



## UvA-DARE (Digital Academic Repository)

### How safe should donor blood be?

Kramer, K.

**Publication date**

2018

**Document Version**

Other version

**License**

Other

[Link to publication](#)

**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 7

### **Are there ethical differences between stopping and not starting blood safety measures?**

*Published as:*

Kramer K, Verweij MF, Zaaijer HL (2017) Are there ethical differences between stopping and not starting blood safety measures? *Vox Sanguinis*, 112, 417–424

## ABSTRACT

Concern with the costs of blood safety is growing, which raises the question whether safety measures that reduce risk only marginally should be discontinued. Withdrawing such safety measures would allow reallocating resources to more efficient health care interventions, but it might raise moral objections.

This paper evaluates two ethical arguments why discontinuing blood safety measures would be more objectionable than not implementing them. The first argument is that whereas withdrawing protective measures *causes* harm to patients, not starting protective measures ‘merely’ *omits to prevent* harm. The second argument is that patients who benefit from protective measures are *historically entitled* to the continuation of those protective measures.

Both arguments are unconvincing. There is only a weak causal connection between removing blood safety measures and harms that transfusion recipients suffer. Moreover, patients are not entitled to the continuation of protective measures that prove very inefficient, unless applying these protective measures rectifies past injustice towards them. Unless stronger ethical objections can be found, blood system operators and regulators should be more willing to withdraw inefficient safety measures.

## 1. INTRODUCTION

Blood services apply donor selection criteria, blood screening tests, and pathogen reduction processes to protect transfusion recipients against transfusion-transmissible infections. Because no safety measure is 100% effective, stacking safety measures is important for blood safety. Still, some safety measures add little safety (for example because other safety measures already minimize the risks they address) and thus offer little ‘value for money’. For example, some blood screening tests are estimated to cost over \$1,000,000 per quality-adjusted life-year (QALY) gained; in the Netherlands and the United States this applies to serological testing for human T-cell lymphotropic virus (HTLV), and to nucleic acid testing (NAT) added to serological testing for HIV, hepatitis C and hepatitis B [1-3]. Such tests are controversial because of their high *opportunity costs*: these tests draw resources away from more efficient medical interventions and thus preclude better public health outcomes elsewhere (especially if low cost-effectiveness is matched by high budget impact) [4, 5].

Since the HIV and hepatitis C crises of the 1980s and ‘90s, efforts to minimize transfusion risks have shown little concern for costs, which has often been defended by appeal to the precautionary principle [6]. In recent years however, concern for the opportunity costs of blood safety measures has increased, culminating in policy-making frameworks in which health economic assessment is a standard step (notably the Alliance of Blood Operators’ ‘risk-based decision-making’ framework) [7, 8]. These frameworks acknowledge the validity of cost concerns in deciding whether to *implement* safety measures. But an important question remains unaddressed: is cost-containment also a valid reason to *discontinue* safety measures?

In practice, blood services are reluctant to discontinue or downscale safety measures with low value for safety but high social or economic costs. For example, while the yield and cost-effectiveness of HIV, hepatitis C, and hepatitis B NAT screening is low in many countries, there seem to be no initiatives to downscale NAT screening. Neither has the questionable relevance of syphilis for contemporary transfusion practice led to relaxed syphilis testing policies [9, 10], or have precautionary deferral policies for donors with Chronic Fatigue Syndrome been recalled after preliminary evidence of transfusion-transmissibility was discredited [11]. Even when safety measures *are* downscaled, the decision-making process and its outcome often portray a very low tolerance for transfusion risks. For example, the permanent rejection of MSM donors has been changed only recently in the Netherlands, the United States and Canada, after sustained public pressure, into temporary deferral that many

still consider unreasonably strict. Likewise, the Netherlands have since July 2013 stopped testing every donation for anti-HTLV, which costed over €40.000.000/QALY gained, but the new policy to test first-time donors still costs over €2.000.000/QALY gained [1, 3].

Discontinuing or downscaling blood safety measures seems even more controversial than not introducing them. For example, U.S. policy-makers opposed relaxing MSM policies if safety would *decrease*, no matter how marginally, but felt no urgency to *increase* safety by switching to 100% supply of single-unit platelets [12]. The asymmetry between stopping and not starting safety measures is stated explicitly in the decision-making rule that “any changes to existing policies (...) must result in an improved or equivalent level of safety by comparison of what now exists” [13: 46, 14]. Taken literally, this rule forbids relaxing safety measures that offer *some* safety, no matter how small, but does not prescribe implementing measures that would improve safety.

Discontinuing safety measures involves particularly challenging issues, including concerns about reputation, liability and compliance with national or international regulations [14, 15]. In addition, decisions to downscale safety measures may evoke stronger negative emotions than decisions not to improve safety, given the general psychological difference between losing and not winning [16]. But how should we evaluate the reluctance to withdraw or relax inefficient safety measures from an *ethical* perspective? Of course, ethical analysis cannot solve all the difficulties surrounding the discontinuation of inefficient blood safety measures. If reputational, legal, and political barriers to withdrawing safety measures persist, no change in policies can be expected. But agreement that there are no ethical differences between stopping and not starting safety measures could be a first step towards more reasonable blood safety policies: it would press us to re-evaluate our legal and regulatory frameworks and to develop communication strategies that minimize political and reputational damage. So far, ethicists and policy-makers have neglected this issue.

The ethical principle of utility, which advocates maximizing well-being in society, arguably supports withdrawing inefficient safety measures. Withdrawing inefficient safety measures allows reallocating funds to more efficient health care interventions, thus securing more health benefits (QALYs) with the same budget [17]. Some arguments against discontinuing inefficient blood safety measures apply equally against not starting them. For example, one might argue that devoting many resources to transfusion recipients is a demand of distributive justice. Theories on distributive justice address what would be an equitable distribution of (health care) resources – for example, ‘prioritarianism’ requires that the worst-off receive the largest shares.

But these theories are silent on *how* everyone should come to have his fair share [18]. Accordingly, stopping a blood safety measure is as just or unjust as not starting it: the end-result is in both cases that resources are not allocated to blood safety but are directed elsewhere. This paper focuses on arguments why discontinuing safety measures would be *more* objectionable than not introducing them.

Can such arguments be offered? Although the decision-making rule that forbids increasing risk but does not prescribe reducing risk is allegedly “supported (...) by important ethical considerations” [13: 53], a clear statement and defence of those considerations seems to be lacking. In the parallel debate on withdrawing and withholding life-sustaining therapies in intensive care units, relevant ethical concerns have been articulated more clearly. This paper applies two main arguments from this debate to blood safety decisions. The first argument is that whereas withdrawing a protective measure *causes* harm to patients, not starting a protective measure ‘merely’ *omits to prevent* harm to them. Because the duty not to cause harm (or the principle of non-maleficence) overrides the duty to prevent harm (or the principle of beneficence), withdrawing protective measures from patients to prevent harm to others would be unacceptable, even if more harm would be prevented than caused. We argue, however, that blood services have only limited causal responsibility for harm patients suffer owing to the withdrawal of blood safety measures. According to the second argument, patients benefiting from protective measures are *historically entitled* to the continuation of those measures. We conclude that transfusion recipients are only entitled to the continuation of inefficient blood safety measures if these transfusion recipients were wronged by historical allocation decisions, and if applying inefficient safety measures can be said to rectify this injustice. Unless stronger support can be offered for the supposed asymmetry between stopping and not starting blood safety measures, the decision-rule that “any changes to existing policies (...) must result in an improved or equivalent level of safety” [13: 46, 14] should be reconsidered.

## **2. FIRST ARGUMENT: “WITHDRAWING SAFETY MEASURES CAUSES HARM, NOT STARTING ALLOWS HARM TO OCCUR”**

The first argument is that withdrawing life-sustaining therapies kills (i.e. *causes* the death of) patients and is therefore inherently objectionable, whereas withholding such therapies ‘merely’ lets patients die [19]. Obviously, withdrawing blood safety measures differs from withdrawing life-sustaining therapies in various respects – for example, transfusion recipients have a

different health status than patients on life-sustaining therapies, they each have only a small chance of suffering harm when protective measures are lifted, and yet they lack reasons to consent with lifting such measures. Nevertheless, the argument that stopping life-sustaining therapy causes the patient's death and is therefore inherently objectionable can be extrapolated to withdrawing blood safety measures: one might argue that withdrawing donor blood safety measures *causes* harm to transfusion recipients, or at least *imposes risks* on them. This would make withdrawing safety measures more objectionable than not implementing them, which would merely *fail to prevent* harm to transfusion recipients by leaving them *exposed* to risks. The argument assumes that transfusion risks will increase (for some patients) when a safety measure is withdrawn, so it does not apply when safety measures add no safety whatsoever. But even if this assumption applies and if one accepts that causing harm is more objectionable than not preventing harm, it remains to be shown that withdrawing a blood safety measure causes and not just fails to prevent harm. Can a criterion be offered on when harm is caused rather than not prevented, and does withdrawing blood safety measures meet this criterion?

Relevant criteria have been proposed in the debate on whether withdrawing life-sustaining therapies kills patients. These criteria are typically based on a counterfactual account of causation: an action causes an event (e.g. someone suffering harm) if that event would not have happened had that action not been performed. Accordingly, causing harm (death or other) by withdrawing some protection requires that the victim would not have suffered that harm had the protection not been withdrawn. Still, additional conditions can be set on how the agent contributes to the fact that the victim suffers harm. A first criterion ('C1', for short) only requires that withdrawing the protection involved acting [20, 21]:

(C1) An agent causes harm to a victim by withdrawing a protection if:

- 1 The agent withdraws a protection by acting
- 2 AND the victim suffers harm
- 3 AND the victim would not have suffered that harm had the agent not withdrawn the protection

The condition that the agent *acts* to withdraw a protection may seem trivial, but it is not. Some protections can be withdrawn by omission (i.e. deliberate inaction) rather than action, in which case C1 implies that the agent does not cause harm to the victim. For example, artificial nutrition can be withdrawn by omitting to replace a depleted dose [22, 23]. Many blood safety measures can in principle be withdrawn similarly. They are typically applied anew for fresh donations: donor eligibility questionnaires must be answered at each visit and most blood tests

are repeated for each donation. These safety measures can thus be discontinued by not applying them to subsequent donations. The high level of automatization in blood services may complicate disrupting safety measures by omission, in particular if safety measures are applied universally rather than selectively. In analogy to stopping artificial nutrition by omission, one option may be to stop restocking testing reagents. One might even stop the replenishment of reagents by omission, namely by not renewing supply contracts when these expire. Of course, such strategies to avoid causal responsibility for harm to transfusion recipients are impractical, and they make sense only insofar as the current argument is taken seriously.

Even if actions are required to withdraw blood safety measures, identifying those actions as *the* cause, rather than just *a* cause, of harm is not straightforward. While one might argue that withdrawing life-sustaining therapy directly effects death [20], withdrawing blood safety measures causes harm only in combination with many other actions: an infected donor must go to a blood service; the blood service must collect his blood; and a physician must administer this blood. Why pick out the withdrawal of safety measures as *the* cause of harm? Doing so assumes that there is something special about withdrawing safety measures, compared to the other necessary causal factors, for example that withdrawing safety is especially problematic from an ethical perspective. But then the claim that withdrawing safety measures causes harm is based on the claim that withdrawing safety measures is ethically unacceptable, rather than the other way around [17].

Anyhow, ethicists agree that C1 does not distinguish between causing and allowing harm in a way that settles any moral issues [20-24]. Whether or not an agent acted to withdraw a protection is insufficient to settle his moral responsibility for the harm victims suffer as a result. In some cases, actively withdrawing a protection may be no worse than omitting to prevent harm. If we want to distinguish impermissibly causing harm from permissibly allowing harm, the agent's causal role in the occurrence of harm should be considered from a broader perspective.

The ethicists McMahan, Foot and McGee argue that it matters whether the agent who withdraws a protection also *provided* that protection [22-24]. If he (or she) did, his withdrawal of the protection merely negates his earlier actions: the net effect of first providing and then withdrawing a protection is equal to not providing it at all. The victim would already have suffered harm had the agent not provided the protection, so it is false that the harm would not have occurred if not for the agent's actions. Viewed from this perspective, a doctor who first

provides and later removes artificial respiration does not cause death but allows the patient's underlying condition to resume its lethal trajectory [22-24]. By lifting a blockade to an ongoing threat (that would already have killed the victim if not for the doctor's actions), the doctor stops preventing death and lets the patient 'die at a delay'. Moreover, as McMahan argues, "if the action is undone by a different person occupying the same role, we regard individual identity as irrelevant" [22: 264, 23]. When an agent withdraws a protection, on this view, it does not matter whether the agent himself had provided the protection or whether his professional predecessor did. But if the agent is neither identical to nor has the professional capacities of the person who provided the protection, which applies for example when someone sneaks into a hospital to remove his enemy's artificial respirator, the agent does cause the victim's death [22, 23].

From an ethical perspective, it may thus matter that blood safety measures are withdrawn by the (official successors of) institutions that decided on their introduction. After withdrawing safety measures, blood system operators and regulators have 'merely' undone their previous actions, for which reason withdrawing blood safety measures can be considered equivalent to never having implemented them at all. This parallels the case of doctors initiating and removing life-sustaining therapies.

One might object here that whereas withdrawing life-sustaining therapies means letting patients die of their underlying conditions, withdrawing blood safety measures means that patients suffer harm caused by the blood service's own actions. After all, these patients would not have been infected had the blood service not supplied infectious donor blood. This objection refers to a second criterion on when withdrawing a safety measure can be taken to cause harm:

(C2) An agent causes harm to a victim by withdrawing a protection if:

- 1 The agent withdraws a protection by acting
- 2 AND the victim suffers harm
- 3 AND the victim would not have suffered that harm had the agent not withdrawn the protection
4. AND the victim would not have suffered that harm had the agents' actions not initiated the threat to the victim.

We have discussed the question whether blood services cause threats to transfusion recipients elsewhere [17]. But while this issue is relevant for the moral acceptability of withdrawing blood safety measures, it is irrelevant for the question whether withdrawing blood safety measures is

*more* objectionable than not implementing them. If the agent's actions initiated the threat to the victim, then the agent causes harm whether he provides and subsequently removes a protection or omits to provide a protection in the first place. In either case, the victim would not have suffered harm if not for the agent's actions.

A final suggestion, again following the ethicist Jeff McMahan [22], builds on the idea that *reinitiating* threats one has averted can be said to kill victims. McMahan offers a case where a mechanic first seals a pipe leaking lethal gasses and then returns to remove the seal. Even though the victims would already be dead if not for the mechanic's previous actions, it seems difficult to deny that he kills the victims. He does not merely allow but causes the victims' deaths, as he actively reinitiates a threat to their lives. Generalizing from this example, a third criterion stipulates that:

(C3) An agent causes harm to a victim by withdrawing a protection if:

- 1 The agent withdraws a protection by acting
- 2 AND the victim suffers harm
- 3 AND the victim would not have suffered that harm had the agent not withdrawn the protection
- 4 AND the protection withdrawn was provided by the agent (or his professional predecessor)
- 5 AND the agent reinitiates the threat to the victim by withdrawing the protection

In a sense, removing safety measures always 'reinitiates' threats, as victims get exposed to threats they were previously shielded from. Presumably, this is psychologically more challenging than not gaining protection from risks one was never protected against. McMahan's example is particular, however, in that the protection removed was 'complete and self-sustaining': no contribution (physical or otherwise) was required to keep it operating [22]. After the seal was installed, the pipe was functioning normally and independently, so removing the seal renewed a threat that had been effectively eliminated. By contrast, life-sustaining therapies do not eliminate the patient's health problems, but merely block their progression into death. Because life-sustaining therapies cannot eliminate the threat to the patient's life in a complete and self-sustaining way, removing such therapies does not reinitiate those threats but ('merely') stops to hold them at bay [22-24].

Removing blood safety measures seems more akin to removing life-sustaining therapies than to removing seals from gas pipes. Blood safety measures must be applied anew for each fresh donation, which each present a new threat to blood product recipients. Although threats found in individual donations are eradicated (and cannot be reinitiated because those donations

are destroyed), preventing the transfusion-transmission of infections through further donations requires the perpetual application of safety measures, which takes effort and consumes resources. Blood safety measures are not ‘complete and self-sustaining’ and can therefore be withdrawn by ceasing contributions to their continuation (which may or may not require acting). Doing so means no longer shielding blood product recipients during new exposures to hazards, but because blood safety measures do not eliminate threats in a complete and self-sustaining way, there is no question of reinitiating threats. (At least not in the sense that removing seals from gas pipes reinitiates threats.) On the argument under consideration, this limits blood services’ causal responsibility for harm that patients may suffer following the withdrawal of safety measures.

To conclude, we have found no strong reasons why withdrawing blood safety measures should be considered *causing* rather than *allowing* harm. Withdrawing blood safety measures need not require acting, and if actions are required, these effect harm only in combination with various other actions. Furthermore, the persons who withdraw blood safety measures merely negate their own actions or those of their professional predecessors. Finally, withdrawing blood safety measures does not reinitiate threats that had been effectively eliminated, but rather stops repetitively shielding blood product recipients during new exposures to hazards. These factors limit blood services’ *causal* responsibility for harms that ensue from withdrawing blood safety measures. Thus, even if we assume that there is something particularly objectionable about causing harm, it does not follow that withdrawing safety measures is ethically unacceptable.

### 3. SECOND ARGUMENT: HISTORICAL ENTITLEMENT TO CONTINUED TREATMENT

Some argue that undergoing treatment entitles patients to continued treatment. The ethicists Sulmasy and Sugarman offer a thought experiment where identical twins, Prima and Secunda, both need artificial respiration [25]. Because only one respirator is available and no medically or morally relevant difference between the twins is found, the doctors toss a coin. Now if Prima wins the toss and artificial respiration is initiated, this fact entitles Prima to continue receiving artificial respiration instead of her sister. Sulmasy and Sugarman support this claim with reference to philosopher Robert Nozick’s entitlement theory [18]. According to this theory, someone is entitled to something he holds if the historical processes through which he

acquired it were just – which includes the ways in which the thing was first appropriated by anyone (*justice in acquisition*), the ways in which it was transferred between persons (*justice in transfer*), and the ways in which injustices with regard to its appropriation or transfer were rectified (*justice in rectification*).

Sulmasy and Sugarman fail to show that withdrawing and withholding therapy are inherently different. Withholding care that someone is entitled to through a just procedure is as illegitimate as withdrawing it [26, 27]. For example, if tossing a coin was just, winning the toss already entitled Prima to receive respiration instead of her sister. What is interesting, though, is the suggestion that past allocation procedures can entitle patients to the continuation of care. Could transfusion recipients claim to be entitled to the continuation of inefficient blood safety measures because these were introduced after just procedures?

What a transfer of holdings entitles the recipient to arguably depends on the (explicit or implicit) presuppositions of the transfer [18]. For example, whereas selling an item confers ownership (and thus certain rights) on the recipient, lending it does not. This explains whether it is legitimate to reclaim or redistribute the item without the beneficiary's consent. To evaluate the argument that transfusion recipients are entitled to continue 'holding' the resources that were allocated to blood safety measures, we thus have to consider the presuppositions under which these resources were 'transferred'. If the presupposition was that blood safety measures would be continued even if they would prove inefficient, transfusion recipients have a strong claim against their withdrawal.

Allocation procedures usually seem to presuppose that reallocating resources is legitimate if the original allocation proves ineffective or very inefficient. For example, there is no legitimate expectation that physicians will continue futile treatments or treatments that deplete scarce resources (such as blood products) for a single patient's benefit [19, 28]. Even though physicians take up a special obligation towards patients they start treating, which may exclude reallocating treatments to prospective patients for whom treatment would be somewhat more beneficial, it does not follow that their patients may expect the unlimited continuation of ineffective or inefficient care. Arguably, this is because continuing very inefficient treatments could make treatment inaccessible for patients with reasonable prospects of benefitting, which would conflict with physicians' obligations towards society at large [19, 29]. Deciding that resources should be reallocated to benefit other patients may be problematic at the bedside, but on a higher policy level (such as hospital or a ministry of health) such decisions are inevitable [30, 31].

There may be different expectations for blood safety. Since the AIDS and hepatitis C crises in the 1980s and 1990s, some blood services have found themselves forced to regain public trust by implementing safety measures aimed at ‘maximum safety’. Their rhetoric frequently suggested that costs are unimportant and, one might argue, have raised the expectation that all safety measures will be continued irrespective of costs. Even so, it does not follow that this expectation is legitimate, and hence that blood recipients are entitled to continuation of these safety measures. To the contrary, given that health care funds are public resources, on which every citizen who needs health care has some claim, the number of people benefitted is always relevant (albeit not necessarily decisive). Because interventions may prove beneficial to fewer citizens than expected, the allocation of health care funds cannot reasonably exclude the possibility of reallocation.

Thus far, we have considered whether blood product recipients are entitled to the continuation of inefficient blood safety measures in virtue of *justice in transfer*, but the argument may be stronger if *justice in rectification* is considered. According to judicial inquiries in the 1990s, blood system operators and regulators should have allocated more resources to blood safety when AIDS and hepatitis C emerged [32, 33]. There may be an ethical ‘duty of reparation’ [34] towards victims of (avoidable) transfusion-transmitted HIV and hepatitis C, for example by giving them priority access to curative treatments and compensating their financial losses. It seems difficult, however, to justify the continued application of inefficient safety measures by referring to a duty of reparation. Blood safety measures do not remove or alleviate the suffering of patients suffering from transfusion-transmissible infections, but primarily benefit patients who have *not* been harmed. (At most, they reduce the risk that surviving victims of transfusion-transmitted HIV and hepatitis C contract dangerous co-infections when they need additional blood products.)

Perhaps maintaining inefficient safety measures rectifies injustice in a different sense: perhaps today’s low tolerance for transfusion risks is just because it offsets having tolerated too much risk during the 1980s and 1990s. Viewed from a resource perspective, transfusion recipients could claim to be entitled to see many resources allocated to blood safety because too few resources were devoted to their safety earlier. Accordingly, they could claim that it was legitimate to expect the continuation of safety measures even if these would prove inefficient.

Even if justice in rectification is taken into account, there must be a limit to continuing inefficient safety measures. Devoting many resources to blood safety only rectifies injustice if any blood product recipients who were wronged (but not necessarily harmed) during the 1980s

and 1990s remain. Blood product recipients that were not themselves wronged by historical allocation decisions cannot claim to be entitled to rectification. Moreover, as Nozick argues, rectifying an injustice by redistributing holdings is itself unjust if the person whose holdings are redistributed ends up with less than he is entitled to [18]. In our case, rectification takes place by allocating collective health care resources to interventions that benefit a particular group of people, namely transfusion recipients. If injustice towards them has been sufficiently rectified, transfusion recipients are no longer entitled to the resources consumed by inefficient blood safety measures; other people may be entitled to benefit from those resources. To what extent historical allocation decisions have wronged transfusion recipients and to what extent these wrongs have been rectified should be assessed country by country. In many cases, rectifying injustice will require offering additional medical and financial support to (the families of) victims of transfusion-transmitted HIV and hepatitis C, rather than maintaining safety measures that barely benefit them.

In conclusion, there is some force in the argument that past injustice entitles blood product recipients to the continuation of blood safety measures that fail to meet general cost-effectiveness standards. But it does not follow that such safety measures should be continued indefinitely. While the rhetoric of the 'paramourncy of safety' has suggested that blood safety measures need not be cost-effective, it is difficult to see how it can be legitimate to expect the indefinite continuation of very inefficient blood safety measures. Past injustice must be considered rectified at some point, depending on the specifics of the past injustice and on the rectification that has taken place.

#### **4. CONCLUSION AND DISCUSSION**

We evaluated, and ultimately rejected, two arguments for the claim that discontinuing (inefficient) blood safety measures is more objectionable than not introducing them. The argument that withdrawing blood safety measures causes rather than allows harm to patients was found unconvincing. The argument that transfusion recipients are historically entitled to the continuation of blood safety measures seemed stronger, but only insofar as this historical entitlement derives from past injustice that has not yet been sufficiently rectified. We conclude that unless stronger arguments can be found, the supposed asymmetry between stopping and not starting blood safety measures is ill-supported.

Stopping safety measures may sometimes even be less objectionable than deciding not to start them [29, 31]. Safety measures may become redundant when other safety measures are introduced (e.g. HBsAg screening after the introduction of screening for HBV-DNA and HBcore antibodies), or become less important because effective cures against transfusion-transmissible infections are developed (e.g. penicilin against syphilis, modern antivirals which rapidly cure chronic hepatitis C). In addition, precautions against poorly understood hazards may prove unnecessary or ineffective (e.g. deferral of donors with Chronic Fatigue Syndrome). When deciding whether to implement precautions, it is often uncertain whether taking precautions is necessary to avoid harm and, if so, which precautions will be effective. But if there is evidence that precautions could be necessary and effective, deciding not to implement them seems harder to justify than deciding to withdraw safety measures that have proven to add little safety. (Although there are also some constraints to observe when implementing precautions, see [6].)

Applying safety measures for a limited period can close (some) knowledge gaps concerning these safety measures' necessity and effectiveness. Transfusion recipients are then protected on a precautionary basis, but the intention should be to continue only safety measures that prove effective and reasonably efficient. (Leukocyte depletion might fit this description: once implemented as an expensive precaution against the possibility that variant Creutzfeldt-Jakob disease [vCJD] would transmit through blood transfusion, evidence that vCJD is transfusion-transmissible has strengthened and additional advantages of leukocyte depletion have emerged.) By announcing periodic review in advance, decision-makers can counter expectations that safety measures will be continued even if they prove inefficient.

This promising approach is unavailable when obstacles to withdrawing safety measures persist. Paradoxically, this may have negative consequences for both the efficiency and the safety of the blood supply: being unable to withdraw safety measures may raise the threshold for decision-makers to implement them at all [19, 31]. For example, developing pathogen reduction technologies for labile blood products seems unappealing if downscaling current safety measures is out of the question. Being prepared to withdraw safety measures that prove inefficient allows applying the precautionary principle more flexibly and paves the way for a more cost-effective blood supply.

## ACKNOWLEDGEMENTS

We thank the participants of the 2016 International Association of Bioethics, the participants of the 2016 Dutch Research School of Philosophy conference, and Sven Nyholm (Technical University Eindhoven) for their useful comments on earlier versions of this paper.

## REFERENCES

1. Borkent-Raven BA, Janssen MP, van der Poel CL, Bonsel GJ, van Hout BA (2012). Cost-effectiveness of additional blood screening tests in the Netherlands. *Transfusion* 52:478–88.
2. Jackson BR, Busch MP, Stramer SL, Dodd RY (2003). The cost-effectiveness of NAT for HIV, HCV, and HBV in whole-blood donations. *Transfusion* 43:721-9.
3. Van Hulst M, De Wolf JTM, Staginuss U, Ruitenber EJ, Postma MJ (2002). Pharmaco-economics of blood transfusion safety: review of the available evidence. *Vox Sanguinis* 83:146–55.
4. Custer B, Hoch JS (2009). Cost-effectiveness analysis: what it really means for transfusion medicine decision making. *Transfusion Medicine Reviews* 23:1–12.
5. Custer B, Janssen MP (2015). Health economics and outcomes methods in risk-based decision-making for blood safety. *Transfusion* 55:2039–47.
6. 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.
7. Alliance of Blood Operators (ABO): Risk-based decision-making framework for blood safety. Available from: <https://allianceofbloodoperators.org/media/115522/rbdfmframework-2-april-2015-v11-for-website.pdf> (last accessed August 2017).
8. Menitove JE, Leach Bennett J, Tomasulo P, Katz LM (2014). How safe is safe enough, who decides and how? From a zero-risk paradigm to risk-based decision making. *Transfusion* 54:753–7.
9. Schmidt PJ (2001). Syphilis, a disease of direct transfusion. *Transfusion* 41:1069-1071.
10. Katz LM (2009). A test that won't die: the serologic test for syphilis. *Transfusion* 49:617-619.
11. Wilson K, Atkinson K, Keelan J (2014). The use of preliminary scientific evidence in public health: a case study of XMRV. *PLoS Medicine* 11:e1001623.
12. Vamvakas EC (2011). Relative risk of reducing the lifetime blood donation deferral for men who have had sex with men versus currently tolerated transfusion risks. *Transfusion Medicine Reviews* 25:47-60.
13. Leiss W, Tyshenko M, Krewski D (2008). Men having sex with men donor deferral risk assessment: an analysis using risk management principles. *Transfusion Medicine Reviews* 22:35-57.
14. Farrell A-M (2012). *The politics of blood: ethics, innovation and the regulation of risk* (eBook). Cambridge: Cambridge University Press.
15. De Kort W, Mayr W, Jungbauer C, *et al* (2016). Blood donor selection in European Union directives: room for improvement. *Blood Transfusion* 14:101-8.
16. Kahneman D, Tversky A (1979). Prospect theory: An analysis of decision under risk. *Econometrica* 47:263–291.

## Chapter 7

17. 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.
18. Nozick R (1977). *Anarchy, state and utopia*. Oxford: Blackwell.
19. Beauchamp TL, Childress JF (2009). *Principles of biomedical ethics* (6th edn). New York: Oxford University Press.
20. Miller FG, Truog RD, Brock DW (2010). Moral fictions and medical ethics. *Bioethics* **24**:453-460
21. Savulescu J (2013). Abortion, infanticide and allowing babies to die, 40 years on. *Journal of Medical Ethics* **39**:257-259.
22. McMahan J (1993). Killing, letting die, and withdrawing aid. *Ethics* **103**:250-279.
23. McGee A (2015). Acting to let someone die. *Bioethics* **29**:74-81.
24. Foot P (2002). *Virtues and vices and other essays in moral philosophy* (2nd edn). Oxford: Clarendon.
25. Sulmasy DP, Sugarman J (1994). Are withholding and withdrawing therapy always morally equivalent? *Journal of Medical Ethics* **20**:218-222.
26. Harris J (1994). Are withholding and withdrawing therapy always morally equivalent? A reply to Sulmasy and Sugarman. *Journal of Medical Ethics* **20**:223-224
27. Gillon R (1994). Withholding and withdrawing life-prolonging treatment – moral implications of a thought experiment. *Journal of Medical Ethics* **20**:203-204,222
28. Sayers MH (2001). Allocation of scarce transfusion resources. In: AuBuchon JP, Petz LD, Fink A (eds.): *Policy alternatives in transfusion medicine*. Bethesda, MD: AABB Press.
29. Vincent J-L (2005). Withdrawing may be preferable to withholding. *Critical Care* **9**:226-229
30. Verweij MF (2008). Equitable access to therapeutic and prophylactic measures. In: World Health Organization (WHO). *Addressing ethical issues in pandemic influenza planning*. Available from: [http://apps.who.int/iris/bitstream/10665/69902/1/WHO\\_IER\\_ETH\\_2008.1\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/69902/1/WHO_IER_ETH_2008.1_eng.pdf) (last accessed August 2017).
31. Wilkinson D, Savulescu J (2014). A costly separation between withdrawing and withholding treatment in intensive care. *Bioethics* **28**:127-137
32. Leveton LB, Sox HC Jr, Stoto MA (eds.) (1995). *HIV and the blood supply: an analysis of crisis decisionmaking*. Washington DC: Institute of Medicine National Academy Press.
33. Krever H, The royal commission of inquiry on the blood system in Canada (1997). *Final report: Commission of inquiry on the blood system in Canada*. Ottawa: Canadian Government Publishing.
34. Ross WD (2002). *The right and the good*. Oxford: Oxford University Press.