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**Patient Safety  
Research Introductory  
Course**

**Session 5**

# Identifying Solutions / Implementation

- Albert W Wu, MD, MPH
- Former Senior Adviser, WHO
- Professor of Health Policy & Management, Johns Hopkins Bloomberg School of Public Health
- Professor of Medicine, School of Medicine, Johns Hopkins University





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## Overview

- To improve patient safety, solutions are needed that tackle the underlying causes of unsafe care. In this session we will explain how we can use research methods to identify **effective** solutions. This implies research designs to **test** these solutions. We will also discuss more briefly how to implement solutions.

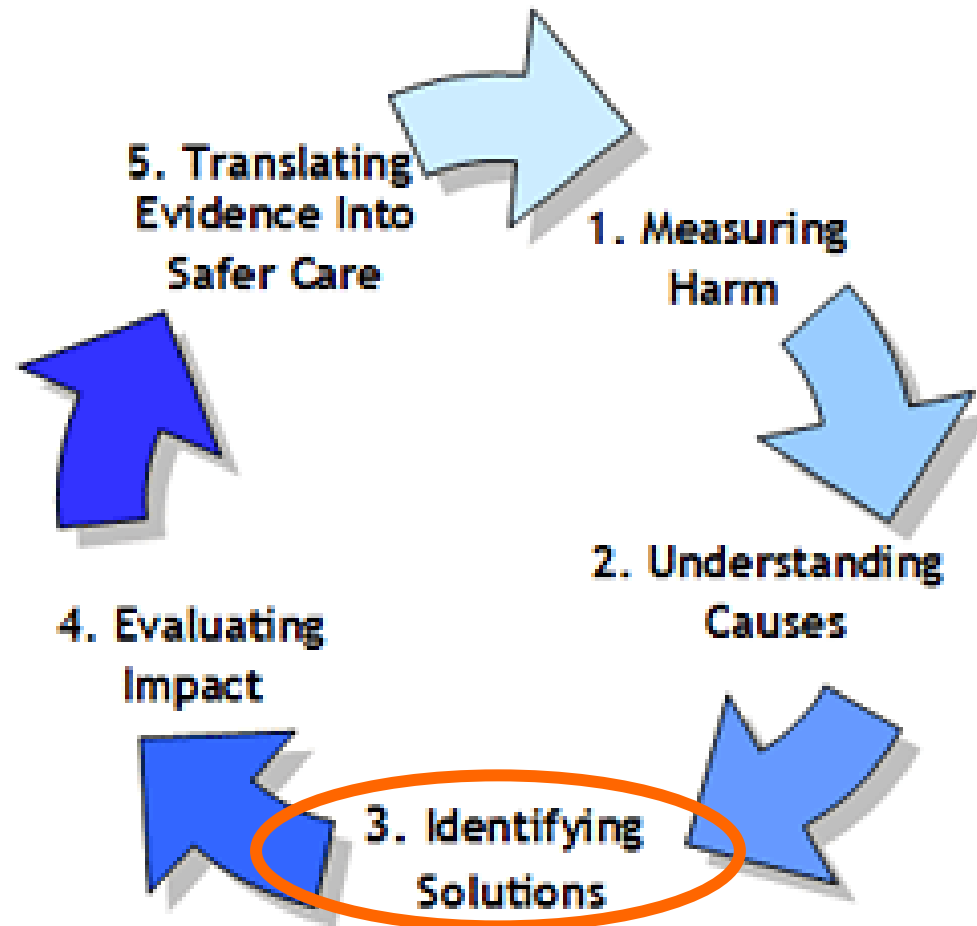


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## Components





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**1. Patient safety interventions can be aimed at:**

- a. Health care workers
- b. Patients
- c. Hospital units
- d. All of the above

**2. Which of the following is FALSE for clinical trials?**

- a. Provide the strong evidence for efficacy of interventions
- b. Always focus on clinical outcome variables
- c. Can control for unmeasured confounders
- d. Are not always acceptable to clinicians



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**3. Which of the following is NOT a design for a clinical trial**

- a. Randomized double-blind controlled trial
- b. Cross-sectional direct observations
- c. Cluster-randomized clinical trial
- d. Open (unblinded) randomized trial

**4. Which of the following patient safety interventions could be studied using a clinical trial?**

- a. New antibiotic regimen to reduce surgical wound infection
- b. A team training intervention
- c. A checklist to prevent catheter related bloodstream infection
- d. All of the above

**5. It is easier to implement a safety intervention if you**

- a. Get hospital leaders to endorse the intervention
- b. Explain that the intervention is very inexpensive
- c. Educate health care workers about the intervention
- d. A and C



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# Identifying 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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# Improving Reliability of Effective Practices

- Aspirin for patients after myocardial infarction
- Antibiotics for pneumonia
- Handwashing



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## **Locus of Intervention**

- Patient
- Health care worker
- Workplace
- System





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# Hierarchy of Research Evidence





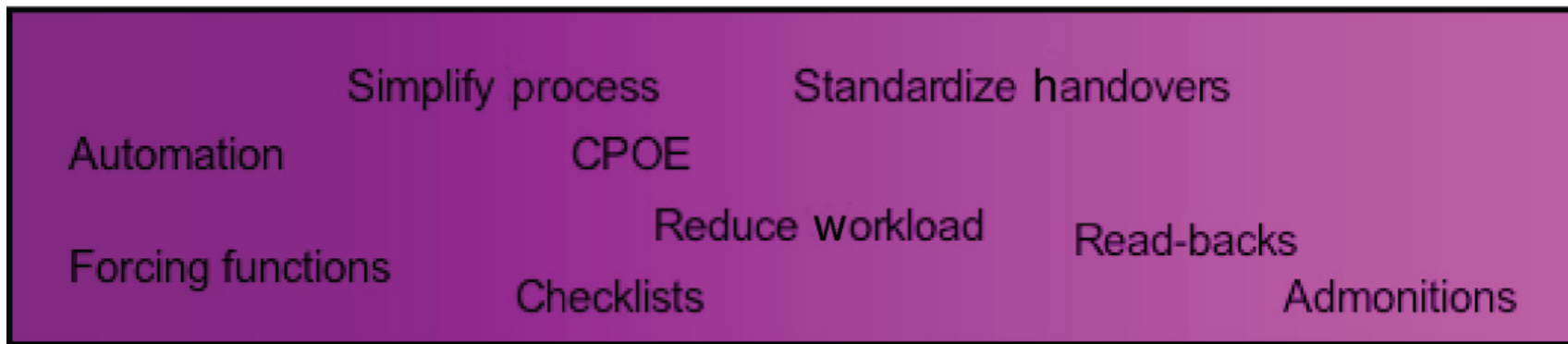
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Strong interventions

Weak interventions



Woodward HI, et al. 2010.

Annu. Rev. Public Health 31:479–97

Annual Reviews



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## Examples

- RCT with 3 year cohort design on 850 patients (Reggiori)
- Non-blinded Cluster RCT of standardized teamwork training (Nielsen)
- Prospective intervention in 108 ICUs in 67 hospitals (Pronovost)



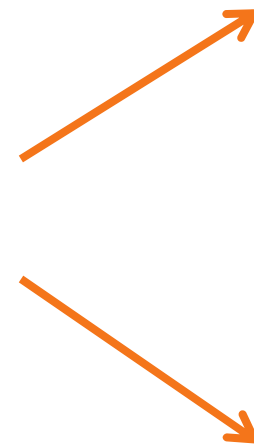
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# Randomized Controlled Trials

- 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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# Reggiori A et al. Randomized study of antibiotic prophylaxis for general and gynaecological surgery from a single centre in rural Africa. *British Journal of Surgery*, 1996, 83:356–359

[Link to Abstract \(HTML\)](#)

[Link to Full Text](#)

Randomized study of antibiotic prophylaxis for general and gynaecological surgery from a single centre in rural Africa.

[Reggiori A](#), [Ravera M](#), [Cocozza E](#), [Andreata M](#), [Mukasa F](#).

Surgical Department, Hoima Hospital, Kampala, Uganda.

In a district rural hospital in Uganda, 850 surgical patients were evaluated prospectively over a 3-year period to compare the clinical efficacy of conventional postoperative penicillin therapy with single-dose ampicillin prophylaxis for hernia repair and ectopic pregnancy, and with single-dose ampicillin-metronidazole prophylaxis for hysterectomy and caesarean section. The high rate of postoperative infection usually encountered in African hospitals after conventional treatment with penicillin for 7 days was significantly reduced with the new regimen: from 7.5 to 0 per cent in hernia repair and from 10.7 to 2.4 per cent in ectopic pregnancy; from 20.0 to 3.4 per cent in hysterectomy and from 38.2 to 15.2 per cent in caesarean section. Length of hospital stay and postoperative mortality rates were also significantly reduced. Single-dose ampicillin prophylaxis with or without metronidazole, although rarely used in developing countries, is more cost effective than standard penicillin treatment.

PMID: 8665191 [PubMed - indexed for MEDLINE]

Can be ordered online at:

<http://www.bjs.co.uk>



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## Background

- **Postoperative wound and deep infection a major concern in developing countries**
  - In sub-Saharan Africa, few studies of postoperative infections but rates as high as 40-70% have been observed
- **Antimicrobial resistance an increasing problem**
  - Pencillin is the most commonly used antibiotic in Uganda and African district hospitals



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## Background:

- Short course, single dose antimicrobial prophylaxis has been shown to be effective in reducing incidence of postoperative wound infection
  - However, all studies have been carried out in developed countries
  - Ampicillin: low cost, broad spectrum, sufficient half-life and high wound concentration
  - Metronidazole: anaerobic activity, long half-life
  - Resistance to both is rare in rural Africa



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# Methods: Study Design and Objectives

- Design: randomized clinical trial
- Objectives:
  - To compare the clinical effectiveness of conventional postoperative penicillin therapy with single-dose ampicillin prophylaxis for hernia repair and ectopic pregnancy
  - To compare the clinical effectiveness of conventional postoperative penicillin therapy with single-dose ampicillin-metronidazole prophylaxis for hysterectomy and caesarean section
  - To measure the impact of different antimicrobial regimes on outcomes, eg, postoperative stay and cost of care





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## Methods: Study Population and Setting

- Setting: Hoima Hospital = 150-bed government institution in rural Uganda sponsored by International Service Volunteers' Association
  - 800 major surgical procedures yearly, 35% as emergencies
  - Six Ugandan and two Italian surgeons on staff
  - No microbiological facilities available locally
- Population
  - 850 consecutive patients aged over 18 admitted to Hoima Hospital for elective and emergency surgical procedures from 1991 to 1993



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## Methods: Data Collection

- Patients divided into two categories by surgical condition:
  - Category 1 - 479 patients: 229 hernia repairs and 250 surgeries for ectopic pregnancies
  - Category 2 - 371 patients: 177 abdominal hysterectomies and 194 caesarean sections
- Patients then allocated by random numbers to one of two selected courses of treatment



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## Methods: Data Collection (2)

- **Group 1:**
  - Single dose of **ampicillin** 2g intravenously at induction of anaesthesia vs
  - Standard postoperative treatment of intramuscular fortified **procaine penicillin**: 1-2 megaunits daily for 7 days
- **Group 2:**
  - 192 randomized to receive a single dose of **ampicillin** 3 g intravenously plus **metronidazole** 500mg at induction of anaesthesia
  - **Benzylpenicillin** 1 megaunit intravenously every 6 hours for one day, then fortified **procaine penicillin** 1-2 megaunits daily for 6 days



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## Methods: Data Collection (3)

- After operation, each patient assessed daily by two supervisors *aware* of the type of prophylaxis used
- Further follow-up was performed 2 weeks after discharge
- Wound infections graded:
  - Grade 1: superficial infection
  - Grade 2: deep infection
  - Grade 3: infection throughout wound (with or without dehiscence)
- Peritonitis = clinical signs and symptoms were evident
- Length of stay and postoperative outcome recorded



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## Results: Key Findings

- Ampicillin regime significantly reduced incidence of postoperative infection vs conventional penicillin:
  - 7.5 to 0% after hernia repair
  - 10.7 to 2.4% after surgery for ectopic pregnancy
  - 20 to 3.4% after hysterectomy
  - 38.2 to 15.2 % after caesarean section
- Patients on ampicillin also had significant reductions in:
  - Length of hospital stay
  - Postoperative mortality rates
  - Post-operative complications for hysterectomy and caesarean



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## Results: Cost Analysis

- Average cost for an admission day in Hoima Hospital in 1992 was \$3 USD, inclusive of personnel cost, drug, supplies and utilities
- Cost savings with new regimes
  - Ampicillin-metronidazole regimens were cheaper than the full penicillin course
  - Duration of postoperative stay was shorter for both groups of patients receiving ampicillin prophylaxis



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## **Conclusion: Main Points**

- Postoperative infection rates in developing countries are often underestimated and undocumented
- High postoperative infection rates can be significantly reduced, even in settings with resource constraints
  - Antibiotic prophylaxis with ampicillin is effective in reducing the postoperative morbidity rate in clean general surgery and gynaecology operations
  - Single-dose ampicillin prophylaxis, though rarely used in developing countries, is more cost effective than standard penicillin treatment



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## Practical Considerations

- Study duration = 3 ½ years
- Cost
  - Conducted primarily within regular hospital working budget
  - \$500 USD spent on additional drugs and incentives for patients
- Competencies needed
  - Utilized clinical expertise of hospital staff
  - One team member was a statistical expert
- Ethical approval
  - Approved by hospital authorities





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## Author: Lessons and Advice

- Research is feasible and applicable in other developing countries

- *"It is applicable everywhere because it is very simple and the result is to again simplify patient care. No technology or sophisticated items were necessary."*



# Nielsen PE, Goldman MB, Mann S, et al. Effects of teamwork training on adverse outcomes and process of care in labor and delivery: a randomized controlled trial. *Obstet Gynecol*, 2007; 109:48-55

[Link to Abstract \(HTML\)](#)

[Link to Full Text \(PDF\)](#)

**METHODS:** A cluster-randomized controlled trial was conducted at seven intervention and eight control hospitals. The intervention was a standardized teamwork training curriculum based on crew resource management that emphasized communication and team structure. The primary outcome was the proportion of deliveries at 20 weeks or more of gestation in which one or more adverse maternal or neonatal outcomes or both occurred (Adverse Outcome Index). Additional outcomes included 11 clinical process measures.

**RESULTS:** A total of 1,307 personnel were trained and 28,536 deliveries analyzed. At baseline, there were no differences in demographic or delivery characteristics between the groups. The mean Adverse Outcome Index prevalence was similar in the control and intervention groups, both at baseline and after implementation of teamwork training (9.4% versus 9.0% and 7.2% versus 8.3%, respectively). The intraclass correlation coefficient was 0.015, with a resultant wide confidence interval for the difference in mean Adverse Outcome Index between groups (-5.6% to 3.2%). One process measure, the time from the decision to perform an immediate cesarean delivery to the incision, differed significantly after team training (33.3 minutes versus 21.2 minutes,  $P=.03$ ).

**CONCLUSION:** Training, as was conducted and implemented, did not transfer to a detectable impact in this study. The Adverse Outcome Index could be an important tool for comparing obstetric outcomes within and between institutions to help guide quality improvement.

**Effects of Teamwork Training on Adverse Outcomes and Process of Care in Labor and Delivery**  
*A Randomized Controlled Trial*

Peter E. Nielsen, MD, Melissa B. Goldman, MD, Susan Mann, MD, David E. Shapiro, MD, Ronald C. Marmer, MD, MS, Stephen D. Pratt, MD, Penny Greenberg, MD, Patricia McInerney, MD, MS, Mary Salzbury, MD, MEd, David J. Birnbaum, MD, Paul A. Ghah, MD, Mark D. Friedman, MD, Heidi King, MD, David N. Terahang, MD, MS, and Benjamin P. Sirota, MD, PhD

**OBJECTIVE:** To evaluate the effect of teamwork training on the occurrence of adverse outcomes and process of care in labor and delivery.

**METHODS:** A cluster-randomized controlled trial was conducted at seven intervention and eight control hospitals. The intervention was a standardized teamwork training curriculum based on crew resource management that emphasized communication and team structure. The primary outcome was the proportion of deliveries at 20 weeks or more of gestation in which one or more adverse maternal or neonatal outcomes or both occurred (Adverse Outcome Index). Additional outcomes included 11 clinical process measures.

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**CONCLUSION:** Training, as was conducted and implemented, did not transfer to a detectable impact in this study. The Adverse Outcome Index could be an important tool for comparing obstetric outcomes within and between institutions to help guide quality improvement.

CLINICAL TRIALS REGISTRATION: [clinicaltrials.gov](http://clinicaltrials.gov), NCT00318554  
 ClinicalTrials.gov identifier: NCT00318554

LEVEL OF EVIDENCE: 1

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## Methods: Study Design

- Design: cluster-randomized clinical trial
  - Intervention was a standardized teamwork training curriculum based on CRM that emphasized communication and team structure
- Objective:
  - To evaluate the effect of teamwork training on the occurrence of adverse outcomes and process of care in labor and delivery



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# Methods: Study Population and Setting

- **Setting:**

- Hospital labour and delivery units at 15 US hospitals
- 1 307 labor and delivery room personnel trained

- **Population:**

- All women with a pregnancy of 20–43 weeks of gestation from December 31, 2002 to March 31, 2004
- 28,536 deliveries analyzed in intervention hospitals

- **Data collection completed for 94.4% of deliveries at control hospitals and 95.9% of deliveries**



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## Methods: Study Recruitment

- A balanced, masked randomization scheme at the hospital level
  - Assigned seven hospitals received teamwork-training curriculum, eight hospitals in control arm
  - All possible allocations of the hospitals to two arms balanced for hospital type and funding level
- Trial was not blinded, with personnel at each site aware of their assignment to either the intervention or control arm



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## Method: Study Administration

- Clinical staff from the seven intervention hospitals attended an instructor training session
  - Coordination Course based on crew resource management and a curriculum used in hospital emergency and obstetric departments
- Trainers returned to their hospitals to conduct onsite training sessions for obstetrics, anesthesiology and nursing staff
  - Structured each unit into core work teams and coordinating teams
- Product: multidisciplinary contingency team of experienced physicians and nurses trained to respond in a coordinated way to obstetric emergencies



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## Methods: Data Collection

- **Data collection was divided into two periods:**
  - Baseline: two months before teamwork training
  - Post-implementation: five months after the teamwork curriculum was adopted
- **All staff training occurred after baseline data collection**
- **Data collected during and immediately after delivery under the supervision of centrally trained data coordinators**



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## Methods: Outcome Measures

- Adverse Outcome Index developed to capture the proportion of all deliveries with at least one undesirable outcome and to serve as the primary response variable
  - Defined as the number patients with one or more adverse outcome divided by the total number of deliveries





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## Results: Key Findings

- No baseline differences in characteristics between groups
- Mean Adverse Outcome Index prevalence was similar in the control and intervention groups
  - Both at baseline (9.4% vs 9.0%) AND
  - After implementation of teamwork training (7.2% vs 8.3%)
- *One* process measure, time from the decision to perform an immediate cesarean delivery to the incision, better after team training (33.3 minutes vs 21.2 minutes)



# Pronovost P, et. al. An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU. The New England Journal of Medicine, 2006, 355:2725-32

• [Link to Abstract \(HTML\)](#)

[Link to Full Text \(PDF\)](#)

ABSTRACT

**BACKGROUND**  
Catheter-related bloodstream infections occurring in the intensive care unit (ICU) are common, costly, and potentially lethal.

**METHODS**  
We conducted a collaborative cohort study predominantly in ICUs in Michigan. An evidence-based intervention was used to reduce the incidence of catheter-related bloodstream infections. Multilevel Poisson regression modeling was used to compare infection rates before, during, and up to 18 months after implementation of the study intervention. Rates of infection per 1000 catheter-days were measured at 3-month intervals, according to the guidelines of the National Nosocomial Infections Surveillance System.

**RESULTS**  
A total of 108 ICUs agreed to participate in the study, and 103 reported data. The analysis included 1961 ICU-months of data and 375,757 catheter-days. The median rate of catheter-related bloodstream infection per 1000 catheter-days decreased from 2.7 infections at baseline to 0 at 3 months after implementation of the study intervention ( $P < 0.002$ ), and the mean rate per 1000 catheter-days decreased from 7.7 at baseline to 1.4 at 16 to 18 months of follow-up ( $P < 0.002$ ). The regression model showed a significant decrease in infection rates from baseline, with incidence-rate ratios continuously decreasing from 0.62 (95% confidence interval [CI], 0.47 to 0.81) at 0 to 3 months after implementation of the intervention to 0.34 (95% CI, 0.23 to 0.50) at 16 to 18 months.

**CONCLUSIONS**  
An evidence-based intervention resulted in a large and sustained reduction (up to 66%) in rates of catheter-related bloodstream infection that was maintained throughout the 18-month study period.

The NEW ENGLAND  
JOURNAL of MEDICINE

ESTABLISHED IN 1812      DECEMBER 28, 2006      VOL 355 NO 26

An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU

Peter Pronovost, M.D., Ph.D., Dale Needham, M.D., Ph.D., Sean Berwick, M.D., David Simpsell, M.P.H., M.B.A., Hsiao Chu, M.D., Ph.D., Sara Coogrow, M.D., Bryan Sexton, Ph.D., Robert Hyatt, M.D., Robert Wake, M.D., Gary Roth, M.D., Joseph Bander, M.D., John Kepros, M.D., and Christine Gosschel, R.N., M.P.A.

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N Engl J Med 2006;355:2725-32  
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www.nejm.org      DECEMBER 28, 2006      2725

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## **Background: Study Rationale**

- **Catheter-related bloodstream infections (CRBSI) in the intensive care unit (ICU) are common, costly, and lethal**
  - 80 000 CRBSI and up to 28 000 deaths in US
  - Total cost is up to \$2.3 billion annually
- **Interventions to decrease infection rate needed to reduce this hospital-acquired infection**
  - Team had developed/implemented program that nearly eliminated CRBSI
  - Could program be scaled up achieve same results in entire state of Michigan, US?



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## Methods: Study Objectives

- **Design: prospective intervention study**
  - An evidence-based intervention used to reduce the incidence of CRBSI
  - Compare infection rates before, during, and 18 months after implementing intervention
- **Primary study hypothesis:**
  - Rate of catheter-related bloodstream infection would be reduced during the first 3 months after implementation of the study intervention as compared with baseline, and sustained
- **Study Population = all hospitals in Michigan, USA with adult ICUs**
  - 108 ICUs in 67 hospitals representing 85% of all ICU beds in Michigan
  - Types of ICUs included medical, surgical, cardiac, medical or surgical, neurologic, and surgical trauma units and a pediatric unit



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## **Methods: Intervention**

- Intervention targeted clinicians' use of five evidence-based procedures identified as having the greatest effect on rate of CRBSI and lowest barriers to implementation
- **Bundle/Checklist**
  - Hand washing
  - Full-barrier precautions during insertion
  - Cleaning the skin with chlorhexidine
  - Avoiding the femoral site if possible
  - Removing unnecessary catheters



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## **ICUs also implemented the use of:**

- A daily goals sheet to improve clinician-to-clinician communication within the ICU
- An intervention to reduce the incidence of ventilator-associated pneumonia
- A comprehensive unit-based safety program to improve the safety culture



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# Implementation

## **Comprehensive Unit Based Safety Program (CUSP)**

1. Safety Culture Assessment
2. Science of Safety Training
3. Staff Identify Safety Hazards
4. Senior Executive Partnership
5. Learn from Safety Defects/Apply Tools to Improve
6. Reassess Safety Culture



Both the median & mean rate of catheter-related bloodstream infection per 1000 catheter-days decreased significantly

- Median rate: decreased from 2.7 infections at baseline to 0 at 3 months after intervention
- Mean rate: decreased from 7.7 at baseline to 1.4 at 16 to 18 months

**Table 3. Rates of Catheter-Related Bloodstream Infection from Baseline (before Implementation of the Study Intervention) to 18 Months of Follow-up.\***

Study Period	No. of ICUs	No. of Bloodstream Infections per 1000 Catheter-Days				
		Overall	Teaching Hospital	Nonteaching Hospital	<200 Beds	≥200 Beds
<i>median (interquartile range)</i>						
Baseline	55	2.7 (0.6–4.8)	2.7 (1.3–4.7)	2.6 (0–4.9)	2.1 (0–3.0)	2.7 (1.3–4.8)
During implementation	96	1.6 (0–4.4)†	1.7 (0–4.5)	0 (0–3.5)	0 (0–5.8)	1.7 (0–4.3)†
After implementation						
0–3 mo	96	0 (0–3.0)‡	1.3 (0–3.1)†	0 (0–1.6)†	0 (0–2.7)	1.1 (0–3.1)‡
4–6 mo	96	0 (0–2.7)‡	1.1 (0–3.6)†	0 (0–0)‡	0 (0–0)†	0 (0–3.2)‡
7–9 mo	95	0 (0–2.1)‡	0.8 (0–2.4)‡	0 (0–0)‡	0 (0–0)†	0 (0–2.2)‡
10–12 mo	90	0 (0–1.9)‡	0 (0–2.3)‡	0 (0–1.5)‡	0 (0–0)†	0.2 (0–2.3)‡
13–15 mo	85	0 (0–1.6)‡	0 (0–2.2)‡	0 (0–0)‡	0 (0–0)†	0 (0–2.0)‡
16–18 mo	70	0 (0–2.4)‡	0 (0–2.7)‡	0 (0–1.2)†	0 (0–0)†	0 (0–2.6)‡

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## Conclusion: Main Points

- A large-scale project focused on reducing the incidence of catheter related bloodstream infection is feasible and can have important public health consequences
  - Evidence-based intervention resulted in a large and sustained reduction (up to 66%) in catheter-related bloodstream infections
  - Reduction maintained throughout the 18-month study period



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## **Translating evidence into practice:**

- 1. Develop the intervention and evaluation, which includes:**
  - Understanding evidence and converting the evidence into checklists,
  - Understanding barriers to implementing the evidence (including local context),
  - Developing measures to evaluate whether safety actually improved
- 2. Pilot test the interventions and evaluation tools in individual hospitals to better understand local context**



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## Summary

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



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- Nielsen PE, Goldman MB, Mann S, et al. Effects of teamwork training on adverse outcomes and process of care in labor and delivery: a randomized controlled trial. *Obstet Gynecol*, 2007, 109:48-55.
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## **Additional Resources**

- TeamSTEPPS Curriculum:  
[www.usuhs.mil/cerps/teamstepps.html](http://www.usuhs.mil/cerps/teamstepps.html)
- TeamSTEPPS CD-ROM and DVD Multimedia Curriculum Kit from the AHRQ Publications Clearinghouse at 1-800-358-9295 or [ahrqpubs@ahrq.hhs.gov](mailto:ahrqpubs@ahrq.hhs.gov).
- <http://www.innovations.ahrq.gov/>
- [www.safetyresearch.jhu.edu](http://www.safetyresearch.jhu.edu)



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**1. Patient safety interventions can be aimed at:**

- a. Health care workers
- b. Patients
- c. Hospital units
- d. **All of the above**

**2. Which of the following is FALSE for clinical trials?**

- a. Provide the strongest evidence for efficacy
- b. **Always focus on clinical outcome variables**
- c. Control for unmeasured confounders
- d. Are not always acceptable to clinicians



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**3. Which of the following is NOT a design for a clinical trial**

- a. Randomized double-blind controlled trial
- b. **Cross-sectional clinical observations**
- c. Cluster-randomized clinical trial
- d. Open (unblinded) randomized trial

**4. Which of the following patient safety interventions could be studied using a clinical trial?**

- a. New antibiotic regimen to reduce surgical wound infection
- b. A team training intervention
- c. A checklist to prevent catheter related bloodstream infection
- d. **All of the above**

**5. It is easier to implement a safety intervention if you**

- a. Get hospital leaders to endorse the intervention
- b. Explain that the intervention is very inexpensive
- c. Educate health care workers about the intervention
- d. **A and C**



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## Interactive

- What are the barriers in your institution to implementing interventions to improve patient safety?





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**Questions?**



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**Thank You**