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

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.
Components

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
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

Identifying Solutions

- Solution not yet identified:
  - Pre-post
  - Randomized (double blind, controlled) trial
  - Cluster randomization

- Known solution
  - Improving reliability of effective practices
Improving Reliability of Effective Practices

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

Locus of Intervention

• Patient
• Health care worker
• Workplace
• System
Hierarchy of Research Evidence

- Systematic Reviews
- Randomized Controlled Trials
- Cohort Studies
- Case-Control Studies
- Case Series, Case Reports
- Editorials, Expert Opinion

Strong interventions
- Automation
- Forcing functions
- Simplify process
- CPOE
- Checklists
- Reduce workload
- Standardize handovers
- Read-backs
- Admonitions

Weak interventions

Annu. Rev. Public Health 31:479–97
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)

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
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
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

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
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

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
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

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
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

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
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.

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
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."


Link to Abstract (HTML)  Link to Full Text (PDF)
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

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**
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

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
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

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
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)


- Link to Abstract (HTML)  
- Link to Full Text (PDF)
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 to achieve same results in the entire state of Michigan, US?

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
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

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
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

Results: Key Findings
- 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>
<thead>
<tr>
<th>Study Period</th>
<th>No. of ICUs</th>
<th>No. of Bloodstream Infections per 1000 Catheter-Days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overall</td>
<td>Teaching Hospital</td>
</tr>
<tr>
<td>Baseline</td>
<td>95</td>
<td>2.7 (0.4–4.8)</td>
</tr>
<tr>
<td>During implem.</td>
<td>96</td>
<td>1.7 (0–4.5)</td>
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<tr>
<td>After implem.</td>
<td></td>
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<tr>
<td>0–3 mo</td>
<td>96</td>
<td>6 (0–13.1)</td>
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<td>96</td>
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<td>7–9 mo</td>
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</tr>
<tr>
<td>16–18 mo</td>
<td>70</td>
<td>0 (0–2.4)</td>
</tr>
</tbody>
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Table 3. Rates of Catheter-Related Bloodstream Infection from Baseline (before implementation of the Study Intervention) to 18 Months of Follow-up.®

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

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
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

References

Additional Resources

- 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).
- [www.safetyresearch.jhu.edu](http://www.safetyresearch.jhu.edu)

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Interactive

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

Thank You