Challenges Care Providers Face Documenting Adverse Drug Events: An Observational Study

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Context

Adverse Drug Events (ADEs)

ADEs are “the unintended and harmful events associated with medication use.”

- ADEs have become a leading cause of ambulatory care and emergency department visits (~12%) and of unplanned hospital admissions.
- Studies from a variety of care settings suggest that 50-70% of all ADEs are preventable and that the incidence of repeat ADEs has been increasing since the 1980s.
- Poor documentation and communication of ADE information between care providers and across healthcare sectors is likely an important factor in the recurrence of preventable ADEs.

An Example...

An 85-year-old woman with mild hyperparathyroidism (a condition caused by overactive parathyroid glands) was admitted to hospital because of delirium. She was taking hydrochlorothiazide for high blood pressure. On admission, had a high calcium level, which was thought to be the cause of her delirium. Hydrochlorothiazide was withdrawn because it likely contributed to the high calcium level. Her serum calcium level decreased, and the delirium resolved.

The Aim of this Study

The aim of this study is to understand frontline clinicians’ workflows, the conditions of the clinical environment, the well-challenges providers face reporting ADEs, and what will facilitate ADE reporting. To develop a system that providers will use, we must be attentive to the nature of collaborative clinical work and interactions between people and technology in the clinical setting.

The introduction of any health technology will change the nature of the care environment, and a successful implementation requires a context-sensitive, user-driven design.

Methods

Qualitative fieldwork included user-engagement workshops and workplace observations. The research was guided by the following principles:

- Participatory design takes as its foundation Suchman’s (2007) insights that plans differ from situated actions, people are often unable to voluntarily describe tacit elements of their work, and the design of technology is only fully completed when it is in use.
- Grounded theory is a qualitative approach that aims to be inductive, rooted in the data discovered in ‘real world’ observation, and sensitive to complexity and variation in perspective.

New Urgency with Bill C-17

On November 6th, 2014, the Canadian government introduced amendments to the Food and Drugs Act through Bill C-17, “Protecting Canadians from Unsafe Drugs”, that mandate the reporting of serious adverse drug reactions, a subset of adverse drug events.

It is unclear how ‘serious adverse drug reaction’ will be defined, what information will be required, what timelines will be expected, and who will be obligated to report.

However, this is an opportunity to evaluate current reporting practices, understand their limitations, and offer alternative models for leveraging reporting to improve safety.

Our Project

A New Approach to ADE Reporting

Our overarching objective is to develop a novel, provider-centric means of capturing patient-level electronic ADE data to facilitate patient care and motivate reporting. This platform will be implemented using PharmIt, BC’s medication information system.

The new reporting platform aims to:

- Add patient-specific ADE information to outpatient medication records to inform clinical decision-making and prevent recurrent ADEs.
- Enable the collection of high-quality patient-level data on ADEs that can be linked to health outcomes, drug exposure and cost data to inform quality improvement, research, and surveillance.

Preliminary Observations

Providers have varying interpretations, attitudes, and assumptions related to ADE reporting.

- It’s too difficult to determine if a particular drug is responsible for an adverse event.
- This single case can’t contribute to universal knowledge.
- I’ll look stupid if I’m wrong.
- I need to be 100% certain!
- Medication risks aren’t the focus of my practice.
- My patients come first.

ADEs are not reported in straightforward ways.

Existing reporting systems are designed for administrators and researchers who want information and terminologies that are standardized and consistent. From the provider’s perspective, however, it is often difficult to fit the ambiguous and contingent real world experience of the ADE into the inflexible fields in the form.

As one provider pointed out:

“Sometimes the complex real story just doesn’t fit – there’s nowhere to specify the ifs, ands, or buts!”

Some examples:

- The “type” of ADE – Some ADEs fall under multiple types, or none of the types listed in a form, or there is uncertainty as to which type at the time of reporting.
- The suspect drug – Often there are multiple suspect drugs, especially in patients that are on as many as 20 medications. What is ‘suspect’ and what is ‘concomitant’?
- Symptoms/diagnoses – In some scenarios, it can be difficult to determine whether the symptoms are due to an underlying condition or the ADE, or perhaps the ADE exacerbated a pre-existing condition.

Implications for the Design of a New ADE Reporting System

- Integrate reporting into the process of care and into the electronic work interface already accessed by care providers. Implement reporting as part of existing workflows so that it is easy, convenient, and useful.
- Motivate providers because reporting matters to their patients. Ensure reporting can make a difference for the individual patient.
- Make the ADE report a “living document”. Enable multiple providers to edit and update details for a report across the entire time period of the ADE.
- Only include fields that are most relevant to clinical practice. Minimize user entry to account for the time constraints of the clinical environment.
- Provide a platform for constant, context-specific knowledge-building. Create a learning-through-practice environment with feedback, collaboration, and shared expertise.
- ‘Stop ADEs before they happen via preventative reports’. Enable providers to enter a prescribing alert so that future providers are aware of specific medication-related conditions or issues.

References


Example “mock-up” screens for new ADE reporting system