



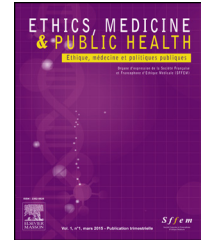
Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.



Available online at
ScienceDirect
www.sciencedirect.com

Elsevier Masson France
EM|consulte
www.em-consulte.com/en



LETTER TO THE EDITOR

COVID-19 and vaccination, or the new misfortunes of the precautionary principle



Keywords Covid-19 pandemic; Precautionary principle; Public confidence

Dear editor,

We have just witnessed a surprising merry-go-round. Whilst the COVID-19 pandemic rages again, intensive care units are filling up to overflowing and we are having to face new variants of the virus, more contagious, a domino effect occurred, with many European countries, suspending one-by-one use of the Astra Zeneca vaccine due to hypothetical adverse effects, before reauthorizing it. The disarray into which this succession of decisions has thrown us is quite vertiginous: we have suddenly found ourselves faced with a “vacuum of thought”, haloed by invocation of a “precautionary principle” [1,2].

Medically, how can we explain such a decision? On the one hand, we had access to a vaccine that had already been approved as safe, and which provided effective protection against COVID-19. On the other, a few cases of thrombosis had been reported among the almost 17 million people vaccinated worldwide, without the establishment of a causal link between these cases and vaccination [3]. Yet, even had this link been demonstrated, would the benefit not have remained infinitely greater than the risk, which is of the order of 1/1,000,000? Even had we detected a hundred, or even a thousand, non-lethal cases, what should the decision have been, given that every day without vaccination is accompanied by 300 deaths [4], even if they occur two to three weeks later? Faced with such a pandemic of a more contagious variant of the virus causing more severe disease, what would the acceptable limit be? Indeed, has the suspension of the vaccination campaign not led to a fringe population being at greater risk of contracting a serious form of COVID-19, amounting to a very real endangering of this group? Clearly, the argument was not based on any medical rationale.

This suspension, we are told, was justified by the “precautionary principle”. In truth, it reveals how problematic the extrapolation of this principle from the domain of the environment to health can be, and it constitutes a real drift away from the original notion, given that there is, in the domain of health, as today for the dispensing of vaccines, a

veritable and reliable evaluation of risks, based on a rational methodology. Indeed, we should remember that this principle was initially developed for application in a very precise area, that of ecology, to allow public decision-makers to suspend the initiation or perpetuation of an activity or product in cases in which there is a risk of serious, irreversible damage to the environment, despite the absence of certainty concerning the real existence of a danger to nature, or the possibility of controlling it.

The basic idea underlying this principle is that there are risks so enormous, threatening, excessive and irreversible for the survival of the human species and for the biosphere in general that not only do they override any benefit-risk ratio, being impossible to calculate rationally, but that waiting for the demonstration of their scientific reality through an evaluation would be a luxury or, even, more than imprudent: a fault. In cases of catastrophe — a perspective that unfolds in the semantic framework of a pandemic — uncertainty becomes “danger”, and it becomes vital to act as quickly as possible. This brings us into line with the thoughts of the German philosopher Hans Jonas [5]. Expressed in his words: in situations of uncertainty or ignorance, we should systematically favor the “bad prognosis over the good”, listen to “prophecies of doom”.

It appears to be this conception of risk that has been transposed to the field of medical activities and techniques, in this case leading to a suspension of vaccination. But are we really dealing with an incommensurable (of the order of 1/1,000,000 and not necessarily lethal) “catastrophic” risk, so excessive that it overrode the nightmare vision of the future already imposed by the framework of the pandemic? For the justification of such a measure, we were not really in the circumstances of the major health scandals of the past, such as “mad cow disease” [6] or the “contaminated blood” scandal [7], both of which have been much discussed in the press. Indeed, what we saw here was that the extrapolation of the precautionary principle to the field of medical activities and techniques led to evaluation — a scientific advance and the only means we have of rationally managing risks — being ignored. We believe that only reason can re-establish public confidence, by providing proof of relative safety, or of the level of public acceptance of a risk associated with the possibility of saving lives.

Human and animal rights

The authors declare that the work described has not involved experimentation on humans or animals.

Informed consent and patient details

The authors declare that the work described does not involve patients or volunteers.

Funding

This work did not receive any grant from funding agencies in the public, commercial, or not-for-profit sectors.

Author contributions

All authors attest that they meet the current International Committee of Medical Journal Editors (ICMJE) criteria for Authorship.

Disclosure of interest

The authors declare that they have no competing interest.

References

- [1] <https://theconversation.com/covid-vaccine-weekly-astrazeneca-is-safe-and-effective-but-facing-supply-issues-157468>.
- [2] https://www.has-sante.fr/jcms/p_3244305/fr/covid-19-la-has-recommande-d-utiliser-le-vaccin-d-astrazeneca-chez-les-55-ans-et-plus.
- [3] https://www.lemonde.fr/idees/article/2021/03/16/astrazeneca-et-le-principe-de-precaution_6073290_3232.html.
- [4] <https://covidtracker.fr/>.
- [5] Jonas H. Le principe responsabilité : une éthique pour la civilisation technologique. Cerf; 1990 [ed 1979].

- [6] https://www.lexpress.fr/actualite/societe/sante/la-crise-de-la-vache-folle_1775435.html.
- [7] https://www.liberation.fr/france/2018/02/07/sang-contamine-que-sont-devenus-les-principaux-acteurs-du-scandale_1628208/.

A. Ivasilevitch^{a,b}, H.-C. Stoeklé^b,
C. Hervé^{b,c,d,e,*}

^a *Laboratory of Business Law and New Technologies (DANTE) (UR4498), Paris-Saclay University (UVSQ), Montigny-Le-Bretonneux, France*

^b *Department of Ethics and Scientific Integrity, Foch Hospital, Suresnes, France*

^c *University of Paris, Paris, France*

^d *International Academy of Medical Ethics and Public Health, University of Paris, Paris, France*

^e *Veterinary Academy of France, Paris, France*

*Corresponding author at: International Academy of Medical Ethics and Public Health, University of Paris, Paris, France.

E-mail address: christian.herve@parisdescartes.fr
(C. Hervé)

Received 23 March 2021;

received in revised form 24 March 2021;

accepted 24 March 2021

Available online 26 March 2021

<https://doi.org/10.1016/j.jemep.2021.100665>

2352-5525/© 2021 Elsevier Masson SAS. All rights reserved.