IMPROVEMENT SCIENCE RESEARCH NETWORK

…improving patient outcomes

Quality Improvement vs. Research: Regulatory Issues in Improvement Science

Christine Goeschel ScD, RN, FAAN

The Armstrong Institute for Patient Safety and Quality

The Johns Hopkins School of Medicine

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January 25, 2012

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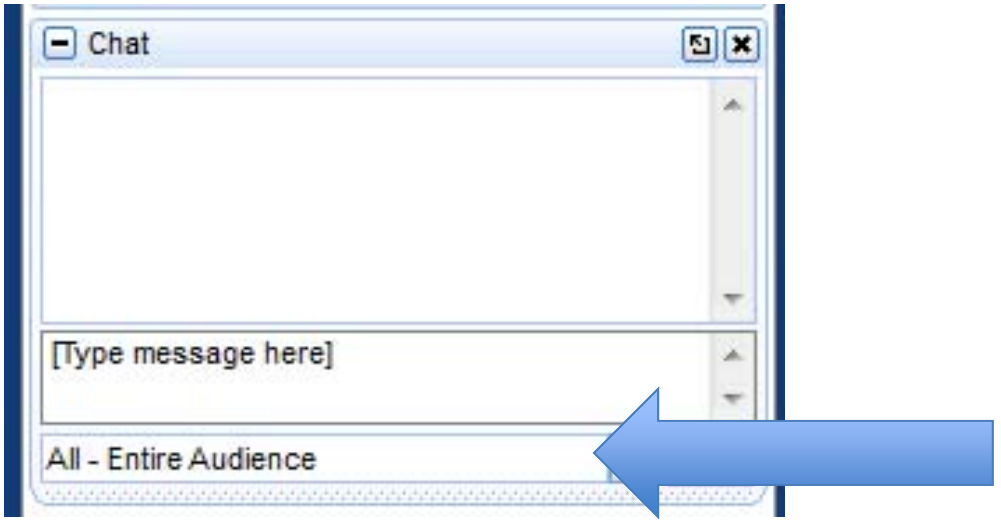

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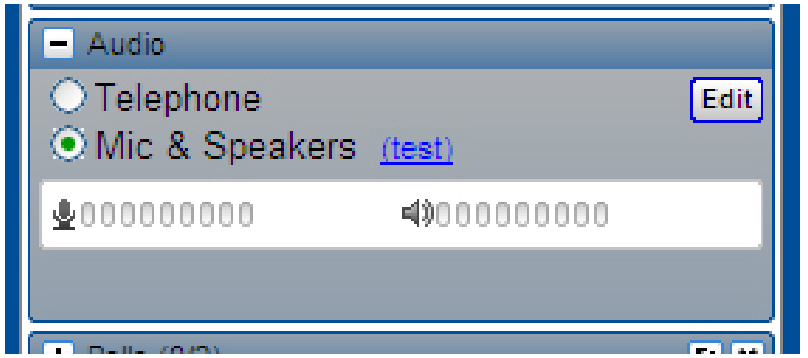

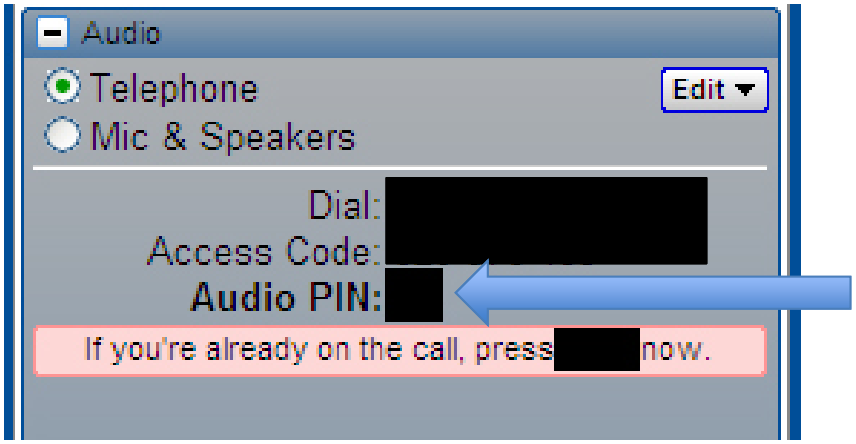

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Introduction

Research

- *a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.*

Presenter

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Disclosures

- Christine Goeschel has no conflicts of interest to disclose
- The information provided is drawn from public domain documents and the experiences of the presenter…
- Information contained herein does not represent official or unofficial policies of the Johns Hopkins University School of Medicine or any of its' Institutional Review Boards

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Learning Objectives

1. Understand the role of OHRP
2. Describe regulatory challenges of quality improvement research
3. Discuss a “defining case”
4. Determine whether HHS regulations for protection of human subjects in research (45CFR part 46) apply
5. What is on the horizon

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1. The Office of Human Research Protections (OHRP)

1. Agency of the Department of Health and Human Services
2. Protect Human Subjects; NOT make life difficult for researchers ☺
3. The Common Rule
4. Rich website; friendly bureaucrats, accessible http://www.hhs.gov/ohrp/

OHRP

"*The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research*"

2. Some Regulatory Challenges : Quality Improvement Research

1. *Implementation Science*
2. *Generalizable Knowledge*
3. *Informed Consent*
4. *Analysis of Administrative Data*
5. *HIPAA*

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3. A Defining Case: Is it QI or is it Research?

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A Success Story in American Health Care:

Eliminating Infections & Saving Lives in Michigan

The Keystone Project's Five Steps to Success

The Keystone Project reduced infections by 66% throughout the state, **saving over 1,500 lives and $200 million in the first 18 months alone.**

The Keystone Project

This work was funded by a grant from the Agency for Healthcare Research and Quality, and **for every dollar invested, approximat $200 was SAVED.**

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TRIP and CUSP Model

TRIP [1]

1. Summarize the evidence
2. Identify local barriers to implementation
3. Measure performance
4. Ensure all patient receive the intervention

[1] BMJ 2008;337:963-965

CUSP [2]

1. Educate on the science of safety
2. Identify defects
3. Assign executive to adopt unit
4. Learn from Defects
5. Implement teamwork & communication tools

[2] Jt Comm J Qual Patient Saf 2010;36:252-60

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What is the Evidence?

- Guidelines for the Prevention of Intravascular Catheter-Related Infections; August 2002. www.cdc.gov

- Mermel LA. Prevention of Intravascular Catheter-related Infections. Ann Intern Med 2000;132:391-402.

Evidence-based Behaviors to Prevent CLABSI

- Remove Unnecessary Lines
- Wash Hands Prior to Procedure
- Use Maximal Barrier Precautions
- Clean Skin with Chlorhexidine
- Avoid Femoral Lines

MMWR. 2002;51:RR-10

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Leading Change

	Senior leaders	Team leaders	Staff
Engage *Adaptive*	*How does this make the world a better place?*		
Educate *technical*	*What do we need to know?*		
Execute *adaptive*	*What do we need to do?* *How can we do it with my resources and culture?*		
Evaluate *technical*	*How do we know we improved safety?*		

Pronovost: Health Services Research 2006

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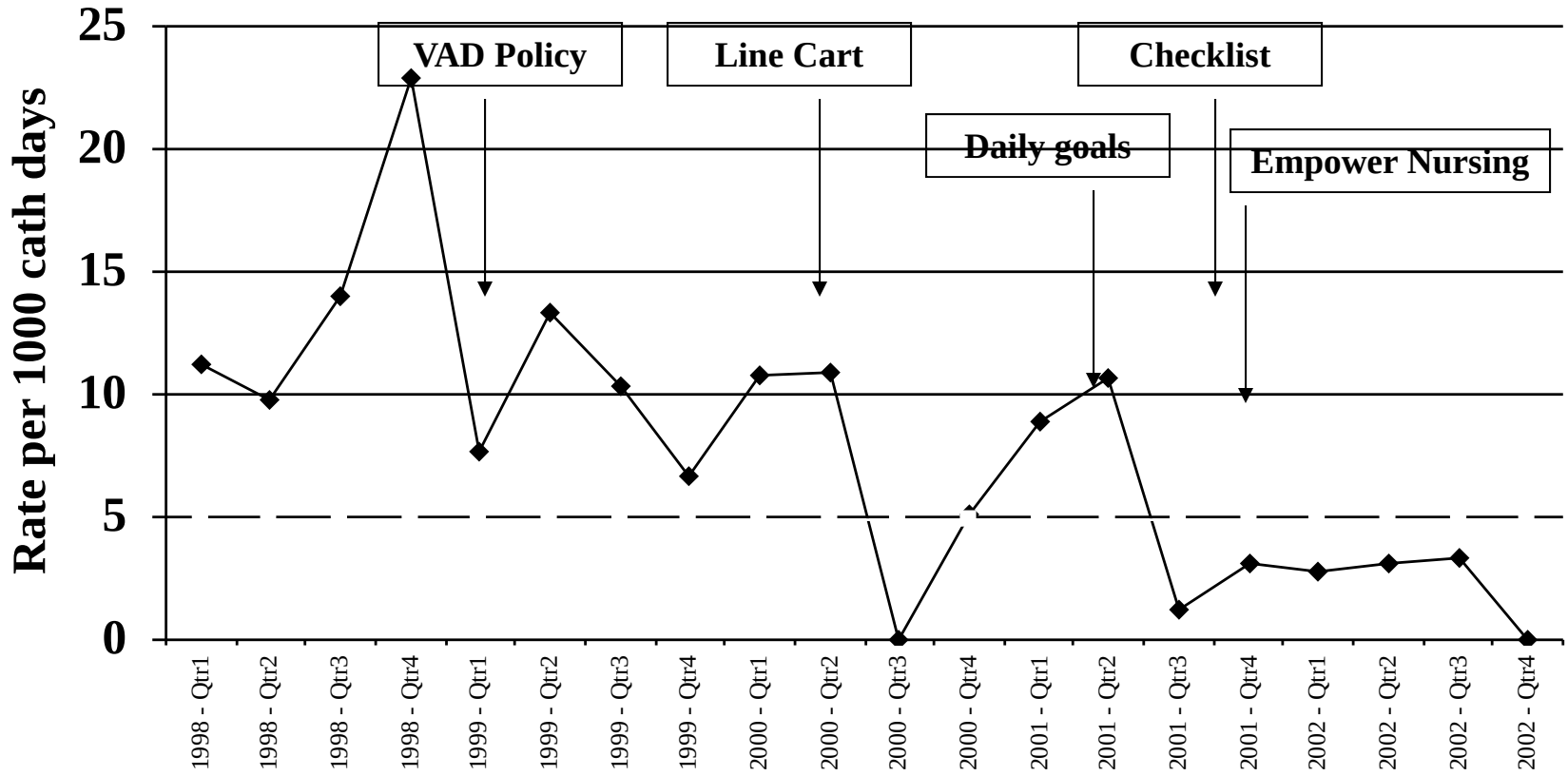
Impact on Catheter-Related BSI



Crit Care Med 2004;32(10):2014.

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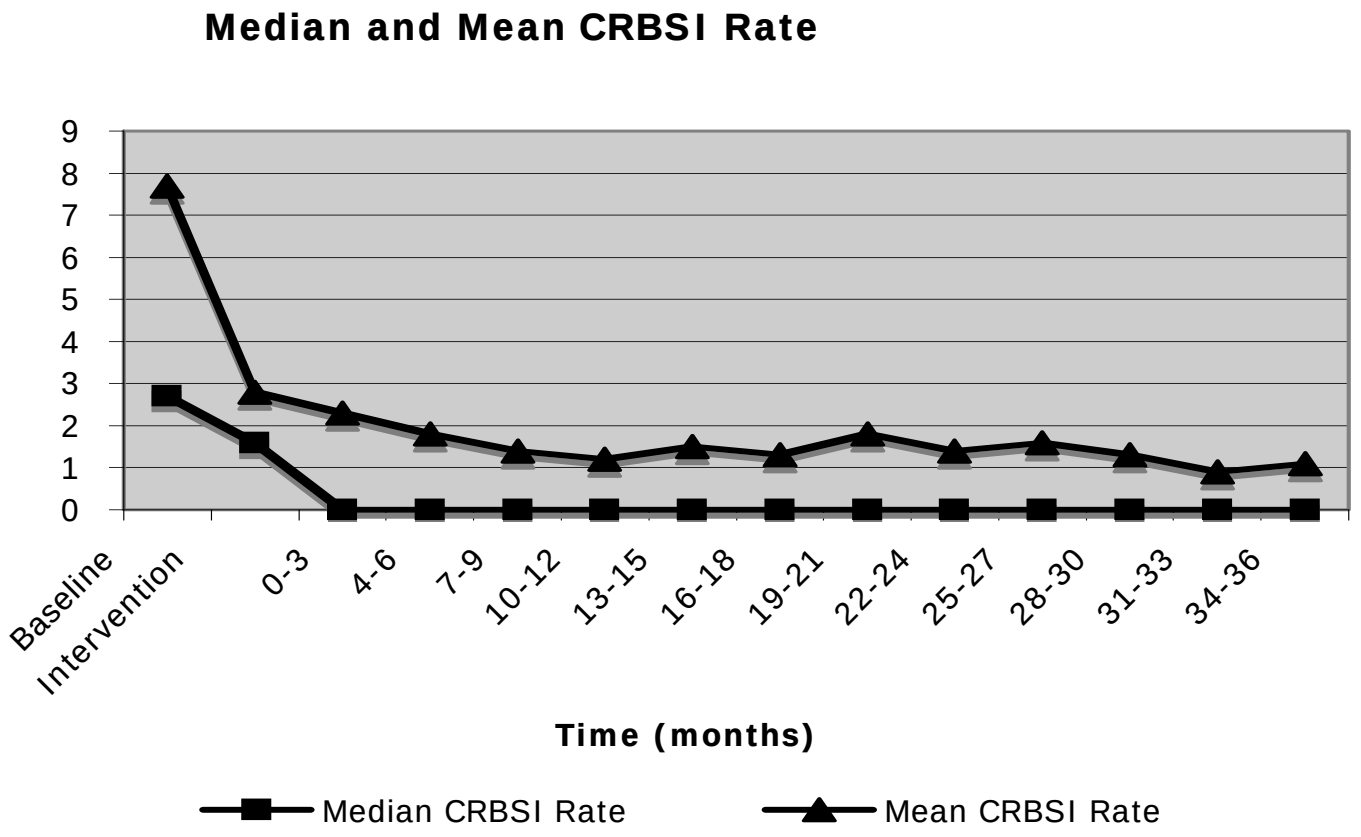
Michigan Keystone ICU



N Engl J Med 2006;355:2725-32; BMJ 2010;340:c309.

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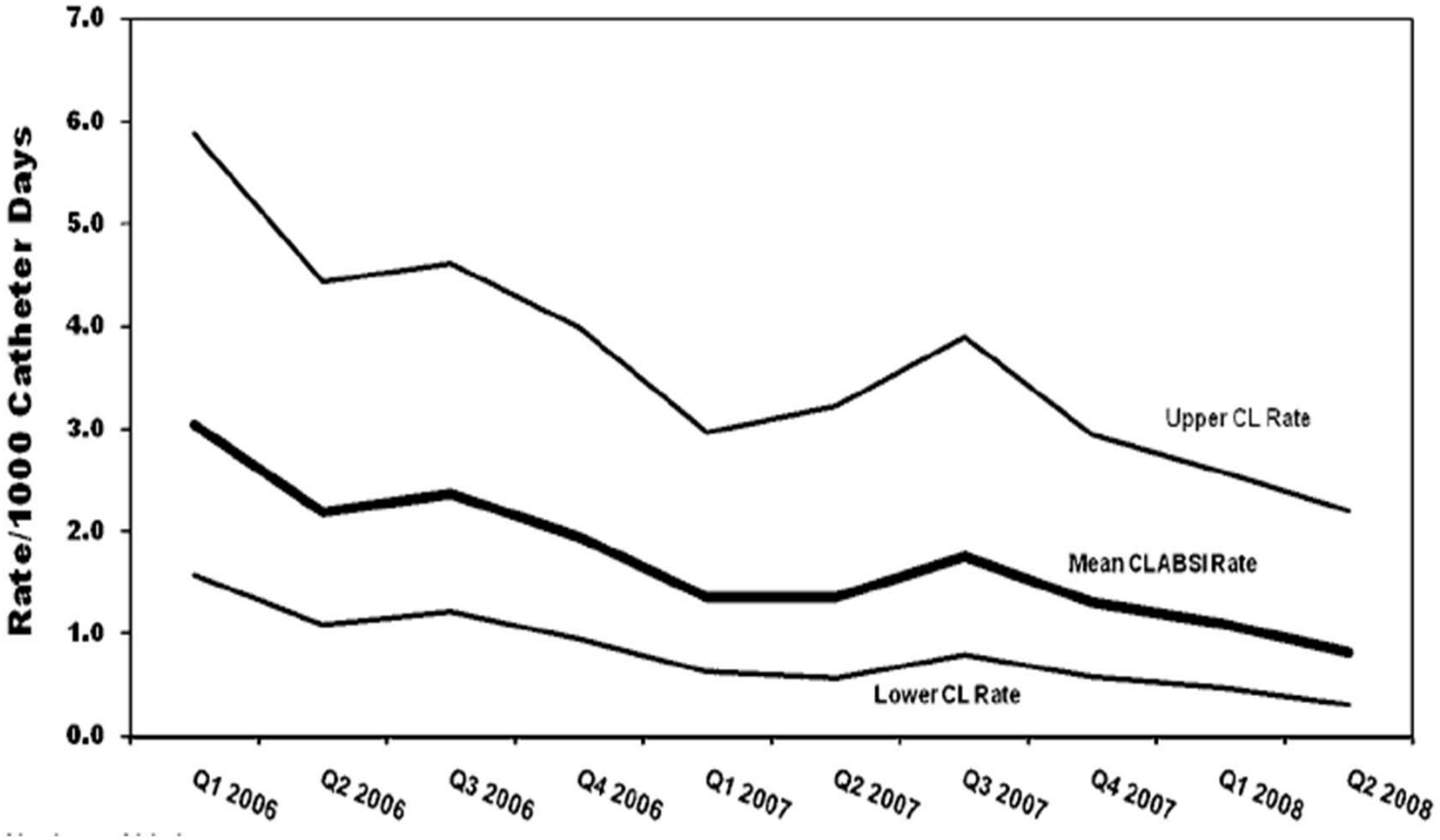
Rhode Island ICU CLABSI Rates

23 ICUs representing 11 hospitals



Qual Saf Health Care 2010;19(6):555-561

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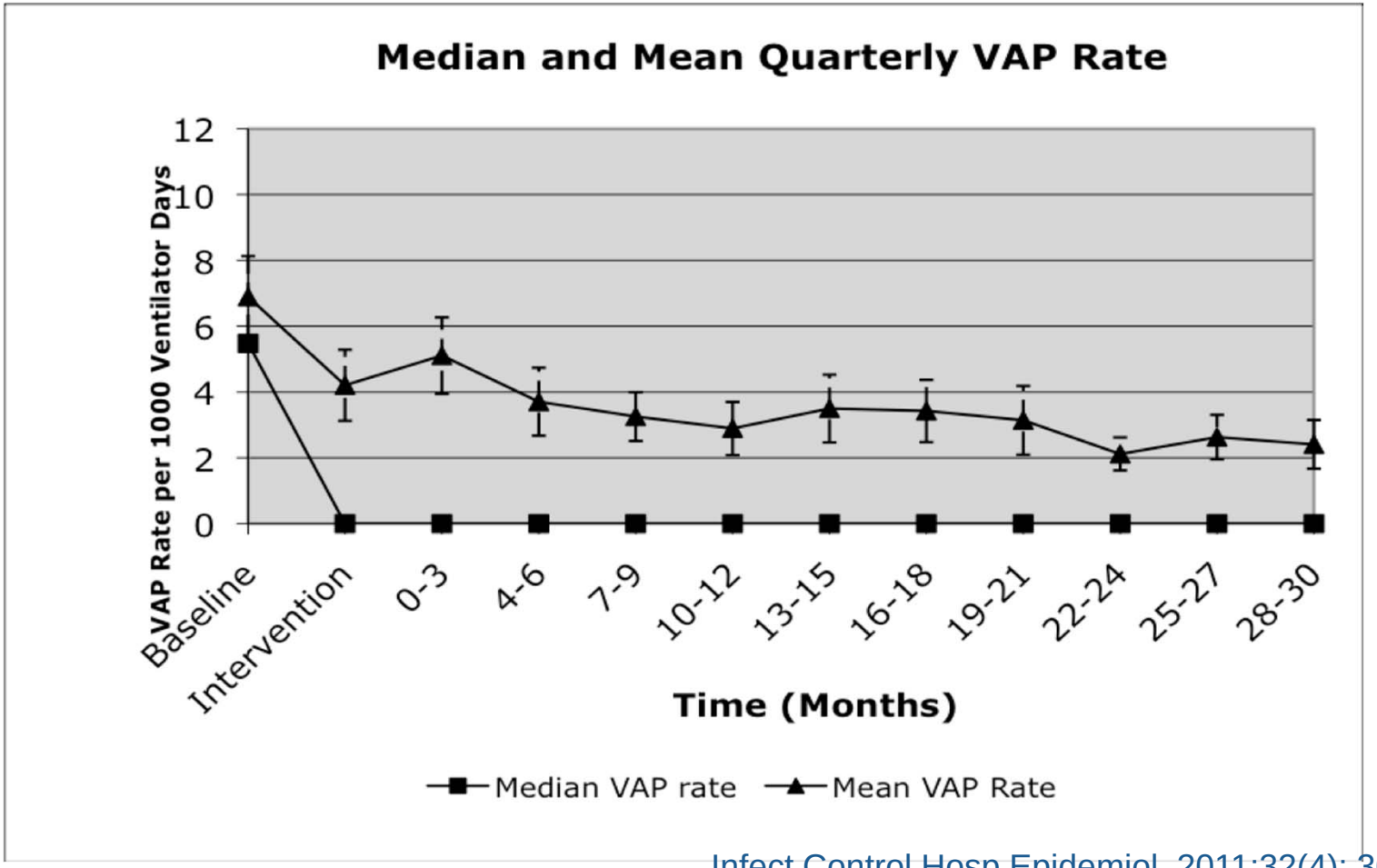
Michigan Keystone ICU



Infect Control Hosp Epidemiol. 2011;32(4): 305-314.

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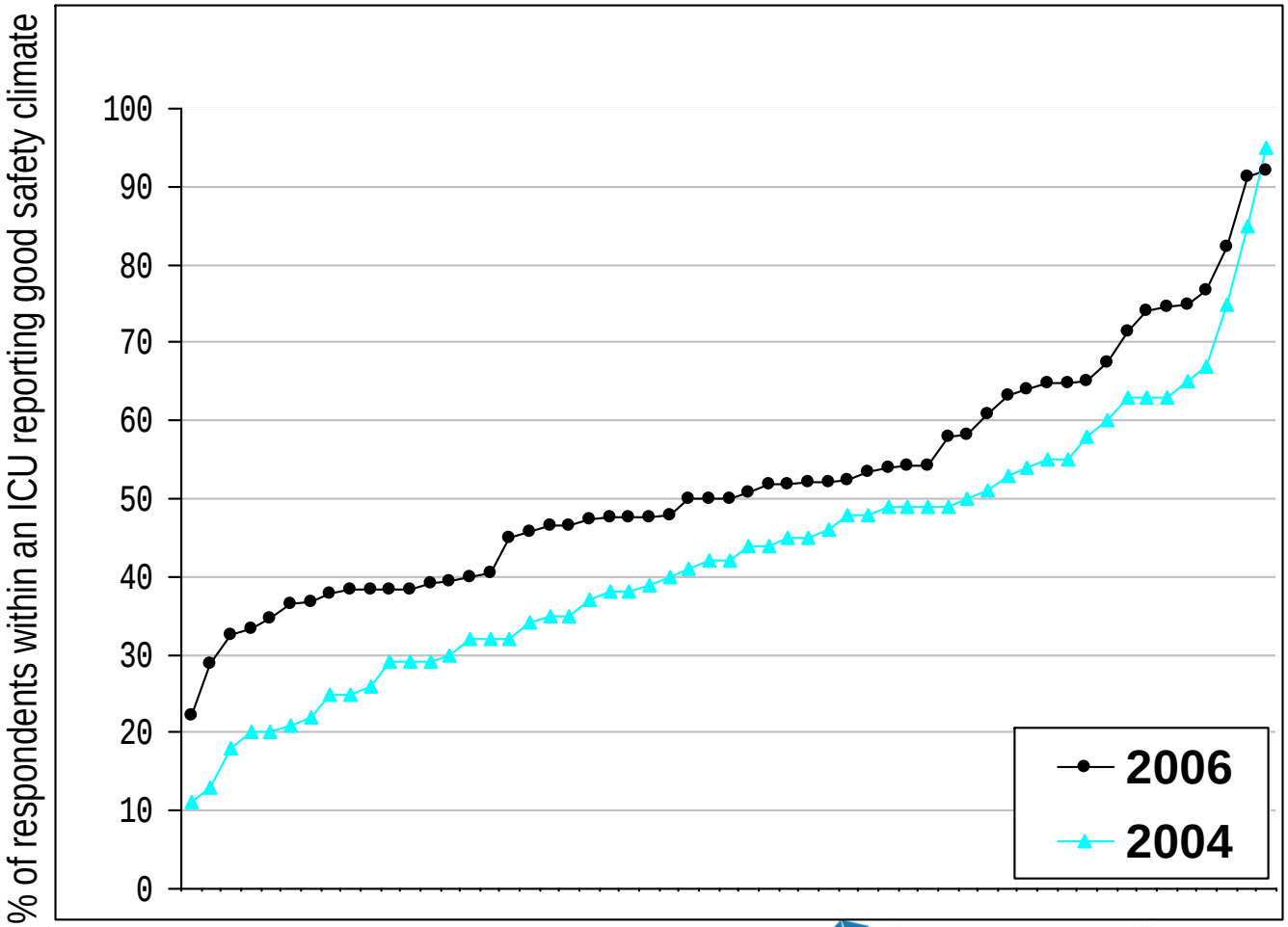
Culture of Safety- Michigan

Safety Climate Across Michigan ICUs



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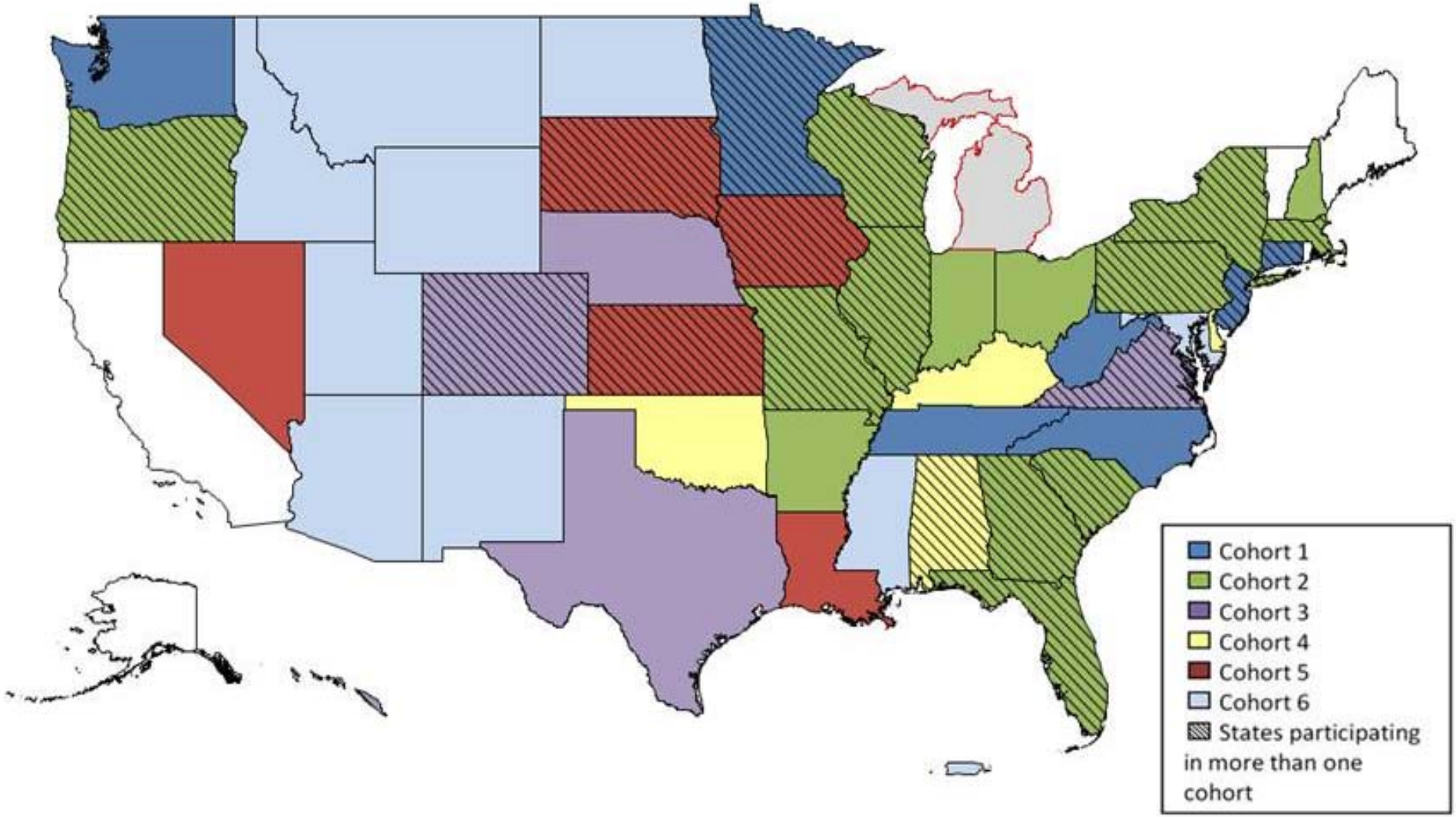
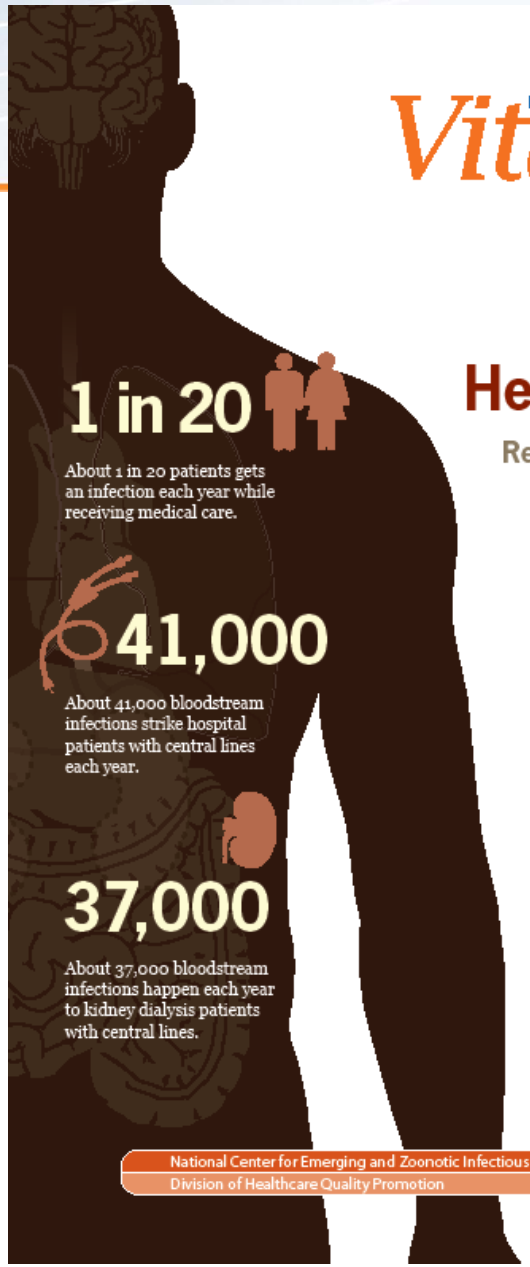
On the CUSP: Stop BSI

(47 States; 1055 hospitals)





CDC Vitalsigns™

March 2011

Making Health Care Safer

Reducing bloodstream infections

1 in 20

About 1 in 20 patients gets an infection each year while receiving medical care.

41,000

About 41,000 bloodstream infections strike hospital patients with central lines each year.

37,000

About 37,000 bloodstream infections happen each year to kidney dialysis patients with central lines.

A central line is a tube that a doctor usually places in a large vein of a patient's neck or chest to give important medical treatment. When not put in correctly or kept clean, central lines can become a freeway for germs to enter the body and cause serious bloodstream infections. These infections can be deadly. Of patients who get a bloodstream infection from having a central line, up to 1 in 4 die. Bloodstream infections in patients with central lines are largely preventable when healthcare providers use CDC-recommended infection control steps. Medical professionals have reduced these infections in hospital intensive care unit (ICU) patients by 58% since 2001. Even so, many still occur in ICUs, in other parts of hospitals, and in outpatient care locations. In 2008, about 37,000 bloodstream infections occurred in hemodialysis* outpatients with central lines.

*Use of a machine to clean or filter the blood when kidneys no longer work.

Learn what you can do to reduce central line bloodstream infections.

→ See page 4

Want to learn more? Visit

www http://www.cdc.gov/vitalsigns

National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion

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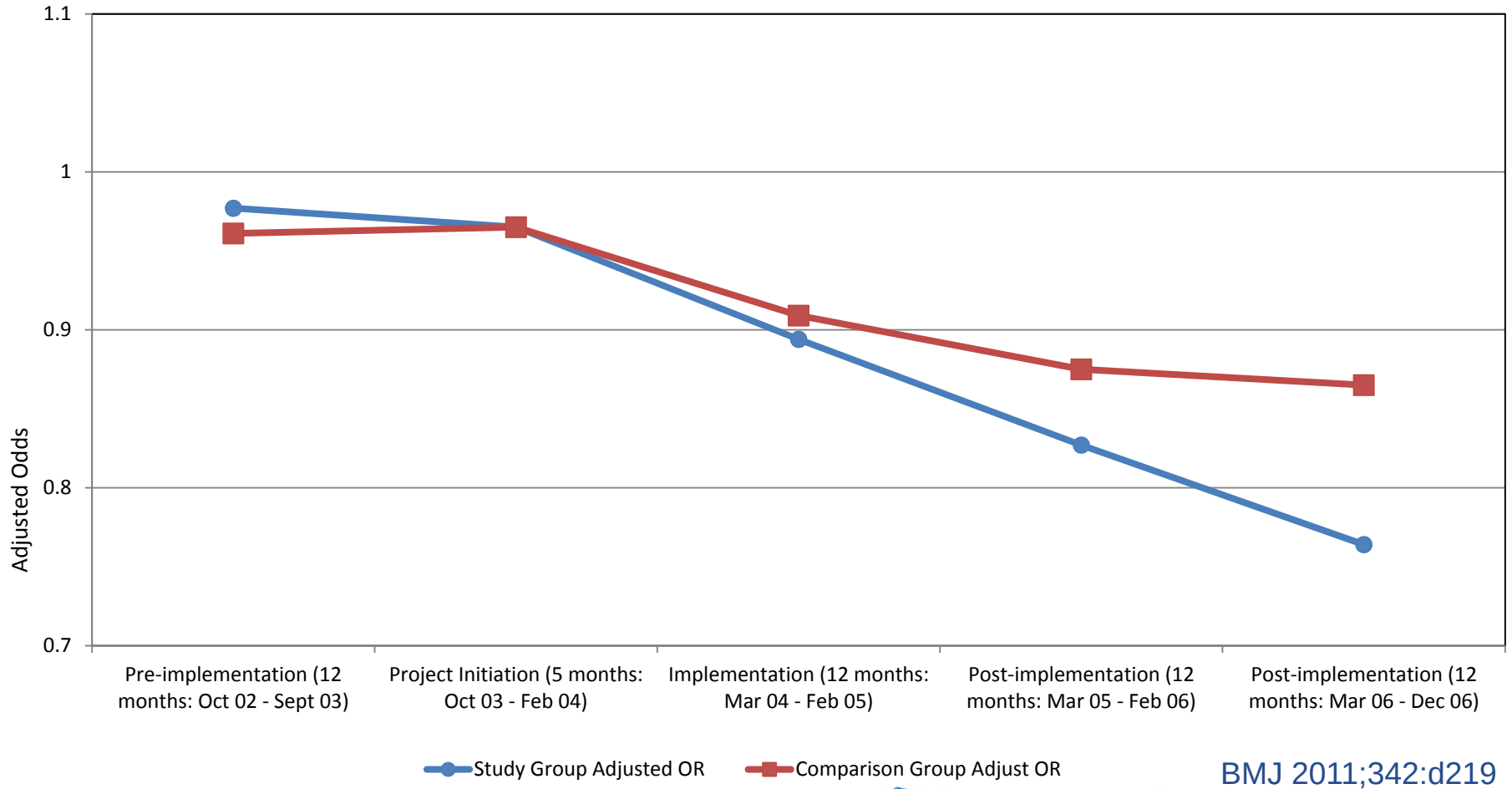
Impact of Statewide Quality Improvement Initiative on Hospital Mortality



BMJ 2011;342:d219

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Keystone ICU project: Business Case

- 30 CLABSIs averted annually
- 18 VAP cases averted annually
- Financial benefits exceed costs of intervention
  - $1.1 million saved per year for average hospital

Am J Med Qual. 2001;26:333-339

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"Explaining Michigan: Developing an Ex Post Theory of a Quality Improvement Program"
Mary Dixon-Woods, Charles L. Bosk, Emma Louise Aveling, Christine A. Goeschel, and Peter J . Pronovost
June 2011 (Volume 89, Number 2)

Archive of Featured Articles

4. Determine if 45 CFR part 46 Applies

1. Does the activity involve *research?*
   - *(45 CFR 46.102 (d))*
2. Does the research activity involve *human subjects (45 CFR 46. 102 (f))*
3. Does the human subjects research *qualify for an exemption? (45 CFR 46.101 (b))*
4. Is the non-exempt human subjects research *conducted or supported by HHS or* otherwise *covered by applicable FWA approved by OHRP?*

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IF Research, then what?

1. IRB review is needed if research involves human subjects, is not exempt, and is conducted or supported by HHS or otherwise covered by and applicable FWA.

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Myths

If my project is research I must get patient informed consent

1. Research may qualify for expedited review with waiver of consent when:

- *The risk to the subjects is minimal*
- *Subjects' rights and welfare will not be adversely affected by the waiver*
- *Conducting research without the waiver is not practicable and*
- *If appropriate, subjects are provided with additional pertinent information after their study participation.*

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If I intend to publish my findings, I must get IRB approval

- Heuristic technique to assess intent~

Federal regs broadly define research as

" a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge"

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What is on the Horizon? CHANGE

July 22, 2011 ~ HHS proposal to improve rules protecting human subjects. Public comment was solicited for:

1. Revising risk based framework to more accurately calibrate level of review to level of risk
2. Using a single IRB review for all domestic sites of multi-site trials

What is on the Horizon?
CHANGE

3. Updating forms and processes used for informed consent

4. Establishing mandatory data security and information protection standards for all studies involving identifiable or potentially identifiable data

5. Implementing a systematic approach to collection and analysis of data on unanticipated problems and adverse events across all clinical trials.

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What is on the Horizon?
CHANGE

6. Extending federal regulatory protections to apply to all research conducted at US institutions receiving funding from the Common Rule agencies

7. Providing uniform guidance on federal regulations

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COURAGE

"Never doubt that a small group of thoughtful committed citizens can change the world. Indeed, it's the only thing that ever has."

Margaret Meade

For More Information

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Closing Remarks

- ISRN Mission
  - To enhance the scientific foundation for quality improvement, safety, and efficiency through transdisciplinary research addressing healthcare delivery, patient-centeredness, and integration of evidence into practice.

- Please join us for our summer conferences July 17 -21 in San Antonio, Texas

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