Medical Device-Related Incidents: Factors that Influence their Occurrence, Recognition, Reporting. And a Taxonomy of Mitigation and Prevention Strategies

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May 7, 2013
Agenda

• Introduction & Issue
• Research Questions & Objectives
• Methods
• Preliminary Results
• Next Steps
Introduction

• Benefits of medical devices

• Associated with up to 62% of adverse events

• Device-related incidents
Post-Marketing Surveillance

• Benefits

• Reality
Issue

• Evidence on safety and effectiveness of medical devices

• Medical device problems in clinical practice

• Collection of evidence for medical device safety policy
Research Objectives

1. Identify common medical/surgical device-related incidents, and for these:

2. Explore factors that influence device-related incident occurrence, recognition, reporting and resolution according to multiple theoretical perspectives

3. Develop a taxonomy of strategies to mitigate or prevent device-related incidents that can support decision-making
Theoretical Framework on Identification and Exploration of Factors

- Device
- Incident occurrence
- Incident reporting

Characteristics:
- Devices
- Clinicians
- Teams
- Institutions
- Systems
- Patients

Human factors
- Cognitive psychology
- Sociology
- Others that emerge

Characteristics:
- Reporting systems
- Professional culture
- Education
- Feedback
- Incentives
Theoretical Framework on Taxonomy

1. Error identified in surveillance system
2. Characteristics of error contained in surveillance system
3. Identification of mitigation and/or prevention strategies
   - Procurement
   - Utilization
   - Process improvement
   - Quality assurance
   - Policy change and implementation
   - Regulation
   - Training
   - Reassessment
   - Disinvestment
4. Resolution
5. Execution of mitigation and/or prevention strategy
   - Frequency
   - Severity
   - Current policies
   - Risk of reputation
   - Risk of liability
   - Ethics
   - Costs
   - Alternative therapies
Methods

Identify and explore factors that influence common device incidents and their recognition/reporting

- Systematic review of published medical and grey literature
- Telephone interviews of 30 physicians
Methods

Develop taxonomy of strategies to mitigate/prevent device-related incidents

• Multiple case study to investigate potential resolutions
  ▪ Interviews
Systematic Review-Preliminary Results

• Selection criteria

• 15 studies included

• Quality assessment
Systematic Review-Preliminary Results (cont’d)

• Nature of incident

• Factors that influence incidents identified by health care professionals

• Impact of interventions/strategies to improve identification and recognition of incidents by health care professionals
Systematic Review-Discussion

• Summary of evidence

• Common barriers to medical device surveillance

• Reporting of device-related incidents
Systematic Review-Knowledge Gaps

- Insufficient evidence available

- Limited generalizability of study results
Next Steps

• Finalize systematic review
• Identify and recruit 30 physicians for interviews
• Define case studies by existence of surveillance system or by common devices prone to errors
Research Outcomes

• Strength post-market surveillance
• Target quality improvement
• Conceptual framework
• Decision criteria
• Enhanced patient safety and health care outcomes
Knowledge Translation

- Involvement of various stakeholders

- Publications in biomedical journals
Questions