

# Examining the CONCOR-1 Rollout in British Columbia to Inform Improvements to Clinical Trial Implementation During Pandemics



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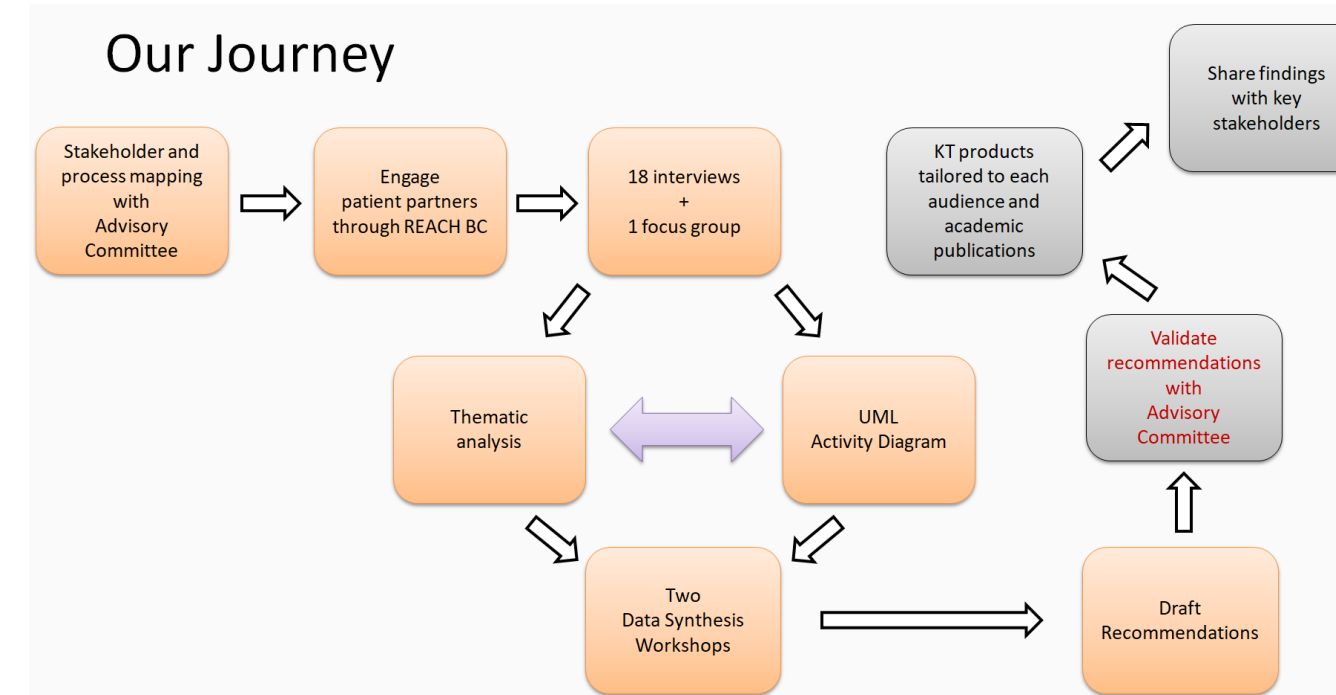
## Background

- CONCOR-1 was a multicentre randomized control trial assessing the therapeutic potential of COVID-19 convalescent plasma (CCP) in 72 sites, including 4 sites in British Columbia (BC)
- Reflecting on its implementation in BC, may guide planning for therapeutic trials during pandemics

## Objectives

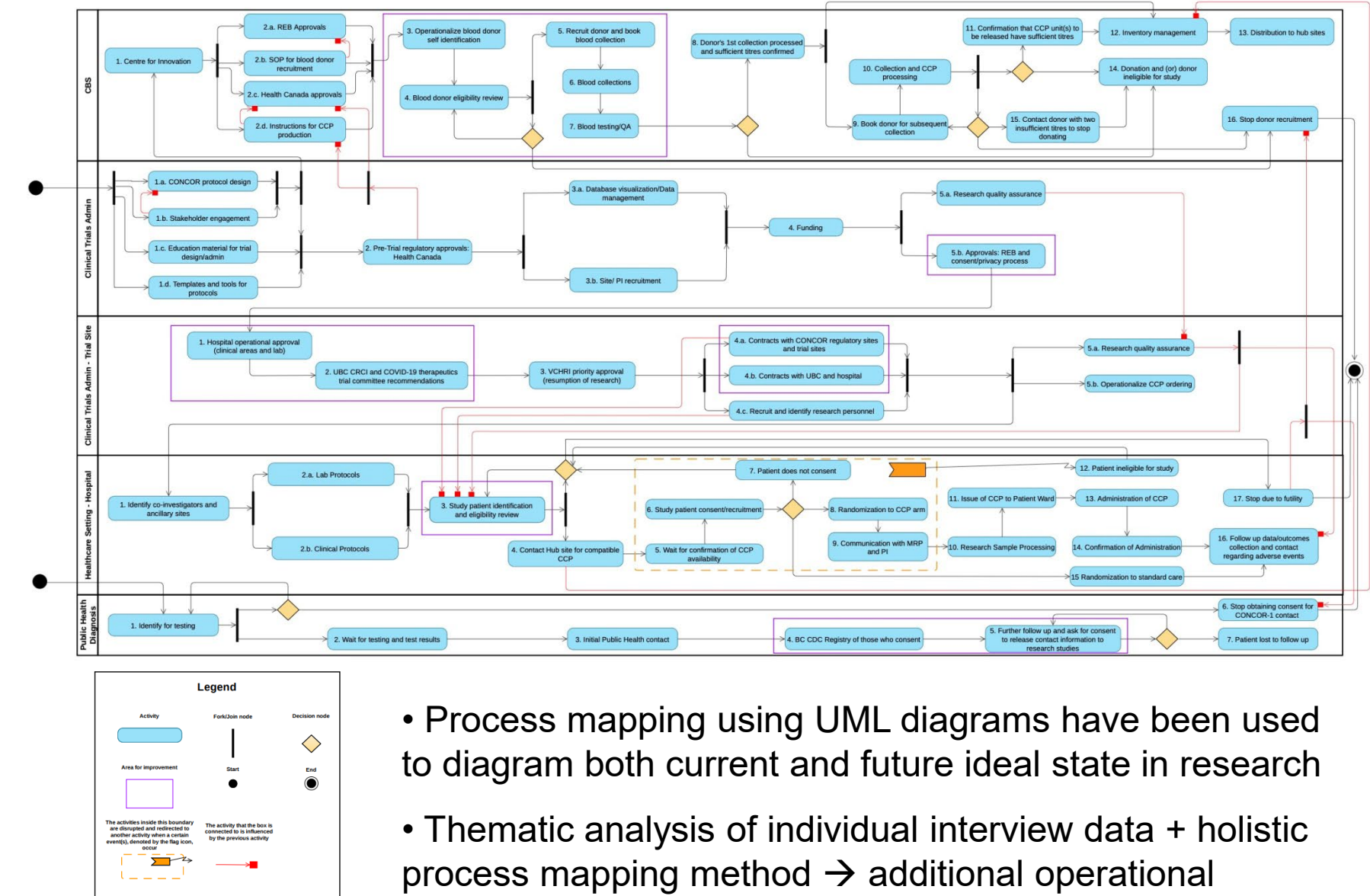
- The main objectives were to:
  1. Create a process map for the delivery of CCP from donor to bedside
  2. Derive themes from identifying their facilitators and barriers, from qualitative analyses of semi-structured interviews of key stakeholders
  3. Produce knowledge translation (KT) outputs to disseminate learnings

## Methods



- The process map was visualized using a Unified Modeling Language (UML) activity diagram, used often in operational research
- Key stakeholder groups included: Canadian Blood Services (CBS), clinical trials administration, hospital/community care settings, public health, universities, and patient partners → identified interview subjects with guidance from advisory committee
- Thematic analysis of interviews done via Nvivo, with two independent investigators and discrepancies resolved by consensus

## Results: Process Mapping



- Process mapping using UML diagrams have been used to diagram both current and future ideal state in research
- Thematic analysis of individual interview data + holistic process mapping method → additional operational observations that may be optimized

## Results: Draft Recommendations from Thematic Analysis of Emergent Themes

Emergent Theme: Treatment and Trial Equity	Emergent Theme: Formal and Informal Collaborations	Emergent Theme: Pandemic Preparedness Planning	Emergent Theme: Patient and Donor Recruitment
<p><b>Indigenous communities</b> – Prioritize a strategy for relationship building to facilitate clinical trial participation</p> <p><b>Equity</b> – Address inequity in clinical trial participation, improving access to potentially life-saving therapies and representation of marginalized groups in the data.</p> <p><b>Community transfusions</b> – Build capacity for transfusions and transfusion research in community settings</p> <p><b>Research capacity</b> – Expand research capacity through building permanent research infrastructure and roles—by framing research as part of health care</p> <p><b>Physician engagement</b> -- Engage physicians to increase awareness of the importance of clinical trials and patient participation in trials.</p> <p><b>Addressing burnout</b> – Establish mental health policies and resources to reduce physician and care provider burnout and maintain health care and research capacity</p>	<p><b>Research networks</b> – Build on the formal and informal collaboration networks created to create a superior communication web, standing committees and an expanded research network, connected nationally</p> <p><b>Linkages to public health (and other organizations)</b> – Create (a) research lead role(s) within organizations to facilitate research collaborations among stakeholders</p> <p><b>Patient partners</b> – Prioritize engagement and compensation of patient partners on trials</p> <p><b>Data coordination</b> – Improve coordination of data among participating partners for greater cohesion and study feasibility.</p> <p><b>Communication infrastructure</b> – Create infrastructure, such as standing committees, websites, Slack channels, and designated email accounts to allow for two-way communication between experts, those implementing expertise, and patients</p>	<p><b>Ethics and data sharing</b> – Establish and communicate centralized “once and done” agreements and transparent requirements</p> <p><b>Community strategies</b> – Explore potential for innovative strategies, such as transfusions in community settings and consider approaches to linking delivery of therapies like vaccines</p> <p><b>Templates and guides</b> – Create clinical trial protocol templates, data management systems and other tools for trials of new therapeutics in pandemics, assessing experience from studies implemented during COVID-19 and other pandemics</p> <p><b>Skeletal trial protocols</b> -- Prepare protocols for assessing convalescent plasma for new pathogens, considering lessons from COVID-19 and CONCOR-1</p> <p><b>Pandemic Preparedness Plan</b> – Develop sections for clinical trial implementation in pandemic preparedness plans for early access to novel therapies</p>	<p><b>Privacy and confidentiality</b> – Explore solutions to address privacy and confidentiality as a major barrier to donor/patient recruitment</p> <p><b>Patient hesitancy</b> -- Create spaces and mechanisms that build trust and addresses participation hesitancy</p> <p><b>Patient partners</b> – Continue to prioritize patient feedback at <u>all</u> stages of research</p> <p><b>Promoting research</b> -- Expand awareness of research through endorsements.</p> <p><b>Research coordinators</b> – Increase the deployment and integration of research coordinators to reduce physician workload and streamline recruitment and conducting clinical trials</p> <p><b>Interdisciplinary collaboration</b> – Promote collaboration with family practitioners, public health, and the general public to raise awareness of the importance of clinical trials and facilitate patient recruitment</p>

## Conclusion and Next Steps

- We are continuing to validate recommendations from data synthesis workshops with advisory committee review, including findings from stakeholders in community and Indigenous settings
- In BC, our research group was invited to provide input in the BC Ministry of Health Rapid Visioning for Clinical Trials process
- We acknowledge that our findings may not be generalizable to other jurisdictions or settings
- KT outputs being considered include: a summary aimed towards transfusion and academic stakeholders, infographics of recommendations, scientific publications, pandemic plan revisions, and a call-to-action proposal for remote/Indigenous communities of care to benefit from therapeutic trials

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