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

**Objectives**
- **Reduce recurrent, preventable ADEs**
- Facilitate clinical decision making
- Facilitate ADE documentation and communication
- Generate data on ADEs for drug safety surveillance

**Focus Groups**

**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.

**Participants 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.

**METHOD**
- **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.

**Next Steps**
1. Finalize system output
2. Implementation
   - I. In PharmaNet
   - II. In hospital EMRs
   - III. For community pharmacies