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

Emergent Theme: Treatment and Trial Equity

Indigenous communities – Prioritize a strategy for relationship building to facilitate clinical trial participation
Equity – Address inequity in clinical trial participation, improving access to potentially life-saving therapies and representation of marginalized groups in the data.

Emergent Theme: Formal and Informal Collaborations

Research networks – Build capacity for transferences and transference research in community settings
Research capacity – Expand research capacity through building permanent research infrastructure and roles—by framing research as part of health care

Emergent Theme: Pandemic Preparedness Planning

Ethics and data sharing – Establish and communicate centralized “once and done” agreements and transparent requirements
Community strategies – Explore potential for innovative strategies, such as transfusions in community settings and consider approaches to linking delivery of therapies like vaccines

Emergent Theme: Patient and Donor Recruitment

Privacy and confidentiality – Explore solutions to address privacy and confidentiality as a major barrier to donor/patient recruitment
Patient hesitancy – Create spaces and mechanisms that build trust and addresses participation hesitancy

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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