Q05-18: Early Detections and Management of Diabetes Complications

Protocol for a systematic review

Prepared for Dr. Catharine Whiteside, Diabetes Action Canada

Study Protocol

Review title and timescale

1	**Review title:**	
	Early Detections and Management of Diabetes Complications	
2	**Anticipated or actual start date:**	
	November 5, 2018	
3	**Anticipated completion date:**	
	June 30 2019	
4	**Stage of review at time of this submission:**	
	This review has not yet started	☐

Review stage *(Please check all that apply)*	**Started**	**Completed**
Preliminary searches	☐	✓
Piloting of the study selection process	☐	☐
Formal screening of search results against eligibility criteria	☐	☐
Data extraction	☐	☐
Risk of bias (quality) assessment	☐	☐
Data analysis	☐	☐

Provide any other relevant information about the stage of the review here: Not applicable

Review team details

5	**Named contact**	
	HTA Unit at the University of Calgary (Fiona Clement/Caroline Corbett)	
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9	**Organisational affiliation of the review**	
	University of Calgary, Cumming School of Medicine, HTA Unit	
10	**Review team members and their organisational affiliations** Give the title, first name and last name of all members of the team working directly on the review. Give the organisational affiliations of each member of the review team.	

Title	First name	Last name	Affiliation
Dr.	Fiona	Clement	University of Calgary: Health Technology Assessment Unit (Director)
Dr.	Caroline	Corbett	University of Calgary: Health Technology Assessment Unit

Dr.	Catharine	Whiteside	Diabetes Action Canada: Executive Director
Dr.	Michael	Brent	University of Toronto: Lead of Diabetic Retinopathy group
Dr.	France	Legare	University of Laval: Knowledge Translation Research Program
Dr.	Sophie	Desroches	University of Laval: Knowledge Translation Research Program
Dr.	Mohammed	Al-Omran	University of Toronto: Foot Care to Prevent Amputations Research Group
Dr.	Valeria	Rac	University of Toronto: Health Technology Assessment and Network Analytics Enabling Research Program
Dr.	Maureen	Markle-Reid	McMaster University: Seniors with Diabetes and Chronic Conditions research group

11 Funding sources/sponsors

SPOR Evidence Alliance
Diabetes Action Canada

12 Conflicts of interest

No Conflicts of interest

Review methods

13 Review question(s):

What are the most effective approaches/models of care for population based screening of diabetes complications related to retinopathy, nephropathy, and foot ulcers?
What are the most cost-effective approaches/models of care for population based screening of diabetes complications related to retinopathy, nephropathy, and foot ulcers?

14 Literature Search:

Comprehensive literature searches of electronic bibliographic databases conducted by an experienced librarian of Medline, Embase, CINAHL and Cochrane. The search strategy will be peer-reviewed by another information specialist (PRESS checklist) and discussed by scientists leading the project. We will limit our grey literature search to HTAs and other types of evidence reviews; we will not complete a broad grey literature search.

15 URL to search strategy:

Not Applicable

16 Condition or domain being studied:

Diabetic complications limited to retinopathy, nephropathy, and foot ulcers

17 Participants/Population:

Adults with both type 1 and type 2 diabetes; not gestational diabetes

18 Intervention(s)/Exposure(s):

Single and multifactorial interventions for screening of retinopathy, nephropathy, and foot ulcers

19 Comparator(s)/Control(s):

Different interventions for screening including no intervention

20 Types of study to be included initially:

All quantitative (effectiveness) study designs with a comparator group (ex. RCT's, comparative controls, C/E studies)

21 Context:

Any context

22 Primary outcome(s):

Effectiveness of screening methods to reduce diabetes-related loss of vision due to retinopathy, diabetes – related chronic kidney disease, and diabetes-related lower limb amputation as measured by the proportion of patients that are participating in screening program.

23 Secondary outcome(s):

Reduction in health system cost related to above complications
Patient experience
Provider Experience
Cost Optimization
Health outcomes

24 Data extraction (selection and coding):

Study selection will be conducted by pairs of two reviewers who will screen titles, abstracts and full text articles independently. Discrepancies will be resolved by discussion or by a third reviewer.
Data extraction will be conducted in duplicate with both reviewers extracting data independently. Discrepancies will be resolved by discussion. Reviewers will extract information from the selected studies using a form based on the Data Collection Form for Cochrane Reviews.
Data to be extracted will include: characteristics of the articles (i.e., study design, lead author, year, Country), population (i.e., age, sex and gender, condition, indigenous population) and models of care (i.e. type of program, type of organizations involved), and primary outcomes (as identified in section 22 above). Additionally, any articles regarding screening in indigenous populations will be flagged and included in a separate knowledge synthesis report.
Knowledge users will be involved throughout this process (i.e., development and piloting of the forms, validation of the extracted data).

25 Risk of bias (quality) assessment:

Studies selected will be assessed by two independent reviewers using the appropriate risk of bias assessment tool for the study design. For example, the Cochrane Risk of Bias Tool will be used for randomized controlled trials, the Risk of Bias in Non-randomized Studies of Interventions (ROBINS) Tool for quasi-experimental trials. Disagreements will be discussed between the two reviewers.

26 Strategy for data synthesis:

Data synthesis will focus on providing a descriptive summary to inform a policy regarding models of care for the screening of the three mentioned diabetic complications. Meta-Analysis will be conducted if deemed appropriate based on quality assessment and data extraction.
Literature will be summarized according to the type of population, intervention, comparators, and outcomes identified.

27 Analysis of subgroups or subsets:

We will perform several subgroup analyses: stratified by age, sex and gender, stratified by type of diabetes and type of approach or model of care.
Heterogeneity will be assessed using I^2 score forrest plots.

Review general information

28 Type of review

Select one of the following:

Review Type	
Scoping review	☐
Rapid review	☐
Systematic review	✓
Other:_____	☐

29 Language

No Language restrictions

30 Country

Canada

31 Other registration details

CRD42019115514

32 Reference and/or URL for published protocol

NA

33 Dissemination plans:

A meeting will be held to present review results to our knowledge users (before writing the final report) to get their feedback on the draft report and discuss the potential implications of this report. Following this, a one-page, standardized, policy brief will be shared with DAC and its knowledge users, with members and partners of the SPOR Evidence Alliance, and broadly (through the SPOR Evidence Alliance Website).
Scientific, peer-reviewed publications will also be developed and published.

Do you intend to publish the review on completion?

Yes ✓
No ☐

34 Keywords

Diabetes, retinopathy, nephropathy, foot ulcers, models of care, screening

35 Details of any existing review of the same topic by the same authors.

NA

36 Current review status

Ongoing

37 Any additional information:

NA

38 Details of final report/publication(s):

Review is ongoing