Canada's Drug and Health Technology Agency

Role of real world evidence (RWE) to support decision-making about care for pediatric low-grade glioma

CADTH RWE Learning Project

July 13th 2022

Land acknowledgement

I would like to acknowledge from Edmonton, Alberta, that I am located on Treaty 6 Territory, traditional and present-day lands of the Metis and Metis Nations of Alberta Region 4. I recognize that we all work in different places and that therefore you work in a different traditional Indigenous territory. I encourage you to take a moment to reflect on that and acknowledge the relationship that the First Nations, Inuit and Métis across Canada have with the land that we live on and enjoy.

I also encourage you to consider how you can personally contribute to Canada's reconciliation with Indigenous Peoples. I am grateful to those whose territory we reside on or are visiting.

- Ping Mason-Lai

Housekeeping/Rules of Engagement

- Virtual room etiquette
- Participation
- Curious mind and open heart
- Confidentiality
- Everyone has wisdom

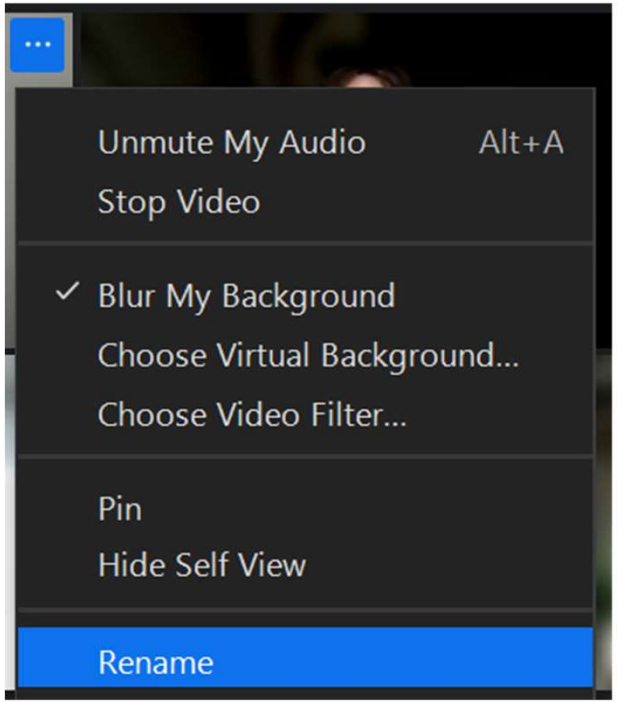
Chatham House Rule

When a meeting, or part thereof, is held under the Chatham House Rule, participants are free to use the information received, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed.

In a polarized world, used effectively, the Chatham House Rule helps to bring people together, break down barriers, generate ideas and agree solutions.

Zoom – How to Change Your Name

1. Move mouse cursor over your picture
2. Click on three dots (…) in the **right top corner of your picture** OR right mouse click
3. Select “Rename”
4. Add your org/group/entity/lived experience



Disclosure

- CADTH is funded by contributions from the Canadian federal, provincial, and territorial ministries of health, with the exception of Quebec.
- CADTH receives application fees from the pharmaceutical industry for:
  - CADTH Pharmaceutical Reviews, including Common Drug Review, pan-Canadian Oncology Drug Review, and Interim Plasma Protein Product Review
  - CADTH Scientific Advice

Why are we doing this?

With the support of Health Canada, CADTH has launched a learning period during which the potential value of RWE to fill gaps in evidence and support decision making **about care for rare diseases** will be explored.

Purpose: Today we want to hear your perspective and discuss as a group what type of information would be important for decision-making about optimization of care for pediatric low-grade glioma.

Objective: More specifically, we would like to hear from each of you about which indicators/outcomes would be the most relevant to measure to meet your decision-making needs.

Topics raised that are out of scope of this discussion will be noted and inform future CADTH work

Some key messages from the literature about multistakeholder dialogue

- Participation in HTA processes by stakeholders such as the HTA workforce, patients, and clinicians is increasing (Trowman et al., 2020) and is recognized as important (Garrett et al., 2022)
- Patient participation is particularly important for rare diseases, as patients are experts in their pathologies (de Andres-Nogales et al., 2021) and because of the degree of unmet need and limited clinical knowledge (HTAi, 2016)
- Involving multiple stakeholders contributes to legitimacy of decision making (de Andres-Nogales et al., 2021) and may increase stakeholders' acceptance of the decisions (Feenstra et al., 2022)
- Multistakeholder involvement builds understanding among stakeholders, incorporates a range of values, and supports quality decision-making (Baltussen et al. 2021, Jiu et al. 2022, Oortwijn et al., 2021

Agenda

I. Introduction

II. Overview of available evidence (disease, patient characteristics, current treatments and ongoing trials)

III. Key messages of the unmet needs/gaps/challenges in the care for pediatric low-grade glioma (PLGG) patients (summary of the input from the patients and the healthcare providers meetings)

IV. Check point by chat (patients and healthcare providers to add commentary if needed)

V. Overview of potential indicators/outcomes to support decision-making

VI. Discussion (what needs to be measured/followed to meet your decision-making needs about the care for PLGG patients? What is missing?)

I. Representatives of each stakeholder group to talk about what should be measured and why

VII. POGONIS Registry Presentation

VIII. Discussion (What should be measured from the existing available data to support decision-making? Which of the discussed indicators would be the most relevant to measure prospectively?)

IX. Evaluation

X. Final Remarks and Next Steps

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Introduction

Public drug reimbursement decision pathway in Canada

Health Canada asks:

Is it safe? Does it work?

CADTH asks:
INESSS

How does it compare with existing treatment options? Is it good value

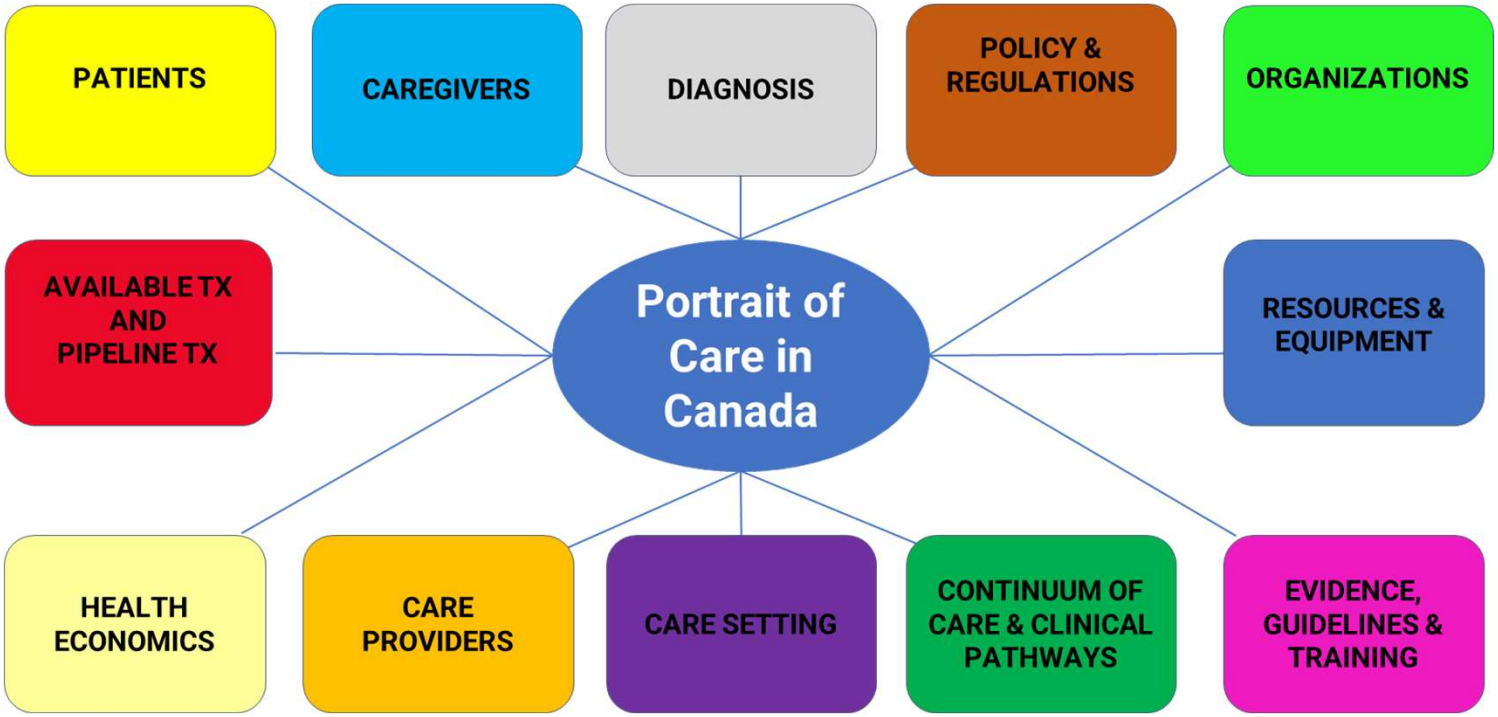
Federal, provincial, and territorial public drug plans and the pan-Canadian Pharmaceutical Alliance ask:

Is it needed? Is it affordable?

What decisions are made by other stakeholders?

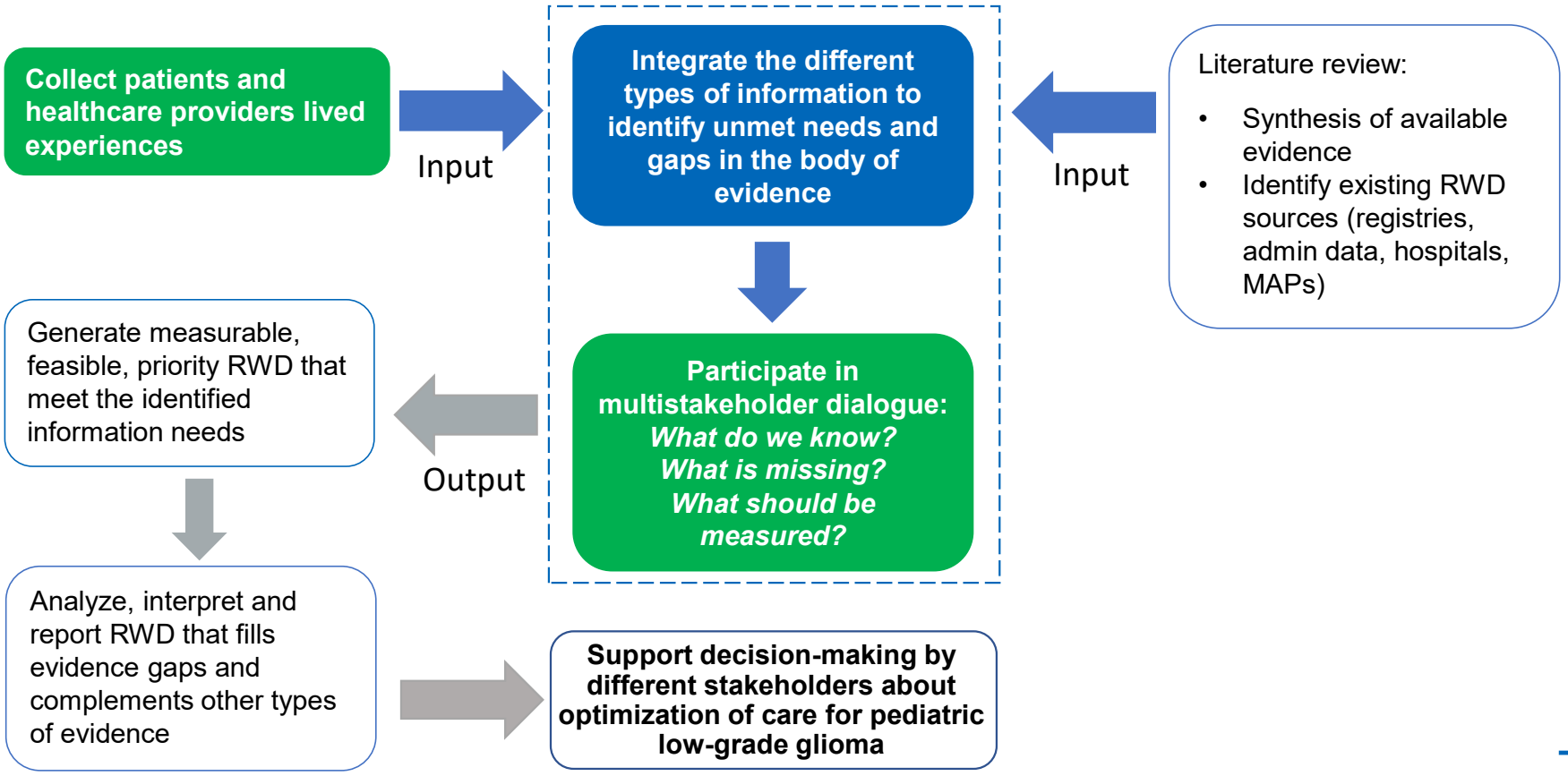
- **Industry**: Where to invest (in which clinical trial?), what patient population, what to measure RCT/RWD?
- **Private payers**: Should this treatment be reimbursed through private health insurance?
- **Healthcare providers**: Should I offer this treatment or not and if so, when?
- **Caregivers**: Should I give this treatment to my child? Will this treatment reduce my child's disease and care burden? Other side effects?
- **Patients**: Should I take this treatment or not? Will this treatment reduce my disease and care burden? Other side effects?
- **Registry and data holders/researchers:** What to measure and when?

- RWE is derived from data collected outside of RCTs
- RWE helps to contextualize RCT results to the Canadian context
- Complementary to RCT data. It fills gaps, not a replacement



Components of the system of care in Canada

Pediatric Low-Grade Glioma Multi-Stakeholder Meeting – July 13th, 2022



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What we have learned from the literature

Patient Characteristics

- Pediatric low-grade glioma is a rare disease with a Canadian incidence (2001-2015) for children 0-14 years of age of 1.41 cases per 100,000 person years.
- Pediatric low-grade gliomas (pLGG) are the most frequent solid primary tumors of the CNS in pediatrics
- Median age of diagnosis: 6-8 y/o
- Hereditary conditions associated with increased risk of developing pLGG
    - Tuberous sclerosis complex (TSC)
    - Neurofibromatosis Type 1 (NF-1)
- pLGGs are a diverse group of tumors that differ greatly in terms of
    - Location in the central nervous system
    - Histology
    - Molecular profile
- Recent research suggests the majority (90%) of pLGG tumors have alterations to the MAPK/ERK pathway

Processes of care: Canadian National Standard of Practice for CNS Tumors (2020): pLGG recommendations

Preferred 1st line treatment = complete surgical removal (resection) of tumor

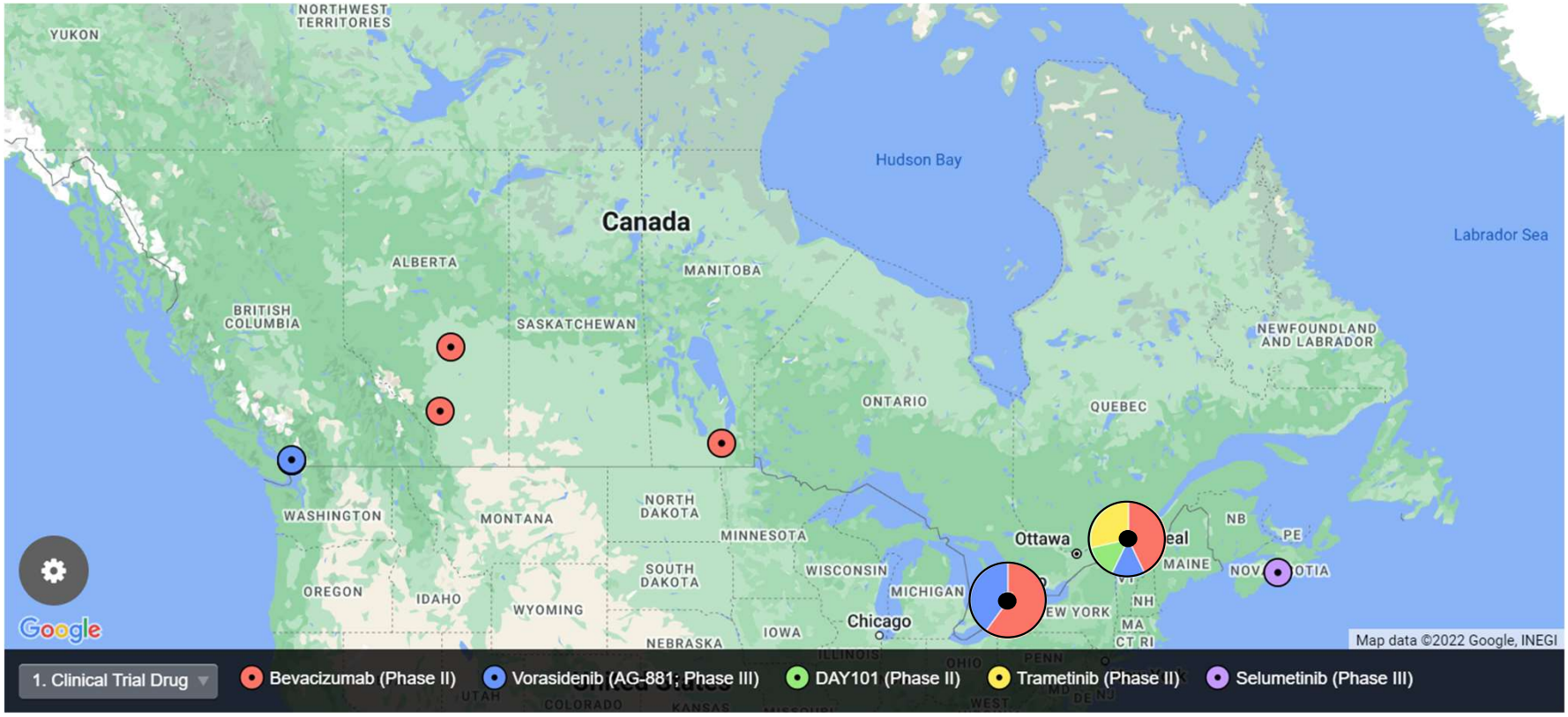
Canadian Treatment Guidelines	Drug Name	Route of Administration	State of Access in Canada
1st line *If surgical removal not possible,* **chemo monotherapy**	Vinblastine (Velban®)	Intravenous	OFF-LABEL
2nd line *If BRAF V600E mutation alteration identified,* **targeted inhibitor**	Vemurafenib (Zelboraf®)	Oral	OFF-LABEL
	Dabrafenib (Tafinlar®)	Oral	OFF-LABEL
2nd line *If BRAF fusion identified or NF1 patient with optic/ suprasellar tumor,* **targeted inhibitor**	Trametinib (Mekinist®)	Oral	OFF-LABEL **Ongoing Clinical Trial**
	Selumetinib (Koselugo®)	Oral	**Ongoing Clinical Trial(s)**
2nd line *If no MAPK alteration identified,* **two chemo agents**	Vincristine (VCR; multiple brands available) *AND*	Intravenous	OFF-LABEL
	Carboplatin	Intravenous	OFF-LABEL

- Radiation avoided for patients of all ages, especially NF-1

Ongoing Clinical Trials for pLGG registered in Health Canada's Database

Drug	Mechanism	Trial Stage	Estimated Study Completion Date	Route of Admin	Study population	Age Range
Bevacizumab (Avastin®)	Vascular Endothelial Growth Factor-directed Antibody	Phase II	Primary: August 2026 Final: August 2026	IV	pLGG chemotherapy naïve children with unresectable or progressive tumors	**6 months to 18 years old**
DAY101	Selective type II pan-RAF inhibitor	Phase II	Primary: March 2023 Final: February 2024	Oral	RAF-altered, recurrent or progressive pLGG and advanced solid tumors	**6 months to 25 years old**
Selumetinib (Koselugo®)	MEK inhibitor	Phase III	Primary: December 2026 Final: December 2026	Oral	Newly diagnosed or untreated LGG (adult and pediatric) not associated with BRAFV600E mutations or systemic neurofibromatosis type 1	**2 to 21 years old**
Selumetinib (Koselugo®)	MEK inhibitor	Phase III	Primary: May 2027 Final: May 2027	Oral	Newly diagnosed or untreated NF1 (confirmed via clinical criteria and/or germline genetic testing) associated low-grade glioma or low-grade astrocytoma (WHO grade I and II) except subependymal giant cell astrocytoma	**2 to 21 years old**
Trametinib (Mekinist®)	MEK inhibitor	Phase II	Primary: June 2026 Final: December 2026	Oral	pLGG or plexiform neurofibroma with refractory tumor with activation of MAPK/ERK pathway Group 1: NF1 with progressing/refractory LGG Group 2: NF1 with plexiform neurofibroma Group 3: Progressing/refractory LGG with KIAA 1549-BRAF fusion Group 4: Progressing/refractory glioma with activation of the MPAK/ERK pathway who do not meet criteria for other study groups	**1 month to 25 years old**
Vorasidenib (AG-881)	MIDH1 & 2 Inhibitor	Phase III	Primary: October 2024 Final: August 2027	Oral	Adult and pediatric LGG - residual or recurrent grade 2 oligodendroglioma or astrocytoma per WHO 2016 criteria with an IDH1 or IDH2 mutation	**12 years old +**

Clinical trials in Canada (colors represent drugs being studied)



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What we learned from talking with patient groups, families and healthcare providers

Patient Community Meetings

May 27th 2022 (6)

Participants (5)

- 1 mother, 1 father, 3 patient group representatives

Observers (1)

- 1 RN, Pediatric oncology (emotional support designate)

May 30th, 2022 (5)

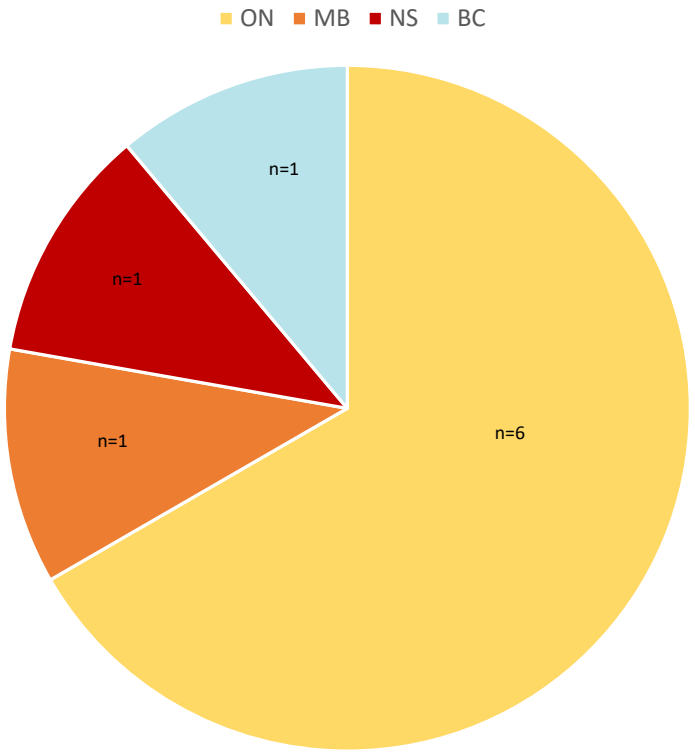
Participants (4)

- 2 mothers, 1 father, 1 patient group representative

Observers (1)

- 1 RN, Pediatric oncology (emotional support designate)

Regional Distribution of Patient Community Meeting Participants



Key unmet needs/challenges/gaps identified by PATIENTS/CAREGIVERS

Access to treatment:

- Accessing treatments is time-intensive for parents and their children and adds to the already heavy burden of caring for a sick child
- Perception of a lack of novel and potentially effective treatments in Canada
- Reliance on communication with other families with lived experience, through virtual platforms, to guide them in their search for treatment options and what to expect from the care process
- At completion of clinical trials or treatment courses, families wait for the next steps in the care pathway

Key unmet needs/challenges/gaps identified by PATIENTS/CAREGIVERS

Variation in care:

- Provinces and territories may have differing approaches to treatment plans
- Clinicians operating in the same institution may have differing approaches to providing care
- Access to specialist physicians and resources can vary based on geographical location
- Perception of a lack of coordination between hospitals across Canada and with care providers in the United States
- The care pathway can make it difficult for children to maintain their personhood
    - Seeing a consistent set of specialists familiar with the child as an individual, as well as integrated access to psychosocial care were perceived as beneficial

Key unmet needs/challenges/gaps identified by PATIENTS/CAREGIVERS

Financial burden of care:

- Drugs for pediatric oncology, and other rare diseases, can often be high-cost and issues can arise when they are prescribed “off-label”
- Out-of-pocket costs can also include:
  - medical tests and procedures,
  - medical supply and equipment costs for at-home care,
  - complementary alternative medicines (vitamins, supplements)
  - psychosocial support, childcare and other non-medical supports
  - cost of travelling within or outside of Canada for their children to receive care (lodging, other accommodations, and/or transportation (gas, parking fees, public transit)
- Some have experienced misalignment in the language and requirements communicated between physicians and the insurance companies and this disconnect often falls on the family to manage.

Key unmet needs/challenges/gaps identified by PATIENTS/CAREGIVERS

Other challenges:

- Orally administered versus intravenous therapies may be preferred because they can be administered outside of treatment centers
    - allows children to miss fewer days at school and with friends
    - reduces burden on caregivers in terms of travel time
    - reduces expenses and potential missed days at work
- Barriers associated with the transition from care in pediatric centers to adolescent/adult centers

Healthcare Provider Meeting

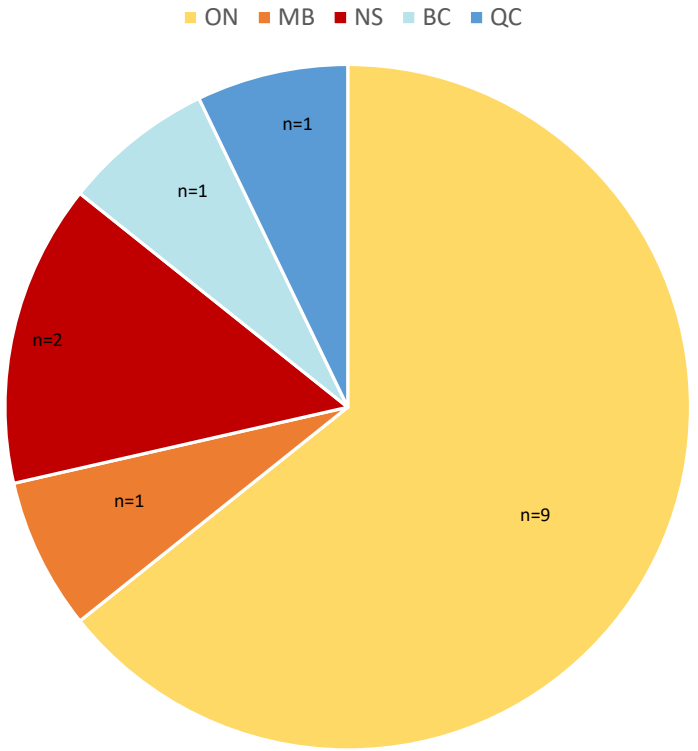
May 30th, 2022 – Healthcare Provider Meeting

Participants

14 healthcare providers total; 12 physicians, 1 nurse, 1 pharmacist

- Pediatric Haematologist/Oncologist with or without Neuro-Oncology Speciality
- Neuropathologist
- Neurosurgeon
- Radiation Oncologist
- Adult Neuro-Oncologist
- Pediatric Haematology/Oncology Clinical Resource Nurse
- Pediatric Haematology/Oncology Pharmacist

Regional Representation - All Healthcare Provider Participants



Key unmet needs/challenges/gaps identified by HEALTHCARE PROVIDERS

Off-label and special access program medications:

- A lot of time and effort to complete the required paperwork
    - No renumeration for efforts
- Approval processes:
    - Intravenous therapies are provided at clinics or institutions; they have an easier approval process
    - Oral therapies require more effort to acquire the necessary approvals
    - Special access approval required for compounded liquid preparations of a medicine
- Managed access programs can be discontinued at anytime by the manufacturer
- There may be burden/costs associated with:
    - Diagnostics
    - Filling prescriptions for oral therapies at pharmacies

Key unmet needs/challenges/gaps identified by HEALTHCARE PROVIDERS

Ongoing clinical trials:

- Harm in waiting for these trials to be completed before making decisions in practice
- Concern that these studies have the right follow up periods to fully capture the necessary end points of interest
- Concern that these studies do not include young adult patients
    - It is very difficult to access treatments for these individuals

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Check point by chat on presented content

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Examples of potential indicators and outcomes to support decision-making

What information do you need about patients to support your decision-making?

Examples of patients characteristics descriptive statistics:

- Age range
- Sex
- Other measures of diversity, equity and inclusion
- Geographical location (where do patients live, rural, urban)
- Type of pediatric low-grade glioma (tumour type)/incidence
- Age at diagnosis
- Tumour site
- Tumour size at diagnosis
- Comorbidities (other health conditions)
- Past treatments received
- Current treatment received
- In a clinical trial, special access program, managed access program or receiving off-label treatment?

What information do you need about the structure of care to support your decision-making?

Examples of potential indicators of structure of care:

- Geographical location of care
- Number and type of specialists
- Volume of patients/center
- Pediatric versus adult center
- Number of doctors per speciality caring for individual patient (consistency of care)
- Child life specialist: yes/no

What information do you need about the process of care to support your decision-making?

Examples of potential indicators of process of care:

- Time from symptoms onset to diagnosis
- Diagnostic procedure
- Frequency, sequencing and duration of treatments/time between treatments
- Routes of administration of current treatments/use of neuro-navigation for surgery/proton therapy
- Time to access current treatment
- Travel time for treatment and follow-ups
- Administrative time required to provide care (off-label or out of the country treatments requests)
- Pharmacy time to prepare pediatric formulations

What information do you need about outcomes to support your decision-making?

Examples of potential outcome measures:

Burden of care

- Out-of-pocket costs (diagnosis, treatment and other expenses such as gas, parking, overnight stays, etc.)
- Time out of school
- Time off work
- Psychosocial burden: relationships, depression, anxiety, self-esteem, etc.

What information do you need about outcomes to support your decision-making?

Examples of potential outcome measures:

Clinical outcomes

- Change in tumour volume (%)
- % of tumour resection
- Progression/event-free survival time
- Radiation free survival or delayed use of increasingly toxic chemotherapy agents
- Response rate (stable, minor response, partial response or complete response)
- Tolerability
- Change in function: vision, motor, cognitive
- Quality of life
- Adverse effects or events (ex.: secondary neoplasms, cognitive impairment, etc.)

Examples of Outcomes/Indicators Measured in at least 3 of 6 identified trials

Indicators	Examples of Measurement Methods
Response Rate	RANO & RAPNO, RECIST 1.1 criteria and volumetric measurement, volume per Blinded Independent Review Committee
Progression/event-free survival	RANO & RAPNO, clinical or radiological progression
Quality of Life	PedsQL, PROMIS, FACT-Br
Overall Survival	Interval from randomization or treatment initiation to death from any cause
Vision	Teller Acuity Cards® II, Visual Field/Acuity exams, Optical Coherence Tomography
Safety	Common Terminology Criteria for Adverse Events (CTCAE)
Cognitive Impairment	NIH Toolbox Cognitive Battery, BRIEF-2, Weschsler Processing Speed Index, CogState, Bailey-III/WPPSI-IV/WISC-V/WAIS-IV
Biological features	Gene expression profiling/mutational analysis/circulating tumor DNA
Change in tumor volume	MRI volumetric analysis
Motor function	Vineland 3 Adaptive Behavior Scales
Tolerability	Treatment discontinued
Imaging	novel MR biomarkers, diffusion-weighted MRI, semi-automated volumetric analysis

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Discussion

Discussion

I. What needs to be measured / followed to meet your decision-making needs about the care for PLGG patients? What is missing?

Representatives of each stakeholder group to talk about what should be measured and why

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BREAK

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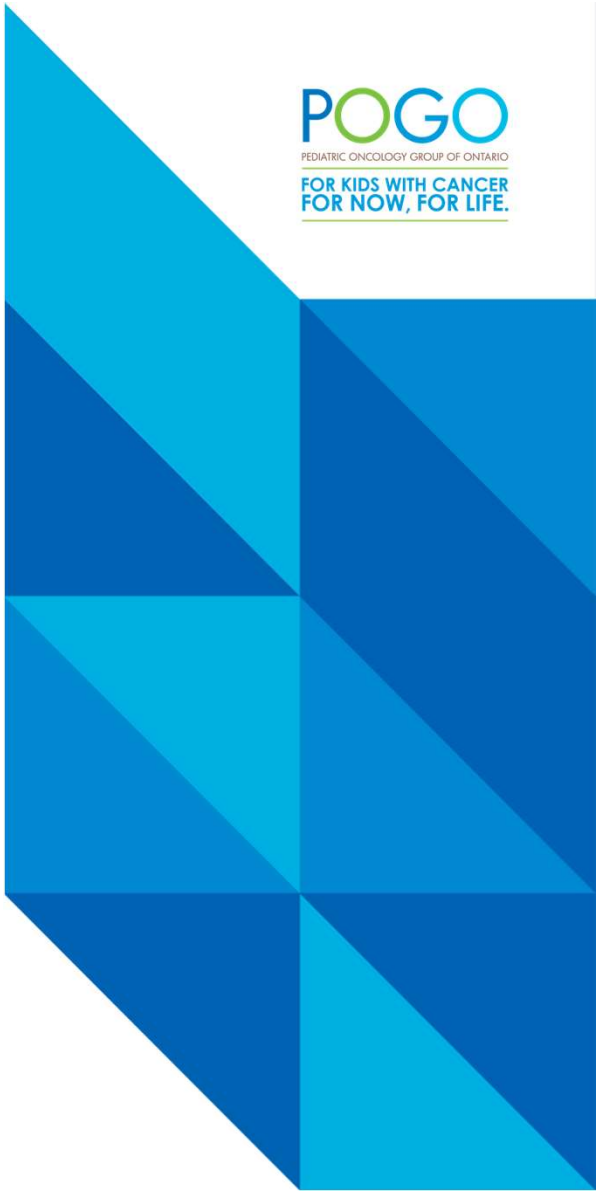
POGONIS: A potential source of real-world data

POGO Networked Information System (POGONIS)

Registry Overview

Presented by: Nicole Bradley
Manager, Health Analytics, POGO



What is POGONIS?
POGO Networked Information System

- **Operated by POGO with funding from Provincial Ministry of Health**
- **Active and prospective data collection since 1985**
  - Registration of **each new childhood cancer case, aged 0–19 years, diagnosed and/or treated in a specialized childhood cancer programs in Ontario** (total of 5 hospitals in ON)
    - **Collected under a waiver of consent**, given it's Prescribed Entity status
  - **Includes malignant neoplasms and neoplasms of indeterminate behaviour/benign CNS tumours** (total of 23,000 cases since 1985)
    - Includes **low-grade glioma cases** (total of 1,595 cases diagnosed since 1985, average of 53 per year in most recent 10-years (2012-2021, 44-69 per year)
  - **Patient characteristics (sociodemographic), diagnostic, treatment and outcomes data**

Who is captured in POGONIS?

- **Complete population-based capture for 0-14 year olds diagnosed with cancer in Ontario**
  - 95% agreement in CNS diagnoses between POGONIS and Ontario Cancer Registry *(Gupta, Pole, 2016)*

- **Capture of adolescents with cancer in Ontario in POGONIS[1]**
  - 33% of adolescents in Ontario, aged 15-19 years, diagnosed with a first primary cancer or benign CNS tumour between 2010 and 2017 were diagnosed and/or treated in a specialized childhood cancer program in Ontario and registered in POGONIS
  - Approx. 60% capture in 15-17 year olds

[1]*Data Source: Ontario Health and Pediatric Oncology Group of Ontario. Adolescent and Young Adults (AYA) Cancer Cohort, 2020.*

POGO
PEDIATRIC ONCOLOGY GROUP OF ONTARIO

What can POGONIS measure with existing data:

- **Number of children diagnosed with LGG per year** (including age-standardized rates for 0-14 year old population)
- **Patient characteristics** (such as sex, age)
- **Predisposing conditions** – such as NF-1, Tuberous sclerosis complex *(collected as free text)*
- **Tumour biology characteristics** (such as BRAF, Fusion BRAF-KIAA1549)
- **Treatment summary** – treatment plans may include surgery, observation only, systemic therapy, radiation, targeted therapy
- **Enrollment on clinical trial**
- **Time to event (survival) analyses** (time to progression, death)
- **Health service utilization** (via linkage to administrative data holdings)

Cancer in Young People – Canada (CYP-C)

- Collaboration between PHAC and C17
- Diagnosed with cancer in Canada ≥ 2001, < 18 years at diagnosis
- 17 pediatric oncology centers
  - Direct entry n=12 (collected via REB consent waiver)
  - Data transfer from POGO n=5
- Diagnosis, treatment, outcomes for **5 years after diagnosis**
- Ongoing plans to link CYP-C to multiple other data sources via Statistics Canada

CANCER IN YOUNG PEOPLE IN CANADA PROGRAM
PROGRAMME CANCER CHEZ LES JEUNES AU CANADA

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Discussion

Discussion

1) What should be measured from the existing available data to support decision-making?

2) In an ideal world, which of the discussed indicators/outcomes would be the most relevant to measure prospectively?

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Output of this meeting

Meeting output

- High level report on the key messages will be published
    - most relevant role for RWE and priority indicators/outcomes to measure to support decision-making about care for PLGG patients
    - participants will have a chance to provide feedback before any publication
- Learnings from this meeting will help to:
    - develop guidance on multistakeholder dialogue
    - inform exploration of real-world data collection/generation to support decision-making
- Topics raised in this meeting that were out of scope have been noted and will inform future CADTH work

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Evaluation of Meeting

If you have further thoughts please email rwe@cadth.ca

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Final Remarks and Next Steps

"It is critical that a multistakeholder team comes together…to say what kind of data is needed and what are going to be the caveats around the quality of that data."

[Best Brains Exchange, 2021]

Thank You

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865 Carling Ave., Suite 600, Ottawa, Ontario, Canada K1S 5S8
865, avenue Carling, bureau 600, Ottawa, Ontario, Canada K1S 5S8
154 University Ave., Suite 300, Toronto, Ontario, Canada M5H 3Y9
154, avenue University, bureau 300, Toronto, Ontario, Canada M5H 3Y9

Pediatric Glioma Concerns and Considerations - perspectives from people with lived experience.

Glossary of terms

Clinical Registry

A patient registry is a collection, for one or more purposes, of standardized health information about a group of patients who share a condition or experience. Other similar terms such as clinical registries, clinical data registries, disease registries, and outcomes registries are also used to describe the same data collection method.

-from National Library of Medicine - Engaging Patients in Information Sharing and Data Collection: The Role of Patient-Powered Registries and Research Networks

Drug Approval Process

The drug approval process refers to the key steps that must occur before a drug can be sold in Canada.

-from CADTH Patient Engagement communications

Health Technology Assessment (HTA)

A method to determine the value of a drug, medical device, or clinical procedure from different perspectives including a patient perspective, a clinical perspective, economic perspective. The purpose is to inform decision-making and promote an equitable, efficient, and high-quality health system.

-from HTAi Glossary of Terms

Indication

An indication for a drug is the reason the drug is used, usually to treat an illness or disease.

-from CADTH off-label use of drugs backgrounder

Indicator
There are many variables that are important to measure when evaluating healthcare systems that are not directly related to the impact of a treatment, policy, programme or other intervention (i.e. they are not an "outcome"). This includes things like patient characteristics (e.g. how far a person lives from a hospital that can deliver the care they need, socioeconomic background, gender) and processes of care (e.g. IV vs oral drug administration, wait times for procedures). The term "indicator" is widely used by organizations like CIHI, Health Canada and the World Health Organization to describe these types of variables.

Off-label use
The term "off-label" refers to any use of a drug beyond what Health Canada has reviewed and authorized to be marketed in Canada and as indicated on the product label. Usually, this means using a drug for an illness or disease other than the authorized reasons for use — in other words, an "off-label indication." However, drug doses, when and how often to take a drug, and the type of patient (e.g., children, pregnant women, and elderly) may be considered "off-label," as well. Off-label use is also sometimes called expanded use.

-from CADTH off-label use of drugs backgrounder

Outcomes
The impact that a treatment, policy, programme or other intervention has on a person, group or population. Depending on the intervention, outcomes could include changes in knowledge and behaviour related to health or in people's health and wellbeing, the number of patients who fully recover from an illness or the number of hospital admissions, and an improvement or deterioration in someone's health, symptoms or situation.

-from NICE Glossary

Pharmaceutical review process at CADTH

Detailed health technology assessments are conducted by a pan-Canadian expert review committee, with opportunities for input by patient groups, the pharmaceutical industry, clinicians, and the provincial advisory group. However, the final funding decision for all cancer drugs reviewed at CADTH remains the responsibility of each individual participating jurisdiction.

-from CADTH Patient Engagement communications

Randomized Controlled Trial (RCT)
A study in which a number of similar people are randomly assigned to 2 (or more) groups to test a specific drug, treatment or other intervention. One group (the experimental group) has

the intervention being tested, the other (the comparison or control group) has an alternative intervention, a dummy intervention (placebo) or no intervention at all. The groups are followed up to see how effective the experimental intervention was. Outcomes are measured at specific times and any difference in response between the groups is assessed statistically. This method is also used to reduce bias.

-from NICE Glossary

Real World Data (RWD)
An umbrella term for data collected outside of Randomized Controlled Trials (RCT).

-from CADTH RWE Information Session

Real World Evidence (RWE)
Evidence about the use, safety, and effectiveness of a medical product, technology, or drug that is based on or derived from analysis of data generated in a real-world health care setting.

-from CADTH RWE Primer