HEALTHETHICS Alliance

Ethical Framework for the Allocation of Personal Protective Equipment (during COVID-19)

Background

This ethical framework is intended to guide institutional resource allocation decisions for Personal Protective Equipment (PPE) during the COVID-19 public health emergency. In a guidance document issued Feb. 27, 2020, the WHO recommends rational use of PPE for treating patients with confirmed or suspected COVID-19. Relevant PPE includes gloves, medical masks, goggles or face shields, gowns, and respirators. The WHO has indicated that the current global stockpile of masks and respirators is insufficient and shortages in gowns and goggles is also anticipated.

The WHO has issued three overarching recommendations for use of PPE:

1) minimize the need for PPE; and
2) ensure PPE use is rationalized and appropriate; and
3) coordinate PPE supply chain mechanisms.

The WHO recommendations have been integrated into this framework. This ethical framework is a living document and will require review and updating as the COVID-19 situation evolves and new evidence emerges. This framework is advisory and was developed to support key decision-makers at the institutional level regarding the distribution of available PPE supply and potential modification to health services to conserve PPE. Although this framework is tailored for the acute care setting, ideally there should be consistency between and among healthcare institutions across the continuum of care to foster a consistent approach, and as a result, promote the ethical principles of justice and fairness. This framework may be adapted to address a broader health system perspective.

This ethical framework is adapted from the *Ethical Framework for Resource Allocation during the Drug Supply Shortage*, which was drafted by an Ethics Working Group convened by the University of Toronto Joint Centre for Bioethics in 2012 and endorsed by the Ontario Ministry of Health. The Allocation of PPE Ethical Framework is comprised of:

a. Allocation principles that are articulated in three stages;
b. Fair process principles; and
c. Guiding values.

Balancing allocation principles and making decisions about PPE allocation should occur according to fair process principles and generally aim to promote seven guiding values. The guiding value of reciprocity has been added to the six principles included in the 2012 Drug Supply Shortage framework. The guiding values are beneficence, equity, reciprocity, solidarity, stewardship, trust, and utility. In addition to the allocation principles and guiding values, fair process principles, such as the Accountability for Reasonableness (A4R) Ethical Framework should help inform how decisions are made. The five fair process principles comprising A4R include relevance, publicity, revision, enforcement, and empowerment.

The following seven guiding values appear in alphabetical order and are not rank-ordered.

Framework Authors: Sally Bean, Kevin Reel, Maxwell J. Smith, Blair Henry, and Maria McDonald
sally.bean@sunnybrook.ca
Version: March 9, 2020

Table 1.Guiding Values

Value	Definition
Beneficence	Promoting highest quality of safe and effective care within resource constraints by: a. Ensuring standard of care and best Infection Prevention & Control (IP&C) practices whenever possible b. Training healthcare providers (construed broadly to include anyone with direct contact with patients including both regulated and unregulated providers, administrative staff, environmental services, porters, etc.) to select the proper PPE, how to safely doff, don, and dispose of PPE after use c. Committing to use best available data/evidence to inform PPE allocation decision-making d. Using alternative PPE where evidence suggests similar or similarly adequate efficacy e. Informing and educating healthcare providers about risks and benefits of alternate PPE including risk mitigation strategies f. Enabling delivery of care in the most appropriate setting, e.g. negative pressure rooms or decontamination areas to help mitigate risk of exposure
Equity	Promote just/fair access to PPE by: a. Using allocation processes for distribution of PPE that do not arbitrarily disadvantage any healthcare provider b. Not discriminating between healthcare providers based on factors not relevant to provision of healthcare (e.g., social status) c. Treating similar cases similarly and treating dissimilar cases in a manner that reflects the differences.
Reciprocity	To support healthcare providers that may be or are exposed to COVID-19 in the course of their employment, mitigate potential harms/burdens this may cause to the individual by: a. Describing the steps healthcare providers should take to reduce exposure or spread to others, including family members b. Working with Occupational Health & Safety to clarify requirements and implications for fitness to work c. Ensure that healthcare providers exposed to COVID-19 are aware of all known ways to reduce symptoms and complications associated with COVID-19 d. Prioritizing healthcare providers most at risk of COVID-19 exposure in the course of their employment for future vaccines or treatments that may be developed or become available e. If hospital visitation is suspended, support use of technology for patients and staff that are isolated from families to safely communicate
Solidarity	To build, preserve and strengthen interprofessional and intra-institutional collaboration is the responsibility of all leaders and decision-makers through: a. Embracing a shared commitment to the well-being of patients and healthcare providers regardless of care setting (i.e. all sites and more broadly across the continuum of care) b. Establishing, encouraging, and enabling open lines of communication and coordination c. Sharing and redistributing PPE within the healthcare institution d. Supporting allocation decisions that are consistent with ethical framework

Framework Authors: Sally Bean, Kevin Reel, Maxwell J. Smith, Blair Henry, and Maria McDonald
sally.bean@sunnybrook.ca
Version: March 9, 2020

	e. Recognizing importance of collaboration with health system partners beyond the acute care setting f. Recognizing some healthcare providers may feel a strong duty to care for patients despite inadequate PPE but this individual decision may have overriding negative consequences, e.g. resources required if the healthcare provider becomes ill g. Acknowledging that due to individual circumstances, some healthcare providers may have competing interests (e.g. ill family members), underlying health issues that put them at an elevated risk if infected, etc. such that they may be unavailable to provide care or might need to be redeployed to other low risk areas h. Providing psychosocial support to healthcare providers delivering care to COVID-19 patients to ensure they feel supported and not marginalized
Stewardship	Upholding principles use of available PPE carefully and responsibly by: a. Ensuring PPE utilization is consistent with best available evidence b. Avoiding stockpiling for personal use c. Postponing elective procedures/treatments that require use of PPE that are in limited supply d. Prioritizing access to scarce PPE based on risk of exposure and pathogen transmission dynamics e. Monitoring PPE utilization and distribution to facilitate course corrections as needed f. If deemed acceptable for IP&C practices, extend life of PPE through extended PPE use (e.g. use same respirator while caring for multiple patients with the same diagnosis without removing PPE)
Trust	Foster and maintain public, patient, and health care provider confidence in PPE distribution system by: a. Communicating in a clear and timely fashion, including expectations around accepting or refusing work assignments b. Making decisions in an open, inclusive and transparent way with clearly defined decision-making authority and accountability c. Being transparent and providing a rationale about what criteria are informing PPE allocation and staff assignment decisions d. Collating short and long-term lessons learned
Utility	While balancing the other principles, maximize the greatest possible good for the greatest possible number of individuals by: a. Promote administrative control measures that minimize direct patient care to essential encounters b. Distributing PPE in short supply to healthcare providers administering direct patient care c. Distributing PPE in short supply to healthcare providers with the highest risk of exposure (e.g. providing direct care and aerosol-generating procedures) and pathogen transmission dynamics d. Sharing PPE within the healthcare institution e. Where feasible, sourcing additional PPE supply f. Identifying healthcare providers that may be at increased risk for the more serious (health-related) impacts of COVID-19 if they were to become infected and potentially redeploy to lower risk areas.

FINAL

Framework Authors: Sally Bean, Kevin Reel, Maxwell J. Smith, Blair Henry, and Maria McDonald
sally.bean@sunnybrook.ca
Version: March 9, 2020

Allocation Principles:

The following allocation principles apply generally across all types of PPE. They provide a foundation to inform discussion and decision-making at the relevant governance level during.

<u>Stage 1</u>. Implement strategies to preserve or approximate standard of care and best IP&C practices to the extent possible within available PPE supply

When there is risk of PPE shortage,

1a. Conserve existing supply of PPE using strategies such as:

- Developing an inventory of available PPE and review at frequent intervals
- Reviewing PPE usage practices in light of best available evidence
- Reducing wastage of PPE (e.g., where evidence does not support use or is weak)
- Minimize need for PPE by using alternatives to face-to-face care such as telemedicine or consultation across physical barriers for appropriate interactions
- Using alternative PPE where evidence suggests adequately similar efficacy to the PPE in short supply
- Limit or prohibit hospital visitation (to reduce or eliminate visitors use of PPE)
- Limit access to PPE to only those providing direct patient care to COVID-19 (or other diseases that require PPE)
- Cancelling non-urgent or elective procedures that require use of PPE
- Co-horting COVID-19 patients (i.e. create a care ecology so that healthcare providers can optimally use PPE for treating a group of similarly situated patients)
- Utilize expired PPE for training purposes and consider if safe to use for direct care
- Delaying new enrollment in research studies using PPE in short supply

1b. Access new supply of PPE by:

- Collaborating with partners and governments to identify and procure alternative sources

And if these strategies are insufficient…

1c. Postpone or reduce procedures/treatments that require the use of PPE in short supply that are not related to COVID-19.

<u>Stage 2</u>. Apply Primary Allocation Principles based on risk of exposure and risk of harm (to self and others, e.g. if work with a patient population that might be more negatively impacted) if infected:

When Stage 1 strategies are insufficient to meet the need for PPE in short supply, give priority access in rank order to:

Framework Authors: Sally Bean, Kevin Reel, Maxwell J. Smith, Blair Henry, and Maria McDonald
sally.bean@sunnybrook.ca
Version: March 9, 2020

2a. Healthcare providers who are at highest risk for exposure to (or risk of harm from) COVID-19 (or other diseases that require PPE) that are providing direct care to patients.

2b. Healthcare providers who are at moderate risk for exposure to (or risk of harm from) COVID-19 (or other diseases that require PPE) that are providing direct care to patients.

2c. Healthcare providers who are at lowest risk for exposure to (or risk of harm from) COVID-19 (or other diseases that require PPE) that are providing direct care to patients.

Meanwhile…

- Continue with Stage 1 strategies, *and*
- Reassess healthcare provider's risk of exposure on an ongoing basis to identify any changes in level of priority.

Stage 3. Apply Secondary Allocation Principles to Ensure Fair Access to PPE

When decisions must be made between healthcare providers within a level of priority as described in Stage 2, prioritize healthcare providers using a fair and unbiased procedure that does discriminate between healthcare providers based on factors not relevant to their risk of exposure (e.g., race, social value, sex, age) or risk of harm if infected such as:

- First come, first served (where queuing is feasible with regular clinical practice), or
- Other procedure that is developed and sanctioned by affected stakeholders (e.g., random selection). A lottery system would mean that only some healthcare providers get PPE and only those healthcare providers would be able to provide care.

Meanwhile…

- Continue with Stage 1 strategies, *and*
- Reassess healthcare providers' risk of exposure on an ongoing basis to identify any changes in level of priority.

A4R Ethical Framework (Process Conditions) for Resource Allocation Decision-Making:

The A4R framework has been adopted by Sunnybrook as a tool to help shape ethically defensible processes for resource allocation decision-making. It outlines 5 fair process principles that help ensure the process fair and perceived as such:

- Relevance; Publicity; Revision; Enforcement; and Empowerment

When considering implementing this framework, every effort should be made to promote fairness in decision-making. Fairness can be promoted by ensuring that this process aligns with Sunnybrook's

Framework Authors: Sally Bean, Kevin Reel, Maxwell J. Smith, Blair Henry, and Maria McDonald
sally.bean@sunnybrook.ca
Version: March 9, 2020

FINAL

framework for organizational decision-making, A4R. Further details of the A4R framework and its use are available on Sunnynet. External individuals can read more about implementing A4R here.

Appendix I:

Areas Requiring Further Consideration:

- Redistributing PPE among health system partners
- IP&C guidelines/direction on PPE minimum standards, PPE substitutions, or alternations to standard usage such as PPE extended use or reuse
- Expectations around reporting to work or self-quarantine if a family member living in the same residence is positive for COVID-19
- Legal context if emergency measures are invoked
- Staff assignments to care for COVID-19 patients
- Healthcare providers ability to refuse "unsafe" work or assignments
- Access to PPE in community and unique challenges of allocation in community setting
- If healthcare providers have contracted COVID-19 and since recovered, what is the risk of re-infection?
- If PPE supply gets to zero, can healthcare providers independently decide to provide care without PPE (i.e. assume risk)?
- End-of-life decision-making issues (withholding or withdrawing treatment)
- Allocation of potentially life sustaining treatments, e.g. ventilators, ECMO, etc.

FINAL

Framework Authors: Sally Bean, Kevin Reel, Maxwell J. Smith, Blair Henry, and Maria McDonald
sally.bean@sunnybrook.ca
Version: March 9, 2020