Assessment framework for donor blood screening

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Executive summary

Health Council of the Netherlands

Donor blood is used for blood transfusions and in the pharmaceutical production of blood derivatives. To prevent transfusion-transmitted infections, blood donations are tested for infectious diseases. Sanquin, the Dutch blood-supply organisation, currently tests all blood donations for five infectious diseases. This screening policy, however, is subject to changes. It sometimes transpires that testing for a certain disease is no longer necessary, while new diseases might emerge that will require testing in the future.

The introduction or discontinuation of a screening test must be approved by the Ministry of Health, Welfare and Sport (VWS). Though there is no standard framework for evaluating donor blood screening, in practice, the following criteria are always considered: the severity and scope of the disease burden, the effectiveness of the screening, potential adverse consequences, the availability of alternatives, feasibility and cost-effectiveness. This last criterion – cost-effectiveness – appears to be contentious in the context of blood safety. Donor blood screening is often not cost-effective according to commonly used reference values. This is not because the tests themselves are particularly expensive, but rather because donor blood is so rarely contaminated. To detect a single contaminated blood donation, a great number of donations need to be screened, which results in an unfavourable cost-benefit ratio. Cost-effectiveness as a criterion in healthcare is based on the premise that, to be justifiable, decision-making should result in the most favourable balance of benefits and costs in society.

Under this premise, cost-ineffective interventions are at odds with the fair distribution of scarce collective resources – after all, the money could have been spent on measures that are more efficient. Still, legitimate arguments can be made for continuing or introducing cost-ineffective measures in donor blood screening. However, what those arguments are exactly is not always specified. At the request of the State Secretary for Health, Welfare and Sport (VWS), the Committee on Ethics and Law of the Health Council of the Netherlands has therefore drawn up an assessment framework for donor blood screening to assist with a more transparent justification of decision-making, taking potentially unfavourable cost-effectiveness ratios into account.

In drawing up the framework, the committee worked under the assumption that decision-making should involve both formal and contextual factors. Formal factors are criteria that have been formalised in an assessment framework and that can often be quantified through clinical or economic analysis. These are the above-mentioned criteria that are already explicitly applied in practice. Contextual factors, on the other hand, look at the situation-specific need for an intervention. Unlike effectiveness, they cannot be expressed as a quantity or number. That is why contextual factors often remain implicit in the decision-making process. However, the committee believes that, in order

to properly justify a decision, it is of particular importance to make both the formal and contextual factors explicit.

Based on the academic literature, the committee identified the relevant contextual factors in donor blood screening. These relate to the specific sociocultural meaning of blood and blood transfusion, the responsibility of the government regarding blood safety and public trust. Blood safety can be especially important due to the particular meaning that blood carries in societies. Blood from another person's body is introduced into the patient's own and becomes part of their circulatory system. Many people thus believe that blood must be especially safe, even more so than other medical interventions. Public trust in the blood supply can be another important reason for accepting unfavourable cost-effectiveness ratios in donor blood screening. One reason people donate blood is to help others, without the expectation of any financial or other compensation, and because they themselves may need a blood transfusion one day (reciprocity). These motivations are entirely contingent on public trust in the government, which carries the responsibility for the availability, quality and safety of blood products. The large-scale contamination of donor blood with HIV in the 1980s severely damaged that trust, and it is partly for this reason that, for some time, blood establishments have adhered to a policy of zero-risk tolerance. The risk of a transfusion-transmittable infection, however, can never be fully eliminated. The question is therefore not how risks can be eliminated with 100% certainty, but rather how to distinguish between acceptable and unacceptable risks, given the safety requirements that legally apply to blood products and blood supply organisations.

Since there is great diversity in both transfusion-transmittable diseases and available screening tests, considerations pertaining to specific infections or tests are also relevant (in addition to general contextual factors) when deciding on screening measures. The first is the societal impact that screening versus not screening will have. Some infections cause more social concern than others, due to aspects such as stigma or the perceived severity of the consequences. There may be public discontent if blood is not tested for an infectious disease that, in daily life, most people can easily avoid through their own behaviour.

Another specific contextual factor is the impact on existing health disparities. Those who are most dependent on blood transfusions often have compromised immune systems and are therefore the ones who are most vulnerable to infections. This was an important consideration in the Health Council's recommendation to continue donor blood screening for hepatitis E virus (HEV). While the consequences of HEV are not serious for most people with healthy immune systems, this is not the case for many recipients of blood products.

Regarding decisions about donor blood screening, the committee advises the explicit

consideration of both formal factors (i.e. criteria) and contextual factors (both general and specific) in the assessment framework given below. This will allow for transparency in decisions to introduce cost-ineffective screening measures, but it can also provide arguments to reject or discontinue existing measures. Both are important in the context of new threats to blood safety on the one hand and sustainable healthcare on the other.

Formal factors can be assessed based on relevant data and expertise from the academic and scientific community, as has been the case until now. The overall weighing of all relevant factors, including contextual factors, demands a broader ethical, legal and societally oriented perspective. The committee therefore believes that decision-making will benefit from stakeholder involvement, including healthcare providers and the recipients of blood products.

The less cost-effective screening measures are, the more important contextual factors will become. This requires a critical assessment; contextual factors are not meant to merely sanction any and all cost-ineffective measures. They may also lead to the conclusion that there are insufficient societal, ethical or legal arguments to justify a testing measure with extremely low cost-effectiveness.

Assessment framework for testing blood donations

Formal factors (criteria)

- disease burden;
- effectiveness;
- likelihood of adverse consequences;
- available alternatives;
- feasibility;
- cost-effectiveness.

Contextual factors (especially where cost-effectiveness is low)

- socio-cultural significance of blood transfusion;
- public trust and government responsibility;
- societal impact of not testing (test-specific);
- effects on health disparities (test-specific).

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