THE ROYAL COLLEGE OF OPHTHALMOLOGISTS

Focus

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External Quality Assurance in Diabetic Retinopathy Management

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Quality assurance (QA) is an integral component of any national screening programme, to ensure that the programme achieves the highest possible standards. This is essential because screening programmes inevitably have both false negatives and false positives (since no screening test can achieve 100% sensitivity and specificity), and there is thus the potential to do more harm than good if standards drift. Quality assurance is generally distinguished from audit, in that it is a continuous process, where specific achievable and minimal acceptable standards are set. These standards are regularly reviewed and tightened (sometimes relaxed if the initial standard has been set too high), so that quality is maintained and progressively increased. It is not to police programmes but to ensure continuous improvement.

Internal quality assurance provides internal processes to reduce the probability of error and provide ongoing service improvement, and raise standards to provide the best possible outcome for the patient.

External quality assurance (EQA) provides external review of programmes against national standards to compare with other services across the country.

The inevitable consequence of the development of a National Public Health Screening Programme for sight-threatening diabetic retinopathy is that interest is being taken by directors of public health in the management outcomes of all patients with diabetic retinopathy.

The screening programme for sight-threatening diabetic retinopathy was the first programme to be introduced after the publication of Shifting the Balance of Power, which meant that screening programmes have to respond to local needs. In order to ensure a consistently high standard across the country, screening programmes are monitored against 19 quality assurance standards (*www.retinalscreening.nhs.uk*). The programme directors have to provide an annual report against these standards and they receive an external quality assurance visit every 3 years.

The QA standards that are relevant for ophthalmologists who are managing patients in eye clinics are standards 1, 10, 11, 12 and 13:

Standard 1

a) Annual blind and partially sighted registration rates
b) Local identification of visual impairment due to diabetes:
VA 6/60 or worse in the better seeing eye
VA 6/18 or worse in the better seeing eye

Standards 10, 11, 12 and 13, with objectives, criteria and minimum and achievable standards are:

	OBJECTIVE	CRITERIA	MIN STANDARD	ACHIEVABLE STANDARD
10	**To ensure timely consultation for all screen-positive patients.**	Time between notification of positive test and consultation:		
		1. Proliferative DR /Advanced diabetic eye diseases, R3	70% <2 weeks	95% <2 weeks
		2. Pre-proliferative DR, R2	70% <13 weeks	95% <13 weeks
		3. Maculopathy, M1	70% <13weeks	95% <13 weeks
		4. All above retinopathy grades	100% < 18 weeks	
11	**To ensure timely treatment of those listed by ophthalmologist.**	Time between listing and first laser treatment, following screening:		
		1. Proliferative DR, R3	90% <2 weeks	95% <2 weeks

12	**To minimise over-all delay between screening event and first laser treatment.**	Time between screening encounter and first laser treatment, if listed at first visit to hospital eye service following screening, does not exceed:		
		1. For patients referred as DR, R3	70% <4 weeks	100% <6 weeks 95% <4 weeks
		2. For patients referred as M1	70% <15 weeks 100% <26 weeks	95% <15 weeks
13	**To follow up screen-positive patients (failsafe)**	Combined cancellation and DNA rate for ophthalmology clinic		
		1. For Proliferative DR, R3 within 1 month	<10%	<5%
		2. For Pre-proliferative DR, R2 within 6 months	<10%	<5%

Electronic data collection systems will need to be put in place for these standards, which will inevitably take time to develop.
At an EQA visit, the following data, which is related to the ophthalmology department, will be looked at:

1. The timelines of a group of patients referred from screening will be looked at to see if patients are being seen and treated within an appropriate timescale.
2. The laser book will be looked at to see if patients who are being treated are on the retinal screening database and were referred in from screening. Even if they present in an ad hoc way, the retinal screening database should have a record of these patients because they have diabetes.
3. A request will be made to see the numbers of patients registered blind from diabetic retinopathy in the last 12 months.

EQA visits are carried out by a team of peer reviewers who are from different disciplines depending on the make-up of the local screening programme. The peer reviewers usually include a public health specialist, regional QA manager, a PCT commissioner, an administrator, a programme manager who carries out a sample grading review and an ophthalmologist.

The format of the day is that the peer review team meets with the local team in the morning and then after the initial discussion, which may last about an hour, the team splits up and the ophthalmologist visits the ophthalmology department. There will have been a request in advance to pull some records that have been identified by the programme manager as ones that have been referred in from screening or identified from the laser book.

Anyone acting as clinical lead for a screening programme or grading within a screening programme will be expected to take part in grading the EQA test set of images that is being developed. In cervical screening, all pathologists and cervical cytologists involved with the programme have to grade a certain number of EQA slides every year. Similarly a test set of digital images has been developed and is being piloted for the National Diabetic Retinopathy Screening Programme. Once the pilot is complete, this will be made available to everyone working within the programme. The exact number and frequency of image grading that will be required has not yet been determined.

Participation in quality assurance is important to avoid incidents such as that in cervical screening at the Kent and Canterbury Hospital in 1995. The Inquiry identified failure to participate in adequate internal and external QA and the development of bad habits in laboratory procedures and slide interpretations. As a result, some cancers were missed.

It is recommended that a single ophthalmologist within a unit should take responsibility for patients with diabetic retinopathy and that this lead ophthalmologist should:

- Ensure that all ophthalmologists seeing patients referred from the screening programme
  - have access to a system which enables them to record the outcome of that appointment for the screening programme, including non attendance;
  - complete the data set for each patient and report the outcome to the local screening service;
  - grade retinopathy levels according to the national criteria;
  - ensure that the screening administration office is informed of discharges from the care of the hospital eye service, as well as the GP.
- Ensure that outcome data on those patients requiring slit lamp bio microscopy assessment due to ungradable images is returned to the screening administration office, if the assessment of these patients is under the hospital eye clinic.
- Ensure that all patients with diabetes under the care of the hospital eye service for any reason are screened annually to national standards. This can be achieved by annual photography and/or slit lamp bio-microscopy in the eye clinic.
- It is recommended that patients are seen by a consultant, associate specialist, staff grade or SPR year III or higher with at least one year's experience of medical retina clinics and is familiar with the aims and objective of the English Diabetic Retinopathy Screening Programme and in the classification of diabetic retinopathy according to NSC guidelines. Alternatively, staff may be assessed as competent using the recommendations for slit lamp biomicroscopy examiners available on the NSC retinopathy website (*www.retinalscreening.nhs.uk*).
- If patients are under the hospital eye service for another chronic eye disease e.g. glaucoma (or being seen in the private sector), a report of the retinal examination performed by an ophthalmologist back to the screening programme is desirable to minimise the number of appointments for the patient. If this is not available, then the patient should continue to be offered a screening appointment.
- Informing the screening programme of any patients who should be excluded from screening because they have no perception of light in BOTH eyes;
- The clinical lead should ensure that adequate incident reporting mechanisms are in place to record incidents, near misses and Serious Untoward Incidents (SUIs) and to ensure that these are routinely reviewed at multidisciplinary team meetings and programme boards.

In summary, quality assurance applies to screening processes as well as the hospital eye service. It is apparent that there may need to be significant changes from current practice for many eye units. Eye units will need to put in place mechanisms to collect the appropriate data and to liaise closely with their local screening service.