

ENVIRONMENTAL SCAN

Minimally Invasive Glaucoma Surgery: Implementation Considerations

Service Line: Environmental Scan
Issue: 76
Publication Date: May 2018
Report Length: 43 Pages

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Cite As: Minimally Invasive Glaucoma Surgery: Implementation Considerations. Ottawa: CADTH; 2018. (Environmental scan; no. 76).

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Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

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Context

Glaucoma is a leading cause of blindness and it is estimated that glaucoma affects more than 400,000 Canadians.^{1,2} The glaucoma treatment spectrum extends from pharmacotherapy involving topical medications (eye drops) as the first-line therapy to traditional, invasive filtration surgeries, such as trabeculectomy and aqueous shunt implantation.³⁻⁵ Challenges associated with pharmacotherapy include ineffective use (e.g., under- or overdosing, incorrect timing, or administration),^{6,7} local or systemic side effects (e.g., irritation) or toxicity,^{8,9} and considerable lifetime costs.¹⁰ Filtration surgical options are typically used in advanced glaucoma cases or when targeting a very low intraocular pressure as a treatment outcome.^{3,11} These invasive surgeries may be considered for medically refractory cases, or when there are such issues as intolerable side effects from the drugs or from ineffective use of the medications.^{3,4,12}

In addition to the more invasive surgeries, a range of surgical interventions commonly termed micro-invasive or minimally invasive glaucoma surgery (MIGS) are relatively new options in the spectrum of treatments for glaucoma.^{5,13} MIGS may be performed alone or in conjunction with cataract surgery.¹⁴ The advent of MIGS devices and procedures offers a newer surgical option that fills a previously existing gap between pharmacotherapy and the risk-fraught filtration surgeries.^{3,13,15,16}

Most MIGS devices and procedures that are currently available in Canada received regulatory approval in the last decade and there is a growing demand for and use of MIGS devices and procedures across the country.^{17,18} At the same time, the cost of MIGS implantable devices can be considerable and inconsistencies appear to exist in most jurisdictions regarding coverage of those devices under the public health insurance plan.¹⁸

As such, this Environmental Scan seeks to clarify current access to MIGS devices and procedures across Canadian jurisdictions, relevant implementation considerations including challenges and enablers to the use of MIGS devices and procedures, and current policy on reimbursements for MIGS across jurisdictions.

Objectives

The objective of this Environmental Scan is to identify and summarize information regarding the current practice and the implementation of MIGS devices and procedures in Canada. The following questions are addressed:

1. How is glaucoma managed across jurisdictions and what is the current availability and use of MIGS devices and procedures in the treatment of adult patients (over 18 years) with glaucoma?
2. How are glaucoma treatments reimbursed in the Canadian public health care system, and how does this vary by jurisdiction in Canada?
3. What are the relevant factors to consider if implementing MIGS devices and procedures in a jurisdiction (across urban, rural, and remote settings) for the treatment of adult patients with glaucoma?
4. What are the challenges and enablers impacting the use of MIGS devices and procedures in Canada for the treatment of adult patients with glaucoma?

Methods

Approach

To understand implementation issues associated with MIGS devices and procedures, a dual-stage, sequential research protocol was followed. The two stages included 1) consultation with key stakeholders (informants), and 2) a review of the published and grey literature. Findings from the literature search were used to supplement the information retrieved during the consultations.

To address reimbursement of glaucoma pharmacotherapy for research Question 2, data regarding reimbursement status was sought from CADTH's Drug Policy Advisory Committee Formulary Working Group on federal, provincial, and territorial public drug plans, and compiled by group. The Formulary Working Group is an advisory body for the CADTH Common Drug Review (CDR) processes, with representatives from these public drug plans and from other health organizations, and they help facilitate sharing of pharmaceutical information between jurisdictions.

Data Collection

Stage 1: Consultations

Consultations were conducted with targeted key informants identified through the clinician networks managed by the CADTH Implementation Support and Knowledge Mobilization team or referred through other informants during consultations. These key informants were consulted in order to provide a general overview of policy, practice and implementation issues related to MIGS as well as to identify relevant literature. To guide the consultations, a semi-structured interview guide was developed (Appendix 2). Interview questions were developed based on research questions and were related to the types of MIGS devices and procedures available, challenges and enablers to the use of MIGS, implementation considerations, physician reimbursement, as well as gaps in the literature. Consultations took place between October and December of 2017 and consent to publish comments and names were obtained from key informants.

Stakeholder feedback was solicited by posting a draft version of the report on CADTH's website and by emails to subscribers to CADTH's mailing lists. Key informants involved in the consultations were also asked to provide feedback.

Stage 2: Literature Search

Search Methods

The literature search was performed by an information specialist, using a peer-reviewed search strategy.

Implementation-related information was identified by searching the following bibliographic databases: MEDLINE (1946–) with in-process records and daily updates, and Embase (1974–) via Ovid; CINAHL (1981–) via EBSCO; and PubMed. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were glaucoma, minimally invasive glaucoma surgery, and minimally invasive glaucoma surgical devices.

Methodological filters were applied to limit retrieval to studies relevant to implementation issues. The search was also limited to English and French language documents published between January 1, 2000 and October 17, 2017. Monthly alerts were run until March 1, 2018.

Grey literature (literature that is not commercially published) was identified by searching the Grey Matters checklist (<https://www.cadth.ca/grey-matters>), which includes the websites of health technology assessment (HTA) agencies, clinical guideline repositories, systematic review repositories, economics-

related resources, public perspective groups, and professional associations. Google and other Internet search engines will be used to search for additional Web-based materials. These searches were supplemented by reviewing the bibliographies of key papers and through contacts with appropriate experts and industry.

Eligibility Criteria

English or French language reports that described implementation and context issues, including challenges and enablers associated with treatment of glaucoma with MIGS were eligible for inclusion.

Screening and Selecting Articles for Inclusion and Data Extraction

Citations arising from the literature searches were screened independently by one reviewer for information related to implementation issues in Canada. From each potentially relevant article, one reviewer extracted the bibliographic details (i.e., the authors, the year of publication, and the country of origin), and data, which was organized under the INTEGRATE-HTA framework.¹⁹ The information from the identified literature supplemented the information provided by the consultations, and attempted to address potential information gaps.

Descriptive analysis and synthesis

Responses from consultations were used to answer the research questions. All research questions were supplemented with information obtained through the literature search. Stakeholder feedback was used to supplement information received from the consultations and literature search.

Information from consultations and findings from the literature were sorted into categories based on the domains of implementation and the domains of context identified by the Context and Implementation of Complex Interventions (CICI) framework from INTEGRATE-HTA¹⁹ to identify themes related to the challenges and enablers associated to the implementation of MIGS devices and procedures.

The framework helps to examine the influence of context and implementation issues as modifiers in an HTA, factors enabling or limiting intervention uptake and facilitating an examination of the influence of these factors on the population reach and effectiveness of an intervention as well as its generalizability and applicability.

The concept of context within the framework is considered to be a set of characteristics or circumstances that interact, influence, modify, facilitate or constrain the intervention and its implementation. Implementation, for the purposes of the framework, is considered to be an actively planned and deliberately initiated effort with the intention to bring a given object into policy and/or practice.¹⁹

Using this framework, the domains of context, socioeconomic, sociocultural, setting, political, legal, geographical, ethical, and epidemiological, were used to guide the categorization of information on challenges and enablers of implementing MIGS across Canadian jurisdictions. The four domains of implementation: provider, organization and structure, policy, and funding, as well as the additional domain of patient were used to further guide the categorization of identified challenges and enablers as they relate to the implementation of MIGS devices and procedures across various levels of health care service delivery.

Findings

Consultations

In total, 21 key informants were interviewed for the purposes of this Environmental Scan (Appendix 1). This included 18 ophthalmology and glaucoma specialist physicians and three health system administrators. Of these key informants, six serve as current, past, or incoming presidents of national professional bodies in the ophthalmology and glaucoma specialty communities.

Efforts were made to contact stakeholders in every province and territory, and responses were received from Yukon, British Columbia, Alberta, Manitoba, Ontario, Quebec, New Brunswick, Nova Scotia, Newfoundland and Labrador, and Prince Edward Island.

Literature Search

The literature search yielded 1,026 citations, of which 19 studies were determined to be eligible to address the research questions. One study was added after suggestion by a stakeholder during the feedback period.²⁰ Seven articles were published in Canada,^{10,20-25} nine articles were published in the US,²⁶⁻³⁴ two articles were published in the UK,^{35,36} and one article was published in Saudi Arabia.³⁷ One article was written by a Canadian surgeon, but contained information relating to use of MIGS in the US.¹⁴ Two articles were systematic reviews,^{24,25} six articles were narrative reviews,^{23,31-33,35,37} one article was a survey of UK glaucoma specialists and their preferences for glaucoma surgery,³⁶ and one article was a retrospective review of billing service claims to analyze trends in glaucoma procedures.²² Additionally, one article was a cost comparison of trabectome, iStent, and endocyclophotocoagulation (ECP) to glaucoma pharmacotherapy.¹⁰ The remaining eight articles were news articles, summaries of proceedings, or editorials.^{14,20,21,26-30,34}

Findings are presented by research question.

How is glaucoma managed across jurisdictions and what is the current availability and use of MIGS procedures?

There is wide variability in the use of MIGS to treat glaucoma, not only by province, but even more so by facility. The use of surgical procedures for glaucoma are also influenced heavily by increases in prevalence of the disease, changes in disease management (for example, in the case of glaucoma, lower target intraocular pressure [IOP] pressure), and change in the number of surgeons who perform these procedures.²² Access for patients to glaucoma treatments and types of MIGS devices and procedures will vary within a city with one facility providing a certain MIGS device and procedure and another providing a different MIGS or none at all. Appendix 3 outlines the current MIGS devices and procedures approved in Canada and their surgical approaches as of March 2018.

The glaucoma treatment spectrum typically begins with pharmacotherapy and laser therapy as first-line treatments to lower IOP for glaucoma patients and offered across all jurisdictions.²³ Traditional invasive surgeries at the opposite end of the spectrum are reserved for patients with uncontrolled moderate to severe glaucoma and include trabeculectomy and implantation of aqueous tube shunts;³⁸ these were found to be performed by glaucoma surgeons across all consulted jurisdictions. However, the consultations indicated that for MIGS devices and procedures, availability of funding for devices, hospital approval, training of staff, and availability of surgeons often determine if MIGS are offered as part of the glaucoma treatment algorithm for a province or facility.

The following describes the glaucoma management and MIGS device and procedure availability in select facilities across Canadian jurisdictions:

Alberta

In Calgary, Dr. Andrew Crichton and Dr. Bryce Ford indicated that, in addition to prescribing medication (drops) for patients with mild glaucoma, they perform trabeculectomies and valve implantations for glaucoma patients at the Calgary Ophthalmology Centre where they both work. (Dr. Andrew Crichton, Division of Ophthalmology, Faculty of Medicine, University of Calgary, Calgary, AB: personal communication, 2017 Nov 17; Dr. Bryce Ford, Division of Ophthalmology, Faculty of Medicine, University of Calgary, Calgary, AB: personal communication, 2017 Nov 24). Regarding MIGS procedures, they are currently using iStent – which is covered by their hospital – and also perform gonioscopy-assisted transluminal trabeculectomy (GATT) procedures. (Dr. Andrew Crichton: personal communication, 2017 Nov 17; Dr. Bryce Ford: personal communication, 2017 Nov 24). Dr. Crichton added that they are currently in the process of applying to have the CyPass, XEN and Kahook blade covered by their facility. (Dr. Andrew Crichton: personal communication, 2017 Nov 17). According to Dr. Karim Damji, a glaucoma surgeon who operates out of Edmonton at the Royal Alexandra Hospital, his facility also offers the full glaucoma treatment spectrum from pharmacotherapy and laser therapies to trabeculectomy. Surgeons at his facility are using mostly iStent and trabectome, and XEN and Hydrus are also being used, albeit to a lesser extent. (Dr. Karim Damji, Professor and Chair Department of Ophthalmology and Visual Sciences, University of Alberta, Edmonton, AB; Edmonton Zone, Alberta Health Services, Edmonton, AB: personal communication, 2017 Nov 23).

In other areas of the province, including Red Deer and further north, according to Dr. Damji, ophthalmologists are using pharmacotherapy, laser therapy, and trabeculectomy to manage patients with glaucoma and may not have access to MIGS at their local facility. (Dr. Karim Damji: personal communication, 2017 Nov 23). However patients who are candidates for MIGS are being referred to his hospital for treatment from Red Deer and Grand Prairie, Alberta and they also are treating patients from Yellowknife, Northwest Territories. (Dr. Karim Damji: personal communication, 2017 Nov 23).

British Columbia

According to Carla Service, at the Royal Jubilee Hospital in Victoria they are able to provide glaucoma treatment through a specialized eye care team which includes ophthalmic operating room (OR) nurses. (Carla Service, Island Health Surgical Ambulatory Clinics and Regional Program, Victoria, BC: personal communication, 2017 Nov 11). Dr. James Taylor, also at the Royal Jubilee Hospital, noted that pharmacotherapy is most common, but their hospital also uses various laser therapies in addition to trabeculectomy and tube shunt surgery. (Dr. James Taylor, Royal Jubilee Hospital, Victoria, BC: personal communication, 2017 Nov 1). Dr. Taylor and Carla Service highlighted that there is funding at their organization for trabectome with an annual limit of 25, while GATT procedures have recently been introduced. Both the iStent and XEN have also been made available in very limited quantities (free of charge from the device manufacturers) for the purposes of evaluating patient outcomes. Some CyPass stents have also been implanted at the Royal Jubilee Hospital in Victoria. (Carla Service: personal communication, 2017 Nov 11; Dr. James Taylor: personal communication, 2017 Nov 1).

Manitoba

In Winnipeg, Dr. Jennifer Rahman of GEM Clinic noted that trabeculectomies are still the most common method used to treat patients with advanced glaucoma in her facility. (Dr. Jennifer Rahman, Glaucoma & Eye Management Clinic, Winnipeg, MB: personal communication, 2017 Nov 24). Gillian Toth added that surgeons at the teaching health centre she works out of are also using laser therapy, Ahmed valves and Baerveldt implants and MIGS procedures including iStents, and GATT. (Ms. Gillian Toth, Misericordia Health Centre, Winnipeg, MB: personal communication, 2017 Nov 28). However, MIGS procedures are not currently covered in Winnipeg by the facility and therefore, in order to make these devices available to patients, the iStent devices are offered for purchase from physicians' offices in a similar manner in which the surgeon sells premium lenses as an upgrade for cataract surgeries (e.g., toric lenses to correct astigmatism). (Gillian

Toth: personal communication, 2017 Nov 28). Dr. Rahman indicated that most patients when presented with the option to purchase the device often do so quite willingly. She added that approximately 40% of patients that the ophthalmology team sees are referred from rural Manitoba, northern Ontario, and Nunavut. *(Dr. Jennifer Rahman: personal communication, 2017 Nov 24)*.

Dr. Guillermo Rocha is the only ophthalmic surgeon in Brandon, Manitoba and he performs selective laser trabeculoplasties (SLTs), trabeculectomies and iStents at the Brandon Regional Health Centre. *(Dr. Guillermo Rocha, Canadian Ophthalmological Society; Faculty of Medicine, University of Manitoba, Winnipeg, MB; Ocular Microsurgery & Laser Centre, Brandon Regional Health Centre, Brandon, MB: personal communication, 2017 Nov 28)*.

However, unlike in Winnipeg, his facility in Brandon funds the iStent. According to Dr. Rocha, his catchment area includes both northern and western Manitoba and eastern Saskatchewan, and roughly 10% of his patients are referred from Winnipeg. *(Dr. Guillermo Rocha: personal communication, 2017 Nov 28)*.

New Brunswick

In Fredericton, according to Dr. Ken Roberts, glaucoma treatments typically include pharmacotherapy and traditional trabeculectomy, however tube shunts are not used. *(Dr. Ken Roberts, Horizon Health Network, Fredericton, NB: personal communication, 2017 Dec 13)*. Currently, the only MIGS procedure being performed at his facility (Horizon Health Network) is GATT (gonioscopy-assisted transluminal trabeculectomy). Usually this procedure is used on patients undergoing cataract surgery who also have glaucoma. According to Dr. Roberts, no other MIGS are being considered at this time. *(Dr. Ken Roberts: personal communication, 2017 Dec 13)*.

Newfoundland and Labrador

Dr. Xavier Campos is able to perform trabeculectomy and insert tube shunts for patients and has also recently introduced MIGS to the province. *(Dr. Xavier Campos, Western Memorial Regional Hospital, Corner Brook, NL: personal communication, 2017 Dec 17)*. Prior to this, glaucoma patients in Newfoundland requiring surgery would be required to travel to Halifax or Toronto. Since his arrival a few years ago, his facility (Western Memorial Regional Hospital) is covering the costs for iStents, GATT and XEN implant devices and Dr. Campos expects that they may introduce CyPass and viscocanalostomy in the near future. *(Dr. Xavier Campos: personal communication, 2017 Dec 17)*.

Nova Scotia

The QEII Health Sciences Centre in Halifax is the primary teaching hospital in the Maritimes providing glaucoma surgeries with patients referred from across Nova Scotia, New Brunswick, Prince Edward Island and parts of Newfoundland, according to Dr. Marcelo Nicolela. *(Dr. Marcelo Nicolela, Ophthalmology Department, QEII Health Sciences Centre, Halifax, NS; Department of Ophthalmology & Visual Sciences, Dalhousie University, Halifax, NS: personal communication, 2017 Oct 31)*. Dr. Paul Rafuse, also working at the QEII Health Sciences Centre in Halifax, indicated that those patients in-province requiring glaucoma treatment tend to have greater access to pharmacotherapy and laser therapy, tube shunts and MIGS procedures. *(Dr. Paul Rafuse, Department of Ophthalmology & Visual Sciences, Dalhousie University, Halifax, NS: personal communication, 2017 Nov 11)*. Their ophthalmology centre also performs a considerable number of trabeculectomies, particularly for those patients referred from out-of-province who Dr. Rafuse notes are usually at a later stage of glaucoma and need more aggressive treatment. *(Dr. Paul Rafuse: personal communication, 2017 Nov 11)*. Dr. Nicolela indicated that their facility is performing a limited number of iStents, XEN gel stents, and trabectomes which are covered by the budget of the hospital's ophthalmology centre. *(Dr. Marcelo Nicolela: personal communication, 2017 Oct 31)*.

Ontario

Dr. Steven Gilberg at The Ottawa Hospital noted that his facility provides a full range of glaucoma treatments from medical and laser therapy to Ahmed and Baerveldt implants, trabeculectomy and trabectome (*Dr. Steven Gilberg, Chief/Head Department of Ophthalmology, Ottawa, ON: personal communication, 2017 Nov 23*). In addition, the four glaucoma surgeons at his facility have included MIGS (iStent and XEN gel implants) in management of their patients. His Department has a fixed amount of financial support for supplying these implants from within his hospital budget. Dr. Gilberg indicated that his facility accepts glaucoma patients referred from eastern Ontario, western Quebec, and Nunavut. The Ottawa Hospital also provides general ophthalmic services for Nunavut and sends specialists to Iqaluit biannually for one week with resident support for patient consults. All major ophthalmic procedures for patients from Nunavut are performed in Ottawa. (*Dr. Steven Gilberg: personal communication, 2017 Nov 23*). The Kensington Eye Institute (KEI) in Toronto, Ontario is an independent not-for-profit health care that provides the majority of surgical education for University of Toronto Ophthalmology residents according to Dr. Sherif El-Defrawy. (*Dr. Sherif El-Defrawy, Department of Ophthalmology & Vision Sciences, University of Toronto, Toronto ON: personal communication, 2017 Dec 11*). The surgeons operating out of KEI are affiliated with teaching hospitals in Toronto but have privileges to perform surgeries at KEI. Dr. El-Defrawy added that surgeons operating out of KEI are performing ECP and trabeculectomy and KEI manages to find funds for a limited number of XEN gel stents per year (*Dr. Sherif El-Defrawy: personal communication, 2017 Dec 11*). Donna Punch from KEI indicated that there have been an increasing number of requests by specialists for more MIGS procedures. While this particular procedure is not currently funded, she noted, they are finding efficiencies in other areas of the organization to help offset the cost of these devices (*Ms. Donna Punch, Kensington Eye Institute, Toronto, ON: personal communication, 2017 Nov 23*).

Dr. Ike Ahmed who operates at Trillium Health Partners in Mississauga, Ontario and the KEI indicated that at both facilities, he is using all MIGS devices (including iStent, CyPass, Xen, and Hydrus) and these devices are combined with cataract surgeries as well as standalone procedures. (*Dr. Ike Ahmed, Trillium Health Partners, Mississauga, ON; Prism Eye Institute, Brampton, ON; Department of Ophthalmology & Vision Sciences, University of Toronto, Toronto, ON; Kensington Eye Institute, Toronto, ON, Hamilton, ON: personal communication, 2017 Oct 30*).

Dr. Catherine Birt operates out of Sunnybrook Health Sciences Centre in Toronto and has hospital privileges at KEI (*Dr. Catherine Birt, Department of Ophthalmology & Vision Sciences, University of Toronto, Toronto, ON: personal communication, 2017 Nov 24*). While she has performed numerous XEN implants at KEI, Sunnybrook does not cover any MIGS procedures, but she is able to perform trabeculectomies at Sunnybrook. Dr. Birt indicated that her hospital includes patients referred from Sudbury and North Bay, Ontario (*Dr. Catherine Birt: personal communication, 2017 Nov 24*). At the Ivey Eye Institute in London, Ontario, Dr. Cindy Hutnik indicated that MIGS devices and procedures are not available at her facility which is a tertiary care academic centre however trabeculectomy and Ahmed valve/Baerveldt tube shunts are (*Dr. Cindy M.L. Hutnik, Schulich School of Medicine and Dentistry, Western University, London, ON: personal communication, 2017 Nov 11*). According to Dr. Hutnik, her facility received a limited number of XEN devices provided free of charge by the manufacturer and these were made available to the four glaucoma specialists on staff (*Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11*). Otherwise, for those patients who are willing and able, they must travel to Toronto for access to MIGS (*Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11*).

Prince Edward Island

According to Dr. Richard Wedge of Health PEI, there are six ophthalmologists in PEI, three of whom are performing surgeries including trabeculectomies and tube shunts. Glaucoma management therapies include drugs, laser, tube shunts, and trabeculectomy (*Dr. Richard Wedge, Charlottetown, PEI: personal communication, 2017 Dec 14*). At the moment, there are no MIGS procedures being performed on PEI and any patient who would be a candidate for MIGS would need to be referred to Halifax (*Dr. Richard Wedge: personal communication, 2017 Dec 14*). However, Dr. Wedge indicated that patients from PEI are very rarely referred to Halifax for MIGS procedures (*Dr. Richard Wedge: personal communication, 2017 Dec 14*).

Quebec

The McGill University Health Centre has four glaucoma surgeons working out of two operative sites according to Dr. Hady Saheb. While each have their preferences, he noted, they are mostly performing tube shunts, trabeculectomy, and MIGS (*Dr. Hady Saheb, McGill University, Montreal, QC: personal communication, 2017 Nov 17*). The McGill University Health Centre, and Dr. Saheb in particular, is also using XEN and CyPass, although on a more limited basis as the hospital has limited further expansion of the MIGS operative budget (*Dr. Hady Saheb: personal communication, 2017 Nov 17*).

Yukon

Dr. Paul Mackenzie is based in the Vancouver, BC area where he works on a team that provides a range of glaucoma therapies including trabeculectomy and tube shunts (*Dr. Paul Mackenzie, Eye Care Centre, Vancouver General Hospital, Vancouver, BC; Faculty of Medicine, University of British Columbia, Vancouver, BC: personal communication, 2017 Nov 24*). He is also one of three surgeons who travels regularly to Whitehorse to provide consults to patients with glaucoma, among other ophthalmic diseases (*Dr. Paul Mackenzie: personal communication, 2017 Nov 24*). With respect to MIGS, Dr. Mackenzie currently performs GATT and CyPass procedures in BC but his facility in Whitehorse has not yet approved MIGS procedures. The few Yukon patients he has performed a MIGS procedure on were required to travel to BC for treatment, however he hopes to provide MIGS procedures in the Yukon in the future (*Dr. Paul Mackenzie: personal communication, 2017 Nov 24*).

How are glaucoma treatments reimbursed in the Canadian public health care system, and how does this vary by jurisdiction in Canada?

The following information regarding the reimbursement of MIGS devices and procedures is based on common themes from the consultations with targeted key informants and physician fee schedules.^{39,40}

Glaucoma treatments, including trabeculectomies and tube shunts, are covered by most hospital budgets and physician services are paid directly through the respective provincial health care insurance plan (*Dr. Sherif El-Defrawy: personal communication, 2017 Dec 11*). Consultations with informants revealed that fees for physician services are reimbursed according to each province's schedule of benefits which lists the amounts payable by the plan for insured services. The consultations suggested at present, no MIGS procedures are listed as an insured service in any Canadian province with the exception of Alberta and Quebec. As such, for billing purposes in all other jurisdictions, physicians performing a MIGS procedure will have to choose an existing procedure— and corresponding fee — from the schedule of benefits that most closely aligns with the MIGS procedure performed. There are usually no criteria for choosing the most appropriate proxy code and this is left to the discretion of the billing physician. The choice of billing code will largely depend on the availability and broad definition of existing codes on the fee schedule. A surgeon may choose an existing procedural or time-based code that reasonably mirrors the time or intensity of the MIGS procedure performed or the skill and expertise required to perform the surgery, but if something similar does not exist on their particular province's schedule, they may have little choice but to select a billing code for a service that may take three times as long as the MIGS procedure they performed.

Even in the absence of an appropriate MIGS fee code, there is a lack of clarity and guidance within jurisdictions as to which proxy codes should be used (*Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11*). Moreover, because provincial fee schedules are negotiated between the provincial medical association and the provincial Ministry of Health, there is high variability across jurisdictions with respect to the types of insured ophthalmological services listed and the fees associated with these services. This is described in further detail below.

MIGS Reimbursement

Alberta

Calgary surgeon Dr. Andrew Crichton indicated that in Alberta, there is a fee code for the iStent (a device which is funded at his hospital) and he expects that any billings for the XEN implants would use the same code as trabeculectomy (*Dr. Andrew Crichton: personal communication, 2017 Nov 17*).

Dr. Bryce Ford was involved in his province's addition of a MIGS-specific fee code to the physician's schedule of benefits (*Dr. Bryce Ford: personal communication, 2017 Nov 24*). Dr. Karim Damji added that glaucoma surgeons were already performing MIGS procedures and having to bill for trabeculectomies or tube shunts so a MIGS-related fee code for angle-based procedures was added that could be used for trabectomes and stents and other similar surgeries, and that paid approximately 30% to 40% less than trabeculectomies (*Dr. Karim Damji: personal communication, 2017 Nov 23*).

British Columbia

According to Dr. James Taylor in Victoria, because there is no code for MIGS procedures in BC, surgeons have needed to use existing glaucoma codes (*Dr. James Taylor: personal communication, 2017 Nov 1*). For example, Dr. Taylor indicated that when he performs a XEN or trabectome, he may use trabeculectomy or an open angle procedural code/goniotomy respectively since the treatments are somewhat similar. He has also used a miscellaneous code for MIGS procedures. Meanwhile, he added, he is aware that other surgeons in the province could be using different fee codes when performing the same MIGS procedures (*Dr. James Taylor: personal communication, 2017 Nov 1*). Carla Service noted that MIGS surgeries require a disposable device (with the exception of GATT), which should allow a hospital to estimate what has been purchased and what procedures have been completed (*Carla Service: personal communication, 2017 Nov 11*).

Manitoba

In Manitoba, Dr. Jennifer Rahman indicated that there is no MIGS-specific code in the province's physician schedule of benefits (*Dr. Jennifer Rahman: personal communication, 2017 Nov 24*). Dr. Rahman highlighted that there is only one fee code for filtering surgery, and this one code must be applied for all glaucoma surgical procedures including both Baerveldt and Ahmed implants, so some procedures are reimbursed at a rate higher than probably necessary while others are not reflective of the true time and intensity needed for the procedure (*Dr. Jennifer Rahman: personal communication, 2017 Nov 24*). In 2019, Manitoba's physicians will be upgrading their tariffs and Dr. Rahman is hopeful that the schedule amendments will include an update to the glaucoma procedural codes (*Dr. Jennifer Rahman: personal communication, 2017 Nov 24*).

New Brunswick

In New Brunswick, according to Dr. Ken Roberts, there are no MIGS-specific fee codes available on the provincial schedule of benefits (*Dr. Ken Roberts: personal communication, 2017 Dec 13*). Dr. Roberts noted that there is a generic code for "procedure for the relief of glaucoma" which could potentially be used if MIGS procedures were being performed in the province (*Dr. Ken Roberts: personal communication, 2017 Dec 13*).

Newfoundland and Labrador

According to Dr. Xavier Campos, in Newfoundland and Labrador there is currently just one code available for glaucoma procedures in the physician schedule of benefits (*Dr. Xavier Campos: personal communication, 2017 Dec 17*). Dr. Campos indicated that he uses this billing code for all glaucoma procedures and has the option to add an extra fee for intraocular device implant such as an Ahmed valve (*Dr. Xavier Campos: personal communication, 2017 Dec 17*). While this billing code may work for some procedures including MIGS, Dr. Campos feels that this is not appropriate for procedures that require multiple lengthy follow-up visits with possible additional in-office minor procedures and adjustments (*Dr. Xavier Campos: personal communication, 2017 Dec 17*). Since his province stipulates that there cannot be a follow-up consult billed for within 42 days post-surgery, he is unable to be paid for the six or more follow-up visits that may be necessary for trabeculectomy patients within these 42 days (*Dr. Xavier Campos: personal communication, 2017 Dec 17*).

Nova Scotia

The physician fee schedule for Nova Scotia was consulted for information regarding fee codes for MIGS devices and procedures in this province. There are no fee codes associated with MIGS devices or procedures in Nova Scotia.⁴⁰

Ontario

Currently, a MIGS-specific code does not exist in the physician schedule of benefits for Ontario according to Dr. Cindy Hutnik (*Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11*). There has been a delay in the creation of MIGS-specific OHIP billing codes in Ontario that match the development of new technologies.²² Donna Punch indicated that surgeons performing MIGS procedures need to use codes for like-procedures in the fee schedule (*Donna Punch: personal communication, 2017 Nov 23*). Dr. Sherif El-Defrawy felt that many physicians are using the billing code commonly used for trabeculectomies (glaucoma filtering procedures) as a proxy for iStents procedures and the tube shunt billing code (Seton implant) as a proxy for XEN implant procedures (*Dr. Sherif El-Defrawy: personal communication, 2017 Dec 11*). Dr. Hutnik and Dr. Catherine Birt both felt that the addition of billing codes for ab externo and ab interno procedures would be inclusive of current MIGS procedures being used in the province and should have a fee more reflective of the time required, nature of the surgery and the complexity of peri-operative care (*Dr. Catherine Birt: personal communication, 2017 Nov 24. Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11*). The creation of more specific billing codes would also allow for better estimation of these treatments' role in glaucoma care and allow for comparison of these procedures with other procedures, such as glaucoma drainage devices.²²

Prince Edward Island

The physician fee schedule for PEI was consulted for information regarding fee codes for MIGS devices and procedures in this province. There are no fee codes associated with MIGS devices or procedures in PEI.³⁹

Quebec

Dr. Hady Saheb from McGill University Health Centre indicated that in Quebec there is a physician billing code for the iStent MIGS procedure and noted that the addition of this code was within the last two years (*Dr. Hady Saheb: personal communication, 2017 Nov 17*). In his opinion, the addition of the fee code to the schedule of benefits occurred with relative ease because of the anticipated cost savings of having a MIGS-specific code that was more reflective of surgical time and intensity compared to other glaucoma surgery codes (*Dr. Hady Saheb: personal communication, 2017 Nov 17*). Dr. Saheb also suggested that additional MIGS-specific codes for additional procedures will be added in the near future (*Dr. Hady Saheb: personal communication, 2017 Nov 17*).

Yukon

Dr. Paul Mackenzie indicated that there is currently no fee code for MIGS in British Columbia where he is based or in Yukon where he also works (*Dr. Paul Mackenzie: personal communication, 2017 Nov 24*).

Dr. Mackenzie noted that there are angle surgery codes that he and his colleagues can use instead and he does not feel that there needs to be a MIGS-specific code added to the schedule (*Dr. Paul Mackenzie: personal communication, 2017 Nov 24*).

Drug Plan Reimbursements

To determine the reimbursement status for glaucoma pharmacotherapy, data were requested from CADTH's Drug Policy Advisory Committee Formulary Working Group for CDR participating public drug plans. Medications for the treatment of glaucoma include prostaglandin analogues, alpha-2 adrenergic agonists, beta adrenergic antagonists, carbonic anhydrase inhibitors, parasympathomimetics (cholinergic agents), and products that are combinations of these medications. The public drug plans provide some form of reimbursement coverage for almost all the glaucoma pharmacotherapy of interest. Coverage ranges from a full benefit mostly, to a restricted benefit or not a benefit for some available strengths or dosage forms of a particular drug.⁴¹⁻⁵¹ The reimbursement and coverage status of medications are described below and detailed tables are provided in Appendix 4. The associated listing criteria for restricted benefit drugs are detailed in Appendix 5.

Information was available for British Columbia, Alberta, Manitoba, Ontario, Saskatchewan, Newfoundland and Labrador, New Brunswick, Nova Scotia, Prince Edward Island, Non-Insured Health Benefits (NIHB) Program, and the Canadian Armed Forces.⁴¹⁻⁵¹

Prostaglandin analogues include travoprost, latanoprost, and bimatoprost. The majority of medications in this group are covered by full benefit with the exception of Ontario, where most of these medications are under restricted access.⁴¹⁻⁵¹

Alpha-2 adrenergic agonists include brimonidine and apraclonidine. The majority of medications in this group are also covered by full benefit with the exception of Ontario, where brimonidine medications are under restricted access, and apraclonidine medications are not a benefit. Apraclonidine medications are also not a benefit in Saskatchewan⁴¹⁻⁵¹

Beta adrenergic antagonists include betaxolol, timolol, and levobunolol. The majority of these medications are full or general benefit.⁴¹⁻⁵¹

Carbonic anhydrase inhibitors include dorzolamide and brinzolamide. These medications are under full benefit except in Ontario, where they are under restricted benefit.⁴¹⁻⁵¹

Parasympathomimetics include pilocarpine and carbachol. Pilocarpine is covered under full or general benefit, and carbachol is under full coverage except in Ontario, Alberta, New Brunswick, Newfoundland and Labrador, Saskatchewan and Nova Scotia. Carbachol appears to have been discontinued in some provinces.⁴¹⁻⁵¹

Combination products are anti-glaucoma drops that contain two or more medications within their formulation. They are under full benefit in all provinces providing benefit information with the exception of Ontario and the Canadian Armed Forces.⁴¹⁻⁵¹

What are the relevant factors to consider if implementing MIGS procedures in a jurisdiction (across urban, rural, and remote settings)?

MIGS devices and procedures are currently available in most Canadian jurisdictions; however, as described in Question 1 of this Environmental Scan, the decision to fund a procedure is often at the discretion of individual facilities. For jurisdictions that consider implementing MIGS on a broader scale, the key informant interviews revealed a myriad of issues that one would need to consider. The sections below summarize some of these important factors identified by stakeholders and the body of MIGS literature.

Benefits of MIGS

As the population ages, and as the technology to diagnose glaucoma improves and allows for earlier diagnoses, the number of glaucoma patients requiring treatment is expected to grow.³⁰ There is a large population of patients living with glaucoma in Canada, explained Dr. Guillermo Rocha, and there is currently a treatment gap between pharmacotherapy and laser therapy on one end of the glaucoma treatment spectrum and trabeculectomy and tube shunts at the other end (*Dr. Guillermo Rocha: personal communication, 2017 Nov 28*). Dr. Hady Saheb maintains that MIGS fill the gap between medications and lasers and more invasive surgeries (*Dr. Hady Saheb: personal communication, 2017 Nov 17*). In his opinion, if a facility does not have access to MIGS, physicians will either relatively under-treat with drugs (drops) alone, or relatively over-treat with aggressive surgeries for those patients that fall somewhere in between and would be ideally suited for MIGS (*Dr. Hady Saheb: personal communication, 2017 Nov 17*).

MIGS devices and procedures are designed to address this treatment gap between pharmacotherapy and more invasive surgeries.^{14,23} Often the effectiveness of MIGS is compared with mitomycin-C trabeculectomy, which may not be an appropriate comparison, as MIGS devices or procedures are not designed to be a direct replacement of these surgeries.¹⁴ The placement of MIGS devices or procedures in the glaucoma treatment pathway is still uncertain,²⁹ and the concept of using MIGS devices or procedures earlier in the treatment paradigm (to replace medications) has created uncertainties in regulatory approval processes for these devices.¹⁴

For Dr. Paul Rafuse, MIGS helps to replace glaucoma drugs (eye drops) which he feels create a great deal of irritation and dryness to the eye (*Dr. Paul Rafuse: personal communication, 2017 Nov 11*). Dr. Rafuse added that often you need to treat the dry eye with other medications, and the series of drops required leads to considerable adherence problems, particularly in elderly patients, and comes with significant costs (*Dr. Paul Rafuse: personal communication, 2017 Nov 11*). Daily doses of glaucoma medications on the ocular surface can also be permanently damaging to the eye and cause chronic issues, according to an ophthalmologist from California.²⁷ Glaucoma surgery, in Dr. Catherine Birt's opinion, is a medical necessity and not a premium lifestyle choice (*Dr. Catherine Birt: personal communication, 2017 Nov 24*). Some of the advantages afforded by MIGS to treat patients whose glaucoma has not progressed to the stage where they need more invasive surgeries, according to Dr. Paul Rafuse, include shorter OR times, safer and less risk-fraught surgeries, less tissue manipulation, faster patient recovery, less post-op care, less scarring, and the ease in correcting with another procedure if MIGS is unsuccessful (*Dr. Paul Rafuse: personal communication, 2017 Nov 11*). Patients who have undergone MIGS procedures or had MIGS devices inserted are not excluded from undergoing further tube shunt surgery or trabeculectomy.^{23,30} Dr. Hady Saheb is of the opinion that those making surgical budget committees decisions need to be aware of these benefits of MIGS as well as the impact on the number of appointments required (fewer for MIGS), patient work time lost (less for MIGS), reduced need for medication following MIGS (*Dr. Hady Saheb: personal communication, 2017 Nov 17*). Dr. Saheb further added that he would offer MIGS to more patients if he had access to additional devices in his facility (*Dr. Hady Saheb: personal communication, 2017 Nov 17*).

Choice of MIGS Procedure

Jurisdictions planning to implement MIGS will need to decide which device(s) and procedure to make available at facilities that can perform glaucoma surgeries. Most MIGS devices have been on the market for the last decade or so, according to Dr. Ike Ahmed (*Dr. Ike Ahmed: personal communication, 2017 Oct 30*). With this in mind, the evidence pointing to the efficacy of a given MIGS device is convincing from the perspective of most surgeons; however, what is still to be figured out is how each of the MIGS devices compares to one another, and which is best for which patients. (*Dr. Hady Saheb: personal communication, 2017 Nov 17*). Additionally, funding challenges for MIGS devices (such as the trabectome) also contributes to the lack of evidence for these devices, and prevents a definitive understanding of their role in glaucoma management.²⁵ Jurisdictions will need to consider the evidence available and make an informed-decision as to which device(s) is most clinically effective and cost-effective for their facility.

At the moment, the choice of MIGS procedure to be used is based on the preference of surgeons in the facility, their training and experience with devices, and their comfort level in performing the procedures (*Dr. Sherif El-Defrawy: personal communication, 2017 Dec 11*). While these factors are important in choosing the right procedure, Gillian Toth noted that there has been pressure from industry at her health centre (*Gillian Toth: personal communication, 2017 Nov 28*). Dr. Saheb indicated that with respect to MIGS at his institution, the surgeons are mostly using the iStent – in large part because it has been on the market the longest and because it is approved and funded by the hospital (*Dr. Hady Saheb: personal communication, 2017 Nov 17*). Dr. Damji indicated that his facility funds iStents through the glaucoma surgery budget and their surgeons tend to prefer the iStent over other MIGS options because of surgical ease of insertion, demonstrated efficacy, and fewer complications (*Dr. Karim Damji: personal communication, 2017 Nov 23*).

With the constant refinement of existing devices and addition of new ones, Carla Service feels that jurisdictions will need to decide which one is best for their population, if a procedure is medically necessary, and what is considered an upgrade over an existing procedure (*Carla Service: personal communication, 2017 Nov 11*). Moreover, for Dr. Catherine Birt, the problem with naming a single MIGS procedure is that you need to have an approach to glaucoma management that is tailored to the individual patient and not simply the device that has been funded (*Dr. Catherine Birt: personal communication, 2017 Nov 24*).

Access to MIGS

Jurisdictions will need to consider how to ensure equal access to MIGS procedures for patients. For many surgeons consulted with, a significant challenge that needs to be overcome is the issue of access. (*Dr. Catherine Birt: personal communication, 2017 Nov 24; Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11; Dr. Xavier Campos: personal communication, 2017 Dec 17; Dr. Paul Mackenzie: personal communication, 2017 Nov 24; Dr. Jennifer Rahman: personal communication, 2017 Nov 24; Dr. Hady Saheb: personal communication, 2017 Nov 17*). Patients in one city may not have MIGS procedures as an option while patients in another part of the province may have access to a host of MIGS procedure tailored to their needs (*Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11*). If they have the financial means to do so and if provided a referral to another specialist, a patient could then travel to another city to have the procedure (*Dr. Xavier Campos: personal communication, 2017 Dec 17*). This becomes further complicated, according to Dr. Catherine Birt, when some patients are required to pay for their device either purchasing it directly from their physician, health care facility, or dispensed to them by a pharmacy, while other patients in the same province receive the device free of charge (*Dr. Catherine Birt: personal communication, 2017 Nov 24*). In the case of the North, it is often more cost-effective for ophthalmologists to travel to a remote area for a few days per month to offer services to patients rather than send all patients out-of-area to be seen by a specialist (*Dr. Paul Mackenzie: personal communication, 2017 Nov 24*). This arrangement can be seen in the Territories where ophthalmologists will visit Whitehorse from Vancouver or in Nunavut where ophthalmic surgeons from Ottawa regularly provide services in Iqaluit (*Dr. Paul Mackenzie: personal communication, 2017 Nov 24; Dr. Steven Gilberg: personal communication, 2017 Nov 23*). Those patients requiring surgery (generally

trabeculectomy) will be sent out-of-province for the procedure, and although the out-of-province costs between PEI and Nova Scotia are comparable, it can be rather costly for the patients themselves to be sent away for lengthy preoperative and post-operative care and follow-up, according to Dr. Richard Wedge (*Dr. Richard Wedge: personal communication, 2017 Dec 14*).

Indications and Patient Selection

Jurisdictions will need to consider who are the most appropriate candidates and for what indications would MIGS be prescribed. For example, will MIGS devices or procedures be made available to all patients with mild to moderate glaucoma, or for patients undergoing cataract surgery as a preventive measure? Will these be approved for use with cataract surgeries only or as standalone procedures? At the moment, the decision as to who benefits from MIGS and for which indications rests with the surgeons, often who have a limited number of devices available to work with (*Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 17*). This lack of data and the uncertainty on the appropriate patient selection for MIGS was also evident in the literature,^{14,24,34,35,52} and there is a lack of consistent views from ophthalmologists on the appropriate assessment of MIGS devices or procedures in this regard.³⁴

For Dr. Andrew Crichton in Alberta where the iStent device is covered by his facility, the patients that get access to the MIGS are the ones he feels are appropriate to have an iStent done at the same time as cataract surgery (*Dr. Andrew Crichton: personal communication, 2017 Nov 17*). Inserting MIGS devices or performing MIGS procedures on patients undergoing cataract surgery also allows MIGS devices to be implanted in patients who have already accepted the potential risks of intraocular surgery.^{14,23} Dr. Guillermo Rocha believes that criteria are necessary regarding how MIGS are performed and on which patients (*Dr. Guillermo Rocha: personal communication, 2017 Nov 28*).

Provider Skill

Consultations indicated that the decision to implement MIGS in a jurisdiction will largely depend on the availability of trained ophthalmologists to carry out the procedures. However, as MIGS devices come at a considerable financial cost, most hospital budgets currently allow for a limited number to be purchased. As such, facilities and jurisdictions will have to consider who are the most appropriate providers to perform the limited number of surgeries. The consultations revealed that glaucoma specialist surgeons are typically performing MIGS procedures and inserting devices in those facilities that are offering the procedures. The rationale for this, according to Dr. Steven Gilberg, is that these specialists are usually performing trabeculectomies and tube shunts, so this is an extension of their skill set (*Dr. Steven Gilberg: personal communication, 2017 Nov 23*). Although, Dr. Ike Ahmed added, many general ophthalmic surgeons performing cataract surgeries have the skill set to implant an iStent, and there are too few glaucoma surgeons in Canada to perform all the potential MIGS procedures needed, especially in rural areas, in his opinion (*Dr. Ike Ahmed: personal communication, 2017 Oct 30*). Similarly, in the US, the number of glaucoma surgeons is not expected to increase to meet the growing demand of patients requiring surgical interventions, which may necessitate the use of other ophthalmologic surgeons to step into the glaucoma treatment pathway.³⁰

With the advances in MIGS devices and procedure and other glaucoma treatments, medical educators will have to train residents in both regular glaucoma management, and in these new therapies and techniques.⁵³ Training on MIGS devices often is provided directly by the manufacturer but other forms of education include peer-to-peer and fellowship training, according to Dr. Hady Saheb (*Dr. Hady Saheb: personal communication, 2017 Nov 17*). The educational skills transfer courses at the annual Canadian Ophthalmology Society meetings have included training on multiple MIGS procedures over the last five years (*Dr. Hady Saheb: personal communication, 2017 Nov 17*). Because there are no training standards in place or formal certification, jurisdictions seeking to implement MIGS will need to consider the credentialing required of surgeons (*Carla Service: personal communication, 2017 Nov 11*). Furthermore, MIGS

procedures require a skilled team of staff in the OR and consideration must be given to the appropriate skill mix required for procedures as well as training required of the staff. Dr. Xavier Campos indicated that his province (Newfoundland and Labrador) had not performed any MIGS procedures before he began working in Corner Brook and therefore he needed to train his OR staff on iStent and XEN implants (*Dr. Xavier Campos: personal communication, 2017 Dec 17*).

It was noted that, in comparison to cataract surgery, the XEN gel implant was easy to learn for surgeons with proper training, regardless of the learning curve and subtleties associated with the procedure.²⁶ Some MIGS procedures or devices (such as the trabecular bypass stents or iStent) may require at least 10 surgeries to be performed before the surgeon starts feeling comfortable with the MIGS approach.^{30,37} The trabectome may require five to seven surgeries before the surgeon is “safe” to perform the procedure, and approximately 30 eyes before they are a “master” of the technique.³³ However, one advantage of MIGS is the relatively less challenging nature of the surgery when compared to the trabeculectomy.³⁶

Funding, Costs, and Reimbursement

Most jurisdictions that consider introducing MIGS into their system will be faced with the question of how to fund the procedures. For MIGS innovations, such as the trabectome, lack of sufficient evidence makes it challenging for decision-makers, hospitals, and surgeons to determine whether the device should be publicly funded or not.²⁵ Unless a Ministry of Health has a quality-based procedural arrangement in place with facilities, the consultations revealed that this decision ultimately belongs to individual hospitals and health regions that are responsible for purchasing the devices and providing OR time to their surgeons. Dr. Hady Saheb noted that those making hospital budgetary decisions are responsible for managing the budget of the OR. And while decreased medication burden for patients and better patient outcomes are positive aspects of offering MIGS to patients, these aspects unfortunately do not impact the bottom line of the operating budget and therefore are often not taken into account in budgetary decision-making (*Dr. Hady Saheb: personal communication, 2017 Nov 17*).

Dr. Gilberg commented that this can be frustrating for his glaucoma surgeons because patients may be on four to five medications for their glaucoma, and if they are over the age of 65 (which many glaucoma patients are), their provincial health insurance plans will usually cover the cost of these prescription drugs but not the MIGS devices (*Dr. Steven Gilberg: personal communication, 2017 Nov 23*). The use of MIGS may be less costly for the health system in the long-term if patients can reduce or eliminate their topical glaucoma drops (*Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11*).⁵⁴ However, it is unknown whether the costs of MIGS devices as well as initial “start-up” costs for MIGS are balanced by the costs of intolerance and ineffective use of medications.¹⁰ Jurisdictions will need to decide whether or not MIGS procedures are medically necessary and therefore required for their population in treating glaucoma relative to the existing options (*Gillian Toth: personal communication, 2017 Nov 28; Dr. Steven Gilberg: personal communication, 2017 Nov 23*). The long-term cost-effectiveness of MIGS versus the long-term use of topical glaucoma medications must be evaluated to validate the anticipated potential savings to the health care system. They may also need to consider the viability of funding models employed in some facilities including patient-pay for patients who may wish to consider these newer technologies thereby giving them greater access and choice (*Dr. Steven Gilberg: personal communication, 2017 Nov 23*).

The cost of the MIGS device itself is generally similar to that of a cataract surgery including fixed and overhead costs, reusables, the price of the implanted lens, consumables, and staff compensation, according to Dr. Marcelo Nicolela (*Dr. Marcelo Nicolela: personal communication, 2017 Oct 31*). For phacoemulsification, if a certain number of lenses are continuously purchased, units can be provided to surgical centres at no extra cost.⁵⁵ Similarly to phacoemulsification, in MIGS, although start-up costs can be prohibitive (especially for procedures such as ECP),³⁰ discounts off the initial capital investment can be given if certain contracts for continuous purchase of the devices are negotiated with the manufacturer.⁵⁵ However, these “start-up” costs can be variable or paid for by local hospital budgets, which makes the

estimation of the true cost of MIGS difficult.¹⁰ For experienced surgeons, Dr. Hady Saheb added, a typical MIGS procedure such as an iStent implant added to cataract surgery, will require approximately 15% to 20% of additional OR time over the usual time needed for a cataract surgery alone (*Dr. Hady Saheb: personal communication, 2017 Nov 17*). While several surgeons in the consultation agreed that two to three iStents (without cataract surgery) could be completed in the time of one trabeculectomy, they acknowledged that the true barrier is simply the cost of MIGS devices. (*Dr. Ike Ahmed: personal communication, 2017 Oct 30. Dr. Jennifer Rahman: personal communication, 2017 Nov 24. Dr. Marcelo Nicolela: personal communication, 2017 Oct 31*).

While facilities and health regions may fund the costs of the devices and surgical procedure, the physician service costs are paid by the provincial health insurance plan. As described in greater detail in Question 3 of this Environmental Scan, introducing a MIGS device or procedure will necessitate a jurisdiction to consider a specific billing code in the physician schedule of benefits. According to Dr. Cindy Hutnik, an appropriate billing code would need to define the nature of the MIGS surgery and a corresponding fee that reflects the surgical time required, intensity of the procedure, the skill of the surgeon needed, and complication risks, for example (*Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11*). Additionally, MIGS are often defined differently by different individuals, and there is no single, widely-accepted definition.³⁴ In provinces where MIGS are being performed and that currently do not have a MIGS-specific physician fee code, current billings may not be reflective of the actual procedures being performed. Moreover, in the absence of any guidance on billing for MIGS in this context, procedures may be billed at rates higher or lower than appropriate. Additionally, the lack of a fee code makes proper estimations for analysis purposes of the prevalence of use and the costs associated with the devices difficult.¹⁰

There are many questions with regard to funding that a jurisdiction considering MIGS would need to address. From a glaucoma surgeon's perspective however, Dr. Catherine Birt would like the ability to choose the best surgery for her patients without needing to consider if she will be appropriately reimbursed, if her facility has budgeted for the device or procedure, or if her patient will be asked to pay (*Dr. Catherine Birt: personal communication, 2017 Nov 24*).

What are the challenges and enablers impacting the use of MIGS procedures in Canada?

Geography and Setting

The questions of this Environmental Scan combine the issues of setting and geography as implementation barriers and enablers are considered across jurisdictions and facilities as well as urban, rural, and remote settings.

The INTEGRATE-HTA domain of geography refers to the broader physical environment, landscapes and resources, available at a given location. Issues of geography can refer to infrastructure (e.g., transportation), access to health care, and geographical isolation.¹⁹ The setting domain according to INTEGRATE-HTA encompasses the immediate physical and organizational environment, in which an intervention is delivered. Issues of setting can refer to region, country (e.g., urban and rural), or type of facility.¹⁹

In considering geographic accessibility to MIGS, Canada's vast geography with sizable populations in rural and remote settings creates a unique challenge in accessing ophthalmic services. In most cases, rural and remote areas of the country do not have centres which offer MIGS devices or procedures (or trabeculectomy) as an option to patients and therefore any patients that is a candidate for surgery will be referred to a specialist, usually operating out of a larger urban centre. The consultations revealed that there are a few exceptions in rural and remote settings where ophthalmologists have the training and facilities to undertake a wide range of ophthalmic surgeries. Examples include Corner Brook, Newfoundland and Brandon, Manitoba where the ophthalmologist operating in these locations have a

catchment area that includes many of the surrounding communities that do not have their own ophthalmic surgeon (see Question 1 for further information) (*Dr. Xavier Campos: personal communication, 2017 Dec 17. Dr. Guillermo Rocha: personal communication, 2017 Nov 28*).

A few informants underscored the benefit of being in a small province when considering MIGS devices and procedures. In Nova Scotia, Dr. Paul Rafuse felt that being in a smaller province and facility with fewer surgeons often meant that ophthalmic surgery costs are more easily contained, and devices more easily approved (*Dr. Paul Rafuse: personal communication, 2017 Nov 11*). Similarly, although MIGS procedures are not available in PEI, Dr. Richard Wedge highlighted the advantage a smaller province has in working with government or health authorities to obtain device or procedure funding, particularly with relatively low volumes among small populations (*Dr. Richard Wedge: personal communication, 2017 Dec 14*). However he also acknowledged the challenge associated with being in a small province in attracting surgeons who are trained in MIGS procedures (*Dr. Richard Wedge: personal communication, 2017 Dec 14*).

However, patients residing in regions where MIGS are not available or living far away from centres that offer the surgeries may be at a disadvantage, according to both Dr. Paul Mackenzie and Dr. Paul Rafuse (*Dr. Paul Rafuse: personal communication, 2017 Nov 11. Dr. Paul Mackenzie: personal communication, 2017 Nov 24*). In the Yukon, Dr. Mackenzie indicated that there is a high prevalence of glaucoma in the patient population and, because of the lack of specialists and access to MIGS procedures, patients are generally being referred at more advanced stages of glaucoma when most MIGS procedures are no longer an option (*Dr. Paul Mackenzie: personal communication, 2017 Nov 24*). Dr. Paul Mackenzie noted that an issue for remote locations is that there is often no specialist available for post-operative care following traditional surgeries (*Dr. Paul Mackenzie: personal communication, 2017 Nov 24*). MIGS has the advantage of requiring few, if any, post-operative visits which makes these procedures particularly attractive for those settings (*Dr. Paul Mackenzie: personal communication, 2017 Nov 24*). Dr. Rafuse echoed this observation and noted that the distance required by some patients across Atlantic Canada to travel to Halifax may be significant and they may elect to continue with pharmacotherapy until their disease has progressed to the point that they require a more invasive surgery such as trabeculectomy (*Dr. Paul Rafuse: personal communication, 2017 Nov 11*). Similar observations were made by surgeons who have experience treating patients from considerable distances from their centre (*Dr. Xavier Campos: personal communication, 2017 Dec 17. Dr. Jennifer Rahman: personal communication, 2017 Nov 24; Dr. Steven Gilberg: personal communication, 2017 Nov 23*).

Ethical

The ethical domain refers to the concepts of morality, which encompasses beliefs, standards of conduct, and principles that guide the behaviour of individuals and institutions.¹⁹

Because most jurisdictions do not provide funding for MIGS devices, the decision to purchase a device is at the discretion of individual facilities and generally limited (with a few exceptions) to those major centres that have glaucoma surgeons available. Because of budgetary restrictions, these devices are usually purchased in limited quantities and therefore not always available to all MIGS candidates.

Alternatively, these costs may be passed on to the patient who has the option to pay for the device should they have the means to do so. This poses a few ethical dilemmas: the first is the unequal access to procedures based on where one resides, the second requires physicians to choose who will benefit from one of the limited devices available, and the third is access to procedures based on ability to pay.

According to Dr. Bryce Ford in Calgary, because the province of Alberta funds certain MIGS devices, he feels that the population gets reasonable access to these procedures (*Dr. Bryce Ford: personal communication, 2017 Nov 24*). Conversely, as Dr. Richard Wedge noted, in provinces like PEI where there are no MIGS surgeries offered, patients rarely are sent out-of-province for the purposes of accessing MIGS (*Dr. Richard Wedge: personal communication, 2017 Dec 14*). However, Dr. Cindy Hutnik noted that even in

larger centres such as London, Ontario, because MIGS procedures are generally not available, accessibility is limited to patients living near a centre where devices are available for research purposes and/or where there may be patient-pay components (*Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11*).

For those facilities where a limited number of MIGS devices become available, depending on volumes and number of devices funded, and in the absence of a formalized list of indications for which MIGS procedures should be prescribed, Dr. Cindy Hutnik points to the ethical issue of providers or institutions needing to create criteria by which to select eligible patients (*Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11*). She added that this may include factors such as ineffective use of pharmacotherapy or adverse reactions and not reflect actual appropriateness (*Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11*).

While MIGS devices in Winnipeg are made available to patients on a patient-pay model, the cost is for the device only and not the procedure itself or the physician's fees (*Gillian Toth: personal communication, 2017 Nov 28. Dr. Jennifer Rahman: personal communication, 2017 Nov 24*). This, however, limits availability to these specific procedures to those that can pay out-of-pocket or through third-party insurance. Although, Dr. Jennifer Rahman indicated that there are few instances in Winnipeg where a patient was not able to have the device covered by direct payment or third-party insurance, in some cases it was offered for free by the device manufacturer (*Dr. Jennifer Rahman: personal communication, 2017 Nov 24*). Nevertheless, this creates an ethical question around the provision of services that some ophthalmologists interviewed consider to be medically necessary and not simply an option or upgrade (*Dr. Steven Gilberg: personal communication, 2017 Nov 23. Dr. Xavier Campos: personal communication, 2017 Dec 17*).

Dr. Steven Gilberg at The Ottawa Hospital described how his facility investigated the possibility of having patients purchase their MIGS devices but there was concern that patient payment may contravene Federal or Provincial regulations. (*Dr. Steven Gilberg: personal communication, 2017 Nov 23*). Dr. Sherif El-Defrawy at the KEI in Toronto also noted his hesitation in charging patients for MIGS devices at his facility, despite the funds needed to purchase additional MIGS devices (*Dr. Sherif El-Defrawy: personal communication, 2017 Dec 11*).

Domains of Implementation

Provider

This implementation domain focuses on the characteristics of the individuals adopting and delivering the intervention. It includes the personal attributes, knowledge, skills, emotions, motivations, intentions and goals.¹⁹ The consultations pointed toward two key areas when considering the role of providers with respect to implementation: training and adoption.

Training

According to all informants, training for MIGS devices is generally provided by the device manufacturers. Dr. Jennifer Rahman and Dr. Paul Rafuse indicated that this training tends to include wet labs done on-site for the physician-in-training, videos, and usually a representative from the company (often a non-physician) will accompany the surgeon in the OR (or watch on a monitor) to supervise and guide them in performing several surgeries until they are comfortable with the procedure (*Dr. Jennifer Rahman: personal communication, 2017 Nov 24. Dr. Paul Rafuse: personal communication, 2017 Nov 11*). Dr. Richard Wedge in PEI felt that the training was generally of high quality and indicated that surgeons may be sent to another province, or country in some cases, in order to receive their training on a MIGS device (*Dr. Richard Wedge: personal communication, 2017 Dec 14*). He added that this may be in the form of a fellowship before they officially start their position so that they can bring the skill set to the province. This may also include shadowing another surgeon, or going to wet labs to learn about the procedure as noted by Dr. Marcelo Nicolela (*Dr. Marcelo Nicolela: personal communication, 2017 Oct 31*).

The Canadian Ophthalmological Society (COS) was also cited by Dr. Xavier Campos and Dr. Ken Roberts as an organization that provides training on MIGS devices to its members. (*Dr. Xavier Campos: personal communication, 2017 Dec 17; Dr. Ken Roberts: personal communication, 2017 Dec 13*). Education on MIGS can also be in the form of user groups, according to Dr. Hady Saheb, which allows groups of surgeons across the country to talk about challenges and share tips about MIGS devices and procedures and patient selection. (*Dr. Hady Saheb: personal communication, 2017 Nov 17*).

Dr. Karim Damji in Alberta and Dr. Guillermo Rocha in Manitoba both underscored the value of peer-to-peer learning for MIGS procedures with physicians often receiving training from their colleagues across facilities or jurisdictions (*Dr. Karim Damji: personal communication, 2017 Nov 23. Dr. Guillermo Rocha: personal communication, 2017 Nov 28*). At the Trillium Health Partners, Prism Eye Institute, and KEI, because of the number of available surgeons who are trained on MIGS procedures, they provide training to other surgeons and fellows in their centres (*Dr. Ike Ahmed: personal communication, 2017 Oct 30. Dr. Sherif El-Defrawy: personal communication, 2017 Dec 11*).

Dr. Hady Saheb also noted many glaucoma fellowship programs today will include training on MIGS devices, therefore most new graduates have already received MIGS training (*Dr. Hady Saheb: personal communication, 2017 Nov 17*). He further added that younger physicians are not only more willing to be trained on MIGS devices than some of their senior counterparts, but have come to expect it from their fellowship training (*Dr. Hady Saheb: personal communication, 2017 Nov 17*). However, Dr. Paul Rafuse in Nova Scotia noted that in academic facilities where MIGS devices are limited, the fellow may receive far less training in MIGS procedures, often with a greater emphasis on more invasive treatment options instead (*Dr. Paul Rafuse: personal communication, 2017 Nov 11*).

Training was also cited as a barrier to implementing MIGS by a few surgeons. Dr. Xavier Campos and Dr. Marcelo Nicolela highlighted the fact that while physicians may receive special training on a MIGS procedure, these surgeries are done as part of a team in the OR and therefore nurses and other staff will need to be trained as well (*Dr. Marcelo Nicolela: personal communication, 2017 Oct 31*). Donna Punch at the KEI in Toronto added that some device manufacturers also provide training to nurses who will be in the OR assisting in MIGS procedures (*Donna Punch: personal communication, 2017 Nov 23*).

While the availability of ophthalmic surgeons available to perform MIGS procedures is a barrier to implementation, Dr. Xavier Campos believes that it is not realistic to refer every glaucoma and cataract patient (especially those with mild disease) to a glaucoma surgeon and there is room for general ophthalmologists to be doing certain MIGS procedures (*Dr. Xavier Campos: personal communication, 2017 Dec 17*). In the opinion of Dr. James Taylor in BC and Dr. Paul Rafuse in Nova Scotia, most general ophthalmologists have the competencies required to perform certain MIGS procedures like iStents and some are already doing this (*Dr. Paul Rafuse: personal communication, 2017 Nov 11; Dr. James Taylor: personal communication, 2017 Nov 1*). Literature from the US also alluded to the potential of surgeons other than glaucoma specialists to perform MIGS procedures, including anterior segment surgeons and cataract surgeons.³⁰

Adoption

Adoption of MIGS devices and procedures can be both a barrier and enabler to implementation. Some glaucoma surgeons including Dr. Ike Ahmed and Dr. Hady Saheb are self-professed early adopters who are comfortable with trying newer technologies and advocate for the use of MIGS procedures for cutting-edge glaucoma care (*Dr. Ike Ahmed: personal communication, 2017 Oct 30. Dr. Hady Saheb: personal communication, 2017 Nov 17*).

Whereas, some physicians may be late adopters needing to see more compelling evidence or not convinced by what they have seen so far in terms of patient outcomes. In accordance with the innovation adoption curve of Rogers,⁵⁶ some hospitals and surgeons may prefer to be relatively cautious in adopting

more innovative procedures until longer-term safety, clinical- and cost-effectiveness data are available (Dr. Cindy M.L. Hutnik: *personal communication, 2017 Nov 11*). Providers and surgeons may also be experienced and comfortable with performing trabeculectomies and are reluctant to change to MIGS devices or procedures, which lie outside of their comfort zone.^{20,36} In some cases, those 'late adopters' may be later in their career and less willing to learn a new procedure given the decades of good outcomes with more traditional surgeries, according to Dr. Hady Saheb (Dr. Hady Saheb: *personal communication, 2017 Nov 17*). However, the growth of companies that specialize in MIGS devices does illustrate the interest and enthusiasm in the MIGS space by analysts and investors.²⁷

With respect to technology adoption, Dr. Jennifer Rahman underscored the importance of practice for the surgeon to become comfortable with their skills in using MIGS devices and procedures (Dr. Jennifer Rahman: *personal communication, 2017 Nov 24*), and Dr. Paul Rafuse noted the considerable learning curve associated with implanting these devices including the iStent (Dr. Paul Rafuse: *personal communication, 2017 Nov 17*). According to Dr. Catherine Birt, she felt that she had achieved positive results with using iStents in Ontario, however she did not perform very many to the point of feeling comfortable enough to adopt this into her practice (Dr. Catherine Birt: *personal communication, 2017 Nov 24*).

The literature noted that for even experienced glaucoma or cataract surgeons, MIGS devices and procedures are still different from traditional surgeries, and therefore may still present a considerable learning curve.^{20,32} For example, stent implantation requires technical abilities which may be challenging, such as familiarity with using a gonioscope, accurate identification of angle structures and anatomy, and proper visualization.³⁰⁻³² Additionally, access to a surgical microscope with good optics, large tilt capabilities, and illumination with a high Kelvin colour temperature was noted as being necessary for success with visualization for MIGS.³²

Adoption may also be hindered by a surgeon's need for compelling evidence in favour of the device or procedure. The need for higher quality, longer-term data and more rigorous studies with respect to MIGS devices was cited by both Dr. Karim Damji and Dr. Paul Rafuse who felt that the current available evidence on clinical effectiveness is lacking (Dr. Karim Damji: *personal communication, 2017 Nov 23*; Dr. Paul Rafuse: *personal communication, 2017 Nov 11*). While recognizing the relatively recent introduction of many MIGS devices, Dr. Rafuse commented that he is waiting to see further evidence on certain procedures and stopped doing some MIGS procedures because he and his team in Nova Scotia felt that these were not efficacious or caused more problems for his patients (Dr. Paul Rafuse: *personal communication, 2017 Nov 17*). This apprehension regarding the data surrounding the efficacy of MIGS devices and procedures was also reflected in news stories from the literature.²⁹

Patient

CADTH considers an additional patient domain that combines sociocultural, socioeconomic, and epidemiological components of the context domains of the INTEGRATE-HTA framework.

The experience of several informants consulted was that patients have been found to be quite willing to undergo MIGS procedures when presented with the advantages and disadvantages, with many knowing about these surgeries and requesting it as an option for their glaucoma management, and willing to pay for the device if required (Dr. Jennifer Rahman: *personal communication, 2017 Nov 24*; Dr. Guillermo Rocha: *personal communication, 2017 Nov 28*; Dr. Hady Saheb: *personal communication, 2017 Nov 17*; Dr. Ike Ahmed: *personal communication, 2017 Oct 30*; Dr. Karim Damji: *personal communication, 2017 Nov 23*). However, Dr. Rahman felt that such procedures, being "medically necessary," should be publicly funded (Dr. Jennifer Rahman: *personal communication, 2017 Nov 24*). One enabler to the implementation of MIGS procedures, according to Dr. James Taylor in BC, is the high rate of acceptance by patients to having these surgeries (Dr. James Taylor: *personal communication, 2017 Nov 1*). Because of the side effects of medications as well as the lifetime costs associated with pharmacotherapy, Dr. Taylor finds his patients are quite willing

to undergo these procedures (*Dr. James Taylor: personal communication, 2017 Nov 1*). Dr. Carlos Buznego from Miami stated in an article that in his personal experience, older patients appeared to be receptive to undergoing MIGS procedures in adjunct to cataract surgery.³⁰ Dr. Ike Ahmed added that patient compliance with taking drops for glaucoma is one of the biggest challenges and MIGS provides a safe solution, with less risk than traditional therapies and far fewer post-operative complications (*Dr. Ike Ahmed, Trillium Health Partners, Mississauga, ON; Prism Eye Institute, Brampton, ON; Department of Ophthalmology & Vision Sciences, University of Toronto, Toronto, ON; Kensington Eye Institute, Toronto, ON: personal communication, 2017 Oct 30*). The fact that there are also fewer post-operative visits required compared to trabeculectomy is a benefit, according to Dr. Xavier Campos, particularly for his patients in Newfoundland who may have to travel upwards of eight hours each way to see him (*Dr. Xavier Campos: personal communication, 2017 Dec 17*). The relatively short recovery time and quick return to work following MIGS procedures were cited as also contributing to high patient acceptance (*Dr. Guillermo Rocha: personal communication, 2017 Nov 28*. *Dr. Marcelo Nicoleta: personal communication, 2017 Oct 31*).

Patient education about MIGS and new surgical techniques can be an enabler, according to Dr. Karim Damji, who noted that many of his patients in Alberta prefer an option that is safer than traditional surgeries, that will reduce the need for medication, and improve their overall quality of life (*Dr. Karim Damji: personal communication, 2017 Nov 23*).

Organization and Structure

This domain comprises the organizational policies, guidelines and practices as well as culture and climate that reside within an organization and on different levels such as the organization as a whole, units, and teams through which an intervention is delivered. Therefore, constructs such as team dynamics, leadership, supervision, and guidance are also comprised.¹⁹

The consultations highlighted the following organization and structure enablers and barriers with respect to implementation: leadership and support, ophthalmology unit structure, and limited operating time availability.

Leadership and Support

Many of those consulted in this Environmental Scan pointed to the key role that hospital leadership and support plays in the implementation of MIGS devices and procedures in a facility. The presence of an OR manager who looks favourably on not only new technologies but also ophthalmology helps, according to Dr. Bryce Ford in Calgary as does having well-regarded leaders in the ophthalmology unit of the facility (*Dr. Bryce Ford: personal communication, 2017 Nov 24*). According to both Dr. Ford and Dr. Karim Damji, these have been enablers to having MIGS funded in their respective organizations (*Dr. Karim Damji: personal communication, 2017 Nov 23*; *Dr. Bryce Ford: personal communication, 2017 Nov 24*).

The strength of ophthalmology leadership in persuading administration and budget managers was underscored by Dr. Catherine Birt in Toronto who highlighted the tremendous work of the leadership at the KEI in acquiring funds for XEN devices (*Dr. Catherine Birt: personal communication, 2017 Nov 24*). Additionally, one of the other contributors to the potential success of MIGS in facilities is the commitment and the contributions of ancillary staff, which includes the involvement of surgery techs, surgery schedulers, and other staff involved in the glaucoma treatment pathway.²⁸

Dr. Ike Ahmed added that an administration that makes better patient care and glaucoma surgery a priority is an enabler to new technologies being introduced (*Dr. Ike Ahmed: personal communication, 2017 Oct 30*). For Gillian Toth in Winnipeg, her administration requires a program review of new technology and an indication by requesting physicians for projected volumes and costs among other things (*Gillian Toth: personal communication, 2017 Nov 28*). While this may seem arduous for some, she indicates that the program review team is generally supportive of new devices and in working with their physicians to find ways to accommodate new technologies (*Gillian Toth: personal communication, 2017 Nov 28*).

Being part of a well-regarded academic institution with a strong glaucoma team will often gain the attention of industry who may want to provide additional devices and training for the centre, according to Dr. Paul Rafuse in Halifax (*Dr. Paul Rafuse: personal communication, 2017 Nov 11*). In BC, Carla Service noted that having a critical mass of patients, specialized staff and a dedicated ophthalmic OR lends well to being viewed as a centre of excellence and gaining the attention of both industry and hospital administration when considering MIGS device funding (*Carla Service: personal communication, 2017 Nov 11*). This notion was echoed by Dr. Steven Gilberg in Ottawa who indicated that his facility aims to deliver the best care using the most advanced technology that is that is possible within the current fiscal reality of government funding (*Dr. Steven Gilberg: personal communication, 2017 Nov 23*). But being part of a small hospital with a supportive board and administration also has its merits, according to Dr. Guillermo Rocha, who highlighted the relative ease in having certain MIGS devices approved at his facility in Brandon, Manitoba (*Dr. Guillermo Rocha: personal communication, 2017 Nov 28*).

Ophthalmology Unit Structure

Those centres serving a large base of patients, with a high volume of glaucoma surgeries performed, often necessitate a dedicated budget and team according to Carla Service in BC (*Carla Service: personal communication, 2017 Nov 11*). At centres such as hers in Victoria, or at Capital Health ophthalmology clinic, special eye care centres exist somewhat as standalone units within the hospital with a separate ophthalmology OR, specialized team, and dedicated budget (*Carla Service: personal communication, 2017 Nov 11; Dr. Marcelo Nicolela: personal communication, 2017 Oct 31*). Dr. Marcelo Nicolela in Halifax added that being able to manage the budget of his hospital's eye centre has allowed them to find funding for MIGS procedures and other technologies (*Dr. Marcelo Nicolela: personal communication, 2017 Oct 31*). Ms. Carla Service also highlighted the benefit of having a separate ophthalmic OR that does not require the presence of an anesthetist or the competition for limited OR time with other specialties (*Carla Service: personal communication, 2017 Nov 11*).

Limited Operating Room Time

The limited number of hours available to surgeons in the OR was cited as a barrier to implementing MIGS devices and procedures. Dr. Catherine Birt noted that most glaucoma surgeons are usually managing lengthy wait lists for surgery and any additional surgeries will only add to the backlog (*Dr. Catherine Birt: personal communication, 2017 Nov 24*). MIGS devices and procedures are highly standardized and faster than traditional glaucoma surgeries.³² MIGS devices and procedures can also be performed or inserted in adjunct to cataract surgeries "with a few extra minutes added".³⁰ Although, given the reduction in time required to perform most MIGS procedures, Dr. Karim Damji noted that more glaucoma surgeries can be performed, thereby using OR time more efficiently (*Dr. Karim Damji: personal communication, 2017 Nov 23*). Dr. Cindy Hutnik also felt that physicians would opt for safer OR surgical procedures that are more efficient in terms of resource management. She added that more efficient use of OR resources could decrease wait times for patients, and subsequently increase access to care (*Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11*). Dr. Hutnik believes that MIGS can result in the reduction in use of glaucoma medications which, in turn, could reduce the morbidity issues associated with ineffective use of medications, side effects and cost related to chronic eye drop use. This, too, would increase the efficient use of health care resources (*Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11*). However, Dr. Marcelo Nicolela pointed out that time in the OR is simply one factor – the overall costs for procedure, particularly MIGS devices, also impact the number of surgeries which can be done (*Dr. Marcelo Nicolela: personal communication, 2017 Oct 31*).

Funding

The domain of funding relates to short-term or longer-term funding mechanisms by governmental, non-governmental, private sector and philanthropic organizations used to implement an intervention.¹⁹ Funding was the barrier to MIGS implementation most cited by stakeholders with all informants indicating that this has been the biggest challenge. The consultations pointed toward three key areas when considering the role of funding with respect to implementation: the limited availability of MIGS devices and procedures, funding options, and out-of-province costs.

Limited Availability of MIGS Devices

Most facilities that are purchasing MIGS devices are able to do so on a fairly limited basis and, according to Dr. Paul Rafuse, glaucoma surgeons at his facility in Halifax need to be careful about which patients receive the limited number of procedures available (*Dr. Paul Rafuse: personal communication, 2017 Nov 11*). With funds available to cover the cost of only a limited number of MIGS devices at his hospital in Ottawa, Dr. Steven Gilberg indicated that wait lists for surgeries continue to grow and patients eventually are offered more risk-fraught and invasive therapies in lieu of MIGS (*Dr. Steven Gilberg: personal communication, 2017 Nov 23*).

With no new funds available for the devices in Halifax, Dr. Marcelo Nicolela indicated that his eye care centre must find ways to absorb these costs into the existing ophthalmology budget (*Dr. Marcelo Nicolela: personal communication, 2017 Oct 31*). However, Dr. Nicolela added that while there may be savings found in reduced OR time for MIGS procedures relative to longer, more invasive procedures, facility overhead costs tend to remain the same for the OR with the added cost of the MIGS device (*Dr. Marcelo Nicolela: personal communication, 2017 Oct 31*).

While MIGS devices such as the iStent are funded by facilities in Calgary, there is still a finite budget that limits the number of devices which can be purchased and procedures performed according to Dr. Bryce Ford (*Dr. Bryce Ford: personal communication, 2017 Nov 24*). Dr. Andrew Crichton indicated that the surgeons at his facility in Calgary use their quota judiciously and do their best to avoid overuse (*Dr. Andrew Crichton: personal communication, 2017 Nov 17*). Dr. Damji noted that while iStents are generally covered at his hospital in Edmonton, these devices involve expenses and administration would like to understand the return-on-investment for these procedures (*Dr. Karim Damji: personal communication, 2017 Nov 23*).

Funding Options

From the perspective of Carla Service in Victoria and Gillian Toth in Winnipeg, health system administrators are under pressure to curtail spending while at the same time being urged by physicians across all specialties to approve devices, expand services, and grow programs. (*Carla Service: personal communication, 2017 Nov 11; Gillian Toth: personal communication, 2017 Nov 28*). Moreover, as Ms. Toth explained, vendors are also demonstrating and trialling new devices with physicians without management approval and physicians will subsequently seek funds for procedures not budgeted for (*Gillian Toth: personal communication, 2017 Nov 28*). In response to pressures to provide the iStent to patients, her facility allows patients to privately pay for the device through their ophthalmologist while the facility covers the costs for surgery time, staff, and supplies (*Gillian Toth: personal communication, 2017 Nov 28*). Charging patients for MIGS devices was deemed not an option at The Ottawa Hospital, according to Dr. Steven Gilberg, and additional funds to support new technologies were not available (*Dr. Steven Gilberg: personal communication, 2017 Nov 23*). The Ottawa Hospital Eye Institute charges patients a small administrative fee for specialty lenses and these fees are then used to support those items not available in their budget like MIGS devices (e.g., iStent, XEN, trabectome) (*Dr. Steven Gilberg: personal communication, 2017 Nov 23*). At the KEI, a similar administrative fee is charged for specialty lenses as dictated by the Ontario Ministry of Health and Long-Term Care (MOHTLC) and this can be used for ophthalmic device purchases according to Donna Punch (*Donna Punch: personal communication, 2017 Nov 23*). Dr. Sherif El-Defrawy highlighted that where there are

many efficiencies that save money in their not-for-profit facility, these can be reallocated to the purchases of technologies, including certain MIGS devices (*Dr. Sherif El-Defrawy: personal communication, 2017 Dec 17*). Ophthalmologists in Canada are remunerated on a fee-for-service basis and remuneration may affect surgical trends in the future.²² A specific issue with MIGS devices and procedures is consistency with how the devices are remunerated into the health care system. Many health care systems are moving toward a “cost-based” model, where cost analyses become important in the decision-making for treatment decisions, but these analyses are lacking for MIGS devices and procedures.¹⁰

Out-of-Province Costs

According to Dr. Cindy Hutnik, those facilities that do not offer MIGS procedures or those jurisdictions or regions where these surgeries are not available have the limited option to send patients out-of-area (local health integration network – or LHIN) or out-of-province for glaucoma therapy (*Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11*). However, she noted that this comes at considerable expense to health regions or provinces and patients including the costs associated with transportation, accommodation and family/caregiver expenses for travel to and from their hometown for pre-and post-operative visits in addition to uninsured services associated with the surgery itself (*Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11*). Dr. Xavier Campos observed that this barrier of needing to travel out of the province for care imposed on patients caused many glaucoma patients to forego treatment until it was too late and MIGS was no longer a viable option (*Dr. Xavier Campos: personal communication, 2017 Dec 17*). Dr. Paul Mackenzie hopes comparing the costs of sending patients from the Yukon to BC for trabeculectomies or tube shunts to what a MIGS device or procedure performed in Whitehorse would cost may help to build the case for funding the device (*Dr. Paul Mackenzie: personal communication, 2017 Nov 24*). Similarly, for Dr. Xavier Campos, his administration was hesitant to fund MIGS devices when looked at from a cost-per-case basis, but saw differently when they looked at the significant reduction in post-operative costs relative to more traditional glaucoma surgeries (*Dr. Xavier Campos: personal communication, 2017 Dec 17*). Although from the outset, MIGS devices and procedures look expensive, the higher safety, fewer follow-up visits, and fewer interventions needed post-MIGS surgery when compared to more invasive surgeries may assist in making MIGS cost-effective, although there are no cost-effectiveness studies to verify this.²¹ However, some implants need more follow-up and post-operative care than others, for example, a survey of UK surgeons found the XEN implant potentially required more post-operative visits and follow-up frequencies than the iStent.³⁶ Therefore, the benefit of fewer post-operative visits for MIGS may not be as prominent for some MIGS devices or procedures, if post-operative manipulations for these devices start to approximate the number required for trabeculectomy.³⁶ This then may influence adoption patterns by surgeons.³⁶

While there is an agreement between provincial health insurance plans to cover the costs of their own patients when receiving treatment in another, this is not usually the case across provincial health regions, according to Dr. Cindy Hutnik (*Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11*). Patients who are unable to have a MIGS procedure in London, Ontario for example may be referred to a facility in Toronto where they can, however the funding from one provincial Local Health Integration Network (LHIN) does not follow the patient to another LHIN where they receive treatment. Whereas there is no boundary for patients who wish or need services from another LHIN, there are no mechanisms for one LHIN to recoup the funding from another LHIN (*Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11*). This issue of costs – both borne by the patient and the treating LHIN - is only exacerbated by the number of follow-up visits that are required for some glaucoma procedures (*Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11*).

Policy

According to INTEGRATE-HTA, the policy domain comprises policy measures and processes of government, public, private or other organizations directly concerning or indirectly influencing the implementation of an intervention.¹⁹

As previously noted, the health authority in Winnipeg has a practice change forum which reviews requests for new procedures and technologies, including the associated costs and benefits, as described by Gillian Toth (*Gillian Toth: personal communication, 2017 Nov 28*). The organization's policy is that a business case for new technologies must be presented to this committee for consideration. While this may appear to be a barrier to MIGS being implemented in Winnipeg, Gillian Toth indicated that it is designed to add a level of control over escalating costs and aid in managing industry sales strategies to have devices funded in the region (*Gillian Toth: personal communication, 2017 Nov 28*). Likewise in PEI, if there is a large capital equipment cost investment needed, including the purchase of new devices, then the ophthalmic team would be required to seek funding from the hospital's foundation, according to Dr. Richard Wedge, the timing of which can be affected by equipment budget cycles (*Dr. Richard Wedge: personal communication, 2017 Dec 14*).

The lack of formal policy or guidelines in most institutions around who should be performing MIGS procedures and for which indications is a barrier to implementation, according to Dr. Bryce Ford in Calgary (*Dr. Bryce Ford: personal communication, 2017 Nov 24*). Dr. Steven Gilberg added that surgeries using the XEN gel implant also require guidance on who is best positioned to perform them. The lack of policy on this can lead to overuse and inappropriate use in the opinion of Dr. Steven Gilberg (*Dr. Steven Gilberg: personal communication, 2017 Nov 23*). Similarly, Dr. Bryce Ford felt that the lack of guidance on indications for which the devices are intended and who would benefit most can also lead to an overuse of MIGS devices (*Dr. Bryce Ford: personal communication, 2017 Nov 24*). In many cases, added Dr. Sherif El-Defrawy, the only controls in place are the limited number of devices funded and the limited number of surgeons who are available or permitted to operate (*Dr. Sherif El-Defrawy: personal communication, 2017 Dec 11*).

The need for guidelines which address the role of MIGS in the glaucoma treatment spectrum, appropriate patient selection, and recommended indications was noted by a number of informants (*Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11; Dr. Hady Saheb: personal communication, 2017 Nov 17; Dr. Ken Roberts: personal communication, 2017 Dec 13; Dr. Bryce Ford: personal communication, 2017 Nov 24; Dr. Guillermo Rocha: personal communication, 2017 Nov 28*). Dr. Cindy Hutnik and Dr. Ken Roberts noted that the COS guidelines were last updated in 2009 and do not refer to MIGS procedures (*Dr. Cindy M.L. Hutnik: personal communication, 2017 Nov 11; Dr. Ken Roberts: personal communication, 2017 Dec 13*). In 2017, both the CGS and Alberta Glaucoma Specialists published position statements on the use, benefits, and indications for MIGS procedures (*Dr. Hady Saheb: personal communication, 2017 Nov 17*).⁵⁷ According to Dr. Guillermo Rocha, current COS President, the COS has recently endorsed the CGS position statement, supporting the role of MIGS in the glaucoma treatment algorithm (*Dr. Guillermo Rocha: personal communication, 2017 Nov 28*).⁵⁷

One Canadian study examined the methodological quality of glaucoma clinical practice guidelines (CPGs) from a variety of countries, and examined their recommendations regarding MIGS devices and procedures.²⁴ Variability in the access to MIGS devices and procedures may have contributed to less understanding of the optimal use of MIGS and their role in the treatment paradigm. There are also a large variety of MIGS devices and procedures available to ophthalmologists, but no guidance on appropriate patient selection or use.²⁴ Only three of the 11 CPGs that were relevant and included in this article²⁴ acknowledge MIGS as a treatment option. This may contribute to barriers to use in all areas, including Canadian jurisdictions, as many policy-makers rely on CPGs to guide decision-making and to see the current landscape of glaucoma management.²⁴

Socioeconomic, Sociocultural, Political, Legal, and Epidemiological

The aging of the population is set to increase pressures on the capacity of outpatient departments, and the potential for MIGS to reduce post-operative care burden may influence surgery choices in the future.³⁶ However, the consultations did not yield any articles which addressed the INTEGRATE-HTA domains of socioeconomic, sociocultural, political, legal or epidemiological. All other domains are described with respect to challenges and enablers of implementation.

Limitations

The findings of this Environmental Scan aim to present an overview of examples and current information regarding the implementation of MIGS devices and procedures across Canadian jurisdictions and are not intended to provide a comprehensive review of the topic. The results are based on a limited, non-systematic literature search and consultations with a limited number of stakeholders. While there was representation from Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Nova Scotia, Ontario, Prince Edward Island, Yukon, and Quebec, not all jurisdictions responded to our request for an interview by the consultation deadline and all respondents were only able to speak on behalf of their own practice or a single facility and not the jurisdiction's health care system as a whole. Moreover, opinions and perspectives provided as part of the targeted stakeholder consultations may not be representative of the views of all stakeholders across Canadian jurisdictions. This includes limited information on the specific MIGS devices and procedures used in various facilities across Canada. The use of a specific MIGS device or procedure in one facility may not represent the use of MIGS devices generally across Canada, and does not reflect the future use of specific brands or type of MIGS devices and procedures. This report is also a snapshot of the current use of MIGS devices and procedures in Canada. It should be noted that this is a constantly evolving field of study and new MIGS devices and procedures are introduced or adopted by surgeons across Canada.

There were also limitations with regards to the literature. These included a lack of literature pertaining to many aspects of the Integrate-HTA framework, including setting, geographical area, epidemiology, socioeconomic and sociocultural aspects, politics, and legal aspects. Although the consultations do fill in the gaps for some of these domains, as previously mentioned, they are the opinions of experts in the field and reflect their particular experiences. The literature also lacked quantitative data regarding the use of MIGS or the costs associated with MIGS in the Canadian context. Many of the articles were also opinion pieces, news articles, or reviews on the clinical effectiveness of MIGS devices and procedures, and did not address implementation issues specifically. This report is also limited as the literature screening and data extraction were performed by one reviewer. This meant there was no opportunity for discussion of literature, or potential for challenges to the initial analyses.

Conclusion

MIGS devices and procedures, alone or in conjunction with cataract surgery, although relatively new in the treatment spectrum for glaucoma, may be useful for filling the gap between pharmacotherapy (for mild glaucoma) and more invasive surgeries such as trabeculectomy (for more advanced glaucoma).^{3,13,15,16} This Environmental Scan sought to clarify current access to MIGS devices and procedures across Canadian jurisdictions, relevant implementation considerations including challenges and enablers to the use of MIGS devices and procedures, and current policy on reimbursements for MIGS across jurisdictions.

Access to MIGS devices and procedures is variable across Canada. Some MIGS devices and procedures are covered financially by hospitals and local facilities, but other MIGS devices and procedures are not covered. Individual hospitals and facilities are often responsible for purchasing MIGS devices or funding procedures, without additional funding provided for this purpose. Additionally, most jurisdictions (with the exception of Quebec and Alberta) do not have a MIGS-specific fee code for any MIGS devices or procedures, which makes estimation of the true cost and time-commitment of MIGS difficult. Issues of

access, including travel costs, limitations of facilities in certain locations, and the requirement for some patients to pay out-of-pocket are also present in Canada, which limits the availability of MIGS devices and procedures for eligible glaucoma patients.

Funding is a major determinant of MIGS use and a barrier to MIGS use in Canada. Some facilities may have specialized eye care teams and specific funding for these newer procedures, or may receive devices directly from the manufacturer or from industry at a lower cost. This variability in funding can act as a barrier to the use of MIGS, especially in areas which are smaller or more rural, and do not have access to these specialized funding opportunities. This unequal access forces some patients to wait until their glaucoma is much more severe before they can receive an intervention such as MIGS or more invasive procedures such as trabeculectomy, putting them at risk of complications.

Another barrier to implementation is uptake by the provider or surgeons themselves. Some surgeons may wish to wait to start using MIGS in their practice until more robust evidence comparing the efficacy of different MIGS devices and procedures to one another is available. Some surgeons do not feel that the current clinical evidence is sufficient to justify adopting MIGS devices and procedures into their practice, but many surgeons are “early adopters” who advocate for these new technologies in practice. There is also a learning curve associated with performing MIGS procedures that some surgeons may not be comfortable with, although this learning curve may be short.

There is a lack of Canadian cost-effectiveness data regarding MIGS devices and procedures, although this aspect of MIGS is currently being looked at by a variety of sources, including MIGS manufacturers and ophthalmologists. It is difficult to incorporate MIGS into the OR, without replacing an existing procedure, there is a limited number of MIGS and facilities that provide MIGS, and the costs of sending individuals for MIGS out-of-province can be high. Supportive glaucoma teams can advocate for the inclusion of MIGS and MIGS fee codes into provincial physician schedule of benefits, find efficiencies in OR budgets to pay for MIGS devices, and work with physicians to assist in the inclusion of MIGS in the OR. High patient acceptability and education (and a willingness to pay out-of-pocket for MIGS devices and procedures), having a separate ophthalmic OR where OR time for glaucoma treatments is not competing with other disciplines, and the growing interest in MIGS by industry and investors are enablers in their use across Canada.

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Appendix 1: Stakeholder Consultations

The following stakeholders were consulted for the purposes of this Environmental Scan. Permission was granted by all interviewees to publish their comments in this report.

Province/Territory	Key Informant
Alberta	<p>Dr. Andrew Crichton MD FRCSC Clinical Professor of Surgery Division of Ophthalmology Faculty of Medicine, University of Calgary Calgary Ophthalmology Centre, Calgary</p>
	<p>Dr. Karim Damji MD FRCSC MBA Professor and Chair, Department of Ophthalmology and Visual Sciences University of Alberta Clinical Section Head, Ophthalmology, Edmonton Zone, Alberta Health Services Royal Alexandra Hospital, Edmonton</p>
	<p>Dr. Bryce Ford MD FRCSC Clinical Assistant Professor Division of Ophthalmology Faculty of Medicine, University of Calgary Calgary Ophthalmology Center, Calgary</p>
British Columbia	<p>Dr. James Taylor MD Ophthalmologist Royal Jubilee Hospital Victoria</p>
	<p>Ms. Carla Service BScN MPA CHE Program Manager, Island Health Surgical Ambulatory Clinics and Regional Pain Program Project Leader, Surgical Programs Vancouver Island Health Authority, Royal Jubilee Hospital</p>
Manitoba	<p>Dr. Jennifer Rahman MD Eye Physician and Surgeon Medical Director, GEM Clinic Glaucoma & Eye Management Clinic Winnipeg</p>
	<p>Dr. Guillermo Rocha MD FRCSC FACS Ophthalmologist President, Canadian Ophthalmological Society Associate Professor, Faculty of Medicine, University of Manitoba Medical Director, Ocular Microsurgery & Laser Centre, Brandon Regional Health Centre Brandon</p>
	<p>Ms. Gillian Toth RN Director of Acute Care Programs Misericordia Health Centre Winnipeg</p>

Province/Territory	Key Informant
New Brunswick	<p>Dr. Ken Roberts MD Ophthalmologist Associate Consultant Ophthalmologist, Horizon Health Network Fredericton</p>
Newfoundland & Labrador	<p>Dr. Xavier Campos MD Ophthalmologist Glaucoma and advanced anterior Segment Surgery Western Health Eye Care Centre Corner Brook</p>
Nova Scotia	<p>Dr. Marcelo Nicoleta MD FRCS Department Chief, Ophthalmology QEII Health Sciences Centre Department Head and Professor Department of Ophthalmology & Visual Sciences, Dalhousie University Halifax</p>
	<p>Dr. Paul Rafuse MD PhD FRCSC Ophthalmologist QEII Health Sciences Centre Associate Professor Department of Ophthalmology & Visual Sciences, Dalhousie University Halifax</p>
Ontario	<p>Dr. Ike Ahmed MD FRCSC Head of Ophthalmology, Trillium Health Partners, Mississauga Ophthalmologist, Prism Eye Institute, Brampton Assistant Professor, Department of Ophthalmology & Vision Sciences, University of Toronto Research Director, Kensington Eye Institute Toronto</p>
	<p>Dr. Catherine Birt MA MD FRCSC Affiliate scientist, Sunnybrook Health Sciences Centre Associate Professor, Department of Ophthalmology and Vision Sciences, Faculty of Medicine, University of Toronto Toronto</p>
	<p>Dr. Sherif El-Defrawy MD PhD FRCSC Professor and Chairman Department of Ophthalmology and Vision Sciences University of Toronto Ophthalmologist-in-Chief, Kensington Eye Institute Toronto</p>
	<p>Dr. Steven M. Gilberg MD FRCSC Chairman and Head University of Ottawa Eye Institute Ottawa</p>

Province/Territory	Key Informant
	<p>Dr. Cindy M.L. Hutnik MD PhD Ivey Eye Institute, London Professor, Department of Ophthalmology Schulich School of Medicine and Dentistry London</p> <p>Ms. Donna Punch RN Clinical Director Kensington Eye Institute Toronto</p>
Quebec	<p>Dr. Hady Saheb, MD MPH FRCSC DABO Glaucoma, Cataract and Advanced Anterior Segment Surgeon Assistant Professor, Ophthalmology Director of Resident Research, McGill University Montreal</p>
Prince Edward Island	<p>Dr. Richard Wedge MD CEO (retired 2016) Health PEI Charlottetown</p>
Yukon	<p>Dr. Paul Mackenzie MD PhD Ophthalmologist Eye Care Centre, Vancouver General Hospital Assistant Professor Ophthalmology and Visual Sciences, Faculty of Medicine University of British Columbia</p>

Appendix 2: Consultation Questions

The following questions were posed to key informants as part of the stakeholder consultation:

1. How do you/your facility manage patients with glaucoma?
2. Is your facility/jurisdiction currently performing MIGS procedures? If so, which one(s)? If not, are any being considered?
3. Are traditional glaucoma surgeries being performed along with MIGS procedures in your facility/jurisdiction?
4. What do you consider to be the main challenges to implementing MIGS procedures in your jurisdiction? (what's getting in the way)
5. What is in place now that assists in best practice as it relates to MIGS procedures? (enablers)
6. How do you determine which patients gets access to MIGS procedures in your facility/jurisdiction?
7. What formal training do your clinicians receive in order to perform MIGS procedures?
8. How are clinicians in your facility/jurisdiction reimbursed for performing MIGS procedures?
9. Are there any research studies regarding MIGS implementation issues that we should be aware of?
10. Are there any individuals (clinicians, researchers, health system administrators) you feel we should consult with for this Environmental Scan?

Appendix 3: Available MIGS Procedures and Devices in Canada

MIGS Device or Procedure	Description
Approach: Reducing aqueous production	
Endoscopic cyclophotocoagulation (or endocyclophotocoagulation) (ECP)	ECP involves targeted ablation of the ciliary body with an endoscope probe to reduce the production of aqueous humour. ^{12,38}
Approach: Increasing trabecular outflow by bypassing the TM using tissue ablation/removal	
Trabectome	The trabectome is a surgical device used to perform an “ab-interno trabeculectomy,” which involves ablation and removal of tissue from the TM and inner wall of Schlemm’s canal using high-frequency electrocautery to facilitate the outflow of aqueous humour from the anterior chamber to the collector channels. ^{5,12,35}
Kahook Dual Blade	The Kahook is a dual-blade single-use instrument designed to perform an ab-interno trabeculectomy, similar to the trabectome. The instrument removes tissue from the TM and inner wall of Schlemm’s canal to create a pathway for improving aqueous outflow. ⁵⁸
Approach: Increasing trabecular outflow by bypassing the TM using a device	
iStent (first generation)	The iStent is a device made of heparin-coated titanium that is inserted into Schlemm’s canal using an ab-interno surgical technique to create a permanent bypass channel for aqueous outflow from the anterior chamber to the collector channels. ^{5,10,12,59} Single or multiple iStents may be implanted. ⁵
iStent Inject (second generation)	The iStent Inject is also made of heparin-coated titanium, but is three times smaller than the first-generation iStent, and is designed for ab-interno injection into Schlemm’s canal using a less challenging surgical technique. ⁶⁰ The iStent Inject is preloaded with two stents, such that both can be placed without removing the injector from the eye. ⁶⁰
Approach: Increasing trabecular outflow by bypassing the TM via 360° suture	
Gonioscopy-assisted transluminal trabeculectomy (GATT)	GATT is a procedure for ab-interno circumferential trabeculectomy using a 360° suture or microcatheter in Schlemm’s canal (i.e., opening the trabecular meshwork pathway without removing tissue). ^{58,61}
Approach: Increasing uveoscleral outflow via suprachoroidal shunts	
CyPass Micro-Stent	The CyPass Micro-Stent is a polyamide tube, 6.35 mm long with a 300 µm lumen, ⁶² that is implanted into the supraciliary space (between the ciliary body and the sclera) ⁶² to create a permanent channel between the anterior chamber and the suprachoroidal space. ^{12,63}

MIGS Device or Procedure	Description
Approach: Creating a subconjunctival pathway for filtration	
XEN 45 Gel Stent XEN 63 Gel Stent XEN 140 Gel Stent	The XEN Gel Stent is a device that is implanted from the anterior chamber into the subconjunctival space to provide a bypass route for aqueous outflow. The cylindrical implant is made of flexible collagen-derived gelatin material cross-linked with glutaraldehyde, ⁶² measures 6 mm in length, and is available in three different options denoted by inner diameters of 45 µm, 63 µm, and 140 µm. ^{11,12,16} However, the manufacturer recommends only the 45 µm size to prevent hypotony. ⁶² The procedure may be augmented with subconjunctival injection of mitomycin-C to reduce scarring. ⁶²
Approach: Dilation of the Schlemm’s canal using a microstent	
Hydrus MicroStent	The Hydrus MicroStent is an 8 mm long nitinol alloy open scaffold device shaped to fit the Schlemm’s canal and is implanted into the Schlemm’s canal via a preloaded injector. ^{5,12}

ECP = endoscopic cyclophotocoagulation or endocyclophotocoagulation; GATT = gonioscopy-assisted transluminal trabeculotomy; IOP = intraocular pressure; MIGS = minimally invasive glaucoma surgery; TM = trabecular meshwork.

Appendix 4: Drug Plan Benefit Listings

Prostaglandin analogues

Prostaglandin analogues include travoprost, latanoprost, and bimatoprost.

Drug	Strength/ Dosage Form	BC ⁴²	AB ⁴³	SK ⁵¹	MB ⁴⁴	ON ⁴⁵	NB ⁴⁶	NL ⁵⁰	NS ⁴⁷	PEI ⁴⁸	NIHB/NU ⁴¹	DND ⁴⁹
Travoprost 0.003% ophthalmic solution (Izba)	5 mL ophthalmic solution	UR	UR	NaB								
Travoprost 0.004% (Travatan Z and generics)	5 mL ophthalmic solution	FB	FB	FB	FB	RES	FB	FB	FB	FB	FB	FB
Travoprost 0.004% (generics)	2.5 mL ophthalmic solution	FB	FB	FB	FB	NaB	FB	FB	FB	FB	FB	FB
Latanoprost 0.005% (Xalatan and generics)	2.5 mL ophthalmic solution	FB	FB	FB	FB	RES	FB	FB	FB	FB	FB	FB
Bimatoprost 0.01% (Lumigan RC)	5 mL ophthalmic solution	FB	FB	FB	FB	RES	FB	FB	FB	FB	FB	FB
	7.5 mL ophthalmic solution											
Bimatoprost 0.03% (Vistitan)	3 mL ophthalmic solution	NaB	FB	NaB	FB	RES	FB	NaB	NaB	NaB	FB	NaB
	5 mL ophthalmic solution											

AB = Alberta; BC = British Columbia; DND = Department of Defense; FB = full benefit; MB = Manitoba; NB = New Brunswick; NaB = not a benefit; NIHB = Non-Insured Health Benefits (NIHB) Program; NL = Newfoundland and Labrador; NS = Nova Scotia; NU = Nunavut; ON = Ontario; PEI = Prince Edward Island; RES = restricted benefit with specified criteria (e.g., special authorization, exception drug status, limited use benefit), SK = Saskatchewan; UR = under review.

Sources: BC PharmaCare Formulary⁴², Alberta Interactive Drug Benefit List⁴³, Manitoba Pharmacare Program Drug Formulary Lookup⁴⁴, Ontario Drug Benefit Formulary⁴⁵, New Brunswick Drug Plans Formulary⁴⁶, Nova Scotia Formulary⁴⁷, P.E.I. Pharmacare Formulary⁴⁸, Non-Insured Health Benefits Formulary⁴¹, Canadian Armed Forces Drug Benefit List⁴⁹, Saskatchewan Online Formulary Database,⁵¹ Newfoundland and Labrador Interchangeable Drug Products Formulary⁵⁰

Alpha-2 Adrenergic Agonists

Alpha-2 adrenergic agonists include brimonidine and apraclonidine.

Drug	Strength/ Dosage Form	BC ⁴²	AB ⁴³	SK ⁵¹	MB ⁴⁴	ON ⁴⁵	NB ⁴⁶	NL ⁵⁰	NS ⁴⁷	PEI ⁴⁸	NIHB/ NU ⁴¹	DND ⁴⁹
Brimonidine (Alphagan and generics)	0.15% Ophthalmic solution	FB	NaB	FB	FB	RES	FB	FB	FB	FB	FB	FB
	0.20% Ophthalmic solution	FB	FB	FB	–	RES	FB	–	FB	–	FB	FB
Apraclonidine (Iopidine)	0.5% Ophthalmic solution	FB	FB	NaB	FB	NaB	FB	FB	FB	FB	FB	FB

AB = Alberta; BC = British Columbia; DND = Department of Defense; FB = full benefit; MB = Manitoba; NB = New Brunswick; NaB = not a benefit; NIHB = Non-Insured Health Benefits (NIHB) Program; NL = Newfoundland and Labrador; NS = Nova Scotia; NU = Nunavut; ON = Ontario; PEI = Prince Edward Island; RES = restricted benefit with specified criteria (e.g., special authorization, exception drug status, limited use benefit), SK = Saskatchewan; – = information not available.

Sources: BC PharmaCare Formulary⁴², Alberta Interactive Drug Benefit List⁴³, Manitoba Pharmacare Program Drug Formulary Lookup⁴⁴, Ontario Drug Benefit Formulary⁴⁵, New Brunswick Drug Plans Formulary⁴⁶, Nova Scotia Formulary⁴⁷, P.E.I. Pharmacare Formulary⁴⁸, Non-Insured Health Benefits Formulary⁴¹, Canadian Armed Forces Drug Benefit List⁴⁹, Saskatchewan Online Formulary Database,⁵¹ Newfoundland and Labrador Interchangeable Drug Products Formulary⁵⁰

Beta Adrenergic Antagonists

Beta adrenergic antagonists include betaxolol, timolol, and levobunolol.

Drug	Strength/ Dosage Form	BC ⁴²	AB ⁴³	SK ⁵¹	MB ⁴⁴	ON ⁴⁵	NB ⁴⁶	NL ⁵⁰	NS ⁴⁷	PEI ⁴⁸	NIHB/ NU ⁴¹	DND ⁴⁹
Betaxolol (Betoptic S)	0.25% Ophthalmic solution	FB	FB	FB	FB	GB	FB	FB	FB	FB	FB	FB
Timolol (Timoptic and generics)	0.25% Ophthalmic solution	FB	FB	FB	FB	GB	FB	FB	FB	FB	FB	FB
	0.50% Ophthalmic solution	FB	FB	FB	FB	GB	FB	FB	FB	FB	FB	FB
Timolol gel-forming solution (Timoptic XE, Timolol maleate EX)	0.25% Ophthalmic solution	FB	EX: NaB	FB	FB	GB	FB	FB	FB	NaB	FB	FB
	0.50% Ophthalmic solution	FB	XE: FB	FB	FB	GB	FB	FB	FB	NaB	FB	FB
Levobunolol (Betagan and generics)	0.25% Ophthalmic solution	FB	0.25%: NaB	FB	FB	GB	0.25%: NaB	FB	FB	0.25%: NaB	FB	FB
	0.50% Ophthalmic solution	FB	0.50%: FB	FB	FB	GB	0.50%: FB	FB	FB	0.50%: FB	FB	FB

AB = Alberta; BC = British Columbia; DND = Department of Defense; EX = exception item for which coverage is determined on a case-by-case basis; FB = full benefit; GB = General Benefit; MB = Manitoba; NB = New Brunswick; NaB = not a benefit; NIHB = Non-Insured Health Benefits (NIHB) Program; NL = Newfoundland and Labrador; NS = Nova Scotia; NU = Nunavut; ON = Ontario; PEI = Prince Edward Island; SK = Saskatchewan.

Sources: BC PharmaCare Formulary⁴², Alberta Interactive Drug Benefit List⁴³, Manitoba Pharmacare Program Drug Formulary Lookup⁴⁴, Ontario Drug Benefit Formulary⁴⁵, New Brunswick Drug Plans Formulary⁴⁶, Nova Scotia Formulary⁴⁷, P.E.I. Pharmacare Formulary⁴⁸, Non-Insured Health Benefits Formulary⁴¹, Canadian Armed Forces Drug Benefit List⁴⁹, Saskatchewan Online Formulary Database,⁵¹ Newfoundland and Labrador Interchangeable Drug Products Formulary⁵⁰

Carbonic Anhydrase Inhibitors

Carbonic anhydrase inhibitors include dorzolamide and brinzolamide.

Drug	Strength/ Dosage Form	BC ⁴²	AB ⁴³	SK ⁵¹	MB ⁴⁴	ON ⁴⁵	NB ⁴⁶	NL ⁵⁰	NS ⁴⁷	PEI ⁴⁸	NIHB/ NU ⁴¹	DND ⁴⁹
Dorzolamide (Trusopt and generics)	2.00% Ophthalmic solution	FB	FB	FB	FB	RES	FB	FB	FB	FB	FB	FB
Brinzolamide (Azopt)	1.00% Ophthalmic solution	FB	FB	FB	FB	RES	FB	FB	FB	FB	FB	FB

AB = Alberta; BC = British Columbia; DND = Department of Defense; EX = exception item for which coverage is determined on a case-by-case basis; FB = full benefit; GB = General Benefit; MB = Manitoba; NB = New Brunswick; NaB = not a benefit; NIHB = Non-Insured Health Benefits (NIHB) Program; NL = Newfoundland and Labrador; NS = Nova Scotia; NU = Nunavut; ON = Ontario; PEI = Prince Edward Island; RES = restricted benefit with specified criteria (e.g., special authorization, exception drug status, limited use benefit), SK = Saskatchewan; UR = under review; – = information not available.

Sources: BC PharmaCare Formulary⁴², Alberta Interactive Drug Benefit List⁴³, Manitoba Pharmacare Program Drug Formulary Lookup⁴⁴, Ontario Drug Benefit Formulary⁴⁵, New Brunswick Drug Plans Formulary⁴⁶, Nova Scotia Formulary⁴⁷, P.E.I. Pharmacare Formulary⁴⁸, Non-Insured Health Benefits Formulary⁴¹, Canadian Armed Forces Drug Benefit List⁴⁹, Saskatchewan Online Formulary Database,⁵¹ Newfoundland and Labrador Interchangeable Drug Products Formulary⁵⁰

Parasympathomimetics (Cholinergic Agents)

Parasympathomimetics include pilocarpine and carbachol.

Drug	Strength/ Dosage Form	BC ⁴²	AB ⁴³	SK ⁵¹	MB ⁴⁴	ON ⁴⁵	NB ⁴⁶	NL ⁵⁰	NS ⁴⁷	PEI ⁴⁸	NIHB/ NU ⁴¹	DND ⁴⁹
Pilocarpine (Isopto Carpine and generics)	1.00%, 2.00% Ophthalmic solution 4.00% Ophthalmic solution	FB	FB	FB (1% discontinued)	FB	GB	FB	FB	FB	2% & 4% – FB 1% – NaB	FB	FB
Carbachol (isopto Carbachol)^a	1.00%, 3.00% Ophthalmic solution	–	NaB	Discontinued but had been FB	FB	NaB	NaB	NaB	NaB	NaB	FB	NaB

AB = Alberta; BC = British Columbia; DND = Department of Defense; FB = full benefit; GB = General Benefit; MB = Manitoba; NB = New Brunswick; NaB = not a benefit; NIHB = Non-Insured Health Benefits (NIHB) Program; NL = Newfoundland and Labrador; NS = Nova Scotia; NU = Nunavut; ON = Ontario; PEI = Prince Edward Island; SK = Saskatchewan; – = information not available.

^a For Carbachol 1% and 3% (Isopto Carbachol) it appears that these products have been discontinued by the manufacturer and there does not appear to be a comparable product currently available in Canada

Sources: BC PharmaCare Formulary⁴², Alberta Interactive Drug Benefit List⁴³, Manitoba Pharmacare Program Drug Formulary Lookup⁴⁴, Ontario Drug Benefit Formulary⁴⁵, New Brunswick Drug Plans Formulary⁴⁶, Nova Scotia Formulary⁴⁷, P.E.I. Pharmacare Formulary⁴⁸, Non-Insured Health Benefits Formulary⁴¹, Canadian Armed Forces Drug Benefit List⁴⁹, Saskatchewan Online Formulary Database,⁵¹ Newfoundland and Labrador Interchangeable Drug Products Formulary⁵⁰

Combination Products

Combination products are anti-glaucoma drops that contain two or more medications within their formulation.

Drug	Strength/ Dosage Form	BC ⁴²	AB ⁴³	SK ⁵¹	MB ⁴⁴	ON ⁴⁵	NB ⁴⁶	NL ⁵⁰	NS ⁴⁷	PEI ⁴⁸	NIHB/ NU ⁴¹	DND ⁴⁹
Brinzolamide/ brimonidine (Simbrinza)	1.0%/0.2% Ophthalmic solution	FB	FB	FB	FB	RES	FB	FB	FB	FB	FB	FB
Brimonidine/ timolol maleate (Combigan)	0.2%/0.5% Ophthalmic solution	FB	FB	FB	FB	RES	FB	FB	FB	FB	FB	FB
Brinzolamide/ timolol maleate (Azarga)	1.0%/0.5% Ophthalmic solution	FB	FB	FB	FB	RES	FB	FB	FB	FB	FB	FB
Dorzolamide/timolol maleate (Cosopt and generics)	2.0%/0.5% Ophthalmic solution	FB	FB	FB	FB	RES	FB	FB	FB	FB	FB	FB
Latanoprost/ timolol maleate (Xalacom and generics)	50mcg/mL – 5mg/ mL Ophthalmic solution	FB	FB	FB	FB	RES	FB	FB	FB	FB	FB	FB
Travoprost/timolol maleate (DuoTrav PQ)	0.004%/ Ophthalmic solution	FB	FB Generic – UR	FB	FB	RES	FB	FB	FB	FB	FB	RES

AB = Alberta; BC = British Columbia; DND = Department of Defense; FB = full benefit; MB = Manitoba; NB = New Brunswick; NIHB = Non-Insured Health Benefits (NIHB) Program; NL = Newfoundland and Labrador; NS = Nova Scotia; NU = Nunavut; ON = Ontario; PEI = Prince Edward Island; RES = restricted benefit with specified criteria (e.g., special authorization, exception drug status, limited use benefit), SK = Saskatchewan; UR = under review.

Sources: BC PharmaCare Formulary⁴², Alberta Interactive Drug Benefit List⁴³, Manitoba Pharmacare Program Drug Formulary Lookup⁴⁴, Ontario Drug Benefit Formulary⁴⁵, New Brunswick Drug Plans Formulary⁴⁶, Nova Scotia Formulary⁴⁷, P.E.I. Pharmacare Formulary⁴⁸, Non-Insured Health Benefits Formulary⁴¹, Canadian Armed Forces Drug Benefit List⁴⁹, Saskatchewan Online Formulary Database,⁵¹ Newfoundland and Labrador Interchangeable Drug Products Formulary⁵⁰

Appendix 5: Drug Plan Benefit Listings Associated Listing Criteria

Ontario was the only province who provided the associated listing criteria for glaucoma medications with restricted benefits.⁴⁵ The Canadian Armed Forces also provided information on their associated listing criteria for medications with restricted benefits.⁴⁹

Ontario⁴⁵:

Travatan Z (travoprost), Xalatan (latanoprost), Lumigan RC (bimatoprost), Vistitan (bimatoprost), Alphagan (brimonidine), Trusopt (dorzolamide), and Azopt (brinzolamide)

- As first-line treatment of elevated intraocular pressure in patients who cannot tolerate an ophthalmic beta-blocking agent or where beta-blocking agents are contraindicated.
- As second-line monotherapy or combination therapy in patients who do not have an adequate intraocular pressure lowering response to ophthalmic beta-blocking agents.
- For use as adjunctive therapy with an ophthalmic beta-blocking agent in an urgent situation (e.g., patients with a high baseline intraocular pressure) where monotherapy is unlikely to be effective.

Simbrinza (brinzolamide/brimonidine)

- As second-line therapy for patients who do not have an adequate intraocular pressure lowering response to monotherapy with brinzolamide or brimonidine.
- For use as initial therapy in an urgent situation (e.g., patients with a high baseline intraocular pressure) where monotherapy is unlikely to be effective.

Combigan (brinzolamide/timolol), Azarga (brinzolamide/timolol), Cosopt (dorzolamide/timolol), Xalacom (latanoprost/timolol), DuoTrav PQ (travoprost/timolol)

- As second-line therapy for patients who do not have an adequate intraocular pressure lowering response to monotherapy with ophthalmic beta-blocking agents.
- For use as initial therapy in an urgent situation (e.g., patients with a high baseline intraocular pressure) where monotherapy is unlikely to be effective.

Canadian Armed Forces⁴⁹:

DuoTrav (timolol combination), Azarga (timolol combination)

- Requests for use are considered for members who have not adequately responded to monotherapy with ophthalmic beta blocker drugs.