BC SUPPORT Unit
Advancing Patient-Oriented Research
British Columbia Academic Health Science Network

Strategy for Patient-Oriented Research
SPOR
Putting Patients First

Advancing Pragmatic Clinical Trials to Support Learning Health Systems:

Opportunities for British Columbia

Discussion Overview:

2021 "Modernization of Clinical Trials" Clinical Trials BC conference

"Real-World Clinical Trials" Methods Clusters' 90-minute virtual session

on pragmatic clinical trials and learning health systems within British Columbia

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Overview

Learning health systems, as defined by the Institute of Medicine, embed processes for collecting and analyzing data created as part of care with the intent to continuously improve care. Through quality improvement and research methodologies, these systems offer the potential to generate new evidence to address knowledge gaps and direct decision-making. Pragmatic clinical trial (PCT) methods support systematic evaluation for how different treatments or ways of delivering care compare. When designed well, they build on existing workflows and data infrastructures to allow learning to occur alongside care. Further, outcomes assessed are determined by those individuals for whom the evidence is intended to inform – patients, clinicians, healthcare administrators, and policymakers. While simple in concept, the design and conduct of a PCT is not a small undertaking. It requires strong partnership between research and healthcare systems; collaboration with stakeholders, patients, care partners, and family members; and, the presence of an environment and infrastructure to facilitate study conduct.

The BC Academic Health Science Network (BC AHSN)'s role is to facilitate this; to enable continuous improvement and strategic transformation in BC's health system. Enabling learning health systems in the province, and pragmatic clinical trials within it, is a strategic direction for the BC AHSN.

Figure 1. BC AHSN Organizational Structure

The 2021 Modernization of Clinical Trials conference hosted by Clinical Trials British Columbia, brought together patients, clinicians, researchers, administrators, and policymakers to learn and discuss clinical trial advancement.[1] As part of this event, the BC SUPPORT Unit's Methods Cluster in Real-World Clinical Trials[2] planned and facilitated a 90-minute virtual session allowing dedicated space to discuss challenges, opportunities, and recommendations for future work for advancing pragmatic clinical trials

to support learning health systems within British Columbia. Three areas of focus – learning health systems, clinical trial design, and ethics – were identified as relevant to the advancement of PCTs within BC and framed the session. This document summarizes the themes from the discussion and presents recommendations to guide future work.

Participants

Individuals with experience or work in the respective topics of interest were identified through the BC AHSN networks via the BC SUPPORT Unit Methods Clusters, Research Ethics BC, and Clinical Trials BC. To help ensure diverse perspectives and informed discussions, the Rural Coordination Centre of BC's Partnership Pentagram Plus model further guided the identification of participants.[3] Table 1 highlights the perspectives represented across the discussion groups. Groups were intentionally limited in size (maximum 20) to help support discussion among the group.

Table 1. **Represented perspectives of discussion group participants**

Primary perspective represented	Learning Health Systems N = Attended (Invited)	Clinical Trial Design N = Attended (Invited)	Ethics N = Attended (Invited)	Total
Patients, communities, care partners, community organizations	2 (2)	1 (2)	1 (2)	4 (6)
Clinicians/Health Professionals	1 (4)	2 (2)	1 (3)	4 (9)
Health Administrators	2 (3)	1 (5)	2 (5)	5 (13)
Policy Makers	0 (1)	1 (3)	1 (3)	2 (7)
Academia	6 (9)	6 (7)	1 (3)	13 (19)
Linked Sectors (Industries with interest in health; non-profit organizations)	3 (3)	2 (6)	4 (4)	9 (13)

Invitations to join the discussion were sent two months in advance of the meeting. Two weeks prior to the meeting, participants received background information for the meeting as well as materials on Learning Health Systems and Pragmatic Clinical Trials to support group discussion (Appendix 1).

Session conduct

The virtual session occurred over 90 minutes (Figure 1). It included a brief introduction to frame the overarching goals for discussion: 1) identify enablers and barriers in BC for pragmatic clinical trials in learning health systems; and 2) generate recommendations for future work. Following the introduction, the group divided into 3 concurrent breakout
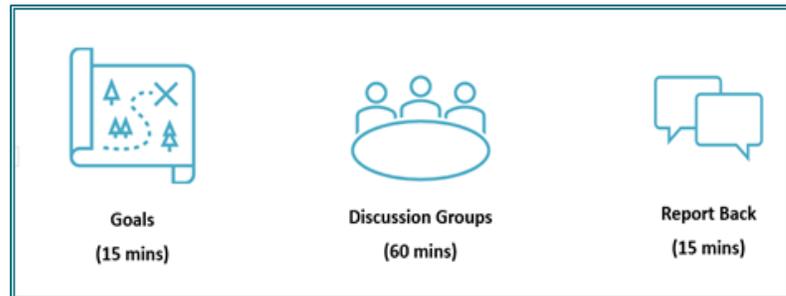

Figure 2. Discussion Group Overview

discussions to address the goals of the meeting grounded by the following topics: learning health systems, clinical trial design, and ethics. Each breakout discussion was co-facilitated by a content expert and member of the BC SUPPORT Unit team. The full group convened at the conclusion to report back themes and recommendations for future work. All sessions were audio recorded and transcribed to support synthesizing the discussion to share back with participants and guide future work.
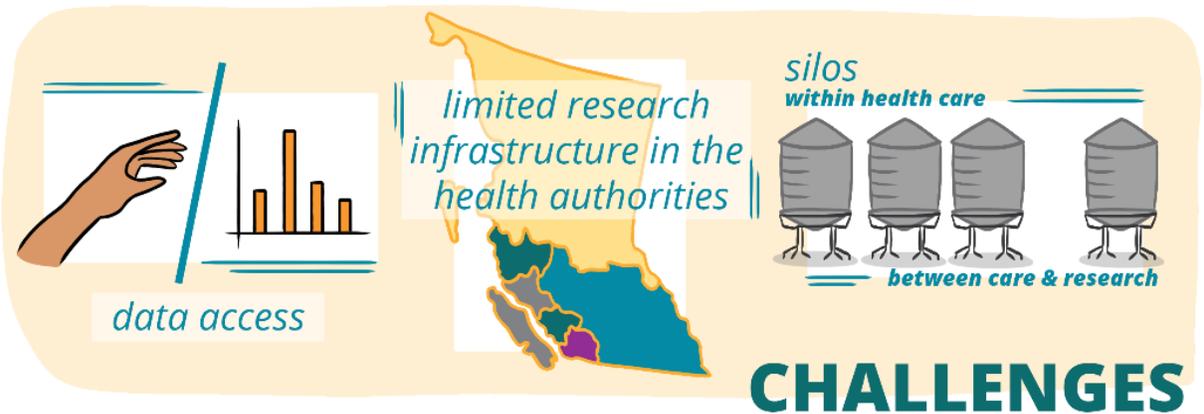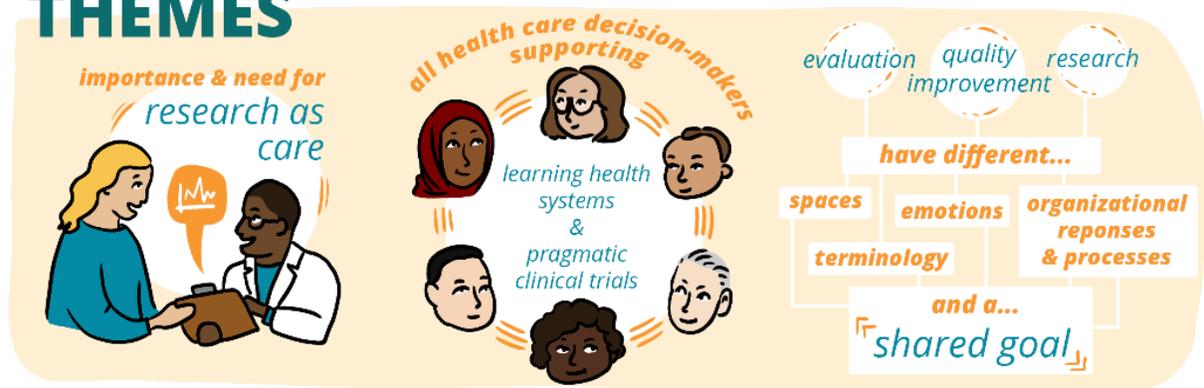
Discussion Overview

Across all discussion groups, similar themes emerged. Themes, described in more detail below, included the importance of and need for shared language; the importance of all healthcare decision-makers (i.e., patients, clinicians, administrators) in supporting the advancement of learning health systems and pragmatic clinical trials; and the recognition that while research, quality improvement, and evaluation have common goals, they live in separate spaces, evoke different emotions/organizational responses, and follow separate processes for conduct. Challenges noted areas such as: data access, limited capacity and infrastructure for the conduct of research within health authorities, and silos that exist both within healthcare and between healthcare delivery and research. Despite challenges raised, each group highlighted the strengths within the province with regards to the collaborative environment and

networks to support clinical trials and patient-oriented research.

THEMES

importance & need for *research as care*

all health care decision-makers supporting

learning health systems & pragmatic clinical trials

evaluation quality improvement research

have different...

spaces emotions organizational reponses & processes

terminology

and a... *shared goal*

data access

limited research infrastructure in the health authorities

silos within health care

between care & research

CHALLENGES

Words divide us. All groups discussed that the different vocabularies used in quality improvement, learning health systems, and research divide us despite similar goals for improving care quality and outcomes. For example, the terminology of 'learning health systems' remains largely isolated within academic spaces in Canada. While strong similarities between the elements of the learning health system framework and elements of quality frameworks for achieving high performing systems are recognized, the different vocabularies create the feeling that something new is being brought to healthcare. These differences further perpetuate the silos in healthcare, preventing collaboration.

Discussions also noted the barriers that accompany research framing and terminology. Research is often perceived to be abstract and uninformed by real world factors. It also remains tainted by the history of harm caused specifically to Indigenous peoples as well as marginalized and racialized communities. Further, research remains viewed by patients, health

> *I think a couple of words can turn off a conversation pretty quickly and they are "research" and "academics".*
>
> *-Clinician researcher*

system administrators, and clinical teams not engaged in academic research as something external to the healthcare system – something that is 'done to' and not 'done with' the goals of healthcare delivery in mind. Moving away from research framing and terminology in learning health systems may better facilitate integration of concepts into healthcare settings.

Recommendations to address language barriers include:

- Co-create a clear and succinct definition and framework for learning health systems and do this in partnership with a diverse range of stakeholders that reflects the BC healthcare environment.
- Ensure plain language is used for all communications.
- Consider how research terminology is referenced to avoid creating barriers to building relationships and trust.
- Work with the Ministry of Health to confirm senior support for learning health systems approaches and recognizes the intersection between research and healthcare.

One goal, two pathways. While quality improvement and research initiatives share a common goal of improving healthcare, the designation of research sets forth a different pathway for conduct. The planning and carrying out of research activities requires formal ethics review approval and oversight to ensure ethical conduct and reduce potential harm to participants. While the Tri-Council policy excludes quality improvement or program evaluation for formal ethics review, it does not mean ethical oversight is not required and is indeed, an obligation by institutions holding Tri-Council funding. In the context of learning health systems, drawing the line between clinical care, improvement and research is sometimes challenging. The blurred lines create great variation between institutions for how ethics review processes are applied at the local levels which leads to confusion and frustration.

Pragmatic clinical trials aim to systematically evaluate and improve care delivery in real-world settings but this approach to embedding research in clinical practice raises important questions. Delineation exists between clinical care, focused on providing direct care to the patient, and research, where the benefit to the patient is more tangential. It is important to recognize that research as part of care is an ask for patients to take part in activities which may not directly benefit them– and, may cause harm. Work is needed to facilitate continuous learning while maintaining transparency with patients, managing conflicts of interest that may exist, and mitigating or managing risks. Creating consistent and transparent processes for ethical oversight while allowing for learning as part of care remains an important area for focus.

Recommendations for future work include:

- Conceptualize an ethical oversight and approval process that mitigates ethical concerns independent of how the project is framed (i.e., quality improvement, research).
- Support efforts to create agreement and consistent approaches to implementing national research ethics guidance and tools.
- Engage patients in creating a culture of "research as care".
- Ensure transparent processes exist for communicating to patients at the outset that knowledge from research activities will be generated with the intent that this knowledge will lead to more effective and efficient care.
- Close the loop with routine reporting back learnings to patients who contribute to research initiatives.

Create a person-centered learning health system. A person-centered learning health system is a tangible aspiration for BC. A noted strength in the province is the foundation and culture for patient involvement in quality improvement and research through leadership of the BC Patient Safety and Quality Council and BC SUPPORT Unit, respectively. Being explicit that the goal is a patient- or person-centric learning health system recognizes the essential role of patients in healthcare as well as the imperative to ensure outcomes support decisions patient face in healthcare. While a strength in BC, considerable work remains in advancing the culture of

> *I think we need to start looking at what shared decision-making looks like in a learning health system, or even in a pragmatic trial. Pragmatic trials help decision makers choose between interventions. Well, I'm a patient, I should be a decision maker, I should be able to choose between my interventions.*
> *- Patient Representative*

patients as partners in healthcare and health research. Continued effort to build capacity for effective collaboration among multistakeholder and interdisciplinary teams is needed. Related to this is advancing a culture for sharing power. Patients, as decision-makers, do not have equal access to information or positions to champion change (or research) which hinders progress.

As person-centered learning health systems are conceptualized, it is important to recognize and address racism in healthcare and research. It is not possible to achieve better outcomes for all as posited by learning health systems if issues around racism and equity are not addressed. Recognition is required that the relationship with Indigenous peoples is distinct because it comes from a history of exploitation

and colonization and a fundamental abuse by the State and by the health system. And we collectively need to earn respect and trust.

Further, deliberate focus to address power dynamics and ensure every single partner is valued and able to contribute equally to decision-making processes is needed. Representation is equally important. This not only includes representation of underserved groups and those that face the most barriers in accessing healthcare in the participation of activities, but also in leading research. The First Nations Health Authority has developed capacity for filtering and prioritizing research as well as principles and criteria for engagement that offers a model to learn from. Finally, it remains imperative that researchers conducting patient-oriented research have the right skills and temperaments to create environments for meaningful engagement and partnership without causing harm.

Recommendations for focus include:

- Engage patients throughout the design and conduct of research activities embedded within healthcare to ensure transparency in informed consent, plain language, and inclusion of outcomes important to patients.
- Create opportunities for patients and the public to identify questions and lead research teams, recognizing the unique perspective that comes with lived experience.
- Ensure meaningful involvement of patients. This includes partnership in research, representation in governance structures, and in visible leadership roles.
- Build capacity for meaningful involvement of patients as partners on research teams – this includes capacity for patient partners, researchers, and healthcare professionals.
- Build capacity and competency among research teams for meaningful engagement without causing harm.
- Ensure research reflects the communities and populations for whom the evidence is generated. Context in healthcare matters and representation from communities reflective of the care environment and population of focus is necessary.

Top-down support needed to facilitate bottom-up leadership. Changing the culture from one that views research activities as separate from goals for achieving high quality care to one that recognizes research as a way of learning to advance patient care is needed. Leadership within government and health authorities need to step forward to advance a culture that promotes learning health systems, research and pragmatic clinical trials. Presently, research is not a strong element within the mandate to

Health Authorities from the Ministry of Health. As a result, research is not recognized as a core function of healthcare systems or the responsibility of those individuals who serve to advance patient care. And so, research infrastructure and capacity are not recognized as essential elements of the system. Despite this, it is acknowledged that legitimate uncertainties exist in how healthcare is delivered and learning from data generated as part of care can address the questions that patients and clinicians have and better guide decisions. Strategies recommended to facilitate the process include the following:

- Advocate for government-directed mandates recognizing the role research could play in Health Authorities and the need to support and sustain infrastructure and capacity.
- Support a culture in healthcare that encourages curiosity/critical thinking and integrates research into day-to-day operations.
- Recognize and reconcile the divergence across health authorities that exists in capacity to take on health research due to limitations in available resources.
- Establish key roles and resources deemed as important for conducting health systems research (e.g., clinical trials nurses, research coordinator roles, etc.) that are prioritized and recognized by the health authority as a component of delivering excellent patient care.

Data access is critical.

Compared to other jurisdictions and other provinces in Canada, data is deemed as a strength in BC but tempered by its inaccessibility for research or initiatives that span institutions or health sectors. If you need data for patient care, it is available at the point of care. For research

And in fact, data should not be owned but rather should be managed and used appropriately to benefit the common goal.
-Researcher

initiatives it becomes harder to access even if the goals are aimed to improve health. Layered to issues regarding access is the need to recognize and respect principles around Indigenous health data. This includes First Nations principles of ownership, control, access, and possession (OCAP®). With regards to concepts of pragmatic clinical trials, seamless data access is important and a barrier that needs resolution. From a patient view, frustration exists regarding data access. Patients do not have access to their own data, making management of their own care and learning from it challenging. Recommendations related to data access include:

- Learn, respect, and abide by the principles around ownership, control, access, and possession (OCAP®) principles.

- Create efficient pathways for accessing data that support learning as part of healthcare.
- Create standard processes for how privacy laws are interpreted and applied.
- Address the culture of risk aversion that leads to barriers to data.

Conclusion

An opportunity exists for advancing learning health system concepts as a way to build a culture of "research as care". Pragmatic clinical trials, when embedded alongside care delivery, provide one way forward for bridging healthcare and research. Notably, pragmatic clinical trials offer the ability to apply rigorous research methods as well as support decision-makers in understanding how evidence applies in real-world settings. Work remains to ensure research questions identified and prioritized for study are driven by decision-makers, inclusive of patients, clinicians, and healthcare administrators. Future success requires continued efforts to break down silos between communities, healthcare systems, and research entities.

Acknowledgements

We would like to acknowledge the individuals who participated in discussion groups that informed this summary. These include (list not exhaustive):

First Name	Last Name	Affiliation
Kim	McGrail	*Professor, UBC School of Population and Public Health & Centre for Health Services and Policy Research; Director of Research, UBC Health, Scientific Director of Population Data BC & Health Data Research Network Canada*
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Nelly	Oelke	*Associate Professor* *School of Nursing* *Faculty of Health and Social Development* *University of British Columbia, Okanagan*
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Colleen	McGavin	*Patient Engagement Lead, BC SUPPORT Unit*
Quyhn	Doan	*Associate Professor, Clinician Scientist, Division of Pediatric Emergency Medicine, Department of Pediatrics, UBC* *Clinical Research Director, BC Children's Hospital Research Institute*
Joel	Singer	*Professor, UBC School of Population and Public Health; Program Head, Clinical trials, Centre for Health Evaluation & Outcomes Sciences*
Terri	Fleming	*Director, Research Ethics BC*
Alison	Orth	*Director, Clinical Trials BC*
Lindsay	Hedden	*Assistant Scientific Director, BC Academic Health Science Network*
Manik	Saini	*Director, Centre for Health Evaluation & Outcomes Sciences*
Victoria	Schuckel	*Executive Director of research, knowledge translation & library services, BC Ministry of Health*

Srinivas	Murthy	*Clinical Associate Professor, Department of Pediatrics, Faculty of Medicine, University of British Columbia*
Hubert	Wong	*Associate Professor, UBC School of Population & Public Health*
		Associate Head, Methodology & Statistics, CIHR Canadian HIV Trials Network
		Program Head, Biostatistics, UBC Centre for Health Evaluation & Outcomes Sciences
Amber	Hui	*Knowledge Translation Specialist, BC SUPPORT Unit*
Stirling	Bryan	*President, BC Academic Health Science Network*

References

1. Clinical Trials BC. (2020) *The Modernization of Clinical Trials Conference: January 26-28, 2021*. Vancouver, BC, Canada. Retrieved April 20, 2021 from: http://www.clinicaltrialsbc.ca/conference/.

2. BC SUPPORT Unit. (2020) *Real-World Clinical Trials*. Vancouver, BC, Canada. Retrieved April 20, 2021 from: https://bcsupportunit.ca/about/methods-clusters/real-world-clinical-trials.

3. Rural Coordination Centre of BC. (2021) *How we work*. Vancouver, BC, Canada. Retrieved April 20, 2021 from: https://rccbc.ca/rccbc/about-rccbc/how-we-work/.

Appendix 1

Pre-meeting outreach sent to confirmed and tentative participants

All,

You are receiving this email as you are confirmed or tentative for the **Learning Health Systems and Pragmatic Clinical Trials Breakout Discussion** scheduled **1-2:30p** on **Wednesday, Jan 27th 2021** (part of [Clinical Trial BC's Modernization of Clinical Trials Conference](#)).

Meeting details

You will be joining approximately 50 invited guests representing key stakeholder perspectives from across the province to inform the provincial agenda for pragmatic trials in BC. Following a short introduction, we will breakout into 3 moderated discussion groups focused on the following topics – 1) Clinical Trial Design and Analysis; 2) Ethics; and, 3) Learning Health Systems. **Your grouping has been pre-assigned to one of these three groups.**

Each group will discuss:

- Opportunities and challenges for advancing pragmatic clinical trials to advance patient care and care quality
  AND
- Key recommendations for future work.

As the modernization of clinical trials advances in BC, we see this as an important starting conversation for future work.

Logistics

To join the meeting: Access is through the virtual conference host platform *OnAir*. All registrants should have received an email from the email address ctbc2021@venuewest.com on January 21. These are your individualized links to access the meeting; thus I am not able to include a direct link in the meeting invite. I will update the calendar appointment with this information as reference. **If you do not have this information please contact the OnAir platform organizers at congress@venuewest.com. You will not otherwise be able to access the meeting.**

Background materials:

For those able to join the morning portion of the conference, you will hear a primer of Learning Health Systems and Pragmatic Clinical Trials from 9-10a, as well as a series of case examples from 10-11a.

For those of you unable to attend or interested in additional context, I am linking to a few background materials.

June 16, 2021

TOPIC	MEDIA	LENGTH	LINK
What are Pragmatic Clinical Trials? Context-setting for what pragmatic clinical trials are and why they are of interest.	Video	4 min	https://rethinkingclinicaltrials.org/training-resources/living-textbook-video-modules/what-are-pragmatic-clinical-trials-living-textbook-video-module/
Commentary on how embedded research pertains to Learning Health Systems. While the focus is not solely on pragmatic clinical trials, it addresses a number of points for discussion.	Journal article	6 pages	Attached to email (Reid2016.pdf)
What are Learning Health Systems? An interview with Charles Friedman about what learning health systems are and how they support healthcare transformation.	Podcast	32 min	https://soundcloud.com/patientengagement/episode-1-learning-health-systems-with-dr-charles-friedman
A framework for Learning Health Systems: provides a more in-depth overview of Learning Health Systems in a Canadian context.	Journal article	13 pages	Attached to email (Menear2019.pdf)

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