

# Adverse Drug Event Reporting: Getting the Message Across

## A systematic review of adverse drug event reporting systems

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**PROJECT CONTEXT**

Adverse drug events (ADEs) are harmful and unintended consequences of medications.

In Canada, ADEs cause approximately 1.7 million visits to Emergency Departments, of which 70% are deemed preventable.

**PROBLEM TO BE ADDRESSED**

Poor documentation of relevant ADE information in electronic patient records has been identified as an important factor in the recurrence of preventable ADEs.

**PROJECT AIMS**

We aim to develop an electronic ADE reporting platform within PharmaNet which captures **patient-level** and **medication-level** ADE reports to enhance the communication of these events **across healthcare sectors** (e.g. from acute to community and vice versa) and **between care providers** (e.g. between pharmacists, nurses and physicians).

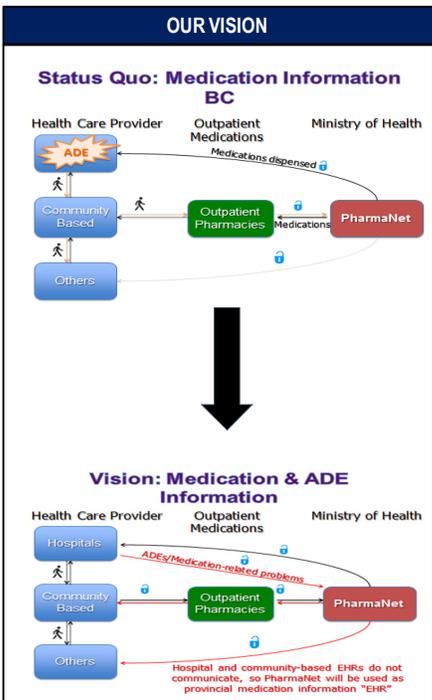
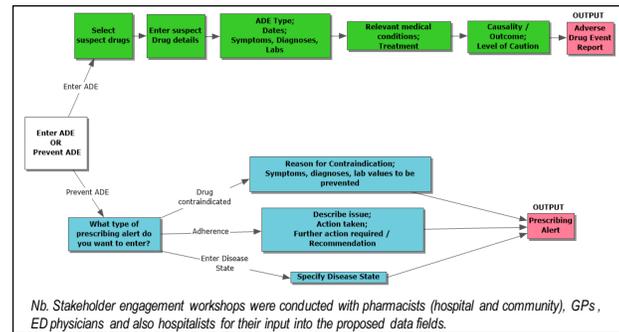
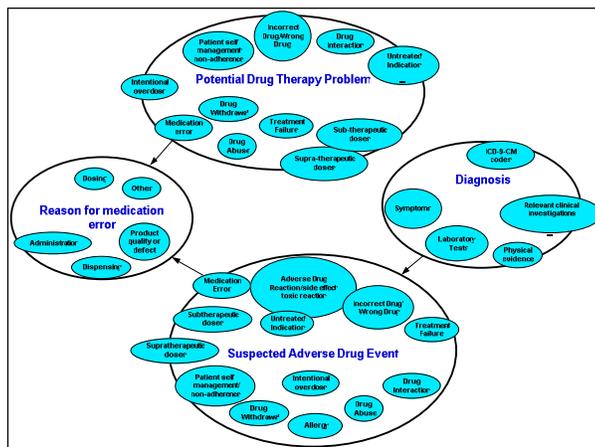
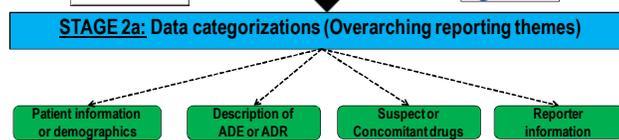
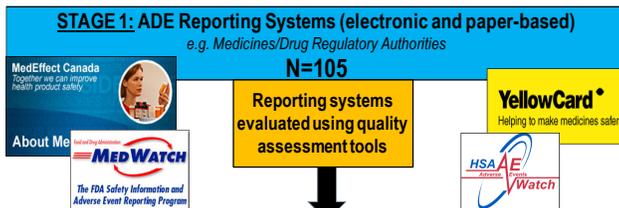


Fig 1. Information flow about adverse drug events between care providers relies largely on patients (walking person), and is presently inadequate (dotted lines). PharmaNet provides a means for reliable electronic access to provincial medication dispensing records (solid lines).



**METHODS**

- STAGE 1:**
- We systematically searched both peer-reviewed and grey literature and identified 105 ADE reporting systems from 7162 citations. We then abstracted data elements for all reporting systems. We evaluated each system using modified quality assessment tools. (see figure)
- STAGE 2a and STAGE 2b:**
- We categorized all data elements in an iterative manner to identify overarching reporting concepts and eliminated duplicate concepts. We identified relationships and any existing hierarchy between reporting concepts and data elements using Inspiration software. (see figure)
- STAGE 3:**
- We conducted stakeholder engagement workshops with end users in order to establish which data fields were required by various staff groups for reporting in order to generate a 'minimum required dataset'.

**LESSONS LEARNED/RESULTS**

- We identified a total of 3249 data fields which were used to report drug therapy problems including ADEs.
- We identified 33 reporting concepts, including, for example, ADE or ADR description, elements of causality, and treatment recommendations.
- We found that there was high degree of variability in the fields used to report ADE data which was based on whether the system was used for regulatory or clinical purposes.
- End-users made significant refinements to the initial draft of data fields and corresponding response options based on their clinical roles and perspectives on ADE reporting.

\*\*\*\*BEST PRACTICE RECOMMENDATION\*\*\*\*

Based on our study, we recommend that there is extensive testing and input from end-users prior to the implementation of systems in order to ensure that they are intuitive and reflective of user needs.

**NEXT STEPS**

Pilot testing of the proposed data fields is planned via paper means within emergency departments in British Columbia, and subsequently with local electronic medical record (EMR) developers in order to ensure that they can be used to report ADEs accurately in PharmaNet.

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