Why we need better drug monitoring

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The use of recombinant activated factor 7 (rFVIIa) despite its potential for adverse events displays the serious shortcomings of Canada's current drug surveillance system, according to a commentary published in *CMAJ* (*Canadian Medical Association Journal*).

Off-label use of this therapy — a blood product — was driven by key physician opinion leaders who thought recombinant factor VIIa could be used to treat or prevent bleeding in patients without hemophilia at risk of death. This shows how promising case reports can change practice prematurely before more data is available.

Use of recombinant factor VIIa in patients without hemophilia is expensive, marginally effective and risky.

"Off-label use of drugs can be beneficial, however, without a process for ongoing evaluation, deaths, disabilities and costs may be accruing without being obvious at the bedside," writes Paul Hébert, Editor-in-Chief, *CMAJ*, with coauthors. "With recombinant factor VIIa, physicians were too eager to believe the anecdotes and did not push for the appropriate studies."

Monitoring drug use as well as safety is complicated and lacks a simple solution, although several changes should be considered. These include improved collaboration between payers and insurers who approve and track usage as well as manufacturers, prioritizing higher risk drugs in an improved drug surveillance system, better evaluation of new drugs and greater surveillance powers for regulatory bodies.

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