What Does the Precautionary Principle Mean for Evidence-Based Dentistry?

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The precautionary principle calls for preventive actions in the face of uncertain information about risks. It serves as a compass to better guide more health-protective decisions in the face of complex risks. Applying precaution requires thinking more broadly about risks, taking an interdisciplinary approach to science and policy, and considering a wide range of alternatives to potentially harmful activities. While often criticized as antiscientific, the precautionary principle represents a challenge to scientists and public health professionals to develop newer and more effective tools for characterizing and preventing complex risks, in addition to being more explicit about uncertainties. This article examines the role and application of precaution in the context of dental practice, where activities that may convey risks also have public health benefits, and risk trade offs are a possibility. We conclude that the precautionary principle is not at odds with, but rather complements evidence-based practice in situations of scientific uncertainty and complex risks.

INTRODUCTION

The precautionary principle is increasingly discussed in circumstances where there is some evidence that a particular activity may result in health or ecosystem damage, but great uncertainty as to the potential magnitude or nature of those impacts. It is a controversial principle in that it advocates action despite gaps in scientific knowledge, which some critics view as a challenge to the tenets of "sound science." Yet, with growing understanding about the complexity and interconnectedness of certain types of risks, scientists and policymakers are beginning to realize the limitations of current scientific tools and policy approaches in supporting preventive actions. The precautionary principle is thus becoming all the more relevant to both science and science (or risk) policy.

The case of dentistry presents a unique challenge to the precautionary principle. Dental procedures are meant to improve health and therefore have important benefits. However, there are indications that some dental procedures (and other activities associated with dentistry) may actually cause subtle harm at a population level. These include mercury amalgams (and other amalgam materials), fluoridation, diagnostic x-rays, impacts associated with the lifecycle of materials used in dentistry (latex, tubing, IVs, flame retardants), and dental medicines excreted and released into surface waters. The question is then how to achieve the benefits of dentistry (or any medical intervention for that matter) without the unintended consequences, upholding the medical credo of "first do no harm." Dentists, as health practitioners, have a responsibility to be aware of the adverse affects of their practice on health and environment—both direct and indirect—and to prevent such affects wherever possible while maintaining a high level of care.

This commentary provides an overview of the precautionary principle and its history and components. We discuss the role of precaution in science and evidence-based practice and approaches and tools for applying precaution. We then present 2 case examples of the relevance of precaution in dental practice—fluoridation and mercury amalgams. These case examples are not meant to pronounce judgments on the science or the risks, but rather to provide examples of how one might approach the issue from a precautionary perspective. Finally, we discuss the challenges of applying the precautionary principle in dental practice. We conclude that the precautionary principle provides an important framework for considering the risks posed by dental practices and that such a framework is not at odds with, but rather complements evidence-based practice.

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HISTORY OF PRECAUTION

The concept of the precautionary principle is increasingly being discussed in debates about threats to health and the environment as these threats become more complex, uncertain, and global in nature.[1] The need for precaution arises because the costs of inaction in the face of uncertainty can be high, and paid at the expense of sound public health. If all potential hazards could be quantitatively assessed with minimal error, then it would be relatively easy to base policy decisions on quantitative analyses, and little else. But in a world in which global weather, aquifers, and growing children still hold many mysteries, the best environmental policies need to be informed by the best available science, and guided by a principle erring on the side of caution.

In a broad sense, the precautionary principle is not a new concept. Precaution, like prevention, is firmly rooted in centuries of medical and public health theory and practice. Public health practitioners study the famous story of John Snow, who removed the handle from the Broad Street pump and stopped a cholera epidemic based solely on observation, informed judgment, and an incomplete understanding of the illness. Florence Nightingale, the mother of modern nursing, noted that pure air and pure water—"removing the offensive thing, not its smell"—were critical to a healthy home, although the affects of a particular contaminant were not well known.[2]

ROOTS OF THE PRECAUTIONARY PRINCIPLE

As a principle of environmental and health decision making, the precautionary principle has its roots in the German *Vorsorgeprinzip*. An alternative translation of this word is the "forecaring or foresight principle," which has the advantage of emphasizing anticipatory action, a proactive idea with a connotation slightly different from precaution, which to many sounds reactive and even negative. The *Vorsorgeprinzip* was established to deal with serious emerging, but not proven, risks to ecosystems and health. It is based on the concept that society should seek to avoid environmental damage by careful social planning that can stimulate innovation, job creation, and sustainable development. Over the past 25 years the principle has served as a guiding element in international treaties addressing marine pollution, ozone-depleting chemicals, genetically modified organisms, fisheries, climate change, and sustainable development.[1,3,4]

The 1994 Maastricht Treaty forming the European Union established precaution as a central element of European environmental health policy, and the Rio Declaration of the United Nations Conference on Environment and Development established precaution as a central element of sustainable development.[1] Although not explicitly mentioned, precaution underscores many health and environmental policies passed throughout the world designed to protect health and the environment when knowledge of risks is incomplete. These include policies pertaining to food safety, water and air quality, occupational health, and chemical substitution. For example, drug regulation throughout much of the world is based on the precautionary notion that pharmaceuticals should be demonstrated safe and effective before people are exposed to them, and that manufacturers have a responsibility to act on knowledge of unintended impacts.

DEFINITIONS OF THE PRECAUTIONARY PRINCIPLE

A widely cited definition of the precautionary principle is the 1998 Wingspread Statement on the Precautionary Principle.

> *When an 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.*[1] p. 353

While definitions differ (as is often the case in international policy), they all have similar elements: if there is uncertainty, yet credible scientific evidence or concern of threats to health, precautionary measures should be taken. In other words, preventive action should be taken on early warnings even though the nature and magnitude of the risk are not fully understood.

IMPLEMENTING THE PRECAUTIONARY PRINCIPLE

Implementing the precautionary principle requires new approaches to environmental science and public policy to make them more effective at anticipating risks and promoting cost-effective alternatives to risky activities, products, and processes. An approach for applying the precautionary principle is outlined below.

Shifting the questions asked in environmental and health policy: One fundamental change the precautionary principle encourages is that scientists and policy makers begin to ask a different set of questions about activities and potential hazards as a priority. Instead of asking, "What level of risk is acceptable?" or "How much contamination can a human or ecosystem assimilate before demonstrable harm?" We must ask, "How much contamination can we avoid while still achieving our goals?" "What are the alternatives or opportunities for prevention?" and "Is this activity needed in the first place?"

This shift reorients the focus of policy from analysis of problems to analysis of solutions and establishment of goals. It allows for an examination of a product or activity as a whole and whether its purpose can be served in a less harmful and possibly more effective way.[5] Focusing on seeking safer alternatives may also allow decision-makers to partially bypass contentious and costly debates over proof of harm and causality, and instead dedicate scarce public health resources to solutions.

Shifting presumptions: In addition to switching the questions decision-makers ask about risks, the precautionary principle shifts the presumptions used in decision making. Rather than presume that specific substances or activities are safe until proven dangerous, the precautionary principle establishes a presumption in favor of protecting public and environmental health in the face of uncertain risks. This places the responsibility for developing information, regular monitoring, demonstrating relative safety, analyzing alternatives, and preventing harm on those undertaking potentially harmful activities.

Transparent and inclusive decision-making processes: Decisions under uncertainty are essentially policy decisions, informed by science and values. Thus involving more stakeholders could improve the ability of decision-makers to anticipate and prevent harm. A more democratic decision-making process would allow nonexperts who think more broadly without disciplinary constraints to see problems, issues, and solutions that experts miss. Lay judgments reflect a sensitivity to social and political values and common sense that experts' models often do not acknowledge, and the lay public may have a better capacity than experts alone for accommodating uncertainty and correcting errors. Finally, broader public participation may increase the quality, legitimacy, and accountability of complex decisions.[6,7]

THE WAYS IN WHICH SCIENCE CAN LIMIT PRECAUTIONARY ACTION

There are many ways in which the methods of scientific inquiry can impede precautionary action, making it more difficult for policy makers to take action in the face of uncertainty. If current scientific methods result in an inability to identify early warnings of effects, or hide the great uncertainties involved in characterizing complex risks, then preventive actions can be substantially hindered. Below we examine some of the limitations in current scientific practice that have the potential to work against precautionary policies and actions. Some of these limitations refer to scientific practice itself (the methodologies and tools used), but some are a reflection of the institutional frameworks that use science and place high expectations for science to provide definitive answers before preventive actions can be taken:

- When designing a health study, scientists make concerted efforts to avoid reaching the false conclusions that a hazardous effect exists when in fact it does not. But, an inherent consequence of minimizing this error is increasing the chances of another kind of error: missing a risk that is real.[8]
- Uncertainty is an inevitable aspect of scientific study, yet the formal evaluation of error or uncertainty in many environmental science papers is limited to a presentation of P values or confidence intervals, and any qualitative examination of limitations of the findings is relegated to the discussion section at the end of the paper. Potentially important errors such as those in the independent variables, errors arising from choice of the wrong form for the model(s) used to analyze and interpret the data, biases from problems in the conduct of the study, and "ignorance" (what we do not know) are rarely discussed in research papers.[8,9]
- Scientists tend to study risks from a single disciplinary perspective, even though it might take an interdisciplinary approach to synthesize sufficient evidence to characterize a problem. We know that emerging risks such as those of global climate change and endocrine disruption would never have been recognized without the combined effect of concerns raised from different disciplines.[10,11]
- Scientists tend to devalue qualitative information, viewing it as of lesser quality than quantitative evidence.[9] But in the face of great uncertainty, such information may be the highest quality information on which to base decisions.
- Time and funding constraints of research results in studies limited to quantifiable aspects of problems, like the relationship between diet and obesity, without examining the potentially more important, but more difficult to prove, aspects of disease such as exposure to toxic substances.[8] The attempt to translate problems into manageable research questions means that we may get extremely precise answers to incomplete or incorrect questions—a "Type III" error.[12]
- Scientists have a tendency to refine understanding and increase detail about specific substances or hazards, rather than explore new questions. In these cases, the search for more detailed understanding may be misinterpreted as insufficient knowledge to act and may mask what is already known about a hazard.
- Scientists often focus research on the "average" individual even though there might be individuals or populations at much higher risk due to their higher exposures, genetic susceptibility, or developmental vulnerability, such as children.
- Scientists generally study the direct effects of single exposures rather than cumulative exposures to multiple chemicals and other stressors—our everyday reality.

Unfortunately, the limitations in scientific methods to quantify causal relationships are often misinterpreted as proof of safety. While the fine points of the scientific evidence are debated, often nothing is done about the potential hazards. Biologist John Cairns has noted that scientists and policy makers often discount highly uncertain risks, while concluding that "Unrecognized risks are still risks, uncertain risks are still risks, and denied risks are still risks."[13]

Even when data are available, uncertainties raised about the nuances of the risk can stall action. For example, it took the Occupational Safety and Health Administration nearly a decade to finalize a standard for methylene chloride. Many of those years of debate—over a chemical known to be problematic—were focused on minutiae about how the chemical was transported through the human body and caused its toxic effects (see US Occupational Safety and Health Administration[14]). While these debates occurred, workers continued to be exposed to what has now been deemed a potential carcinogen. This approach to environmental science is not only inefficient, it can be harmful to health and ecosystems. Indeed, if scientific research had been focused on analyzing alternatives to methylene chloride in various industrial operations while *simultaneously* exploring the substance's mechanism of action, these debates over toxicologic mechanism might have been avoided and workers would have been better protected sooner because debates over toxicologic mechanism would not have been the only focus of research.[15]

HOW SCIENCE CAN MORE EFFECTIVELY SUPPORT PRECAUTIONARY POLICIES

The precautionary principle has many implications for environmental science: what we study, how we study it, and how we summarize and communicate results. Environmental science is critical to solving some of our most pressing, uncertain, and complex environmental problems and hence can be very supportive of precautionary policies. As environmental science faces the increasing challenges of more complex risks with greater uncertainty and ignorance, the nexus between science and preventive policy becomes even more important. In this context, we believe that there is no contradiction between good science and precaution. Rather than demanding less science, the precautionary principle demands more rigorous and transparent science that provides insights into how health and ecosystems are disrupted by technologies, identifies and assesses opportunities for prevention and restoration, and makes clear the gaps in our current understanding of risks.[8,16]

A shift to more precautionary policies creates opportunities and challenges for scientists to think differently about the way they conduct studies and communicate results. The 2001 Lowell Statement on Science and the Precautionary Principle, drafted by 85 scientists from 17 countries outlines changes in science and science policy that would more effectively address uncertain, complex risks, including the following[16]:

- A more effective linkage between research on hazards and expanded research on primary prevention, safer technological options, and restoration;
- Increased use of interdisciplinary approaches to science and policy, including better integration of qualitative and quantitative data;
- Innovative research methods for analyzing (1) the cumulative and interactive effects of various hazards to which ecosystems and people are exposed, (2) impacts on populations and systems, and (3) the impacts of hazards on vulnerable subpopulations and disproportionately affected communities;
- Systems for continuous monitoring and surveillance to avoid unintended consequences of actions, and to identify early warnings of risks; and
- More comprehensive techniques for analyzing and communicating potential hazards and uncertainties (what is known, not known, and can be known).

In environmental and health policy there is much discussion about what has been termed "sound science"—a term often used to represent the standard methods of quantitative risk assessment (see *http://www.epa.gov/epahome/research.htm*). A quantitative risk assessment may not be the most appropriate scientific method for uncertain risks because the type of evidence reviewed is too rigid and does not consider that alternative methodologies can shift the very concept of acceptable risk.[5,17] A more precautionary approach should be informed by the most "*appropriate science,*" which can be understood as a framework for choosing methods and tools chosen to fit the nature and complexity of the problem.[18] Critical to this framework is the flexibility to integrate a variety of research methods and data sources into problem evaluation, and an ability to consult many constituencies to understand the diversity of views on a problem and seek input on alternative solutions. Complex environmental problems that arise in poorly understood systems also require new approaches to examining evidence as a whole rather than its separate parts. Appropriate science is solutions-based, focused on broadly understanding risks, but also on finding ways to prevent their inception. With this approach, the limitations of science to fully characterize complex risks are openly acknowledged, making it harder to use incomplete knowledge to justify preventive actions.

Sir Bradford Hill, the often misquoted father of modern epidemiology, recognized the need to act on the basis of limited scientific knowledge, informed judgment and common sense when he said "All scientific work is incomplete—whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have or to postpone the action that it appears to demand at a given time."[19] p. 299 The critical question for decision-makers under an appropriate science and precautionary approach (and in environmental and health policy in general) is not causality but rather whether there is enough evidence to act to prevent a particular risk. In this respect environmental science, being an applied science, serves the purpose of informing policy, of helping decision-makers understand when and if there is enough evidence to act. When there is enough evidence to act depends on the nature of the problem and is a function of the following:

- The available knowledge and accumulated understanding;
- The complexity, magnitude, and uncertainty of the risk;
- The presence of high-risk populations;
- The availability of options to prevent the risk;
- The potential implications of not acting to prevent the risk; and
- Social and public values.

PRECAUTION AND EVIDENCE-BASED PRACTICE

One could argue that acting in the face of uncertainty is at odds with the tenets of evidence-based practice. The goals of evidence-based practice are laudable—a systematic and scientific approach to the evaluation of medical interventions. Within this framework, the Random Clinical Trial (RCT) is viewed as the "gold standard" of evidence practice.[20,21] The

RCT may be appropriate in examining interventions that are controllable, at the individual level, and with linear, short causal chains. However, such studies become problematic when dealing with population-based interventions (communities, workplaces), where causal chains are complex and there is high variability from one population to another (resulting in heterogeneity in studies), and where an intervention in one setting may be ineffective in another. Further, the nearly exclusive reliance on quantitative data may exclude other important types of qualitative information and judgment. Victoria et al[21] note that the reliance on RCTs as the gold standard of evidence "may limit the knowledge base needed to make sound decisions about public health priorities and policies." p. 404

Clearly, precautionary decisions should be based on the best available evidence, but that evidence should be drawn from the widest array of research methods, including qualitative ones such as Community Based Participatory Research.[22] Slavin[23] has proposed the idea of "Best Evidence Synthesis" whereby the "gold standard" of evidence varies by the details and type of problem being studied. It combines the quantification of traditional methods with a detailed analysis of study characteristics and critical issues of studies. A precautionary approach encourages scientists to examine the whole of the evidence regarding risks and prevention opportunities as well as individual studies and pieces of that evidence base. Tools, such as research synthesis, are needed to enable scientists to combine studies from disparate disciplines and methodologies to form a coherent understanding of a particular risk or intervention.[24]

TOOLS FOR APPLYING PRECAUTION

Applying the precautionary principle should be considered a continuous process of seeking out economically sustainable means to reduce public health impacts. This includes (1) reducing and eliminating exposures to potentially harmful substances, activities, and other conditions; (2) redesigning production processes, products, and human activities to minimize risk creation; (3) establishing goals for restoring human and ecosystem health; and (4) a research agenda designed to provide "early warnings" to make possible rapid interventions to prevent damage to health and to understand potential unintended consequences of activities. Precautionary decisions should be preventive and should not simply transfer risks from humans to ecosystems, from workers to consumers, and so on. This then involves shifting attention upstream in the chain of health determinants (the "root" causes rather than simply the "proximate" ones).

By itself, the precautionary principle provides little guidance as to how to evaluate problems and solutions and how decisions should be made. There is no "recipe" for precaution or prevention, but a heuristic—a process flow that guides sound decision-making process is useful. Such an approach[25] allows for learning based on accumulated knowledge and understanding as well as flexibility to adapt decisions to the specific nature of an environmental health problem and change course as new evidence and understanding arise (a Bayesian-influenced approach[26]).

Precautionary actions can range from informing the public about risks and uncertainties while further study is undertaken to characterize them, to phasing out activities that have been found to be particularly harmful. Some policy tools for implementing a precautionary approach to public health include the following:

- Goal-setting. Foresight involves the establishment of long-term goals for protection of health, a practice that is fairly common in public health, as seen in the smallpox eradication campaign, the US Public Health Service Healthy People 2010, and smoking-cessation programs. Goal setting focuses not on what futures are likely to happen but rather with how desirable futures can be obtained.[27] Once established, goals help to focus attention on the development of policies and measures to achieve goals while minimizing social disruption and unintended consequences (also known as "backcasting"). The Scandinavian countries have pioneered goal setting for environmental health by focusing on goals for reductions in hazardous substances and activities and establishment of "red flags," deterrent signals as to which activities might harm health.
- Clean production and pollution prevention. Clean production and pollution prevention involve changes to production systems and products to reduce pollution at the source (in the production process or product development stage). This includes reducing raw material, energy, and natural resource inputs, as well as reducing the quantity and harmful characteristics of toxic substances used in production systems and products.[28,29] It involves understanding the purpose of a potentially harmful substance or material and whether its function or "service" can be provided in a less potentially damaging way (ie pesticides control pests, solvents clean surfaces). Massachusetts embodied a precautionary approach in its Toxics Use Reduction program, which has led to a 75% reduction in chemical emissions and a 57% reduction in chemical waste, while saving industry more than $15 million (see *www.turi.org*).
- Methods for measuring and understanding impacts on health and ecosystems. Decisions made under the precautionary principle should not be considered permanent but rather part of a continuous process of increasing understanding of human impacts on health and the environment. The realization that what cannot be measured cannot be managed is critical for applying the precautionary principle. Progress toward more sustainable forms of production and living requires indicators and metrics. Such metrics provide important information in understanding the improvements or declines in the health status of the population, the impacts of activities, including precautionary actions, as well as to provide early warnings

of potential harm. They can also stimulate continuous improvement in environmental performance and technological innovation. Surveillance has long been a critical part of public health. Recent initiatives such as the Pew-sponsored Health Tracking[30] and Institute of Medicine discussions on health indicators will help augment the ability of public health professionals to track environmentally related chronic illness.

CASE EXAMPLES OF PRECAUTION AND DENTISTRY

To illustrate some of the considerations necessary under a more precautionary approach to science and policy, we present 2 case examples of environmental and health hazards that have been discussed with respect to the practice of dentistry: those of fluoride and mercury.

Fluoride

Fluoride has been added to drinking water the United State since 1945 for the exclusive purpose of preventing dental cavities.[31] One could argue that it is the most widely used medicine in history. Since its inception, water fluoridation has been promoted as a "safe and effective way of preventing tooth decay,"[32] and the Centers for Disease Control and Prevention (CDC) now calls fluoridation "one of the great public health successes of the 20th century."[33] However, some studies have raised concerns about the safety and efficacy of the practice.[34,35] Some issues that make fluoridation ripe for applying a precautionary approach include the following:

- Consideration of efficacy and benefits. A precautionary approach calls on us to understand what benefits the activity (fluoridation) provides to health and whether those benefits (or the "function of fluoride"—reducing cavities) can be achieved through less potentially harmful means (for example campaigns to improve dental hygiene, topical fluoridation, dietary interventions, etc.). While there are many peer-reviewed studies supporting the efficacy of fluoridation, there are also many reputable sources questioning it.[36] The National Institute of Dental Research, for instance, conducted the largest study of its kind in 1989 and found that there was little difference in the incidence of cavities between children receiving fluoride and those who were not.[37] Further, studies have shown that the incidence of cavities has fallen throughout the western industrialized world regardless of fluoride use.[38-40] Studies indicate that fluoride does not help to prevent pit and fissure decay, which is estimated to cause more than 85% of tooth decay in the United States,[41] nor baby bottle tooth decay, which is prevalent in poor communities.[42] Also, there is increasing evidence that fluoride provides its protective benefits through topical exposures, rather than by ingestion.[43]
- Broader consideration about hazards and cumulative exposures. Given the widespread use of fluoride, a second question that must be asked is: What does the whole of the evidence tell us about fluoride exposures, hazards, and risks? While limited, studies indicate an association between long-term, low-dose exposure to fluoride and increased incidence of hip fractures. They further indicate an association between elevated fluoride exposure in children and decreased IQs.[44] Similar animal studies investigating the health effects of fluoride have shown increased hyperactivity, effects on the central nervous system, damage to the brain, confusion, and drowsiness.[45] One study found that boys who drank water with 30% to 99% of the fluoride levels recommended by CDC increased their risk of osteosarcoma by 5 times.[46]

The American Dental Association (ADA) maintains that fluoride levels administered in water are closely monitored to ensure the safe, "optimal" level of fluoride to prevent decay.[47] However this claim is problematic since it does not consider cumulative exposures from many other sources, (toothpaste, pesticide residues on foods, mechanically deboned meat, and many processed foods and beverages made with fluoridated water). The result is a total exposure level that can, in some cases, equal this "optimal" fluoridation level without ever consuming treated water. Despite these additional sources of fluoride exposure, the amount added to drinking water continues at the same level as was established in the 1940s.

In the face of uncertain evidence it is important to act in a manner that protects public health. A precautionary approach to fluoridation would consider all the available evidence on efficacy, safety, and alternatives. Given the temporal (throughout a lifetime) and spatial (broad population exposure) exposure to fluoride in drinking water, a more detailed analysis of potential impacts, including population variability and identification of potentially vulnerable populations would be prudent under a precautionary framework. Given the potential magnitude and scale of impacts, if they were real, one might accept a lower level of proof before taking preventive actions. Such actions could include a detailed analysis of whether cost-effective alternatives to achieve the function of fluoride exist (reducing cavities). Given the uncertainties and broad population exposure, dialogue with affected communities or their representatives would also allow a more thorough weighing of risks, benefits, and alternatives.

Mercury Amalgams

The use of mercury amalgams has been supported as a safe option for tooth restoration because the mercury contained in the mixture chemically bonds with other metals to make it stable and appropriate for use in the mouth. Amalgams, according to the ADA, have been used in dentistry for over a century without evidence connecting them to any medical condition.[48] The ADA statement on amalgams notes that "no controlled studies have been published demonstrating systemic adverse effects from amalgam restorations … the small amount of mercury released from amalgam restorations, especially during placement and removal, has not been shown to cause any … adverse health effects."[49]

In contrast to this statement, the US Public Health Service concluded in 1995 that there is no safe level for mercury exposure.[50] Given that mercury has been associated with neurological disorders, learning disabilities,[51] and impairment,[52] and recent implications that it may be a factor in Alzheimer's disease,[53] it is important to take a broad look at the evidence on risk and alternatives that could serve in fillings as part of a precautionary approach.

Evidence of risks The Swedish Dental Material Commission published a report in 2003 that included an overview of scientific literature relating to the health hazards of amalgams published over the 5 previous years. Cited studies suggest possible negative health impacts of amalgams, including one study recording levels of mercury released from amalgams to be at or above levels known to cause symptoms of kidney, central nervous system, and immune system impairment, as well as hazards to fetal development. The report concluded that amalgams can produce negative health consequences in sensitive populations and that alternative materials should be used whenever possible.[54] Further, the Swedish Chemicals Inspectorate (KemI) published a report recommending that, given the known toxicity of the metal and that viable alternative filling materials exist, the use of mercury amalgams be banned, apart from exceptional circumstances.[55]

Studies have indicated that mercury vapors continue to be released from amalgam fillings after being set,[56] and that the amount of vapor released into the mouth was between 30 and 100 times higher than the maximum allowable concentration for air quality set by EPA.[57-61] These vapors are inhaled, absorbed by the lungs into the bloodstream, and circulated throughout the body[62] to collect primarily in the kidneys, brain, and liver.[63] In the past 10 years research has shown that the amount of mercury released is more than previously believed, and that amalgams contribute to a person's overall exposure to mercury.[64]

In addition to possible implications to human health, a study conducted in Finland showed that the probability of exceeding the allowable limits of mercury in wastewater doubled with every 10 additional amalgam-filled tooth surfaces and that the use of amalgams in heavily populated areas can damage surrounding ecosystems with mercury pollution.[65] The potential danger from mercury amalgams is 2-fold, then, as the population is exposed once directly when teeth are filled, and a second time, indirectly, upon ingesting fish or other food sources that became contaminated through mercury in the environment. Due in part to these concerns, the use of amalgams is being discouraged internationally, including efforts to ban their use in Norway[66]and Denmark,[67] a New Zealand Ministry of Health recommendation that patients give informed consent of the risks and benefits of amalgam fillings before undergoing the procedure,[68] and a German Health Ministry recommendation that amalgams not be given to women of child-bearing age.[69]

Seeking safer alternatives While taking steps to substitute a potentially harmful substance with safer alternatives is in line with precautionary thinking, it is equally important to be cautious when considering the alternatives to amalgams to ensure they do not present countervailing risks. In 1996 the US National Institute of Dental Research spent $33 million to study the safety of amalgams and their alternatives.[70] These investigations are warranted. One amalgam alternative, Bisphenol-A (BPA), has been shown to have the potential to disrupt endocrine systems and is a possible carcinogen.[71] Glass ionomer, as another example, was found to release fluoride into the mouth while inside the tooth,[72] and some of the cement components used for these fillings were found to be mutagentic.[73] In an effort to protect consumers, the National Institutes of Health (NIH) recommended in 1991 that makers of filling materials include an insert of some type outlining product ingredients and that the Food and Drug Administration (FDA) establish a program to investigate adverse health effects relative to filling materials.[74]

The Norwegian Directorate for Health and Social Welfare published the "National Clinical Guideline for the Use of Dental Filling Materials," which makes practical use of both the precautionary principle and the principle of substitution by suggesting that use of amalgams be phased out in place of emerging alternatives. The guidelines go a step further and mandate that safer materials be used whenever possible. Until phase-out can be achieved, the Directorate advises that dental work not be done during pregnancy, and that the dental community focus on cavity prevention as a practice and use amalgams only as a last choice in filling materials when cavities do occur.[75]

A precautionary approach to mercury amalgams would consider the clear evidence of mercury toxicity, the lifecycle risks of amalgams, and a broad range of alternatives. While the potential health risks from mercury amalgams to healthy adults with fillings is likely low, one must consider the lifecycle of the amalgam, including cumulative exposures and the potential for greater impacts when exposures occur at sensitive times in development—pregnancy, childhood. This case illustrates the challenges of alternatives assessment—in finding those that are both effective and safe—and the trade-offs that are often involved. However, the lack of currently available alternatives should not stall intermediate actions to minimize exposure to mercury.

AVOIDING TRADE-OFFS

Seeking to avoid creating new problems while solving existing ones is an important aspect of the precautionary principle. Goldstein[76] notes how well-intended, precautionary public health interventions can result in serious adverse consequences. Further, a potentially hazardous activity may have important public health benefits, as in the case of pesticide spraying to reduce transmission of a mosquito--borne virus, or even fluoridation or changes in amalgam materials. Unintended consequences are a serious concern in all precautionary public health interventions and should be thoroughly considered. However, concern about these trade-offs should not keep public health practitioners from taking preventive actions in the face of uncertainty.

Not taking action on accumulating knowledge has consequences of its own, as outlined in a detailed report from the European Environment Agency.[77] Rather, trade-offs should be considered in their broadest possible sense. By exploring and implementing a wide range of preventive options (ie, the choice is not just between the use DDT and people dying from malaria), including a broad range of perspectives in decision-making processes, using a multidisciplinary scientific lens and systems perspective to examine risks, and developing methods to monitor public health interventions for signals of problems, such trade-offs can be minimized or avoided.

CONCLUSION—ARE PRECAUTION AND EVIDENCE-BASED PRACTICE AT ODDS?

The idea of precaution is entirely consistent with good science and good public policy. Acknowledging the inherent uncertainty and limitations in our understanding of complex risks challenges us to develop new methods and tools to characterize these threats and focuses our attention on opportunities for prevention and innovation. Precaution acknowledges that public health decisions in the face of great uncertainty should be informed by science but are ultimately political.

Applying precaution in dentistry presents a unique, although not insurmountable challenge to precaution. Dental (and medical and public health) interventions are primarily intended to improve health (benefits which do not normally accrue to an economic entity such as in the case of industrial pollution). However, while the benefits of dental interventions often accrue at the individual level, the possible impacts of these interventions often occur at the population level. Under a more cautious approach, environmental impacts resulting from dental practice should be viewed as similar to adverse drug reactions or even medical errors—they are an unintended, although, in most cases, preventable aspect of practice. As medical providers, dentists have a responsibility to understand and prevent potential unintended impacts of their interventions.

We believe that the precautionary principle can provide an important framework for considering the potential unintended health and environmental impacts of dental practice. Precaution encourages the use of a broad range of tools, evidence, and collaborations to characterize uncertain risks as well as outline uncertainties and that such an examination be integrally linked to examining preventive options. It involves asking new questions about problems—understanding their root causes, the pros and cons of alternative courses of action, and variability and distribution of risks and benefits. Initiatives, such as Health Care Without Harm, demonstrate the viability of this approach (see *www.noharm.org*). Health Care Without Harm is a coalition of 443 organizations representing health professionals, health care providers, and environmental advocates dedicated to reducing "iatrogenic" pollution caused by the health care industry. Through research, outreach, and demonstration projects focused on holistically understanding problems and viable solutions, the initiative has made great strides in substituting the use of mercury, latex, and PVC plastics in hospitals with safer alternatives.

We conclude that precaution and evidence-based practice are complementary. Basing decisions on the best evidence is critical. However, the laudable desire for good evidence to justify public health interventions must be balanced against the necessity of acting to prevent illness and injury, in the face of substantial uncertainties.

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