handling for Serious Incidents in screening programmes.

9.4 Communications Responsibilities The following communication requirements apply specifically to screening programme serious incidents.

Collaboration between organisations for communications is essential, since it is possible for the local serious incident and its handling to impact negatively on the whole national screening programme and may unduly discourage the target population for screening from accepting the offer of future screening tests. It may also make those who have been screened unduly concerned about the accuracy of their own results.

National

The National Screening Committee and, individually, some of the national programme centres, have appointed their own communications teams. These are responsible for providing a suite of standard statements and to describe the purpose and progress of each national screening programme. They act as a resource to represent the national screening programmes, but also to provide

resources and advice to regional and local communications teams. It is critical that the Regional/Local Teams inform, consult and seek guidance from these National Teams in statements and public messages. The National Communications Team would take leadership of communications when the issue ceases to be a local issue and becomes a national media story, in some instances.

The contact for each NSC programme communications lead is on the NSC website and on each programme centre's website.

Resources for information and key messages about the programme are on the NSC website and on each programme centre's website.

Regional

The communications team for each SHA should support its PCTs and provider Trusts by preparing a suite of standard statements explaining what each programme is, its purpose, its benefits and its risks. These should be available at short notice in case of a serious incident and provided to the local organisation which has responsibility for the serious incident. These statements will have been originally generated and disseminated by the national communications teams.

The SHA Screening Lead should maintain and publish a list of screening programme contacts for each programme and in each PCT. These should be published on the SHA's website with links from each PCT website.

The SHA Communications Team should support the local organisation with advice and may in some cases take the lead on communications for a serious incident, with due regard for the responsibilities which still remain with the local organisation.

Local

The local organisation(s) should represent themselves, with due regard for the impact their statements may have for the reputation of the wider regional and national screening programme. They should work with the Regional Communications Team or the National Communications Team for the National Screening Committee. It is critical that local communications teams must seek guidance in statements and messages from the regional/national

communications teams if advised to do so by the SHA Screening Lead or by the regional/national screening expert who is supporting the investigation of their serious incident.

A local communications team may choose to hand-over responsibility for leading communicating around an serious incident to the PCT or SHA communications team in large multi-organisational serious incidents.

10. CLOSURE OF SERIOUS INCIDENTS

The point at which a Serious Incident in screening is closed, is determined by the Investigation Team. It is possible for a local organisation and SHA or PCT to have properly investigated, managed, reported on and closed the Serious Incident, but at the same time for the QA Director or the national Programme Centre to have a continuing interest in the serious incident, and carry out further investigations if necessary.

It is the responsibility of the QA Director and the national Programme Centre to continue its own investigations and to commission further enquiries if it is necessary. The local organisation must support and participate in this if required.

11. SHARING LEARNING

The *National Framework for Reporting and Learning from Serious Incidents requiring Investigation*¹. sets out the process and responsibilities for sharing general learning arising from serious incidents.

Learning from serious incidents in screening or potential serious incidents is to be shared in the following ways:

Local organisation writes an incident report with agreed actions and some recommendations and reports to their own SHA Patient Safety Team and to the National Patient Safety Agency. A formal written report of the serious incident should be prepared.

Regional SHA Screening Lead shares the details of the serious incident with their SHA Screening Lead counterparts in all other Regions during the time that the incident investigation is ongoing.

National Programme

Each national programme centre should publish key messages with all the relevant stakeholder organisations, which commission, quality assure and provide the components of the screening programme.

UK National Screening Committee

The UK National Screening Committee should publish an annual report of serious incidents in their screening programmes, showing:

- Quantitative breakdown by SHA, screening programme and types
- A summary analysis of serious incidents and key messages for each screening programme

The Regional Screening QA Organisations (QARCs and others) will hold events and meetings each year to actively disseminate this learning to local programme staff and provider Trusts. They will also highlight some key messages at their regular professional QA meetings. A strategy for this should be agreed with the SHA Screening Lead.

APPENDIX 1 – SUGGESTED PROGRAMME OF TRAINING

Target audience:

- Regional Directors of Public Health
- National Screening Programme Centre and National Office staff
- Regional screening leads and QA staff in conjunction with local and regional clinical governance leads
- PCT-level screening leads, Directors of Public Health and clinical governance leads
- Foundation Trust clinical governance leads
- Communications leads
- Experts who may be involved in the advising of incident handling

Outline of training programme:

- Responsibilities for handling screening incidents
- Culture of learning and no-blame for incident handling
- Basic incident reporting and handling pathway in your region
- Definition of a screening incident
 - To include worked examples from a range of screening programmes
- Root cause analysis (separate day)
- Providing information for patients and public
- Media communications
- Commissioning for good serious incident handling

APPENDIX 2 – COMMUNICATIONS STRATEGIES

This is not an exhaustive template for handling serious incidents. It is assumed that due judgment will be applied in deciding when patient help lines and counseling is necessary; how patients are contacted - by post, by phone, directly by health staff or GPs; and when to hold press briefings on and off the record, as well as press conferences. This should be for the judgment of the communications professional in consultation with the serious incident team.

Media Unaware

Serious incidents in screening may involve a failure to screen properly, failure of administration and failsafe systems, a loss or contamination of samples or results, or harm caused through the act of screening. Most usually require contacting patients for recall or at the very least reassurance.

All attempts should be made to inform patients and the relevant population of a potential problem so that correct information can be provided to all, including the interested media in a timely manner.

An agreed approach is needed to informing members of the public who are affected by the SUI prior to notifications taking place, and for handling follow-up enquiries. An important principle is that information should concern the individual only – NOT the scale of the incident.

It is essential that there is cross health organisation agreement to this strategy with agreed lines for spokespeople to take and a full work through of worse case scenarios. It may be helpful to prepare sample “questions and answers” to aid the preparation of spokespeople.

Keep staff informed.

It is essential that in any incident all staff are able to provide uniform and non conflicting information. All staff should be fully aware of the Trusts policy and process of providing public information.

It is important to note that ‘staff’ includes GPs and other independent providers, who will have an important role to be aware of the incident and the reassurance and possible actions they should take. This is particularly important when the media become involved and concerned patients will be presenting to their GPs seeking information and reassurance.

Therefore managers must:

- Keep staff informed;
- Show they are taking their concerns seriously and acting upon them;
- Include staff so that they have ownership and understand the need to observe **patient and service confidentiality**.

You must be able to show that you **understand the problem**, are taking steps to **put it right** and **reassure** staff.

Media unaware but, proactive media handling necessary.

Follow a proactive media approach where time and wider public health concerns can only be addressed through this route. For example, where the only way a large number of patients can be contacted is by public appeal after the loss of personal records.

Make sure your media plan is complete and ready to action. For example, be clear about the extent of the problem, why you need the media's assistance, how you will support patients and what you have done to ensure there will be no repeat of the serious incident.

Understand the problem

Put it right

Reassure

(Note: You will probably be doing a measure of all of these at the same time. This is not the order they have to be done in although understanding the problem is likely to greatly increase your ability to offer reassurance to patients and the wider public.)

Media Aware

Handling a serious incident in screening in the full glare of media scrutiny can be time consuming but necessary. The serious incident team requires time and space to do its work. It is the job of professional communicators to provide this space whilst keeping journalists informed.

Remember:

Understand the problem

Put it right

Reassure

Keep the public and media informed whilst balancing the needs of the affected patients. Giving as much factual information as possible to ensure that the Trust is able to present its own understanding of the situation and therefore reduce public anxiety and prevent misinformation occurring.

Keep staff **INFORMED** so that they understand why and how you are acting, their role and ownership in fixing the problem and why leaking will harm patients.

Good communications for Serious Incidents is equally important for all relevant stakeholders including:

- **Staff**
- **Related providers, PCTs, SHAs, QA organisations**
- **National Programme Centres**
- **Related professional bodies**
- **Other similar screening programmes**

Appendix 3 – Specific examples of potential Serious Incidents in National Screening Programmes

The national screening programmes are each at a different stage of development in terms of their experience of serious incidents. Each has been asked to provide a guide list of incidents, which they would consider to be potential serious incidents, on which a judgement needs to be made in terms of impact and scale.

These are not definitive lists. For all Screening Programmes, these lists have been developed in the light of experience to date and will continue to be updated. Each Screening Programme will publish details and disseminate information about probable Serious Incidents through their own networks and websites.

Theme	Categories of Serious incident	Programme specific examples of POTENTIAL serious incidents
Identify population	Failure to identify the eligible population Failure to run fail-safe system to invite those who have moved house and / or GP	DRS No data received from single GP No data on new diagnoses communicated by GPs for whole year NBS No Data from Child Health Records Dept
Inform	Consent not sought for screening	NBS No system for reporting NBS results to parents

<p>Invite</p>	<p>Failure to offer screening to the eligible population inc substantial inappropriate exclusions. Sending an appointment to the parents of a deceased baby or a deceased person. Harm from condition screened for in people unknown to screening programme, who should have been notified to the screening programme</p>	<p>AAA Uninvited man in which aorta ruptures Interval ruptures whilst AAA less than 5.5cm DRS Large numbers of inappropriate exclusions patients not being invited. Single patient inappropriately excluded or not invited leading to symptomatic presentation/ loss of sight. SCT Failure to use Family Origin Questionnaire in low prevalence areas</p>
<p>Uptake</p>	<p>Failure to administer the test in those who have accepted screening (or their parents)</p>	<p>NBS Failure to identify babies who have missed screening > 17 days of age up to one year of age</p>
<p>Test: To maximise performance of the screening test</p>	<p>Test failure/laboratory error Failure to report abnormal result/refer person/baby Affected person/baby not identified through screening Failure to follow the correct screening protocol / procedure Recording of incorrect screening test results or outcomes Misinterpretation of images/test results</p>	<p>SCT specific Failure to identify a baby in the antenatal period Failure to offer prenatal diagnosis so that results and any subsequent action can happen by the end of 12 weeks gestation Failure to report by product findings in newborn screening Failure to identify babies after an at risk pregnancy for sickle cell and thalassaemia Failure to inform parents of results of screen positive babies by four weeks of age Failure to identify a transfused baby with sickle cell</p>

		<p>disease</p> <p>FASP</p> <p>Risk calculation parameters changed and are incorrect Risks recalculated using an a different version of software</p> <p>Blood samples not reaching the laboratory from the clinic Assay used in the lab show a large “lot to lot” variability which is not adjusted for in the medians Infections</p> <p>Confirmatory tests not undertaken</p> <p>DRS</p> <p>Single significant miss resulting in avoidable disease progression / sight loss.</p>
Minimising harm	<p>Person/parents of a baby who has died contacted for repeat test</p> <p>Process and contingency/back-up failure that interrupts screening</p> <p>Report not sent to GP or clinician</p>	<p>NBS</p> <p>Person/parents of an affected baby receive normal results letter</p> <p>SCT</p> <p>Failure to identify a baby in the antenatal period following fertility treatment</p> <p>DRS</p> <p>Single patient lost to follow up resulting in avoidable disease progression / sight loss</p>
To maximise performance of diagnostic test	Affected person/baby not confirmed through diagnostic test	<p>FASP</p> <p>Diagnostic techniques undertaken without ultrasound SCT</p> <p>Any cases of error in prenatal diagnostic analysis such as contamination</p>

Referral	Referral from screening not made	Referral from screening not made and AAA ruptures DRS Single referral not made leading to avoidable loss of sight.
Diagnosis/assessment	<p>Failure to offer assessment/diagnosis to screen positive people/babies</p> <p>Failure to record pregnancy outcome following prenatal diagnosis</p> <p>Error in prenatal diagnostic analysis (e.g. errors in sampling or analysis such as contamination)</p>	<p>DRS</p> <p>Failure to offer appointments to several patients following referral</p> <p>Failure to offer appointment to single patient resulting in avoidable loss of sight.</p> <p>Delays in slit lamp bio-microscopy of >15 weeks</p> <p>NBS Failure to refer PKU, CHT, CF or MCADD screen positive babies to treatment in accordance with clinical referral standards</p>
Intervention/ Treatment	<p>Delays in treatment/intervention leading to known serious harm in single patient or potential harm in several patients</p> <p>Reporting lead times too long for appropriate clinical actions to be taken</p>	<p>AAA Death after AAA surgery - Surgeons mortality rate for elective procedures rises above nationally agreed level High rates of readmission with AAA related complications after surgery</p> <p>SCT Failure to start treatment of affected babies by eight weeks of age</p> <p>Infections Breakdown in referral for vaccination or in vaccination schedule for Hep B</p> <p>DRS Delays in slit lamp bio-microscopy ungradables/unassessables >15 weeks.</p>

		<p>Failure to assess/ treat patient within national timescales leading to avoidable loss of sight.</p> <p>Failure to assess/treat several patients within national timescales putting patients at risk of serious harm.</p> <p>Laser treatment failure due to technical issue or operator error</p>
To optimise population and individual health outcomes in target population	Adverse outcome in a diagnosed person/baby with treatment/management	
To ensure that the whole screening programme is provided by a trained and competent workforce	<p>Deliberate contamination of the sample</p> <p>Untrained screening / grading staff participating in screening programme</p>	<p>NBS</p> <p>Failure to tackle poor performance</p> <p>DR</p> <p>Large scale unassessables/unobtainables due to operator error.</p> <p>Image sets attached to the wrong patient episode leading to wrong result letter</p>
Equipment failure	<p>Equipment not serviced or maintained</p> <p>Images/results lost/delayed</p>	<p>SCT</p> <p>Equipment failure, for example incorrect reporting of haemoglobin variants eg reporting HbC as HbS</p> <p>Failure to identify babies after an at risk pregnancy for sickle cell and thalassaemia</p> <p>FASP</p> <p>Ultrasound machine measuring incorrectly on callipers</p>
Info and IT	<p>Inappropriate access and use of national IT solution at local screening programme level</p> <p>IT failure – leading to rescreening</p> <p>Loss of patient data / images breaking confidentiality</p>	<p>DR</p> <p>Server/ back-up/ transfer of data issues leading to loss of patient episodes.</p> <p>Loss of laptop containing patient identifiable episodes.</p>

<p>To ensure effective (i) commissioning and (ii) governance of the screening programme</p>	<p>Programmes approaching or crossing an unsafe threshold for performance standards</p> <p>Programme delays/backlogs leading to delayed screening</p>	<p>DR : Grading backlogs > 3 months to conclude episode.</p>
---	---	---

REFERENCES

1. National Framework for Reporting and Learning from Serious Incidents requiring Investigation. National Patient Safety Agency. March 2010

ENDORSEMENTS

Managing Serious Incidents in National Screening Programmes - Guidance on behalf of UK National Screening Committee is endorsed by the National Patient Safety Agency.



National Patient Safety Agency