



Exclusions, Suspensions and Management of Ungradables

Version 0.10, 07 March 2012

To provide a definitive policy on exclusions and suspensions for the
NHS Diabetic Eye Screening Programme

Screening Programmes

Diabetic Eye

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0.2	26.4.11	HK	Amendment of previous version
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0.6	18.10.11	SC	Amendment from Pathway – prep for consultation
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0.9	5.3.12	SC	Amendments following Programme Advisory Committee
0.10	7.3.12	LL	Amendments for final draft issue

Review / approval

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v0.10 7 March 2012

Screening Programmes

Diabetic Eye

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FINAL DRAFT

1 Purpose and Definitions

- 1.1 This policy describes the management of people on the Programme Registerⁱ of their Local Diabetic Eye (DE) Screening Programme. It defines the eligible population and which people should be invited for screening, excluded and suspended. It also provides guidance in special circumstances.
- 1.2 **Eligible:** The population that is *entitled* to an *offer* of screening from the NDESP. All people with diabetes are eligible EXCEPT those below the age of 12 years or those over 12 years with no perception of light in both eyes. All other people with diabetesⁱⁱ are eligible.
- 1.3 The local screening programme should separate eligible people who are not invited into one of two categories: exclusions and suspensions. **Suspensions:** people who are suspended are under surveillance for diabetic retinopathy or assessment and/or treatment of their diabetic retinopathy from a clinician who has taken clinical responsibility for the care of their diabetic retinopathy. **Exclusions:** people who are excluded are not invited for screening and are not screened or assessed for diabetic retinopathy.
- 1.4 **Suspended:** Eligible people who are **not** invited for annual digital screening **and** continue to have their retinae checked for diabetic retinopathy (DR). An eligible person who is suspended can be in one of the following states:
- Under the care of the Hospital Eye Service (HES) for management/treatment of DR
 - Under surveillance for DR in either a slit lamp biomicroscopy (SLB) surveillance clinic for the assessment of their DR, (this includes patients who have ungradable images) or a digital imaging surveillance clinic, sometimes referred to as Ophthalmic Photographic Diabetic Review (OPDR)

All people who are SUSPENDED are not invited for annual digital screening by the DE screening programme and should be monitored through the **failsafe system**ⁱⁱⁱ.

1.5 **Excluded:** Eligible population on the Programme list who are **not** invited for annual digital screening and **DO NOT** have their retinae checked for DR in another part of the screening pathway. This includes:

- Those who have made a written informed choice to opt out of DESP
- Those who could never be able to receive and/or benefit from treatment due to another existing condition
- Those who have been assessed by the Clinical Lead as never being able to be screened by digital photography or SLB

1.6 This policy describes the management of people on the Programme Register of their Local Diabetic Eye (DE) Screening Programme. It defines the eligible population and which people should be invited for screening, excluded and suspended. It also provides guidance in special circumstances.

2 Excluding people with diabetes from invitation for screening

2.1 People with diabetes aged 12 and over should be sent an annual invitation for Diabetic Eye (DE) screening and given the opportunity to make their own informed choice^{iv} about whether to accept the invitation. In cases where there is doubt over whether the person with diabetes should be invited or not, they should be sent an invitation.

2.2 When a decision is made to exclude a person with diabetes from screening and not to send an invitation for DE screening, it should only be done after a careful assessment of the person and their circumstances.

2.3 Exclusions of people with diabetes from screening should form a very low proportion of the programme register; the national acceptable range is less than [level to be agreed]

2.4 A pathway must be in place to allow people to request to be returned to normal recall and be invited for screening at any time.

2.5 An annual audit of exclusions should be carried out by the screening programme.

2.6 The process for excluding and suspending people from retinal screening is detailed in Table A.

3 Suspending people with diabetes from invitations for screening

3.1 People with diabetes are suspended from screening when they are:

- Under the HES for treatment of their DR
- Under surveillance for DR in either:
 - A SLB clinic^v. This includes patients who can never be screened by digital photography but can be assessed using SLB **and** in the opinion of the programme Clinical Lead^{vi} could benefit from annual assessment and treatment if it is required
 - A digital imaging clinic^{vii} (OPDR)
 - Note: Patients with non-DR lesions under the care of HES are NOT suspended (see section 5.5)

3.2 Only the local screening programme can suspend people from screening. GPs cannot suspend individuals as 'under-care' of ophthalmology as not all assessments in the hospital eye clinic will involve a regular examination of the retina and the ophthalmologist may not know that the person has diabetes.

3.3 Only people who have been seen by the screening programme can be suspended. People who are under the care of ophthalmology, but have not yet been imaged by the screening programme, should either be seen once by the screening programme or have documented evidence from the hospital eye service that they are being managed /treated for DR. If appropriate, the screening programme can then suspend the person.

3.4 People who are suspended should be monitored through the failsafe system.

3.5 People who are suspended should be put in one of the categories in the software as described in Appendix A

4 Categories for ineligible, exclusion and suspension

The following categories will be covered under the policy:

- No perception of light in both eyes
- Informed opt-out

- Medically unfit for screening. This includes the following circumstances
 - Terminally ill
 - Unable to be treated
 - Unable to be screened by digital imaging or another approved screening method

4.1 People with no perception of light

All people who are registered with severe sight impairment should be assessed by an ophthalmologist as some may still have some residual vision and therefore qualify for continued DE screening. People should continue in screening unless there is no perception of light in **both** eyes.

These people **will no longer be eligible for screening.**

4.2 Informed opt-out

4.2.1 Some people may choose not to be invited for retinal screening and may ask to have their name removed from the list of people invited. Before this request can be implemented, the following conditions must be satisfied:

- The person must be provided with sufficient information to enable him/her to make an informed decision about withdrawing from the screening programme. This must be in a format which is accessible to him/her. It should include information on the condition being screened for i.e. diabetic retinopathy, the screening process (including risks and benefits) and the consequences of attending or ceasing to attend
- The person must be informed that withdrawing from the programme will prevent him/her from receiving any future invitations or reminders about retinal screening
- It must be made clear to the person that he/she can return to the programme at any time on request

- The person should put his/her request to withdraw from the programme in writing to confirm that he/she has made an informed decision. A template letter with appropriate wording is available (Appendix B). If a person is unable to sign a standard form, for example because of a severe physical disability, then alternative methods of communication are acceptable according to individual circumstances. If the decision has been discussed with the GP then the GP should record the discussion in the patient's notes.

4.2.2 The letter from the person requesting they should not be invited should be retained by the screening programme.

4.2.3 A copy of a confirmation letter stating that the person has opted out of the screening programme should be sent to both the person and his/her GP. This should be filed in the patient notes by the GP.

4.2.4 The screening programme should automatically re-invite the person after three years asking them if they would like to re-consider their decision to opt out of the screening programme. This letter should be accompanied by a new opt-out letter for the person to complete if they so wish.

4.3 People who are terminally ill

4.3.1 Terminally ill is defined as a person who is suffering from a progressive disease, and where their death can be reasonably expected within six months. In these circumstances a GP or other caring physician can issue a DS1500^{viii}.

4.3.2 The least restrictive option is for the person to remain in call/recall and receive screening invitations. The invitations can be considered and accepted or declined on each occasion.

4.3.3 Alternatively, the GP or other caring physician can discuss whether or not the person wishes to continue to attend screening and the patient can, if they wish, make an informed decision to opt out.

4.3.4 In some circumstances, where the GP or care team believe that receiving invitations or completing an informed opt-out will cause distress to the person

or their carer they can decide that it is in the person's best interest to exclude them in order to stop invitations being sent.

4.4 People who will never be able to benefit from and /or receive treatment due to a pre-existing condition

4.4.1 People who will never be able to benefit from and/or receive treatment due to a pre-existing condition should be assessed by either their GP or the Clinical Lead. If their clinician confirms that this is the case

The person can be EXCLUDED under 'medically unfit' category

4.5 People with diabetes who can never be screened with digital photography:

- Those who can never have a digital image *taken* in both eyes due to a pre-existing condition
- Those who can never have a digital image *graded* in both eyes due to a pre-existing condition (See below on managing ungradable images)

4.5.1 People who will never be able to have a digital image *taken* or *graded* in **both eyes** due to a pre-existing condition that cannot be treated, should be assessed by the Clinical Lead according to an agreed protocol. If a digital image can be taken in one eye then the person should continue to be screened using a digital photograph. (see flow-chart Appendix ..)

4.5.2 If the Clinical Lead, in discussion with the individual (and if relevant, their carer), considers they could benefit from regular review using SLB **and** could benefit from treatment for DR if required, then the individual should be referred to the SLB surveillance Clinic.

These individuals should be SUSPENDED from the Screening Programme and monitored through the failsafe system.

4.5.3 If the Clinical Lead, in discussion with the individual (and if relevant their carer), considers they would NOT benefit from regular review using SLB **or** could NOT benefit^{ix} from treatment if required, then the Clinical Lead can EXCLUDE the individual from the Screening Programme

4.5.4 The Clinical Lead should confirm any changes in the status of the patient (excluded or suspended) in writing to the person and their GP. The appropriate documentation should be completed by the Clinical Lead and retained by the screening programme.

5 Situations that require special consideration

5.1 People with ungradable images

5.1.1 Programmes should classify ungradable images in line with existing policy.

5.1.2 Ungradable images can be classified in the following way:

- Ungradable at this visit because of person specific factors
- Digital image possible in one eye, ungradable in second eye
- Ungradable in both eyes due to a condition amenable to treatment
- Ungradable in both eyes due to a condition amenable to treatment but for which treatment is not yet indicated
- Ungradable in both eyes due to a condition not amenable to treatment, possible to visualise the retina using SLB
- Ungradable in both eyes and not possible to visualise the retina with any other method

5.1.1 An individual can be found to have ungradable images at a visit because of person specific factors, such as difficulty in keeping still, and the screener believes a gradable image can be obtained if the individual can be seen again. The person should then be re-invited for screening^x.

5.1.2 When an individual is able to have a digital image taken in one eye (and the grade is non-referable in that eye) they should continue in the digital screening programme. If the other eye has a lesion that is amenable to treatment, e.g. cataract, and the patient wants it treated, they should be referred to the hospital eye service. In this circumstance they should continue to receive annual invitations for digital screening.

5.1.3 When an individual is found to have ungradable images in both eyes but the cause is amenable to treatment and the patient wants it treated, (e.g., cataracts), the patient's screening due date may be postponed to accommodate treatment and recovery time. The patient will remain active on the register during this time, and will not be

suspended or excluded from the screening programme unless either screening or treatment for DR-related conditions is determined to be impossible, at which point the patient would be excluded.

5.1.4 When an individual is found to have ungradable images in both eyes due to a condition that is not amenable to treatment but it is possible to visualise the retina using SLB, they should be managed according to 4.5.2 and 4.5.3. This can include patients who have cataract preventing adequate photography, but where surgery is not indicated.

5.1.5 When an individual is found to have ungradable images in both eyes and it is not possible to visualise the retina with SLB they should be assessed by the Clinical Lead. In these circumstances the Clinical Lead can EXCLUDE the individual from the Screening Programme

5.2 People who have a disability

5.2.1 In most cases a person with a disability should be able to access their Local DE Screening Programme. Local programmes should ensure they provide a service that is accessible to them in accordance with Disability Discrimination legislation.

5.2.2 In a small number of cases a person may have a disability that prevents them from being screened by digital photography. In these circumstances the Clinical Lead should discuss their situation and options with them (and if appropriate with their carer and GP) on an individual basis. These situations should be dealt with as in 4.5.2 and 4.5.3 above.

5.2.5 It is not appropriate for either the GP or screening programme staff to exclude a person with a disability from screening when they have capacity to make their own decisions.

5.3 Excluding in a person's best interests

5.3.1 It is important for screening staff to recognise that a person who lacks the mental capacity to consent to screening should not be permanently removed from a screening recall programme unless a 'best interest decision' to do so has been taken on his or her behalf. In most cases, the least restrictive option

is for that person to remain in call/recall and receive screening invitations at routine intervals. The invitations can be considered and accepted or declined on each occasion. In exceptional circumstances, a care team may decide it is in the best interests of a person who lacks mental capacity to withdraw from a screening programme. Screening staff should be satisfied that the best interest decision has been reached in accordance with their local code of practice. The person making the best interest decision to exclude a person from screening should be aware that the person can be re-invited at any time if circumstances change and screening is then considered to be in the person's best interests.

5.3.2 Screening programmes will need to ensure there is evidence that any best interest decision has adhered to the principles of the Mental Capacity Act and that all relevant factors, reasonable adjustments and alternatives have been considered.

5.3.3 It is recommended that DE screening programmes work with their commissioners and local stakeholders to develop good practice guidance in regard to the access to DE screening for people with mental incapacity. This can take into account any reasonable adjustments and alternative arrangements that may enable people with limited mental capacity to consent to and participate in DE screening.

5.4 Housebound Patients

5.4.1 Diabetic eye screening and laser photocoagulation treatment require special equipment which is not portable and cannot be provided in people's homes.

5.4.2 People in institutional or residential care or who are housebound and able to benefit from screening and treatment should continue to be invited for screening. There should be provision for a service that is accessible to them in accordance with Disability Discrimination legislation

5.4.3 Every endeavour should be made to ensure housebound patients can access the programme. The GP and, if appropriate, care home staff will have a role in making sure patients are encouraged to attend for screening and subsequent treatment if necessary.

5.4.4 Patients who are unable to travel outside their home or who have a disability that would preclude treatment should be assessed in line with points 4.5.2 and 4.5.3

5.4.5 Domiciliary assessment is not part of the screening service and if provided should be commissioned, funded and managed separately from DESP

5.5 Patients found to have referable non DR conditions at screening

5.5.5 Patients who are found to have a referable eye condition other than diabetic retinopathy or maculopathy (non-DR eye condition) will require referral for their condition. The screening service should provide the necessary clinical information to the patient's GP who will then be responsible for the referral.

5.5.6 Screening programmes should have local protocols for direct referral to HES for conditions that require urgent referral.

5.5.7 Some screening programmes may also have local protocols governing referrals which have been agreed with local GPs.

5.5.8 Patients who are referred and followed for a non-DR eye condition will continue to require annual digital screening. These patients will remain within the active patient register, eligible for annual recall, and will not be excluded or suspended from the screening programme.

5.5.9 In cases where the patient's non-DR eye condition would prevent effective screening (e.g., cataracts awaiting surgical removal), the patient's screening due date may be postponed to accommodate treatment and recovery time. The patient will remain active on the register during this time, and will not be suspended or excluded from the screening programme unless either screening or treatment for DR-related conditions is determined to be impossible, at which point the patient would be excluded (*refer to section regarding exclusions for inability to screen or treat sections 4.4 and 4.5*).

5.6 Private Patients

Patients who attend private ophthalmologists should be treated in the same way as those attending NHS DESP screening and NHS HES services with the private ophthalmologist indicating prior agreement to follow DESP protocols and informing their patients of the options open to them.

Private patients should not be excluded from invitations to the screening programme. They can be excluded if they wish and they return an opt out form.

6 Programme and commissioner responsibilities

- 6.1 Programmes should have operating procedures that provide detailed arrangements for the implementation of this policy. This will include, but is not limited to, the following:
- Retention of documents and supporting evidence
 - Audit of exclusions
 - Procedure for exclusions
 - Procedure for suspension and failsafe
 - Protocol for exclusion under best interest decision as agreed with commissioning PCT's Director of Public Health
- 6.2 Programmes and programme boards are encouraged to work with their stakeholders to develop good practice in relation to the management of people with disabilities in relation to screening for DR.
- 6.3 Commissioners should commission a dedicated surveillance SLB clinic as part of the screening service (DESP) to meet the requirements of this guidance.

Appendix A: Administration and software

The changes proposed are not intended to require any changes to the current software system offered by the suppliers. Calculations for the annual report should be possible using existing data fields. The National Team is working with the software suppliers to ensure that the policy as described can be delivered.

Table A summarises the changes and aligns this to annual report headings and the old categories of inactive and active.

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Screening Programmes

Diabetic Eye

Eligibility, Exclusions and Suspensions Table A

Excluded or suspended ?	Category	Category description	Responsibility for the decision	To be included in Annual Report Lines 3.1.3 (Patients marked inactive according to category)	Old categories (inactive/active)
NOT ELIGIBLE					
Not eligible	Blindness (NPL)	A person with diabetes who does not have perception of light in both eyes	Ophthalmologist NPL form to be counter signed by Clinical Lead	3.1.3 b Having no perception of light in both eyes	INACTIVE - Permanent
EXCLUSIONS					
Excluded	Informed choice to opt out	A person with diabetes who has made his or her own informed choice that he or she no longer wishes to be invited for screening	Person supported by GP (or senior practice or diabetes specialist nurse) or screening programme. Opt out form to be completed by person.	3.1.3 a Informed opt-out	INACTIVE - Temporary
	Terminal illness	A person with diabetes who is terminally ill	GP or other senior member of care team Exclusion form to be signed by relevant health professional.	3.1.3 c Being terminally ill	INACTIVE - Temporary
	Best interest exclusion	Best interest decision for person to be excluded from screening following the requirements of the Mental Capacity Act (2005)	Best interest exclusion form with check list signed by appropriate person according to local protocol	3.1.3 e Having a learning or mental disability preventing either screening or treatment	INACTIVE - Temporary

	Medically unfit	A person who has been assessed by the Clinical Lead and in discussion with the individual (and if relevant their carer) considers they could NOT benefit from treatment if it was required.	Clinical Lead Screening programme exclusion form.	3.1.3 d Having a physical disability preventing either screening or treatment	INACTIVE - Temporary
	Medically unfit	A person who has been assessed by the Clinical Lead and in discussion with the individual (and if relevant their carer) considers they would NOT benefit from regular review using SLB or could NOT benefit from treatment if it was required.	Clinical lead. Screening programme exclusion form.	3.1.3 d Having a physical disability preventing either screening or treatment	INACTIVE - Temporary

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SUSPENSIONS					
Suspended	Under the care of an Ophthalmologist for the treatment of diabetic retinopathy	A person with diabetes who is currently under the care of an ophthalmologist for the treatment and follow-up management of diabetic retinopathy and where the ophthalmologist has accepted clinical responsibility for their diabetic retinopathy care.	Programme Manager or Clinical Lead according to local failsafe protocol. Suspension form	3.1.3 f Currently under the care of an ophthalmologist for the treatment/follow up of diabetic retinopathy	INACTIVE - Temporary
	Under a surveillance slit lamp bio-microscopy clinic	A person with diabetes who is under a surveillance SLB clinic for the assessment of their DR. This will include patients who can never be screened by digital photography but can be assessed using SLB and in the opinion of the Clinical Lead could benefit from annual assessment and treatment.	Programme Manager or Clinical Lead according to local failsafe protocol Suspension form	Currently no suitable category for this to be counted in the annual report, so; 3.1.3h Other	No inactive category for this
	Under digital imaging surveillance clinic - OPDR	A person who is under review in a digital imaging surveillance clinic or assessment clinic	Clinical Lead according to local protocol,	Currently no suitable category for this to be counted in the annual report, so; 3.1.3h Other	No inactive category for this

Screening Programmes

Diabetic Eye

Appendix B

Dear.....

You recently contacted the Diabetic Eye Screening office/GP (please delete as appropriate) to inform us that you do not wish to participate in the NHS Diabetic Eye Screening Programme

In England, we invite all people with diabetes aged 12 and over to take part in the NHS Diabetic Eye Screening Programme. Evidence shows that regular screening for diabetic retinopathy can significantly lower the risk of loss of sight.

I understand that you do not wish to receive any more invitations to take part in the Screening Programme. It is possible to remove your name from the list of people to be invited. However, your written confirmation is needed to ensure there is no misunderstanding.

Please sign and return the lower part of this letter to confirm your wishes. You can change your mind at any time by contacting your General Practitioner or the Diabetic Eye Screening Administration office.

In three years time we will contact you again to see if your circumstances have changed and you would like to rejoin the screening programme.

If you do not send the completed form back, you will be recalled within the year.

Yours sincerely

GP/Diabetic Eye Screening Office (delete as appropriate)

To: Insert address

Please do not send me any more invitations to take part in the Diabetic Eye Screening Programme.

I assume full responsibility for this decision and confirm that I have read the statement that retinopathy screening can reduce the risk of loss of sight.

I understand that I can change my mind and request a diabetic eye screening test if I wish. I can do this by contacting my General Practitioner or the Diabetic Eye Screening Administration office at any time in the future.

Name:..... Address:.....

.....

Signed:..... Dated.....:

FOOTNOTES

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- ⁱ Programme Register: sometimes referred to as the single collated list or programme list.
- ⁱⁱ People with Diabetes – this includes all people with a diagnosis of diabetes according to (ref). It does not include women with gestational diabetes or impaired glucose intolerance.
- ⁱⁱⁱ Failsafe system, as described by national documents.
- ^{iv} Informed Choice should include appropriate information provided with the invitation letter.
- ^v Where a reference is made to a Slit Lamp Biomicroscopy (SLB) Clinic, this refers to a specific SLB service that has been commissioned as part of the NDESP programme to provide assessment of DR.
- ^{vi} Where the term Clinical Lead is used in this document it refers to the Clinical Lead or a clinician designated by the Clinical Lead with appropriate training and under the clinical lead's supervision. In cases where the Clinical Lead is a diabetologist, a Consultant Ophthalmologist should be identified to provide clinical responsibility in those areas where a specialist ophthalmology opinion is required.
- ^{vii} Where a reference is made to a virtual clinic (OPDR), this refers to this service that has been commissioned as part of the NDESP programme to provide assessment of DR.
- ^{viii} DS1500 are issued by a GP or other caring physician for a patient to enable the patient to claim certain benefits. They are only issued when the clinician believes the patient is unlikely to survive more than six months and therefore can be used as an indicator of when a patient meets this criteria.
- ^{ix} Benefit means: An individual assessment that is patient specific and will be based on a holistic assessment of whether or not a patient can benefit
- ^x Only the second episode should be counted if an image was obtained at a second visit.