



# Coronavirus COVID-19

BC Centre for Disease Control | BC Ministry of Health



## Ethical Framework for Allocating Scarce Drug Therapies During COVID-19

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## Introduction

On March 11, 2020, the World Health Organization (WHO) declared COVID-19 a global pandemic. British Columbia (BC) followed by declaring a public health emergency under the province's *Public Health Act*, and a provincial state of emergency under the *Emergency Program Act*.

Relevant key facts based on information currently available include:

- SARS-CoV-2, the virus that causes COVID-19, spreads from an infected person to others by liquid droplets when an infected person coughs, sneezes, sings, shouts, or talks.
- For up-to-date information regarding the transmission of COVID-19, please refer to the BC Centre for Disease Control.<sup>1</sup>
- In the context of a global COVID-19 pandemic, BC has implemented several public health measures to prevent the spread of the virus.
- Public health officials have recommended several strategies to mitigate the risk of transmitting COVID-19 including effective hand washing, physical distancing, and self-isolation if symptomatic. For people with suspected and/or confirmed COVID-19, self-isolation is considered an effective containment strategy and is recommended by the BC Provincial Health Officer.
- The risk of harm from COVID-19 transmission is significant. People in facilities such as hospitals and long-term care are often the most medically vulnerable due to age and comorbidities and, thus, may be disproportionately impacted by non-adherence from other people.
- There is increasing evidence that COVID-19 can survive on surfaces for hours or days.<sup>2</sup>
- There is no cure for COVID-19.

In BC, there are various research studies currently underway to examine multiple impacts from COVID-19, including treatment and drug therapy options. COVID-19 presents several ethical issues. In particular, the COVID-19 pandemic has given rise to a range of resource scarcities, including available drug therapies and the issue of who has access to them.<sup>3</sup> Drug shortages and scarcities are not issues exclusive to COVID-19, however, demands for any available and/or possible pharmaceutical treatment option for COVID-19 has raised ethical questions about how best to allocate existing and future scarce drug supplies.

## Purpose

This document examines the issue of critical drug scarcity during the COVID-19 pandemic and offers an ethical framework (Framework) from which allocation decisions might be made. The Framework acknowledges that drug scarcity affects not only people affected by COVID-19, but those with other conditions that rely on the drug in question.

## Scope

This Framework includes ethical considerations related to use and allocation of drug therapies both with and without a robust scientific evidence and/or emerging evidence base.

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<sup>1</sup> BC Centre for Disease Control. (2020). How it Spreads. Retrieved from <http://www.bccdc.ca/health-info/diseases-conditions/covid-19/aboutcovid-19/how-it-spreads>

<sup>2</sup> As is currently understood, there is some evidence that COVID-19 may survive on surfaces for hours or days. See: BC Centre for Disease Control. (2020). Common Questions. Retrieved from <http://www.bccdc.ca/health-info/diseases-conditions/covid-19/common-questions>.

<sup>3</sup> Health Canada (2021) Tier 3 Drug Shortages. Retrieved January 28, 2021 from <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods/information-provisions-related-drugs-biocides/tier-3-shortages.html>.

## Ethical Principles and Values

Further information on the foundational ethical principles that support this Framework can be found in [Appendix A](#).

## Evidence-based Principles for Drug Allocation

A prevailing principle in the allocation of scarce resources (including drug therapies) is to seek to maximize benefit—that is, to prioritize patients with highest needs and greatest likelihood of benefit, maximizing health benefits overall.<sup>4</sup> Thus, a foundational approach to the ethical distribution of a drug therapy that is scarce is:

- 1. To the degree possible, preferential access to a scarce drug therapy should be given to the patients with both the highest need and the greatest likelihood of benefiting,<sup>5,6</sup> maximizing the health benefits of the population. As such, preference should usually be given to patients who are prescribed the drug therapy for an existing condition, outside COVID-19.**

This overarching assessment is grounded in the public health ethical obligation: the duty to steward scarce resources to promote the public's health by prioritizing scarce drug therapy to patients with the highest need and greatest likelihood of benefitting (*Efficiency and Effectiveness*). Doing this aims to promote the maximum benefits overall (*Utility and the Harm Principle*).

A second foundational principle seeks to recognize—and possibly ameliorate—the disproportionate impact that illnesses has within society. COVID-19 has also created greater burdens for some populations, compared to others (e.g., residents in long-term care homes, visible minorities) and thus a second approach to an ethical distribution is:

- 2. In order to maximize the health benefits to the population, prioritize access of proven scarce drugs therapies in a manner that does not exacerbate the impact of COVID-19 on specific populations. Where social inequities have resulted in a greater burden on some populations or groups, then to the degree possible, seek to lessen the impact of these inequities.**

This analysis promotes the distribution and allocation of scarce drug therapies in a manner that lessens the impact of social inequities on COVID-19 outcomes for populations disproportionately incurring inequities, including those who have suffered disproportionate health burdens prior to the onset of the pandemic.<sup>7</sup> Care must also be taken to ensure patients are not refused access on the basis of ethically irrelevant criteria.

This Framework clarifies that as grounds of discrimination in the Human Rights Code, RSBC 1996, c.210., race, colour, ancestry, place of origin, religion, marital status, family status, physical or mental disability, sex, sexual orientation, gender identity or expression, or age must NOT be used to determine allocation alone. Persons with disabilities must NOT have resources removed or withheld based on stereotypes or presumptions about quality of life.

<sup>4</sup> Valiani, S., Terrett, L., Gebhardt, C., Prokopchuk-Gauk, O., & Insinger, M. (2020). Development of a framework for critical care resource allocation for the COVID-19 pandemic in Saskatchewan. *CMAJ*, 192(37), E1067-73. Pg. E0167

<sup>5</sup> DeJong, C., Chen, A., Lo, B. (2020). An ethical framework for allocating scarce inpatient medications for COVID-19 in the US. *JAMA*, E1-2; Pg. E1.

<sup>6</sup> Bean et al. (2020). Ethical framework for drug shortages that occur during the COVID-19 pandemic in Ontario. Retrieved January 28, 2021 from <http://icb.utoronto.ca/news/documents/Ethical-Framework-for-Drug-Shortages-during-COVID-Pandemic.pdf>. Pg. 3.

<sup>7</sup> White et al. (2020). Model hospital policy for fair allocation of scarce medications to treat COVID-19. University of Pittsburgh. Retrieved January 28, 2021 from <https://ccm.pitt.edu/sites/default/files/2020-05-28b%20Model%20hospital%20policy%20for%20allocating%20scarce%20COVID%20meds.pdf>.

The questions of (1) how to identify and quantify the extent to which social inequities have resulted in certain populations bearing disproportionate burden of disease in a public health crisis such as COVID-19, and (2) how to address this heightened burden, are complex. While a clear solution is unlikely in the short term, options such as a weighted lottery<sup>8</sup> or a multi criteria decision analysis approach<sup>9</sup> have been suggested as possible ways forward.

There are special considerations owed when a scarce drug therapy lacks robust evidence to support its use for COVID-19 treatment. Where there is an absence of evidence and a scarce drug is unproven, an ethical approach should satisfy the first prevailing principle (i.e. to prioritize patients with highest needs and greatest likelihood to benefit, to maximize health benefits for all):

- 3. Prioritize access to unproven drugs in situations in which evidence collection is most likely to occur and inform an emerging evidence base.**<sup>10,11</sup>

### Allocation Framework

In the event of a drug scarcity during the COVID-19 pandemic in BC:

- 1. Promote equitable distribution of proven and, when authorized and evidence-based, unproved drug therapies throughout the Province:**
  - a. Allocation should be managed at the highest level possible (Provincial Government or delegated authority), with centralized supply chains to ensure equitable distribution throughout the province.
  - b. Enact guidance and protocols to prevent hoarding, wastage and ensure any unused supply is put back into the Provincial supply.
  - c. Provincial distribution should account for the amount of scarce drug supply needed to provide existing appropriate care to patients e.g., protecting supply for patients currently prescribed the medications for reasons outside COVID-19.
  - d. In circumstances where an existing scarce drug supply is preserved for current patient care, and where evidence of that scarce drug reveals greater benefits and higher need in another population, reallocation towards the populations who have the greatest benefit should be considered<sup>12</sup>. In any circumstances where an existing scarce drug supply is allocated away from a current patient and/or patient population, a fulsome analysis, including an Ethicist, of the risks of harm and benefits is required and should take into account any effective alternatives for both

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<sup>8</sup> White et al. (2020). Model hospital policy for fair allocation of scarce medications to treat COVID-19. University of Pittsburgh. Retrieved January 28, 2021 from <https://ccm.pitt.edu/sites/default/files/2020-05-28b%20Model%20hospital%20policy%20for%20allocating%20scarce%20COVID%20meds.pdf>.

<sup>9</sup> Laba TL, Jiwani B, Crossland R, Mitton C. (2020) Can multi-criteria decision analysis (MCDA) be implemented into real-world drug decision-making processes? A Canadian provincial experience. Int J Technol Assess Health Care. doi: 10.1017/S0266462320000525.

<sup>10</sup> Bean et al. (2020). Ethical framework for drug shortages that occur during the COVID-19 pandemic in Ontario. Retrieved January 28, 2021 from <http://jcb.utoronto.ca/news/documents/Ethical-Framework-for-Drug-Shortages-during-COVID-Pandemic.pdf>. Pg3. DeJong, C., Chen, A., Lo, B. (2020). An ethical framework for allocating scarce inpatient medications for COVID-19 in the US. JAMA, E1-2. PgE1.

<sup>11</sup> DeJong, C., Chen, A., Lo, B. (2020). An ethical framework for allocating scarce inpatient medications for COVID-19 in the US. JAMA, E1-2.

<sup>12</sup> For example, drug A is used to treat rheumatoid arthritis (RA) and has been shown to be marginally superior to drug B for reduction in joint pain at 6 months. New evidence reveals drug A reduces overall mortality in patients COVID-19. Weighing the maximal benefit and need between these two groups should account for the availability of an effective alternative in one patient but not the other, as well as the overall mortality benefit. In this example, re-allocation would be justified. However, if there was no effective alternative available for RA patient, and where the overall benefit and need (e.g., morality, morbidity) are equal, current therapy should continue and not be withdrawn. If equal and if neither patient had prior access to the drug, a lottery should be used to determine. If no effective alternative is available for the RA patient, and where there is consideration of withdrawing, an independent appeal process should become available.

population groups. Where analyses between patients reveals equal risk and benefits, individuals who are already receiving an allocation of the scarce drug supply should be continued (i.e. the scarce drug should not be withdrawn). Where analyses between patients is equal, and where neither had any prior allocation of the scarce drug, a lottery should be used. In any circumstance where withdrawal of a current scarce drug supply is being considered from an existing patient, an independent appeal process should be available. Promote equitable distribution across BC, within each health authority, and within individual facilities. One approach is to build systems where experts review prescriptions and/or drug therapy uses.

e. Ensure all decisions are transparent and timely, both to internal partners and to the public.

**2. Triage and allocation decisions should be procedurally fair, and processes should promote equitable distribution:**

- A multidisciplinary triage/allocation committee should be created to responsible for making triage and allocation decisions.
- Such a triage committee ensures that allocation decisions are not made at the bedside and promotes openness, transparency, consistency, and accountability.<sup>13,14,15</sup>
- Ensure allocation decisions are documented, and documentation is standardized for all partners.

**3. Maintain flexibility**

- As new evidence becomes available, ensure clinical decision-making guidelines are updated to guide decision makers on the patients and populations most likely to benefit from the drug.

**4. Conserve supply, share and borrow, procure, or access new drug supply**

- Purchases of scarce drugs must be justified by the benefits.
- Engage with existing drug decision processes and bodies (e.g., Provincial Drug Benefit Council, Expensive Drug Review Committee).

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<sup>13</sup> DeJong, C., Chen, A., Lo, B. (2020). An ethical framework for allocating scarce inpatient medications for COVID-19 in the US. JAMA, E1-2.

<sup>14</sup> White et al. (2020). Model hospital policy for fair allocation of scarce medications to treat COVID-19. University of Pittsburgh. Retrieved January 28, 2021 from <https://ccm.pitt.edu/sites/default/files/2020-05-28b%20Model%20hospital%20policy%20for%20allocating%20scarce%20COVID%20meds.pdf>

<sup>15</sup> Lim, S., DeBruin, D., Leider, J et al (2020). Developing An Ethics Framework for Allocation Remdesivir in the COVID-19 Pandemic. Mayo Clin Proc, 95(9), 1946-54.

## Appendix A: Foundational Ethical Principles

This Framework is underpinned by the following ethical principles and values:

### Procedural considerations

- Efficiency and Effectiveness
- Procedural Justice (Fair Process):
  - Openness and transparency
  - Inclusiveness
  - Accountability
  - Reasonableness
  - Consistency
- Flexibility
- Integrity
- Solidarity

### Substantive considerations

- Distributive Justice:
  - Equitable distribution (Fairness)
    - Equality
    - Equity
  - Just distribution of benefits and harms risks and burdens
- The Harm Principle
- Utility – seek to balance overall benefits and harms
- Respect
- Cultural Safety
- Least Coercive and Restrictive Means
- Reciprocity
- Proportionality

## Appendix B: Contributors

### The COVID-19 Provincial Ethics Advisory Team

#### Co-Chairs:

- Alice Virani, Provincial Health Services Authority
- Bethan Everett, Vancouver Coastal Health Authority

#### Members:

- Mojisola Adurogbangba, Fraser Health Authority
- Allen Alvarez, Fraser Health Authority
- Jillian Boerstler, Providence Health Care
- Karen Burton, Vancouver Island Health Authority
- Jocelyn Chase, Providence Health Care
- Jennifer A. Gibson, Providence Health Care
- Julia Gill, Vancouver Coastal Health Authority
- Bashir Jiwani, Fraser Health Authority
- Jeff Kerrie, Vancouver Island Health Authority
- Maria Michael, Fraser Health Authority
- David Migneault, Vancouver Coastal Health Authority
- Tammy Molina, Interior Health Authority
- Nina Preto, Provincial Health Services Authority
- Kirsten Thomson, Northern Health Authority