

National Diabetic Retinopathy Screening Programmes, Principles, Processes and Protocols. (C&G Unit 301)

Much of the information covered here is from the NSC workbook on retinopathy screening which can be found on the NSC website <http://www.retinalscreening.nhs.uk/pages/> (which has been moved recently from <http://www.nscetinopathy.org.uk>) the workbook can be downloaded from the front page

The precise address is:-

<http://www.retinalscreening.nhs.uk/userFiles/File/Diabetic%20Retinopathy%20Screening%20Workbook,%20Release%204.2%202008-03-19.pdf>

It is important to use the current version (as of writing, this was V4.1 released August 2007)

What is screening?

The word “Screening has long been used in Optometry to describe many of the things we do during sight test. However over the last 20 yrs or so the word screening has come to mean a very different thing to the rest of the medical world.

The National Screening Committee (NSC) definition of screening is:-

Screening is a public health service in which members of a defined population, who do not necessarily perceive they are at risk of, or are already affected by a disease or its complications, are asked a question or offered a test, to identify those individuals who are more likely to be helped than harmed by further tests or treatment to reduce the risk of a disease or its complications

http://www.nsc.nhs.uk/whatscreening/whatscreen_ind.htm

The main points to note are that:

- 1) This is a population based process which requires considerable effort to create a robust database of that population
- 2) The process is one of risk reduction not risk removal
- 3) The condition should meet the criteria set by Wilson and Jugner

Wilson and Jugner criteria for a condition that justifies screening:-

Knowledge of disease:

- *The condition should be important.*
- *There must be a recognisable latent or early symptomatic stage.*
- *Natural course of condition, including development from latent to declared disease, should be adequately understood.*

Knowledge of test:

- *Suitable test or examination.*
- *Test acceptable to population.*
- *Case finding should be continuous (not just a "once and for all" project).*

Treatment for disease:

- Accepted treatment for patients with recognised disease.
- Facilities for diagnosis and treatment available.
- Agreed policy concerning whom to treat as patients.

Cost considerations:

- Costs of case finding (including diagnosis and treatment of patients diagnosed) economically balanced in relation to possible expenditures on medical care as whole

From all this it follows that we should try to refrain from describing a sight test as “screening for Glaucoma”. The NSC’s view is that we are merely doing “opportunistic case finding” however, one could argue that given regular recall and ongoing monitoring etc sight tests perform some aspects of screening but NOT on a population basis.

So how does DR screening meet the above criteria?

- The population at risk is easily defined and identified
- DR is asymptomatic until very advanced in almost all cases
- Optimum stage for treatment is still asymptomatic
- Untreated advanced retinopathy will lead to blindness (ie important!)
- Diabetic Retinopathy as a condition is well understood

- Retinopathy is visible on the retina well before it reaches the sight threatening stage and there is good data (eg ETDRS study) on when to treat
- The test is pretty non-invasive except for dilation!
- The difference between a screening programme and “opportunistic” case finding is in the continuous nature of the monitoring

- Treatments do exist and are available and funded
- Good data on when to treat (eg ETDRS)

Which makes DR an ideal candidate for a formal population based screening service.

The Royal College of Ophthalmologists have published guidelines on retinopathy screening [3], which state:

The evidence of effectiveness of screening is based on evidence of treatment efficacy presented later in Sections 7.3.1 and 9.3, especially after early detection, and of cost- effectiveness. Screening for diabetic retinopathy has been shown to be cost-effective in health economic terms. A Department of Health (DoH) commissioned three-centre study of cost-effectiveness in diabetic eye screening reported relatively high costs per true positive case detected. This was improved in later studies using screening techniques with higher sensitivity and specificity. A health economics study of the effectiveness of changing from opportunistic to systematic

*screening reported a small incremental cost for a large increase in cases of sight threatening diabetic retinopathy (STDR) detected. **Diabetic retinopathy therefore represents an 36 excellent paradigm for screening as laid out in the principles for screening of human disease described by Wilson and Junger in 1968.***"

Look at:- <http://www.clinicalanswers.nhs.uk/index.cfm?question=4278>

Care must be taken to understand and appreciate that a DR screening programme DOES NOT attempt to diagnose any other eye disease. Occasionally some other pathology will be so obvious as to be totally unavoidable (eg retinal detachment within the area of the photos) and require some steps to manage it but less clear cut conditions (eg 0.7CD ratio) are not the concern of the retinal screening programme. For this reason all NSC literature advises a regular sight test as well as retinal screening. Of course in an optometry based programme like S Manchester or Cheshire many screenings take place alongside a sight test which makes things easier. Of course some care is needed in setting up protocols to deal with what a second grader sees when the first grader has already dealt with the issue through the GOS!

Any test and in particular any screening test will have both a sensitivity and a specificity defined as follows:-

Sensitivity and Specificity

Sensitivity : The fraction of those with the disease correctly identified as positive by the test.

Specificity: The fraction of those without the disease correctly identified as negative by the test.

The “Exeter Standards” are that a DR screening programme must achieve 80% sensitivity and 95% specificity. More information can be found at:-

<http://www.clinicalanswers.nhs.uk/index.cfm?question=4876>

The NSC requires programmes to achieve 80% Sensitivity and 95% Specificity.

Psychological issues

Screening itself is a very stressful process for many patients. Reasons include:

- 1) Denial
- 2) Risk to job/career if screen positive
- 3) Risk of incorrect result being given either +ve or -ve. (eg high profile breast/cervical cancer screening “scandals”)

DR Screening has a few unique issues as well:

- 1) “My eyesight is fine” I don’t need screening!
- 2) Diabetic patients have a lot of health care encounters eg checks with GP, HbA1C tests, foot screening, diabetologist checks, nurse led checks etc etc. DR screening is yet another of these

- 3) Patients don't like "the drops"... mostly because they can't drive!

Informed consent is required for any health procedure. Most patients consent very readily to DR screening following the information given on the invitation leaflets. Occasionally you may be asked to explain the risks/benefits of the process eg tiny risk from Tropicamide etc. However you will very occasionally come across a patient who will want to opt out of screening and it is important that such patients are counseled carefully on the risks to their eyesight of not having regular screening. In particular the lack of any warning symptoms before irreversible damage must be understood by the patient before they opt out.

Components of a Systematic Screening Programme

- 1) Robust central data base of ALL diabetic patients in the area. This is managed by regularly updated extracts from all local GP practices from their "practice based registers"
- 2) Central call/recall/management of patient attendance. This is managed by having a single call/recall centre for the whole screening programme.
- 3) Robust QA of all stages of the screening/grading process. This is managed by the central call centre using the screening software.

The model used locally has several good and bad points:

Advantages

- 1) Photographic screening gives good QA
- 2) Good easy access for patients to a wide choice of optometric practice locations
- 3) Wide choice of appointment times
- 4) Patients mostly used to optometric based screening
- 5) Very elastic screening capacity. (practices can easily accommodate say 20% extra patients across the board if numbers were underestimated)

Disadvantages

- 1) Photographic screening is poor at detecting macular oedema
- 2) Somewhat less flexible due to constraints of centralized recall etc (eg can't screen a patient who isn't on the database such as newly diagnosed patient until GP informs DRSS admin team)
- 3) More difficult to manage large number of screening locations in an optometrist based scheme than a mobile van service eg N Manchester (cf 1 and 2 above of course)
- 4) Large number of graders makes QA more difficult
- 5) Relatively expensive for PCT to use an optometric model

Consequences of poor performance by a screener

Poor performance by a screener can cause problems for the patient, the screener, and the whole screening service:-

For the Patient

- Missed sight threatening disease leading to loss of visual function or even blindness

- Anxiety due to a false positive referral

For the Service

- Risk of being sued for missed pathology or anxiety/stress
- Lack of confidence in service if problems publicized
- Additional cost/time in managing poor performance

For the Screener

- Removal from screening service
- Possibility of being sued directly (probably only applies to Optometrists/doctors doing screening)
- Additional training requirements

Quality Assurance Systems

A full discussion of these can be found in section 2 of the workbook (p44...)

Internal QA mostly compares graders with the other graders within their programme. This should show up any grader who consistently has arbitrations “against” them and allow early identification of poorly performing graders.

External QA measures graders against national standards and so ensures that a service is at a satisfactory level as well as self consistent. This is to guard against a service where for example, all the graders consistently miss venous beading. External QA also measures the overall performance of the local programme against other programmes in England to serve as a benchmark and provide peer review. The 19 standards shown in Appendix 2 of the Workbook are part of external QA

Performance indicators

The standards set by the NSC for screening programmes can be found in the workbook in Appendix 2.

The Database

Any screening programme will stand or fall depending on the quality of its database. The database must be robust and well maintained. It is important to ensure that ALL diabetic patients are included in the database and that ONLY diabetic patients are included. Without an accurate register, it is inevitable that patients will get missed from screening and reports will not accurately reflect the patient coverage.

Also it is vital that data entry errors are kept to a minimum by electronic transfer of data wherever possible. Also a single unique identifier number should be the ONLY key to all the data. This should really be the patient’s NHS number to avoid confusion and the extra complication of adding a different number just for this purpose.

Some programmes have reported very odd results such as screening 120% of their patient base or having a patient base half as big as the total reported by their local GP practices...

A lot will depend on the accuracy of the GP practice registers on which it is based and experience shows that this is VERY variable indeed. It is not uncommon for a patient to wander into an optometrist claiming to be diabetic who is not on the register. On checking back with the GP surgery, the patient is not listed as diabetic but has had a repeat prescription for insulin for 10 yrs (in Cheshire about 5% of patients attending regularly over the last few years for screening are not recorded as diabetic by their GP's computer system!). Equally a few patients who think they are diabetic turn out not to be... (currently Cheshire has around 30 of these out of ~16,000 patients...).

Non-compliance with screening

Patients may have any number of reasons for not attending for screening. The commonest include:-

Issues to do with the screening process itself

- "I can see fine, I don't need screening"
- "I had my eyes tested at ??????? last week so they are Ok"
- "I don't like the drops"
- "I don't want to be without my car for 6-8hrs...."

Psychological issues eg

- Risk of finding out they have disease
- General worry
- Head in the sands approach

Scenarios

For the test you will also need to discuss the 2 following scenarios. They are not dissimilar to those which occur fairly frequently in normal optometric practice and should be fairly straightforward.

1) A patient who has died is invited for an annual screening appointment. The patient's wife is very distressed when she phones to inform the programme that her husband has died. How can the programme guard against this situation?

2) A patient phones up to say that they don't think it is necessary for them to come for screening as they have regular checks with their optician. It is clear that they don't want to come for retinopathy screening. How do you reassure the patient and encourage them to attend?

Conclusions

Look at the Workbook contains almost all of the information that you need. Make sure that you have V4.1.

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April 2007 (2nd edition)