National Diabetic Retinopathy Screening Programme
Principles, Processes and Protocols

City & Guilds Unit 001

This document is intended as a resource and help document to assist you in answering the questions in Unit 1. It is the case that C&G are more pedantic about answers than we are used to, and the pass mark is very high. This is, in part, because these are not “exams” but rather continual assessment processes. It is possible to resubmit having corrected and rejected answers.

When you submit your work to our own assessor, he will indicate where your answers differ from the model answer required by C&G and will give you guidance on correcting those answers.

The main resources required to answer Unit 1 are the NSC Workbook 4.2, available from the NSC website at www.retinalscreening.nhs.uk, and the lecture notes from Lyndon Taylor’s talk, which are available at www.smdrs.co.uk. There is also an audio recording of Mr Taylor’s talk which is available for download.

All questions should be answered in your own words after reading all available resources. **PLEASE ANSWER EACH QUESTION FULLY AND REMEMBER THAT THE INTERNAL VERIFIERS OF THE C&G GLOUCS SPOT MARK OR SAMPLE INDIVIDUAL QUESTIONS, SO REFERRING TO PREVIOUS ANSWERS IN YOUR DOCUMENT UNFORTUNATELY WILL NOT DO.**

**Task A**
The first question (a) needs a statement which defines screening, which is a process in which members of a defined population who may be at risk of a disease or complication are offered a test intended to identify those who are likely to be suffering from the condition and who may be helped by appropriate treatment. So ‘screening’ is a process of reducing the risk for the members of the defined population, who may not realise they are at risk of the disease or condition in question.

In (b) the criteria normally quoted to define the criteria for a condition that justifies screening are those of Wilson and Jugner

- The condition should be important.
- There must be a recognisable (detectable) latent or early symptomatic stage.
- The natural course of the condition, including development from latent to actual disease, should be adequately understood.
- There must be a suitable test or examination.
- The test must acceptable to the population being screened.
- Screening should be a continuous process, not a one-off
- There must be an accepted treatment for patients with recognised disease
- Facilities for diagnosis and treatment must be available.
- There must be an agreed policy concerning whom to treat as patients.
- Screening must be cost-effective – in other words, the cost of case finding, diagnosis and treatment must be reasonable and sustainable.
In question 2 it is simply necessary to state that screening for diabetic retinopathy is intended to detect STDR (Sight Threatening Diabetic retinopathy) at an early stage at which it is treatable and before any significant visual loss.

In question 3 you should indicate that DR remains the major cause of blindness in people of working age because DR is asymptomatic until it is in its advanced stages; untreated advanced retinopathy is sight threatening and the treatment of DR has a better prognosis if it is done in the earlier stages of the disease – so it can be reasonably successfully treated in most cases so long as it is identified at an early stage – generally this means before the person is aware of any problem.

In question 4 you should point out that screening schemes are unlikely to ever detect every instance of a DR and there will generally be a number of false positives – apparent cases of DR which turn out to be normal. In the case of DR screening the standards are the so called Exeter Standards for sensitivity (the extent to which true positives are detected) and specificity (the extent to which false positives are recorded), which are 80% and 95% respectively.

It is worth adding that screening does not set out to detect any other eye disease, although it may find some opportunistically.

In 5a you should point out that screening itself can be stressful due to worry and concern about the outcome, even though this may turn out to be normal. Patients may prefer not to think about the potentially serious consequences of a positive finding which could cause them serious stress and worry and affect their life. A positive finding may have the potential to affect their job and income, as well as their health which can be stressful if the result is positive and stressful to think about ahead of screening, even if there is no reason to expect a positive finding of DR.

Question 5b requires you to discuss that DR screening is unique in that it involves screening a population who already have an identified health condition and is testing for a particular complication of that condition. Other screening schemes involve screening a defined, but healthy population.

Question 6 refers to the process of ensuring patients are sufficiently well informed to be able to make rational decisions about participating in a screening programme. This means that they need to be informed about the whole of the process and its consequences. They need to know:

- What is involved
- Any risks
- What happens if they test positive
- How often they need to attend if they test negative
- How their information is stored and used
- The potential consequences of choosing to opt out of screening
Question 7a requires you to list the important components of a systematic screening programme for DR. These will include

- The target population must be accurately identified – this effectively means from GP records.
- A robust register of all patients with diabetes within the area covered by the screening programme must be created and which should be kept up to date at all times.
- There must be provision for a robust central call/recall of patients from a single centre for their screening.
- Screening must use digital imaging with grading to national standards.
- SLBIO should be used in cases where the images are inadequate.
- There must be protocols for imaging, grading and referral to national standards, all of which is undertaken by trained and accredited staff.
- There must be robust and effective quality assurance of all stages of the screening programme. The use of a software management system contributes towards this.

Within SMDRSS (7b) the central register is assembled and maintained via regular extracts of patients with diabetes from GP practice management systems. Each participating PCT is responsible for assembling the data from its locality and submitting that on a monthly basis to the SMDRSS office for upload to the central register within the software management system. The call/recall is then managed centrally from the SMDRSS office using the HISL Vector software. Screening is provided from optometry practices, where the 1st grade is also performed. 2nd grading is also provided by optometrists within the programme, which arbitration grading is carried out by a small number of optometrists. SLBIO in case of inadequate images is carried out by optometrists. All optometrists are undertaking the City and Guils modules in DR screening and have also attended a number of lectures and continuing education sessions. The quality is assured by using the software to manage 2nd, arbitration and referral triage grading and by producing management reports on grader performance and other aspects of the screening programme.

Question 7c The local model has a number of advantages and disadvantages. Patients have a wide choice of local optometric practices with easy access, and wide choice of appointment times. Patients in the area are already used to optometric based screening, and are able to have an eye examination at the same time if they wish. Slit lamp biomicroscopy (SLBIO) is also available. Practices can easily accommodate an increase in number of screenings if required so capacity is very elastic. Also there is good QA of the photographic screening with grading of the images being independently re-evaluated by a 2nd Optometric grader.

Software/Hardware enables the patient details to be effectively delivered stored and graded and managed, including communicating results to the patient and relevant health professionals.

There are also disadvantages which include the large number of locations making the programme slightly more challenging to manage and quality assure; the large number of graders making practical assessments more challenging and the fact that some have suggested it may be more expensive than other models, though there is no hard evidence of this. A general disadvantage of photographic screening is often said to be that it cannot detect macular oedema as effectively as SLBIO. Whilst this
may be true, photographic screening relies on surrogate markers for maculopathy – such as exudates and is still quite sensitive.

One disadvantage with photographic screening is that it is poor at detecting macular oedema but SLBIO and other tests may be available in the practice at extra cost to the NHS PCT. An optometric based system is relatively expensive for the PCT. It can be more difficult to manage a large number of screening locations, and a large number of graders can make QA more complicated.

In question 8 there are a number of possible consequences of poor performance; sight threatening eye disease may be missed, with the attendant consequences of unnecessary sight loss; this might result in litigation against the NHS and the practitioner; an excessive number of false positives would have the consequence of causing additional cost to the programme/NHS; unnecessary patient stress and anxiety may be caused, either by missing disease or by false positive findings and, ultimately, any of these might put patients off the screening process.

Question 9a requires a discussion of internal QA, which is the routine monitoring of grading performance by comparing the grading results of all graders against each other so that any outliers can be identified – as per the recently produced graphs. This would identify individual poor performers, but would not identify if all graders within the programme were performing poorly. Internal QA can be carried out by the personnel within a programme.

By contrast, external QA evaluates graders and programmes against national standards and evaluates programmes against each other. This would identify if an individual programme was performing generally poorly. External QA will generally be carried out by independent personnel from outside the individual programme – either by making a visit, or routinely by comparing the annual reports of each programme against the others. EQA grading tests allow evaluation of graders against a peer reviewed standard.

Question 9b requires a discussion or list of the benefits of QA which include; minimising errors, both false positive and false negative; identifying graders who perform below standard; ensuring a consistent standard of grading; identifying entire programmes which perform poorly; assisting in benchmarking programmes against each other and, in due course, the provision of a regular national external testing system for all graders.

In question 10, by “your national screening programme” it means the English programme (ass opposed to Wales, NI or Scotland). What is required here is to list the 19 quality assurance indicators from Workbook 4.2, and to give a short explanation of the purpose behind each one and/or what it measures. The answers below indicate the purpose, but you should also add in the min and achievable targets from the workbook. [NB, with the publication of Workbook 4.3, the QA indicators have moved to a separate document at: http://www.retinascarning.nhs.uk/userFiles/File/Service%20Objectives%20and%20Quality%20Assurance%20Standards%20-%20Release%206%20-%202009-06-16.pdf]
1. To reduce new cases of blindness due to diabetic retinopathy
   - This is the principal purpose of the screening programme and the reduction of avoidable blindness also forms one of the main Vision2020 targets

2. To invite all eligible people with diabetes for DR screening
   - Unless all eligible people are invited, some will be left out and this may result in some cases of avoidable blindness

3. To ensure the central database is accurate
   - If the database is not accurate, some people may be missed and others may be invited inappropriately

4. To maximise the number of patients who accept the invitation to be screened
   - The service is for the benefit of patients and so it is necessary to ensure that patients understand what they are being offered so that they will wish to take up the invitation. Otherwise, there will be cases of avoidable blindness

5. To ensure photographs are of adequate quality
   - Poor quality photos will reduce the chance of detecting disease and will increase costs as patients have to be brought back for SLBIO or repeat photographs. This is also inconvenient for the patient.

   [NB, remember that in most programmes the patient is recalled for SLBIO. This is not always the case in ours, but your answer will be more to C&G’s expectation if you stick with the idea that patients have to be brought back for SLBIO]

6. To ensure grading is accurate
   - Inaccurate grading will increase the risk of missing disease and will add to costs as more images end up going for a 3rd opinion due to disagreement amongst the first two graders

7. To ensure optimum workload for graders, to maintain expertise
   - Graders need to grade a reasonable number of patient episodes each year to maintain their experience and to ensure that there are sufficient episodes to quality assure their work in a statistically meaningful way.

8. To ensure timely referral of R3 cases (urgent)
   - R3 cases are potentially sight threatening quite quickly and so need urgent attention, ideally within one week and certainly within two weeks

9. To ensure the GP and patient are informed of the result
   - Patients and GPs should not be kept waiting for results. For patients this can lead to unnecessary anxiety.

10. To ensure timely consultation for all patients who are screen-positive
• Any patient who is referred may have potentially sight threatening eye disease. As indicated above, R3 requires referral within 2 weeks. Other retinopathy should be seen within 13 weeks

11. To ensure timely treatment of those listed by an ophthalmologist
• Secondary care need to ensure that patients are dealt with in a timely manner. The delay between listing and laser treatment should be not more than 2 weeks for R3 and 10 weeks for M1.

12. To minimize delay between screening and first laser treatment
• Adding the delay from screening to first outpatient appointment to standard 11 gives overall times from screening to first laser of not more than 6 weeks for R3 and 26 weeks for M1 and ideally 4 weeks and 15 weeks.

13. To follow up screen-positive patients (minimize cancellations and DNA rate in ophthalmology clinic.
• Secondary care clinics need to ensure that they follow up all screen positive patients – R3 within 1 month and R2 and M1 within 6 months, with fewer than 10% (and ideally 5%) failing to attend due to DNA or cancellation.

14. To minimise anxiety associated with screening due to inappropriate referral (by minimizing false-positives)
• The false positive referral rate should be monitored to ensure it is not more than 25% of all referrals and ideally 20% or fewer.

15. To ensure timely re-screening of people with diabetes
• Programmes need to ensure that recall letters are sent out in a timely manner. They can either aim to re-screen at least 70% within 12 months of the previous screen, or 95% within 15 months.

16. To ensure that the public and health care professionals are informed of the performance of the screening programme at regular intervals by the production of an annual report
• An annual report is the means of reporting performance to all who wish to know. This should be produced to national standards for the preceding financial year by 31st October.

17. To ensure the programme participates in external quality assurance
a. providing evidence of participation of all graders in the external image test set scheme
• This is important in order to ensure that all graders are working to consistent national standards and to ensure that a programme is not under-performing because all graders are poor and so none stand out as outliers

b. participation in peer-review visit programme
• This is important in order to exchange good working practice between programmes which, again, ensures that a programme is operating to a consistent national standard.

c. annual submission of the national minimum dataset by 31st October.
18. To optimise programme efficiency and ensure the ability to quality assure the service
   • A certain critical mass of patients is required in order to ensure the programme can run in a cost effective manner, and also so that there are sufficient screening encounters to ensure statistically significant quality assurance

19. To ensure that screening and grading of retinal images are provided by a trained and competent workforce.
   • It is important that the workforce is appropriately trained and the target is that all staff should be appropriately accredited within 2 years of commencing work within the programme.

In question 11 “State the targets for screening provision for your own national screening programme” - once again, by “national” it means the English National Screening Programme.

The target quoted in the NSF Delivery Strategy for Diabetes was paragraph 3.7:

3.7 By 2006, a minimum of 80% of people with diabetes are to be offered screening for the early detection (and treatment if needed) of diabetic retinopathy as part of a systematic programme that meets national standards, rising to 100% coverage of those at risk of retinopathy by end 2007.

The National Diabetes Support team later interpreted the above to mean:

- March 2006 80% to have been offered screening within the previous 12 months.
- June 2006 70% of those offered screening (above) to have actually received screening.
- Dec 2007 100% to have been offered screening by digital imaging within the previous 12 months.
- March 2008 80% of those offered screening in 2007 to have actually received it

The measurement of those offered and screened should be as part of a systematic screening programme that meets national standards

Question 12 asks for reasons for the importance of an accurate database of people with diabetes. These include:

- Ensuring that no patients with diabetes miss out on an invitation to be screened
- Ensuring that only people with diabetes are invited for screening
- Ensuring that, so far as possible, invitations are sent to the correct address
- Ensuring that invitation are not sent to people who have left the area
- Ensuring that invitations are not sent to people who have died
Minimizing avoidable sight loss

Question 13 requires asks for the various reasons why a patient may not comply with an invitation to be screened. These include:

- The process has been inadequately explained and they do not understand the consequences.
- They believe that, as they can see perfectly well, there cannot be anything wrong.
- They don’t like the mydriatic drops.
- They do not wish to be without their car until the drops wear off.
- They do not wish to find out that they may have a problem.
- They believe they are already being checked by their optometrist during a sight test.
  [NB, this may not apply much in this area but remember that many areas have screening that does not involve optometrists]
- They may be housebound and physically unable to leave the house.
- They may be housebound and able to leave the house with assistance, but have no-one to accompany them.
- They may have physical disabilities which prevent successful photography or slit lamp BIO and so they choose not to attend.

Task B

The answer to question 1 should be written as a short piece of prose which includes the following points:

- The programme can guard against this scenario by ensuring that the central register of patients is accurate and up to date.
- This will require frequent extracts from GP systems in order to refresh the data in the central register.
- The register will need to be checked for recent deaths.
- The more that all of these processes can be automated, the lower the chance of errors.
- To be perfect would require constant live refreshes of the register. This is not possible.
- Therefore this unfortunate situation will crop up from time to time.
- Admin staff need to be sympathetic to the situation.
- Apologise for any distress caused and assure the relative that the register will be updated so that they will not be disturbed again.
- The member of staff must ensure that this update does happen.

The answer to question 2 should also be written as a short piece of prose which includes the following points:

- Whilst their optometrist checks their eyes for many conditions, they are not a part of the quality assured screening programme.
• The screening programme is geared to look specifically and carefully for retinopathy, and the graders are trained and experienced.
• There is rigorous quality control which includes 2nd grading of many images in order to minimise errors.
• In the event of disagreement between 2 graders, a third and more experienced grader will make a decision.
• The optometrist may be excellent but they will be unable to replicate the quality assurance of 2nd grading within the practice.
• The screening programme stores the results and makes them available to healthcare professionals who may be looking after the patient's diabetes. A simple check at the optometrist will mean that any findings are not available in this way.
• However, the patient should be assured that they are doing the correct thing in seeing their optometrist as well, since the screening programme is designed exclusively to detect retinopathy and is not intended to detect other eye conditions. The sight test, on the other hand, does look for other conditions such as glaucoma, so the 2 tests are complimentary and the patient should have both, not one or the other. So in order to protect their eyesight, and to ensure their doctors have the correct information available, they should attend for DR screening as well as for a sight test.