Assessment of the economic value of the INTERCEPT blood system in Belgium

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The health technology under investigation was the INTERCEPT blood system for platelets (IBSP). IBSP is a safety measure for platelet transfusion which inactivates different types of pathogens through irreversible binding to RNA/DNA in the blood.

Type of intervention
Other: Safety measure for platelet transfusion.

Economic study type
Cost-utility analysis

Study population
The study population comprised a hypothetical cohort of patients receiving transfusions of platelets inactivated with the IBSP, compared with the same cohort receiving untreated platelets, taking into account the risk of bacterial infection, hepatitis C virus (HCV), hepatitis B virus (HBV) and human immunodeficiency virus (HIV) infection. The target population included patients with haematological malignancies undergoing bone marrow or peripheral stem cell transplantation (acute lymphoid leukaemia, acute myeloid leukaemia, chronic myeloid leukaemia and non-Hodgkin's lymphoma); breast cancer patients undergoing stem cell transplantation; and patients undergoing coronary artery bypass graft.

Setting
The setting was not clearly reported. The economic study was carried out in Belgium.

Dates to which data relate
The effectiveness evidence was derived from studies published during 1995 to 2004. The resource use data were gathered between 1996 and 2002. The price year was not reported.

Modelling
A decision analytical model was used to simulate the clinical outcomes of patients requiring platelet transfusion in a world with, and in a world without the IBSP. Three scenarios were developed; these included different levels of IBSP benefits from the prevention of infections up to multiple processing benefits. The model was based on two main assumptions: first, pathogen inactivation is 100% effective; and second, pathogen inactivation is not associated with major or costly adverse events. The time horizon for the model was lifetime. The model was developed using TreeAge DATA software.

Study designs and other criteria for inclusion in the review
The effectiveness data used in the economic analysis included:

- the average life expectancy per underlying disease in the absence of transfusion-related infection;
- the risk of known infections with untreated platelet components, taking into account the risk of bacterial infection, HCV, HBV and HIV infection;
- the risk of emerging pathogens;
the efficacy and safety of IBSP;
the additional benefits of ISBP, and;
the impact of transfusion-transmitted infections.

**Sources searched to identify primary studies**
The effectiveness data were derived from published literature, expert opinion and the Belgian Red Cross.

**Methods used to derive estimates of effectiveness**
The methods used to obtain the data were not reported.

**Measure of benefits used in the economic analysis**
Quality-adjusted life-years (QALYs) were used in the economic analysis. The utility values used in the model were obtained from a published study (Dusheiko et al. 1995, see 'Other Publications of Related Interest' below for bibliographic details).

**Direct costs**
The direct costs included the costs per transfusion for single donor platelets (SDP) and for average random donor platelets (RDP), the cost of inactivation using the IBSP, the costs for treating diseases related to viral infections, and the legal costs of transfusion-associated infection with HIV or with emerging virus. The costs per transfusion included gamma-irradiation and donor screening tests except NAT. The cost of inactivation included the cost for the system itself, as well as the costs for material and personnel to perform the procedure.

The costs per transfusion for SDP and for average RDP were from official sources (RIZIV/INAMI, Red Cross Belgium). The costs for treating diseases related to viral infections were from published studies. The legal costs were based on law suits or governmental action reports from different countries, including Belgium.

The resource quantities and the unit costs were reported separately. The price year was not reported. Despite the fact that costs were incurred over a lifetime, it appears that discounting was not carried out.

**Statistical analysis of costs**
The cost data were deterministic. Standard deviations were given only for cost data for HIV.

**Indirect Costs**
Indirect costs included productivity loss from transfusion-associated infections. The indirect costs data were derived from the National Institute for Statistics website and published studies. The quantities and the costs were reported separately. The price year was not reported. Despite costs being incurred over a lifetime, it appears that discounting was not carried out.

**Currency**
Euros (€).

**Sensitivity analysis**
Uncertainty was investigated through a scenario analysis and through a threshold analysis.

The scenario analysis was carried out to investigate the impact of the assumption of the absence of viral risk as a result of the implementation of the IBPS.

The authors presented the base-case scenario (scenario 1) as a double scenario, taking into account a similar probability of absence and presence of an emerging virus. To the presence of an emerging virus, different levels of risk were attributed between 1 in 100,000 and 1 in 1,000.
In the second and third scenarios, the implementation of the IBPS was assumed to eliminate the risk for HIV, HCV, HBV, bacterial and emerging HCV like virus. In addition, a series of processing benefits was considered.

In scenario 2, the elimination of BactAlert testing, storage time prolongation to 7 days, leading to 50% decrease in overdue platelets waste, the elimination of SDP ALT testing on SDP platelets and the elimination of gamma-irradiation were assumed to be associated with the IBSP.

In scenario 3, the following benefits were assumed in addition to the benefits in scenario 2: the elimination of NAT tests and syphilis tests (VDRL) on SDP units leading to reduced costs (NAT costs eliminated).

In the threshold analysis, the authors identified, for the three different scenarios, the level of emerging infection risk so that the IBSP becomes the dominant strategy for all indications.

**Estimated benefits used in the economic analysis**
The authors reported a very extensive series of results. For this reason, only the range of estimated benefits is reported in this abstract. These values are dependent on the underlying disease.

In the base-case scenario and in the absence of emerging virus, the estimated QALYs gained ranged from 1.99953 to 32; for the risk level of emerging virus of 1 in 100,000, the estimated QALYs gained ranged from 1.99952 to 32; and for the risk level of emerging virus of 1 in 1,000, the estimated QALYs gained ranged from 1.9985 to 32.

In scenarios 2 and 3 (risk level of emerging virus of 1 in 100,000), the estimated QALYs gained ranged from 1.9995 to 32.

**Cost results**
As with the estimated benefits, only the range of estimated costs is reported in this abstract and values are dependent on the underlying disease.

In the base-case scenario and in the absence of emerging virus, the estimated costs ranged from € 360 to € 6,161; for the risk level of emerging virus of 1 in 100,000, the estimated costs ranged from € 361.3 to € 6,161; and for the risk level of emerging virus of 1 in 1,000, the estimated costs ranged from € 493 to € 6,492.

In scenarios 2 and 3 (the risk level of emerging virus of 1 in 100,000), the estimated cost ranged from € 361 to € 5,552.

**Synthesis of costs and benefits**
A synthesis of the costs and benefits was carried out by calculating an incremental cost-effectiveness ratio (ICER; i.e. the incremental cost per QALY gained). As with the previous two sections, only the range of estimated ICERs is reported in this abstract and values are dependent on the underlying disease.

In the base-case scenario and in the absence of emerging virus, the estimated ICER ranged from € 3,459,201 per QALY to € 195,364 per QALY; for the risk level of emerging virus of 1 in 100,000, the estimated ICER ranged from € 3,355,308 per QALY to € 165,051 per QALY; and for the risk level of emerging virus of 1 in 1,000, the maximum estimated ICER was € 223,255 per QALY.

ICERs were also calculated by comparing the strategies from scenarios 2 and 3. These ranged from € 2,143,435 per QALY to € 99,924 per QALY.

The authors reported that the IBPS was the dominant strategy in the majority of cases. At 1/100, the IBST strategy became dominant in all cases, although these results were not reported.

The thresholds of emerging infection risk for the IBSP to become dominant in all indications were 1/1,074 transfusions in scenario 1, 1/1,697 transfusions in scenario 2 and 1/1,791 transfusions in scenario 3.
Besides the risk of infection with the emerging pathogen, the cost-effectiveness ratio was highly sensitive to the indication and age group considered, and to the inclusion of processing benefits of the IBSP.

**Authors’ conclusions**
The authors concluded that, considering thresholds for cost-effectiveness that are apparently applied in the field of blood transfusions, the implementation of the INTERCEPT blood system for platelets (IBSP) could be considered cost-effective and even a dominant strategy, taking into account the potential risk of emergence of a new pathogen in the future.

**CRD COMMENTARY - Selection of comparators**
The justification for the comparator used was given implicitly, namely that "a world without IBSP" represented current practice. You should decide if this represents current practice in your own setting.

**Validity of estimate of measure of effectiveness**
The estimate of effectiveness was based on an ad hoc review of the literature. No systematic review was undertaken. Although this is common practice with models, it does not always ensure that the best data available are used in the model. The estimates of effectiveness were arrived at by narrative synthesis. For several parameters the authors reported that a weighted average was adopted to reflect differences in sample size. The authors did not consider the impact of differences between the studies identified when estimating effectiveness. The estimates of effectiveness were also based on expert opinion and authors' assumptions. The authors did not provide any justification for their choice of the two main assumptions underlying the model.

**Validity of estimate of measure of benefit**
The measure of benefit used was QALYs. Their use as the summary benefit measure was appropriate as they capture the impact of the intervention on two key dimensions of health (i.e. survival and quality of life). Furthermore, the choice of QALYs will permit the results of this study to be compared with other health care interventions. The utility values were derived from published studies. Despite the lifetime horizon of the analysis, it appears that health benefits were not discounted.

**Validity of estimate of costs**
The analysis of the costs was performed from a societal perspective. Given that perspective, it appears that all the relevant categories of costs have been included in the analysis and, within each category, all the relevant costs appear to have been included. The legal costs for transfusion-associated infection types other than HIV or emerging virus were not included, owing to prolonged legal procedures. The unit costs and the resource quantities were reported separately, thus enhancing the reproducibility of the study in other settings. The resource use data and unit costs were obtained from official sources. As with the health benefits, although costs were incurred over a patient's lifetime, it would appear that no discounting was conducted. The price year was not reported, which will hinder any future reflation exercise.

**Other issues**
The authors compared their findings with those from other studies and, in general, found them to be in agreement. The authors did not directly address the issue of the generalisability of the results to other settings. The authors do not appear to have presented their results selectively, and their conclusions reflected the scope of the analysis. The authors did not report further limitations to their study.

**Implications of the study**
From a public health perspective, and taking a more pro-active viewpoint, the apparent risk of emerging viruses should be taken into account. At emerging viral risks beyond 1/1,000 to 1/2,300 transfusions, the IBSP strategy becomes dominant, i.e. it saves money and produces health gains.

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None stated.

**Bibliographic details**
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Other publications of related interest
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