

The precautionary principle

# The precautionary principle: in action for public health

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## Better health, better environment, better science: better use the precautionary principle

Article 174 of the Amsterdam Treaty of the European Union says “Community policy on the environment [...] shall be based on the precautionary principle”. European law, at its highest level, is explicit and uncompromising. As promotion and protection of human health is one of the key motivations of environmental preservation, the provision of the Treaty is good news for public health too. In fact the importance and relevance of the precautionary principle in the health domain has been attracting growing interest.<sup>1</sup> Ministers of health, together with ministers of environment of the Member States in the World Health Organization (WHO) European Region (52 of them in 2004) declared: “We reaffirm the importance of the precautionary principle as a risk management tool, and we therefore recommend that it should be applied [...]”.<sup>2</sup> These are only two of many acts or laws where the precautionary principle is referred to. So what is this principle and why is it important for public health as well as the environment?

Born in the environmental domain in the 1970s, the precautionary principle gained political profile in the 1980s and 1990s, and has attracted the attention of many involved in matters of environmental protection.<sup>3</sup> Despite its resonance, there is no unanimously agreed definition of the principle. Quite simply, it is usually taken to state that lack of scientific certainty must not be used as a reason to ignore or postpone preventive or remedial action when there are other good reasons to do so, as has happened many times in the past.<sup>4</sup> The prescription to err on the side of caution, the “better safe than sorry” approach, may seem little more than common sense. Indeed it is implied by the principles of clinical medicine, in particular by the principle of non-maleficence, more familiar to the public health profession. The concept of precaution is deeply rooted in the history of public health, and environmental health is no exception. Several established risk factors, such as air, water

and soil contaminants, are known for their adverse effects on human health. The best strategy for dealing with these is prevention, and some prudence in, for example, setting protection standards, as when safe levels are divided by factors of 10 or more to allow for possible inaccuracy in risk estimates. But this is not the crucial area of application of the precautionary principle. Prevention applies to known causes; precaution, strictly speaking, is more relevant for uncertain determinants, complex scenarios, suspected risk factors, unpredictable circumstances.

Caution may be common sense, but such common sense seems to be badly needed, and in big supply, at times when we are faced with increasing complexity and uncertainty, when potential health threats can be far-reaching and irreversible; when technological development and societal organisation evolve fast enough to outpace, in numerous cases, the accumulation of data, knowledge and evidence; when the adverse consequences of policies may be felt at great distances, or by future generations. In areas such as climate change, chemical safety, genetically modified organisms and nanotechnologies, to mention just a few, the potential for health damage is great. The deterioration or loss of life support systems, the persistence of ubiquitous endocrine-disrupting chemicals, the cross-breeding of genetically modified species, the introduction of nanoparticles in human tissues, for example, may be harmful to health through direct but also indirect effects; some of these effects can be difficult to detect and measure, but with serious consequences, perhaps borne by the most vulnerable, or elsewhere, or tomorrow. Pointing out that many of us live longer and better than never before is of limited relevance: we are highly uncertain of what scenarios we might be facing, and we do not know how likely different outcomes are; furthermore, we do not know what these outcomes might be at all. Often, we do not know what we do not know.

The precautionary principle, however, is not only about uncertainty, ignorance and

caution, but also about policy and action. Applying precaution does not result in systematically rejecting new technologies or in a “zero tolerance” attitude. On the contrary, despite the lack of a universally accepted definition, several implications on how to exercise precaution while dealing with uncertainty emerge in several formulations of the precautionary principle and can be seen as its distinctive elements: (1) the principle suggests to adjust the balance of burden of proof from the need to prove that agents or technologies are harmful before they are removed or controlled (an onus usually borne by recipients) to the duty (for the proponents or beneficiaries) to demonstrate that they can be used safely; (2) it stresses the fundamental importance of participation, openness and transparency in decision making under uncertainty, recognising that participatory models of decision-making are an almost inevitable response to high uncertainty and complexity; (3) it recommends that, when faced with a possible threat, alternative courses of action should be considered and explored, preferably before arriving at the awkward evaluation of acceptable levels of risks, where one might have, for example, to assign monetary values to life and death. After all, the precautionary principle was born as the German *Vorsorgeprinzip*—that is, the “fore-sight” principle, a more positive concept than precaution, which emphasises a proactive, anticipatory, imaginative attitude according to which preventing or bypassing exposures and possible adverse effects is preferable to mitigating them or analysing whether they are worth the benefits.

What about scientific evidence? Science has a central role to play to achieve these goals, especially when used critically. Invoking the use of sound science to support decisions is ambiguous: “evidence-based” policy, meant to imply “evidence-determined” decisions, is not a realistic option in modern governance.<sup>5</sup> The direct translation of evidence into wise decisions is, in fact, fraught with difficulties. First, defining and framing the policy question is a social process, not an expert task. Second, the same evidence can have different implications depending on the underlying ethical viewpoint, especially when a utilitarian framework clashes with a deontological one.<sup>6</sup> Third, evidence on the problem may be solid and abundant, while evidence on the solutions (costs and acceptability of policies, for example) may be scant. Fourth, the expert-driven process of identifying optimal decisions in the light of available knowledge is vulnerable to manipulation by vested interests. And so on.

Rather than determining univocally the preferable course of action, available evi-

dence and scientific reasoning must be part of the deliberative process, perhaps on par with the other interests and values at play. The literature on the precautionary principle has paid considerable attention to these questions.<sup>7</sup> For a start, the assumptions and limitations of science must be realised and made explicit. For example, epidemiological enquiry following the Popperian scheme of hypothesis generation and testing typically has high specificity and low sensitivity—that is, false positives are penalised more heavily than false negatives.<sup>8</sup> As taught in textbooks, the recurrent snags of epidemiological studies, such as measurement error, exposure misclassification and many forms of bias, push risk estimates towards the null more often than the other way around; complex questions on broad health determinants are broken down into workable operational research goals—an often necessary reductionist strategy that makes it difficult to re-compose the full picture. These intrinsic characteristics, per se, are not a good reason for rejecting the current scientific paradigm (in the Kuhnian sense), if only because a new paradigm has yet to be articulated. Nonetheless, enhanced methods are needed for knowing, describing and dealing with uncertainty. Innovative tools are desirable for more comprehensive risk assessment and comparison of alternatives, for studying upstream health determinants, multi-causality, complex systems. Thus, precaution requires more and better science. As precaution can also stimulate

technological innovation and create new markets through the development and production of cleaner alternatives, the precautionary principle is best seen as an overarching concept,<sup>9 10</sup> which “has relevance to the whole risk assessment, management and communication process”, as declared by European Ministers in the 4th Ministerial Conference on Environment and Health.<sup>2</sup>

The debate on these themes is instructive, sometime controversial, but fascinating, and has been instrumental for reflecting critically about public health, its environmental determinants, the relevance of scientific evidence and its use in decision-making—generally speaking, about science and society. We hope that the debate continues and involves more people engaged in public health.<sup>11</sup>

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## Webcast: International Forum on Quality and Safety in Health Care

Plenary sessions at this year’s International Forum on Quality and Safety in Health Care were filmed and broadcast live over the internet. The sessions are still available to view free, on demand and at your own convenience at <http://barcelona.bmj.com>. Each session is accompanied by a panel discussion.

The webcast includes the following, in either English or Spanish translation:

- **Donald M Berwick**: Can health care ever be safe?
- **Richard Smith**: What the quality movement can learn from other social movements
- **Lucian Leape and Linda Kenney**: When things go wrong: communicating about adverse events
- **John Prooi and Harry Molendijk**: Partnering for patient safety