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**Patient Safety
Research Introductory
Course**

Session 8

Knowledge Strengthening for Patient Safety

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Overview

- In a last session, we will try to reflect on questions and comments from the participants and also review the previous sessions. We will also suggest how to advance learning and where to find other useful resources for future study.
- Review of Key Messages: Lectures 1-7





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A Transforming Concept

Corollary # 1:

It makes no sense to punish people for making errors

Corollary # 2:

You can decrease errors by improving systems



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Safety Culture

...exhibits the following five high-level attributes that health care professionals strive to operationalize through the implementation of strong safety management systems.

(1) A culture where all workers (including front-line staff, physicians, and administrators) accept responsibility for the safety of themselves, their coworkers, patients, and visitors.

(2) [A culture that] prioritizes safety above financial and operational goals.

(3) [A culture that] encourages and rewards the identification, communication, and resolution of safety issues.

(4) [A culture that] provides for organizational learning from accidents.

(5) [A culture that] provides appropriate resources, structure, and accountability to maintain effective safety systems.



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Common Themes

- Patient safety appears to be a problem in all nations
- Definitions are important so we can count the same things
- Common themes include issues with human performance, human factors, and communications
- Need more information about the frequency of adverse events, errors by country and setting
- Research needed to:
 - Identify and describe safety issues
 - Develop and test safety solutions

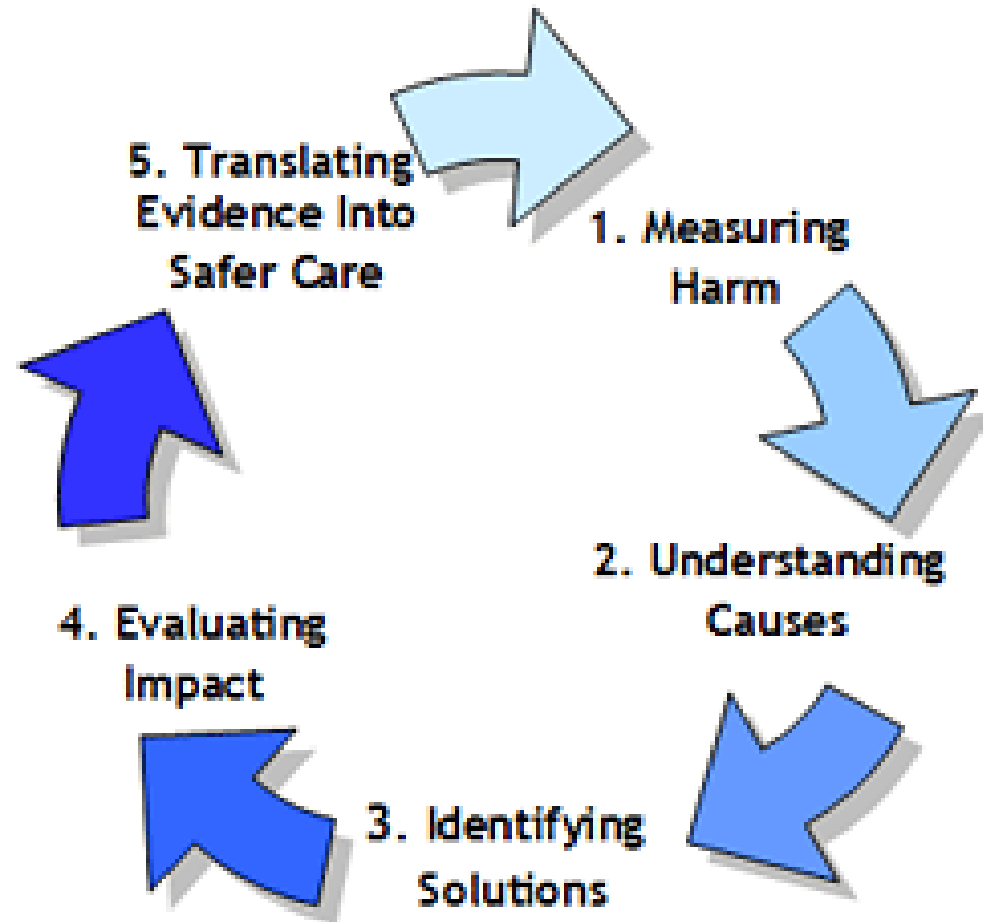


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Components





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Patient Safety Research Overview

- Five key domains in patient safety research
 - Selection of study type will depend on domain
 - Also on resources available
 - Qualitative and quantitative studies are both valuable
- Need more evaluations of solutions in particular
 - But often have to define problem in a particular setting and having data can enable move to action



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What Are We Trying to Measure?

- Errors: the failure of a planned action to be completed as intended or use of a wrong plan to achieve an aim
 - Latent errors: defects in the system eg, poor design, understaffing
 - Active errors: errors made by frontline health staff eg, dose errors
- Adverse Events: harm caused by health care
- Safety targets: medication errors, HAI, surgical complications, device complications, identification errors, death



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4 Basic Methods of Collecting Data

- Observation
- Self-reports (interviews and questionnaires)
- Testing
- Physical evidence (document review)



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Measurement Methods

- Prospective
 - Direct observation of patient care
 - Cohort study
 - Clinical surveillance
- Retrospective
 - Record review (Chart, Electronic medical record)
 - Administrative claims analysis
 - Malpractice claims analysis
 - Morbidity & mortality conferences/autopsy
 - Incident reporting systems

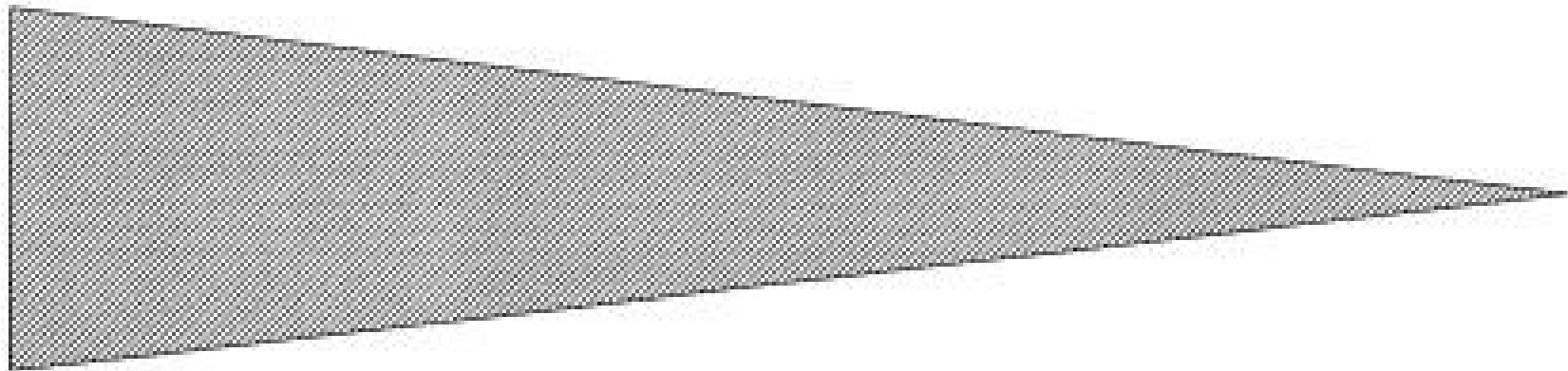


Relative Utility of Methods to Measure Errors

Latent errors

Active errors

Adverse events



- Incident reporting
- Autopsies and morbidity and mortality conferences
- Malpractice claims files analysis

- Chart review
- Administrative data analysis
- Information technology

- Direct observation

- Clinical surveillance

Thomas & Petersen, JGIM 2003



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Direct Observation

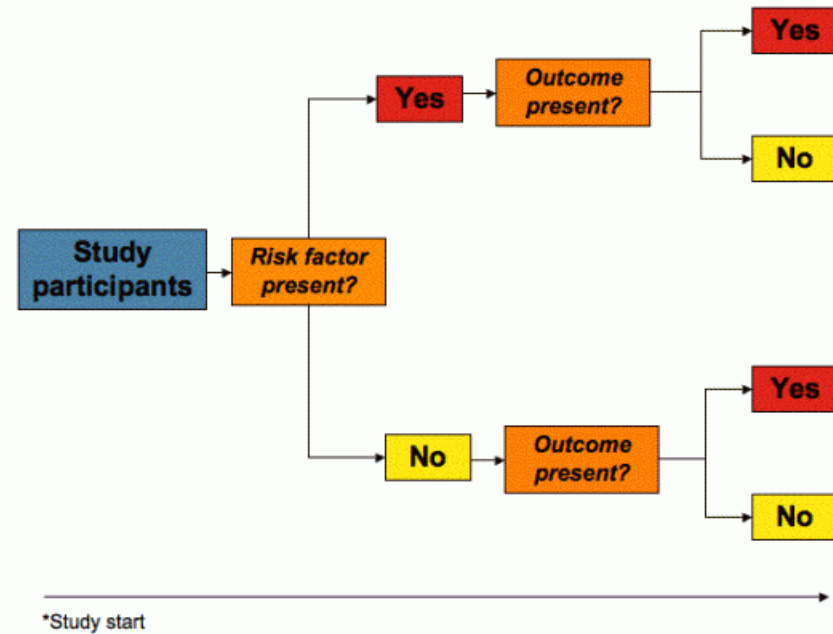
- Good for active errors
- Data otherwise unavailable
- Potentially accurate, precise
- Training/expensive
- Information overload
- Hawthorne effect?
- Hindsight bias?
- Not good for latent errors





Cohort / Clinical Surveillance

- Potentially accurate and precise for adverse events
- Good to test effectiveness of intervention to decrease specific adverse event
- Can become part of care
- Expensive
- Not good for detecting latent errors





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Chart Review

- Uses readily available data
- Common
- Judgments of adverse events not reliable
- Expensive
- Records incomplete, missing
- Hindsight bias





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Provider Survey

- Good for latent errors
- Data otherwise unavailable
- Wisdom of crowds
- Can be comprehensive
- Hindsight bias (bad outcome = bad care)
- Need good response rate





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Malpractice Claims Analysis

- Good for latent errors
- Multiple perspectives (patients, providers, lawyers)
- Hindsight bias
- Reporting bias
- Non-standardized source of data





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Reporting & Learning System

- Can detect latent errors
- Provide multiple perspectives over time
- Can be a standard procedure
- Reporting bias
- Hindsight bias

**All accidents must
be reported.**

*... explain exactly
what happened*





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Summary

- Different methods to measure and understand errors and adverse events have different strengths and weaknesses
- Mixed methods approaches can improve understanding



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Two Types of Solutions

- Solution not yet identified:
 - Pre-post
 - Randomized (double blind, controlled) trial
 - Cluster randomization
- Known solution
 - Improving reliability of effective practices



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Locus of Intervention

- Patient
- Health care worker
- Workplace
- System





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Hierarchy of Research Evidence





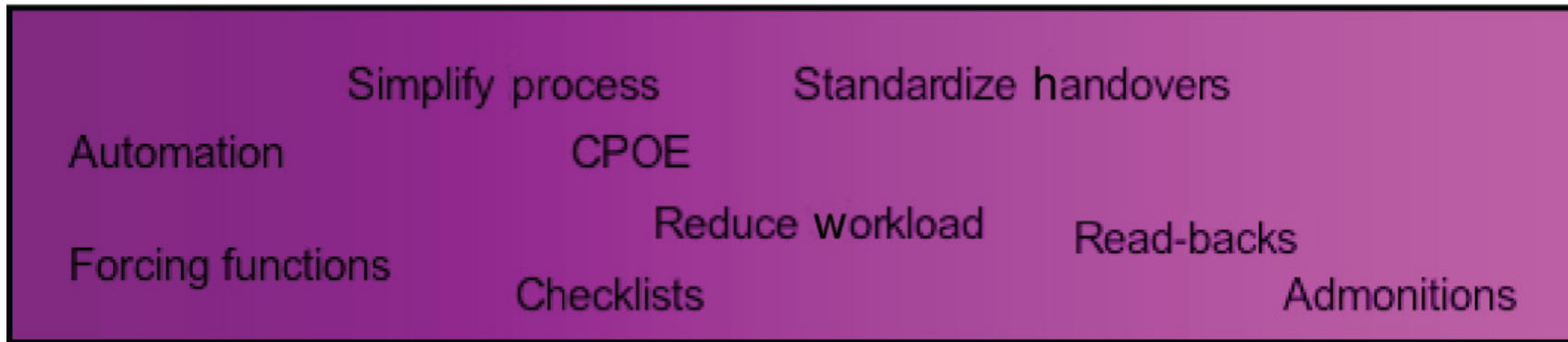
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Strong interventions

Weak interventions



Woodward HI, et al. 2010.

Annu. Rev. Public Health 31:479–97

Annual Reviews



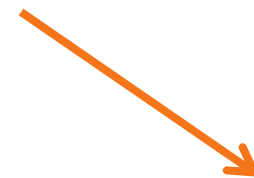
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Randomized Controlled Trials

- Strong evidence for efficacy
- Control for unmeasured variables
- Require acceptability/
equipoise to be conducted
- Not ideal for effectiveness
- Expensive, time-consuming
- Not good for subgroups



CONTROL



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Interventions to Improve Safety

- **Much needs to be learned about effective interventions to improve safety**
 - **Identifying effective interventions requires well designed and conducted studies**
- **There are evidence based procedures and interventions that can improve safety**
 - **Once implemented, need to be evaluated**



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How do we know if we are safer?

- Harm (outcome)
- Appropriate care (process, explicitly defined)
- Learning
 - Measure **presence** of policy or program
 - Staff **knowledge** of policy or program (testing)
 - Appropriate **use** of policy or program (direct observation)
- Safety culture



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Integrated Approach to Translating Evidence to Practice

- A focus on **systems** (how we organise work) rather than care of individual patients
- Engagement of **local interdisciplinary teams** to assume ownership of the improvement project
- Creation of **centralised support** for the **technical work**
- Encouraging **local adaptation** of the intervention
- Creating a **collaborative culture** within the local unit and larger system.

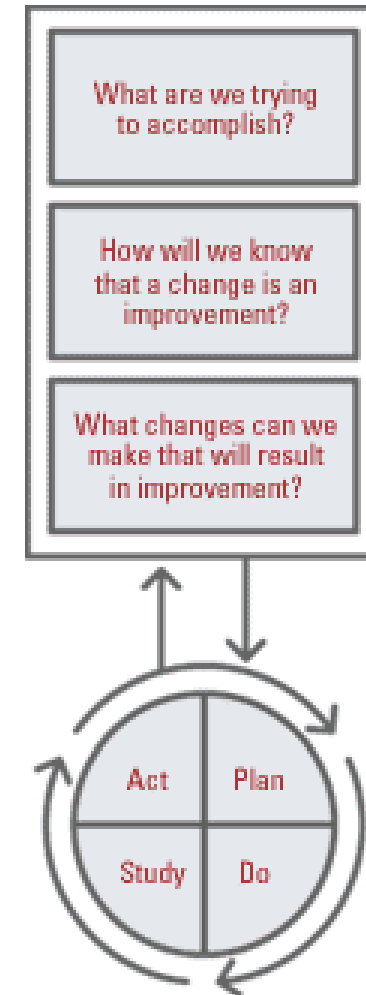


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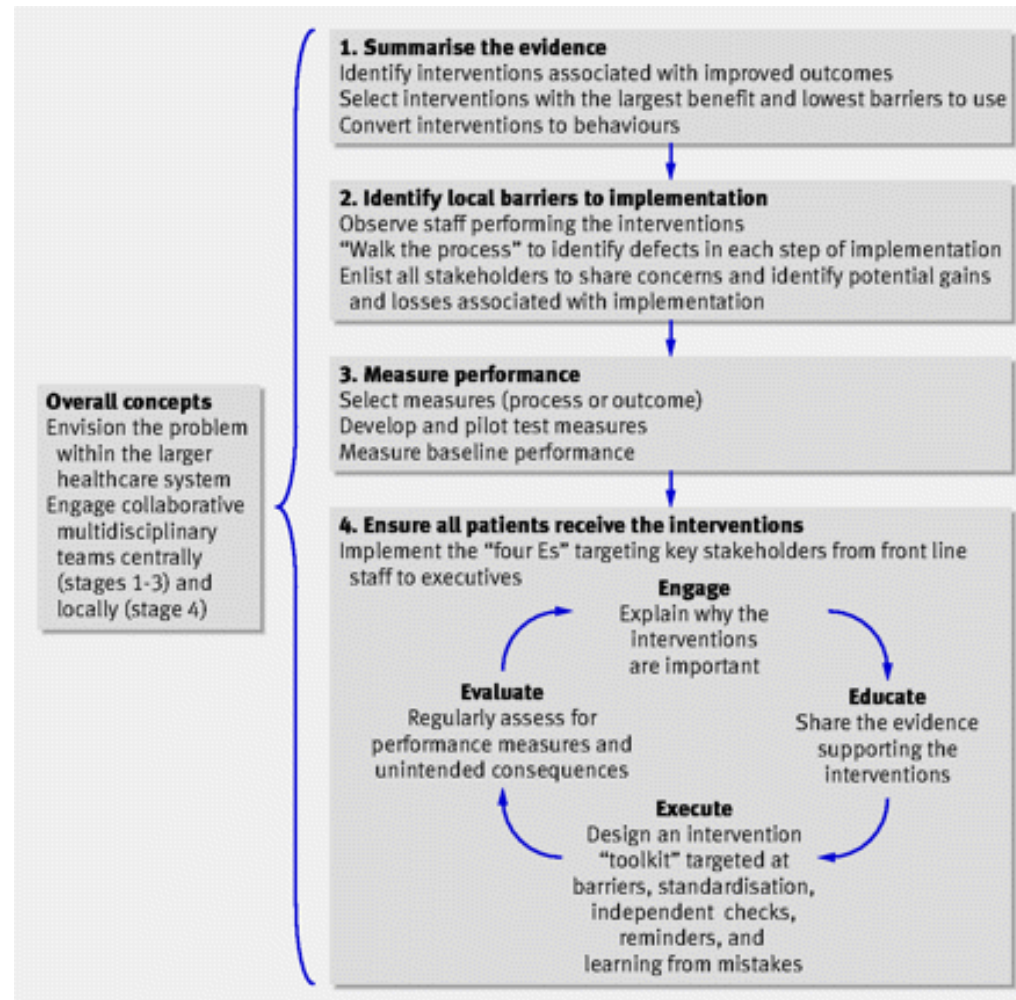
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Institute for Healthcare Improvement (IHI) Model for Improvement





Strategy for Translating Evidence to Practice





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Ensure All Patients Receive the Intervention

- Final and most complex stage is to ensure that all patients reliably receive the intervention
- Interventions must fit each hospital's current system, including local culture and resources
- 4 "Es"
 - Engage
 - Educate
 - Execute
 - Evaluate



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Concluding Remarks

- Additional skills beneficial
- Research ethics
- Mentored research experience crucial
- Proposal writing skills, identification of funding sources
- Additional learning opportunities
- Online resources



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Additional skills beneficial

- Basic epidemiology and biostatistics
- Data management
- Survey research methods
- Writing, dissemination



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The Research Protocol

- Research question
- Significance
- Design
 - Subjects
 - Entry Criteria
 - Recruitment
 - Variables
 - Predictor
 - Outcome
 - Statistical issues
 - Sample size and power



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Data Management

- Defining the variables
- Creating the study database and data dictionary
- Entering the data and correcting items
- Creating a dataset for analysis
- Backing up and storing the dataset



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Survey Research Methods

- Identifying the concepts to be measured
- Selecting good instruments, or
- Designing good questions
- Assembling the instruments for the study
- Administering the instruments





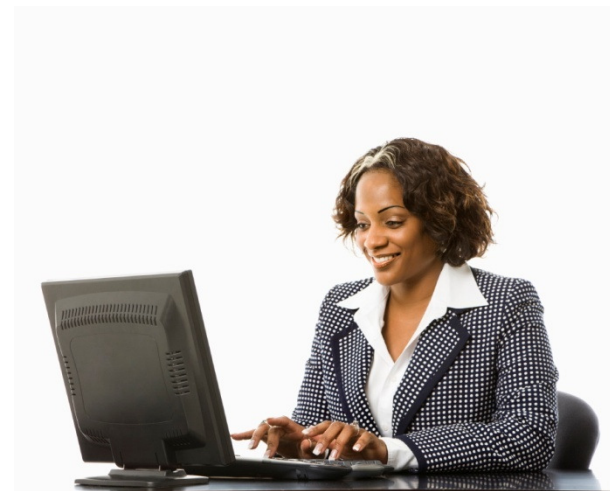
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Writing, Dissemination

- Papers for publication
- Presentations
- Press releases
- Policies, protocols, guidelines
- Grant proposals





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Research Ethics

- Basic Principles
 - Respect for persons
 - Beneficence
 - Justice
- Institutional/Ethical Review Board
- Additional considerations
 - What are appropriate comparison groups?
 - Affordability of interventions
 - Status of collaborators





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Mentored Research Experience

- A mentor is someone who doesn't rest until you succeed
- The strongest predictor of academic success
- Single mentor or committee of mentors





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Proposal writing skills

Identification of funding sources

- Practice in writing proposals
- Elements of proposals
- Characteristics of good proposals
 - Scientific quality
 - Technical quality
 - Responsiveness
- Funding sources of support





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References

- Hulley S. et al. Designing clinical research. Lippincott Williams & Wilkins; 3rd edition (2006)
- AHRQ Patient Safety Network <http://www.psnet.ahrq.gov>
- American College of Surgeons National Surgical Quality Improvement Project <https://acsnsqip.org/login/default.aspx>
- Joint Commission National Patient Safety Goals <http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/>
- WHO Patient Safety www.who.int/patientsafety



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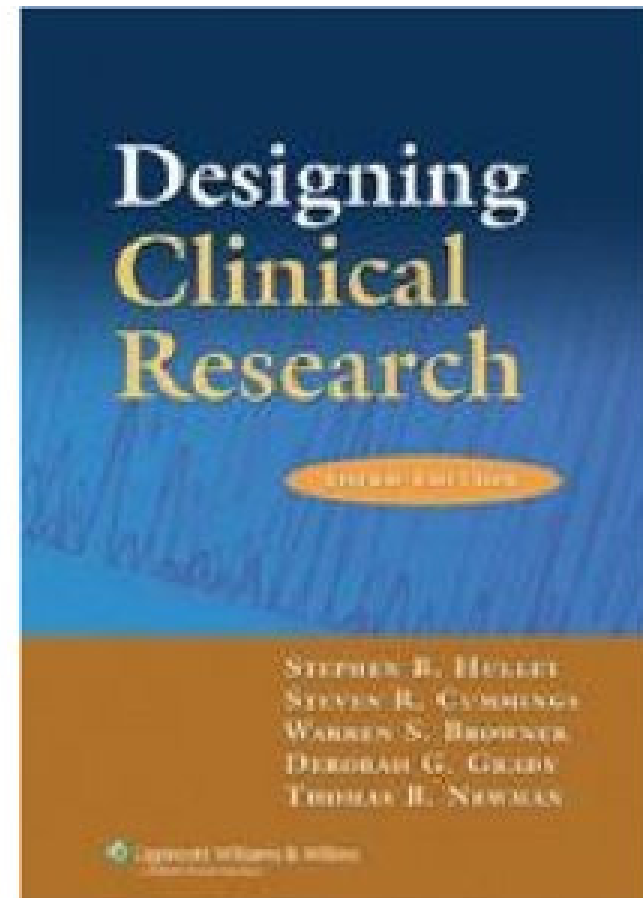
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Designing Clinical Research

Hulley S et al.

Lippincott Williams & Wilkir

3rd Edition





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<http://www.psnet.ahrq.gov/>

United States Department of Health & Human Services [Skip Navigation](#)

 **AHRQ** Agency for Healthcare Research and Quality

Advancing Excellence in Health Care www.ahrq.gov

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What's New This Week 05/12/10

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Journal Articles

[Effect of bar-code technology on the safety of medication administration.](#)
Poon EG, Keohane CA, Yoon CS, et al. N Engl J Med. 2010;362:1698-1707.

[Decrease in hospital-wide mortality rate after implementation of a commercially sold computerized physician order entry system.](#)
Longhurst CA, Parast L, Sandborg CI, et al. Pediatrics. 2010 May 3; [Epub ahead of print].

[An intervention to decrease patient identification band errors in a children's hospital.](#)
Hain PD, Joers B, Rush M, et al. Qual Saf Health Care. 2010 Apr 3; [Epub ahead of print].

[Interruptions and distractions in healthcare: review and reappraisal.](#)

Patient Safety Primers

Each primer guides you through a key concept in patient safety, discusses background and context, and highlights related content.

[Medication Reconciliation, Error Disclosure, Never Events, Rapid Response Systems, More...](#)

Browse the Collection

Browse by Resource Type
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Safety Target
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<http://webmm.ahrq.gov/>

The screenshot displays the AHRQ WebM&M website. The header includes the AHRQ logo and the text "Agency for Healthcare Research and Quality" and "web M&M Morbidity & Mortality Rounds on the Web". A search bar is located in the top right. The main content area is titled "Cases & Commentaries: APRIL 2010" and features three columns of articles:

- Medicine:** "Bad Writing, Wrong Medication" (SPOTLIGHT CASE) by Beth Devine, PharmD, MBA, PhD. A medication dispensing error causes nausea, sweating, and irregular heartbeat in an elderly man with a history of cardiac arrhythmia.
- Emergency Medicine:** "Nosy Business" by Richard R. Orlandi, MD. A man with a history of a blood clotting disorder presented to the emergency department three times within 3 days for severe epistaxis (nose bleed).
- Medicine:** "Anticoagulation: Held Too Long" by Andrew S. Dunn, MD. An elderly woman with a history of mitral valve replacement with a mechanical prosthesis was admitted to the hospital for evaluation of abdominal pain.

Each article includes a "Commentary by" section and a "CME/CEU available" indicator. At the bottom of the main content area, there are buttons for "Submit Case" and "Register".

The left sidebar contains navigation links: Home, What's New, My PSNet, Subscribe to Newsletter, CLASSICS, Most Popular, Patient Safety Primers, Advanced Search, Advanced Browse, Glossary, AHRQ WebM&M, About, and Contact Us.

The right sidebar features "Perspectives on Safety" with a "View All" link. It highlights "This month: The National Quality Forum: A Key Player in Quality and Safety" and lists two items: "In Conversation with..." by Janet Corrigan, PhD, MBA, and "The Role of the National Quality Forum (NQF) in the Quest for Transparency in U.S. Hospitals' Patient Safety Performance" by Lance L. Roberts, MS; Marcia M. Ward, PhD; and Thomas C. Evans, MD. A "Submit your Perspective" link is also present.

Below this is the "AHRQ PSNet patient Safety Network" section, which includes "What's New" about bar coding technology and a link to "Visit AHRQ PSNet".

The bottom right section, "Did You Know?", features a bar chart titled "Types of wrong-site surgery observed in the previous 6 months by orthopedic surgeons". The chart shows the following data:

Type of Surgery	Percentage (%)
side	59%
site - (te)	23%
ture	14%
-ient	5%



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<https://acsnsqip.org/>

ACS
NSQIP

AMERICAN COLLEGE OF SURGEONS
National Surgical Quality Improvement Program

- About ACS NSQIP
- Program Specifics
- Getting Started
- Resources
- Contact Information
- Home

About ACS NSQIP

Program Overview

The ACS National Surgical Quality Improvement Program (ACS NSQIP) is the first nationally validated, risk-adjusted, outcomes-based program to measure and improve the quality of surgical care. The program employs a prospective, peer controlled, validated database to quantify 30-day risk-adjusted surgical outcomes, which allows valid comparison of outcomes among all hospitals in the program. Participating hospitals and their surgical staff are provided with the tools, reports, analysis, and support necessary to make informed decisions about improving quality of care. The program involves the following key components:

ACS NSQIP Presentation

Click [here](#) to sign up for a Webinar or request the program's PowerPoint overview presentation.

DATA COLLECTION

ACS NSQIP collects data on 136 variables, including preoperative risk factors, intraoperative variables, and 30-day postoperative mortality and morbidity outcomes for patients undergoing major surgical procedures in both the inpatient and outpatient setting. The data are collected, validated, and submitted by a trained Surgical Clinical Reviewer (SCR) at each site.

DATA MONITORING & VALIDATION

Once trained, the SCR submits data to ACS NSQIP through a secure Web-based system with built-in software checks and user information prompts to ensure completeness, uniformity, and validity of the data. Data automation tools are also available to lower the data entry burden on the SCRs and to improve the quality of data being captured. In addition, Inter-Rater Reliability (IRR) audits are conducted to ensure the data are examined on a routine basis.

REPORT GENERATION

Hospitals enrolled in ACS NSQIP have their data presented to them via comprehensive semiannual reports and real-time, continuously updated, online benchmarking reports. Both sets of reports allow participating sites to continually



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- CERTIFICATION PROGRAMS
- STANDARDS
- PATIENT SAFETY**
- SENTINEL EVENT
- PUBLIC POLICY REPORTS
- PERFORMANCE MEASUREMENT
- LIBRARY
- ABOUT US

- "Do Not Use" List
- Eisenberg Award
- Hospitals, Language, and Culture
- Infection Control
- National Patient Safety Goals
- Solutions
- Speak Up
- Universal Protocol

Home > Patient Safety > National Patient Safety Goals

National Patient Safety Goals

The Joint Commission seeks input on revised medication reconciliation National Patient Safety Goal. [Read More](#)

2010 National Patient Safety Goals (NPSGs) Effective July 1, 2010

Included below are links to the 2010 National Patient Safety Goals (NPSGs) outlines and chapters for applicable programs. This version of the NPSGs includes minor changes to NPSG.03.04.01, Element of Performance 3, and NPSG.07.03.01, Element of Performance 3, that will become effective July 1, 2010. See the March 10, 2010 issue of [Joint Commission Online](#) for specific changes.

(Requires [Adobe Reader](#))

- Ambulatory Health Care
 - [Outline](#) | [Chapter](#) (Includes Universal Protocol)
- Behavioral Health Care
 - [Outline](#) | [Chapter](#)
- Critical Access Hospital
 - [Outline](#) | [Chapter](#) (Includes Universal Protocol)
- Home Care
 - [Outline](#) | [Chapter](#)
- Hospital
 - [Outline](#) | [Chapter](#) (Includes Universal Protocol)
- Laboratory
 - [Outline](#) | [Chapter](#)
- Long Term Care
 - [Outline](#) | [Chapter](#)
- Medicare/Medicaid Long Term Care
 - [Outline](#) | [Chapter](#)
- Office-Based Surgery

http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/



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www.who.int/patientsafety

The screenshot shows the WHO Patient Safety website with a blue header containing the WHO logo, navigation links in multiple languages (Arabic, Chinese, English, French, Russian, Spanish), a search bar, and radio buttons for "All WHO" and "This site only". A left sidebar lists navigation options: Home, About WHO, Countries, Health topics, Publications, Data and statistics, Programmes and projects, Patient safety (highlighted), Research, Campaigns, Education & training, Implementing change, Patient engagement, Information centre, and News and events.

The main content area is titled "Patient safety" and includes a breadcrumb trail: WHO > Programmes and projects > Patient safety > Patient Safety Research. Below this is a section for "Patient Safety Research" with the sub-header "Working to facilitate the spread and use of research findings to inform safer health care in all WHO Member States". A banner image shows a group of people in a meeting, with the text "Better Knowledge for Safer Care".

The "Global patient safety research priorities" section explains that patient safety is a global issue and lists research priorities. It includes links to a report (270KB), an advocacy booklet (1.05MB), and more information about global research priorities. A red circle highlights the "More information about global patient safety research priorities" link.

The "AREAS OF WORK" section includes:

- WHO Patient Safety Small Research Grants:** Set up to stimulate research on patient safety priority areas by providing seed funding for small research projects.
- Methods and measures:** The focus of WHO Patient Safety is on clarifying the methods and measures necessary to advance the knowledge around patient safety issues particularly in developing and transitional countries, and to respond to new and as yet unmet research questions.
- Strengthening capacity:** Emphasis on strengthening and scaling up sustainable

The right sidebar contains:

- ABOUT US:** WHO Patient Safety (with a photo of a man), The research programme team, Background to the research programme, Focus of WHO Patient Safety Research.
- HIGHLIGHTS:** Patient safety research introductory online course (7 April - 26 May 2010), ISQua Conference Scholarships - Call for applications (Applications close 17 April 2010), Case studies - patient safety research (with a diagram showing a cycle of research).
- Research information booklet [pdf 1.01Mb]**
- Primary care patient safety research** (with a photo of a person at a desk).
- OTHER PROGRAMMES:** Reporting & Learning WHO Draft Guidelines for Adverse Event Reporting and Learning.



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Questions?



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Course Evaluation



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Thank You