COVID-19 Reiterates the Critical Need for Clinical Trials Transparency: A Call to Action at McGill

WHY CLINICAL TRIAL TRANSPARENCY MATTERS

1 THE PUBLICATION BIAS

Positive results are more likely to be reported in journals and registries. Medical professionals advise patients based on this data. If negative results aren't reported, patients can't make informed healthcare decisions.

2 UNECESSARY DUPLICATION

Besides the waste of resources, unnecessary duplication endangers patients. If a trial for a harmful treatment isn't reported, more patients might unknowingly consent to the treatment. This has happened before.

3 GLOBAL KNOWLEDGE SYNTHESIS

Registries are shown to be better sources of safety data and give researchers an overview of the evidence for or against a treatment. Higher reporting rates mean shorter roads to effective treatments.

4 ACCESS TO RARE TREATMENTS

For many rare and understudied diseases, publicly accessible clinical trial registries are the main way to find novel tratements.

5 OBLIGATION TO PATIENTS

When subjects register for clinical trials, it's under the assumption that their participation may eventually help others receive safe, effective treatment. If results aren't reported, there's no chance of this.

6 CHANGE WITHIN REACH

Pharmaceutical companies have consistently higher reporting rates than academic institutions. European universities and law makers have embraced the importance of health data transparency, significantly raising their rates. UAEM campaigns in the US have sparked retroactive trial reporting at leading universities. It's time for Canada to join the movement.

7 PUBLIC FUNDING DESERVES PUBLIC RESULTS

In Canada, over $37.2 million in public funding has been awarded to universities for work on a COVID-19 vaccine. Over $30.8 million has been allocated for research on COVID-19 therapeutics and over $10.5 million for diagnostics. Our taxes fund this research. The results shouldn't be hidden behind paywalls or worse, not published at all. (Data reported in UAEM COVID-19 Public Investment Mapping Tool)

7 EARN PUBLIC TRUST

Under COVID-19, we've seed unprecedented R&D timelines, politicization of science, and a rise in vaccine hesitancy. To gain public (and expert) trust, we need full transparency regarding COVID-19 data.

UAEM
UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES

COVID19 VACCINE TRACKER

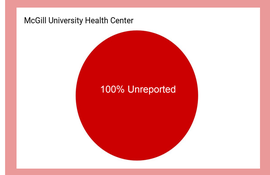
McGill University professor Nicole Basta and her team have created an interactive online COVID-19 vaccine tracker, that provides real-time updates on progress in developing a safe and effective vaccine. Find it here: https://covid19.trackvaccines.org

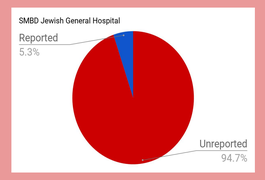
WHY HAS COVID NECESSITATED THE NEED FOR GREATER CLINICAL TRIAL TRANSPARENCY?

Calls for greater transparency in COVID-19 vaccine trials have **underscored** a variety of concerns over the past several months.

- THE NEED FOR DEVELOPERS TO SHARE THEIR TRIAL PROTOCOLS PUBLICLY
- THE NEED TO INCREASE RECRUITMENT OF PARTICIPANTS WHO ARE PART OF GROUPS MOST IMPACTED BY THE PANDEMIC
- THE NEED TO ENSURE TRANSPARENCY THROUGHOUT THE APPROVAL PROCESS
- THE NEED TO END THE CONCENTRATION OF RESOURCES AND TRIAL SITES IN HIGH-INCOME COUNTRIES

Dismal reporting rates at McGill affiliated hospitals





Rates represent trials completed after October 2018 (aligning with the 2 year grace period allowed in the US) which have been preregistered in clinicaltrials.gov and have not published results in a journal or on clinicaltrials.gov.

This likely represents a small fraction of McGill-affiliated trials since many trials are not pre-registered. Lists of all publicly funded trials are not easily accessible.

While other registries exist, clinicaltrials.gov is widely used in Canada.

Even with publication of results in a registry or journal, quality and accessibility of results is another question entirely.

COVID-19 AS LEVERAGE

"Amid a wave of research into potential Covid-19 therapies, a new analysis warns that some trials are being run by universities and companies in Europe that either have no track record filing any trial results with a European database or have failed to do so in the past. As a result, there is a risk that past performance might undermine the ongoing search for safe and effective treatments, according to the advocacy group that conducted the analysis.

Specifically, two-thirds of the 118 Covid-19 trials analyzed in June were run by universities and companies that have no record of uploading clinical study results to the European Union Drug Regulating Authorities Clinical Trials Database, or EudraCT, which trial sponsors are required to do so under EU rules. Of these, 39 trials are being run by sponsors that, in the past, violated requirements to upload results." -Ed Silverman

With clinical trials transparency suddenly in the spotlight, COVID-19 presents an opportunity to raise awareness, assess barriers, and allocate resources to ensure that ALL trials are preregistered and all results are reported. Scientsists may need additional support including funding, training, and updated reporting guidelines. *Given the spending on R&D and IP, universities and funders have no excuse not to answer this call.*

EXPERTS SPEAKING OUT

Challenges for the COVID-19 Vaccine Tracker: *"In developing the site, we encountered a significant need for improved clinical trial reporting"*

- Nicole Basta, Associate Professor in the McGill Faculty of Medicine

On transparency in the pandemic: *"The fact is, most physicians are not trained to recognize good science from bad. Nor do they have the time to analyze every study, and too many are willing to ignore the need for reliable evidence when fear sets in. Even in non-pandemic times, doctors often favor treatments that have long been in use, seem biologically plausible, are highly remunerative, or have been heavily marketed by manufacturers."* -Jeanne Lezer and Shannon Brownlee

On biased sampling in existing trials: "*A vaccine that has been proved to reduce the risk of symptomatic disease by a certain proportion should, you might think, reduce serious outcomes such as hospital admissions and deaths in equal proportion...But when vaccines are not equally effective in all populations the theory breaks down.....*

This is hard to evaluate in the current trials because there are large gaps in the types of people being enrolled in the phase III trials."

- Peter Doshi, who has been pursuing the public release of vaccine trial protocols, and co-signed an open letter to the FDA calling for independence and transparency in covid-19 vaccine related decision making.

CASE STUDY: Reboxetine

Pfizer marketed Reboxetine as a new treatment for clinical depression. They published one study which showed 65.4% efficacy compared to placebo. Doctors prescribed the drug. It was later revealed that Pfizer didn't report data from 74% of their patients. Overall, Reboxetine had 11.2% efficacy and produced more adverse effects than placebo.

CASE STUDY: Chloroquine and Hydroxychloroquine

Just 52 trials (33%) meet the highest design standard (randomized, masked, and placebo controlled).

- the Oxford COVID-19 Evidence Service Team Centre for Evidence-Based Medicine, Nuffield, the Department of Primary Care Health Sciences at the University of Oxford

PROGRESS IN THE WORKS

GLOBAL LEADERS ADVOCATING FOR TRANSPARENCY: COCHRANE LETTER TO THE EMA

FREE THE VACCINE CAMPAIGN ADVOCATING FOR OPEN COVID PLEDGE AND WHO C-TAP

YOU DISCOVER WAYS TO ADVOCATE FOR TRIALS TRANSPARENCY AT ANY LEVEL

SCAN ME

TBOM CANADA PRESSURES CANADIAN GOVERNMENT TO ADOPT OPEN SCIENCE PRINCIPLES

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