NHS
Central Mersey
Diabetic Retinopathy Screening Programme

SCREENING PROTOCOL

September 2018

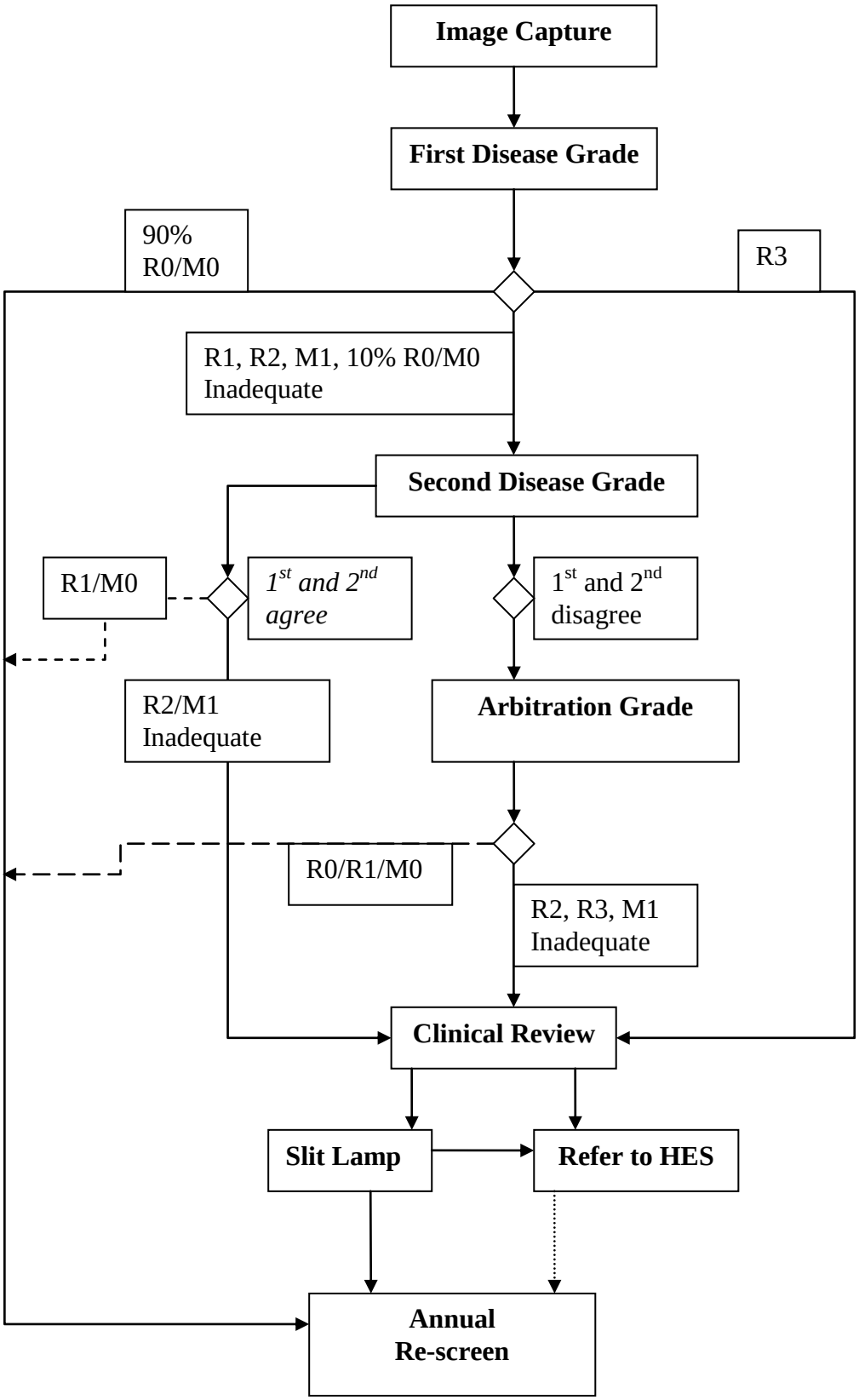
Please note that adherence to this protocol forms part of the contractual arrangement between providers and the programme.

Failure to comply with the protocol constitutes a breach of contract.

For review: September 2019

Contents

1. Screening Pathway



2. Screening Staff

All members of staff carrying out work for the programme will need to be on the Registered Staff list. The list will include the following staff categories, with respective levels of access to the software:

- Programme management and administration
- Grader
- Screener
- Slit Lamp Screener
- Trainee Screener
- Receptionist

Any prospective new registered staff member must complete the 'Central Mersey Diabetic Eye Screening Programme Registered Staff Application Form' and submit it to the Programme Manager for accreditation.

Each applicant for a role as a Screener or Trainee Screener will need to undertake an interview with the programme management. Those wishing to accredit as a Screener will need to submit evidence of relevant qualifications and experience. Those applying as a Trainee Screener will need to work under supervision and provide evidence they have enrolled for the national qualification (See Training and Accreditation section below).

Every accredited member of staff will have their own OptoMize username and log-in password. Under no circumstances must this username be used by anyone else to access OptoMize. Any transgression will lead to immediate suspension from the programme pending disciplinary measures. This may lead to removal from the programme as well as referral to any relevant professional body, e.g. GOC.

Appropriate access to screening software

- Receptionists will only be able to set diaries, make and alter appointments, but will have no other access to patient data. Training on the software should be carried out by the screening venue, but they do not need to undertake external training and accreditation

- Registered Screeners, who have attained the appropriate training and accreditation can add pre-screening details and undertake image capture within the programme

- Screeners may take additional modules to enable them to measure VA and instil drops. Screeners who are optometrists are exempt from this requirement

- Screeners will be unable to access the grading list and undertake grading, but will be able to review grading outcomes up to 6 months after grading, as set out in section 4

- Trainee Screeners undertaking the national qualification can only work under supervision from an accredited screener, as specified in the Programme's Training and Accreditation policy. The supervising screener takes full responsibility for the work carried out by the trainee. Any transgression from the required level of supervision could lead to immediate suspension from the programme pending disciplinary measures. This may lead to removal from the programme as well as referral to any relevant professional body, e.g. GOC

- The programme management reserves the right to restrict the number of registered screeners per screening venue, to ensure all screeners obtain sufficient regular experience to maintain expertise

Training and Accreditation

The old City and Guilds DES Screening Diploma was replaced by a new qualification in April 2016, Level 3 Diploma in Health Screening (Diabetic Eye Screener). Trainee Screeners will need to complete mandatory modules and those relevant to the role they expect to undertake in the screening programme to achieve the Diploma. There are some exemptions for optometrists and allowance for prior learning and experience, as set out in the Public Health England's 'Rules of Combination' document.

Any staff members starting work after 1st April 2016 will now need to complete all the relevant modules to obtain the Diploma before being granted accreditation as a screener and then be able to work unsupervised.

NB: Any Screener who completed the C&G Diploma will not need to take the new qualification and so will remain accredited to the programme.

3. Invitation for screening

Inclusion criteria

- All people aged 12 years old and over diagnosed with diabetes (type I or type II); and
- Registered at a GP practice within the boundaries of Halton CCG, Knowsley CCG, St Helens CCG or Warrington CCG or
- The unregistered population living within the boundaries of the programme; or
- Any others deemed appropriate by the programme manager.
- Please note this includes patients falling into the above categories who are under the care of an ophthalmologist for other eye disease

Exclusion criteria

- People with no perception of light at all
- People who exclude themselves having made an informed choice to do so
- People who have been excluded on the advice of the clinical leads, for instance:
    - People who are too unwell to participate
    - People with physical or mental disabilities which prevent either screening or treatment
- People under the care of an ophthalmologist for treatment and/or follow-up of diabetic retinopathy

If a Screener believes a patient has become unsuitable for screening due to physical or mental infirmity, they should flag this up with the Failsafe Officers and Clinical Adviser, as per Section 16 of this protocol. When deciding if a patient has become unsuitable for screening, screeners should particularly consider their ability to undergo Slit lamp examination and any subsequent treatment if required.

The programme management will give the matter due consideration with the clinical lead. The final decision as to whether exclusion is warranted rests with the Clinical Lead.

4. Accessing patient's screening records

For access to the patient's screening records via the VPN token access at an optometry site, you will require the following information:

- NHS Number
- Patient's date of birth

For access to the patient's screening record at an NHS site, you will only require the NHS Number.

If the patient requests or attends for screening, but does not have their invite letter, the NHS number can be obtained from the Screening Office. To request the NHS number, the screening venue must supply **all** the following information, with the permission of the patient:

- Full name
- Date of birth
- Full address

Acceptable access

- Receptionists, not registered with the programme as screeners, can only access the software to make and alter appointments once the patient has made an appointment and given the practice their NHS number and date of birth. **They must not access or review the patient's screening record**

- Access to a patient's screening record is acceptable only by a screener registered to the programme. Screeners may only access the records for up to **six** months after the screening date. This will be required for the following:
    - Making and altering appointments
    - Capturing images
    - Grading images (registered graders only)
    - Reviewing screening outcome

- Where the patient has had an eye test, a registered screener at the same venue may grant temporary access to the optometrist who carried out the eye test to view the current and old images, as well as screening and grading details of that patient

- Access by a screener to a patient's screening record **over six months after the screening date is deemed unacceptable.** Any transgression could lead to disciplinary action and ultimately suspension or removal from the programme as well as referral to any relevant professional body, e.g. GOC

- If circumstances occur where a screener needs to access a patient record after this 6-month period, they should seek permission from the programme manager, Kimberley Gallienne via an OptoMize alert message, including the patient ID and stating full reasons why access is required. The programme management will make the final decision to grant access

Data entry

Screeners should not, under any circumstances, change any patient demographic data, e.g. name, address, NHS Number. This data is critical to maintaining data integrity between the software and GPs/Hospitals. It should only ever be changed by the screening Administration Team.

If a screener finds an error in any demographic data, they should ring the screening administration office and report the error to the Failsafe officer immediately.

SCREENERS OR THEIR STAFF SHOULD NEVER CHANGE ANY DEMOGRAPHIC DATA THEMSELVES

5. Appointments

When the patient contacts a venue to make an appointment, the venue must ensure the patient is fully aware of the procedures to be followed, as set out in the invite letter. They must ensure the patient consents to have dilation drops instilled, which will blur their vision and increase light sensitivity. The screening venue must also reiterate that they will be unable to drive or return to work for several hours afterwards.

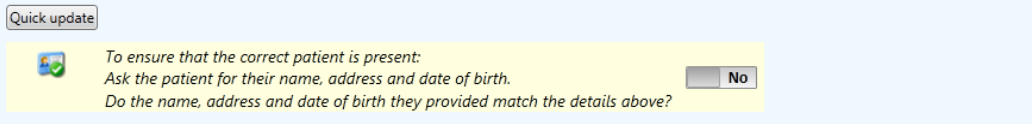
Once the patient has contacted the screening venue, the appointment **MUST** be made in OptoMize within 48 hours. Delays in making appointments on OptoMize can lead to the patient receiving a letter stating that they have not made an appointment and need to do so. This causes some patients significant distress and reduces trust in the programme as well as leading to unnecessary work for staff at the screening office'

Where an appointment can't be made in OptoMize within 48 hours, this should be flagged up to the screening office and the reasons must be clearly reported in the patient's screening record as soon as practically possible. Persistent failure to meet this requirement will lead to suspension, pending disciplinary measures and may result in removal of the screening venue from the programme.

Please note that any venue which is experiencing difficulties in fulfilling this requirement should contact the screening office at the earliest opportunity. The screening office will do what they can to resolve any issues which prevent you from fulfilling this task, but they can only do this if they are aware of the difficulty.

Screening appointment: Establishing correct patient record

When the patient has attended for a screening appointment, the screener should access the patient record by clicking on the patient's details in the front screen clinic list.



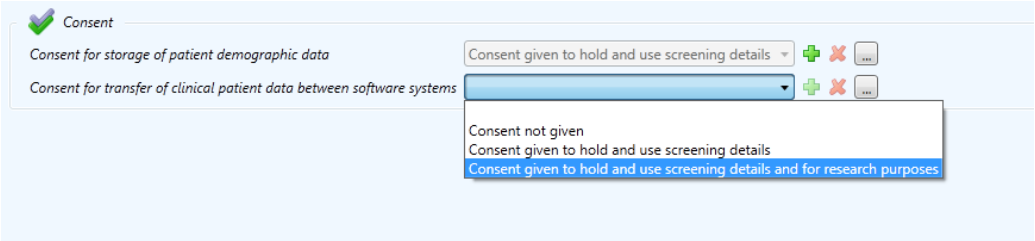
The screener must first establish they have the correct patient in front of them by asking the patient their name, address and date of birth and confirming if these are correct by clicking on Yes. **This should be repeated each time this screen is accessed.**

If any of the demographic details are incorrect, the screener should suspend the screening episode, call the Screening office and flag this with the Failsafe Officer. If Failsafe give permission to proceed, the screener can restart the screening episode and make a note to record this in the patient record. If Failsafe don't grant permission to proceed, the screener should cancel the episode and await further instructions before rebooking the patient.

Patient Consent

When the patient has received their invite letter and booked an appointment at their choice of venue, the programme considers that there is implied consent for screening. The onus is on the patient to exclude themselves from screening, if they so wish.

On the day of screening, screener should confirm that the patient consents to their details being used for screening and research purposes before selecting the appropriate consent response from the drop-down list.

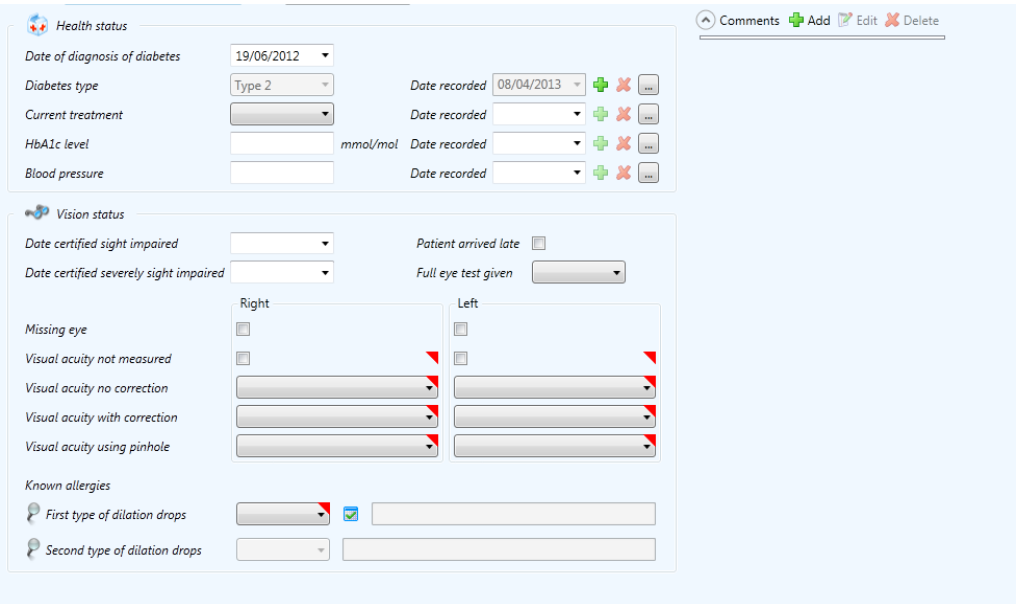


The screener should ensure the “Consent given to hold and use screening details and for research purposes” tab has been ticked in both parts of the patient’s screening record.

If the patient refuses to give this consent, the screener should suspend the screening episode, call the Screening office and flag this with the Failsafe Officer. If Failsafe give permission to proceed, the screener can restart the screening episode and make a note to record this in the patient record. If Failsafe don’t grant permission to proceed, the screener should cancel the episode and await further instructions before rebooking the patient.

Pre-screening details

Moving onto the next screen, the screener should always record the following:



- Whether a sight test was carried out or not (see section 10)
- The VA and how it was measured (see section 6)
- Details of the drops (see section 7)
- Whether there are any known reactions to drops (see section 7)
- Any relevant comments, e.g. regarding ocular history (see sections 9 and 18)

6. Visual Acuity

The VA should be measured using an appropriate test chart, which must be set at the correct working distance. VA should be recorded in the patient's OptoMize record in all cases. Please give best VA only and use the various sub-levels to assist with audit.

The best VA will be:

- With spectacles, if brought
- With Contact lenses if wearing
- Best corrected VA after refraction if patient is having an eye test at the same time
- With Pinhole, if no visual correction brought, i.e. spectacles or contact lenses and the VA unaided is 6/12 (+0.30) or worse
- With Pinhole, if there is no current visual correction and the VA unaided is 6/12 (+0.30) or worse
- With Pinhole, if they are using correction and the VA is 6/12 (+0.30) or worse. The Pinhole can be used either over the correction or without at the discretion of the screener

The VA must be recorded in a LogMar figure, e.g. -0.08, +0.20. A "VA Comparison Chart" is available to convert from Snellen to LogMar for the purposes of recording Snellen results.

It will be sometimes necessary to record a non-standard VA level:

- If the patient has VA in one eye worse than 3/60 or 6/120, set the VA as +2.00
- If the patient can only see Count-fingers(CF) or Hand-movements (HM), set the VA as +3.00
- If the patient can only just detect light, set the VA as "PL"
- If the patient cannot detect light at all, set the VA as "NPL"
- **In all the above cases, clearly state the reasons for using these settings as "Comments" in the pre-screening section**

VA not measured

If it is impossible to satisfactorily measure VA, e.g. Learning Difficulties, Dementia or Language barriers select the “Not measured” option, where the software asks for “Visual Acuity Method”.

Clearly state the reasons for using these settings as “Comments” in the pre-screening section.

Missing Eye

- If the patient has lost an eye altogether and has a false or prosthetic eye, set the VA as “Missing Eye”. This eye will automatically drop out of the grading form and assist workflow

- “Missing Eye” may also be chosen if the patient has untreatable media opacities, which make it impossible to ever take satisfactory images in this eye, e.g. corneal ulceration, inoperable dense cataract. In this case, the screener does not need to take images

- “Missing Eye” may also be chosen if one eye has untreatable ocular disease with resultant VA less than 6/60 (+2.00 onwards), e.g. advanced AMD beyond treatment, old CRAO. In this case, the screener should still take best images possible

- **“Missing eye” should not be used in eyes with reduced VA due to Amblyopia-unless the other conditions also apply, as detailed above**

- **If “Missing Eye is selected, the case should always be set as amber**

- **If “Missing Eye is selected, clearly state the reasons as “Comments” in the pre-screening section**

- **“Missing Eye” should never be chosen in any other circumstances**

7. Dilation

Every patient presenting for screening should be dilated, unless contra-indicated. The standard procedure for dilation is 3 drops of 1% Tropicamide in the Minims format, allowing at least 20 minutes for maximum effect.

When there is poor dilation, the Clinical lead believes there are no risks in using 1 drop of 2.5% Phenylephrine additionally. This is summarised in the document, “Safety of Phenylephrine”, which should be read in conjunction with this protocol. **NB. Phenylephrine should never be used with pregnant ladies.**

The following standard dilation procedure should be followed:

- Instil 3 drops of 1% Tropicamide
- Assess the effect of dilation after 20 minutes
- If dilation is sufficient, proceed to image capture
- If dilation is insufficient to capture satisfactory images, instil at least 1 drop of 2.5% Phenylephrine (Patient records should be annotated to suggest this is required)
- Ask the patient to wait at least another 20 minutes and then take best images possible

When used previously or if its necessity is anticipated, instil Phenylephrine straight after Tropicamide, as this is more efficient and reduces the time required for full dilation.

Drops should be procured, stored and used according to NSC protocol, as well as National Programme accreditation (for lay Screeners) and the College of Optometrists guidance (for optometrist Screeners).

Details of the Tropicamide drops used, including dosage, batch number and expiry date should be recorded on the patient’s screening record. Screeners must also record below this line if there has been an adverse reaction or not.

If 2.5% Phenylephrine is required, this should be recorded under “Second type of dilation drops” in the pre-screening section, including details of the batch number and expiry date. Screeners should also record if there has been an adverse reaction or not.

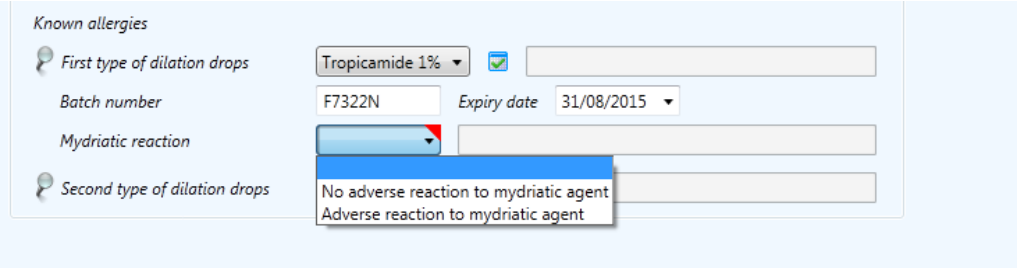
If a patient can’t be dilated for any reason, screeners should select “Undilated” from the drop-down list, take the best images possible and make suitable notes by way of explanation. These cases should <u>always</u> be set as amber.

Adverse Reactions to Mydriatic Drops

Screeners should always give each patient sufficient warning regarding drop actions, possible contraindications and side effects of the drops used for dilation. As well as discussing this with the patient in advance of installation, screeners should back this up by giving the patient a standard programme leaflet on dilation drops afterwards.

On the day of screening

Where a patient suffers a known adverse reaction to dilated drops on the day of screening, this must always be reported in the patient's screening record, once known. The correct procedure is as follows:



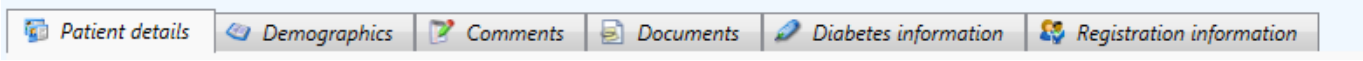
- In the pre-screening section:
  - Select "Adverse Reaction to Mydriatic" in the Mydriatic Reaction Line
  - Add a comment in the Pre-screening section explaining the circumstances
- Send a "Warning" message to the Failsafe Officer
- Refer the patient for medical attention, clearly stating what drops were used, including the batch number and expiry date

At the time of screening a patient may mention that they experienced an adverse reaction after the last screening episode, although they didn't report it to the programme at the time. Even if the patient recovered soon after and did not need to obtain medical attention, screeners should not use the same type of drops again. In these cases, take the best images possible, undilated, following the procedures on page 16. The screening programme will decide on the best course of action if the images prove too poor to make a grading decision.

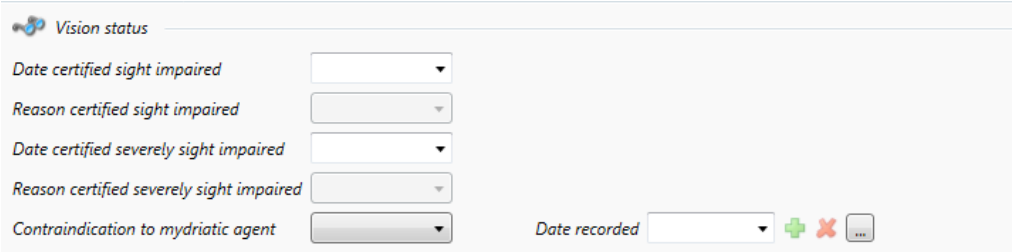
After screening has been completed

If the patient suffers an adverse reaction to drops after screening is completed, screeners should undertake the following procedure:

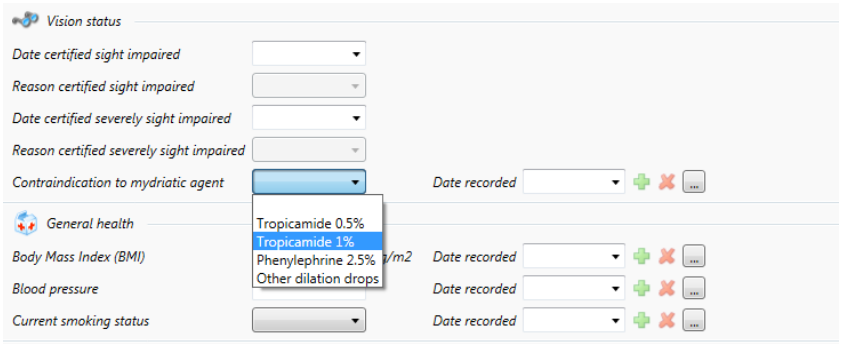
- On the OptoMize front screen, alter the screening date to the date the patient was screened and highlight the patient in the list



- Select “Update” from the options in the middle spine
- Select the “Diabetes information” tab
- Go to the “Contraindications to mydriatic agent” line



- Select the mydriatic agent from the drop-down list



- Record the date when the contraindication was reported by the patient
- Save the changes

8. Pregnancy

Significant retinopathy present at the start of the pregnancy can progress rapidly. Additionally, treatment can become difficult later in the pregnancy. Therefore, pregnant women need urgent HES attention and treatment needs to be carried out early.

The procedure for screening in pregnancy:

- Pregnant woman sent invite for screening
- If no retinopathy or only background retinopathy is found:
    - Re-screened again in 3 months
- If still no retinopathy or only background retinopathy is found:
    - Re-screened again in 3 months
- If still no retinopathy or only background retinopathy is found:
    - Re-screened after 6 months, i.e. after the end of the pregnancy
- If images are unacceptable, the patient will be referred to the HES, rather than for Slit Lamp grading
- **If the patient has referable grade retinopathy, they will all be treated as an urgent referral**

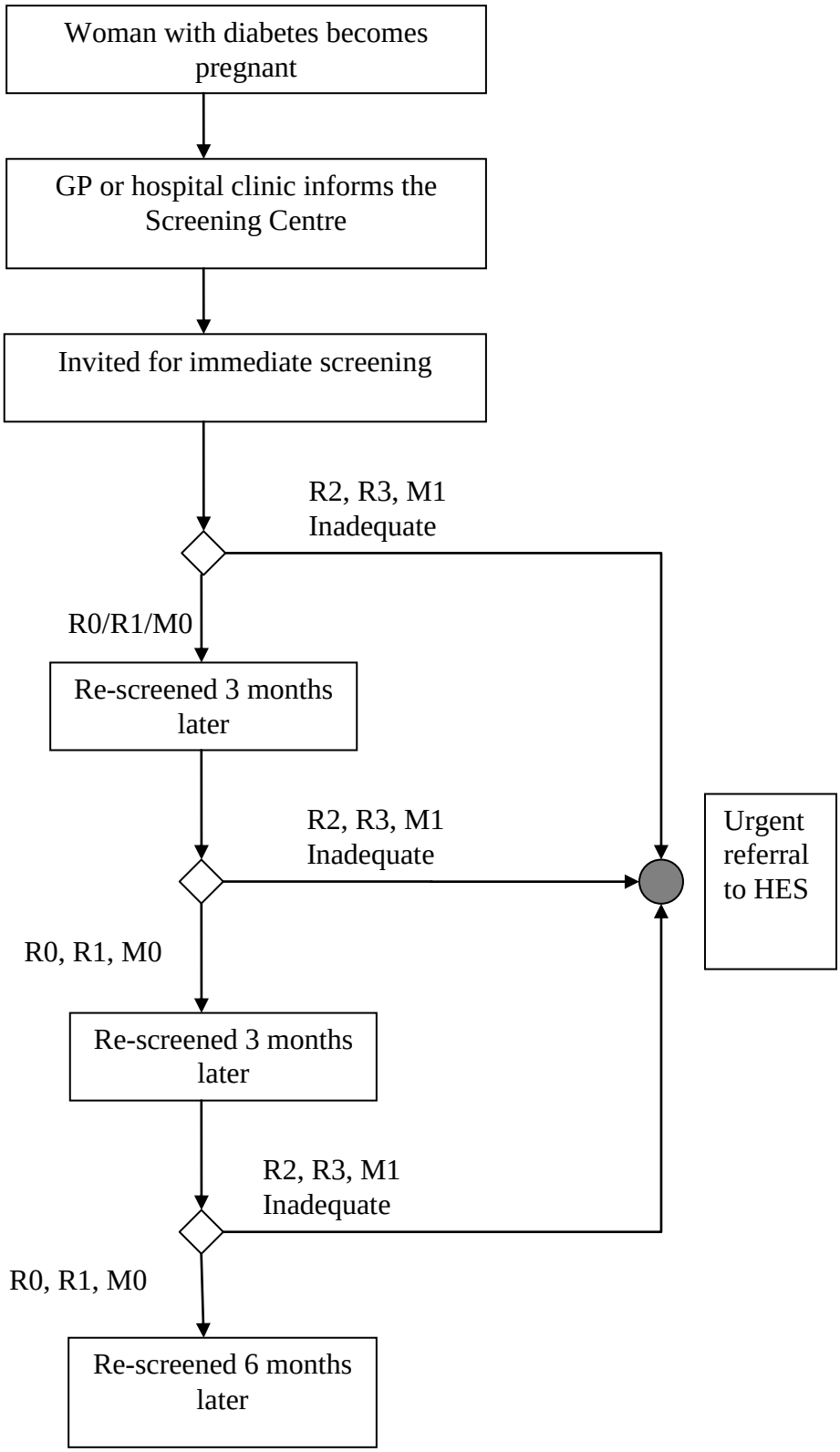
Dilation with 1% Tropicamide in pregnancy

Although the NSC guidance advises that digital screening after mydriasis should be used in pregnancy it also states that Tropicamide should be used under the supervision of registered doctors in pregnant women.

When the screening office is informed that a woman is pregnant the GP is asked to give permission for dilation with Tropicamide to occur. **Check the Patient's screening record and if it has been stated that the GP has given permission, 1% Tropicamide can be used. If there are no such notes in the record, screeners should not use Tropicamide to dilate but still take images undilated. Also, screeners should flag this up with the screening office, but never wait until permission has been granted. Wherever possible, screening should be undertaken on the day and not delayed, due to the increased risk of progression.**

PHENYLEPHRINE SHOULD NEVER BE USED WITH PREGNANT WOMEN

Screening Pathway during pregnancy



9. Ocular History

All screeners must follow this procedure to ascertain the patient's ocular history:

- Ask if they have had a recent eye test at the opticians
- Ask if they have ever worn spectacles for distance vision
- Ask if they have ever had any eye treatment
- Ask if they have always had poor vision in one eye and the reason why
- Ask the patient if they have any current eye conditions and if so, are they are still under the care of the Hospital Eye Service(HES)
- Ask if they have had any eye conditions in the past

Screeners should always advise patients that they still need to have regular eye tests, as the screening process does not identify all possible eye conditions. In many cases this will be annual but may be less frequent according to the clinical judgment of their own optometrist.

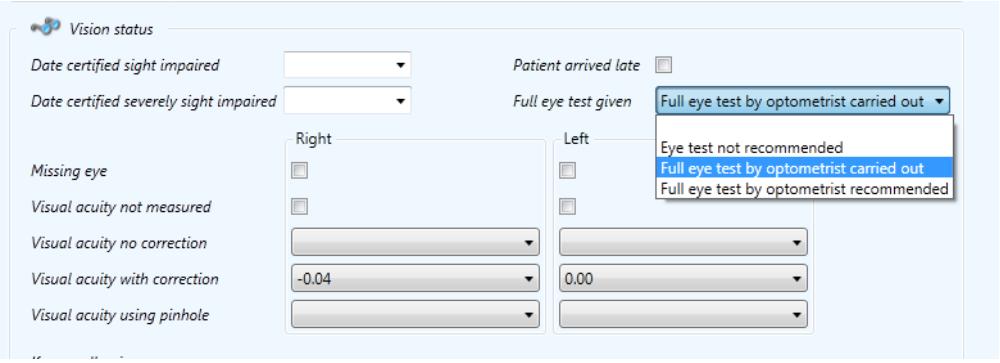
Record in the pre-screening comments if the patient has not brought any spectacles they normally use for distance vision, even if not worn permanently.

Record any eye conditions and eye treatment reported by the patient in pre-screening comments or patient notes, unless if it has been recorded previously and hasn't altered. However, if the patient has a known history of ocular disease, always record whether they are currently under the HES.

If the patient attending only for screening mentions any recent ocular symptoms or concern about their eyesight, please advise them to have an eye test as soon as possible, regardless of the outcome of screening. Also, tick the "Full eye test by optometrist recommended" tab in the pre-screening section and report this in comments.

10. Eye Tests at the same time as screening

Screeners must **always** fill in the “Full eye test given” field by choosing one of the lines from the drop-down menu.



1. In many cases, the patient will have had an eye test at the time of screening, so where this applies, the option “Eye Test by Optometrist carried out” should be chosen

2. Patients are always encouraged in the invite letter to have a regular eye test as well as screening. If the patient attends only for screening and doesn’t have an eye test at the same time, the screener should routinely choose the “Full eye test by optometrist recommended” option

3. Chose “Full eye test by optometrist recommended” even if the patient indicates that they don’t wish to have an eye test. **In these cases, the screener must always record this as “Comments” in the pre-screening section**

4. If the patient attends for screening only and the screener suspects other ocular pathology during the screening process, they should advise the patient to have an eye test and chose the “Full eye test by optometrist recommended” option. **In these cases, the screener must always record this as “Comments” in the pre-screening section or “Notes” in the capture screen section.**

5. If the patient attends for screening and the screener suspects non-diabetic ocular pathology during the screening process, they believe requires urgent referral they should contact the Failsafe officer by phone immediately, stating all relevant details. **In these cases, the screener must always record this as "Comments" in the pre-screening section or "Notes" in the capture screen section**

6. The "Eye test not recommended" option should **only ever** be chosen If the patient has already had an eye test within the last 3 months, has **no** current symptoms **nor** signs of ocular disease on the images. **If choosing this option, the screener must always record this as "Comments" in the pre-screening section to confirm why an eye test is not advised**

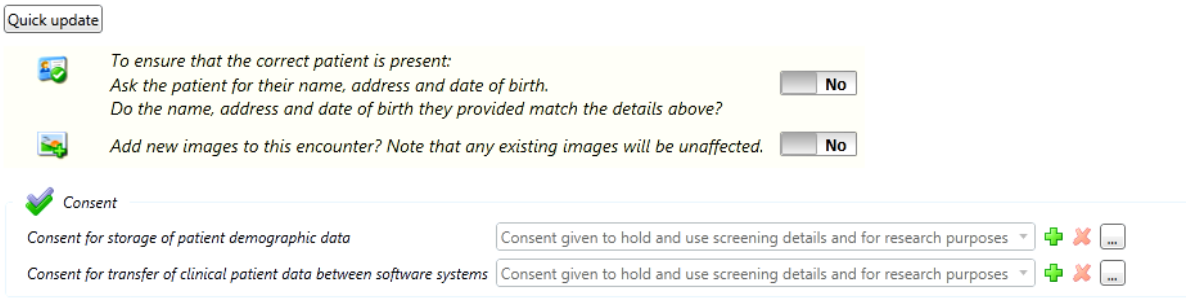
7. **Screeners should not choose the "Eye test not recommended" option for any other reason, as non-diabetic ocular pathology may be found during the screening process**

11. Image Capture

Reopening patient record

When the patient returns for image capture once fully dilated, the screener should access the patient record by clicking on the patient's details in the front screen clinic list.

The screener must first establish again that they have the correct patient in front of them by asking the patient their date of birth and confirming if this is correct by clicking on Yes. If the answer is no, the screener should suspend the screening episode and call the Screening Failsafe Officer for further instructions. **This should be repeated each time this screen is accessed.**



The screener must then confirm that the patient has given the required consent or indicate on the rare occasions if they have not given full consent.

Moving onto the next screen, the screener should always confirm the following is correctly recorded:

- Whether a sight test was carried out or not (see section 10)
- The VA and how it was measured (see section 6)
- Details of the drops (see section 7)
- Whether there are any known reactions to drops (see section 7)

Camera settings

The Cheshire digital imaging document demonstrates the correct camera setting. A copy of the document can be accessed at www.centralmerseyloc.org/diabetic-retinopathy-screening/

Image positions

The NSC policy document states the following:

Macular

- Centre of fovea ≤1DD from centre of image and vessels clearly visible within 1DD of centre of fovea
- Vessels visible across >90% of image

Adequate:

- Centre of fovea >2DD from edge of image
- Vessels visible within 1DD of centre of fovea

Nasal

- Centre of disc ≤1DD from centre of image and fine vessels clearly visible on surface of disc
- Vessels visible across >90% of image

Adequate:

- Complete optic disc >2DD from edge of image
- Fine vessels visible on surface of disc

Wherever possible, images should be taken in the order Right Macular/Right Nasal/Left Macular/Left Nasal. This will minimise errors, such as incorrect image field, missing or duplicate images. It will also avoid confusion for graders, who may record lesions for the wrong eye.

12. Poor quality images

Screeners should follow these procedures to obtain the best possible images during capture:

- After capture, open each image by double clicking on the image to enlarge and inspect each image carefully for positioning, quality and artefacts
- Retake every image that is blurred, incorrectly centred or with artefacts
- Carefully inspect any further images
- If some parts of the image remain poor, take additional images at offset angles, using external fixation if necessary, to capture the unclear parts of the retina
- Take an anterior shot if the images are dull or cloudy to demonstrate any media opacities, if present
- Delete the poorest images, ensuring all fields are adequately covered as far as possible

Having followed this procedure, if screeners still have had difficulty obtaining good quality images, they should make a comment in the patient's screening record on the capture screen.

The main reasons for poor quality images include:

- Patient positioned away from camera
- Poor dilation
- Cataract
- Ptosis
- External ocular condition, e.g. Corneal scar
- Learning disabilities

Where there are media opacities, e.g. cataract or corneal lesions, screeners should take external images to demonstrate.

Flash Level

If the images are dull, even after every attempt has been made to obtain maximum dilation, increase the flash level to improve image quality.

Where the images are dull, screeners should increase the flash level up 1 or 2 steps at least and retake images. If the new images are better, the other images should be deleted, and the new ones retained.

Additional Images

Where it is not possible to obtain ideal images, additional images at varying angles can ensure the fullest coverage and may avoid graders needing to set the images as inadequate. This process is known as “Jigsawing”

Where the images are poor quality, screeners should always utilise external or offset fixation to take additional images at varying angles, so the full set of images covers all the area usually covered by the standard set.

Artefacts

The main reasons for artefacts include:

- Dust
- Dirt
- Condensation
- Smudge

If there is an obvious artefact, make a comment in the patient’s screening record**.** Screeners should make every attempt to ensure the camera is well maintained.

All screening sites have a responsibility to ensure their camera is always clean and free of artefacts.

13. Prioritising Image sets

Once images have been captured, the screener must prioritise all image sets for the grading process. There are 3 choices within the capture screen, Green, Amber or Red and one must be chosen after capture for each patient screened.

Red:

Red should only be chosen when:

- There are signs of advanced diabetic retinopathy, such as:
  - New Vessels on the optic disc
  - New Vessels elsewhere
  - Pre-retinal Haemorrhage
  - Vitreous Haemorrhage
  - Fibrosis
  - Retinal Detachment

- Samples of these lesions can be seen in the "Proliferative Retinopathy Image library", available for download on the Central Mersey LOC website.

- Samples of old proliferative lesions can be seen in the "Stable Proliferative Retinopathy Image library", available for download on the Central Mersey LOC website.

Where screeners prioritise as Red they must also carry out all the following procedures:

- **Make notes in the patient record card to inform the screening programme why they have flagged as Red, e.g. New Vessels, Pre-retinal Haemorrhage, Fibrosis or Retinal Detachment**

- **Phone the Failsafe Officer at the programme Screening Office immediately, stating the patient details**

- **Send an alert message to Bob Wilkes, the Clinical Adviser**

Amber:

Amber should be chosen:

- Where there are signs of Maculopathy or more advanced Diabetic Retinopathy, such as:
  - Multiple blood spots
  - Larger blood spots
  - Vessel abnormalities
  - Cotton-wool spots
  - Any Exudates on the macular images

  Samples of these lesions can be seen in the "Amber Priority Image library", available for download on the Central Mersey LOC website.

- Where there are signs of previous laser treatment, but none of the signs listed in the red category

- Where the VA, in at least one eye, is 6/12 (+0.30) or worse, or where it has not been possible to measure VA

- Where "Missing eye" has been selected

- Where it has only been possible to obtain a partial set of images, or poor-quality images

- If there are signs of other, non-diabetic disease that affects the retina visible on the images

Notes should always be made when Amber has been chosen.

Where screeners have any concerns regarding these patients, or want them to be assessed more urgently, they should phone the Failsafe Officer at the Screening Office and send an alert message to Bob Wilkes, Clinical Adviser.

Green:

Green should be chosen when:

- Where there are only minor signs visible, such as one or two small blood spots
- Where there are no signs of diabetic retinopathy at all

If there are any doubts about whether to set the patient as Green or Amber, Screeners should select Amber and make suitable notes by way of explanation.

Please note that the Red, Amber or Green priority must always be chosen in the capture Screen before completing the episode. It is not possible to re-set the priority after saving. If you realise later that you have set the wrong priority, report it to Failsafe by phone immediately and via alert message to the Clinical Adviser.

14. Completing image capture

Once all images have been taken, chose the most appropriate priority (see section 13) and click “finish”. The images tend to take around 10 minutes to upload but may take up to 20 minutes to fully save in the database.

To ensure all images have been uploaded to the screening programme database, undertake the following procedure before the next patient:

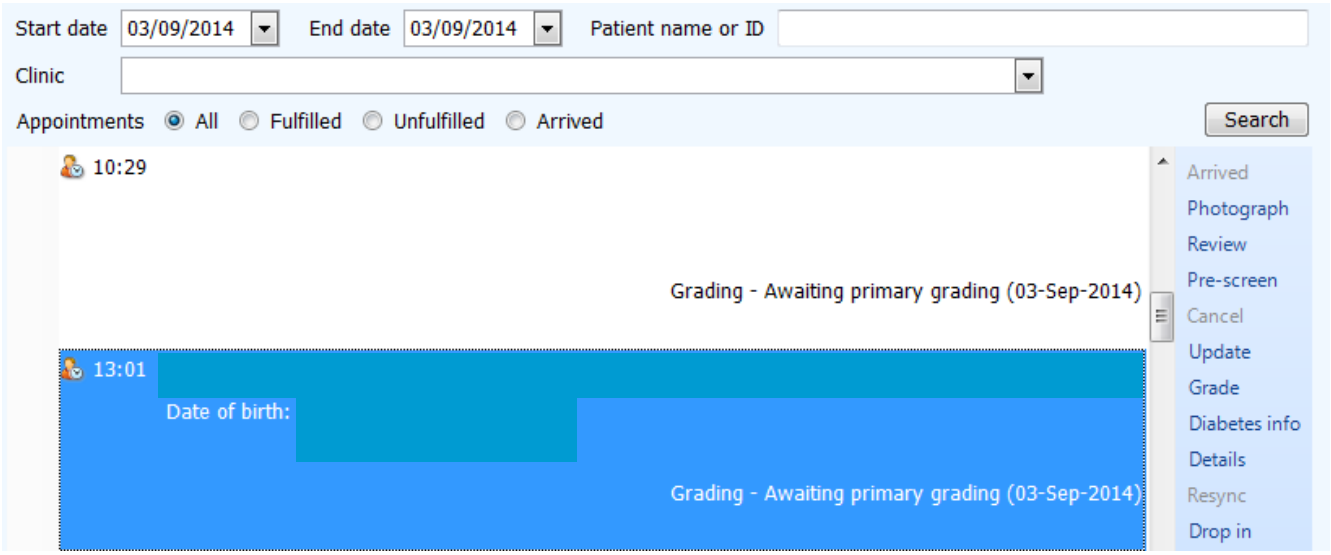
- Click on “Resave Images” underneath “System Maintenance” on the main OptoMize screen
- Click start
- If there is an error message, take whatever action is advised in the message and also contact the Failsafe Officer
- When the process is complete “Operation ended” will appear as the last line in the Status box
- Access the patient again via the Patient Review option
- See if the images are now all present and correct
- If not, contact the Failsafe officer immediately and the screening office will assist in rectifying the situation
- If the images cannot be recovered, it may be necessary to re-screen the patient. Follow the instructions of the screening office to rectify

Reviewing patient images

There are 2 possible ways to review patients, once screening is complete. As per section 4, screeners can review patients up to 6 months post screening, or once they have rebooked a screening appointment.

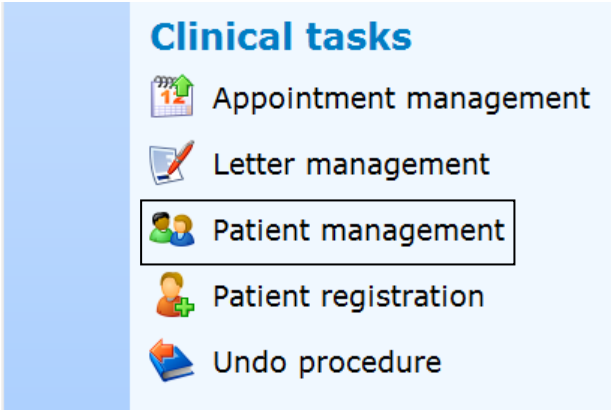
On the day of screening:

On the front screen, highlight the patient in the clinic list, by clicking on their information until the box is shaded in blue. Click “Review” in the middle section of the screen. This will take you to the review screen mode, where you can see the images and make further comments in the “Patient Notes” tab.

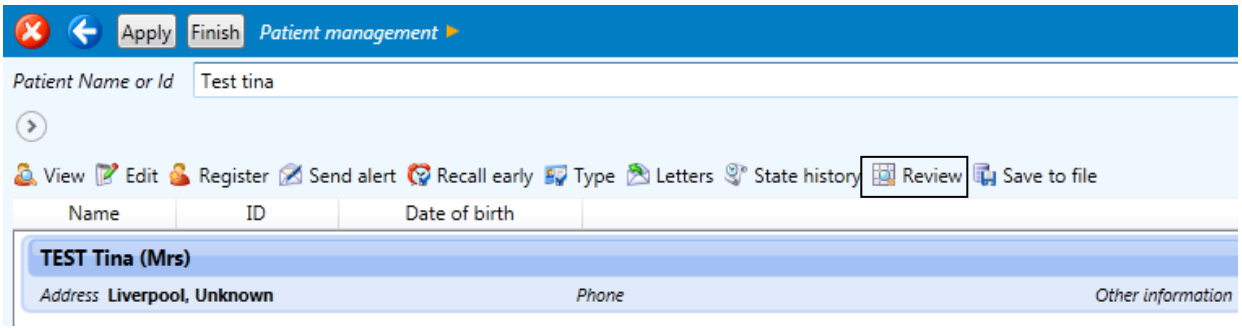


After the day of screening:

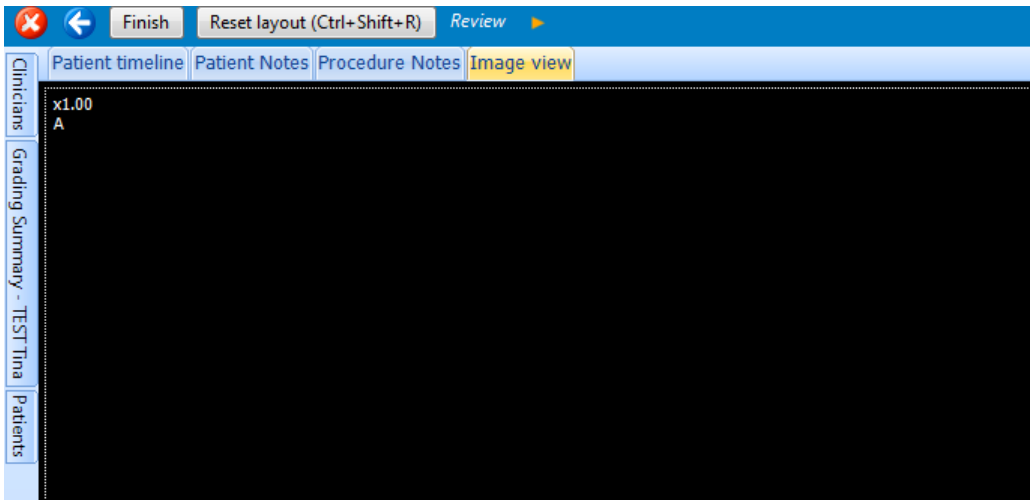
On the front screen, under the heading “Clinical Tasks”, click the “Patient management” tab.



Type the patient’s NHS number into the box headed “Patient’s name or ID” and the date of birth, where required and click search. This will bring up the patient in the viewing plane. Highlight the patient and click the “Review” icon.



This will take you to the review screen mode, where you can see the images and make further comments in the “Patient Notes” tab, if required.



15. Exception Reporting

Where a screener finds it impractical or impossible to screen a patient, they should inform the screening office. This will enable the programme to decide the best course of action for the patient.

Typical instances where this may be appropriate:

- Equipment failure
- An uncooperative patient, e.g. with Dementia
- Patient physically unable to reach the camera

Procedures for reporting exceptions

- Inform the Failsafe Officer at the Screening Office, providing all relevant details

- Please indicate if you feel exclusion from screening is in the best interests of the patient

- Screener should take a dummy image, say of the back of their hand, so there is at least one image saved against the patient

- Send an alert message to:
  - Failsafe Officer
  - Clinical Adviser including the patient's NHS number, name and date of birth

In most cases the programme will still send for slit lamp screening to obtain further assessment and advice. In some cases, it may be appropriate to consider exclusion from screening, on the advice of the screener, as well as family and carers, if slit lamp screening is likely to be impossible also.

After this, the programme administration team will seek the advice of the clinical leads and if approved, will arrange to exclude the patient if this is considered appropriate. In most cases, the patient will also be referred to HES for further assessment.

Image Quality setting at capture

Screeners should not alter the image quality setting to "Inadequate" when in the capture screen mode, as this causes some administration issues. **Screeners should always leave this set as "Adequate" <u>in all circumstances.</u>**

16. Where images cannot be captured to Optimize

There are certain instances when it is not possible at all to capture images using OptoMize at the time of screening, e.g. due to VPN connection loss, computer hardware or software malfunction. However, these should only be isolated, rare occasions.

If you experience circumstances that mean you are unable to capture straight to the capture screen and have to capture using alternative software which can be added later, the following Failsafe procedure **must** be followed:

- Contact the Failsafe Officer at the Screening office by phone **immediately** after you experience the problem, stating clearly the reasons why you cannot capture in the usual way

- Provide the screening office with full details of all patients affected, as per the office's instructions

- Inform the Clinical Adviser via phone, alert message or email (Observing protocol set out in section 21)

- The screening office will make suitable arrangements for the images to be added to the patient's record and the episodes completed. All such episodes will be monitored by the programme management to ensure the correct images are assigned to the correct patients. **Do not send images unless expressly asked to do so by the programme management**

- Screeners must **never** use the Folder Capture option to add images to a patient record unless given express permission to do so by the programme Failsafe Officer, Programme Manager or Clinical Adviser

- If the problems precluding normal capture run into another day, the screening venue **must** contact the Failsafe Officer at the Screening Office for permission to continue screening using alternative software

- If permission is granted to continue screening using alternative software, the procedures set out above must still be followed

Under no circumstances should screeners add images later unless specifically advised to do so by the programme management. Any transgression will lead to immediate suspension from the programme pending disciplinary procedures. This may lead to removal from the programme as well as referral to any relevant professional body, e.g. GOC for breach of clinical protocol.

17. Making notes

Notes should be made very regularly to explain and inform the programme and assist the graders. All notes made in the patient's screening record are internal, so please keep comments clear, concise and relevant.

Screeners **must always** make notes in the following cases:

- If the amber or red priority has been chosen, to confirm what lesions were seen
- To confirm why the VA is 0.3 (6/12) or worse or to inform the programme that no reason is known
- To explain the reasons for difficulties in screening where any part of an image field is incomplete
- To explain the reasons where due to difficulties in screening one or more images is missing
- To provide details of any known diabetic ocular condition, as well as previous treatment
- To provide details of any known non-diabetic ocular condition, as well as any known treatment
- To confirm if a patient is currently under the HES
- To provide details of any non-diabetic condition suspected during an eye test at the same time as the screening
- To confirm if a sight test was particularly recommended due to signs or symptoms identified during the screening process
- To confirm reasons why a sight test was not recommended at the time of screening

Mostly, these notes should be made as "Procedure Notes" when in the pre-screening or capture screen. Once the images have been saved, screeners should make any subsequent notes in the Review mode, using the "Patient notes tab.

18. Referrals following screening

Diabetic Retinopathy

All referrals for Diabetic Retinopathy must go through the screening programme. If any screener or other member of the provider's staff feels the patient requires referral for diabetic retinopathy, they should:

- Flag the image set up as red if new vessels, pre-retinal/ vitreous haemorrhage or fibrosis is suspected. For all other DR, flag up as Amber
- Make comments in the patient's OptoMize record
- Phone the failsafe Officers at the Screening Office
- Also, send an alert message to the Failsafe officers and Clinical Adviser
- The office will then fast track the grading through the system to ensure the correct referral process is carried out

Non-Diabetic conditions

If the patient did have a sight test at the same time as screening, the practitioner undertaking the sight test has the sole legal responsibility to identify and manage non-diabetic conditions appropriately, under local protocol. Therefore, if the screening venue refers the patient for non-DR conditions, this should be clearly stated in comments of the patient's screening record.

If the Optometry screening venue is unsure if an eye condition found in the screening process is diabetic retinopathy and whether they need to refer or not, they should make comments in the patient's records and contact the Clinical Adviser for advice.

Although the screening programme has no duty to identify any ocular pathology other than diabetic retinopathy it will make referrals to the Hospital Eye Service for other eye conditions shown on the images, if considered necessary. Alternatively, the programme may add notes to the GP outcome letter, so the GP can take appropriate action.

Unless the screening venue has made specific comments to state that they have referred the patient themselves, the screening programme may have to refer non-DR conditions identified from the images to the GP or Hospital Eye Service.

19. Completing the screening episode

Once image capture is complete, the screener should inform the patient about the rest of the screening process. The following information should be discussed with the patient:

Images

Screeners should generally show the patient the images if they wish to see them, particularly if they specifically request it. However, if a screener, in their own judgment, feels it would be not in the patient's best interests to see the images, they should suggest the patient contacts the screening office for further advice. Alternatively, they could contact the screening office or clinical adviser on the patient's behalf.

Diabetic Retinopathy

Screeners should use their own judgment whether to discuss diabetic retinopathy with the patient. If they consider it is not in their best interests, e.g. if the patient feels unduly anxious or distressed, they should suggest the patient contacts the screening office for further advice. Alternatively, they could contact the screening office or clinical adviser on the patient's behalf.

Further information

If the patient requests further information regarding the screening and grading process or diabetic retinopathy in general, advise them to contact the screening office for further advice. Alternatively, screeners could contact the screening office or clinical adviser on the patient's behalf.

If the patient wants to access online information regarding NHS Diabetic Retinopathy screening, they can go to the official NHS Choices website: http://www.nhs.uk/conditions/diabetic-retinopathy/Pages/Introduction.aspx

The Grading Procedure

- All screening episodes will go through at least one grade, the First Grade

- Most image sets with some diabetic retinopathy present will proceed to a Second Grade by a different retinal grader than the First Grade

- Image sets with signs of proliferation at the first grade will be fast-tracked to Referral Outcome Grading (ROG)

- 10% of those found to have no diabetic retinopathy present at First Grade will be chosen randomly for a second grade. This is to assist in monitoring grading performance

- Where the First and Second Grades disagree, there will be an Arbitration Grade, by a more senior grader, who didn't do either of the first 2 grades

- All graders in the programme do First and Second Grades, but only senior graders do Arbitration Grades

- All cases where referable diabetic retinopathy is found as well as those where the images are inadequate will undergo a final Referral Outcome Grade (ROG)

- The Referral Outcome Grade will decide upon 3 possible outcomes:

    - Refer to HES

    - Bring back for Digital Surveillance screening in 3 months

    - Send for Slit Lamp screening

Screening Outcome

- Over 90% of cases require no referral to the HES, just recall for further screening

- Some cases with more significant diabetic retinopathy may be recalled sooner for Digital Surveillance screening rather than be referred to the HES. In all such case, they will be recalled 3 months later for Digital Surveillance

- Patients recalled for Digital Surveillance screening will receive similar invite letters and screening will be carried out using the same procedures as for all other screening

- In some cases, where it is not possible to make an adequate decision based on the images, the patient will receive an invite for Slit Lamp BIO screening

- A small number of cases, around 7%, will receive an appointment from the HES local to where they live to attend for further assessment. The patient should liaise with the hospital trust sending out the appointment letter or the Screening Office if the appointment is inconvenient

- The patient should receive an outcome result letter within 3 weeks of screening. If the patient does not receive their letter, they should contact the screening office

- The GP should receive a similar letter around the same time

20. Digital Surveillance

After grading is completed, a small percentage of patients will be sent to the Digital Surveillance list. The first time a patient is added to the Digital Surveillance list, they will be invited again 3 months later.
The common reasons for digital surveillance includes:

- Referable retinopathy which ROG decides only requires monitoring
- Patients maintained by Digital Surveillance graders
- Patients discharged from HES
- Pregnant ladies who require more frequent examination
- R3s patients with signs of stable proliferative changes, e.g. old fibrosis

When the patient attends for Digital Surveillance, the Digital Surveillance graders will decide on further outcome. This would include:

- Invite for further Digital Surveillance in 3, 6 or 9 months
- Refer to HES
- Discharge back to the general screening list for the usual annual recall

21. Screening queries and notification

Queries regarding screening that require patient identifying information, e.g. NHS number, date of birth; address etc. should **only** be communicated via OptoMize Alert messages. Screeners should not send messages including patient identifying information via email, unless both the sender and recipient are using NHS email addresses. However, it is acceptable for screeners to send an email message to inform someone that they have sent them an alert message, but it must never include patient identifying information.

Any transgression will lead to immediate suspension from the programme pending disciplinary measures. This may lead to removal from the programme as well as referral to any relevant professional body, e.g. GOC.

Alert Centre

Screeners should access the Alert Centre each time they log on and read all new messages present. They should also respond to all messages promptly and make appropriate replies, where required.

The latest document available on correct use of the OptoMize Alert Centre, “Messages in Optomize November 2016” can be downloaded on the Central Mersey LOC Website.

- To send an alert message regarding a specific patient, screeners should always use the “Patient Management” mode and select the “Send alert” option, so patient details are included in the message

- **Patient ID should never be included in the subject line of any OptoMize message**

- **<u>Never</u> select the “All users” option, which should only ever be used by the programme management in exceptional circumstances**

22. OptoMize Problems

The correct procedure if you experience any problems accessing OptoMize or it crashes during screening and you can't get it working again:

- Complete any image capture on patients already dilated using alternative software
- Save all images taken to a unique file on your PC, with all images correctly titled as set out in Section 16
- Suspend screening on any further patients
- Contact the Emis Health Helpdesk on 01954 207300
- Inform the Failsafe Officer at the Screening Office, providing all relevant details
- Inform the Clinical Adviser via phone, alert message or email (Observing protocol set out in section 21)
- Carry out any instructions given to you by Emis Health and the screening office to rectify the situation
- Only return to screening when the situation is fully resolved and OptoMize is working normally again, unless temporary permission has been granted by the Failsafe officer to use alternative software, as per section 16

23. VPN connection Problems

The correct procedure if you experience any problems logging onto the VPN token or you lose connection during screening and you can't get it working again:

- Complete any image capture on patients already dilated using alternative software
- Save all images taken to a unique file on your PC, with all images correctly titled as set out in Section 16
- Suspend screening on any further patients
- Contact IT on 0151 676 5678
- Inform the Failsafe Officer at the Screening Office, providing all relevant details
- Inform the Clinical Adviser via phone, alert message or email (Observing protocol set out in section 21)
- Carry out any instructions given to you by IT and the screening office to rectify the situation
- Only return to screening when the situation is fully resolved, and the VPN token is working normally, unless temporary permission has been granted by the Failsafe officer to use alternative software, as per section 16

24. Resources

Screening Office

Millbrow Clinic
Widnes
Cheshire
WA8 6RT
Tel: 0151 495 5100

Failsafe Officers

Ring the general number, 0151 495 5100 and ask for the duty Failsafe Officer.

Programme Manager

Kimberley Gallienne
Email: k.gallienne@nhs.net

Clinical Lead

Dr I Kumar
Email:Indu.kumar1@nhs.net

Clinical Adviser

Bob Wilkes
Email: bob.wilkes@nhs.net
Telephone: 0151 426 2214 or 078502 46331

Documents

All documents required for screening will be available to download on the LOC website at: www.centralmerseyloc.org/diabetic-retinopathy-screening/

25. Amendments to previous version, July 2017

- Section 2: Extensively re-written, particularly to consider new national qualifications and updated procedures for staff accreditation
- Section 3 Page 7: first paragraph rewritten
- Section 4: A small amount of rewording
- Section 5: Extensively rewritten; New procedures regarding patient consent
- Section 6: New procedures regarding use of Pinhole; New procedures for use of “Missing eye”
- Section 7: Dilation: new procedures for use of Phenylephrine; New requirement to always take images undilated in all cases, if the patient cannot be dilated; Updated procedures to record adverse effects of dilating drops
- Section 8: Pregnancy: new procedures if permission to use Tropicamide has not been added to the patient record
- Section 10: A small amount of rewording
- Section 12: Poor quality images: some rewording
- Section 13: Prioritising image sets-new wording for red and amber criteria
- Section 15: Exception Reporting: Renumbered and extensively re-written; Removes requirement to record exception on capture screen
- Section 16: Some rewording and procedures for handling images removed. All such cases will be treated on an individual basis in future
- Section 18: Modified procedures for dealing with Non-DR conditions
- Section 19: Pages 39 & 40: some additional wording
- Section 20: New section on Digital Surveillance

- Section 21: Screening queries: additional wording; Obligates screeners to use the optimum method to send alert messages

- Section 22: OptoMize problems Some rewording

- Section 23: VPN connections problems: Some rewording

Signature Sheet

- I am a retinal screener registered with the Central Mersey Diabetic Retinopathy Screening Programme
- I have read the Screening Protocol September 2018
- I agree to fully comply with the Screening Protocol

Signature:

Name:

Date:

This form must be completed and signed by all screeners registered in the Central Mersey Diabetic Retinopathy screening programme. Please return a paper copy of this form to the Clinical Adviser at Millbrow by 5.00PM on Friday 28th September 2018. Screeners who do not return the form by this date will be suspended from accessing the OptoMize software until further notice.