

Stratifying the NHS Diabetic Eye Screening Programme: into the unknown?

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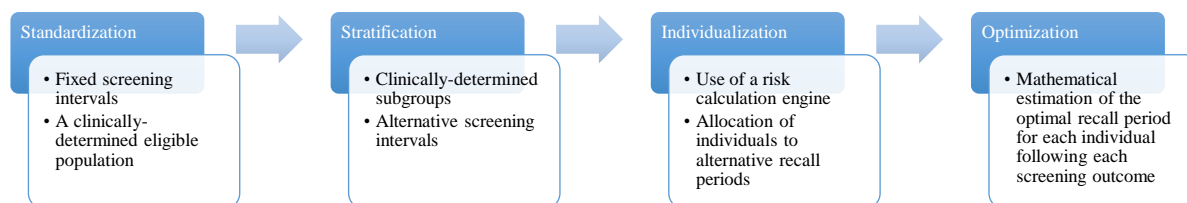
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In this commentary we consider the recent recommendation by the UK National Screening Committee (NSC) that people with diabetes at low risk of sight loss should be invited to screening every 2 years rather than annually. [1] We broadly support this recommendation but believe there are important outstanding questions that require attention before such a policy is implemented. We discuss the decision in the context of the history of the NHS Diabetic Eye Screening Programme (NDESP) and reflect on the current state of evidence including work cited by the NSC. [1- 4]

Development of the NDESP

Systematic screening for diabetic eye disease was introduced across Britain by 2007, with all people with diabetes over the age of 12 invited for screening annually. Evidence suggests that most people could be safely screened less frequently, [4] while high-risk patients could benefit from more frequent screening. [2]

The NSC recommendation represents a move to stratification: a step in the development of the NDESP beyond a 'one-size-fits-all' approach. Contrary to recent claims [3] stratification according to screening outcome does not amount to 'personalisation'. Individualisation (a more precise term for 'personalisation') requires the use of information about the individual beyond simply their current disease state, and allocation of screening pathways according to individual risk. For example, a risk calculation engine may be used to allocate individuals to alternative screening recall periods based on their individual risk of disease onset. Further to this, the pathways can be adjusted based on individual risk in order to achieve an optimised programme (see Figure). For example, an individual may be allocated to the minimal recall period at which their risk level would be expected to reach some threshold for eligibility.



[Figure: Development of screening programmes for diabetic retinopathy]

Challenges of transition

The NSC recommendation signals transition from standardisation to stratification. Transition raises new questions requiring research evidence. The NSC has identified a number of conditions to be met before stratified screening is introduced. [1] We expand on these challenges and highlight key outstanding questions and shortcomings in the evidence base.

Is the basis for stratification clinically, statistically and practically robust?

Stratification must not be arbitrary. [5] There must be a strong basis on which to offer people differential care depending on their allocation to a subgroup. The Four Nations report, which forms part of the NSC's supporting evidence, [1] specified 9 risk subgroups based pragmatically on photographic gradings at two consecutive screening visits. [2] The report's conclusions are balanced, but no justification is provided for this risk grouping. It is unclear whether it would be valid across

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different regions of the UK. Similar limitations can be observed in Scanlon et al [3] which used different and again pragmatic subgroups. Stratification by grading outcome may seem practical, but it is not clear whether the prescribed approach could be operationalised and the resource implications are unknown. The NSC highlighted the need for data and IT systems to be put in place, but the cost of such systems and additional data collection has not been estimated. Scanlon et al assumed no additional cost associated with stratification, which may be unrealistic. Though they present important findings regarding the accuracy of grading at different stages of disease, there remain uncertainties about screening test performance in the subgroups. Photography, grading and slit lamp biomicroscopy may be less accurate in the low-risk subgroup. Differences in sensitivity or specificity could undermine the basis for stratification. There are also ethical concerns associated with stratification. [6] There is potential for unwarranted variation in the accuracy of stratification that might lead to poorer outcomes in certain regions or socio-economic groups. The Four Nations study highlighted inadequacies in grading and data collection that could lead to some people who should be referred immediately being recalled at 2 years.

Are the alternative pathways appropriately defined?

Having identified suitable subgroups, it is important to appropriately define the alternative pathways that will be offered. The basis for allocation to either 12 or 24 month recall has limited justification. In their modelling study, Scanlon et al suggested that longer intervals were justified. Indeed, previous evidence has supported 3-yearly screening in people without retinopathy. [7,8] There may be practical reasons for defining recall periods in terms of whole or half years, but this could be tested. In the Four Nations study, the use of a 2.5% 'yield' appears arbitrary and unfounded, and implications derived from it are uncertain. A threshold approach of this nature requires transparent justification.

Will stratification affect attendance/uptake?

The principal unanswered question associated with a transition to stratified screening is the effect on attendance. This concern was duly raised in the NSC's consultation. The NSC recommendation states that "a large observational study was carried out which showed that it was safe to invite people in [the] low risk group every two years rather than annually". This conclusion cannot be drawn from the Four Nations study unless it is assumed that stratification will have no effect on attendance. A literature review supporting the NSC recommendation found no evidence to inform this assumption. [1] This therefore represents a major unknown risk. Some countries outside the UK with extended intervals have not identified effects on attendance, but delivery of these services differs substantially from the NDESP. For Sweden, Agardh et al [7] specifically noted high compliance in their population. Scanlon et al did not evaluate the potential impact of stratification on attendance and thus assume that it will have no impact. Differences in uptake could undermine the cost-effectiveness of the programme. [9] The NSC has specified the need for stakeholder and service user involvement, but the acceptability of stratified screening has not yet been evaluated. The limited currently available evidence suggests that extended intervals may prove not to be acceptable, and may require a more complete evidence base. [10]

How will stratification affect follow-up and treatment outcomes?

The benefits of screening derive from the effectiveness of treatment for those screened positive. Stratification alters the profile of the population that screens positive. Treatment may be less effective if some people are treated later. This will have implications for follow-up, assessment and treatment that are currently unknown. The literature review supporting the NSC recommendation found no evidence that extending intervals would be harmful, but did not find any observational evidence of the impact of different recall periods in the UK. The analysis by Scanlon et al used a cost-

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effectiveness model based on assumptions about the impact of altering screening intervals that may not hold. For example, disease states used in the model combined different stages of retinopathy ('R2' and 'R3'), meaning that the model could not detect differences in progression to treatment between standardised and stratified screening. This could have significant cost implications. The Four Nations study excluded people who had fewer than 3 episodes with fully graded images for both eyes. Such exclusions result in a lack of information about the possible impacts of stratification on outcomes for particular groups of people.

Conclusion

We believe that the NSC recommendation represents a rational approach but advise proceeding with caution and close monitoring. The Four Nations report itself stated that "the available evidence is inadequate to fully inform a policy decision". [1] The necessary research to answer the questions outlined above may arrive concurrently with findings that support transition to individualisation, in which case a stratified programme may be short-lived. Current efforts should focus on establishing data systems with the long-term development of current programmes in mind. New arrangements must be adaptable and investment should be in flexible information technology. It is important that resources are not wasted on programme adjustments that may be quickly revised as more research becomes available and more effective and efficient approaches are developed.

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