



UvA-DARE (Digital Academic Repository)

How safe should donor blood be?

Kramer, K.

[Link to publication](#)

Creative Commons License (see <https://creativecommons.org/use-remix/cc-licenses/>):
Other

Citation for published version (APA):
Kramer, K. (2018). *How safe should donor blood be?*.

General rights

It is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), other than for strictly personal, individual use, unless the work is under an open content license (like Creative Commons).

Disclaimer/Complaints regulations

If you believe that digital publication of certain material infringes any of your rights or (privacy) interests, please let the Library know, stating your reasons. In case of a legitimate complaint, the Library will make the material inaccessible and/or remove it from the website. Please Ask the Library: <https://uba.uva.nl/en/contact>, or a letter to: Library of the University of Amsterdam, Secretariat, Singel 425, 1012 WP Amsterdam, The Netherlands. You will be contacted as soon as possible.

Chapter 6:

Interpreting and Applying the Precautionary Principle

Published as:

Kramer K, Zaaijer HL & Verweij MF (2017). Interpreting and Applying the Precautionary Principle: A Response to Open Peer Commentaries on “The Precautionary Principle and the Tolerability of Blood Transfusion Risks, *The American Journal of Bioethics*, 17(4), W4-W6

In our paper “The Precautionary Principle and the Tolerability of Blood Transfusion Risks” we have criticized the idea that the precautionary principle would justify extremely risk averse (or ‘zero-risk’) blood safety policies [1].¹ Such appeals to the precautionary principle ignore the social and economic harms caused by safety policies, or indeed set these aside as irrelevant. While we acknowledged the importance of precaution in blood safety policy-making, we argued that precaution does not imply extreme risk intolerance. Precautions should be consistent, non-counterproductive and proportional, which requires tolerating certain risks. In what follows, we respond to Open Peer Commentaries on our paper and discuss how these contribute to the interpretation of the precautionary principle and its application to blood safety issues.

A main motivation to write our article was the recognition that being committed to the precautionary principle can have (overall) undesirable consequences. Maheshwari and Savić [2] distinguish three ways that following the precautionary principle can be counterproductive in this ‘broad’ sense: (1) when the precautionary principle prescribes precautions with undesirable consequences; (2) when inconsistent recommendations lead to decisional paralysis and decisional paralysis has undesirable consequences; (3) when being committed to the precautionary principle leads to brushing aside other ethical principles and duties. Maheshwari’s distinctions fit well with our account. The constraints we call ‘avoiding counterproductivity’ and ‘consistency’ address the first and second routes to counterproductivity in the broad sense. Furthermore, our account of harm suggests how ethical concerns can be accommodated when applying the precautionary principle, and is thus relevant for avoiding the third route. We argued for applying an inclusive, non-normative notion of harm, but we also stressed that the weighting or balancing of harms should be informed by ethical considerations. Taking precautions makes sense only if the harms prevented are considered more serious than the harms caused by taking precautions. Thus, the precautionary principle cannot replace judging how serious harms are; to the contrary, such judgments are a precondition for applying the precautionary principle. Here it should be recognized that the seriousness of harm may depend on moral features besides the size of impact. Our account does not pretend to offer guidance on which ethical considerations affect

¹ We thank our commentators for their insightful analyses of our target article, and we are grateful to AJOB for providing the opportunity to engage in a constructive discussion on this topic.

the seriousness of harms. We believe that this is context-dependent and should therefore be fleshed out for particular domains of application.

Petrini [3] raises two questions that relate to expanding the application of the precautionary principle from environmental hazards to health hazards. First, should the criteria applied for the protection of human health be the same as those applied for the protection of the environment? Petrini argues that the precautionary principle cannot apply across such disparate domains as marine protection and blood transfusion. These domains differ so vastly that only highly abstract principles could apply universally. Second, is it appropriate to speak of a precautionary ‘principle’? A proper ‘principle’ is absolute and without exceptions, but flexibility is crucial when setting precautionary policies. Saunders’s [4] commentary differs from Petrini’s in interesting respects. Saunders asserts that versions of the precautionary principle do have a common core: if there is evidence of danger, authorities are not obliged to wait for full proof of harm before they may act. This interpretation of the precautionary principle is supposedly valid across the diverse contexts in which it is applied.

We agree with Saunders that there may be accounts of precaution that apply across very diverse contexts, but we share Petrini’s concern that only a very general principle or concept of precaution would qualify. This raises a problem, as general accounts of precaution may be too vague to be action-guiding. Saunders acknowledges that his core principle “neither prescribes nor forbids anything”, as it addresses when authorities *may* act and not when they *must* act. Yet decision-makers must also judge when taking precautions is reasonable or ethically desirable. Capturing the essence of precaution in creeds like ‘it is better to be safe than sorry’ and ‘look before you leap’ faces a similar problem. Although such proverbs may be valid in diverse contexts, their vagueness precludes an effective application to particular cases. Do they require taking every possible precaution against every conceivable risk? Do they allow limiting attention to relatively serious and probable risks?

In our view, it is more important to insist on the precautionary principle’s potential to guide action than on its generality. Moreover, the application of the precautionary principle should be sensitive to domain-specific ethical concerns, including the distribution of risks and ethically relevant features of at-risk populations. (We reject the idea that principles should be absolute or without exception, which excludes sensitivity to context and to the plurality of values at stake.) It thus makes sense to develop versions of the precautionary principle for application in limited domains, such as public health or even the subdomain of blood safety. The suggestion in our article is that action-guiding versions of the precautionary principle can

be developed by specifying a knowledge condition, a harm condition, and a recommended precaution, where acceptable specifications must avoid inconsistency, counterproductivity, and disproportionality.

Wilson and Atkinson [5] agree with our assumption that an account of precaution for blood safety should be action-guiding. The core of their ‘calibrated’ approach is that if there are “more than minimal harms associated with the introduction of precautionary measures”, then “the degree of a precautionary measure needs to balance the competing risks”. Wilson and Atkinson’s advice on how to balance risks is primarily procedural: they suggest taking both public acceptance and expert assessments into account and propose adjusting policies when relevant evidence emerges. As a source of inspiration for which factors to consider in this balancing act, Wilson and Atkinson refer to the Alliance of Blood Operators’ [6] framework.

Arguably, some form of ‘weighting’ or ‘balancing’ competing values is inevitable, but what this means in practice often remains obscure. In our view, consistency, avoiding counterproductivity, and proportionality help to clarify what it means to ‘balance’ risks. These constraints explicate that precautionary policies should not introduce risks that are unacceptable according to the version of the precautionary principle which motivated precautionary action, that bring more harm than the risks averted would, or that could be avoided by taking alternative adequate precautions. Arguably, the concept of risk averseness explains what it means to balance risks in a precautionary fashion. On this concept, avoiding relatively serious risks is more important than avoiding relatively plausible ones (see section three of our target article). But it does not follow that the plausibility of harm should be ignored: as long as seriousness gets most weight, risk averseness is perfectly compatible with giving plausibility some weight too. (See [7] for interesting proposals on how to flesh out this idea.) That said, we repeat that our account does not address what factors determine the seriousness of harms, which must in our view be context-sensitive. We have discussed some ethically relevant features of blood transfusion risks elsewhere [8], but much work in the ethics of blood safety remains to be done.

Stabell [9] observes that an action-guiding account of precaution must define the notion of uncertainty and the related notion of plausibility. Stabell is correct that following the decision-theoretic interpretation of uncertainty – knowing the possible outcomes of alternative decisions but lacking knowledge about their probabilities – leads to inconsistency. If the mere possibility of harm were sufficient to trigger precautionary action, then almost no precaution could be taken consistently. But we disagree with Stabell that this problem surfaces when

opportunity costs are taken into consideration: it is nearly always possible that precautions cause harm, even apart from their opportunity costs. With this more general argument, our article (section three) reached the same conclusion Stabell does: the precautionary principle cannot apply to harms that are merely ‘possible’, but only to sufficiently plausible harms. (Also, we argued that the precautionary principle applies only to relatively serious harms, which means that precautions with plausible but mild opportunity costs can be taken consistently.) We agree that the notion of plausibility requires further clarification, for which Stabell proposes interesting directions. We suggest specifying what makes harms plausible in particular domains of application. For example, factors can be identified that increase the plausibility that some emerging disease is infectious and will strike blood product recipients, including the discovery that the causative micro-organism is blood-borne and that donors can be asymptotically infected. A general account of plausibility may help to clarify when transfusion hazards are plausible, but should be connected to insights that hematology, microbiology, and related disciplines produce and that decision-makers use almost routinely.

Our article illustrated how our approach can be applied to real-life policy-making by discussing the deferral of men who have had sex with men (MSM) as blood donors. This issue is also frequently engaged in the Open Peer Commentaries. Timmermann [10] and Wilson and Atkinson [5] recognize that donor deferral policies can be harmful to health if their being perceived as discriminatory leads to blood shortages. This insight is not new, but our approach allows casting it in a different light: deferral policies that are sufficiently likely to lead to harmful blood shortages may be inconsistent, counterproductive, or disproportionate, in which case the precautionary principle cannot be invoked to support them. This shows that restricting attention to particular types of harm (e.g. transfusion-transmissible infections) at the expense of others (e.g. the availability of blood products in emergencies) misapplies the precautionary principle. Accordingly, the precautionary principle cannot be invoked to brush aside concerns about MSM deferrals, but rather requires frank discussion on how harmful these deferrals are. Without engaging this discussion, our article makes room for critical reflection on MSM deferrals within a precautionary decision-making approach.

Timmermann [10], Vernillo [11], and DeCoster [12] follow this line of thought and broaden the perspective on the harms involved in deferring MSM. Timmermann calls attention to the consequences of eroding MSM’s trust in the healthcare system and of setting barriers to the inclusion of MSM in society. DeCoster discusses how MSM deferrals shape the perception (and self-perception) of LGBTQ community members as unclean, dangerous or otherwise

disvalued. We concur with the legitimacy of these authors' perspectives on this issue. What needs to be discussed is what harms are attributable to MSM deferral policies, how serious those harms are, and how this compares to the hazards avoided by such policies. Rather than misusing the precautionary principle to avoid discussing such issues, policy-makers should explicate how their policies balance different harms. Taking any precaution presumes that the harms introduced are less serious than the hazards plausibly averted, and that less harmful adequate precautions were unavailable. Accountability requires explicating and defending this presumption, for example in public education campaigns, as Timmermann proposes.

Interestingly, none of the commentaries challenges our article's main thesis, namely that opportunity costs can be a legitimate reason to tolerate blood transfusion risks. Yet this idea is controversial in decision-making practice [13]. For example, concern about opportunity costs seems absent in the recent FDA decision to screen all donations for Zika virus [14]. Less expensive safety measures were available, such as screening only in areas where mosquito-to-human transmission occurs or testing blood products for at-risk patients only. On our account, one might judge that the current policy is disproportionate because these alternatives would have been adequate. We acknowledge that such judgements are difficult and controversial. More reflection and public deliberation is needed on when to tolerate transfusion risks, and we hope our work encourages such discussion.

REFERENCES

1. Kramer K, Zaaijer HL, Verweij MF (2017). The precautionary principle and the tolerability of blood transfusion risks. *The American Journal of Bioethics* 17:32-43.
2. Maheswari K, Savić L (2017). Precautionary principle and the problem of counterproductivity. *The American Journal of Bioethics* 17:58-59.
3. Petrini C (2017). Is the “precautionary principle” a principle?. *The American Journal of Bioethics* 17:48-50.
4. Saunders PT (2017). Being clear about the precautionary principle. *The American Journal of Bioethics* 17: 47-48.
5. Wilson K, Atkinson K (2017). Towards NeoPrecaution – a new approach to applying the precautionary principle to public health. *The American Journal of Bioethics* 17:44-46.
6. Alliance of Blood Operators (ABO) (2015). Risk-based decision-making framework for blood safety. Available from: <https://allianceofbloodoperators.org/media/115522/rbdm-framework-2-april-2015-v11-for-website.pdf> (last accessed August 2017).
7. Munthe C (2011). *The price of precaution and the ethics of risk* (eBook). Dordrecht: Springer.
8. Verweij MF, Kramer K (2016). Donor blood screening and moral responsibility: How safe should blood be? *Journal of Medical Ethics*. Published Online First: February 11, 2016.
9. Stabell ED (2017). Constraints on the precautionary principle and the problem of uncertainty. *The American Journal of Bioethics* 17:56-57.
10. Timmermann C (2017). The precautionary principle and the social institution of blood donation. *The American Journal of Bioethics* 17:52-54.
11. Vernillo A (2017). The precautionary petard: Who should tolerate blood transfusion risks? *The American Journal of Bioethics* 17:54-55.
12. DeCoster B (2017). Structural concerns for MSM health in revising the precautionary principle. *The American Journal of Bioethics* 17:50-52.
13. Kramer K, Verweij MF, Zaaijer HL (2015). An inventory of concerns behind blood safety policies in five Western countries. *Transfusion* 55:2816–2825.
14. Food and Drug Administration (FDA) (2016). FDA advises testing for Zika virus in all donated blood and blood components in the US. Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518218.htm> (last accessed August 2017)