Certificate Training Program
Session 5

Welcome!: Before We Start

Sign-in at the back
Sit with your CTP team at your assigned table

Institute for Healthcare Quality,
Safety and Efficiency
SCHOOL OF MEDICINE
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Oasis

Congratulations, Spencer McClelland!

Teacher of the Year for the Denver Health Advocacy LIC

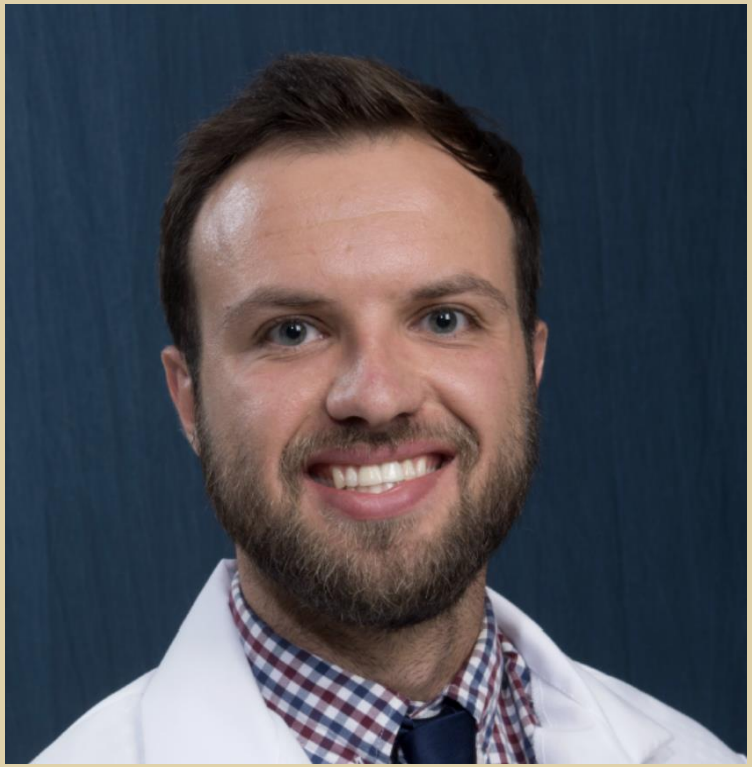
Many Patients Learn They Could Have Cancer in the Emergency Department

It's not uncommon, says Gregory Adams, DO, of the CU Department of Emergency Medicine, and it happened to his own father.

5 minute read

by Mark Harden | September 24, 2025

CTP's **Gregory Adams** in the news!



The IHQSE is expanding!

Know someone who may be interested in joining our team as a **Program Coordinator**?

Reach out to IHQSE@cuanschutz.edu with questions or candidates.

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Curriculum Overview

8/19	#1	Welcome	Beginning with the End in Mind	Objectives & Introductions	Overview	Leadership Defined	Team Norms			Understand Process
8/26	#2	CHCO Inpatient Pediatric Rehab	Thriving as a Leadership Imperative	Value Defined	Introduction to Quality Improvement	IHQSE Model of Change	Coaching			Understand Process
		Coaching								
9/9	#3	UCH Whole Blood Program	Investigate the Problem	Problem Statement	Voice of the Customer	Stakeholder Analysis	Process Mapping	Coaching		Baseline data
		Coaching								
9/23	#4	UCH Rheumatology Clinic	Investigate the Problem	Understanding Root Causes	Data: Uses in QI and Finding it	EMR Process & Data	Business Case			Baseline data
		Coaching								
10/7	#5	CHCO Digestive Health	QI vs. Research	Leading Change						Baseline data
		Coaching								
10/28	#6	UCH Pre-Procedure Services	Leading Change: Vision	Wellness	Leading Change: Sense of Urgency					Process Optimization
11/4	#7	DHH OB/GYN Clinics	Data Collection Plan	Myers Briggs						Process Optimization
		Coaching								
11/18	#8	UCH ED & Radiology	Hone the Intervention	This Place Called Academia	Understanding Business Drivers	Negotiating for what You Need				Finalize Need
		Coaching								
12/9	#9	CHCO Health Clinic & Dev. Peds.	Design Thinking	Positive Deviance	QI & Health Equity					Finalize Need
12/16	#10	UCH Antimicrobial Stewardship	Leading Change: Guiding Coalition	Aim Statement	Optimizing EMR Requests	Overcoming Resistance	Stakeholder Analysis	Team Logo		Submit Ticket
		Coaching								

KEY	Team Check-in	Inspiration	Background	Process Improvement	Leadership	Quality/Safety	Coaching

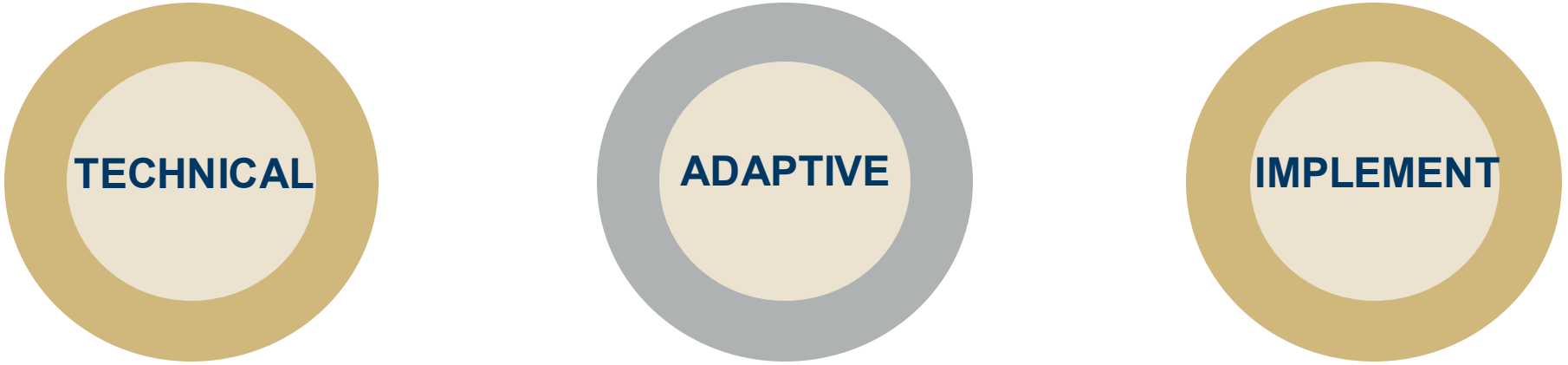
Session	Topic	Key Question(s)	Assignment	Due
#4 Sept. 23	Team Check-in: UCH Rheumatology Clinic	Who are my colleagues?	❑ **Complete Affinity Diagram** *Due Dec.9* ❑ **Reading for next session:** Kotter, John. *Leading Change: Why Transformation Efforts Fail* ❑ **Meet with Dr. Moksha Patel** *Due Nov. 4* ❑ **Draft Business Case** *Due Nov. 18*	
	Baseline Data	How do I identify key metrics?		
	Investigate the Problem	How do I understand the problem I'm trying to solve?		
	EMR and Process Data	How does the EMR enable data attainment? What EMR changes do I need to make to complete my project?		
	Understanding Root Causes	What tools can I use to organize information about my process?		
	Business Case	How do I make the financial case for my improvement work?		
Coaching	**Baseline data, root causes, business case**			
#5 Oct.7	Team Check-in: CHCO Digestive Health	Who are my colleagues?	❑ **Complete Myers-Briggs Assessment** *Due Oct. 24* ❑ **Complete literature review and program eval/QI/research tool** *Due Nov. 18*	✓ **Reading for next session:** Kotter, John. *Leading Change: Why Transformation Efforts Fail*
	Leading Change	What are the components of successful change?		
	QI vs. Research	How do I determine if my QI work is a research project?		
Coaching	**Literature search, QI/Research tool, voice of the customer, stakeholder analysis, process map**			
#6 Oct. 28	Team Check-in: UCH Pre-Procedure Services	Who are my colleagues?	❑ **Wellbeing Analysis** *Due Dec. 9* ❑ **Health Equity Analysis** *Due Dec. 9*	✓ **Complete Voice of Customer, Build Stakeholder analysis, and Develop a problem statement**
	Leading Change: Vision	How do I tie my project back to a larger vision?		
	Wellness	How do we ensure that our work enhances, not worsens wellness?		
	QI and Health Equity	How can we apply a health equity lens to QI?	❑ **Develop/utilize current vision trying to project** *Due Dec. 9*	

Today's Objectives

1. Recognize the key components to successful change
2. Determine if your project is a QI project or a research project

I H Q S E

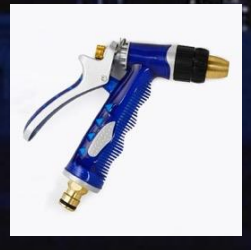
Investigate → **Hone** → **eQuip** → **Start** → **Embed**

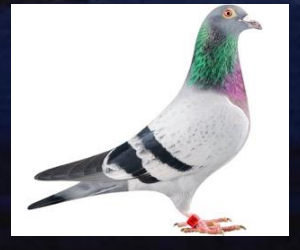


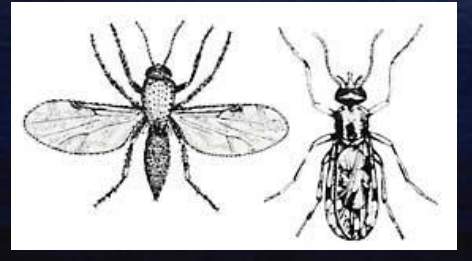
Investigate	Hone	eQuip	Start	Embed
❑ Search literature ❑ Acquire Baseline Data ❑ Capture Voice of Customer ❑ Capture Voice of Business ❑ Create Problem Statement ❑ Analyze stakeholders ❑ Complete Process Map ❑ Create Affinity Diagram ❑ Identify Key Metrics ❑ Build a Business Case ❑ Create Aim Statement	❑ Apply Pareto Principle ❑ Assess Positive Deviants ❑ Use Hierarchy of Interventions ❑ Perform Design Thinking ❑ Identify 2 - 3 interventions ❑ Determine Research or QI ❑ Create Effort/Impact matrix ❑ Complete Equity Analysis ❑ Craft Well-Being Analysis ❑ Create Data Plan ❑ Complete Pre-mortem ❑ Finalize Implementation Plan	❑ Create Sense of Urgency ❑ Develop a Guiding Coalition ❑ Align with the Vision ❑ Build Motivation Plan ❑ Apply Diffusion of Innovation ❑ Identify & Remove Barriers ❑ Address Resistance ❑ Craft Awareness Campaign ❑ Create Logo ❑ Create Short-term Wins	❑ Pilot Intervention ❑ Ignite Awareness ❑ Launch Intervention ❑ Apply Motivation & Diffusion ❑ Track Data and Refine ❑ Recognize New Resistance ❑ Celebrate Short-term Wins ❑ Credibility for More Change	❑ Track Run Charts, SPC ❑ Remove New Barriers ❑ Celebrate More Wins ❑ Reconcile Business Case ❑ Present to Stakeholders ❑ Disseminate Project Work ❑ Create sustainment plan

It is critical to identify the root cause(s) and not only address what lies upon the surface.

Five Why's







Step 5: Affinity Diagram

EHR	Communication	Process	Materials Environment	Knowledge
No Indications	RN/MD/PT use Different language	not discussed in discharge rounds	Busy	Don't know indications for PT
RN assessment not visible	Providers don't know this language	2	No geographic cohorting	2
No feedback loop	7 6		1	

Define the problem

Is it a problem?

How do you know?

Who is affected?

By how much?

Are there best practices to refer to?

PROVE IT.

(ahem, with data ☺)

Conceptual vs Operational definitions

Daily order of CBCs and BMPs on inpatients ordered by day team residents

Number of CBCs

+

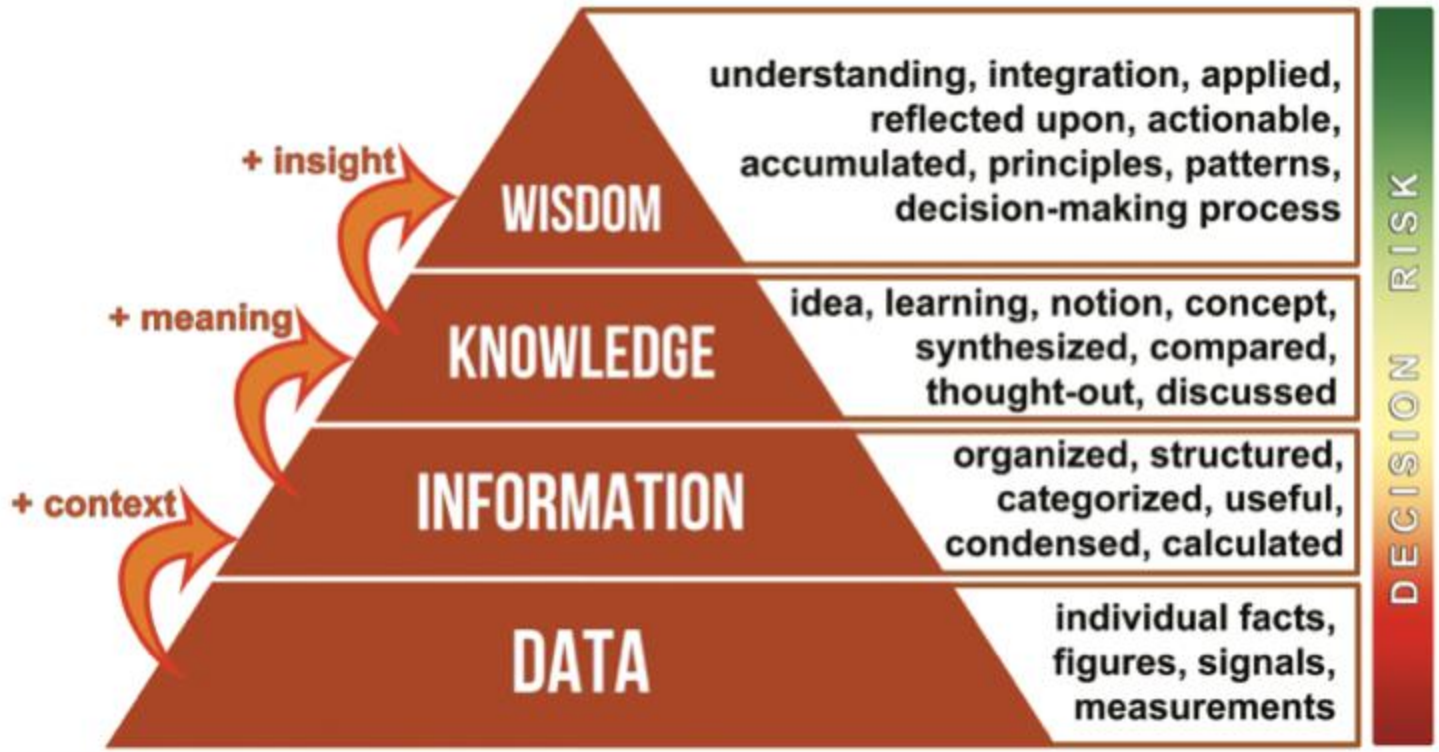
Number BMPs on inpatients ordered by day team residents between 1200am – 1159pm

---

Total medicine team census per day

Key Question	Data Element Name	Operational Definition	Parameters	Source	Who	Frequency
What is the length of stay?	Length of stay (LOS)	LOS = Admit time to Discharge time	• Date range: 1/1/2020 - 12/31/2020 • One listed for every patient by CSN • Format: time in hours	EHR -- ADT	Which team member is in charge of collecting?	Monthly data pull, 1st of month

Understanding Data: *Data Hierarchy*



Tedeschi L. O. (2019). ASN-ASAS SYMPOSIUM: FUTURE OF DATA ANALYTICS IN NUTRITION: Mathematical modeling in ruminant nutrition: approaches and paradigms, extant models, and thoughts for upcoming predictive analytics1,2. *Journal of animal science*, *97*(5), 1921–1944. https://doi.org/10.1093/jas/skz092

How?

Step 1: What are you trying to do?

Step 2: What is the benefit?

Step 3: How do I show the benefit?

Step 4: What data do I need?

Team Check-in: CHCO Digestive Health

Background & Problem

For the CTP team check-in be prepared to succinctly share 3 items:

1) Introduce each team member (1 minute)

2) Tell us about your program (2 minutes)

3) What is the problem you think you will focus on? (3-5 minutes)
   - *E.g., What are the pain points for you, your staff and customers?*
   - *E.g., Do you have any data to understand your problem?*

Our Team: Digestive Health Institute & Procedure Center, Children's Hospital Colorado

- The Digestive Health Institute (DHI) includes our GI, Liver, and GI Surgery programs. We have 55 faculty members, have a large OP practice across 7 sites of care and additional outreach locations, run two IP services, and complete >5500 procedures annually.
- The procedure center at Anschutz is one of 4 procedures/OR locations across the CHCO system. We complete >6500 cases annually in over 15 specialties.

The Problem:

Procedure center space and provider time are valuable and limited. GI is the largest procedural program across the hospital. The data below suggest there are efficiency opportunities within our GI program in the procedure center.

- We start on time less than half the time (49%)
- On average only 72% of our block time is utilized
- We hypothesize that our hard coded turn-around time (23 minutes) between cases is too high; several QI efforts & studies suggest ~15 min is optimal and possible!

All of this contributes to waste, and thus $$ lost.

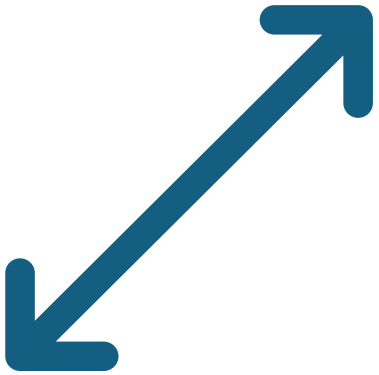
The Context:

The DHI historically was a very profitable section. However recently due to changes in payment structures for several services, we've seen a huge shift in our financials.

Procedures have always been a large driver of the profitability of the Digestive Health Institute generating over $8M in revenue annually; although the payment landscape has had some shifts outside of our control, this is likely where we have the most opportunity to shift our financials.

We perform over 3000 GI cases annually in the Anschutz Procedure Center (almost half of the cases in the procedure center), thus an improvement here has impacts not only on GI, but on broader hospital operations.

Goal:



Maximize the volume of procedures per GI block.

Minimize the resources needed to complete these cases without compromising quality of care or provider/team member satisfaction.

Change Management
Why won't they follow?

Jeff Glasheen, MD

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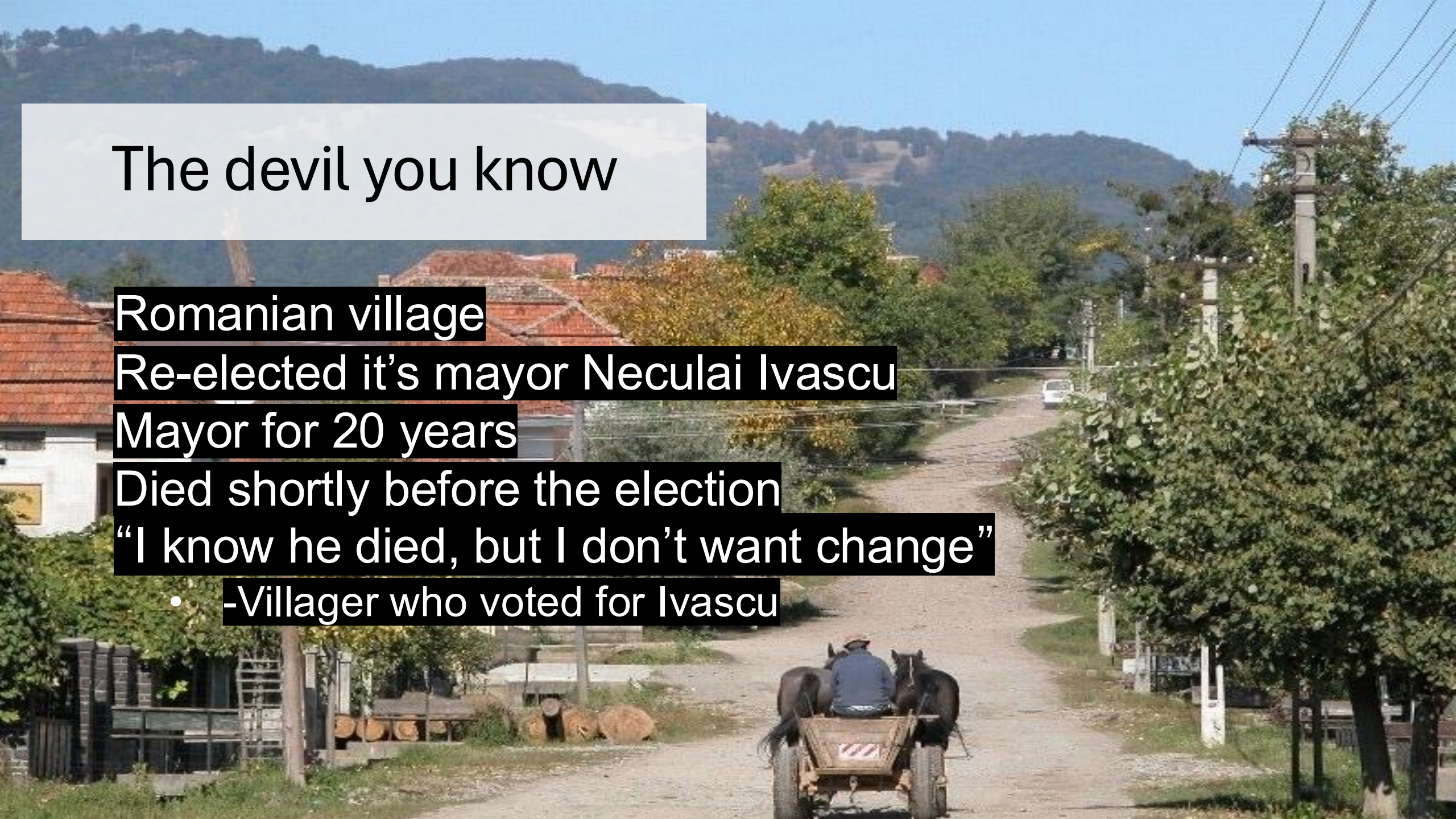
What we'll discuss

- Change leadership
- 8 steps to leading change
- Apply to your CTP project

The devil you know



Romanian village
Re-elected it’s mayor Neculai Ivascu
Mayor for 20 years
Died shortly before the election
“I know he died, but I don’t want change”

- -Villager who voted for Ivascu

Vancomycin use in the ICU

- Only 50% of 1st vancomycin troughs within range of 10-20 mcg/mL
- Develop simple weight-creatinine based nomogram
- ICU and Pharmacy leadership buy-in
- Rolled out nomogram for the ICU, email sent to residents/faculty every month

Vancomycin use in the ICU: Email orientation

- I wanted to make everyone aware of the ongoing QI initiative in the MICU addressing initial vancomycin dosing. The standard 1 gram every 12 hours is not appropriate for many ICU patients and the first troughs have been in the therapeutic range of 10-20 mcg/mL only about 50% of the time. We have developed a very simple dosing nomogram (attached) that also includes guidelines on dosing for HD and CVVH, and when the troughs should be checked. Based on the existing data, we expect this nomogram to eliminate about 75% of subtherapeutic troughs and 50% of supratherapeutic troughs.

- The nomogram requires only the patient's actual body weight and MDRD-estimated GFR with age, gender, race, and serum creatinine (online at www.mdrd.com).

- We rely primarily on you as treating physicians to follow the nomogram and correctly order the antibiotics, decreasing the risk of under- or over-dosing your critically ill patients in the crucial initial 24-72 hours of therapy until the first trough is obtained. The MICU pharmacists will be helping you with the nomogram as well.

- Thank you in advance for your help and your hard work. We welcome all questions and feedback on this quality improvement initiative.

Vancomycin use in the ICU: Outcomes

- Pre-intervention trough 10-20 50%
- Post-intervention trough 10-20 50%
- Protocol concordance rate 20%

Vancomycin use in the ICU: Why didn’t they follow?

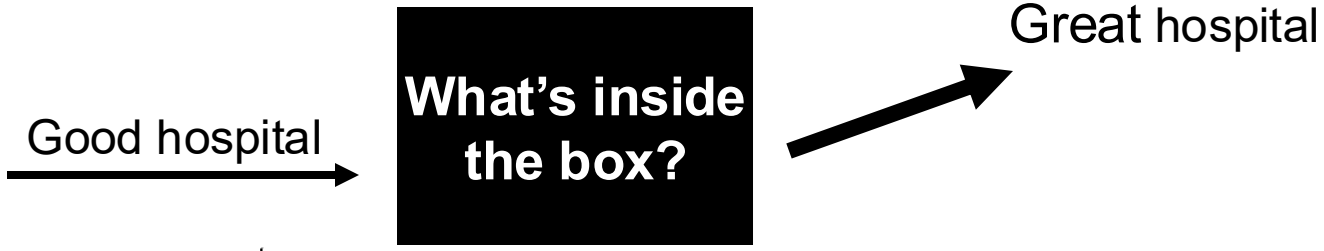
- Group Discussion
  - Why do you think the intervention didn’t work?
  - Why didn’t the doctors follow?

Thinkin’ caps

- Do you work at a great hospital?
  - What’s keeping it from being great?
  - Do the leadership, staff and doctors want greatness? Do you?
- If we all want to work at a great hospital…

Why don’t we have great hospitals?

- People generally want things to be different
    - They just don’t want to have to change
- Successful organizations change
- But change is very hard
- Good is the enemy of great
    - Good + change being difficult = no change
- We don’t have great hospitals b/c we have good ones



Leadership

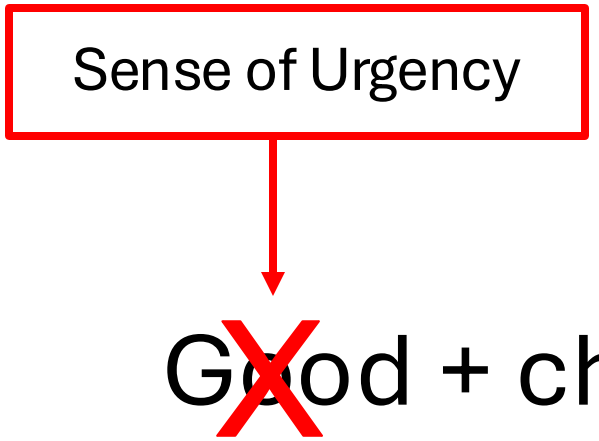
- Dictionary.com
  - Leadership: Ability to lead
  - Leader: A person or thing that leads
  - Lead: A soft, dense, metallic element
  - Lead: A guiding or directing head
- Getting people to go somewhere they otherwise wouldn’t go


BREAK-TIME
Come back at 2:10

Step 1—Establish a sense of urgency

- People need to think there is a problem
  - Is this an important problem?
  - What is the crisis?
  - What are the opportunities?
  - How can these be related to your colleagues?
- If you cannot create a sense of urgency…
  - Stop!
  - It’ll fail. Guaranteed!
  - Don’t go to step 2 unless you’ve got this

Good is the enemy of great



~~Good~~ + change being difficult = no change

Vancomycin Project

- Apply concepts to the Vancomycin Project

- Step 1: Create a Sense of Urgency
  - How will you build that burning platform/aspiration?

Step 2—Create Guiding Coalition, AKA Leadership

- Leadership is not being in charge, a position of power, autocratic
- Not just the Dean, Chair, hospital CEO
- Find the thought leaders and engage
  - Who are the thought leaders?
  - Don’t forget the other professions
  - Does this group have enough clout/frontline to make this happen?
  - Get this group together; convince them of #1

Step 3—Develop a vision and strategy

- Vision should inspire
  - Power of collective vision
  - Overcome barriers and self interests
  - Follow plans that we don’t like…that tie back to the vision
  - Should be inspirational and aspirational

Beth Israel Deaconess Medical Center

- BIDMC will eliminate all preventable harm.
- Now, what is your vision? Not your plan!
- Develop specific strategies, tactics, plans.

Urgency vs. Vision

- Urgency → Why they should care
- Vision → Where you are taking them
- Goal → What you are going to do
- Tactic → How you are going to do it

Step 4—Communicate the change vision

- Dogged & constant
  - Think of as many ways as possible to disseminate your strategies.
  - Ensure the guiding coalition role models these behaviors.
  - How many times do you need to tell people about the change?

Vancomycin Project

- Apply concepts to the Vancomycin Project

- Step 4: Communicate the Vision
  - List at least 10 ways you'll communicate your vision.
  - Many of these will be more basic or routine.
  - A few should be something novel. The more novel the more likely folks will remember it.

Step 5—Remove Obstacles

- Why aren’t people already doing this?
- What systems or structures are undermining the vision/strategy?
- How can you remove these barriers?
- Take it a step further—how can you make it easier to do the right thing?

Step 6—Generate short-term wins

- Reward the “changers”

- What rewards will motivate behavior change?

Cake!

Step 6—Generate Short-term Wins

- Reward the “changers”
- What rewards will motivate behavior change?
- Plan and create these prospectively

University of Colorado Hospital
Geriatric Hip Fracture Program

Dear team,

On behalf of the UCH Geriatric Hip Fracture Program, we wanted to say **THANK YOU** for the outstanding teamwork and patient care provided to our inaugural patient.

Mr. D is a 79-year-old man who was admitted on Saturday, November 1, 2014, with a left intertrochanteric hip fracture after a mechanical fall. He had recently moved out to Denver from Chicago, IL to be closer to his family. He arrived to the ED at 8:46 AM, was evaluated promptly by both **Orthopaedic Surgery** and the **Medicine Consult Service**, and was in the OR by 1:00 PM, less than 4 hours later! The patient was successfully admitted to the **8W Unit**. He received appropriate osteoporosis evaluation and treatment, already has a visit scheduled in the Seniors Clinic to establish care, and has a referral pending to the Metabolic Bone Clinic. Social work/case management are working with family on disposition, as we strive to decrease length of stay for this population.

Congratulations to **Meredith Mayo** and **Chris Chen** for being the first Orthopaedic residents to admit a patient using the UCH Geriatric Hip Fracture Admission and Pre-Op Order Sets. Congratulations to **Colin Anderson** for being the first to use the UCH Geriatric Hip Fracture Post-Op Order Set. Honorable mention goes to **Phil York**, who attempted to admit a hip fracture patient on October 31st, but, sadly, Kaiser requested that the patient be transferred to Good Samaritan.


100
KNP

Steps 7 & 8—Consolidate Gains into Culture

- Use credibility for more change
  - What are next steps to extend your gains?
  - What other structures/systems could be changed to make this even more successful—beyond the short-term win?
- Anchor new approaches in the culture
  - Begin to hire/promote/develop people who believe in this type of culture?
  - Develop future goals that tie into your new culture.

The Change Process

- Establish a sense of urgency
  - People need to think there is a problem
- Creating a guiding coalition
  - Find the thought leaders and engage
- Develop a vision and strategy
  - “Where” going and “how” things will change
- Communicate the change vision
  - Must be dogged & constant: coalition on board
- Empower broad-based action
  - Remove obstacles
- Generate short-term wins
  - Plan and create these; reward the “changers”
- Consolidate gains, produce more change
  - Use credibility for more change
- Anchor new approaches in culture
  - Make this part of the culture going forward

Change

Change is not mandatory

But then again, neither is survival

-W. Edwards Deming
(paraphrased)


BREAK-TIME
Come back at 3:45!

QUALITY IMPROVEMENT AND THE IRB

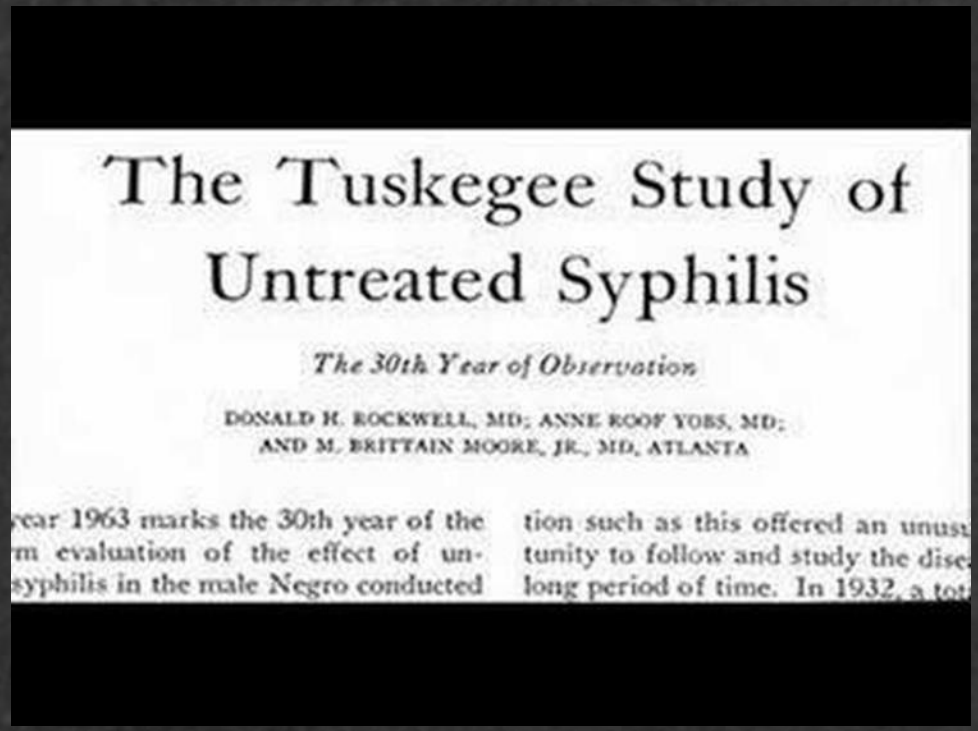
Ethan Cumbler MD, FHM, FACP

Professor in Departments of Medicine and Surgery

Faculty Institute for Healthcare Quality, Safety, and Efficiency

University of Colorado Anschutz Medical Campus

A Cautionary Tale



The Tuskegee Study of Untreated Syphilis

The 30th Year of Observation

DONALD H. ROCKWELL, MD; ANNE ROOF YOBS, MD;
AND M. BRITTAIN MOORE, JR., MD, ATLANTA

ear 1963 marks the 30th year of the
m evaluation of the effect of un-
syphilis in the male Negro conducted

tion such as this offered an unusu
tunity to follow and study the dise
long period of time. In 1932, a tot

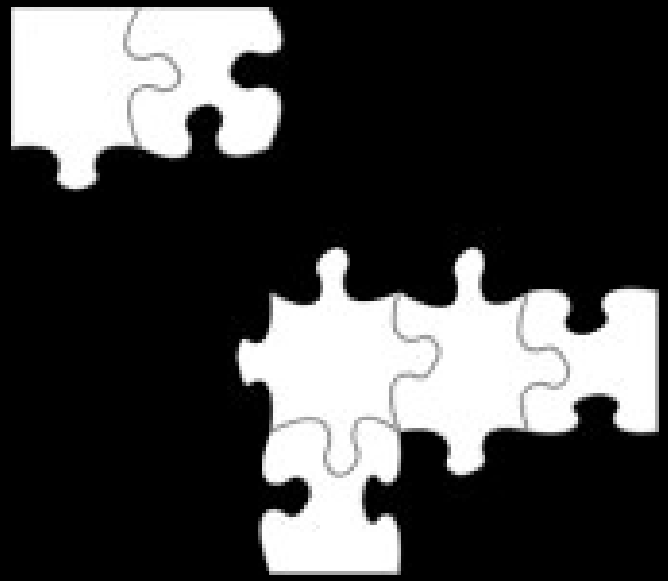
http://www.cdc.gov/tuskegee/timeline.htm

When does change to systems of care….

become experimentation on individuals without consent?

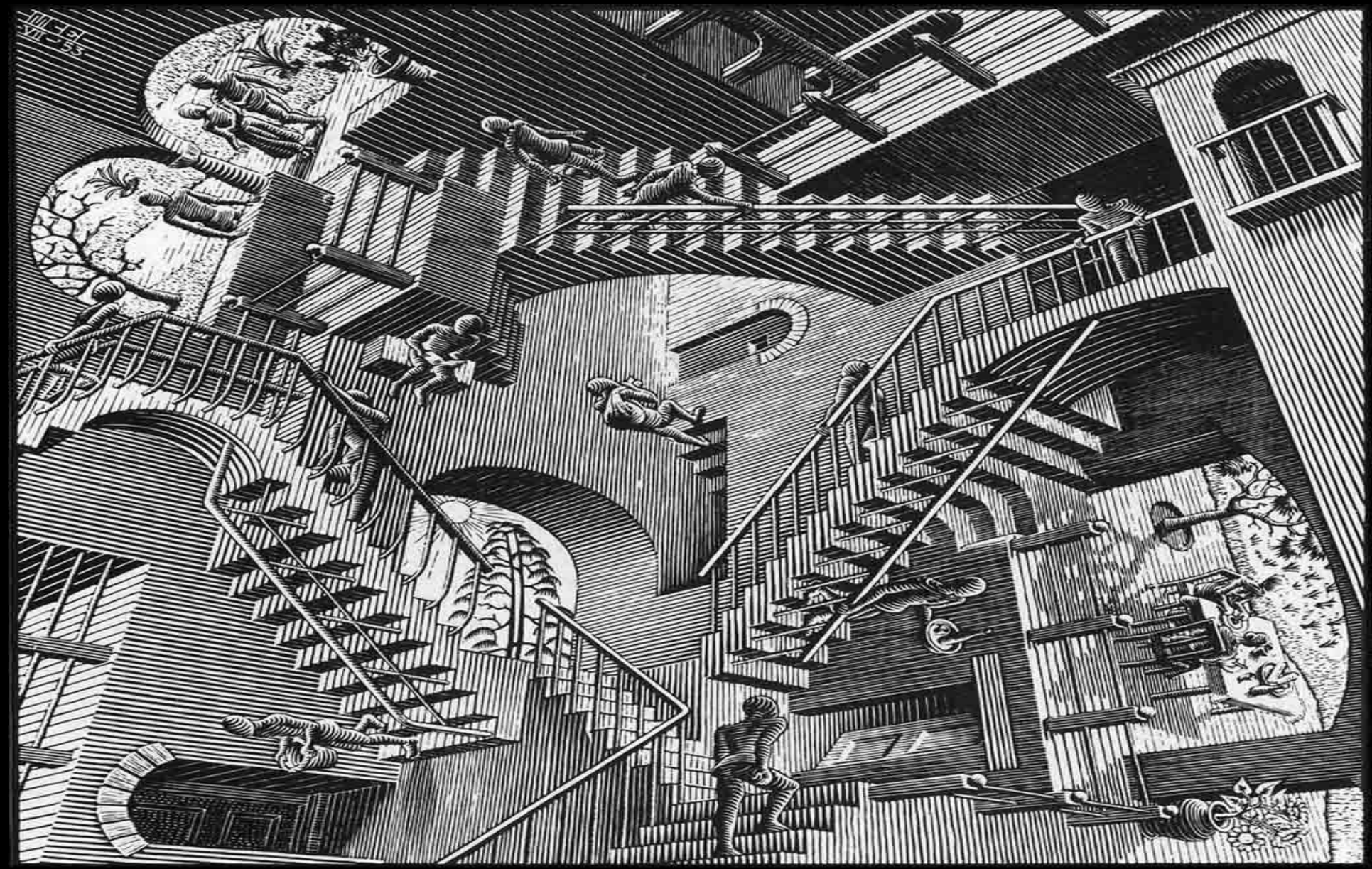
QI vs. Research

- QI is the art of implementation



- Research is the science of discovery

This may seem confusing



Definitions

- Research is “A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” – US Dept of Health and Human Services

- QI is "systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of health care in particular settings" *- The Hastings Center*

If you are asking
“is this efficacious”
then this is a research question

If you are asking
“how do we apply an effective intervention reliably in our system”
then this is a QI question

Human Subjects Research

- Must have both critical elements
  - Systematic investigation
    - Prospective study using data collection and analysis to answer a study question
      - Good QI should also include systematic assessment
      - QI projects think about data differently than research projects
  - Contribute to generalizable knowledge
    - Research seeks to draw general conclusions or inform policy
    - QI is unique to its milieu- Results not generalizable
- *Because QI is not Human Subjects Research it does not require IRB monitoring*

QI is not Human Subject Research

- Organizational QI is required by the J.C.
- Encouraged by Magnet
- Facilitated by Federal Law (Patient Safety and Quality Improvement Act of 2005)

- You engage in QI to improve the operational efficiency and effectiveness of an organization

Human Subjects Research and Quality Improvement Projects: What's the Difference? American Journal of Nursing. 2025 , Volume 125 (4), p 50 – 53

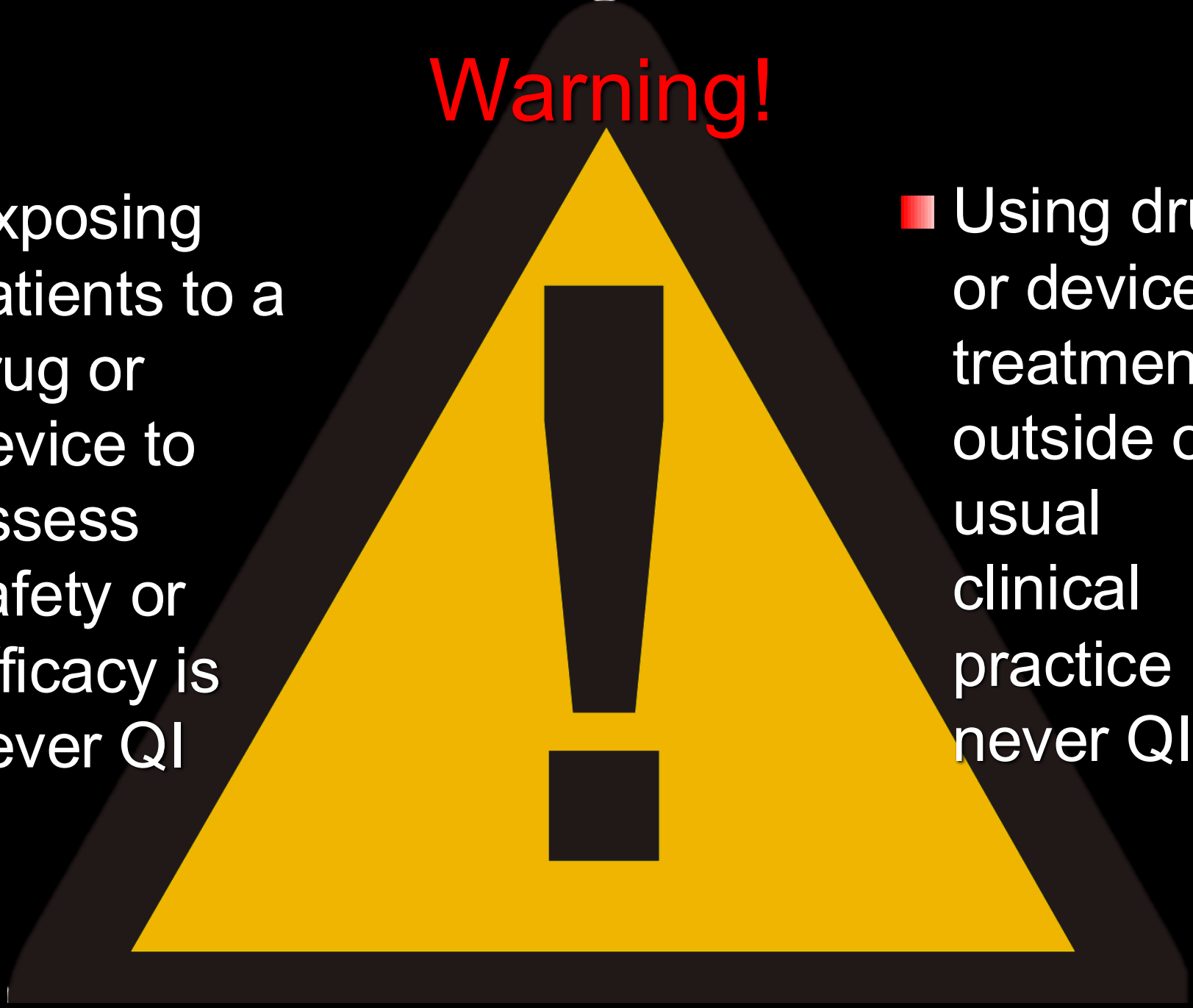
Example

- Dr. X is working on a QI project to improve post-operative pain scores.
- She has a theory that a new medication approved for chronic pain might also improve acute post-operative pain
- She wants to give all patients on the unit this drug for 3 days peri-op and do pre-post analysis to see if pain scores change.

QI or Research?

Warning!

- Exposing patients to a drug or device to assess safety or efficacy is never QI



- Using drug or device treatments outside of usual clinical practice is never QI.

Example

- Doctor Y wants to examine whether a bundle of evidence-based interventions could reduce central line catheter infections in his ICU.

QI or Research?

- What if he coordinates the same project state-wide across 103 ICUs in Michigan?

INTENT

- QI
  - Improve institution-specific care in accordance with known best practices

- Research
  - Create new generalizable knowledge

Example

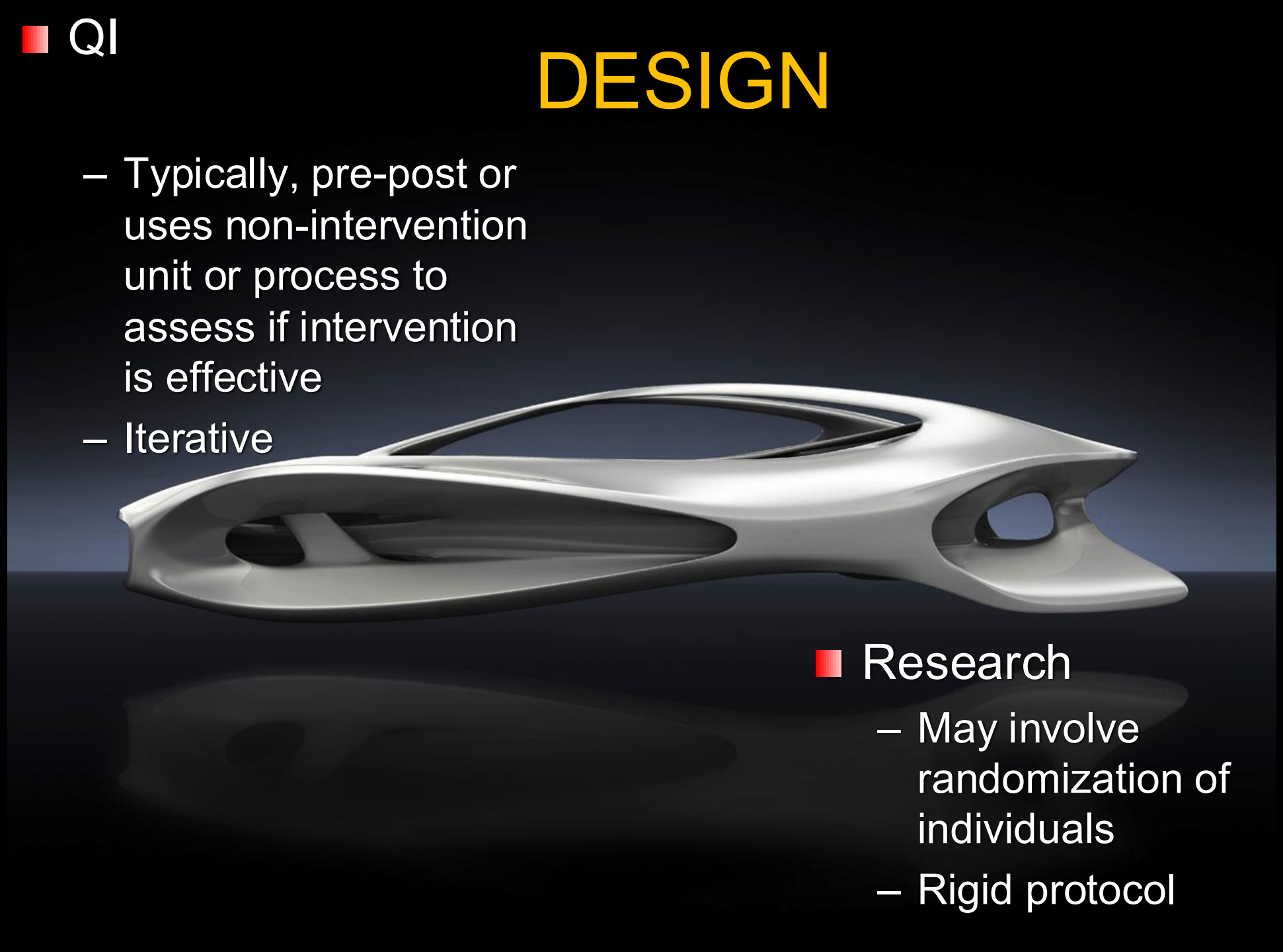
- Pharmacist Z wants to examine whether displaying the eGFR could reduce drug prescriptions inappropriate for renal function.
  - Potential to reduce adverse drug events which would improve quality

- The design would randomize patients by last digit of the MR# to have, or not have, this eGFR field displayed in the EMR

QI or Research?

DESIGN

- QI
  - Typically, pre-post or uses non-intervention unit or process to assess if intervention is effective
  - Iterative



- Research
  - May involve randomization of individuals
  - Rigid protocol

Population

- QI
  - Attempts to reach all patients in program

- Research
  - Subset of patients are studied to draw conclusions for larger population

Example

- The unit is engaged in a QI initiative on patient satisfaction. Nurse Q wants to do structured “voice of the patient” interviews with a sample of unit patients to explore the relationship of race concordance between patient and nurse on patient satisfaction.

QI or Research?

Effect

QI

-Benefits process, program or system
-May or may not benefit patients during QI roll-out
-Expected to benefit future patients

Research

-Expected delayed benefit by increasing knowledge
-Participants generally can not expect direct benefit

Example

- Dr. C has completed a QI study on improving time to treatment for stroke patients in the ED. It used value stream analysis to re-design the ED process to reduce time to treatment for a high-risk medication by omitting a time consuming, but rarely positive, safety doublecheck.

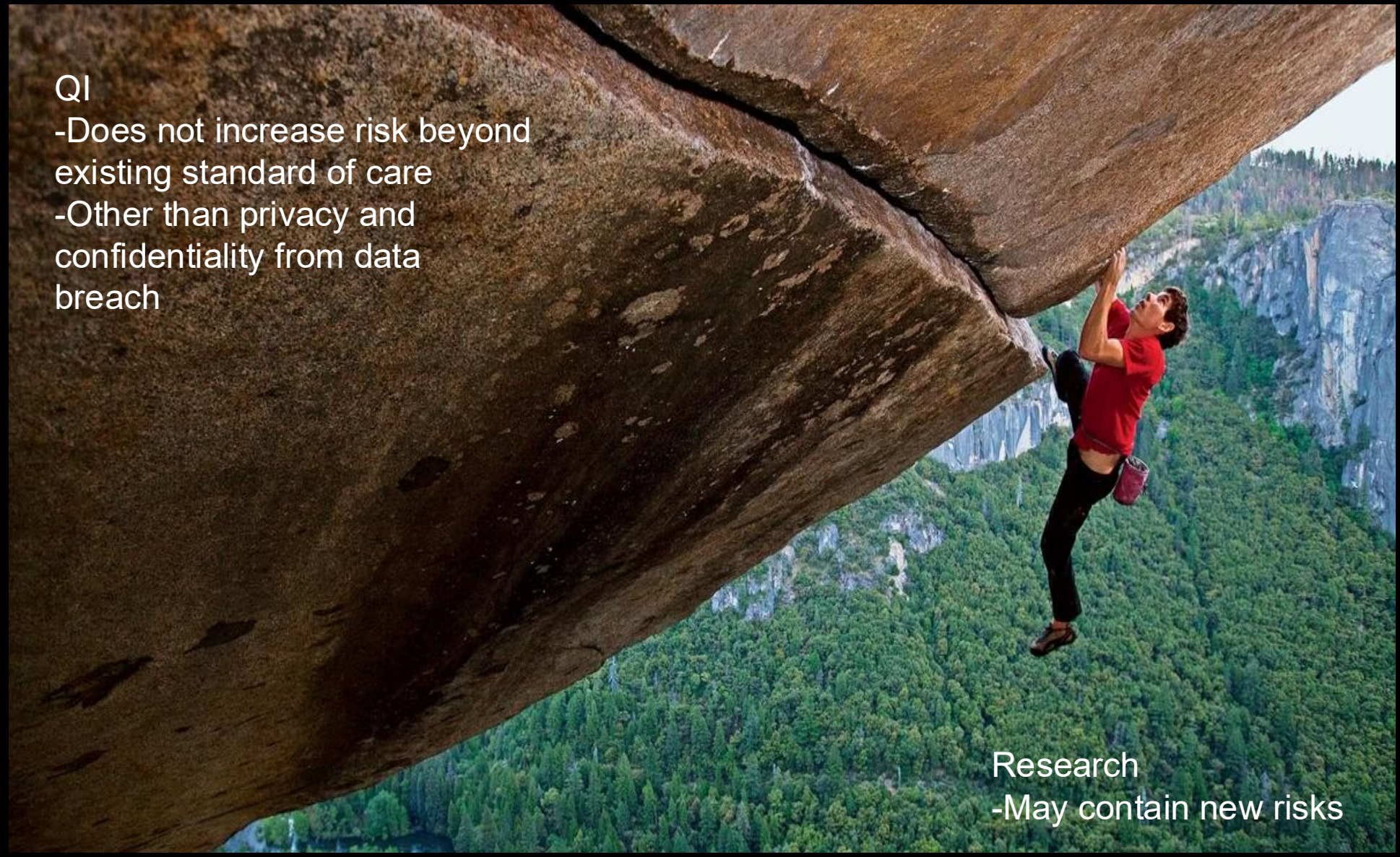
QI or Research?

Mandate

- QI
  - Organization leadership directs the initiation of this QI work

- Research
  - Investigator led
  - Hospital typically only has stake if it interferes with operations

Risk


QI
-Does not increase risk beyond existing standard of care
-Other than privacy and confidentiality from data breach
Research
-May contain new risks

- Does publication turn this into research?

QI is not Generalizable*

*You are required to state this in any publications

But Lessons from QI may be Transferable

Dissemination

- QI
  - Can be published but…
  - The point of publication is to share strategies and methods
  - Publication must have disclaimer

Be aware of organizational sensitivities when sharing results

- Research
  - The point of publication is to share results
  - Results reproducible
  - Expected to add to scientific knowledge
  - Generalizable

ORIGINAL RESEARCH & CONTRIBUTIONS

Geriatric Hip Fracture Care: Fixing a Fragmented System

Mary E Anderson, MD; Kelly McDevitt, RN, MS, ONC; Ethan Cumbler, MD; Heather Bennett, MS, MBA; Zachary Robison, MBA; Bryan Gomez; Jason W Stoneback, MD

Perm J 2017;21:16-104

E-pub: 04/14/2017

https://doi.org/10.7812/TPP/16-104

QI Publication from IHQSE Team

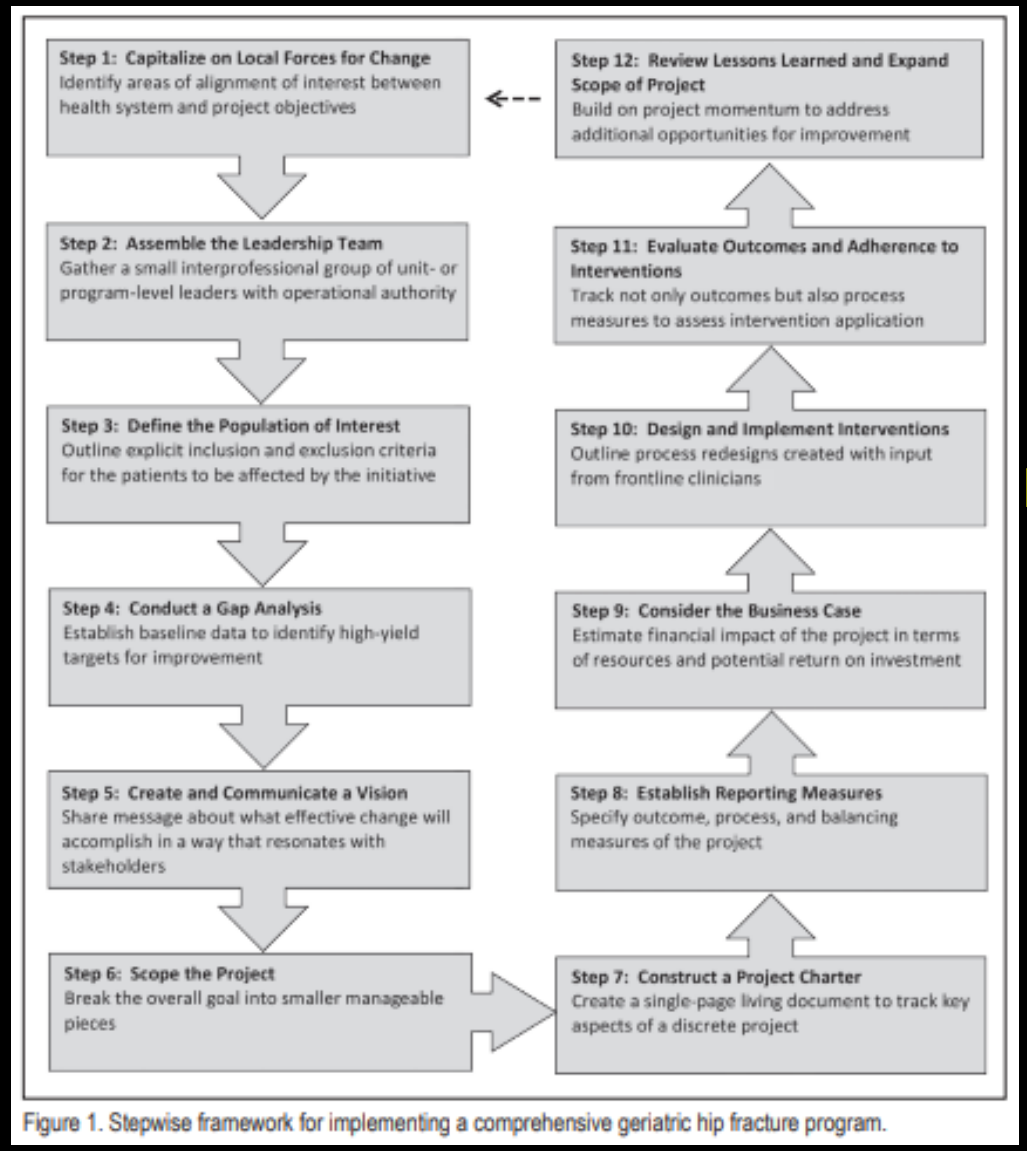


Figure 1. Stepwise framework for implementing a comprehensive geriatric hip fracture program.

Primarily Shares Methods

Application to Local Environment is Used as Example

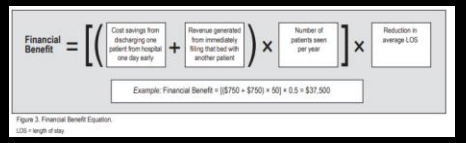


Figure 3. Financial Benefit Equation.
LOS = length of stay.

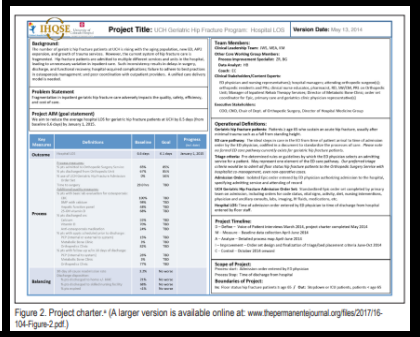


Figure 2. Project charter.* (A larger version is available online at: www.thepermanentejournal.org/files/2017/16-104-Figure-2.pdf.)

ORIGINAL RESEARCH & CONTRIBUTIONS

Fixing a Fragmented System: Impact of a Comprehensive Geriatric Hip Fracture Program on Long-Term Mortality

Mary Anderson Wallace, MD[1]; Andrew Hammes, MS[2]; Micol S Rothman, MD[3]; Anastasiya A Trizno[4]; Christine D Jones, MD, MS[1]; Ethan Cumbler, MD[1]; Kelly McDevitt, RN, MS, ONC[3]; Nichole E Carlson, PhD[2]; Jason W Stoneback, MD[4]

Perm J 2019;23:18.286

E-pub: 11/01/2019

https://doi.org/10.7812/TPP/18.286

Is this a QI publication… or is it Research?

ABSTRACT

Context: Geriatric hip fractures are increasingly common and confer substantial morbidity and mortality. Fragmentation in geriatric hip fracture care remains a barrier to improved outcomes.

Objective: To evaluate the impact of a comprehensive geriatric hip fracture program on long-term mortality.

Design: We conducted a retrospective cohort study of patients aged 65 years and older admitted to our academic medical center between January 1, 2012, and March 31, 2016 with an acute fragility hip fracture. Mortality data were obtained for in-state residents from the state public health department.

Main Outcome Measures: Mortality within 1 year of index admission and overall survival based on available follow-up data.

Results: We identified 243 index admissions during the study period, including 135 before and 108 after program implementation in October 2014. The postintervention cohort trended toward a lower unadjusted 1-year mortality rate compared with the preintervention cohort (15.7% vs 24.4%, p = 0.111), as well as lower adjusted mortality at 1 year (relative risk = 0.73, 95% confidence interval = 0.46-1.16, p = 0.18), although the differences were not statistically significant. The postintervention cohort had significantly higher overall survival than did the preintervention cohort (hazard ratio for death = 0.43, 95% confidence interval = 0.25-0.74, p = 0.002).

Conclusion: Fixing fragmentation in geriatric hip fracture care such as through an orthogeriatric model is essential to improving overall survival for this patient population.

Research can come out of QI Work

- Later asking a research question using data generated from QI work is permissible
- It would not generally address the same question that the QI project attempted to answer
- This would be human subjects research and would need to go through IRB review

University of Colorado
Denver | Anschutz Medical Campus
Colorado Multiple Institutional Review Board (COMIRB)

COMPARISON OF THE CHARACTERISTICS OF RESEARCH, QUALITY IMPROVEMENT, AND PROGRAM EVALUATION ACTIVITIES

Use the chart below if you have questions whether your project should be considered a Research, Quality Improvement activity, or Program Evaluation. If your project satisfies any of the conditions in the Research column, it should be submitted to COMIRB for review prior to implementation. COMIRB cannot provide retroactive approval after your research project commences. If you would like assistance in evaluating your project, contact COMIRB@ucdenver.edu. Additional information on what constitutes human subjects research is available here.

	RESEARCH	QUALITY IMPROVEMENT	PROGRAM EVALUATION	COMMENTS
FUNDING	Funded by a research grant, award or contract, or unfunded. If funded as research, all activities supported by the funding must be considered research.	Typically unfunded. May be funded by awards specifically for quality improvement; confirm IRB requirements, if any, with funder.	Often funded by a grant, award or contract for the purpose of developing or improving a service program. If the funding specifically requires evaluation of the program, the evaluation component may be considered research; confirm with funder. May also be unfunded.	
INTENT	To develop or contribute to generalizable knowledge.	To improve a specific business practice. In a hospital, this may include improving the quality and/or consistency of care in a specific unit or the entire hospital.	To evaluate the effectiveness of a specific program in meeting the intended goals of the program.	
DESIGN	The methodologies for conducting Research, Quality Improvement, and Program Evaluation projects are similar and are all systematic. Differential aspects are provided below as a guideline.			
	• Hypothesis driven • Statistically rigorous • May involve a placebo • May involve significant deviation from usual care or standard practice • Multi-site or single-site • May evaluate investigational drugs or devices	• Often designed as part of a cyclical program to implement, test and evaluate modest improvements in the delivery of care, or in some other business process, e.g., Continuous Quality Improvement (CQI), Plan-Do-Study-Act (PDSA) • May or may not be hypothesis driven • Usually involves modest improvements to usual care or standard practice • Rarely multi-site • Never evaluates investigational drugs or devices	• Designed to evaluate whether the program was successful, and/or whether it should continue • May be multisite if evaluating a single program at multiple sites	
PUBLICATION	Publication alone does not define an activity as research. Differential aspects are provided below as a guideline.			
	Clear intent to publish results as research (e.g., in scientific journal, research poster/abstract, or other research/scientific fora). Publishing is presumed as part of professional, scholarly expectations and obligations.	Project results will be disseminated internally (e.g., within the institution, department, or practice) soon after project completion to determine if the change improved delivery of care or another business practice, and to inform business decisions and operations. If methodology or results are interesting, results may be published. Publication must note that the project was carried out as QI, and did not meet the definition of research per DHHS regulations. The project may not be described as research.	Intent to publish or present results generally presumed at the outset of the project. Evaluation results will be provided to the program owner and stakeholders, and to the funder. Unless the evaluation was carried out as research with IRB approval, any publication should note that the project was carried out as Program Evaluation, and did not meet the definition of research per DHHS regulations. The project may not be described as research.	
MANDATE or ENDORSEMENT	Activities conducted to fulfill academic obligations to conduct and publish research, to complete a research project as graduation requirements, or as defined by a funding award.	Project is endorsed or mandated by the institution or clinic as part of CQI operations. Project may be mandated by educational requirements (e.g., requirement to design and complete a QI project). To document endorsement, COMIRB may ask for a letter of support from the head of the involved clinic or department, acknowledging the project as QI.	Activity endorsed or mandated by program owner and funder.	
IMPACT	Findings of the study are not expected to immediately and directly affect institutional or programmatic practice.	Findings of the project are expected to immediately and directly improve an institutional practice.	Findings of the evaluation are expected to immediately and directly demonstrate the success and/or shortcomings of the program.	
POPULATION	Carefully defined through individual inclusion and exclusion criteria in the research protocol. Participation is voluntary.	Generally includes all participants of the practice in which improvements are being implemented (e.g., all patients and providers in a specific practice). Participation may or may not be voluntary.	Generally includes all stakeholders of the program being evaluated (e.g., all program clients, staff, and leaders). Participation in the evaluation may be voluntary for some but mandatory for others.	
BENEFITS TO PARTICIPANTS	Primary benefit is from the scientific knowledge gained. Individual participants may or may not benefit directly. Benefits to others (e.g., future patients, society) is not generally immediate.	All participants are expected to benefit directly from the QI intervention.	Program clients are expected to benefit from participation in the program. Participants will not directly benefit from the evaluation of the program.	

This table may also be used as a tool to conduct and document a self-evaluation of the project. In that case, the project leader should indicate above where the project fits on each row. If any of the boxes in the research column are checked then the project must be submitted to COMIRB for review and approval. If the tool indicates that this is quality improvement (QI) or program evaluation (PE) only, complete the rest of this form, obtain any necessary signatures, and keep this in your project records.

Acknowledgment

I have appropriately used this tool to evaluation my project entitled: _____

By my signature below, I affirm that this project meets the definition of:

Circle the appropriate term: **Quality Improvement** **Program Evaluation**

I certify that I will conduct my project in compliance with all federal, state and local laws and policies. If during the course of the project it is amended in such a way as to meet the definition of human subject research under 45 CFR 46 or 21 CFR 56 then I understand that I must submit to COMIRB for review prior to continuing the project.

_____ _____ _____ _____
Signature of Project Leader Date Signature of Mentor *(if applicable)* Date

I have reviewed this project proposal and determine that meets the criteria for quality improvement or program evaluation as outlined above and is an appropriate project to be conducted within this Division/ Department/ School/.

_____ _____ _____
Signature of Appropriate Authority (*or their designee*) Title/Position Date

COMIRB has a handy tool for evaluation of whether your work represents QI or research

A key element is MANDATE and the form prompts you to get a signature from an appropriate authority IN ADVANCE to attest that your work is an organizational QI priority.

Some work may lie in the gray zone

There is such a thing as QI Research

If in doubt… Put it to the IRB to make a determination

If you would do it
even if it could not be published

Anywhere
Ever
No matter what…

Simply because it is the right thing to do

Then you just might be doing QI

Colorado Multiple Institutional Review Board (COMIRB)

Regulatory Compliance

Office of the Vice Chancellor for Research

General Information | Submission Guides | Forms | Guidance and Policies | Training | IRB Members | About COMIRB

Quality Improvement and Program Evaluation

Quality Improvement (QI) and Program Evaluation (PE) projects are not considered human subjects research and do not require approval by COMIRB. If you intend to conduct a QI or PE project, **utilize COMIRB's QI/PE decision tool** to confirm that your project is not in fact a research study.

The most crucial consideration in making this determination is the intent of the project: If you are simply evaluating the effectiveness of a specific program in meeting its intended goals, or if you are measuring a planned improvement to a specific clinic or business practice, you are not conducting human subjects research and do not need to submit to COMIRB for approval. On the other hand, if the purpose of the project is to generalize your findings so that they can be applied to other institutions or practices, the project would be considered a human subjects research study and would require COMIRB approval.

If you would like to discuss your project, contact COMIRB or attend COMIRB office hours.

Practical Application

- Utilize the COMIRB Document
  - “QA Program Evaluation/QI/Research Tool”
- Review your QI program using this guideline BEFORE starting.
  - Obtain signatures from Hospital/Division/Department/or School authority
- If you think your QI work might also be research….
  - Put it through the IRB first

Speaking of Research…

Now is about the right time to check your problem/potential intervention against the existing research on the topic

Search for the Best Evidence
Use PICOT Question to Identify Searchable Keywords

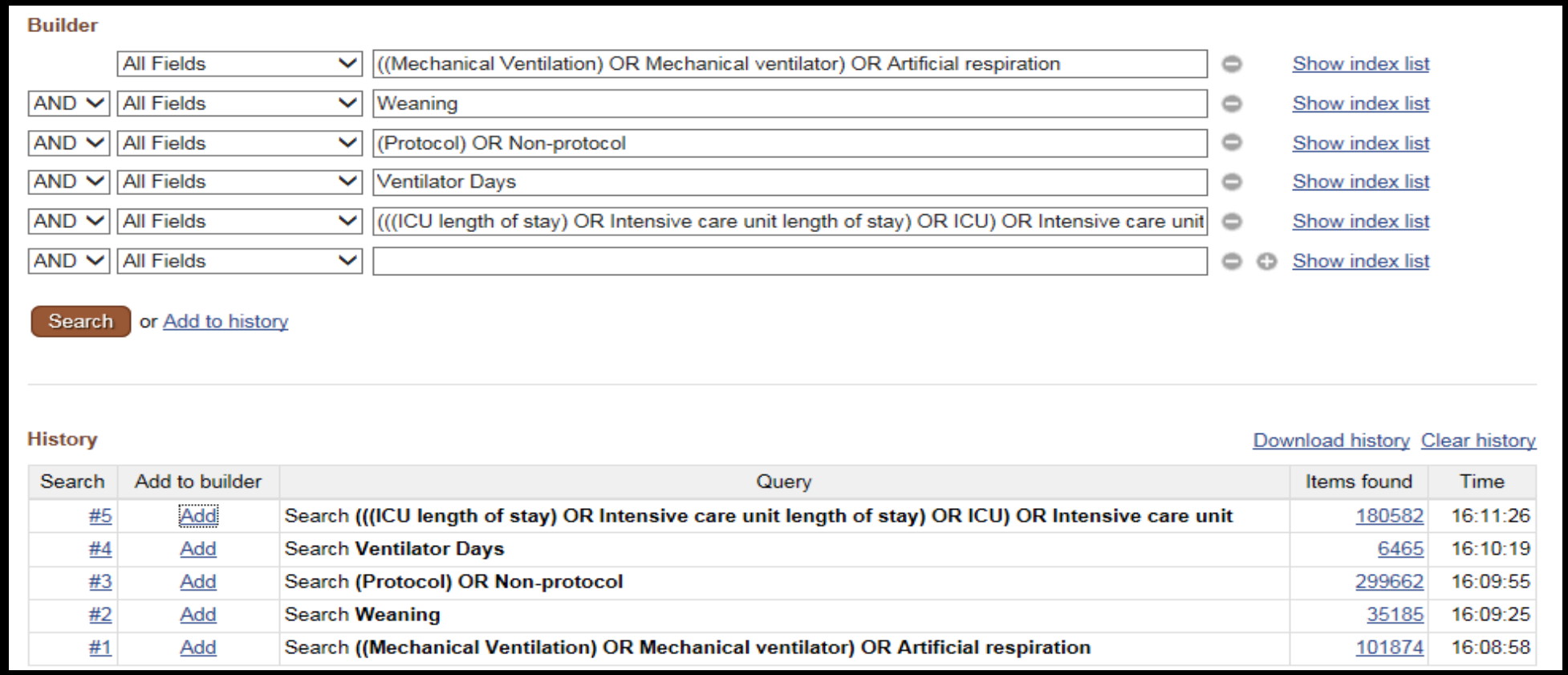
In mechanically ventilated patients (P), how does a weaning protocol (I) compared with no weaning protocol (C) affect ventilator days (O) during ICU length of stay (T)?

Population	Intervention		Comparison	Outcome	Time
Mechanical ventilation Mechanical ventilator Artificial respiration	Weaning	Protocol*	Non-protocol*	Ventilator Days	ICU length of stay Intensive care unit length of stay ICU Intensive care unit

Melnyk, Fineout-Overholt, Stilwell, Williamson, 2010

Credit for this slide to Ashley Anderson, BSN, RN, PhD Candidate

Construct a Basic Pub-Med Search using Search Terms



Builder

	All Fields	((Mechanical Ventilation) OR Mechanical ventilator) OR Artificial respiration	Show index list
AND	All Fields	Weaning	Show index list
AND	All Fields	(Protocol) OR Non-protocol	Show index list
AND	All Fields	Ventilator Days	Show index list
AND	All Fields	((((ICU length of stay) OR Intensive care unit length of stay) OR ICU) OR Intensive care unit	Show index list
AND	All Fields		Show index list

Search or Add to history

History

Download history Clear history

Search	Add to builder	Query	Items found	Time
#5	Add	Search **(((ICU length of stay) OR Intensive care unit length of stay) OR ICU) OR Intensive care unit**	180582	16:11:26
#4	Add	Search **Ventilator Days**	6465	16:10:19
#3	Add	Search **(Protocol) OR Non-protocol**	299662	16:09:55
#2	Add	Search **Weaning**	35185	16:09:25
#1	Add	Search **((Mechanical Ventilation) OR Mechanical ventilator) OR Artificial respiration**	101874	16:08:58

Reference librarians are awesome!

Add filters to help make list manageable

Article types
Clinical Trial
Review
Customize ...

Text availability
Abstract
Free full text
Full text

Publication dates clear
5 years
✓ **10 years**
Custom range...

Species clear
✓ **Humans**
Other Animals

Clear all

Show additional filters

Format: Summary **Sort by**: Best Match **Per page**: 20 **Send to**

Search results

Items: 1 to 20 of 87

<< First < Prev Page 1 of 5 Next > Last >>

Filters activated: published in the last 10 years, Humans. Clear all to show 101 items.

1. Implementation of an Early Extubation **Protocol** in Cardiac Surgical Patients Decreased **Ventilator** Time But Not **Intensive Care Unit** or Hospital **Length of Stay**.
Richey M, Mann A, He J, Daon E, Wirtz K, Dalton A, Flynn BC.
J Cardiothorac Vasc Anesth. 2018 Apr;32(2):739-744. doi: 10.1053/j.jvca.2017.11.007. Epub 2017 Nov 8.
PMID: 29229252
Similar articles

2. The Combination of SAT and SBT **Protocols** May Help Reduce the Incidence of **Ventilator**-Associated Pneumonia in the Burn **Intensive Care Unit**.
Lee YL, Sims KD, Butts CC, Frotan MA, Kahn S, Brevard SB, Simmons JD.
J Burn **Care** Res. 2017 Mar/Apr;38(2):e574-e579. doi: 10.1097/BCR.0000000000000451.
PMID: 27755248
Similar articles

3. Early Mobilization Reduces Duration of **Mechanical Ventilation** and **Intensive Care Unit Stay** in Patients With Acute Respiratory Failure.
Lai CC, Chou W, Chan KS, Cheng KC, Yuan KS, Chao CM, Chen CM.
Arch Phys Med Rehabil. 2017 May;98(5):931-939. doi: 10.1016/j.apmr.2016.11.007. Epub 2016 Dec 13.
PMID: 27979608
Similar articles

4. Efficacy of a high-observation **protocol** in major head and neck cancer surgery: A prospective study.
Barber B, Harris J, Shillington C, Rychlik S, Dort J, Meier M, Estey A, Elwi A, Wickson P, Buss M, Zygun D, Ansari K, Biron V, O'Connell D, Seikaly H.
Head Neck. 2017 Aug;39(8):1689-1695. doi: 10.1002/hed.24599. Epub 2017 Jun 20.
PMID: 28631342
Similar articles

5. Cough augmentation techniques for extubation or **weaning** critically ill patients from **mechanical ventilation**.
Rose L, Adhikari NK, Leasa D, Fergusson DA, McKim D.
Cochrane Database Syst Rev. 2017 Jan 11;1:CD011833. doi: 10.1002/14651858.CD011833.pub2. Review.
PMID: 28075489 **Free PMC Article**
Similar articles

Small Group Exercises

1. Take the problem that you are seeking to solve
   - Have you done a comprehensive literature search to determine if an existing best practice or guideline exists?
     - If not your in-class task is to design the search
   - Have you done a literature search to find the results of other groups that have attempted to tackle the same problem?
     - If not your in-class task is to design the search

Homework Assignment

Execute your search and review the best articles you identify

1. What do you plan to share outside the organization?
   - Describe in your group what aspect of your QI project would be of interest to others
   - If desired you can Mock-up a QI dissemination poster (or multiple)

Homework Assignment

Complete the Program Evaluation/QI/Research tool

Provide this along with your QI Project proposal or charter to the relevant hospital/Unit/Clinic authority

Have it signed

Appreciative Debrief

Share with the group 1 thing you found most intriguing from this session

Next Steps

Date Assigned	Assignment	Due Date
#1 – Aug. 19, 2025	• Develop group ground rules • Complete Leadership Defined Self-assessment	#3 – Sept. 9, 2025
#2 – Aug. 26, 2025	• No new assignments	
#3 – Sept. 9, 2025	• Complete voice of customer • Build stakeholder analysis • Develop a problem statement	#6 – Oct. 28, 2025
	• Complete a process map	#7 – Nov. 4, 2025
#4 – Sept. 23, 2025	• Reading: Kotter, John. *Leading Change: Why Transformation Efforts Fail*	#5 – Oct. 7, 2025
	• Meet with Dr. Moksha Patel	# 7 – Nov. 4, 2025
	• Draft business case	#8 – Nov. 18, 2025
	• Complete affinity diagram	#9 – Dec. 9, 2025
#5 – Oct. 7, 2025	• Complete Myers-Briggs Assessment	Friday, Oct. 24, 2025
	• Complete literature review • Complete Program Evaluation/QI/Research Tool	#8 – Nov. 18, 2025
#6 – Oct. 28, 2025	• Well-being Analysis • Finalize Sense of Urgency • Develop/utilize current vision tying to project	#9 – Dec. 9, 2025
#7 – Nov. 4, 2025	• Complete data collection plan	#10 - Dec. 16, 2025
#8 – Nov. 18, 2025	No new assignments	
#9 – Dec. 9, 2025	• Health Equity Analysis	#11 – Jan. 13, 2026
	• Complete Design Thinking Exercise • Complete Positive Deviance Exercise • Develop list of potential interventions	#12 – Jan. 27, 2026
#10 – Dec. 16, 2025	• Complete aim statement • Finalize guiding coalition	#11 – Jan. 13, 2026
	• Finalize logo	#13 – Feb. 10, 2026
#11 – Jan. 13, 2026	• Draft mid-year report out	#12 – Jan. 27, 2026
	• Create and implement a communication plan	#14 – Feb. 24, 2026

Assignments

Due October 24

- **Complete Myers-Briggs Assessment**

Due October 28:

- **Voice of the Customer**
    - Summarize key findings / themes; do not need to include all surveys/interviews
- **Stakeholder Analysis**
- **Problem Statement**

It is okay if these are not all finalized! We realize you may still be meeting with stakeholders and finalizing your problem statement.

Evaluation

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