



<b>Title</b>	<b>Recombinant Activated Factor VII in Treatment of Hemorrhage Unrelated to Hemophilia: A Systematic Review and Economic Evaluation</b>
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## Aim

To assess the implications of adopting rFVIIa in managing uncontrolled bleeding in individuals without hemophilia or other inherited bleeding disorders in the following off-label indications: treatment of bleeding associated with blunt or penetrating trauma; surgery unrelated to trauma; gastrointestinal bleeding; and intracerebral hemorrhage (ICH).

## Conclusions and results

Based on the available evidence, we found no clearly demonstrated benefit or harm from using rFVIIa relative to usual care in uncontrolled bleeding due to blunt or penetrating trauma, surgery that is unrelated to trauma, gastrointestinal bleeding, or ICH in individuals without hemophilia, inherited platelet disorders, or other coagulopathies. Dose-response relationships in the safety and efficacy of rFVIIa were inconsistent. Economic impact was uncertain due to the weakness of current clinical efficacy data. Potential cost effectiveness can only be confirmed by future research.

## Recommendations

Not Applicable.

## Methods

A systematic review of clinical and economic literature was performed along with an economic evaluation and budget impact analysis. The economic evaluation focused on the routine use of rFVIIa compared to standard care without rFVIIa, from the perspective of the publicly funded healthcare system. The budget impact of using rFVIIa for blunt trauma was viewed from the perspective of the Canadian Blood Services.

## Further research/reviews required

The potential cost effectiveness of rFVIIa in severe blunt trauma can only be confirmed by further research.