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How safe should donor blood be?

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Chapter 8:

Summary

Blood services apply various safety measures to prevent the transmission of infections through blood transfusion, some of which have very high cost-effectiveness ratios (over €1.000.000 per quality-adjusted life-year saved). This dissertation considers whether it is ethically acceptable to apply such inefficient safety measures. From a utilitarian perspective, these safety measures should be forgone: they consume resources that could probably be used more beneficially elsewhere in the healthcare system, thus saving more (quality-adjusted) life-years. Are there good ethical arguments to apply inefficient blood safety measures nonetheless?

Part I presents qualitative empirical research that aimed to identify such arguments. Our analysis of policy documents, on which we report in chapter 2, reveals that a broad set of concerns shaped decision-making on expensive blood safety measures. Policy-makers did not only balance safety versus costs, but also considered supply, operational feasibility, consistency, and legal, political, and ethical issues. Policy-makers invoked principles on how to prioritize safety versus costs, but these principles differed widely: some principles declared safety paramount and declared costs unimportant, others allowed trade-offs between costs and safety. Cost considerations were thus balanced against safety concerns in diverse ways, and were weighed against various other concerns.

Chapter 3 presents possible arguments for assigning a higher or lower priority to safety, based on interviews and focus group discussions with stakeholders in the Dutch blood supply. Stakeholders' arguments appealed to the clinical impact, the probability, or the avoidability of getting infected, to the health benefits, the costs, or miscellaneous consequences of safety measures, to non-consequentialist ethical concerns, or to the interests of stakeholders. Various respondents concurred with the ethical premise of the utilitarian perspective: they would limit expenditures on blood safety measures if doing so would allow helping more people elsewhere in the healthcare system. Some respondents doubted economic assumptions behind the utilitarian argument: given the small budget impact of blood safety measures and the possibility to cut other budgets, funding inefficient blood safety measures would not exclude funding more efficient healthcare interventions. We also found arguments that might override the utilitarian argument. Some of these arguments suggest directions for future research (see the Discussion of this dissertation).

Part II evaluates ethical arguments why blood safety measures should be applied even if they are inefficient (and more lives or QALYs could be saved by not applying them). Chapter 4 draws three arguments from ethical literature: the 'rule of rescue' argument, according to which saving identifiable individuals justifies applying inefficient safety measures; the 'risk imposition'

argument, according to which safety measures against risks imposed by healthcare interventions should be exempt from general cost-effectiveness criteria; and the 'manufacturing standard' argument, according to which cost-effectiveness standards should not apply to procedures preventing the contamination of manufactured medical products. While these arguments may be sensible in general, they prove unconvincing when applied to blood safety. The 'rule of rescue' argument fails because inefficient blood safety measures do not save individuals who are identifiable in advance; persons who need blood products may be identifiable, but persons who will get infected are not. The 'risk imposition' argument is unpersuasive because the claim that blood services impose risks on patients (and do not merely leave patients *exposed* to risk) presupposes that they should have taken stricter safety measures, which begs the question. Finally, the 'manufacturing standard argument' applies poorly to publicly funded institutions: while forgoing safety measures in private pharmaceutical firms has no public benefit, cutting budgets in blood services allows funding other public goods.

Chapter 5 addresses the precautionary principle. While the precautionary principle is often invoked to defend strict blood safety policies, we observe that its definition and its role in policy-making are contested. We identify three constraints which any version of the precautionary principle should heed: *consistency* forbids prescribing safety measures that the precautionary principle itself deems intolerably risky; *avoiding counterproductivity* forbids taking safety measures that do more harm than they avert; and *proportionality* forbids prescribing precautions that are more harmful than alternative adequate precautions. Chapter 5 then argues that blood safety measures can be inconsistent, counterproductive, or disproportional in virtue of their (opportunity) costs. Acceptable versions of the precautionary principle must thus tolerate some risks, potentially even to save costs.

Chapter 6 discusses a number of published commentaries on our account of the precautionary principle. Some of these commentaries challenge our interpretation of the precautionary principle, others apply our account to the question whether men-who-have-sex-with-men should be deferred as blood donors. However, none of the commentaries challenge the thesis that when the (opportunity) costs of precautions are high, it may be legitimate to tolerate blood transfusion risks.

The final chapter, chapter 7, evaluates arguments for the view that discontinuing inefficient blood safety measures is more objectionable than not introducing them. We reject the argument that stopping safety measures *causes* harm and not starting safety measures *omits to prevent* harm. We apply three criteria for when removing a protection causes harm, none of

which clearly support the view that withdrawing blood safety measures means causing harm. It may be possible to withdraw blood safety measures without acting, and if actions are required, these are insufficient for harm to occur. Furthermore, persons who withdraw blood safety measures merely undo their own actions (or those of their professional predecessors). Finally, withdrawing blood safety measures does not reinitiate threats that had been eliminated, but omits to shield transfusion recipients from new exposures to danger. The argument that transfusion recipients are historically entitled to the continuation of blood safety measures seems stronger, but only insofar as continuing these safety measures rectifies past injustice towards transfusion recipients.

In sum, there seem to be no persuasive arguments that override the utilitarian argument, that is, no good reasons to fund inefficient blood safety measures if funding other health care interventions saves more lives (or QALYs).