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How safe should donor blood be?

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Chapter 10:

General Discussion

Since the emergence of AIDS and hepatitis C in the 1980s and 1990s, blood services have implemented numerous safety measures against the transmission of infectious diseases through blood transfusion and blood products. Cost-effectiveness analyses have concluded that some safety measures cost over €1.000.000 per quality-adjusted life-year (QALY) saved, while live-saving medical interventions are usually expected to cost well under €100.000 per QALY. Yet the occasional introduction of cost-ineffective (or 'inefficient', for ease of exposition) safety measures continues, and the termination or relaxation of inefficient safety measures is rare.

From a utilitarian perspective, applying blood safety measures with very high cost-effectiveness ratios seems unethical. Such inefficient blood safety measures consume funds that could probably be used more beneficially elsewhere in health care. If so, more QALYs could be saved by forgoing inefficient blood safety measures than by applying them. This dissertation did not evaluate the utilitarian argument as such, which would have required extensive economic analyses that were beyond our expertise. Instead, this dissertation sought to identify and evaluate ethical arguments that would override the utilitarian argument, i.e. reasons to apply inefficient blood safety measures even if directing funds elsewhere would save more QALYs. Compelling arguments were not found, from which we (tentatively) conclude that blood safety policies should be more efficient.

In what follows, we offer recommendations for policy-making, reflect on the strengths and limitations of our research methodology, and propose directions for future research.

RECOMMENDATIONS FOR BLOOD SAFETY POLICY-MAKING

Our analysis has some implications for blood safety policy-making. We recommend as follows:

- Policy-makers should explicitly address the cost-effectiveness and the opportunity costs of blood safety measures. Other stakeholders, including recipients of blood products, seem sensitive to the utilitarian argument that blood safety measures should not be applied if more lives or QALYs could be saved by funding different healthcare interventions. It may not be true that funding inefficient (i.e. not cost-effective) blood safety measures by itself excludes funding more efficient healthcare interventions. Policy-makers should then consider whether there is a collective responsibility for efficiency in healthcare and consider what this entails for blood safety. (See chapter 3.)
- Policy-makers should use precautionary arguments with care: they should avoid introducing inconsistent, counterproductive, or disproportionate precautions. They

should hence consider to what extent precautions may themselves be harmful, where 'harm' should be interpreted broadly. This excludes extreme risk intolerance, but may allow moderately risk-averse policies. (See chapters 5 and 6.)

- Policy-makers should be more prepared to withdraw safety measures that have proven to be very inefficient. (See chapter 7.)
- Policy-makers should explicitly counter any expectations that inefficient safety measures will be continued. They should make clear that the efficiency of safety measures will be evaluated and that inefficient safety measures may be terminated. Policy-makers may even introduce safety measures for a fixed term, and announce that this term will only be extended if the safety measures prove to be sufficiently cost-effective. This means safety measures can be ended (relatively) passively, while prolonging them requires an active decision. (See chapter 7.)
- Policy-makers should engage stakeholders in deliberation about reasonable blood safety, including the framing of policy-making problems. Our qualitative research revealed that some recipients of blood products were more concerned about the well-being of their families than about their own health. Discussing such concerns may open up different policy options, e.g. ensuring practical and financial assistance for victims of transfusion-transmissible infections rather than taking inefficient safety measures. (See chapter 3.)

METHODOLOGICAL REFLECTIONS

The two parts of this dissertation followed distinct but complementary methodologies. Part I used qualitative empirical research methods to chart policy-making issues and stakeholder views regarding inefficient blood safety measures. Chapter 2 sketched a broad background for the ethical analyses in part II. Connecting to actual policy decision-making served to identify concerns that might be ethically relevant and may, conversely, help to translate ethical insights into practice. To be sure, some policy-making concerns fell outside of our ethical scope (e.g. legal and political issues). Chapter 2 thus revealed limitations of our perspective and identified perspectives with which it might clash. The second empirical study, presented in chapter 3, was in fact completed later than our ethical chapters were. In this way, it served to establish whether our ethical analyses addressed the most pressing arguments against efficiency in blood safety, or whether we had overlooked prominent perspectives. Our respondents formulated some of the arguments we had derived from ethical literature, including the 'imposed risk'

argument (chapter 4) and arguments for the view that stopping blood safety measures is particularly objectionable (chapter 7). Chapter 3 also analysed some arguments part II did not address, although this analysis was tentative and primarily served to explore conceptual resources by which stakeholder arguments may be related to ethical theory.

Our analyses in part I were (primarily) 'bottom up': we first identified relevant passages in our materials, which we then gave initial labels, clustered according to content, and captured under increasingly general categories. This resulted in comprehensive taxonomies of policy-making issues and stakeholder views. The analysis was also (largely) 'pre-theoretical': by bracketing preconceived ideas on what matters in blood safety, we strived to be open to new perspectives in our materials. It is well-recognized, however, that interpretation cannot avoid all preconceptions. According to philosophical hermeneutics, interpreting texts (or other meaning-bearers) requires interpreting their constituent parts, which in turn requires a conception of the text as a whole. Having some preconceptions regarding the object of interpretation is thus necessary for interpretation to get off the ground. In our case, knowledge of ethical concepts and theories may have affected our interpretation of policy-making concerns and stakeholder views. To remain receptive to perspectives that are poorly captured in ethical theory, our initial analysis of policy-documents and stakeholder utterances tried to stay clear of ethical terminology (that did not occur in our materials). Integrating views on blood safety with ethical theory, where applicable, was considered legitimate in the later stages of our analyses. We therefore allowed ethical labels for general categories of policy-making concerns and stakeholder views, provided that these labels unified the categories better than non-ethical labels did. We ensured transparency by showing which particular policy-making concerns and stakeholder utterances were clustered under which general headings. Our analysis may not have been completely 'bottom up' and 'pre-theoretical', as it did connect some data to ethical theory, but it avoided squeezing all data into pre-existing theoretical frameworks.

Part II applied ethical principles to blood safety. The main question was whether these could override the utilitarian argument: whether they provided reasons to fund inefficient blood safety measures even if funding different health care interventions would save more lives (or QALYs). The ethical principles we applied have been invoked to override efficiency considerations, whether in blood safety policy-making (e.g. the precautionary principle) or in other domains (e.g. the rule of rescue). Typically, our strategy was not to question general principles, which would have required abstract ethical theorizing, but to consider how well they applied to blood safety. Applying ethical principles does not consist in checking whether

certain conditions apply (or 'ticking boxes'), but requires interpretation [e.g. 1,2]. For example, the ethical principle of non-maleficence forbids causing harm to someone, but does this include performing medical procedures with adverse side-effects? Does it forbid taking small chances that someone will be harmed? Such questions are not answered by the principles themselves: there is a conceptual gap between general ethical principles and particular moral issues. Bridging this gap means adding something to ethical theory: the principles receive a more specific interpretation, which is sensitive to the context of application [2]. Part II of this dissertation built various conceptual bridges between ethical theory and blood safety issues, for example between causing harm and withdrawing blood safety measures (chapter 7) and between harm and the costs of safety measures (chapter 5). Making ethical principles applicable to specific issues requires not just conceptual analysis, but also normative analysis: plausible interpretations of ethical principles must have acceptable ethical implications. Our ethical analyses built on this idea in two interlocking ways. First, we evaluated interpretations of ethical principles that might support inefficient blood safety policies by considering their implications. This led us to reject some interpretations of principles. We dismissed the interpretation of the precautionary principle as a call for 'zero risk', for example, because the precautionary principle would on this interpretation require stopping many beneficial activities (or even daily life). Second, we considered whether plausible interpretations of ethical principles supported inefficient blood safety policies. This was our argumentative strategy when we applied the rule of rescue and the norm not to impose risks on others (chapter 4): we argued that if these ethical rules are interpreted plausibly, they do not support ignoring cost-effectiveness thresholds in blood safety. These two argumentative strategies came together, for example, in our discussion of the precautionary principle. We rejected extremely risk intolerant interpretations of the precautionary principle by appeal to their implications, set constraints for plausible interpretations of the precautionary principle, and argued that these constraints excluded ignoring the costs of blood safety measures.

In sum, our analysis combined 'bottom up' and 'top down' research strategies: part I worked up from views on specific blood safety issues to more general ethical views, and part II set out to bridge the gap from the other side. Following reflective equilibrium theory, different levels of theorizing support each other insofar as they 'cohere' or 'fit' as a whole [2-4]. Views on specific moral issues can be supported or undercut by ethical principles, but the converse also holds: ethical principles gain or lose credibility insofar as they fit well-informed moral views. As explained, an intermediate level of theorizing may be required to connect the more

abstract and the more concrete levels. This intermediate level of theorizing involves the specification of ethical principles (which are thus both general and flexible): to show how these can be plausibly interpreted in (a range of) specific contexts [2]. The coherence between these different parts justifies the whole, which in turn justifies each part [2-4].

The question whether applying inefficient blood safety measures is ethical thus requires a comprehensive treatment. The conclusion will not follow deductively from indubitable premises, but must cohere with a plurality of ethical considerations and perspectives. Which conclusion fits best is in the end a matter of judgment [cf. 5,6]. This judgment is always provisional: it should be open to revision, for example when new considerations surface.

In that regard, it is important to consider the dialectical context in which this thesis was written. Policy-makers and scholars have expressed unease with the escalating costs of blood safety and with the decision-making principles that motivated safety policies (e.g. the precautionary principle). They have performed health economic evaluations of blood safety measures, have formulated utilitarian considerations to heed efficiency [e.g. 7], and have developed more cost-sensitive decision-making approaches [8, 9]. But as far as we know, this dissertation constitutes the first comprehensive attempt to identify arguments for allowing inefficient blood safety measures and to evaluate such arguments from an ethical perspective. The conclusions of our work, and the recommendations we made, should therefore not be received as final or decisive. Yet we do think our work alters the dialectical situation. For example, chapter 5 criticized unreflective appeals to the precautionary principle, and chapter 7 problematized the view that terminating blood safety measures is more objectionable than not starting them. Our arguments arguably change the burden of proof: a stronger justification is demanded for the implementation and continuation of inefficient blood safety measures. Unless better reasons to apply inefficient blood safety measures are spelled out, current blood safety policies seem to lack an ethical foundation. Future research may take up this challenge by addressing issues that were set aside in this dissertation.

DIRECTIONS FOR FUTURE RESEARCH

There have been few attempts to integrate ethical theory and thinking about blood safety, and we could treat only a selection of all relevant issues and perspectives in detail. Ethical approaches that we ignored may apply to blood safety, and some stakeholder views or policy-making concerns deserve a more thorough ethical analysis.

Possibly relevant ethical approaches are theories of justice (e.g. prioritarianism) as applied to health care, rights-based and contract-based approaches, and care ethics. We will not explore these approaches here, but only note that ethical theory still has various resources that can be applied to blood safety. We hope other scholars will continue this work.

There are also more specific issues that require further theorizing. In chapters 2 and 3, we found that being consistent was an important concern for policy-makers. Safety policies were expected to be consistent among each other, to be consistent across time, and to be consistent across geographical regions. Even if we focus at applying a single safety measure at a single time, the question remains what it means to be consistent and why this is important. Perhaps consistency means applying a safety measure in exactly the same manner across different regions, product types, and patient groups. For example, nucleic acid testing on Zika-virus might follow the same parameters for all donations across the country. Being consistent in this way has operational advantages and may be considered just, as all transfusion recipients are treated equally. However, an undifferentiated application of safety measures will not even out differences in the risks patients face (which may derive from factors like geographical location and medical condition). Moreover, safety measures that are efficient (or cost-effective) in high-risk contexts may be inefficient when extended to low-risk contexts. Can consistency be conceptualized differently, in a way that harmonizes operational concerns, justice, and efficiency?

Another important issue is trust. Chapter 3 presented some arguments for risk intolerance that appealed to trust: it was considered important that blood product recipients, physicians, and the general public maintain trust in the safety of blood products. What this trust amounts to requires further attention. Trusting that blood products will never transmit infections seems unrealistic; this expectation cannot be met and should not be fostered. Trusting that blood services will ensure 'maximum' safety by taking every possible safety measure also seems unrealistic. Strictly speaking, there may not be a maximum to safety, or an end to the safety measures that could be applied: further donor screening questions, blood tests, and pathogen inactivation procedures may be developed, safety procedures can be repeated for enhanced effectivity, larger volumes of blood can be tested, etcetera. In addition, blood services may be trusted to use public resources responsibly, which excludes taking unreasonably inefficient safety measures. Future research should consider what blood services are actually trusted to do, and what they can reasonably be trusted to do. Such inquiries should recognize that trust may be indeterminate or open-ended. Trusting someone does not involve prescribing what he

ought to do in every conceivable situation, which is impossible. The person (or institution) trusted must use his 'power of discretion': he must interpret new situations and judge how he should discharge his responsibilities [8]. Thus, further research should not only address which safety decisions blood services are expected to take, but also which decisions are left to their discretion.

Finally, some economic assumptions behind the utilitarian argument against funding inefficient blood safety measures require scrutiny. Some stakeholders in the Dutch blood supply argued that applying inefficient blood safety measures does not exclude funding more efficient health care interventions, given the low budget impact of blood safety measures and given the possibility to cut other costs within blood services. The utilitarian argument could be defended by showing that not taking inefficient blood safety measures is necessary and sufficient to reap more substantial health benefits. Perhaps, though, it suffices to show that inefficient health care interventions collectively have suboptimal outcomes, and to establish a collective responsibility for efficiency in health care.

CONCLUSIONS

We found no strong arguments to fund inefficient blood safety measures if funding alternative health care interventions saves more lives (or QALYs). It does not follow that only safety measures costing under €100.000 per QALY, or some other suggested threshold, should be introduced or continued. Safety decisions must balance a variety of concerns and there may be ethical considerations we have not addressed. However, it seems reasonable to demand a clearer justification for applying extremely inefficient safety measures, like those costing over €1.000.000 per QALY. Unless such a justification is forthcoming, public money should be spent more efficiently.

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