UK National Screening Committee

Screening for Diabetic Retinopathy

19 November 2015

Aim

1. To ask the UK National Screening Committee to make a recommendation, based upon the evidence presented in this document, whether to extend the screening intervals for diabetics at low risk of sight loss in the diabetic eye screening programme.

   This document provides background on the items addressing the proposed modification to the NHS Diabetic Eye Screening programme.

Current programme policy and area impacted by the proposed change

1. Screening for diabetic retinopathy is offered to all people aged 12 and over with type 1 or type 2 diabetes. Current policy is to invite all eligible people for a screening test annually.

2. The proposed modification relates to the screening intervals:

- That the diabetic eye screening programme extends screening intervals for people with low risk of sight loss, from one year to two years.

- That the current screening interval for people with a high risk of sight loss should be retained.

The rationale for the proposal is summarised in Annex A.

Consultation

3. A three month consultation was hosted on the UK NSC website, and 22 organisations were contacted directly. Stakeholders were invited to comment on any aspect of the supporting documents and on whether they agree or disagree with the proposed modification. Annex B

4. Responses were received from the following 5 stakeholders: College of Optometrists, Diabetes UK, Royal College of Ophthalmologists, and the Public Health Agency Northern Ireland, Royal College of Physicians. All comments are in Annex C.

There is overall support for the proposal, and the main concern was for the need to clarify how changes should be developed and implemented, including any communications regarding the changes to be made. For example concern was raised for the lack of evidence on the impact on test uptake, in those at a low risk of sight loss.

In addition there were comments on the need for robust information that describes 'risk' in a way that is accessible to all patients. The programme plans to address these in work streams within an implementation group formed to oversee and develop a full implementation plan should the change be agreed.

Two responses noted that the modification was not without risk, albeit a very low risk. These responses suggested that patients in the low risk group should be given the option of an annual review as this may provide a level of reassurance which may be lost through implementation of the modification. However, the risk of progression had been considered by the screening programme as part of the development of the proposal. It had been noted that the annual rate of referable progression was ~0.7% and that cases identified later would still be treatable. In addition the programme's recommendation was conservative in comparison to other assessments of the issue. For example one observational study (Agardh 2011) reporting incidence of sight threatening diabetic retinopathy (STDR among type 2 diabetics in the low risk group concluded that three-year intervals are recommendable. In addition the screening programme has advised that good communication of risk is a more practical approach to continued reassurance.

Recommendation

5. The Committee is asked to approve the following modification to the NHS Diabetic Eye Screening Programme:

For diabetics at low risk of sight loss, the interval between screening tests should change from one year to two years. The current one year interval should remain unchanged for the remaining people at high risk of sight loss.

Extending diabetic eye screening intervals for people at low risk of developing sight threatening retinopathy: a consultation

Proposal for consultation:

The UKNSC would like to propose the following modification to the Diabetic Eye Screening Programme.

- That the diabetic eye screening programme extends screening intervals for people with low risk of sight loss from one year to two years.
- That the current screening interval for people with a high risk of sight loss should be retained.

There is no proposal to change other aspects of the programme.

The proposal is based on the four attached documents. These are:

Appendix 1: Report on the findings of the Four Nations Diabetic Retinopathy Screening Intervals Project Study Group
Appendix 2: Rapid review of the literature: Would changing diabetic eye screening intervals from the current annual recommendation lead to changed clinical outcomes?
Appendix 3: Rapid review of the literature: Does a change in screening interval lead to a subsequent change in uptake?
Appendix 4: Cost utility analysis

Stakeholders are invited to comment on any aspect of the documents and on whether they agree or disagree with the proposal.

Summary

About five in 100 (5%) people in the UK have a diagnosis of diabetes. Most, 90 in 100 (90%) have type 2 diabetes (T2DM). The number of people with T2DM is rising because more people are living longer; are obese; have low levels of physical activity and come from ethnic groups at higher risk. The number of people with T2DM is also growing because of increased levels of testing e.g. the introduction of 'health checks'. The number of people with Type 1 DM is also rising by around 5% per year, for reasons which remain unknown.
Diabetic retinopathy is a complication of diabetes and is one of the leading causes of sight loss and blindness across the world. People living with diabetes may be unaware they have the problem before it is too late. Screening services were established in the UK to detect retinopathy so it can be found and treated before it becomes sight threatening.

Annual screening for changes in the blood vessels at the back of the eye (diabetic retinopathy) in people with diabetes is recommended for all those with diabetes aged 12 and above. Those found to have a problem (sight threatening diabetic retinopathy (STDR) are referred on for further tests and, if required, treatment. Treatment of STDR with laser therapy reduces the risk of vision loss.

Screening for diabetic retinopathy was introduced at annual intervals for pragmatic and administrative reasons. However the evidence base to support this interval was very limited. In order to ensure that people being invited for screening get the best care, the diabetic retinopathy screening programmes across the four UK countries carried out a formal audit on people screened to determine whether there are some groups who could safely be

screened less often. Findings from the audit were published in November 2014 (Leese et al 2014 - appendix one) and the outcome of a linked literature review (appendix two and three), support the view that there is a sizeable group of people with diabetes who have no retinopathy after two successive screens. These people are thought to be at low risk of developing sight threatening retinopathy and could safely be screened less often. Reducing the number of screening episodes for selected patients would also release capacity that can be used to invite the increasing number of people with diabetes. Those people who are at low risk will also not have the inconvenience of having to attend every year.

On the basis of these documents the UK National Screening Committee is proposing to extend screening intervals from one year to two years in patients at low risk of developing sight threatening diabetic retinopathy (STDR).

Evidence presented to UK National Screening Committee

An observational study (appendix one) was undertaken linking retinal grading result data from seven diabetic retinopathy screening programmes across the U.K. (Scotland, Wales, Northern Ireland and four programmes from England) for the period 2005 and 2012. Patients with absent, or background retinopathy, were followed up for progression to the point at which referable retinopathy and treatable retinopathy (proliferative retinopathy) was identified.

The study was the largest of its kind ever undertaken. In total 354,549 patients were observed for up to 4 years during which 16,196 patients progressed to referable retinopathy:

- in patients with no retinopathy in either eye less than 0.3% progressed to either referable retinopathy or proliferative retinopathy (treatable eye disease) during a two year period in which there were two successive annual screening episodes

- in patients with bilateral background retinopathy 13 – 29% progressed to referable retinopathy and up to 4% progressed to proliferative retinopathy (treatable eye disease) in a two year period in which there were two successive annual screening episodes.

- in patients with no diabetic retinopathy at baseline a small proportion, 0.4% to 1.3%, progressed to referable retinopathy in a two year period in which there were two annual screening episodes

The outcome of the study indicated that it may be possible to stratify patients into groups at high and low for risk of progression to both referable retinopathy and proliferative retinopathy, according to baseline retinal criteria. The practical conclusions in terms of programme policy are that:

- screening intervals for the different groups of patients could safely be modified according to this risk, and that
- extension of the intervals would apply to low risk patients only. No amendment to the screening intervals for high risk patients is being proposed.

The literature review (appendix 2) concluded that the published evidence, although quite limited in some respects, confirmed the findings of this UK study.

Cost Utility – value of the proposed change

A cost utility assessment (appendix four) was carried out by the Health Improvement Analytical Team of the Department of Health. The assessment concluded that it is cost effective to increase screening intervals from one year to two years for low risk diabetic patients, defined as those that are graded as having no background retinopathy in either eye and to re-deploy the appointments in efforts to increase uptake in the eligible diabetic population.

Outcome of UK NSC discussion

The UKNSC considers that the documents supported the proposal to modify the screening intervals. However the Committee also noted that there are a number of important factors that must be in place before the modified intervals could be implemented:

- Accurate and consistent grading should be taking place in programmes.
- Robust data and IT processes should be in place to ensure the safe identification and management of patients along a pathway.
- Vital stakeholder and service user communication.

The UK Four Nations Diabetic Retinopathy Screening Group continues to work together on the proposal for risk based screening intervals. The group is agreed that different approaches to implementing a change would need to be put in place across each country.

The Group has agreed that the points raised by the UKNSC should provide a set of principles to guide implementation in each country. However the need for variation on some matters is acknowledged and country specific implementation plans are being developed. These will be developed and shared with the relevant stakeholders in each country.

The emphasis of the current consultation is to gauge the views of national stakeholders on whether they agree with the UKNSC that the evidence supports the proposed modification.

Annex B

List of organisations contacted:

1. Action for Blind People
2. Association of British Clinical Diabetologists
3. Association of Optometrists
4. British Association of Retinal Screening
5. College of Optometrists
6. Diabetes Research and Wellness Foundation
7. Diabetes UK
8. Faculty of Public Health
9. Foundation of European Nurses in Diabetes
10. Institute of Diabetes in Older People
11. Insulin Dependent Diabetes Trust
12. International Diabetes Federation
13. Juvenile Diabetes Research Foundation
14. Medical Imaging DRSS
15. National Diabetes Information Service
16. National Eye Research Centre
17. Primary Care Diabetes Society
18. Royal College of General Practitioners
19. Royal College of Ophthalmologists
20. Royal College of Physicians
21. Royal National Institute of Blind People (RNIB)
22. Young Diabetologists Forum

Annex C

Name:	Simon O'Neill	**Email address:**	**xxxx xxxx**
Organisation (if appropriate):	Diabetes UK		
Role:	Director of Health Intelligence and Professional Liaison		

Do you consent to your name being published on the UK NSC website alongside your response?

Yes X **No** ☐

Section and / or page number	**Text or issue to which comments relate**	**Comment** *Please use a new row for each comment and add extra rows as required.*
P2: Evidence presented	In patients with no retinopathy, less than 0.3% progressed to either referable retinopathy or proliferative retinopathy during a 2 year period	The evidence base presented to argue for a move to biennial retinal screening is very strong and Diabetes UK is happy to support this move in principle. However, it is important to note that this move is not without some element of risk for some individuals and it will be necessary to explain this level of risk to people so that they can make an informed choice as to whether they would want to have an annual review through an alternative means in addition to a biennial review under the Diabetes Eye Screening Programme. If 0.3% of people in the study with no retinopathy at baseline went on to develop some form of retinopathy over a 2 year period, this is still around 1,000 people. If this was 0.3% of the English population with diabetes, this would equate to over 8,000 people. We realise that this includes retinopathy that may not require treatment, only referral, and that some people in the existing programme still have some risk of developing proliferative retinopathy within a single year. But it is important to explain that this move is not completely risk free for a small number of individuals

P3 Outcome of UK NSC Discussion	There are a number of important factors that must be in place before the modified intervals could be implemented	Diabetes UK supports the need to ensure that the listed factors **must** be in place before any changes are made to retinal screening intervals. • **Accurate and consistent grading** is essential to ensure patient safety and to prevent unnecessary sight loss. This must be demonstrably in place before any changes to the screening intervals are implemented, with the data publicly available. • **Robust data, IT and follow up processes**: It is essential that the system is fully competent to track, invite and follow up people with diabetes to ensure that people do not fall out of the system and that biennial screening does not start to lead to an increase in referable retinopathy in practice. This is particularly true for younger people with Type 1 diabetes who are already less likely to access their regular care reviews and who, in attending University and moving for work, are often a more mobile population, crossing providers' boundaries. Although we know that some people with diabetes choose not to attend retinal screening, it is essential that all eligible people are invited when appropriate (whether annually or biennially) and that they know which screening interval they should be offered and why. We do have a strong concern that people who are moved to biennial screening may misunderstand this and believe that they are no longer at risk of retinopathy and cease to attend retinal screening appointments. We also need to be assured that the systems are robust enough that only those who are suitable for biennial screening are invited to this and that all people with early signs of retinopathy are monitored annually, as proposed. • **Vital stakeholder and service user communication.** Diabetes UK strongly supports this. It is essential that the proposed changes are communicated effectively to all people living with diabetes. We are already concerned that many people with diabetes do not understand the difference between a retinal screen through the DESP and an annual eye health check with their high street optician and have concerns that the move to biennial screening may confuse this further. Furthermore, when all other diabetes risk reduction processes are expected to be undertaken annually, a biennial screen is likely to cause confusion to some as it is easier to think about getting everything checked once a year. This is a significant issue and communication of who needs to be screened annually and who (on the basis of the risk modelling) can be seen biennially will need careful consideration to ensure consistency. • **Evaluation of the uptake, impact and outcomes** of those who are only offered biennial screening to track the effect of this change and whether greater numbers of people with

		diabetes are developing signs of sight threatening retinopathy. • **Changes in glycaemic control.** It is well known that sudden improvements in glycaemic control after several years of poor control can speed up the progression of diabetic retinopathy. Likewise for people who have a sudden deterioration in glycaemic control, their risk of retinopathy will increase. It is therefore vital that clinicians have the opportunity to refer people back in to the service whose risk profile may have changed within a two year period or where retinopathy is suspected and clear guidance should be produced for clinicians about how to re-refer. In addition, we would like to raise some other communication concerns: • Blindness is probably the most feared complication of diabetes. Many people living with the condition get reassurance from the annual eye screen. Although we appreciate that they are at very low risk of developing retinopathy over a two year period, it is essential that any changes to the programme are comprehensively explained to provide reassurance. • We do have a concern that those who may choose to continue with annual retinal screening, using free services such as that offered to the over 40s by SpecSavers, may choose not to then take up the national programme invitation. Although their eye health may be being monitored, there is not necessarily good Quality Assurance, and their data will be lost to the national programme. • Key to ensuring take up of retinal screening is the conversation with GPs and specialists about its importance. We are already concerned that the removal of retinal screening from the Quality Outcomes Framework may be having a detrimental effect on GPs referring patients into the system and we would be concerned if confusion around biennial screening led to GPs referring fewer patients. Communication with GPs and specialists about these proposed changes must be in place to ensure there is clarity about referral. • Currently only 35.9% of all people with diabetes are meeting targets for HbA1c, BP and Cholesterol. Although this has been static for some year, if overall diabetes care does worsen over time, then it will be important to ensure that a biennial screening interval is still appropriate and safe for the vast majority of people with diabetes and that underlying care is not having a negative impact. • Consultees felt that the invitation letter needs to be much stronger, especially if this is only going to be a biennial screen, to really express the importance of attendance and to stress that

		this is in the patient's best interest and is not a 'cost-cutting' exercise

Name:	Dr Adrian Mairs	**Email address:**	**xxxx xxxx**
Organisation (if appropriate):	Northern Ireland Public Health Agency		
Role:	**Public Health Lead for the Northern Ireland Diabetic Eye Screening Programme**		

Do you consent to your name being published on the UK NSC website alongside your response?

Yes ☒ **No** ☐

Section and / or page number	Text or issue to which comments relate	Comment
		The document would benefit from the addition of page and paragraph numbers.
Proposal for consultation: Page 1, para 1.	That the diabetic eye screening programme extends screening intervals for people with low risk of sight loss from one year to two years.	The Public Health Agency (PHA) supports the proposal to extend the screening intervals for people with low risk of sight loss from one year to two years. Programmes doing this should meet the current screening interval standard and ensure that people with low risk of sight loss are offered screening every 24 months.
	That the current screening interval for people with a high risk of sight loss should be retained	The PHA supports retaining the current screening interval for people with a high risk of sight loss and that programmes should meet the current screening interval standard.
Summary Page 2, para 1.	Reducing the number of screening episodes for selected patients would also release capacity that can be used to invite the increasing number of people with diabetes. Those people who are at low	It should be made clear that the reason for extending the screening interval is to maximise the benefits of the programme (e.g. promoting informed choice to maximise uptake) and reduce harms (e.g. participant anxiety and

	risk will also not have the inconvenience of having to attend every year.	opportunity costs).
Outcome of UK NSC discussion Page 3, para 2.	However the Committee also noted that there are a number of important factors that must be in place before the modified intervals could be implemented: • Accurate and consistent grading should be taking place in programmes. • Robust data and IT processes should be in place to ensure the safe identification and management of patients along a pathway. • Vital stakeholder and service user communication.	The PHA agrees with each of the factors recommended by the UKNSC. In addition there should be robust programme management and failsafe procedures in place to ensure that all individuals at low risk of sight loss are offered screening every 24 months. Mechanisms need to be in place to ensure that women who are, or become pregnant, are screened at appropriate intervals.

Name:	David Parkins	**Email address:**	**xxxx xxxx**
Organisation (if appropriate):	The College of Optometrists		
Role:	**President**		

Do you consent to your name being published on the UK NSC website alongside your response?

Yes ☒ **No** ☐

Section and / or page number	Text or issue to which comments relate	Comment
General		The College of Optometrists agrees with the UKNSC proposed modification to the Diabetic Eye Screening Programme to extend the interval between screening tests from one year to two years for people at low risk of sight loss, while the current interval between screening tests should remain unchanged for people at high risk of sight loss.

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29 October 2015

Adrian Byrtus
Evidence Review & Policy Development Manager
UK National Screening Committee/NHS Screening Programmes
Floor 2 Skipton House
80 London Road
London
SE1 6LH

Dear Adrian

Re: Diabetic Eye Screening Programme Consultation

Thank you for the opportunity to contribute to the public consultation on whether to make a significant modification to the national Diabetic Eye Screening Programme.

The College has reviewed the consultation documents and considered and notes the following:

1. There is no evidence in the literature to identify the impact of changing screening intervals on patient uptake of services.
2. There has been no validation of risk prediction algorithms in a data set collected in a real world setting; even if one were available the changing demographics of the population may make any risk prediction inapplicable in the current setting.
3. There is no plan on how the potentially high risk cases if detected would be managed if and when screening moves to a two year interval.
   The consultation does not mention the patient perspective and evidence emerging of people being screened wanting annual screening.
4. The proposals do not attempt to refine referral thresholds and the continued reliance on maculopathy referral based on 2 D surrogate markers of maculopathy seems increasingly inappropriate. OCT technology is now commonplace and could form the basis for more accurate and timely referral algorithms. The use of automated grading as used in the Scottish program should also be seriously considered as this too offers opportunities to concentrate precious manpower resources on grading only those patients with retinopathy.

FW: Diabetic Eye Screening Programme; consultation open

Rochelle Keenaghan [Rochelle.Keenaghan@rcplondon.ac.uk] on behalf of Consult [Consult@rcplondon.ac.uk]

Sent: 30 October 2015 11:59
To: Evidence Screening (PUBLIC HEALTH ENGLAND)

Dear Adrian

The RCP is grateful for the opportunity to respond to the above consultation.

We have liaised with our experts at the Association of British Clinical Diabetologists and would like to note our support of the screening programme.

I would be grateful if you could confirm receipt.

Best wishes

Rochelle Keenaghan | Committee manager
Membership Support and Global Engagement Department | Royal College of Physicians
11 St Andrews Place | Regent's Park | London NW1 4LE

Dear Adrian,

Having looked at this documentation I can see no transparent recommendations for patients in the seven intermediate risk groups, i.e. those with background DR in one eye at first screen and no DR recorded at second screen. Have I missed something?
Irene

Irene M. Stratton M.Sc. FFPH
Honorary Associate Professor (University of Warwick Clinical Sciences Research Institute)
Senior Statistician Gloucestershire Retinal Research Group Above Oakley Ward Cheltenham General Hospital Sandford Road Cheltenham Gloucestershire
GL53 7AN.
xxxx xxxx

Dear Irene,

Thank you, we will consider your comments along with other responses to the consultation.

Please note that the Four Nations Study concluded that if accurate and consistent grading were assured that an appropriate yield for identifying diabetic retinopathy in screening would be 2.5%, at which point the optimal intervals would be two to three years for the low risk group, annually for medium risk, and six monthly for the high risk group.

We are consulting on the option of extending screening intervals to two yearly for the low risk group only. This was supported in the cost utility work carried out.

Additionally, as detailed in the consultation paper, the cost utility did not support reducing the intervals for high risk people. The annual intervals for medium risk is as the current policy, and therefore is not deemed to be a required proposal in terms of this consultation.

Kindest regards,

Adrian Byrtus
Evidence Review & Policy Development Manager
UK National Screening Committee

Dear Adrian,

Those results are well known to me because I was the person who calculated them.

There are not 3 but 9 risk groups in the original paper (Stratton et al, attached) and the numbers of cases of referable retinopathy are given by risk group. The paper

by Leese et al (I'm second author there) concentrated on groups 1,5 and 9 because of space considerations.

If you look at Stratton et al you will see that the intermediate group 2 also has expected 2 year rate of referable DR under 2.5%, in fact 1.9%.

Group 2 is those who have R1 in one eye in screening episode 1 and R0 in both eyes at the second screen.

Including those in the 2 year screening interval group would increase the size of the "2 year screening interval" group by 17.5%. A not inconsiderable difference in terms of numbers of screening episodes. This does not seem to have been considered.

Irene M. Stratton M.Sc. FFPH
Honorary Associate Professor