NHS Diabetic Eye Screening Programme
Management of patients not included on the screening register

Guidance for regional Screening Quality Assurance Service teams
V14.0. 09.09.16

Public Health England leads the NHS Screening Programmes
About Public Health England

Public Health England exists to protect and improve the nation’s health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

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About PHE Screening

Screening identifies apparently healthy people who may be at increased risk of a disease or condition, enabling earlier treatment or better informed decisions. National population screening programmes are implemented in the NHS on the advice of the UK National Screening Committee (UK NSC), which makes independent, evidence-based recommendations to ministers in the four UK countries. The Screening Quality Assurance Service ensures services are safe and effective by checking that national standards are met. PHE leads the NHS Screening Programmes and hosts the UK NSC secretariat.

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Purpose

Each local diabetic eye screening service is required to have a Single Collated List (SCL) of all people in the local population who are eligible for screening.

This paper gives commissioners and provider organisations guidance on managing incidents related to the SCL. It gives guidance in particular on the management of newly identified diabetic patients who were previously unknown to the screening service and should now be included on the SCL.

Identification of cohort from GP practices to the screening service can be by electronic data transfer (for example Miquet query, or from the GPES/GP2DRS Cohort Management System), or by direct referral from GP practices through manual validation methods.

Background

Diabetic eye screening services rely on GP practice referrals to identify patients with diabetes who are eligible for screening. Once referred to the screening service, patient information is maintained on a SCL which the service uses to manage call and recall functions. Referring all patients into the service is essential for the eligible population to be offered screening.

In order to check that all patients have been referred from GP practices to the service, the service will perform periodic validations of the SCL (in line with the national service specification). Many identification of cohort screening incidents have occurred and been managed. Lessons learned from these are documented in Appendix 1. Example communication document templates can be provided by the Screening Quality Assurance Service (SQAS).

There have been several incidents in services where large numbers of patients have not been included in the screening cohort as they were not known to the screening service. The introduction of electronic GP extraction methods is likely to increase the number of these incidents in the short term.

Circumstances under which large numbers of patients may need to be included in the SCL are as follows.
Patients previously unknown to the screening service

This could be due to several factors, including:

- incomplete or irregular GP participation in validation process
- incorrect coding of patients with diabetes
- misunderstanding of the validation process by GP practice staff
- lack of resource within the service to carry out regular validation

Changes in service provision due to reprocurement or reconfiguration

“New” services may face challenges in obtaining data due to:

- GPs not sharing patient demographics through misunderstanding of consent requirements/LMC constraints on data sharing
- GP practice boundary reconfiguration and/or organisational change

There are often concerns about transferring data to private sector providers of NHS services although the requirements for these services are identical to those for NHS providers.

Changes in service due to national factors

During times of significant change, for example, change to service specification or software configuration, services may lose network connectivity between one data provider and another which may then not be reconnected automatically.

Other significant changes to software can trigger incidents, particularly when there has been insufficient planning ahead of implementation.

This document advises providers, commissioners and the SQAS on how to manage a large cohort of newly identified patients and how to define and manage the risk within this cohort.

Key factors to consider

A cohort of patients missing from the SCL should be considered as a potential screening safety incident or serious incident. Services should follow national guidance on reporting and managing screening incidents. SQAS and commissioners should be
informed of all suspected incidents as soon as possible (Managing Safety Incidents in NHS Screening Services, October 2015).

Depending on the scale of the incident, it may be appropriate to declare a serious incident and manage this in accordance with the Serious Incident Framework (NHS England, 2015).

Services and commissioners should make decisions on categorisation and handling with advice from SQAS. If the incident has occurred solely outside the screening pathway, such as in a GP practice, a summary of the facts should be documented. This should be communicated to the commissioner and provider so they can organise the investigation and management of the incident. An update to the National Institute for Health and Care Excellence (NICE) guidance (July 2016) made it clear that referral for diabetic eye screening should be done immediately on diagnosis of diabetes to ensure the patient is screened within three months.

Factors to consider when deciding if the concern constitutes a screening safety incident or a serious incident are the degree of risk and the likelihood of the situation being easily rectified:

- number of patients missing from the SCL per GP practice
- number of patients missing from the SCL across the local service as a whole
- systematic failure of processes or operational issues resulting in missed patients
- impact of incident on capacity of service/provider organisation to offer additional screening
- impact of incident on ability of service to hand over patients safely into treatment services
- reputational damage resulting in loss of patient confidence in the service

When there is actual or potential avoidable severe harm – or the likelihood of significant damage to the reputation of the organisations which could potentially affect the screening service – a serious incident (SI) should be declared. A ‘near miss’ can be a serious incident where there is a significant existing risk of a system failing (Managing Safety Incidents in NHS Screening Services, October 2015).

If it appears that serious or permanent reduction in a patient’s vision may have occurred as a result of the delay in referral to the service, there should be a review by the programme’s clinical lead or lead consultant ophthalmologist. In these circumstances, the organisation hosting the service should consider whether the circumstances meet the definition of a serious incident and, in addition, whether Duty of Candour regulations (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20 ii) should apply. The flowchart in Appendix 4 highlights the process. Further advice is available from SQAS if required.
Responsibility

SCL incidents span primary care and services and can occasionally lead to questions about which organisation is responsible for managing and investigating the incident. In these circumstances, the screening safety incident guidance (Managing Safety Incidents in NHS Screening Services, October 2015) should be followed. It advocates use of the RASCI methodology (responsible, accountable, supporting, consulted, informed) to agree roles. If there is uncertainty about responsibility, the commissioner should lead the investigation.

Responsibilities of organisations are as follows:

- GPs have a “duty of management” to their patients so need to refer patients to diabetic eye screening when they are diagnosed with diabetes
- GP practices have a responsibility to refer patients to services in a timely manner and to participate in validation exercises using accurate processes (National service specification no.22, NHS Diabetic Eye Screening Service and NICE guidance, July 2016)
- services should undertake scheduled validation exercises in line with national guidance (National service specification no.22, NHS Diabetic Eye Screening Service)
- clinical commissioning groups (CCGs) and primary care commissioning teams should support Screening and Immunisation Teams to resolve issues with non-participating GP practices

All organisations should have clear and regular lines of communication. The flowchart in Appendix 3 highlights the pathway.

Issues around responsibility may arise for the following reasons:

- lack of Standard Operating Procedures (SOPs) and associated documents for timely referrals from GP
- a local diabetic eye screening service can be provided by multiple organisations and create confusion as to which is the lead provider and where the patients should be referred, for example an optometrist-based model may have service management/failsafe managed by the screening service and the call/recall function managed by an alternative provider
Communication

It is the provider organisation’s responsibility to ensure that Duty of Candour regulations are followed (Care Quality Commission Duty of Candour regulations). These regulations require organisations to be open and transparent with patients and service users. When a notifiable safety incident occurs (Regulations Part 20(2)(a)) the organisation should offer an apology.

The definition of a notifiable safety incident is not the same as a screening safety incident, for example the threshold for declaration is different and the investigation of a screening safety incident includes external organisations such as Screening and Immunisation Teams and SQAS. Individuals affected should be told the facts, what further enquiries are being carried out, and receive an apology in person which is then confirmed in writing.

The NHS standard contract includes a duty of candour

A communications plan should be developed and implemented to support the effective management of the incident and should be proportionate to the severity of the incident. The requirement for this plan should be included in the incident team’s terms of reference.

Recommendation for the management of large cohorts of patients who have been missed from the SCL

1. **Risk stratification.** Where the cohort is large (proportional to service size), it may be necessary to stratify the risk within the cohort to prioritise screening appointments. Obtaining ‘relevant personal confidential data’, including clinical information, may be necessary to prioritise the risk. The transfer and use of additional clinical information may require patient consent depending on the local systems in place. If in doubt, the local service should seek advice from the Caldicott Guardian and/or senior information risk officer associated with that service.

   There is a regulatory framework which supports NHS England to access patient identifiable information through GP records (The Medical Profession Responsible Officers Amendment Regulations 2013). In these situations the additional information
required is ‘relevant’ in order to manage each patient safely. This differs from the usual pathway where only demographic patient details are transferred in order to invite them for screening.

2. **Tracking of patient outcomes.** Patients should be monitored and referrals tracked to identify where there has been potential or actual harm to patients identified, and whether Duty of Candour should be applied. The anonymised patient tracker should be included with the final RCA incident report.

3. **Capacity planning.** Capacity within screening, grading and treatment centres should be considered, particularly where the cohort of unscreened patients is large. Additional resources, or re-allocation of resources within the service and treatment centre may be needed to ensure the cohort is managed and referrals are within national timescales.

   If a service does not have enough screening/grading capacity to manage the additional cohort and all options to increase capacity have been explored, a risk management strategy will be needed to minimise risk of harm. This should be developed by providers and agreed by commissioners with advice from SQAS. This strategy should be closely monitored in order to avoid significant delays to patients.

4. **Expediency of patient referral into hospital treatment centres if sight-threatening diabetic retinopathy is identified with appropriate tracking and failsafe management.** Providers should coordinate with treatment centres to highlight the incident and agree the process for expediting these patients.

5. **All safety incidents and serious incidents should be investigated in accordance with national guidance using a root cause analysis approach.** This should establish why patients were not referred or captured as part of previous validation exercises and be the basis for remedial action. Lessons should be identified from the investigation which can then be shared more widely to reduce the risk of recurrence. A final incident report should record this. This should be approved through appropriate provider and commissioner governance mechanisms before the incident is declared closed.

National incidents – NHS England directors may convene and lead a national and/or a regional serious incident team depending on the scale, size and complexity of the serious incident. PHE Screening may decide to coordinate its input to an incident nationally in order to facilitate sharing of information between regional QA teams and agreement on actions required at national and regional level.
Appendix 1: Identified issues and lessons learnt from SCL incidents

<table>
<thead>
<tr>
<th>Issue identified</th>
<th>Lessons learnt for managing incidents of this nature (see Glossary for definitions of abbreviations)</th>
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</thead>
<tbody>
<tr>
<td>Inconsistent GP participation in reconciliation and validation</td>
<td>Local initiatives in place to maintain GP practice engagement.</td>
</tr>
<tr>
<td>Confusion around reconciliation process</td>
<td>Development of a DESP SOP to populate the screening database with notifications from GP practices.</td>
</tr>
</tbody>
</table>
| Errors in coding (for electronic SCL updates) resulting in inaccurate service SCL | Review of the DESP SCL validation process ensuring nationally determined Read-codes are used during electronic data extraction.  
Multi-agency (DESP, SIT, CCGs, GPs, CSU) cooperation provides an effective, joint response to this issue.                                                                                         |
| Lack of SOPs for escalation of GP practices not responding to requests for validation data | DESP to produce a local SOP utilising the national service specification and available national guidance. Escalation processes for non-responding GP practices to be agreed between DESP and the SIT/CCG. |
| GP practice not referring patients to DESP due to a lack of understanding of the referral process, criteria and exclusion/exception reporting, such as medically unfit, post-bariatric surgery and patients known to be in the care of hospital eye services | Development of a service-specific SOP for identification of cohort eligible for screening and referral to DESP which is shared with GP practice.  
A review of all exclusions (medically unfit and opt-outs), ineligible patients (no longer diabetic and NPL) and off-register patients (deceased and moved) to ensure compliance with current national guidelines. Patients moved into the correct status within the software with full audit trail maintained in the patient record.  
If no evidence of signed opt-out form, the patient is re-invited for screening. Local SOPs reviewed and assurance provided to the service board. |
<p>| GP practice waiting to refer patient to DESP                                    | GP practices to review internal processes for DNA                                                                                                                                                                                                                     |</p>
<table>
<thead>
<tr>
<th>Issue</th>
<th>Suggestion/Recommendation</th>
</tr>
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<tbody>
<tr>
<td>DESP following review by the diabetic nurse. The patient DNAs so the referral does not occur</td>
<td>Consideration of the use of electronic data extraction systems to eliminate delays caused by manual referrals.</td>
</tr>
<tr>
<td>GP practice has a change to staff and there is no formal handover of SCL and registration processes.</td>
<td>GP practices to review internal referral process for newly diagnosed patients. Communication between DESP and GP practice managers to be improved to encourage new referrals in a timely manner.</td>
</tr>
<tr>
<td>The service delays registration of newly diagnosed patients/received referrals by the GP to the SCL due to a lack of understanding in administration practices.</td>
<td>Sufficient managerial, analytical and administration resource needs to be available within DES services. A SOP for systematic SCL reconciliation should be developed and implemented.</td>
</tr>
<tr>
<td>Service providing the GP practices with a list of diabetic patients held on the SCL. GP practices unable to validate this list accurately.</td>
<td>Suggestion that this procedure is reversed and the GP practice provide the patient list to the service for validation, using nationally determined Read-codes to identify and extract patients from the GP system.</td>
</tr>
<tr>
<td>Providers lack managerial, technical or clinical leadership to manage data validation or reconfiguration</td>
<td>Where the issues lie in primary care, the SIT (with support from NHS England Public Health Commissioners as appropriate) ensure providers implement an appropriate recovery plan.</td>
</tr>
</tbody>
</table>
Appendix 2: Consent to obtain patient identifiable data to manage incidents

The NHS Diabetic Eye Screening Service has produced specific guidance for local screening services on how to manage consent and exchanges of information between services and healthcare providers (NHS Diabetic Eye Screening: Consent and Cohort Management, June 2016).

Services that have declared screening safety incidents/serious incidents relating to list validation since the NHS transition in April 2013 have overcome consent/governance obstacles. The following have been agreed:

1. **Patient Information Advisory Group (PIAG)** – Consent. Explicit patient consent is not required due to the 2005 PIAG guidance. The advisory group agreed that call and recall for retinopathy screening was part of the care pathway. As such, it is implied that patients consent to a GP notifying the screening service of their diabetes status for the purposes of ensuring they receive a screening invitation. Patients then have an opportunity to withdraw permission/opt of screening at any point.

2. **Release of patient demographic data (NHS Act 2006)** – NHS DESP does not require specific approval due to diabetic eye screening being part of the diabetes pathway and therefore classed as direct care.

3. **Caldicott 2** – section 3.2 of the report ‘Information: To Share or not to Share’, September 2013. Direct care is the term used by the review to include clinical care, social care and public health activity relating to individuals.
Appendix 3: Flow chart of accountability

<table>
<thead>
<tr>
<th>GP practice diabetic register</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newly diagnosed or newly registered patient</td>
</tr>
<tr>
<td>Patient identified for screening</td>
</tr>
</tbody>
</table>

**GP practice refer patient at point of first diagnosis (email/fax/internal post/electronic referral)**

**Patient invited for screening within 3 months by DESP**

**Patient follows DESP pathway**

**Regular validation**
- Monthly/quarterly diabetic register submitted to DESP (electronic / manual)

**DESP to validate GP list against SCL**
- Make demographic changes
- Remove deceased patients
- Verify that patients have not been removed due to diabetes in remission (eg bariatric surgery or pancreatic transplant)
- Verify any newly identified patients belong to the GP practice
- Invite new patient(s)
- Local investigation as to why patients were not referred at the time of diagnosis
- Escalate breaches to the SIT via Programme Board meetings
Appendix 4: Flowchart for determining patient harm

Patients with delayed screening

Patients not referred at next screening episode

Assume no harm

Patients referred at next screening episode

Patients not treated when seen

Have any patients got reduced vision due to diabetic retinopathy or maculopathy?

If not assume no harm

If any patients have reduced vision due to diabetic retinopathy or maculopathy – investigate individually

Patients where treatment was arranged when seen

Have any patients got reduced vision due to diabetic retinopathy or maculopathy?

If not, assume no harm

If any patients have reduced vision due to diabetic retinopathy or maculopathy – investigate individually preferably asking an independent ophthalmologist to look at the images and patient records
Glossary

Clinical commissioning groups (CCGs)

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

- hold the contracts for maternity services which are providers of antenatal 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

Commissioning Support Unit (CSU)

CSUs provide a wide range of commissioning support services that enable clinical commissioners to focus their clinical expertise and leadership in securing the best outcomes for patients and driving up quality of NHS patient services.

General Practice Extraction Service (GPES)

The General Practice Extraction Service (GPES) collects information from GP clinical systems in England and forms part of HSCIC’s GP Collections service.

General Practice to Diabetic Retinopathy Screening (GP2DRS)

GP2DRS is a system to automate the sharing of data between GP practices and local screening services to aid the management of patient registers and electronic data validation.

Local Medical Committee (LMC)

LMCs are local representative committees of NHS GPs and represent their interests in their localities to the NHS health authorities. LMCs interact and work with the General Practitioners’ Committee as well as other branches of practice committees and local specialist medical committees.
MIQUEST (Morbidity Information Query and Export Syntax)

MIQUEST is a methodology and an approach to common data access which enables enquirers to execute queries and extract data from different types of general medical practice computer systems using a common query language.

National Institute for Health and Care Excellence (NICE)

NICE provides national guidance and advice to improve health and social care. NICE is a non-departmental public body (NDPB) and is accountable to the Department of Health.

Single Collated List (SCL)

An accurate database of the eligible population within a local diabetic eye screening service in a single collated list.

Screening and immunisation team (SIT)

Embedded within local offices of the four NHS England regions, these teams provide local system leadership and commissioning of screening and immunisation services.
Resources

Care Quality Commission Duty of Candour regulations
http://www.cqc.org.uk/content/regulation-20-duty-candour

The Medical Profession (Responsible Officers) Amendment) Regulations 2013

www.england.nhs.uk/ourwork/patientsafety/

National Institute for Health & Care Excellence, June 2016
https://www.nice.org.uk/guidance/ng28/chapter/1-Recommendations
https://www.nice.org.uk/guidance/ng17/chapter/1-Recommendations

NHS public health functions agreement 2015-16, Service specification no.22, NHS Diabetic Eye Screening
