



# Alberta HOPE Covid-19 Trial

Luanne Metz, MD FRCPC

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# Covid19– the lack of good information

- Covid19 and the SARS-Cov2 virus
- Massive amount of disinformation out there
- Our goal is to bring high quality information to bear on the problem of a potential treatment with hydroxychloroquine for Covid19 infection

## Trump suggests sunlight and disinfectant injections could cure coronavirus

Some scientists point to the spread of virus in warm countries to disprove the claim, while others warn of dangers of ingesting cleaning materials

By AGENCIES and TOI STAFF  
24 April 2020, 11:14 am



US President Donald Trump speaks about the coronavirus in the James Brady Press Briefing Room of the White House, April 23, 2020, in Washington. (AP Photo/Alex Brandon)

The White House is pitching “emerging” research on the benefits of sunlight and humidity in diminishing the threat of the coronavirus as US President Donald Trump encourages states to move to reopen their economies.

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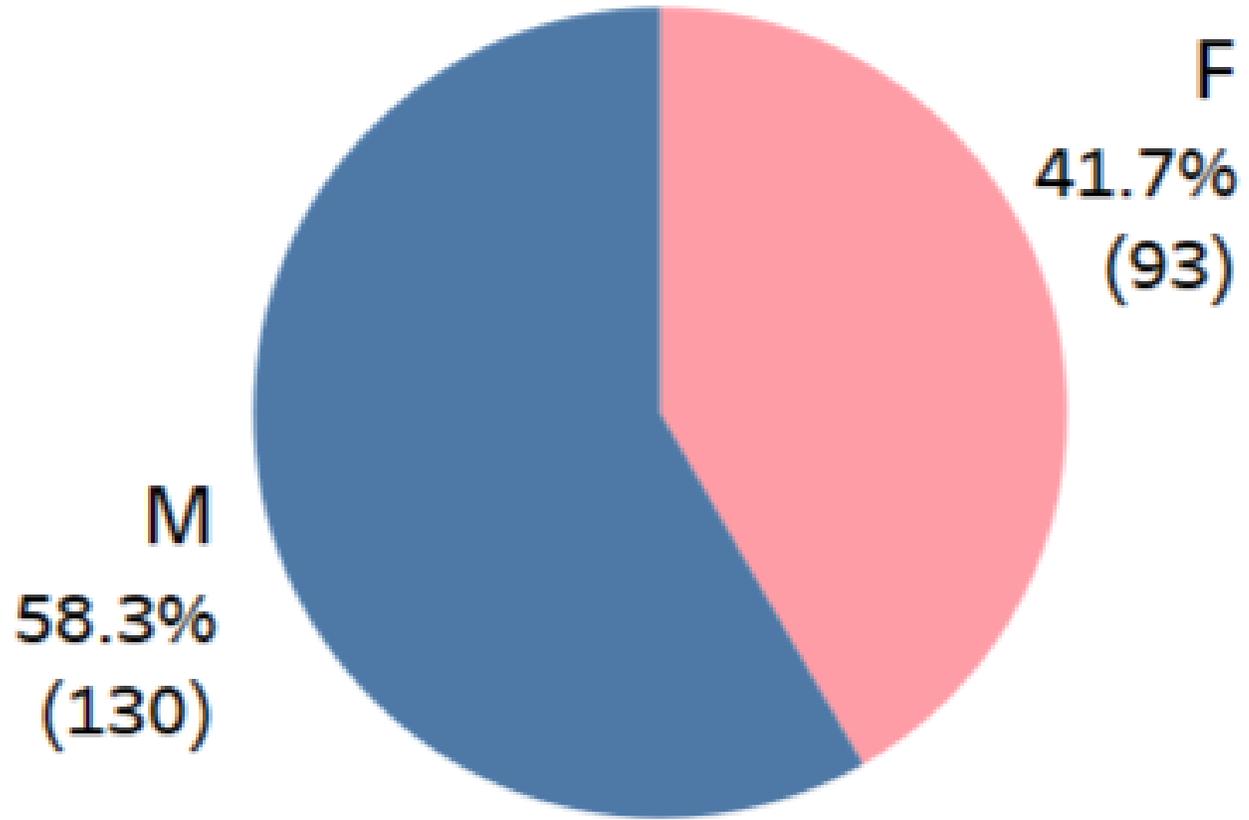
# COVID-19 Numbers – as of May 20

- Cases: 6,735
  - First case March 5th
- Deaths: 128 (32 deaths occurred in hospital)
- Hospitalizations:
  - Total: 325 (5%) – 223/325 *were in Calgary*
  - Ever in ICU: 67 (1%) – 20% of people who are hospitalized – 47/67 *were in Calgary*
  - Current: 58 (7 in ICU) –
  - Peak was Apr 29-May 6 when the daily number of people in hospital was about 74; we are now at about 75% of the peak
- Proportion who have been hospitalized or die has been about 6.5%

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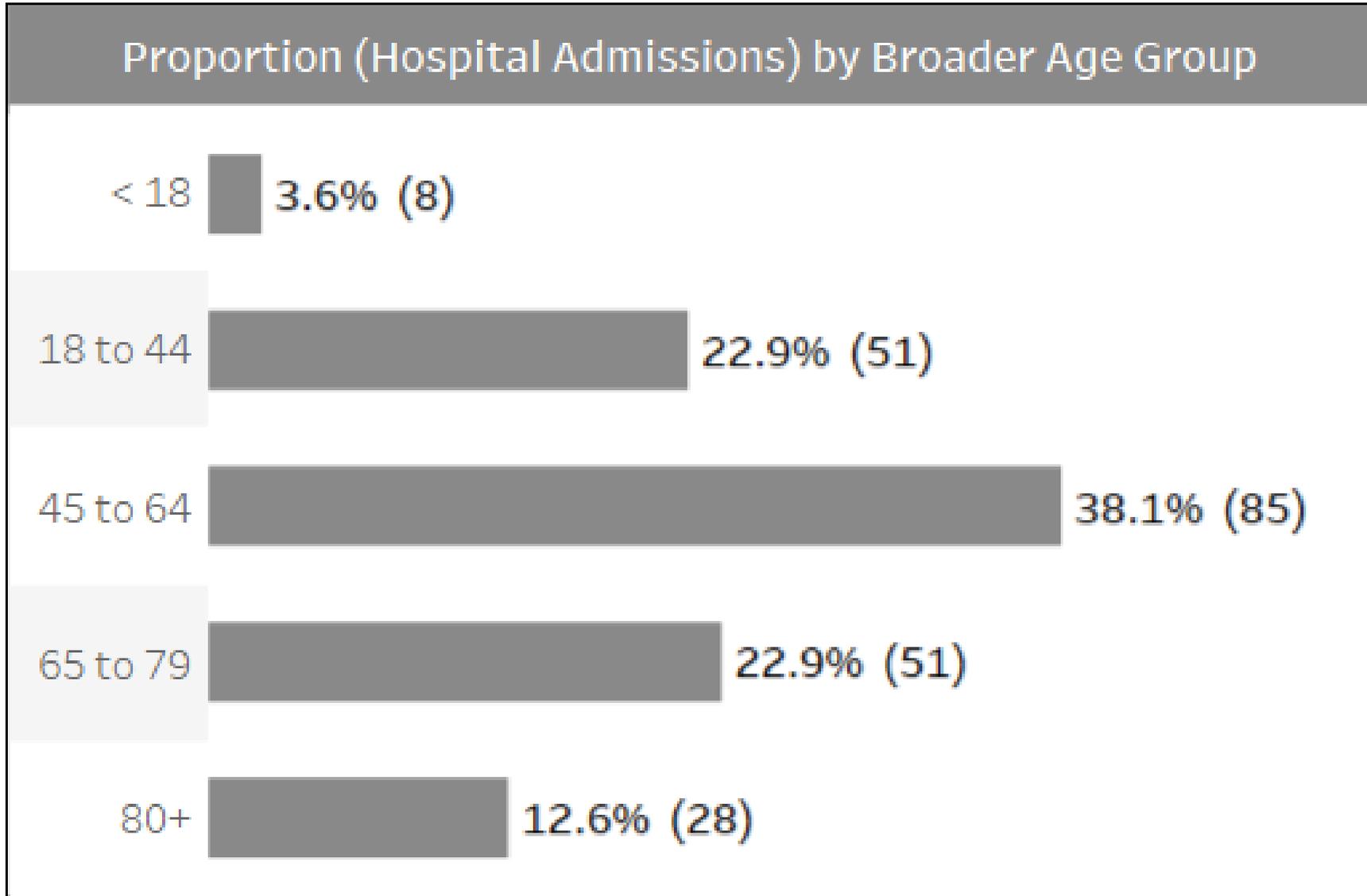


## Proportion (Hospital Admissions) by Gender

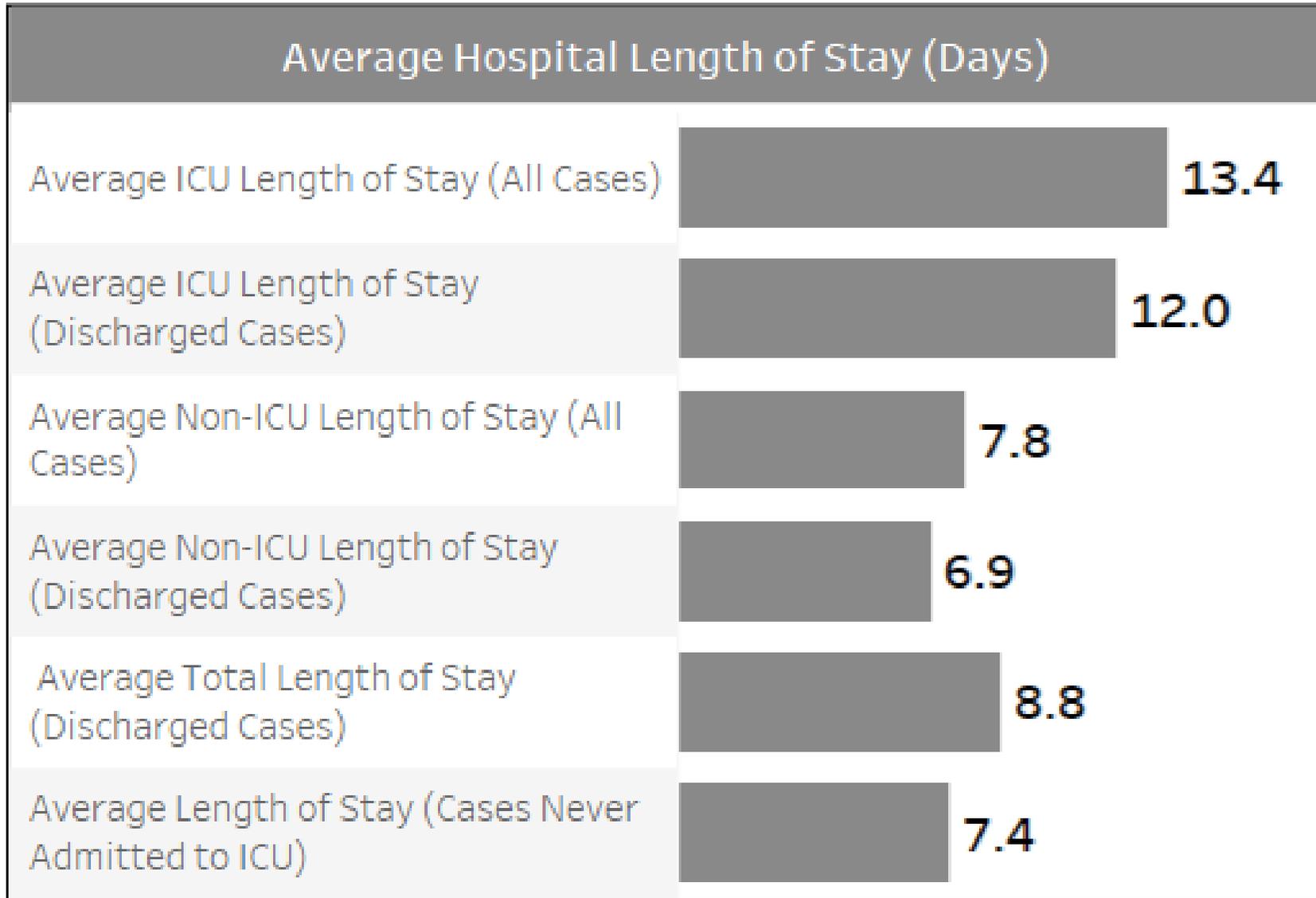


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# Disclosure



- **Financial affiliations:**

- **Honoraria, other rewards:** None
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- **Grants, clinical trials:** **MS Society of Canada**
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- **Investments in health organizations:** None
- **Other influential affiliations:** None

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# A randomized, double-blind, placebo-controlled trial to assess the efficacy and safety of oral hydroxychloroquine for the treatment of SARS-CoV-2 positive patients for the prevention of severe COVID-19 disease



- Primary Goal - to determine if early treatment with HCQ among people with COVID-19 infection, who are at increased risk, can **prevent severe** Covid19 disease
- HOPE = **H**ydroxychloroquine for **P**revention
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# Rationale



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- HCQ is already an approved drug with a known safety profile.
- It is very inexpensive
- It reduces the multiplication of corona viruses inside the cell
- It modulates the immune system to prevent an over-exuberant immune response. It is the immune response that causes most of the symptoms and bodily injury in COVID-19.
- HCQ was used during the SARS-Cov1 outbreak in Hong Kong and Toronto in 2003; but, it was only used in **cohort studies**.
- Reports to date from COVID-19 are **NOT** from randomized trials, or they use **very high doses** of chloroquine, **not hydroxychloroquin**, and all were for **treatment of hospitalized patients** when it is likely too late to be very effective.

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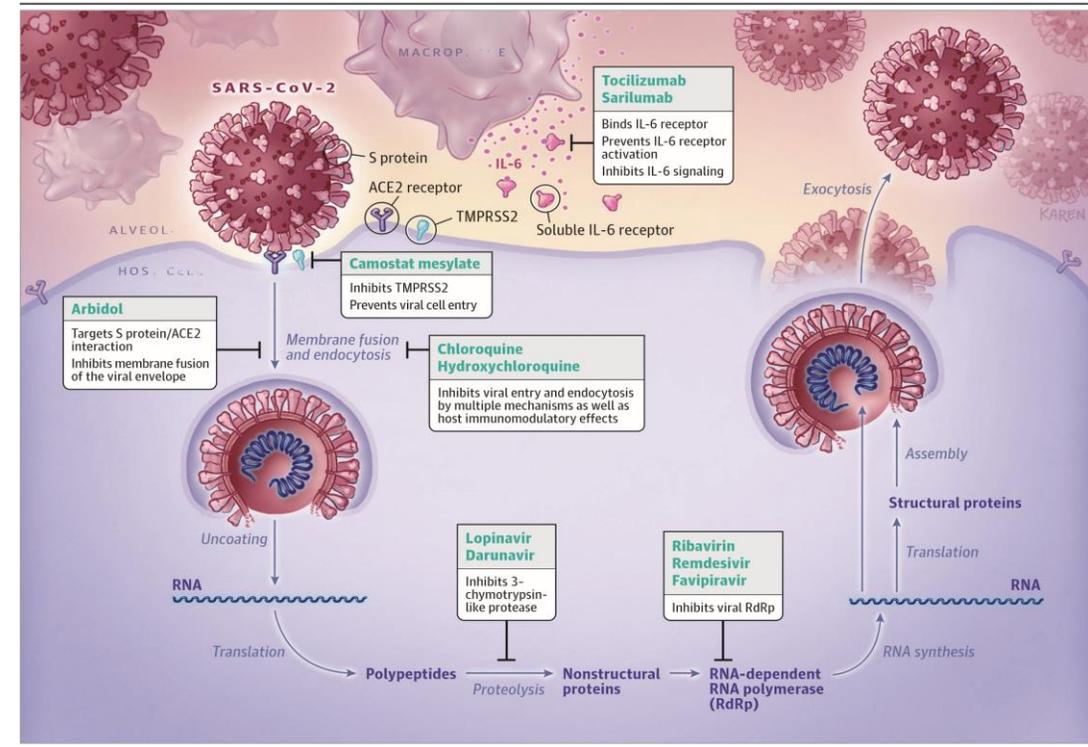
# Hydroxychloroquine (HCQ)



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- Oral medication
- 200 mg QID day 1; BID days 2-5
- Generally well tolerated with few side effects
- Major concern is cardiac risk – prolong QTc with risk of cardiac rhythm problems- **this can be addressed by careful screening**

Figure. Simplified Representation of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Viral Lifecycle and Potential Drug Targets



Sanders et al. *JAMA*. doi:[10.1001/jama.2020.6019](https://doi.org/10.1001/jama.2020.6019) Published online April 13, 2020.



# What we are NOT studying

- Chloroquine – less safe and less tolerable
- Zinc added to HCQ
- Azithromycin, an antibiotic
- Kaletra (ritonavir/ lopinavir)
- Remdesavir



# Trial Process

## Process

- Patient is told by Public Health that they have a positive test
- AHS asks for their permission to pass along their details to us
- We get an automated list and we approach them for telephone consent

## Consent and Randomization

- Consent, screen, and randomize by telephone
- Review Alberta Netcare as part of screening
- Courier drug to the participant
- Telephone FU at 7 and 30 days



# Key Inclusion Criteria



1. Laboratory confirmed Covid-19 infection
2. Some typical symptoms
3. Enroll within 12 days of onset – earlier is better
4. Enroll with 4 days of a positive test result
5. Informed consent

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# Key Exclusion Criteria

1. Currently or imminently planned admission to hospital
2. Any **contraindication to hydroxychloroquine** (see next slide)
3. Current use of hydroxychloroquine or chloroquine
4. Inability to swallow pills



# Major Contraindications to Hydroxychloroquine



- Known retinal eye disease with vision impairment, in which hydroxychloroquine is a known contraindication
- Known history of QTc prolongation or sudden cardiac death
- Known significant liver disease
- Uncontrolled epilepsy
- Current use of **drugs that are known to prolong the QTc.** (see *list*)

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# Drugs that prolong QTc and are exclusions



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Amiodarone	Droperidol	Methadone
Amitriptyline	Erythromycin	Moxifloxacin
Azithromycin	<b>Escitalopram</b>	Pentamidine
Chlorpromazine	Flecainide	Pimozide
Ciprofloxacin	Fluconazole	Pentamidine
<b>Citalopram</b>	Fluoxetine	Procainamide
Clarithromycin	Haloperidol	Propafenone
Desipramine	Ibutilide	Quinidine
Disopyramide	Imipramine	<b>Sertraline</b>
Dofetilide	Itraconazole	Sotalol
Doxepin	Ketoconazole	Thioridazine
Dronedarone	Levofloxacin	<b>Venlafaxine</b>
	Maprotiline	Voriconazole

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# Timelines & Progress



- 148 randomized to date, 3 hospitalizations so far (all due to COVID)
- We expect to enrol 1660 Albertans
- Enrolment speed will depend upon the overall evolution of the pandemic, ongoing review



# Potential Readiness for Interested and Vulnerable Individuals



- Provide written information about the trial ahead of need.
  - Sharing with families recommended.
  - Inform staff and physicians.
  - Include information about all exclusion criteria – especially drugs that would exclude an individual.
  - Include the consent form.
- Invite participation in webinars where questions can be asked.

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# Also consider...

- Enhanced readiness for participation before infection, perhaps in places where there is an outbreak (to facilitate earlier treatment)
  - Written consent provided by participant
  - Provide contact information for individual, alternate decision maker/ surrogate and/ or family
  - Attending physician approval
- If individual becomes infected
  - Screening completed
  - Consent confirmed
- Would health centres be interested in participating in drug delivery/ administration/ reminders?

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# Principle Investigators



- **Luanne M. Metz MD FRCPC**  
Professor Department of clinical Neurosciences, University of Calgary,  
Co-Lead Multiple Sclerosis Program of the Hotchkiss Brain Institute,  
Interim Site Medical Director, Foothills Hospital
- **Michael D Hill MD MSc FRCPC**  
Professor University of Calgary, Director, Stroke Unit;  
Department of Clinical Neurosciences, Hotchkiss Brain Institute, O'Brien Institute for Public Health
- **Ilan Schwartz MD FRCPC**  
Assistant Professor, Department of Medicine Division of Infectious Diseases University of Alberta
- **Lawrence Richer MD FRCPC**  
Associate Dean, Clinical & Translational Research/Associate Professor &  
Division Director of Pediatric Neurology, Department of Pediatrics, Division of Pediatric Neurology

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Perhaps there might be interested research collaborators from FNIHB?

P: 866-990-1231 W: [hopecovid.ca](https://hopecovid.ca) E: [albertahopecovid19@ucalgary.ca](mailto:albertahopecovid19@ucalgary.ca)

