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."[1]

- ADEs have become a leading cause of ambulatory care and emergency department visits (~12%) and of unplanned hospital admissions.[2]
- 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.[2,3,4]
- 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 hyper-parathyroidism [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 Hydrochlorothiazide was withdrawn because it likely contributed to the high calcium level.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 patient was treated with cinacalcet [to treat hyperparathyroidism] and her serum calcium remained stable. However, several months later she presented to the emergency department with recurrent delirium and a dangerously high calcium level.

Her family physician had re-prescribed hydrochlorothiazide.[5]

The Problem with Spontaneous Reporting

- Current adverse event reporting systems have been designed to support administrative data needs rather than clinician needs at point of care.
- Submitted ADE reports have no immediate bearing on individual patient care and aren't attentive to the 'real-world' challenges of documenting ADEs.

As a result, **clinicians underreport ADEs.** Underreporting is a serious limitation of spontaneous reporting systems - studies of reporting rates for various national reporting agencies suggest that <1-10% of events are reported.[6,7]

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.

Second Session, Forty-first Parliament,
62-63 Elizabeth II, 2013-2014

STATUTES OF CANADA 2014

CHAPTER 24

An Act to amend the Food and Drugs Act

ASSENTED TO

6TH NOVEMBER, 2014
BILL C-17

5. The Act is amended by adding the following after section 21.7:

21.8 A prescribed health care institution shall provide the Minister, within the prescribed time and in the prescribed manner, with prescribed information that is in its control about a serious adverse drug reaction that involves a therapeutic product or a medical device incident that involves a therapeutic product.

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 would be implemented in PharmaNet, 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.

The Aim of this Study

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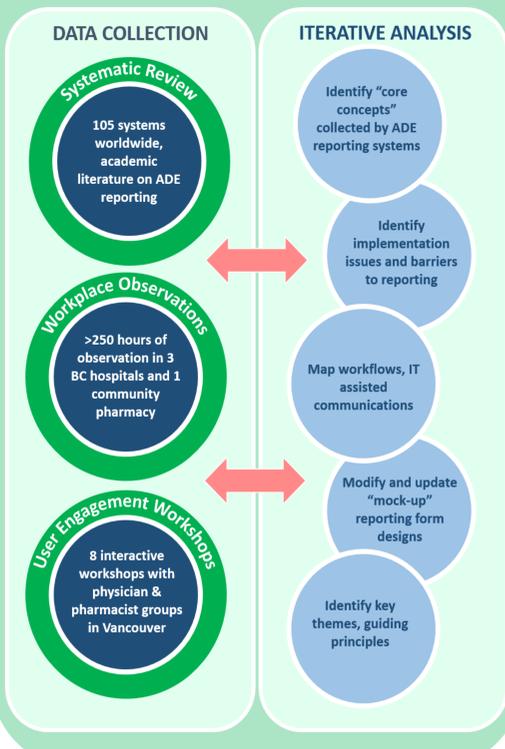
To develop a system that providers will *use*, we must be attentive to the nature of collaborative clinical work and interactions between people and technology in the clinical setting.

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.
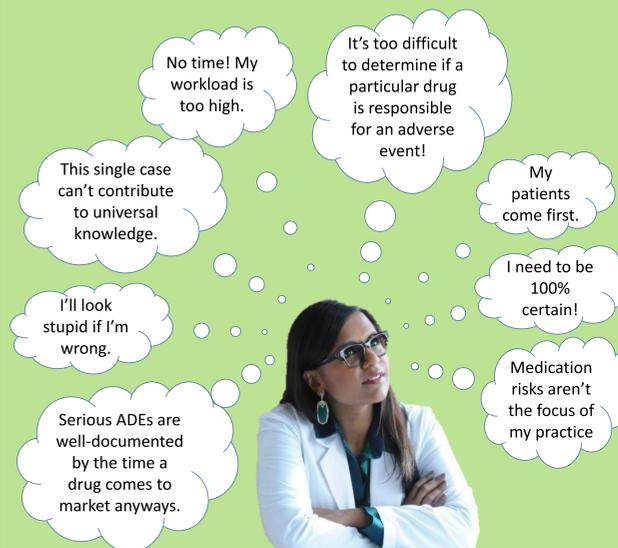
Methods

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.[8]
- **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.[9]

DATA COLLECTION

Systematic Review
105 systems worldwide, academic literature on ADE reporting

Workplace Observations
>250 hours of observation in 3 BC hospitals and 1 community pharmacy

User Engagement Workshops
8 interactive workshops with physician & pharmacist groups in Vancouver

ITERATIVE ANALYSIS

Identify "core concepts" collected by ADE reporting systems

Identify implementation issues and barriers to reporting

Map workflows, IT assisted communications

Modify and update "mock-up" reporting form designs

Identify key themes, guiding principles

Preliminary Observations

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

> No time! My workload is too high.
> 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.
> My patients come first.
> I'll look stupid if I'm wrong.
> I need to be 100% certain!
> Serious ADEs are well-documented by the time a drug comes to market anyways.
> Medication risks aren't the focus of my practice.

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. Yet, the event is very serious, and providers want to report it.
- 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.

ADEs are not clear-cut events.

Existing reporting systems do not account for the complexity and uncertainty inherent in diagnosing ADEs. Education or 'mandatory' reporting initiatives can miss the fact that many providers don't report ADEs because there is so much ambiguity in their identification.

- **Complex medication regimens.** Complex regimens can make it difficult to identify culprit drugs, or there may be multiple events identified in a patient.
- **Fluctuating dosages.** Dosages may be out-of-date or incorrect when the patient presents.
- **Varying patient adherence and self-management.** Patient adherence varies significantly and provider-patient interviews can yield varying information depending on the dynamics of the interaction.
- **Expected events.** There is uncertainty about whether to report known events (e.g. known side effects or responses).
- **Varying severity of events.** Severity plays a significant role in determining what providers feel is important to report – but different providers have different interpretations of what is 'severe'.
- **Medication errors.** Many ADES can also be interpreted as medication errors. Reporting these events can create uncomfortable social dynamics or duplicate documentation work.
- **Previously unknown ADEs.** In practice, many providers may dismiss events that are not already associated with a drug as unrelated.
- **Incomplete information.** Time constraints and documentation limitations mean that providers may have to make decisions without all relevant information.

ADEs are identified, treated, and reported through *processes*, not as discrete tasks or events.

Existing reporting systems are amenable to reporting events that are short and discrete – the report is like a "snapshot" of all of the important details related to the event. Yet in many cases it is unlikely that a provider will be able to observe an ADE and its treatment outcome from start to finish – it may take days, weeks, or months and involve multiple care providers.

Health providers are not diagnosing, reporting robots, they take time to

- Deliberate and collaborate with others
- Weigh factors and evidence, consider contexts
- Consider alternative hypotheses
- Create personalized treatment approaches

> *"People don't do 'tasks' – they make context-sensitive, knowledge-driven decisions."[10]*

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-making.** 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.
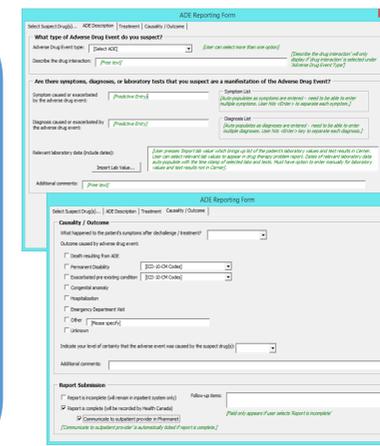
Example "mock-up" screens for new ADE reporting system

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