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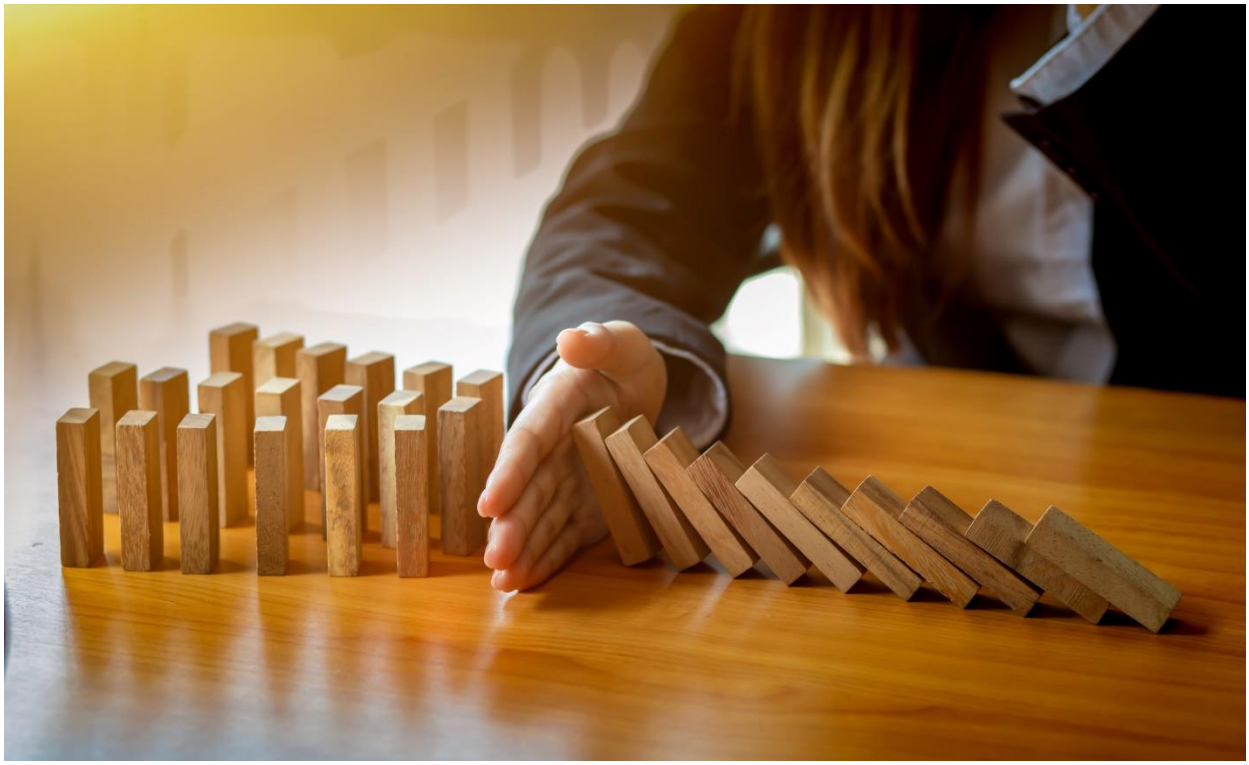
FOCUS ON

Precautionary Principle—Applications Relevant to Public Health Emergency Preparedness



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Introduction

Public health can be disrupted by emergencies or disasters with serious and irreversible impacts on human health. The mandate of public health organizations is to protect and promote the health of populations. While evidence-based decision-making forms the backbone of public health practice in some instances where situations and available evidence are rapidly evolving, measures intended to protect public health may need to be quickly implemented and further refined as evidence evolves over time. In these instances, when there is an absence of evidence on the health risks posed by an emergency or disaster, the precautionary principle can help guide public health decision-making.

The precautionary principle evolved in its definition and application to inform public health decision-making in the context of incomplete knowledge on a public health risk.[1] In public health, the precautionary principle is a type of primary prevention: problems and risks are avoided by not engaging in certain activities until it is certain that the activities will not lead to harm. The principle was first articulated in the context of environmental hazards and is relevant where potentially dangerous effects

are identified and the science does not allow the risk to be determined with certainty. It was first referenced internationally in policymaking in Principle 15 of the United Nations 1992 Conference on Environment and Development in Rio de Janeiro to describe a proactive approach to risk mitigation in the face of serious and irreversible threats to the environment amid scientific uncertainty.[2]

The precautionary principle has been applied in managing environmental health risks (i.e., radiologic/nuclear disasters or chemical spill/contamination) and public health emergencies of infectious origins. A recent example occurred early in the Coronavirus Disease 2019 (COVID-19) pandemic. In March 2020, several international jurisdictions cancelled upcoming mass gatherings due to the emergence of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), amidst scientific uncertainty about SARS-CoV-2 modes of transmission and severity.[3] There was; however, understanding that communicable disease risks are generally increased at large mass gatherings.[4] Similarly, early on in the pandemic period, evidence had not yet been generated on the effectiveness of face masks in the general population; however, several jurisdictions and experts recommended the use of face masks as source control on the basis that most viral respiratory pathogens are primarily transmitted via respiratory particles, and a physical barrier could theoretically limit exposure.[5] Once additional information was available on SARS-CoV-2 transmission, public guidance on physical distancing and the use of face masks was able to be further refined.

Given the scope and diverse applications of the precautionary principle in the context of emerging risks, it is unclear how the precautionary principle has been applied upstream in preparing for a disaster or emergency. This Focus On provides an overview of the precautionary principle. In addition, examples are summarized where the principle has been applied to preparing or planning for emergencies and disasters of both infectious and non-infectious origins that have an impact on human health. Application of the principle that relate to response or recovery phases of an emergency/disaster was out of scope.

Background

Defining the Precautionary Principle

Public health emergency preparedness requires a reflection on values, as scientific information alone does not drive policy and decision-making.[6] In 1992, the United Nations Conference on Environment and Development in Rio de Janeiro offered the first definition of the precautionary principle in relation to policy making. Principle 15 of the Rio Declaration states:[2]

"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."– Principle 15 of the Rio Declaration on Environment and Development of 1992

The Wingspread Statement on the Precautionary Principle offers another definition of the precautionary principle, which was drafted and finalized by experts at the Wingspread Conference on the Precautionary Principle in 1998. While different definitions exist, the Wingspread Statement suggests that the precautionary principle could be summarized as:[7]

"When activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context, the proponent of an activity, rather than the public, should bear the burden of proof. The process of applying the precautionary principle must be open, informed and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action." – Wingspread Statement, 1998

The European Commission published a communication on the precautionary principle detailing when it is appropriate to invoke the principle, and guidance for decision-makers on its use.[8] According to the Commission, the principle may be invoked when a phenomenon, product or process may have a dangerous effect identified through a scientific and objective evaluation, in instances where this evaluation does not allow the risk to be determined with sufficient certainty. The Commission stresses that the precautionary principle may only be invoked in the event of a potential risk to the environment or health and that it should not be used to justify arbitrary decisions.

Applying the Precautionary Principle

The European Commission established guidelines for applying the precautionary principle. This may be necessary when decision-makers are aware of a risk (to the environment or health), where non-action may have serious consequences, and a decision must be made about appropriate action to protect the environment or a population group.[8] The European Commission states that the precautionary principle may only be invoked when the following three preliminary conditions are met:[8]

- Identification of potentially adverse effects
- Evaluation of the scientific data available
- Extent of scientific uncertainty

In addition, actions or measures implemented based on the precautionary principle should follow the general principles of risk management:[8]

- Proportionality between measures and chosen level of protection
- Non-discriminatory application
- Consistency with similar measures implemented in similar situations

- Examination of the potential benefits and costs of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis)
- Measures should be subject to review, in light of new scientific data

Risk reduction activities should account for negative effects that occur in the future. The European Commission's Communication states that the evaluation of the risks/benefits that occurs within risk reduction activities must give public health a greater weighting than the economy: "The Commission affirms, in accordance with the case law of the Court that requirements linked to the protection of public health should undoubtedly be given greater weight that economic considerations".[8]

To help understand the role of the precautionary principle in disaster and emergency preparedness (rather than response), this Focus On summarizes examples of the application of the precautionary principle to planning and preparedness activities for disasters or emergencies. The disasters and emergencies described are limited to those related to public and/or population health.

Methods

Public Health Ontario (PHO) Library Services conducted a literature search on January 21, 2022 in several databases (i.e., MEDLINE, Scopus, Business Continuity and Disaster Recovery Reference Center and the National Institute of Health COVID-19 Portfolio for pre-prints) for English-language articles on the applications of the precautionary principle in disaster planning scenarios published between 2000 and 2022. The full search strategy is available upon request.

In addition to the PHO Library Services search, a grey literature search was conducted on February 3, 2022 using key word searches in Google Custom Search engines and websites of key organizations. This grey literature search aimed to document applications of the precautionary principle in preparation for an infectious or non-infectious disaster.

Records were included if they described applications of the precautionary principle in preparation for an infectious or non-infectious emergency that impact human health. Papers were excluded if: the precautionary principle was applied after the emergency/disaster had occurred, if applications were in a non-Organisation for Economic Co-operation and Development (OECD) country, if the article did not apply the precautionary principle, and if the article was a commentary.

Results

The PHO Library Search identified 956 articles in the indexed and pre-print literature, and after screening 18 articles met criteria for inclusion. In addition to the Library search, the grey literature search identified four documents that met criteria for inclusion: one that applied precautionary principles to of pandemic influenza, and three reports that summarized various applications of the principle to health hazards or disasters. Therefore, a total of 22 articles were included in this Focus On that describe the application of precautionary principle in preparation for an infectious or non-infectious emergency that impact human health. Relevant findings from the PHO Library search and grey literature search are summarized below.

Applying the Precautionary Principle to Infectious Diseases

The precautionary principle has been applied to preparedness and planning for several infectious disease emergencies including pandemic influenza, blood-borne infections and blood donation policies, water-borne infections, and zoonotic diseases. In addition, it has been applied to the use of genomics in public health research. There were ten articles that discussed the application of the precautionary principle more specifically to preparedness and planning for emergency/disaster of infectious origins.

PANDEMIC INFLUENZA PLANNING

Three articles discussed the application of the precautionary principle in pandemic influenza planning, one from the Canadian context, one from the United Kingdom (UK), and one from the United States (US).[9-11]

In 2018, the Canadian Pandemic Influenza Preparedness (CPIP) Task Group introduced a risk management approach to decision-making to manage the uncertainties inherent to pandemic influenza preparedness planning.[9] In this context, risk management is a systematic approach to setting the best course of action in an uncertain environment by identifying, assessing, acting on and communicating risks. This approach is supported by the CPIP principles of evidence-based decision-making, proportionality and flexibility, and a precautionary/protective approach in uncertain conditions.[9]

In 2011, the UK Department of Health, Social Services and Public Safety published their *Influenza Pandemic Preparedness Strategy* which describes the Government's strategic approach for responding to an influenza pandemic.[11] The precautionary principle was embedded in the strategy as one of three tenets: precautionary, proportionality and flexibility. The strategy states that the response to any new virus should take into account the risk that it could be severe in nature, cause severe symptoms in individuals and cause disruption to society. The health measures undertaken in the initial response phase should be precautionary in nature, and unless reliable data is available from other countries, the initial presumption should be that the virus will produce symptoms of at least moderate severity.

The precautionary principle has also been used to develop a model for decision-making for the stockpiling of antiviral drugs in preparation for avian influenza in the US. Basili et al. (2013) created a model to help understand what a precautionary approach would suggest with respect to the production and procurement of known antiviral drugs.[10] The model attempts to support national decision-making with respect to determining the probability of efficacy of the drugs and the estimated potential impacts of the avian influenza. The model suggests that it would be appropriate to adopt a strategy involving the diversified stockpiling of both Tamiflu and Relenza (two drugs known to be effective against seasonal influenza) and the continuous monitoring of the avian influenza viruses.[10]

BLOOD DONOR POLICIES

Three articles discussed the application of the precautionary principle to blood donation and blood transfusion policies which restrict people who have human immunodeficiency virus (HIV), hepatitis C (HCV) or variant Creutzfeldt-Jakob disease (vCJD) from donating blood.[12-14] As a result of previous scientific uncertainty around the transfusion transmission potential of HCV and HIV and a perceived failure in existing risk management strategies, national blood systems have moved toward applying precautionary decision-making standards for matters pertaining to the safety of the blood supply.

EBOLA WASTEWATER MANAGEMENT

Practices related to wastewater management to prevent the transmission of Ebola have incorporated precautionary approaches.[15] Despite a lack of strong evidence for transmission via wastewater, a precautionary approach has been adopted for wastewater handling recommendations to recognize uncertainty in this area by recommending the disinfection of latrines and holding of wastewater prior to handling to allow Ebola virus inactivation. Some wastewater facilities have also opted to provide additional disinfection prior to disposal of liquid waste into sewer systems.

ZOONOTIC DISEASES

Within a "One Health" perspective, the health of animals, humans and the environment are recognized as intertwined.[16] However, precautionary measures to combat zoonotic health problems can lead to moral dilemmas within the One Health framework. Van Herten and Bovenkerk (2021) propose a "precaution-as-prevention" approach to zoonotic disease preparedness, which implies that attention be paid to the underlying human drivers of zoonotic disease outbreaks such as intensified farming or wildlife meat consumption. Additionally, the risk of single zoonotic disease outbreaks cannot be completely eradicated; therefore, it is more effective to examine and address the root causes of zoonotic disease at the system level.[16]

Applying the Precautionary Principle to Non-infectious Health Hazards

The precautionary principle has traditionally been applied in managing environmental threats. Twelve articles discussed topics that included application in EU legislation related to food, nanoparticles, electromagnetic fields, nuclear energy, radiological emergencies, and climate change. The examples below are sourced from the included literature.

ENVIRONMENTAL LEGISLATION AND POLICY

The precautionary principle has influenced EU environmental policies and laws, for example Article 191 of the consolidated version of the Treaty of the Functioning of the EU which states that policies on the environment should be based on the precautionary principle and on principles of preventative action.[8] The multiple case study report by Garnett and Parsons (2017) investigated the application of the precautionary principle in EU legislation and legal decisions. The authors interpreted the strength of the application of the principle by categorizing into three levels: "strong" meaning there are threats of harm to avoid, evidence of safety is required, and banning is likely; "moderate" meaning there are potentially dangerous effects to avoid, more research is required, and banning is possible; and "weak" meaning there are serious and irreversible damage to avoid, full scientific certainty is not necessary, and banning is rare.[17]

Garnett and Parsons (2017) report that overall, the precautionary principle was used to take action under uncertainty to avoid serious or irreversible risks, but was applied inconsistently across the cases in the type of precautionary action.[17] The cases included in their report were focused on the application of the principle to genetically modified organisms (GMOs), pesticide machinery, hazardous substances, food safety, alien aquatic species, offshore safety, and use of food flavourings. Three cases were determined to be a "strong application", another three "moderate application", and two were a "weak application". For example, in the case of GMOs, proof is needed that the products are safe (strong application), while for food flavourings, proof is needed that the products cause harm (weak application).[17]

CLIMATE CHANGE

The health effects of climate change include impacts from extreme weather events (e.g., heatstroke, death), disruption of food systems and worsening air quality.[18] Watson (2015) discussed adaptations of South Australia's planning regime on coastal impacts and how it integrates concepts of ecologically sustainable development (ESD).[19] The concept of ESD invokes the precautionary principle by taking action even when there is a lack of full scientific certainty. However, the South Australian Planning Policy Library does not expressly state the precautionary principle or ESD, only operates as a 'silent' consideration. For new coastal developments, climate change is adopted as an irrefutable fact with guaranteed future impacts; therefore, precautionary measures are assumed to apply. Overall, the precautionary principle is not viewed in isolation, but rather as part of a package in the context of other principles of ecologically sustainable development.

GENETICALLY MODIFIED ORGANISMS (GMO)

The health and environmental benefits and hazards of genetically modified organisms (GMOs) continue to generate debate. GMOs are believed to involve systemic risks to both ecosystems and human health.[20] Ecologically, GMOs present a risk of cross-breeding with other wild-type plans which is associated with unknown disadvantages and harms. With respect to human health, foods derived from GMOs are not tested prior to entering the market for human consumption leading to unknown consequences.[20] Some jurisdictions (i.e., Peru, Germany, and more EU Member States) have adopted the precautionary principle and established moratorium policies banning the cultivation of GMO crops, based on the uncertainty of available science on the effects of GMOs on public health and ecosystems.[21,22]

GENOMICS IN PUBLIC HEALTH RESEARCH

Following an analysis of pandemic influenza legislation in Quebec in 2012, the precautionary principle was identified as a possible justification for government access to and use of genomic databases for public health research.[23] However, Cousineau et al. (2012)'s suggested that government public health powers in Quebec were not well adapted to the expansion of genomics in public health research.[23] The authors suggested that a "strategic" version of the precautionary principle should guide collective choices in genomic matters. This strategic approach is based on the notion that obtaining scientific certainties cannot always be done in time to allow for guidance of collective choices, and its proponents argue that a policy of prevention based on medium and long-term objectives should be adopted. In these situations, attention should shift from advances in the understanding risks, to understanding the evolution of the technological and economic resources available for risk prevention. The strategic approach can legitimate power authorities to use genetic databanks for research purposes and to utilize their findings in the context of public health interventions.

ELECTROMAGNETIC FIELDS

Two articles discussed the application of the precautionary principle on exposure from electromagnetic fields. Kheifets et al. (2001) found the majority of research on adverse effects of electromagnetic fields on human health focused on the association with cancer; however, there were considerable uncertainties in validating those associations because it is difficult to assess exposure, there is a lack of a dose-response relationship, and the possibility of uncontrolled confounding bias.[24]

Since there are clear benefits of electricity and its use is so highly integrated in daily life, governments have responded to the electromagnetic field issue in very different ways. ~~Overall, there are few established standards for electromagnetic field exposure~~. In Canada, Safety Code 6 provides safety limits

for human exposure to radiofrequency electromagnetic fields and is based on Health Canada research and ongoing review of relevant evidence.[25] Other national and international organizations have used the precautionary principle to set local limits or adopt a policy of prudent avoidance.[24]

NANOPARTICLES

Four articles discussed nanoparticles, which are tiny particles between one and 100 nanometres that have novel physiochemical properties that are useful for industrial and biomedical purposes.[26] There is inconclusive evidence on the hazardous human health impacts of exposure (e.g., inhalation is one concern) to nanoparticles due to limited availability of measurement techniques, numerous exposure scenarios, and unforeseen interaction effects.[27] In this uncertain landscape, the precautionary principle has been applied and operationalized to varying degrees across the EU, such as zero exposure for trade union groups in France and the United Kingdom, control banding concept by combining evaluation of hazard with probability of worker exposure, and development of occupational exposure limits (OELs).[26] There are several unofficial OELs that have been developed by national organizations, however, they are not consistent with different limits for the same type of nanoparticles and using different definitions in terms of size range for particles.[26]

The Netherlands Health Council advised that nanoparticles be used in the workplace in the same way as dangerous chemicals.[27] Many documents from the Social and Economic Council of the Netherlands mention the precautionary principle as a guiding principle for decisions concerning exposure to nanoparticles in the workplace. In practice, this usually means keeping the exposure as low as possible. There are several online tools and guidelines that offer strategies for employers to assess and manage the uncertain risk of nanoparticles; the paper by Spruit (2017) goes into more details on two Dutch based guidelines.[27]

The position of European trade unions and environmental nongovernment organizations was to apply the precautionary principle when developing nanotechnologies.[28] This was developed through the structured capacity-building project called NanoCap, which ran from 2006 to 2009.[28] To create an operational and comprehensive approach, the following tools were agreed upon: the "no data, no exposure and no data, no emission" principles, reporting of the content and type of nanoparticles in products, the registration of workers possibly exposed, transparent communication about known and unknown risks, creation of workplace exposure limits, development of an early warning system, and pre-marketing approval for all nanotechnologies and materials.[28]

Groso et al. (2010) in collaboration with stakeholders from the Swiss government, accident insurance, researchers and experts for occupational safety and health, applied the precautionary principle in developing safety procedures in research laboratories that use nanomaterial. The procedures included a decision tree to determine hazard class of nanomaterials and a list of protective measures along with a proposed cleaning management.[29]

NUCLEAR SAFETY AND RADIATION

One article by Yin and Zou (2021) discussed the degree to which the precautionary principle was applied to nuclear safety regulations.[30] In 1992 during the United Nations Conference on Environment and Development, the precautionary principle was more explicitly defined in managing nuclear waste. Since then, the precautionary principle has had increasing awareness in nuclear safety documents during the last few decades. Overall, the authors conclude that the precautionary principle has been implemented in a flexible way in nuclear safety regulation. The principle is embedded in different terms in nuclear safety documents, but not in any legally binding nuclear safety treaties or conventions.

Limitations and Strengths

This Focus On was limited to OECD countries and articles published in English. The precautionary principle appears to be most common in EU legislation and policy, thus, it is possible non-English articles were missed from EU countries that publish in other languages. Furthermore, the addition of a grey literature search may have helped to capture additional applications of the principle that were not summarized in the peer-reviewed literature.

The methods for this document only included a review of indexed and pre-print literature. Two authors completed the screening of peer-reviewed literature and independently double-screened 20% of the records therefore enhancing the reliability of these findings.

Discussion and Implications for Practice

The precautionary principle helps to inform decisions about managing risk and preventing harm to humans and the environment. This Focus On identified a range of circumstances where the precautionary principle has been applied in preparedness or planning policies for several infectious and non-infectious hazards to public health. Specific content areas included pandemic influenza, zoonotic diseases, and Ebola, as well as policies related to food policy, environmental hazards, and climate change.

The available literature summarized in this document highlighted several strengths and limitations to the application of the the precautionary principle in public health emergency preparedness planning. The principle is generally used to inform decision-making when the likelihood and extent of a potential emergency or disaster are not known. However, one critique of the precautionary principle that appeared across several included articles is its vague definition, making it difficult to adopt in practice.[17,30,31] While the EU Commission Communication defined the principle, it has not been consistently applied according to this definition.

The application of the precautionary principle to blood regulation policies highlights the unintended consequences that may arise as a result of the principle's application. The regulation of blood on the basis of the precautionary principle (i.e., regulation with the intent of absolute minimization of risk arising from hazards) led to neither rational identification of hazard nor quantification of risk and in the face of sometimes critical supply issues this restrictive regulation is rarely reversed.[14] These policies have been criticized for creating a form of anchoring bias toward highly risk-averse policies such that even when new evidence arises, the policy is not amended.[14] As a consequence, transfusion medicine has been presented with significant challenges to removing precautionary policies despite strong scientific evidence supporting their reversal.

Regarding a moratorium on GMOs, proponents of a strong application defend the precautionary approach as an effort to prevent possible negative impacts on biodiversity and the health of people consuming genetically modified products. In contrast, those advocating for a relatively relaxed application argue that a moratorium impacts progress and affects the availability of food, especially in developing countries.[22]

Southern Australia has embedded the precautionary principle into coastal climate change flood planning policies. These policies have been criticized by some for being too precautionary due to the fact that South Australia has not yet experienced genuine coastal climate change-related harm.[19] However, others note that the focus of adaptation and protection measures on new developments is likely to be

deemed a reasonable response in devising appropriate coastal planning policies due to the probable balance of coastal harm due to climate change.[19]

In applying the principle to public health emergencies, early stages of the COVID-19 response applied precautionary approaches to keep populations safe as new information about the virus emerged. As new pathogens emerge or variants of existing pathogens emerge, a precautionary approach may be applied using what is known about the pathogen to limit further transmission while awaiting additional evidence to inform decision making (e.g., the use of a ring vaccination strategy in the context of the monkeypox virus[32]). Emergency planning is critical to ensuring that public health and health systems have the tools to mitigate the impact of impending emergencies, disasters or pathogens. Applying lessons learned from the COVID-19 pandemic and other applications of the precautionary principle can support early decision-making for future public health emergencies.

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For Further Information

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Public Health Ontario

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