



Technology

Solvent/detergent-treated human plasma (S/D plasma) is a form of virus-inactivated plasma product. The inclusion of the S/D treatment during the manufacturing process potentially reduces the risk of adverse events during plasma transfusion, including transmission of some viral infections, transfusion-related acute lung injury, and allergic reactions.

Condition

Three chronic hematological conditions were targeted by the research on the optimal use of S/D plasma:

- thrombotic thrombocytopenic purpura (TTP) (both congenital and acquired forms)
- hemolytic uremic syndrome (HUS) with associated factor H deficiency
- clotting factor deficiencies for which specific licensed concentrates may not be readily available (e.g., factor V, factor XI, factor XIII).

These conditions are of interest because patients affected by them typically receive a high volume of plasma annually.

Issue

Over the years, significant progress has been made in reducing the risk of pathogen transmission through blood transfusions. However, there remains a risk from both known and emerging pathogens.

S/D plasma is currently the only Health Canada-licensed, commercially available plasma component that includes an effective pathogen inactivation step – S/D treatment – in its manufacturing process. As a result, Canadian jurisdictions (except Quebec) must decide whether to add S/D plasma to the portfolio of plasma protein products that is distributed to hospitals through Canadian Blood Services.

The Canadian Agency for Drugs and Technologies in Health (CADTH) developed a recommendation on the optimal use of S/D plasma to support this decision-making process.

Key Messages:

S/D plasma may be considered as an alternative to standard plasma for certain patients who need a high volume of transfusions annually because they have one of the following conditions:

- TTP (both congenital and acquired forms)
- HUS with associated factor H deficiency
- or clotting factor deficiencies for which specific licensed concentrates may not be readily available (e.g., factor V, factor XI, factor XIII)

and they:

- have experienced an allergic reaction to frozen plasma, or
- have a pre-existing lung disorder, or
- need frozen plasma, but a blood group-compatible product is not available in a timely manner.

Methods

Research efforts to develop the recommendation for the optimal use of S/D plasma focused on:

- clinical evaluation (systematic review) comparing S/D plasma with standard plasma
- economic analysis and budget impact analysis on S/D plasma
- ethical assessment of issues related to the use of S/D plasma
- comments from a public call for feedback.

CADTH's Panel of Experts used clinical, economic, and ethical evaluations, as well as stakeholder feedback, to develop the recommendation.

Results

The systematic review included 15 studies involving patients from randomized controlled trials and observational studies, and one multinational hemovigilance study. From a clinical perspective, there is no high-quality evidence to suggest that the use of S/D plasma is associated with more effective treatment of the hematologic conditions targeted by the recommendation.

The cost-effectiveness analysis indicated that S/D plasma treatment is more expensive than frozen plasma and produces only a small increase in quality-adjusted life-year (QALY) (a measure of the effectiveness of the treatment), whereas the incremental cost per QALY (\$934,000) is very high. Based on traditionally accepted cost per QALY standards, the use of S/D plasma is not cost effective.

From an ethical perspective, the precautionary principle (or the importance of taking due precaution to not cause harm to patients) requires that a potentially safer treatment be made available whenever possible.

Based on its assessment, and acknowledging that the risk associated with the transfusion of plasma products is low, the Panel of Experts recommends that S/D plasma be made available to patients at higher risk of adverse events because they need a high volume of plasma and face specific clinical circumstances.

For complete project information: www.cadth.ca

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