Designing an Adverse Drug Event (ADE) Reporting System to Prevent Unintentional Re-exposures to Harmful Drugs

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Background

- ADEs are the unintended harmful consequences of medication use and a leading cause of ED visits and unplanned hospital admissions.
- Up to 30% of ADEs recur within six months due to unintentional re-exposure to culprit medications.
- Low reporting rates, estimated at 6%, hinder drug safety.
- Existing systems are not user-friendly; data entry is cumbersome and time-consuming.
- Systems design tends to accommodate the needs of researchers and regulatory agencies, failing to support clinical processes.

Rationale

- Test assumptions and observe roles of relevant actors/actants that might otherwise go unconsidered for design
- Bottom-up collaborative design, allowing end users to highlight challenges and opportunities, propose solutions, and point to other issues.
- Focus on data needs of clinical care providers, rather than data needs of organizations engaged in drug safety surveillance.
- Address methodological gap in the way that ADE reporting systems have been conceptualized, designed and implemented.

METHODOLOGY

participatory design · action research

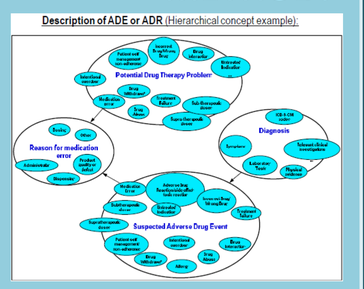
Systematic Review

GOALS:

- Identify what data about ADEs is currently being collected, how, and by whom.
- Use findings to establish a preliminary set of data fields.

METHOD:

- 108 systems identified through a grey literature search and systematic review.
- Data fields grouped into overarching concepts.



Participatory Observations

GOALS:

- Understand clinical workflow, the work environment, how ADEs are diagnosed and reported, and barriers to reporting.

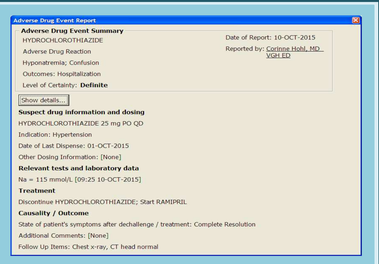
METHOD:

- Observations in EDs and wards of 3 hospitals, in a rural ambulatory care centre, and in 3 community pharmacies in BC.
- Shadowed clinical pharmacists, nurses, and physicians.

Focus Groups

GOALS:

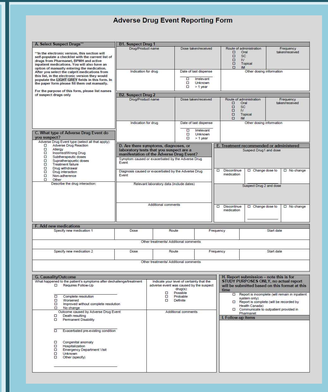
- Obtain feedback and refine the form.
- Identify challenges, opportunities, and solutions
- Engage end users.



METHOD:

- 11 workshops among emergency physicians, family physicians, hospitalists, hospital pharmacists, and community pharmacists.
- Preliminary ADE reporting form presented to clinicians.

Pilot Testing



GOALS:

- Test the content, functionality, and clarity of the form.
- Understand required linkages to other electronic systems.

METHOD:

- Paper-based pilot testing in the clinical setting before electronic build.

Objectives

- Reduce recurrent, preventable ADEs
- Facilitate clinical decision making
- Facilitate ADE documentation and communication
- Generate data on ADEs for drug safety surveillance
- Contribute to literature on qualitative research on ICT solutions in health
- Meet future Health Canada reporting requirements

Next Steps

1. Finalize system output
2. Implementation
3. Process evaluation

I. In PharmaNet
II. In hospital EMRs
III. For community pharmacies