



Title **Leukoreduction. Considerations for a National Blood Transfusion Safety Policy**

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Reference Sept 2004. KCE Reports vol. B. www.kenniscentrum.fgov.be/nl/publicaties.html (in Dutch), www.kenniscentrum.fgov.be/fr/Publications.html (in French)

Aim

To evaluate the scientific rationale of universal leukoreduction in Belgium and to assess the clinical, economic, social, and legal consequences.

Conclusions and results

The safety and quality of transfusion blood is high in Belgium, as it relies on unpaid voluntary donors and strict quality control. The incremental cost to the healthcare payer is € 25 per unit for filtering white blood cells from red blood cell concentrates for transfusion. The consensus is that selective leukoreduction is highly effective and cost effective relative to no leukoreduction. Selected patients groups include immunocompromised patients, pregnant women, transplant patients, polytransfusion patients, and patients with HLA alloimmunization. It is unclear whether universal leukoreduction, ie, leukoreduction for all units of blood, is cost effective. The decision to implement universal leukoreduction in most European countries was aimed at preventing the transmission of variant Creutzfeldt-Jakob disease (vCJD) by blood transfusion. Outside the UK, this risk is low, and universal leukoreduction is probably of limited clinical benefit. The incremental cost to the healthcare payer for universal leukoreduction is estimated to be € 7.71 million per year in Belgium (2003 prices). A basic problem is legal accountability. The law is vague on this issue, and blood banks are increasingly faced with legal uncertainty. They pay huge insurance premiums that are disproportional to the quality and safety measures they take. The (European) law suggests that maximum blood safety should be pursued, which inevitably leads to investments defined by technological possibilities rather than by objective need and efficiency.

Recommendations

The major issues concern financial and legal accountability for hazards related to blood transfusion. If policy makers decide not to implement universal leukoreduction in Belgium, they need to take over this financial and legal accountability from the blood banks. If it is

decided to implement universal leukoreduction, the public should be appropriately informed about the consequences, ie, the loss of efficiency in allocating scarce healthcare resources.

Methods

The literature on the clinical benefits and economic consequences of leukoreduction was reviewed. Experts in the field were actively involved in the research. The incremental cost of universal leukoreduction for healthcare payers was based on the number of blood donations in 2003, the percentage blood units currently leukoreduced (25%), and the reimbursement of leukoreduced versus nonleukoreduced blood. The perspective of the healthcare payer was taken.

Further research/reviews required

More research is needed on the legal issues of accountability for hazards related to blood transfusion. A precautionary blood safety policy should be based on the participation in decision making of all relevant actors: blood donors, patients, and healthcare providers. More research is needed on how these actors can be involved in decision making.