Adaptive Platform Trial Scientific Meeting

September 28 – 29 • Toronto, Canada

CanTreatCOVID

Canadian Adaptive Platform Trial of Treatments for COVID in Community Settings

“This is our chance to get results fast”:

Moral experiences of clinician-investigators and staff involved in adaptive trials during the first wave of the COVID pandemic

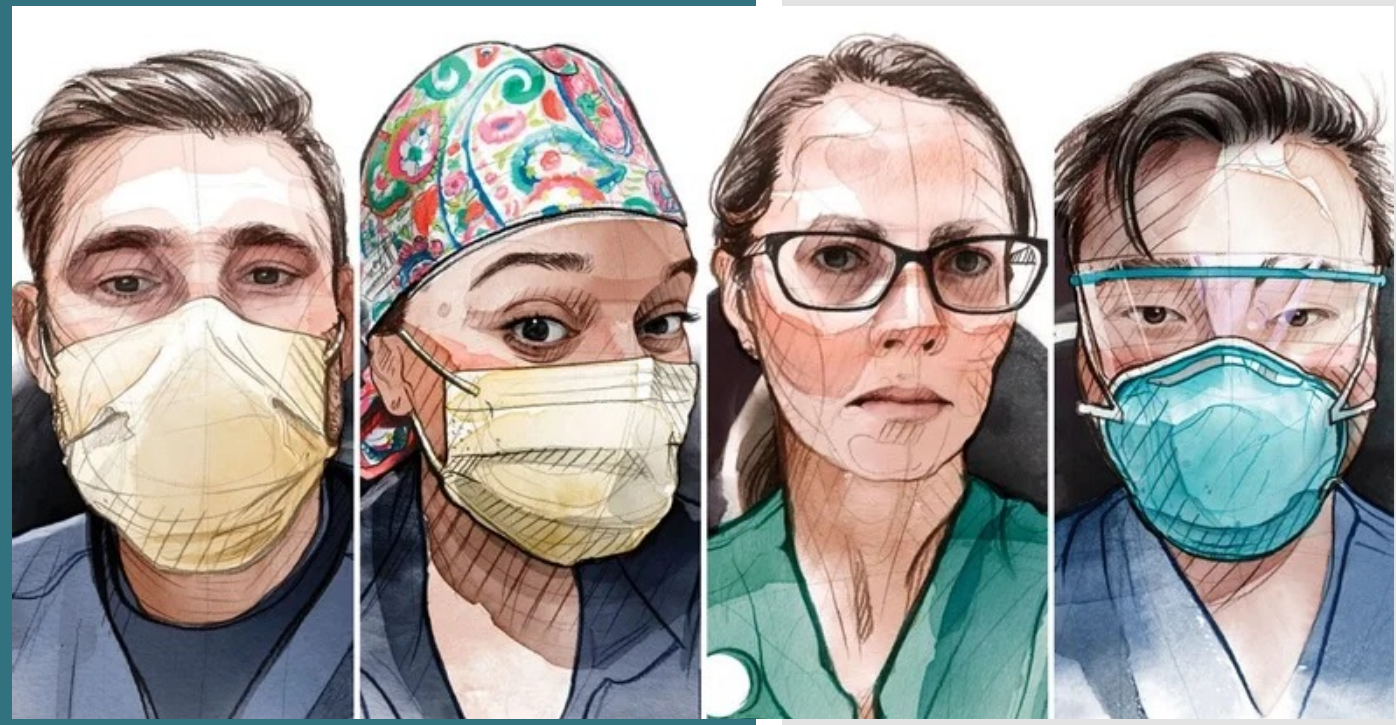


Image source: https://www.scientificamerican.com/interactive/grief-on-the-front-line-and-beyond/

Presenter: Rachel Yantzi, RN, MSN/MPH, PhD (c)

Co-authors: Matthew Hunt, Sandra Moll, Olive Wahoush, Takhliq Amir, Eliza Yadav, and Lisa Schwartz

McGill | M[i]4 Interdisciplinary Initiative in Infection and Immunity

McMaster University | DEPARTMENT OF HEI Health Research Methodology

This project was funded by the McGill Interdisciplinary Initiative in Infection and Immunity COVID-19 Emergency Fund and the McMaster COVID-19 Research Fund

Research ethics approval was granted by the Hamilton Integrated Research Ethics Board and the McGill University Faculty of Medicine Institutional Review Board

Background

- Critical role of research during emerging pathogen pandemics
- Rapid increase in number of COVID studies
- Potential tension between research, clinical, and public health priorities
- Experience of West African Ebola outbreak
- Complex methodology of adaptive trials and adaptive platform trials

Study Aim

- To understand the moral experiences of health and research personnel with the production and utilization of COVID-19 evidence during the first wave of the pandemic, including their experiences with adaptive and adaptive platform trials.

Methods

- Interpretive Description (Thorne, 2016)

26 Total participants

10 Participants involved in an adaptive trial

9 Participants involved in an adaptive platform trial

Role	Number of participants
Regional lead	2
Local principal investigator/ clinical care of COVID patients	6
Research coordinator	1
Research/clinical pharmacist	1

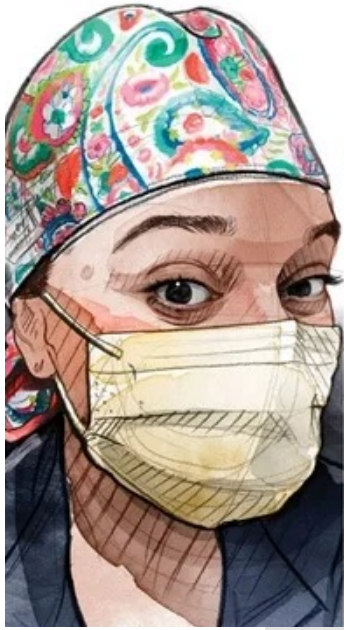
Country	Number of participants
Canada	8
USA	1
Eastern Europe	1

Findings

Adaptive trials as something we can offer our patients

- “Because of the paucity of data, we said that really no therapeutic intervention should be undertaken outside of a clinical trial. And so I think it's my ethical obligation to then provide a trial because I can't tell clinicians and patients that they can't have these therapeutics without also providing a trial for them”

  -Clinician-investigator/LPI, Canada (P-15)



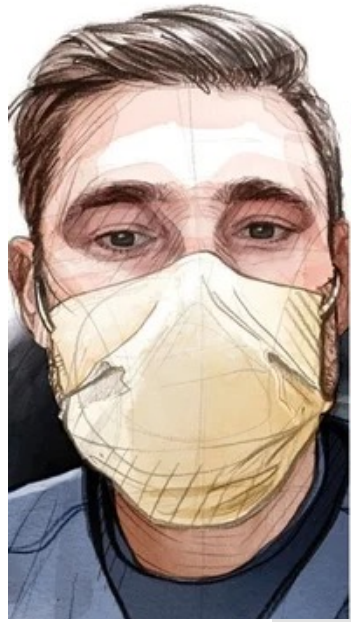
Findings

Adaptive trials as translatable to practice

- "When I did the [adaptive platform trial], I have to say that it's put me at peace a little bit with randomized controlled trials because it does feel closer to real clinical life"

- "The adaptive trial, I find, is an amazing thing because it's pragmatic, because it reflects what we always do in clinical care"

-Clinician-investigator/LPI, Canada (P-12)



Findings

Concerns about consent and information overload

- “And so, it's how to navigate [the consent process] to not cause burden to families, especially since they've never seen their family member, right? They dropped them off at the ER and, and that's it”

-Research Coordinator, Canada (P-22)

- “One of the big ethical challenges is, as we have multiple different interventions, REBs want us to enumerate all of the side effects associated with all the interventions so our consent form is over 20 pages right now, which really is not a consent form. There’s no way someone can read it realistically.”

-Regional Lead (P-23)

Findings

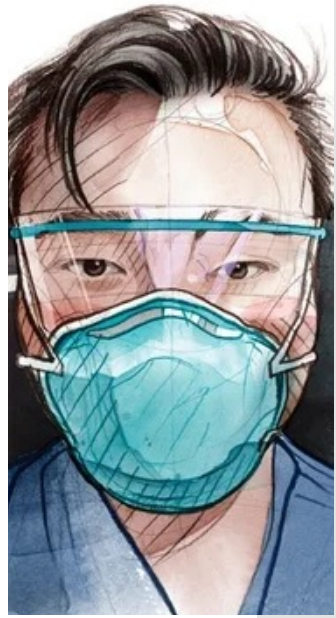
Risks and workload realities

- “They’re calling these studies adaptive design so they’re all of a sudden changing arms to apply these to new agents and interventions. So basically, I’m rebuilding these studies again under the same name… there’s not always an appreciation of the workload that that requires”

  -Research/clinical pharmacist, Canada (P-24)

- “You’re working 12 or 14 hours in the hospital and you're retaining thousands of emails and everyone wants to do the research, but it was put on the same people”

  -Clinician-investigator, Eastern Europe (P-14)



Discussion & conclusions

- Research as something we can offer patients
- Potential to expand access to research during a pandemic
- Questions for consideration

Thank you to our funders and the busy health professionals and researchers who took the time to speak to us early in the COVID pandemic

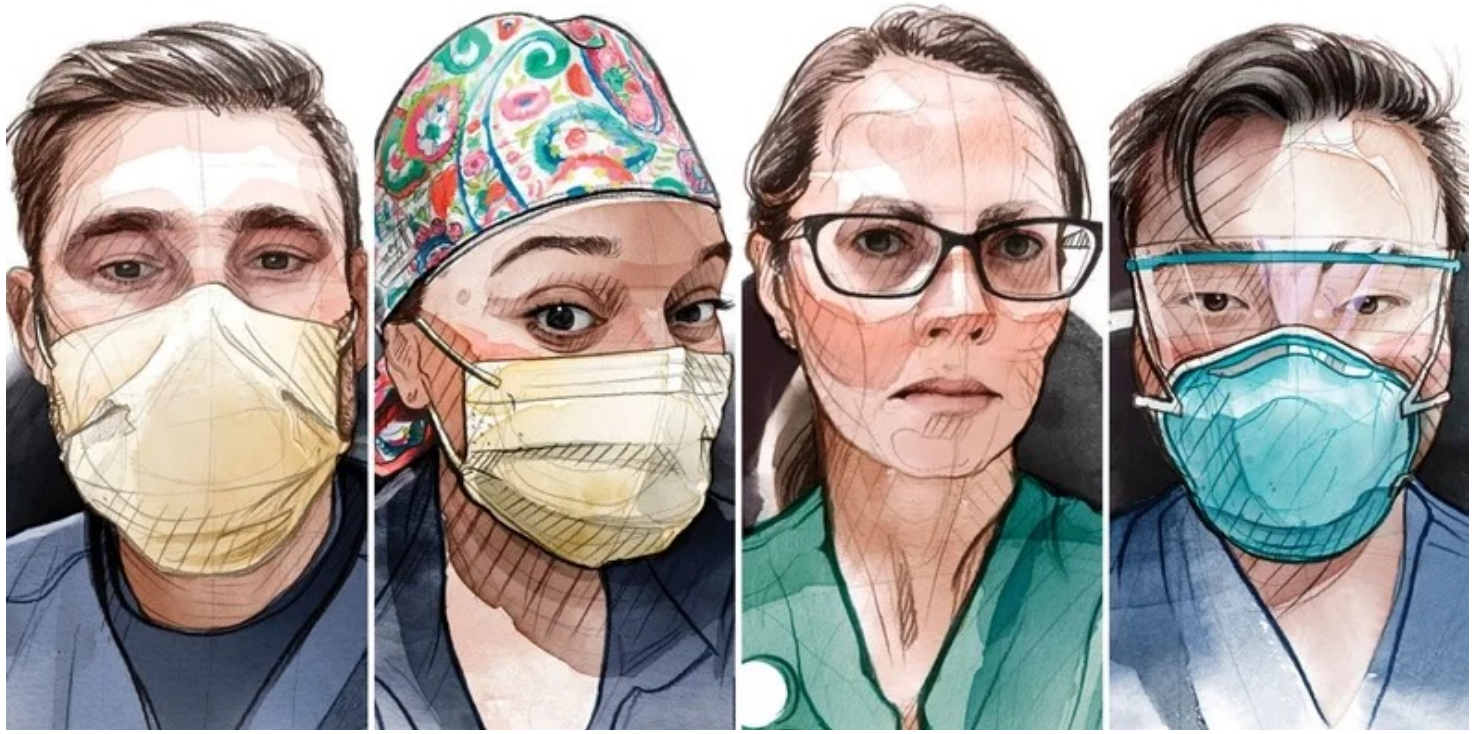


Image source: https://www.scientificamerican.com/interactive/grief-on-the-front-line-and-beyond/