



New Brunswick College of Pharmacists
Ordre des pharmaciens du Nouveau-Brunswick

Commentary: Ethical Decision Making During a Public Health Event

Companion document to the New Brunswick College of Pharmacists Code of Ethics (Policy GM-PP-CE-01)

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ACRONYMS

VBDM	Values-Based Decision Making
COVID-19	SARS-CoV-2 2019

LEARNING OBJECTIVES

This Commentary guides pharmacy professionals in making ethical decisions during a public health event and clarifies patient care priorities during an event that impacts societal health.

After reviewing this document, the pharmacy professional will be able to:

1. Identify and explain why aspects of pharmacy practice present ethical challenges during a public health event
2. Recognize the position of the New Brunswick College of Pharmacists regarding expectations of pharmacy practice during a public health event
3. Apply Values-Based Decision Making (VBDM) employing the ethical principles utility and solidarity to practice issues in the context of a public health event
4. Justify ethical decisions made during a public health event

AUDIENCE

- Pharmacy professionals practicing direct patient care during an emergency
- Pharmacy managers supervising staff during an emergency
- Pharmacy professionals practicing in non-direct patient care environments
- The public of New Brunswick
- Government of New Brunswick
- Other healthcare professionals

INTRODUCTION

This Commentary supplements the New Brunswick College of Pharmacists Code of Ethics.¹ Commentary is authored for ethical dilemmas that require expansion due to their complexity, controversy, breadth, or magnitude of risk to stakeholders.

This document was created in 2020 to provide guidance during the COVID-19 pandemic^a, however the scope is such that it can support ethical decisions in any future public health event. Public health events may be due to infectious disease, natural disaster, nuclear incidents, large chemical spills, power or communication grid outages, war or terrorist threats.³ Public health events can be localised or national in breadth and may or may not be formally declared by local or national government. This Commentary should be used in conjunction with applicable emergency regulations of the College and direction from the New Brunswick's Department of Health.

This Commentary:

1. Describes practice demands during a public health event
2. Presents relevant ethical concepts and how they interplay during a public health event
3. Promotes the use of Values Based Decision Making (VBDM) in the context of a public health event and the expanded bioethical principles
4. Applies VBDM and principles of utility and solidarity to a case example

The Commentary is intended for pharmacy professionals who provide health care directly to patients. However, those practicing in managerial and policy roles may also find the Commentary relevant. All practitioners must negotiate the tension between:

- a) Duties to self and family vs. duties to the public/patient vs. duties to other stakeholders^b
- b) Individual patient benefit vs collective societal health benefit

Stakeholders will share some values and interests and diverge on others. The common language of ethics allows professionals to systematically analyse issues, plan and execute action, communicate transparently with stakeholders, and reassess decisions in light of new information. Decision-making based on ethical principles and values can be fair, accountable, inclusive, considered, and justifiable to stakeholders.

The following material is provided with the goal of preparing and empowering pharmacy practitioners to provide ethically-informed patient care decisions in unique circumstances that present during a public health event.

^a A pandemic is defined by the World Health Organization as “the worldwide spread of a new disease”.²

^b Other stakeholders may include employers, government, institutions such as long-term care homes, hospitals, private insurers, or corporate entities.

KEY MESSAGES

- In a public health event, **utility is prioritized** over beneficence, non-maleficence and sometimes respect for persons. Essentially, maximization of benefit for the public's collective health is often invoked and prioritized over the health of the individual, particularly when resources are scarce.
- When necessary, pharmacy professionals may **be limited to providing essential services** to maximize the benefits of care for the most patients, to preserve scarce resources, or to ensure the safety of patients and the pharmacy team.
- A focus on **stewardship and solidarity** requires collective responsibility for the management of the pharmaceutical supply chain regionally, nationally, and internationally. Redeployment of professionals and non-professional staff and pharmaceutical products may be required to ensure equitable access to resources for patients.
- Within reason, professionals have an ethical duty to **care for patients despite facing personal risk**, and potential risk to their family members.

PRACTICE DEMANDS DURING A PUBLIC HEALTH EVENT

A public health event compels pharmacy professionals to practice in possibly unfamiliar, complex, uncertain, and perilous conditions. A public health event may result in shortages of medications and supplies, human resource deficit, increased patient volume, time-pressure, and threats to occupational health (e.g. lack of personal protective equipment during pandemic). The resulting anxiety experienced during a public health event adds to the challenge of making and implementing good ethical decisions.⁴

RELEVANT ETHICAL CONCEPTS DURING A PUBLIC HEALTH EVENT

The Code of Ethics provides two central paradigms that apply to ethics whether a public health event is in progress or not.

- Professional Duties (center of Figure 1)
- Bioethical Principles (peripheral circles of Figure 1)

Professional Duties

The duties of the pharmacy professional are to patients, public and the pharmacy profession:

“to promote and protect the health, well-being, safety and interest of the public.”

and

“to hold forth the independence, integrity and honour of the profession¹”

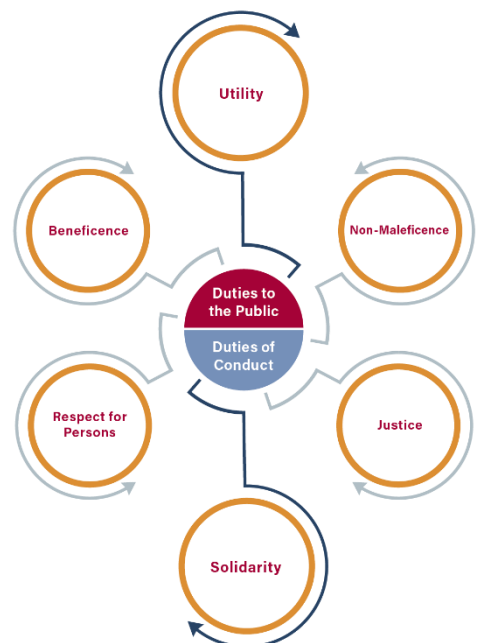


Figure 1: Professional Duties and Bioethical Principles

During a public health event, personal duties (to self and family) must be carefully balanced with professional duties. Stakeholders have a duty to support pharmacy professionals' practice. The term reciprocity is used to denote the obligation of employers, public health authorities, government, and pharmacy advocacy bodies to provide resources (human, personal protective equipment) and policy to support pharmacy professionals to practice in a safe environment and minimize their personal (and family) risk in caring for patients during a public health event.^{4,5} The public also has a duty to be respectful towards pharmacy professionals serving their communities during public health events. The references and suggested resources at the end of this Commentary contain further reading on these other non-professional duties.

Bioethical Principles^c

The Code of Ethics includes four bioethical principles that form the basis for the normal course of patient care: Beneficence, Non-Maleficence, Respect for Persons, and Justice.^c Public health events cause professionals to consider two other bioethical principles: Utility and Solidarity.

Utility

Utilitarianism is:

“a theory that the aim of action should be the largest possible balance of pleasure over pain or the greatest happiness of the greatest number.”⁶

According to the theory of utilitarianism, utility should guide actions, programs, and policies.⁷ In a public health event utility is prioritized over beneficence and non-maleficence and often over respect for persons. Essentially, population-centered care is prioritised over patient-centered care. Utility provides flexibility in light of the risks so that no rule is absolute.

Resources and time will be scarce during a public health event. Decisions should be made that will benefit the most people possible. Some examples of prioritisation of utility over beneficence, non-maleficence, and respect for persons are contained within each of these following sections.

Solidarity

Solidarity is:

“unity (as of a group or class) that produces or is based on community of interests, objectives, and standards.”⁸

During a public health event, pharmacy professionals are simultaneously presented with multiple competing interests, values, and priorities in making patient care decisions. In the context of

^c Readers are referred to the Code of Ethics for explanation of each bioethical principle.¹

public health, solidarity results in a collective commitment to assisting others who are linked by means of a shared situation or cause.⁹ Because there is potential for profound system failure during public health events, the competition, self-interest, and territoriality among pharmacy professionals, pharmacies, and institutions must become secondary to maintaining the health and well-being of the community and society. Specific examples of solidarity include:

- Sharing of medication supply (as opposed to stockpiling) between pharmacies.
- Area pharmacies coordinating and communicating opening times to maintain local service while facilitating health and well-being for all staff.
- Collaboration between multiple organizations messages and strategies to maintaining public health.
- Minimizing risk of infection in vulnerable pharmacy professionals through reassignment of these professionals to non-patient care duties to ensure ongoing human resourcing exists to maintain patient care.

Beneficence and Non-Maleficence

To protect the public from harm during a public health event, actions may need to be taken which impinge on individual patient benefit or preferences. Collective societal health benefit outweighs individual patient benefit during a public health event.¹⁰ Examples include:

- Distribution decisions on a COVID-19 vaccine will need to initially ensure priority is given to vaccinating populations (both internationally and domestically) that maximize societal benefit rather than simply providing it to any given individual (beneficence) requesting it.
- Health practitioners might be inclined (for interests of self or patient) to provide treatment with little or no research on safety and/or efficacy (non-maleficence and beneficence) during a public health event. Pharmacists are obliged to provide evidence-based care during a public health event.¹⁰ Experimental treatments must be provided through research protocols to establish evidence for use.
- During public health event related staffing shortages, pharmacy professionals may be needed outside of their normal area of practice in order to achieve the greatest benefit to the greatest number of patients (utility). Establishing basic competency is necessary to do no harm to patients (non-maleficence) while positively impacting on patient's health (beneficence). Pharmacy professionals should feel supported^d in competency development in unfamiliar aspects of pharmacy practice.¹⁰

Respect for Persons

Patient-centered care attempts to meet (respect) patient needs and preferences. Patient-centered care does not mean meeting all patient preferences. The principle of utility makes it clear that not all patient demands will be met in a public health event. Instead, pharmacy professionals shift to ensuring population health through maintaining essential services.

^d See "Stand on Guard for Thee" in the recommended readings for information on reciprocal duty.

- Pharmacy professionals can assist patients in recalibrating their expectations of the healthcare system (e.g., rationing of medication supply, eliminating face-to-face consultation, wait times) so that even in times of scarcity and changes to standard of practice, therapeutic relationships and public trust are maintained.¹⁰
- A patient's right to privacy is foundational to the public's trust in the profession of pharmacy; however, public health events may necessitate the prioritization of protecting the public from harm over privacy rights.⁵ Practitioners faced with divulging patient information must carefully consider^e how to divulge the minimal amount of information in order to achieve the necessary outcome. For instance, during a pandemic, contact tracing of infection cases may require the provision of patient information to public health to prevent disease transmission.

Justice

Restrictions and allowances during a public health event should be proportionate to the actual or potential threat and should not exceed what is necessary.¹⁰ An example of a proportionate response could be:

- only deferring administration of non-essential injections rather than all injections. Non-essential injections are those that are assessed as not posing immediate risk to patient health.
- Stewardship is important during a public health event where resources are scarce.⁵ Allocation decisions must attempt to achieve the best patient and public health outcomes. Allocation can pertain to goods or services. Examples where stewardship is evident include:
 - Conservation of unused portions of pharmaceutical products used in sterile preparation of unit doses to reduce wastage.
 - Managing rational use of personal protective equipment (PPE) during a public health event through formalized assessment of a service as 'essential' and requiring PPE-enabled patient-professional contact.
 - Preserving pharmaceutical supply chain through careful apportioning of medications to prevent patient stockpiling and coordination across jurisdictions and between wholesalers, distributors, and manufacturers.
- Canadians expect equitable healthcare access. Public health events may justify difficult decisions on deferring care, providing less effective medication therapy, and rationing of scarce resources. Where care is not provided equitably it can be provided fairly. Special attention must be paid to inequitable distribution that results from resource allocation decisions on already disadvantaged populations. Actions that can lead to justifiable and fair provision of care include:
 - Application of resource allocation principles to ethically justify provision of patient care resources to those most likely to benefit, those considered most critically ill or individuals providing essential services.

^e Consulting with other authorities such as Public Health, the College and/or legal counsel may be advisable.

- Provision of drugs in short supply should be made in accordance with provincial and national guidelines regarding medication supply. These decisions should also be made using available evidence at the time.¹⁰
- Prioritization of continuing medication therapy rather than optimizing therapy. The expertise required for optimization of therapy may prevent other patients from receiving attention. Note: The opposite applies when stewardship is of importance as optimization might allow for conservation of critical drugs.^{10,11}
- Provision of minimally acceptable levels of care rather than striving for perfection.¹⁰ Time and resources are limited during a public health event and pharmacy professionals must strive to provide services to as many patients as possible to a safe and acceptable degree.

Trust in the pharmacy profession is strengthened when professionals fulfill their duty to the public during a public health event. Competing personal interests of professionals and competing obligations to other stakeholders challenge pharmacy professionals in achieving their duty to care especially during public health events. The prioritisation of utility can result in moral distress^f to both patients and the professionals involved in ethical decisions as some individual patient health outcomes may be poor. The following section on ethical decision making provides some guidance to professionals in navigating these challenging decisions.⁵

ETHICAL DECISION MAKING

The emotional energy, pressure and responsibility associated with caring for individual patients, maintaining collective public health, and caring for self and family during a public health event makes for challenging decisions on the part of pharmacy professionals. With use, the VBDM process provides a familiar thought process that focuses on a best possible outcome.¹ During public health events, when ethical decisions abound, using VBDM to apply ethical values and principles can help guide the decisions of pharmacists, pharmacy technicians, and their teams.

Pharmacy professionals may worry about being penalized for less-than-ideal outcomes resulting from their decisions. Pharmacy professionals are reassured that any decision called into question will be evaluated based on the circumstances and information available at the time of the decision and not with the benefit of hindsight.¹⁰ Decisions during a public health event must be based on pure motivations for the good of society. They should be reasoned and informed by the best available evidence and information at the time. It is conceivable that in order to achieve the best outcome for the greatest number of patients, a departure from strict legal requirements might be justifiable. Pharmacy professionals should use the VBDM process as a tool for reasonable, justifiable decisions, especially during public health events. VBDM can effectively communicate facts and possible options with peers and authorities regarding an ethical

^f Moral distress occurs when a clinician makes a moral judgment about a case in which he or she is involved and an external constraint makes it difficult or impossible to act on that judgment, resulting in “painful feelings and/or psychological disequilibrium”¹²

dilemma.⁵ Collaborative discussion and decision-making with experienced peers, authorities, and patients spreads the responsibility and can lessen moral distress^f associated with making difficult ethical decisions.

Upon deciding on a course of action, the professional must make a brief record of the plan that includes justification for the decision and any circumstances that influenced the decision.⁶ This documentation should be retained as a part of the patient record.

After determining a decision using the VBDM framework, the action must be carried out in the correct way. It must be carried out in the correct manner, at the correct time, with the correct people and for the correct reasons.¹ The decision should be evaluated at a later point in time to understand if it continues to be the best decision given that circumstances rapidly change in times of public health event.

There is an ethical case work-up using VBDM appended to this Commentary.

CONCLUSION

Ethically-sound decision-making during a public health event necessitates prioritising the interests of the greater public over that of individual patients. The bioethical principle of utility generally prevails above other bioethical principles during times of public health events.⁷ The VBDM process allows practitioners to apply a systematic approach, considering all factors and interests before deciding on a justifiable course of action.

CITATIONS

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FR: http://www.health.gov.on.ca/fr/pro/programs/drugs/supply/docs/ethical_framework_f.pdf

12. Perni S. Moral Distress: A Call to Action [Internet]. Journal of Ethics | American Medical Association. American Medical Association; 2017 [cited 2020May15]. Available from: <https://journalofethics.ama-assn.org/article/moral-distress-call-action/2017-06>

RECOMMENDED READINGS

- Ethical Framework for Resource Allocation During the Drug Supply Shortage
EN:
http://www.health.gov.on.ca/en/pro/programs/drugs/supply/docs/ethical_framework.pdf
FR:
http://www.health.gov.on.ca/fr/pro/programs/drugs/supply/docs/ethical_framework_f.pdf
- Stand on Guard for Thee: Ethical considerations in preparedness planning for pandemic influenza
http://icb.utoronto.ca/people/documents/upshur_stand_guard.pdf
- Royal Pharmaceutical Society guidance on ethical, professional decision making in the COVID-19 Pandemic
<https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Coronavirus/00239%20001a%202004%20COVID19%20Ethical%20guide%20document%20WEB.pdf?ver=2020-04-09-111739-353>

VBDM CASE

Context: Sara is a 68-year-old community pharmacist practicing in a small New Brunswick town. The date is March 22, 2020. The government has declared a public health emergency due to the COVID-19 pandemic. Residents of New Brunswick may only leave their home for essential needs. The pharmacy has 50 sets of PPE (surgical masks and hand sanitizer). This is sufficient to provide 10 close (non-aerosol generating) patient encounters per week for the next 5 weeks. The manager has called a staff meeting for later that evening to discuss ongoing pandemic planning.

Narrative: Sara gets a call from one of her patients, a 16-year-old female named JW wanting an appointment to get her final dose of HPV vaccine. JW told Sara before her receiving her first dose of vaccine that she is sexually active. She received the first dose of HPV vaccine on March 30, 2019 and her second dose on May 31, 2019. She had no complications or adverse reactions to the previous 2 doses, other than minor arm soreness for 2 days. Prior to receiving her first dose on March 30, 2019 JW had never had an HPV vaccine. JW is anxious on the telephone. She wants to make sure that she gets the vaccine as soon as possible because she read on the internet that you should get all three shots within one year of receiving the first dose. The HPV vaccine that she received was Gardasil-9 and the ideal dosing schedule is 0, 2 and 6 months. JW insists on coming in today to get the third dose. Sara is unsure given the pandemic-associated restrictions if JW should come in. She attempts to call JW's family physician to confer however, the family physician's office is closed and not accepting messages. What should Sara do?

Values-Based Decision-Making Process	
Step 1	<p>Establish the facts</p> <ul style="list-style-type: none">• JW is 16-year-old sexually active female.• JW received her first HPV vaccine March 30, 2019 and the second dose May 31, 2019.• Gardasil-9 vaccine-3 doses must be given within one year (according to product monograph in the CPS). The one-year timeline is coming up in a week.• JW therefore should receive the last dose before March 30, 2020.• No other non-injectable replacement exists.• Since JW has not received a HPV vaccine before receiving Gardasil, a 3 dose series is recommended for her (Lexicomp).• JW cannot inject it herself.• It is unknown if JW's family physician is open this week and could administer the vaccine. Similar issues with potential transmission of the COVID-19 virus exist in visiting the family physician, as vaccine would have to be dispensed and transferred to physician's office.• Sara (pharmacist) is 68 years old. This places her at higher risk of COVID-19 associated risk of morbidity and mortality.

	<ul style="list-style-type: none"> • Sara does have PPE and it is reserved for essential services. • Sara is familiar and able to appropriately use PPE. • Department of Health has decreed only essential health services should be occurring. • The vaccine is in stock and is not in short supply (stewardship not an issue). • JW’s issue does not warrant a visit to the Emergency Room as this is not an emergent issue and it would be an unnecessary drain on resources.
Step 2	<p>Ensure (to the extent possible) that everyone agrees on the facts</p> <ul style="list-style-type: none"> • Pharmacotherapy: The vaccine is due. There is no good efficacy data for extending the schedule beyond the 12-month period. This is not (currently) in dispute. • Public Health (assuming) and Sara agree that injections should not be provided without adequate PPE because they require ‘close’ contact with the patient. Therefore, PPE will be required. • Given her age, Sara is at increased risk if she contracts COVID-19 (research finding). • PPE, if used properly will substantially lower the risk of contraction (research finding). • Public Health, Sara and JW all understand that leaving home may present risk to JW and the community if COVID-19 is transmitted.
Step 3	<p>Identify the conflicting or competing values of the parties involved</p> <ul style="list-style-type: none"> • The patient values getting the injection today to be protected from HPV-associated cancers (beneficence). • Sara and JW should be concerned about JW being unnecessarily exposed to COVID-19 (non-maleficence) in visiting the pharmacy. • Sara has a concern that JW could have an adverse reaction to the vaccine causing a hospital visit (non-maleficence). This would add stress to an already strained healthcare system during a pandemic (stewardship of hospital resources). • Sara and her colleagues are concerned about unnecessary use of scarce PPE resources (stewardship of supplies). • Public Health values prevention of transmission of COVID-19 (utility).
Step 4	<p>Prioritize the core value of promoting and protecting the public interest (utility)</p> <ul style="list-style-type: none"> • There are many of the bioethical principles in play here. Beneficence (through the protection a vaccine provides) vs. Non maleficence (avoid harm to the patient either from a potential ADR or contracting virus while out in public) vs. Utility (to protect the public by adhering to Public Health directives regarding physical distancing) vs. self-interest (the pharmacist is worried that she may contract COVID-19 if JW comes in). • The priority here is to uphold the collective health of the community (utility). JW’s injection is not deemed an essential service today as the schedule for the third injection indicates the vaccine is required by March 30,2020.

	<ul style="list-style-type: none"> • The use of precious PPE for this non-urgent injection may place someone who has urgent need of close-contact care in danger of not receiving care (utility). • In addition, there may be COVID-19 transmission risk to Sara and potential life-threatening outcome of transmission to her. The community could also suffer if her services were no longer available.
Step 5	<p>Make a decision</p> <ul style="list-style-type: none"> • Defer JW’s vaccine administration given the risks to JW, the community and Sara. • Manage JW’s expectations. Explain to her that she is not late for her vaccine at this point and that a plan will be made for her to receive it when it is appropriate (see below for documentation of decision and communication) and safe. • Recognize that another decision will be required within the week regarding JW’s final dose of vaccine.

As discussed in the preceding Commentary, once a decision is made it must be carried out in the correct manner, at the correct time, with the correct people and for the correct reasons. Sara should be transparent in her explanation to JW about current COVID-19 restrictions (remaining at home unless absolutely necessary to be out and only essential medical services being provided at this time) according to Public Health and the necessary injection protocols involving PPE and its rationing. The conversation should happen between Sara and JW. Further, this decision applies for now but will be re-evaluated within days given that factors rapidly change during a public health event.

Documentation Sample:

March 22, 2020

JW called to receive her third dose of HPV vaccine. She believed that she needed to receive her third dose soon as it had been almost a year since she got her first dose. She received her first dose on March 30, 2019 and her second dose on May 31, 2019. All three doses must be given within one year (CPS) so she needs to receive her third dose within the next week. Currently we are experiencing the COVID-19 pandemic and Public Health directs that only essential medical services should be occurring; people only may leave home for essential services and we are having to ration PPE in the pharmacy. I deem this vaccine to not be essential today as she needs to get all three doses within one year and that deadline will be in one week. I called the patient and reviewed the Public Health guidance and the PPE requirements and rationing. The patient will require reassessment in five to seven days to determine if she can receive the vaccine. Further research to be done on efficacy of receiving only two doses or a late third dose in the event this vaccine may not be administered in one week’s time. Staff meeting later today should

include an agenda item on prioritizing the use of PPE for particular purposes. Pharmacists and manager need to triage potential patients for this week that take priority for care requiring PPE.

Sara Brown, RPh

Consider how would your response change if:

1. The injection was for a COVID-19 vaccine?
2. The injection due was a regularly-scheduled antipsychotic and the physician was unavailable to administer it as per usual?
3. Essential healthcare restrictions were lifted?
4. The pharmacist was 34 years of age with no major health concerns?
5. JW was two weeks beyond the one-year limitation and wanted to receive it?