Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Scoping Report Protocol

Extended Interval Screening by the Diabetic RetinaScreen Programme in Ireland

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Safer Better Care

Scoping Report Protocol for Extended Interval Screening by the Diabetic RetinaScreen Programme in Ireland

1. Background

Diabetic retinopathy is a common cause of vision impairment and sight loss.[1] It is estimated that approximately one third of all people with diabetes mellitus worldwide have signs of diabetic retinopathy and a further one third of these have sight-threatening diabetic retinopathy (STDR).[2] Diabetic retinal screening programmes can prevent STDR by timely detection and treatment of cases. These programmes have been implemented in various jurisdictions globally, including in Ireland.[3] Although the screening interval in Ireland is every one year, some national programmes have moved to 2 year[4] or 3 year[5] intervals for those considered to be at low risk of diabetic retinopathy progression.

Diabetic RetinaScreen commenced on a phased basis in 2013, and provides free diabetic retinopathy screening and if necessary, treatment, for all individuals with diabetes aged 12 years and older on the Diabetic RetinaScreen register. The HSE's National Screening Service (NSS) is responsible for the development and implementation of Diabetic RetinaScreen, and has proposed the accelerated introduction of a planned new 2 year screening pathway (Extended Interval Screening).[6]

The aim of this scoping report is to provide an overview of the evidence pertaining to the extension of diabetic retinal screening intervals from one to two years for those at low risk of diabetic retinopathy progression. As evidence relating to the impact of extending the screening interval will likely include data from other organised national diabetic retinopathy screening programmes, a brief overview of how screening is organised in such programmes is also included for context and to provide evidence of the potential applicability of data from international screening programmes to the Irish healthcare system.

2. Review questions

The following three key review questions have been identified:

1. In patients who have no reported retinopathy or maculopathy (i.e., those with a worst final grade of R0M0) and no non-diabetic eye disease (NDED) and whose disease is stable, what is the evidence that a change in the interval of diabetic retinopathy screening from 1 year to 2 year affects patient outcomes?

2. In relation to a change in the interval of diabetic retinal screening from 1 year to 2 year:

    a. How should this change be communicated?

    b. Could this change cause confusion to patients?

    c. Would the reassurance provided by an annual screen be lost?

3. How is diabetic retinopathy screening conducted in other organised, national programmes?

3. Population, Intervention, Comparator, Outcome, Study design (PICOS) criteria

The applicability of each study will be considered in relation to the following PICOS.

Population	Patients with Type 1 or Type 2 Diabetes Mellitus at low risk of diabetic retinopathy progression meaning they have no reported diabetic retinopathy at baseline and whose disease is stable. These are defined as patients meeting either of the following criteria : ▪ patients who have been screened with a worst final grade of R0M0 and NDED in both eyes for two consecutive years ▪ patients graded R0M0 in one eye and no perception of light in the other for two consecutive years.
Intervention	2 year diabetic retinopathy screening interval (extended interval screening)
Comparator	1 year diabetic retinopathy screening interval (usual care)
Outcomes	**Review Question 1:** ▪ incidence and progression of diabetic retinopathy (retinal or macular changes), measured according to an internationally recognised grading system (e.g. International Clinical Diabetic Retinopathy And Diabetic Macular Edema Disease Severity Scale) ▪ attendance at follow-up visits ▪ proportion of positive screens. **Review Question 2:** Knowledge, Experience, Attitudes, Practices and Awareness: communication of changes, confusion caused by changes, reassurance of annual checks. **Review Question 3:** Structure of national programme, screening intervals, technology and grading systems used, service evaluations.
Study design	**Include:** Health technology assessments (HTAs), systematic reviews, randomised controlled trials, non-randomised controlled trials, cohort studies, case-control studies, cross-sectional studies, qualitative studies, economic evaluations and mathematic modelling studies.‡ **Exclude:** Case reports/series and expert opinions.

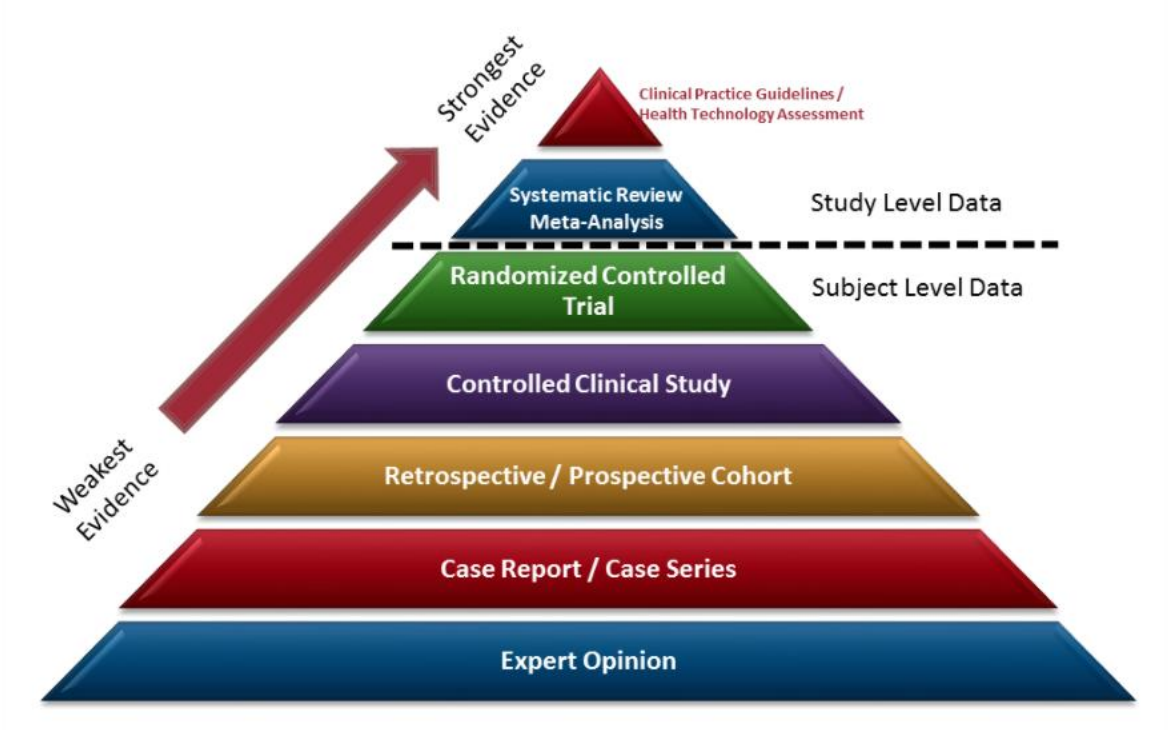
±Only the highest levels of evidence will be used and so not all of the study designs listed above will necessarily be included in this scoping report

4. Synthesis

This review will follow the scoping report methodology as developed by the HTA Directorate.[7] Hence the findings of the scoping report will represent an extensive, but not exhaustive search of the literature.

The focus for all review questions will be on the highest available level of evidence (that is, HTAs, systematic reviews and meta-analyses). However, lower levels of evidence from randomised and non-randomised controlled trials (RCTs and NRCTs), observational studies (but not case reports or case series) will be considered if higher levels of evidence are unavailable (Figure 1). Additionally, qualitative, mixed-methods studies, clinical guidelines, economic evaluations and mathematical modelling studies will also be considered, where appropriate.

Figure 1: Hierarchy of evidence[8]



HTA databases will be checked for relevant published or ongoing HTAs in the first instance. This includes The Centre for Reviews and Dissemination database (https://www.crd.york.ac.uk/CRDWeb/), the International HTA database (https://www.inahta.org/hta-database/) and the European Network for HTA (EUnetHTA) planned and ongoing projects (POP) database (https://eunethta.eu/pop-database/). PROSPERO will be searched to identify any ongoing systematic reviews.

The literature search will be conducted using the *PubMed Clinical Queries* tool. The search terms used will be ("diabetic retinopathy" AND "screening") OR ("diabetic retinal" AND "screening"). Only studies conducted in humans will be included. No date restrictions will be applied.

If a broader search of PubMed is required in order to address some of the qualitative research questions, then results should be filtered by "best match". For qualitative literature searching, the following adaption to the PICOS framework will be used; Population, Phenomenon of Interest and Outcomes. Hence the following search terms will be used ("diabetic" OR "diabetes") AND (("retinal" OR "retinopathy") AND "screening") AND ("attitudes" OR "experience" OR "knowledge" OR "awareness" OR "practices").

Irish data, reports, guidelines, policies and other grey literature may be used to supplement the findings of the scoping report. These may be retrieved using the Lenus repository (www.lenus.ie). National Institute for Health and Care Excellence (NICE) Evidence (filter by 'guidance') will also be searched for relevant international guidelines (https://www.evidence.nhs.uk/).

Studies will be screened by title only and by one reviewer. However, a second reviewer may be consulted for studies of uncertain relevance. As the literature search will not be exhaustive, no flow diagram of included studies will be reported.

A brief overview of known national organised diabetic retinopathy screening programmes will be provided to address the third review question. The source of these data will be Retina International (http://retina-ded.org/screening-innovation-and-clinical-trials/screening-programs-by-geography/). However, this will be supplemented by other data retrieved using the scoping report methodology outlined above. Additionally, a targeted search of government documents from countries where these programmes are established will be undertaken.

This will not necessarily be a complete register of all organised, national diabetic retinopathy screening programmes in existence worldwide, but will provide a broad overview of the programmes for which there are data. As noted, this brief overview will provide evidence of the potential applicability of data from international screening programmes and particularly those that have implemented a change in screening interval, to the Irish healthcare system.

5. Data extraction and quality appraisal

In line with the scoping report methodology, minimal data extraction will be undertaken, with a focus on the main results and key study characteristics that are relevant to the topic under consideration. Although no formal quality appraisal will be undertaken, the hierarchy of evidence will be used as the basis for assessing the quality of the literature retrieved (Figure 1). The study design and hence the level of evidence, will be clearly reported for each finding. The applicability of each study to the Irish context as defined by the PICO, will also be considered.

In keeping with the scoping report methodology, the report will be structured as follows:

- introduction and description of technology/programme
- scope and research question
- literature search
- potential clinical impact

- potential economic impact
- decision-making and policy considerations
- conclusions.

6. Timeline

This scoping report will be completed by 1 October 2020 and will be submitted to the National Screening Advisory Committee for review.

7. References

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7. HIQA. Standard Operating Procedure: Development of Scoping Reports for HTA Prioritisation 2020.

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For further information please contact:

Health Information and Quality Authority
George's Court
George's Lane
Smithfield
Dublin 7
D07 E98Y

Phone: +353 (0) 1 814 7400
info@hiqa.ie
www.hiqa.ie