Public Health England

Protecting and improving the nation's health

Incident reporting policy

National Chlamydia Screening Programme

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1. Introduction and scope

1.1. Introduction

This document describes the policy for reporting serious incidents that may occur across England during delivery of the Nationlal Chlamydia Screening Programme (NCSP) in any testing service type, and replaces the policy that was published in 2017.

Local serious incidents could threaten the national reputation and therefore public participation in the programme. It is important that the roles and responsibilities in the reporting and management of serious incidents are clear. The aim of this policy is to clarify the role of commissioners, providers and Public Health England (PHE) within this process.

It is important for PHE to be informed about serious incidents related to the chlamydia management in 15-24 year olds regardless of setting, to enable collation of data at national level, to share learning, and to manage any national issues arising from these incidents.

PHE is committed to sharing lessons learned in order to reduce as far as possible the number of serious incidents that may occur in the course of screening for chlamydia.

1.2 Scope

This policy covers all chlamydia screening providers in England. It will not duplicate local and national policies, but provides additional information regarding the process for reporting serious incidents in the chlamydia management of 15-24 year olds in any setting to PHE. Commissioners and providers are requested to reference this document in their policies and contracts.

Appendix 3 describes the context: current incident reporting processes relevant for local authorities, NHS England & NHS Improvement/Clinical Commissioning Groups, and the Care Quality Commission.

The definitions on serious incidents and examples of the type of serious incidents that we encourage to be reported to PHE can be found in Appendix 1. Even though the definitions refer to NHS-funded services, as explained in ‘Sexual Health: Clinical

Governance'[1], they are equally applicable to clinical services commissioned by local authorities.

If in doubt whether an incident needs to be reported to PHE, commissioners and providers are advised to contact their Sexual Health Facilitator based at their local PHE Centre, the PHE's Head of Quality Assurance and Standards for the NCSP, the Clinical Lead, or Head of the NCSP. This can be done through emailing: NcspTeam@phe.gov.uk

[1] Sexual Health: Clinical Governance
Key principles to assist service commissioners and providers to operate clinical governance systems in sexual health services, Department of Health and Public Health England, October 2013

2. NCSP incident reporting procedure

PHE strongly encourages providers and commissioners of chlamydia screening and treatment services to share serious incidents in chlamydia management in 15-24 year olds in any setting, because we:

- can ensure that any risks identified or lessons learned are shared with other programme areas in order to continue to improve performance and minimise risk across the country
- may need to update national guidance to include learning points identified through serious incidents reported to the programme

When a serious incident (or near miss) occurs the individual who has identified it should follow the local/regional incident reporting policy, including reporting to commissioners. In addition to normal reporting requirements the organisations are encouraged to inform PHE and to send reports to NcspTeam@phe.gov.uk as soon as key details of the incident become clear. The NCSP Head of Quality Assurance (QA) and Standards will log the serious incident on our record of incidents and will liaise with the provider or commissioner who reported the incident to ensure the relevant details are obtained and to ascertain whether or not a lessons learned report is appropriate.

Due to the varied nature of incidents reported to the NCSP, and to avoid duplication, the NCSP does not provide a specific report format for serious incidents. Providers and commissioners may wish to forward their local incident report documentation to the NCSP, or provide an e-mail summary of the details. In exceptional circumstances where the incident is deemed to be extremely serious (eg, patients have been harmed, a service is suspended, or the reputation of the programme is seriously compromised), and the local programme or services from one or more providers need to be suspended, we request that the Head of NCSP at PHE be informed within 2 working days, who will also inform the local PHE centre as appropriate.

If a PHE Sexual Health Facilitator (SHF) in one of PHE Centres, or any other member of the NCSP team at PHE becomes aware of an event that should be classified as an incident they should speak immediately to the local provider and advise them to report the incident locally as per their organisation’s incident reporting policy. (Similarly, if PHE receives a complaint, the patient will be referred to the commissioner or provider, in line with information governance policies.)

2.1 Look backs

If the service cannot be confident that results are reliable, and disease may have been missed or wrongly diagnosed, a recall exercise may be necessary. This would only be

considered if a systematic failure had led to performance well below published standards or norms and warranted a review of work. The commissioner should discuss any such move with the director of public health (DPH), local PHE centre and inform PHE before taking action.

The Head of QA and Standards at PHE will inform the Head of the NCSP, Clinical Lead, member of PHE's communications team and other senior staff if deemed necessary, and escalate through PHE's reporting system as appropriate.

2.2 Investigating and closure

Each organisation will have its own process for investigating incidents. The duty of investigation is with the local programme, not PHE. It is important that incidents are appropriately investigated so that the root cause is identified, and any learning recognised and improvements implemented. The outcome of the investigation, including follow-up action, should be fed back to PHE, when the entry in the database will be closed. Where there is a decision not to investigate an incident further, the Head of NCSP at PHE may discuss this decision with the DPH to identify whether an investigation is necessary.

2.3 Dissemination of learning

Where risks or learning relevant across the NCSP have been identified, either by the commissioner, the provider or PHE, these will be disseminated so that learning is shared across the country. This will be the responsibility of the Head of QA and Standards and will be done at a minimum through the SHF team and their local provider and commissioner's networks. Where appropriate a 'lessons learned' report will be circulated by the NCSP's Head of QA and Standards. As the main purpose is to prevent similar serious incidents, reports will be published anonymously on the NCSP Lessons Learned reports webpage.

2.4 Monitoring of incidents

The Head of QA and Standards at PHE will monitor serious incidents reported to PHE and provide reports at regular intervals and issue lessons learned reports when deemed necessary by the NCSP management team at PHE.

2.5 Communications

Communication with patients will be the responsibility of the organisation where the incident occurred. Where communications with the media are needed as the result of a serious incident, a member of the PHE communications team will support the commissioner or provider communications teams as appropriate.

Any queries received from members of the press/media should be passed on to the National Infections Press Office. The contact details are:
phe-pressoffice@phe.gov.uk
Tel: 020 8327 7901

3. Responsibilities

When an incident occurs, the organisation's reporting policy should be used. The serious incident policy of every commissioner and provider should include reference to these guidelines and guarantee that the NCSP is included in the reporting process of serious incidents.

Following local investigation, the NCSP asks to be informed of the outcome of the findings and any local follow-up action. The NCSP will ensure that sharing the learning from serious incidents will be disseminated through the sexual health facilitators and their local commissioners and providers networks. If appropriate, an anonymous lessons learnt report will be published on the NCSP's Lessons Learned webpage.

Commissioners are responsible for securing a comprehensive service within available resources, to meet the needs of their local population. They must commission 'regulated activities' from providers that are registered with the CQC, and should contract with the provider to deliver continuously improving quality care. They must assure themselves of the quality of services they have commissioned, and should hold providers to account for their responses to serious incidents. This means commissioners quality assure the robustness of their providers' serious incident investigations and the action plan implementation undertaken by their providers. Commissioners do this by evaluating investigations and gaining assurance that the processes and outcomes of investigations include identification and implementation of improvements that will prevent recurrence of serious incidents[3].

Commissioners should:

- ensure that the requirement for any provider (NHS and non-NHS) to comply with local/regional governance arrangements is part of the service specification when tendering for services and in subsequent contracts
- ensure that the requirement to inform the NCSP of serious incidents forms part of the service specification
- monitor providers' compliance with this requirement
- ensure that PHE has a current name and contact details for the sexual health/chlamydia screening lead in their organisation

Commissioners and providers should:

- maintain proper incident reporting policies and procedures, ensuring that all incidents are properly dealt with, reported and investigated where necessary
- ensure that PHE has a current name and contact details for the sexual health/chlamydia screening lead in their organisation

The NCSP Head of QA and Standards at PHE will:

- log all reported serious incidents to the NCSP's record of serious incidents, together with their status and outcomes, and keep this updated as necessary
- provide updates as appropriate on the frequency and type of serious incidents
- ensure that learning is shared with the sexual health facilitators and their local provider and commissioners' networks, as well as the relevant PHE centre, and published on the website if appropriate

A member of PHE's communications team will:

- work with the communications teams in the commissioning and provider organisations to implement a suitable and coherent strategy as required, and facilitate accurate reporting ensuring that appropriate information is shared when necessary

This process is summarised in a flowchart in Appendix 2.

Appendix 1: Definitions and examples

Definitions

Even though the definitions refer to NHS-funded services, they are equally applicable to clinical services commissioned by bodies with new responsibilities, including local authorities

This policy adheres to the following definitions:[3]

Serious Incidents in the NHS include:

- acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:
  a) unexpected or avoidable death of one or more people. This includes suicide/self-inflicted death; and homicide by a person in receipt of mental health care within the recent past
  b) unexpected or avoidable injury to one or more people that has resulted in serious harm
  c) 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; or serious harm
  d) actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where healthcare did not take appropriate action/intervention to safeguard against such abuse occurring; or where abuse occurred during the provision of NHS-funded care. This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident
- a Never Event - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death. See Never Events Policy and Framework for the national definition and further information
- 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:
  a) failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues;
  b) property damage
  c) security breach/concern

d) incidents in population-wide healthcare activities like screening and immunisation programmes where the potential for harm may extend to a large population
e) inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS)
f) systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services
g) activation of Major Incident Plan (by provider, commissioner or relevant agency)

- major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation

In addition, PHE classifies anything as a 'serious incident' that might have a damaging effect on the reputation of the NCSP or PHE. Providers and commissioners are asked to report all such incidents to PHE as outlined below.

Examples of serious incidents

The NCSP does not fall under the remit of the National Screening Committee, but its guidance[2] helps to clarify the definition of an serious incident in relation to screening programmes. The guidance refers to the NHS England's Framework mentioned above, but also explains that screening safety incidents include (section 1.2):

- 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 system(s), or equipment or IT

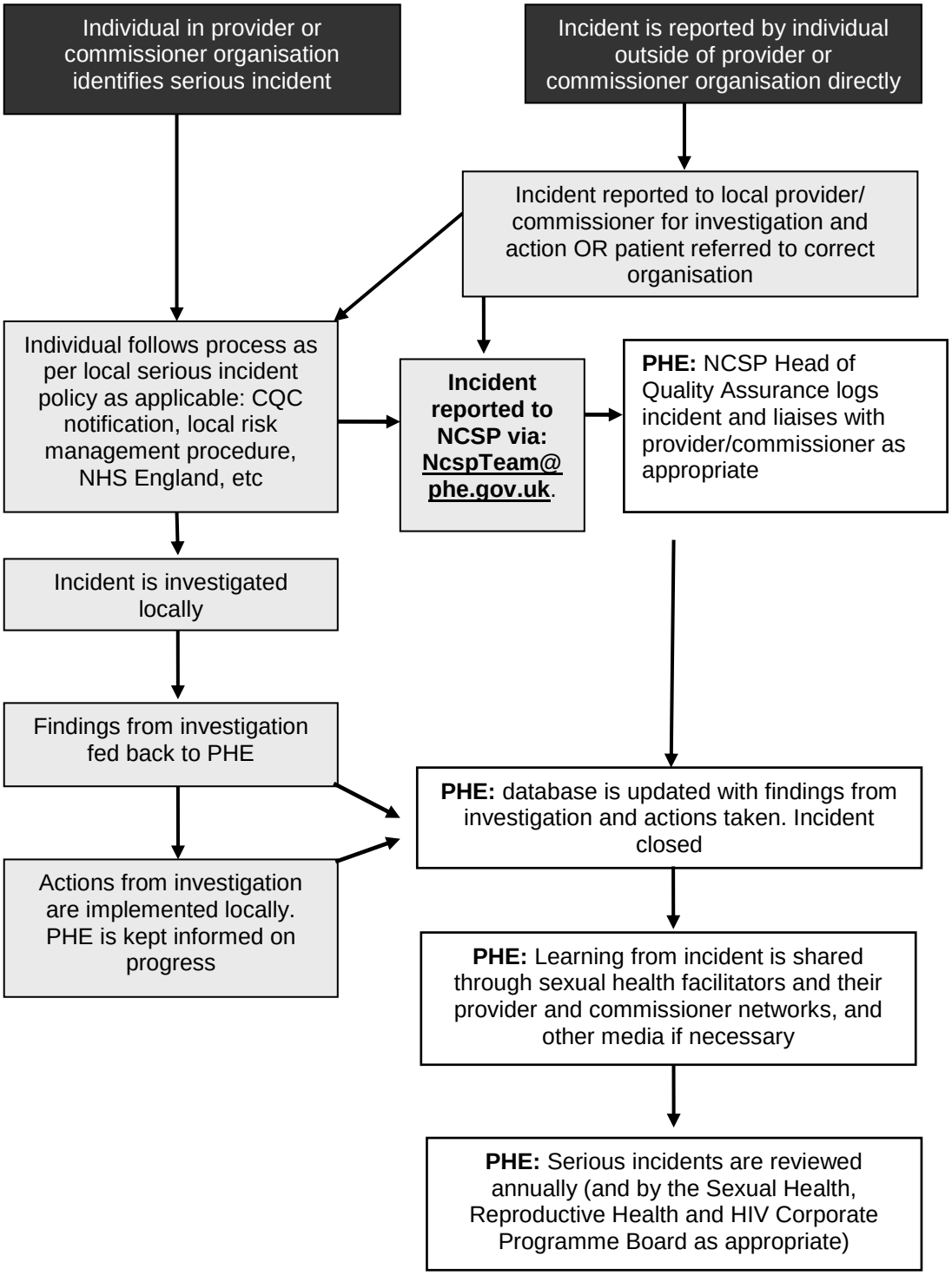
[2] PHE Managing Safety Incidents in NHS Screening Programmes
Developed in collaboration by NHS Screening Programmes and NHS England, August 2017

- 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

Some examples of serious incidents within the NCSP might include:

- serious harm to a patient, member of staff, visitor or member of the public
- breach of confidentiality
- fabrication of results or data
- allegations of young people being coerced into providing a sample or of under 16 year olds being asked to take the test without Fraser competence being assessed
- loss of test samples or results
- failure to inform patients of their test results
- mix up of data, ie, informing patients of the wrong test result
- incorrect treatment of positives
- adverse national media coverage

Appendix 2: NCSP flow chart for reporting incidents



Appendix 3: Context: current incident reporting processes

There are a number of organisations that have processes relating to incident reporting in the services they commission, inspect or support. This section briefly outlines those for:

- PHE
- local authorities
- NHS England/Clinical Commissioning Group (CCGs)
- the Care Quality Commission

For NHS Trusts, the role of other organisations such as NHS England (NHSE)/NHS Improvement (NHSI) may also be relevant, more on this can be found in NHS England's Serious Incident Framework[3].

Local authority commissioners

Local Authority commissioners should ensure that effective clinical governance procedures are in place and monitor providers' compliance with the contract specifications around incident reporting. This is particularly important in screening programmes, since more than one organisation may be involved and the commissioner may need to ensure that the wider implications of a serious incident in a screening programme are taken into account by the provider(s).

The following 2 Department of Health documents support the reporting of incidents in sexual health services:

- the suggested National Service Specification for Integrated Sexual Health Services 2018[4] contains a section on Clinical Governance that allows for providers to have clear operational policies and procedures for the reporting and management of Serious Incidents
- the Department of Health's guidance 'Sexual health: clinical governance, key principles to assist service commissioners and providers to operate clinical governance systems in sexual health services'[1]. Particularly paragraphs 31 to 37 on incident management, and paragraphs 26 and 49 are relevant

[3] Serious Incident Framework, NHS England Patient Safety Domain, March 2015
[4] Department of Health/Public Health England: Integrated Sexual Health Services – A suggested national service specification, August 2018

The Guidance explains that:

- local authorities can make sure that the contracts they have with providers of clinical services contain provisions which will enable them to check that providers have systems in place and that these systems are operating correctly
- even though definitions may refer to NHS funded services, they equally apply to services commissioned by bodies with new responsibilities, including local authorities (paragraph 31)

NHS England/NHS Improvement

NHS England/NHS Improvement has a direct commissioning role as well as a role in leading and enabling the commissioning system. As part of the latter role, NHS England/NHS Improvement maintains oversight and surveillance of serious incident management within NHS-funded care and assures that CCGs have systems in place to appropriately manage serious incidents in the care they commission. When NHS providers deal with serious incidents, they will need to apply guidance from NHS England/NHS Improvement.

NHS England/NHS Improvement's 'Serious Incident Framework' – supporting learning to prevent recurrence'[3] is designed to inform staff providing and commissioning NHS funded services in England who may be involved in identifying, investigating or managing a serious incident. It is relevant to all NHS-funded care in the primary, community, secondary and tertiary sectors. This includes private sector organisations providing NHS-funded services. We are referring to it here because it may apply to NHS organisations who are providing sexual health services, even if they are funded by local authorities. The Framework explains which serious incidents will need to be reported. Local operational guidance for serious incident management (within commissioning and provider organisations) must be consistent with this Framework. Part 2 of the Framework outlines clarifies the roles and responsibilities in relation to serious incident management, makes reference to legal and regulatory requirements and signposts to tools and resources.

Care Quality Commission

By law care providers (whether NHS or not, and therefore relevant to providers of sexual health services) must register for each of the regulated activities they carry out. Regulated activities are listed in Schedule 1 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Not all regulated activities will be relevant to the services provided, so providers need to determine which are relevant to them, and register these with the Care Quality Commission (CQC). The scope of registration (March 2015) can be found here: scope of regulated activities.

When activities are required to be registered with CQC, CQC will then check that the services provided are likely to meet the fundamental stardards below which care must never fall. Providers need to report all serious patient safety incidents to the CQC as part of its registration process. This is covered in regulation 18 of the 2009 Regulations 'notification of other incidents'.

The CQC makes authoritative judgements on the quality of health and care services, according to whether they are safe, effective, caring, responsive and well-led. The chief inspectors rate the quality of providers accordingly, and clearly identify where failures need to be addressed. They have a role in encouraging improvement and may use the details of incident reports, investigations and action plans to monitor organisations' compliance with essential standards of quality and safety, to assess risks to quality and to respond accordingly. The CQC works closely with commissioners and providers to gather intelligence and information as part of their pre-inspection process. The Health and Social Care Act sets specific requirements for registered organisations in relation to the type of incidents that must be reported to them. Further details are published online: www.cqc.org.uk/content/notifications