



Public Health
England



NHS Diabetic Eye Screening Programme Consent and Cohort Management

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.

Public Health England, Wellington House, 133-155 Waterloo Road, London SE1 8UG

Tel: 020 7654 8000 www.gov.uk/phe

Twitter: @PHE_uk Facebook: www.facebook.com/PublicHealthEngland

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 programmes are safe and effective by checking that national standards are met. PHE leads the NHS Screening Programmes and hosts the UK NSC secretariat.

PHE Screening, Floor 2, Zone B, Skipton House, 80 London Road, London SE1 6LH

www.gov.uk/topic/population-screening-programmes

Twitter: @PHE_Screening Blog: phescreening.blog.gov.uk

For queries relating to this document, please contact: phe.screeninghelpdesk@nhs.net

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Published June 2016

PHE publications gateway number: 2016093



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Introduction

The NHS Diabetic Eye Screening Programme aims to reduce the risk of sight loss among people with diabetes by inviting all eligible people diagnosed with diabetes for screening and ensuring the early detection, appropriate monitoring and treatment of diabetic retinopathy. Local diabetic eye screening programmes need to identify accurately all people who should be invited for diabetic eye screening and ensure that those who require treatment receive it within appropriate timescales.

This document provides a governance framework for patient consent and cohort management within the NHS Diabetic Eye Screening Programme. The patient pathway for diabetic eye screening crosses healthcare provider boundaries. This document therefore includes guidance for local screening programmes on how to manage exchanges of information between healthcare providers.

This guidance is underpinned by:

- outcomes from formal consideration by the Patient Information Advisory Group (PIAG) before the implementation of a national screening programme
- the principles contained within the Caldicott 2 report
- guidance prepared by the Royal College of GPs when considering automatic transfer of data between GP practices and the NHS Diabetic Eye Screening Programme

This document should be read in conjunction with the following guidance documents:

- Service Specification: NHS Diabetic Eye Screening Programme
- Diabetic Eye Screening programme: standards and objectives
- Failsafe: NHS Diabetic Eye Screening
- Transfer of Information within the diabetic eye screening
- Diabetic Eye Screening: Internal Quality Assurance Toolkit
- Diabetic Eye Screening: Use of Personal Information
- NHS population screening: confidential patient data
- Diabetic Eye Screening: keep checking the numbers to maintain accurate patient lists
- Diabetic Eye Screening: audits can ensure patients don't slip through the net
- Diabetic Eye Screening: Exclusions and suspensions and managing ungradable images

Available at: www.gov.uk/topic/population-screening-programmes/diabetic-eye

General principles

Duty to share Information

The duty to share information can be as important as the duty to protect patient confidentiality ([Information: To Share or Not to Share? The Information Governance Review, March 2013](#))

Health professionals need to have relevant information about a patient in order to act in that patient's best interest.

For the purpose of direct care, relevant personal confidential data should be shared among the registered and regulated health and social care professionals who have a legitimate relationship with the individual.

Information should be shared unless there is a specific reason not to do so.

Distinguishing between personal information and clinical information

Different types of data have different rules governing them for the purposes of screening. Personal information or data allows a programme to invite a patient to screening. Clinical (other) data items provide additional medical information beyond that required to invite a patient for screening.

Method of transferring data

It is important to acknowledge that the method of data transfer is not relevant to the rules around data processing and transfer. Governance rules apply equally if a programme receives data in an nhs.net email or by electronic data feed.

Types of consent

There are important consent rules around data sharing for screening purposes. Consent must always be present before data is transferred between agencies. This consent may be 'implied', 'explicit' or may be 'withheld'.

Provision and management of information on people diagnosed with diabetes

Responsibility for providing information

GPs are responsible for communicating a diagnosis of diabetes with a patient. A discussion between GP and patient regarding attendance at diabetic eye screening should take place early in the diabetes care pathway.

GPs are the primary source of care for people diagnosed with diabetes. They are responsible for ensuring relevant information on each person diagnosed with diabetes aged 12 and over is provided to the local diabetic eye screening programme associated with their practice. This information includes name, date of birth and contact details as a minimum.

GPs should make patients aware which organisation will provide their diabetic eye screening and how their information will be managed. Commissioners and providers should ensure that the systems in place to maintain information governance should not delay the timely and prompt release of invitations for screening.

The GP should inform the diabetic eye screening programme of a patient's personal details (name, date of birth and contact details) on the basis of implied consent. This is acceptable because regular diabetic eye screening forms part of direct patient care within the diabetes care pathway. Disclosure of confidential information that is needed to offer or provide direct care is routinely done within the NHS on the basis of implied consent. It is therefore appropriate for information to be disclosed to the associated local screening programme so that programme can invite eligible patients for screening.

When inviting patients for screening, the local diabetic eye screening programme will give them information regarding diabetic eye screening and the use of their information. They will make patients aware of the details and type of information the local programme receives from their GP practice and holds in the diabetic screening programme management system. This will include details of any additional information the programme is intending to receive, such as blood sugar levels, mobility status, date of diagnosis and type of diabetes. General information for patients regarding this is available from NHS Choices at www.nhs.uk/Conditions/Diabetes/Pages/diabetic-eye-screening-faqs.aspx

The transfer and use of additional clinical information may require additional patient consent depending on the local systems in place. If in doubt, the local programme

should seek advice from the Caldicott Guardian and/or senior information risk officer associated with that programme.

General Practice to Diabetic Retinopathy Screening (GP2DRS) is a system for automating the sharing of patient information between general practices and local diabetic eye screening programmes. Programmes may opt to continue with local agreements for the transfer of information already in place prior to the implementation of GP2DRS; upon which a nationally approved consent model to support GP2DRS will be implemented.

Timely provision of information

Information on people newly diagnosed with diabetes should be passed to the local screening programme upon diagnosis. Patients should learn about their diagnosis of diabetes before receiving an invitation from the diabetic eye screening programme. In the cases of electronic transfer of information, GP practices and the screening programme should agree and develop procedures to ensure this occurs.

Responsibility for maintaining an accurate screening programme register

The local screening programme has responsibility to hold and maintain an up to date and accurate single collated list containing all people diagnosed with diabetes aged 12 and over within their commissioned area. The local programme is responsible for developing and maintaining effective links with their associated GP practices to ensure systems to enable a regular exchange of information are in place. Such relationships will include links with relevant organisations to ensure all people diagnosed with diabetes in the programme area are included on the single collated list. This includes prisoners and members of the armed forces.

Immigration Removal Centre (IRC) populations are exempted from inclusion into the national screening programmes. Due to the transient nature of the population who are within IRCs and their short length of stay, the ability to **invite individuals** to the full screening pathway including diagnostic and treatment services with related fail safe mechanisms, is not possible. Those who move into the community will be supported in accessing primary care registration, which will enable them to access national screening programmes.

Programmes should work with GP practices to validate their single collated list on at least a quarterly basis to ensure changes in patient cohort are reflected.

Responsibility for carrying out additional checks

Local programmes should carry out additional checks to ensure an accurate and up to date single collated list. These checks should include the following:

- an annual check of data published by the Care Quality Reporting Service (CQRS). This data is published annually as part of the Quality Outcomes Framework (QOF) and can be accessed via HSCIC. Data published provides an opportunity for programmes to compare numbers of patients recorded with diabetes via the QOF with numbers referred into their programme on a per practice basis. Further guidance can be found on the [PHE Screening blog](#)
- regular checks on the Spine/Open Exeter systems
- regular checks with linked paediatricians, diabetes specialist nurses and GP practices to ensure all children aged 12 and older diagnosed with diabetes are known to the screening programme, particularly where no automatic electronic transfer of information from GP practices is in place

Local programmes should take care to ensure information provided and held is restricted to people diagnosed with diabetes only. Checks should be in place to ensure any missing or incorrect transfer of information is promptly identified and corrected. Programmes should follow up any identified issues immediately to enable all eligible people to be sent an invitation for screening within acceptable timescales.

Coding and classification of people diagnosed with diabetes

The local programme and associated GP practices should discuss and agree coding practice for people diagnosed with diabetes in GP software systems to ensure clarity on which codes and system entries trigger any transfer of information. This applies whether electronic or manual methods of transfer are used. People diagnosed with diabetes (with the exception of people diagnosed with gestational diabetes) should be offered diabetic eye screening for life. Practices should ensure patients whose diabetes is in remission due to an intervention, such as bariatric surgery, are not coded in the practice system as 'diabetes resolved', but as 'diabetes in remission' to ensure they will still be made known to the programme and not removed from the screening cohort.

Programmes should ensure patients who should be invited for screening are not marked as 'not diabetic' in their screening programme software system. Further guidance can be found on the [PHE screening blog](#).

Retention of information and records

Programmes should comply with their local health record retention guidance when archiving records of patients who are deceased or have moved out of area or where

patients have opted not to continue with screening. Additional consideration may be required for specific groups that need a lengthier retention period – for example, when archiving notes relating to children and young people. To support patient relocation it is best practice for programmes to make historic clinical records available to the receiving programme or the receiving GP practice. This should be facilitated in a secure manner.

Consent for screening and for use of information throughout the screening pathway

How a patient may consent for screening (opt in)

By agreeing to attend a screening appointment or by attending a screening appointment it can be implied that the patient consents for screening until such an opportunity that consent can be sought in person.

The local programme will seek such consent subsequently at the first screening appointment the patient attends and record that as consent given for screening purposes in the diabetic eye screening programme management system. Other data items present in the software regarding consent for education or research purposes are not required for national screening programme purposes.

How a patient may withhold or withdraw consent for screening (opt out)

The local programme should provide patients with clear information on how to make further enquiries and how to opt in/out of the screening process.

A patient may withdraw consent and opt out of screening for up to three years. In such cases they should not be invited for screening during this time period. A copy of a confirmation letter stating that the patient has opted out of screening should be sent to both the person and his/her GP. The programme should automatically make contact with the patient after the opt out period has expired to check whether or not circumstances have changed and whether the person now wishes to attend screening.

A patient may withhold or withdraw their consent for data sharing between GP and programme. In such cases they can no longer be screened.

A patient may state that they do not wish their data to be sent electronically. In such cases the patient may not be screened if the practice routinely relies on electronic means to inform the programme about all its patients with a diagnosis of diabetes. If a patient objects at any time to their personal information being transferred to the screening service, or wishes to permanently opt out of screening they should raise this with their GP who can record the objection and not proceed with the transfer of this information. If this happens at the time of diagnosis then the patient would remain unknown to the screening programme. If the programme already has a record of this

patient then the GP should inform the programme that the patient wishes to opt out so they do not receive an invitation in future. In these instances the programme would mark the patient as off-register 'refused demographic transfer, but known to programme'.

It is the GP's responsibility to ensure that patients who object to the transfer of their personal information and want to permanently opt out of screening are aware of the risks and are offered the opportunity to opt back into screening.

Local programme clinical leads are responsible for managing the process of assessing patient suitability for screening.

For further guidance on opting out, excluding for medical fitness, capacity and best interest grounds see [Exclusions, Suspensions and Management of Ungradable images guidance](#).

Consent for research and educational purposes

If local programmes ask for consent to use patient information for research purposes then they should follow national guidance regarding consent for research studies (see www.hra.nhs.uk). This use of information is outside the remit of the screening programme, constitutes a new use of the patient data and is not covered by consent models for screening.

The following considerations may help programmes that want to use retinal images for teaching or training purposes:

- General Medical Council guidance on making visual and audio recordings of patients (see www.gmc-uk.org/guidance/ethical_guidance/7818.asp paragraphs 10 to 12)
- whether or not images include any patient identifiable information
- whether or not patients have previously consented to using their information for educational purposes