The IARC Monographs: a resource for precaution and prevention

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Commentary on the editorial by Martuzzi (see page 569)

In an excellent discussion, Marco Martuzzi describes the precautionary principle as meaning that scientific uncertainty must not be used as a reason to delay taking action.¹ Deeply rooted in the history of public and environmental health, the precautionary principle has been embraced by ministers of health and environment across Europe. Martuzzi asserts that precaution is especially needed in areas fraught with complexity and uncertainty, for threats that may be irreversible or felt across generations, or when technological or societal change outpaces the accumulation of data.

Martuzzi is correct that the role of science is central to the application of the precautionary principle, but "caution" means something different in science. The hypothesis testing at the core of the scientific method tends to avoid false positives and tolerate false negatives. To illustrate, epidemiologists make a strong distinction between the terms "association" and "causal association". The latter is used only when there are studies of high quality and a rigorous examination shows that other factors are unlikely to explain an association.² There are also inherent limitations to what epidemiology is able to study. For example, it is often difficult to attribute causality to a single factor, epidemiology cannot rule out a cancer hazard until more than 20 years of exposure have occurred, and it cannot rule out a 1-in-10 000 risk unless tens of thousands of people have been exposed. A stress on avoiding false positives generally implies an abundance of false negatives.

Given this, is scientific caution antithetical to the precautionary principle? No, because science and risk management operate at different stages. Scientists describe the potential implications and limitations of their data, and risk management officials should be prepared to act on this knowledge, giving appropriate consideration to findings that are plausible but not fully established.

Here the IARC Monographs may provide some instructive lessons. Briefly, the IARC Monographs (named for the cancer research agency of the World Health Organization) are a series of scientific reviews which identify environmental factors that can cause human cancer. The IARC Monographs

are developed by the experts who did the original scientific research, yet they communicate their conclusions in clear terms that can be understood by people outside the field. The epidemiological evidence is characterised using standard descriptors that span a range of levels of evidence:³

- *Sufficient evidence of carcinogenicity*: A causal interpretation is credible, and chance, bias, and confounding could be ruled out with reasonable confidence.
- *Limited evidence of carcinogenicity*: A causal interpretation is credible, but chance, bias, or confounding could not be ruled out with reasonable confidence.
- *Inadequate evidence of carcinogenicity*: The available studies do not permit a conclusion regarding the presence or absence of a causal association.
- *Evidence suggesting lack of carcinogenicity*: Several adequate studies are mutually consistent in not showing a positive association at any level of exposure.

Based on this description of the epidemiological evidence and a parallel description of the experimental evidence, potential cancer hazards are classified into a range of groups:³

- Group 1: The agent is *carcinogenic to humans*.
- Group 2A: The agent is *probably carcinogenic to humans*.
- Group 2B: The agent is *possibly carcinogenic to humans*.
- Group 3: The agent is *not classifiable as to its carcinogenicity to humans*.
- Group 4: The agent is *probably not carcinogenic to humans*.

The IARC evaluations do not build in precaution, rather, they strive for a balanced evaluation of the overall weight of the evidence. The graded nature of the evaluations (*sufficient evidence, limited evidence, ... ; carcinogenic, probably carcinogenic, ...*) communicates the level of credibility of a potential hazard. Precaution does not mean taking *limited evidence* and calling it *sufficient*. Precaution means that risk management officials are prepared to act on less than sufficient evidence when warranted. The scientific evaluation serves to indicate when precaution may be appropriate in risk management.

Martuzzi mentions the difference between prevention, a public health concept that applies to known causes, and precaution, which can be invoked when causes are complex or uncertain or consequences are complex or unpredictable. In this light, a risk management decision to reduce exposure to a Group 1 carcinogen (such as tobacco smoke or asbestos) is preventive, because these are known to cause cancer in humans. On the other hand, a risk management decision to reduce exposure to a Group 3 agent is precautionary (if taken for the purpose of reducing a potential cancer hazard), because the evidence does not yet demonstrate the presence or absence of a cancer hazard. In between, risk management decisions for agents in Groups 2A and 2B have elements of both prevention and precaution, because there is scientific consensus that these agents may pose a cancer hazard to humans, although the evidence is uncertain to some degree.

Martuzzi also stresses that precaution requires more and better science, and that methods of science must continue to evolve. For example, better insight into the molecular process of carcinogenesis may make it possible to identify human carcinogens without waiting years for tumours to develop. One cautionary note: better science often means more complex science, and as complexity increases, the number of scientists who can understand and effectively debate the issues becomes smaller. This makes science increasingly vulnerable to manipulation by vested interests, something Martuzzi warns about. The *Lancet Oncology* recently commented on the measures the IARC takes to avoid manipulation^{4 5} and advised that they could serve as a model for other health agencies.⁶

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