QI in Academics

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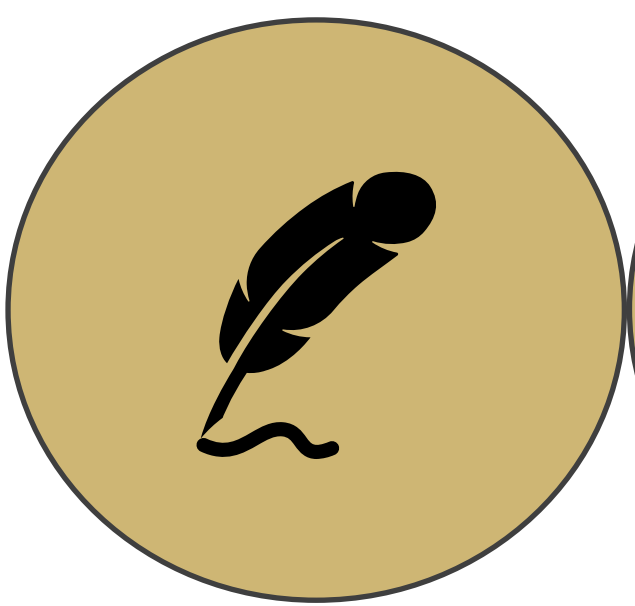
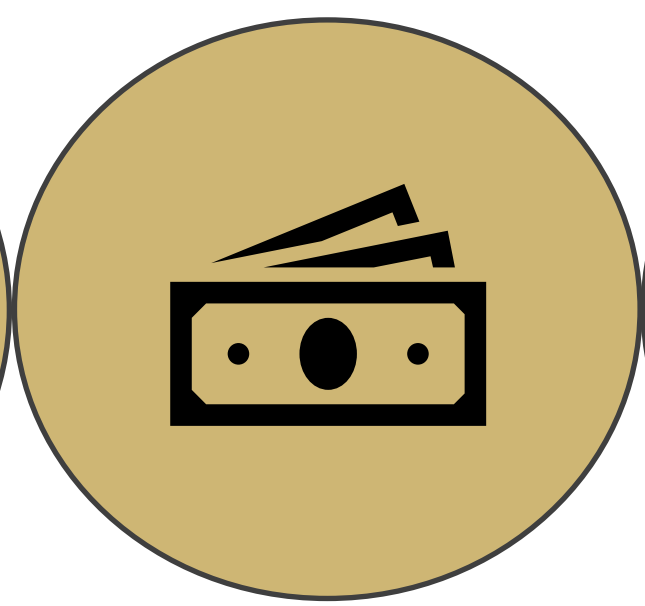
Quality and Safety Academy
UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

AGENDA

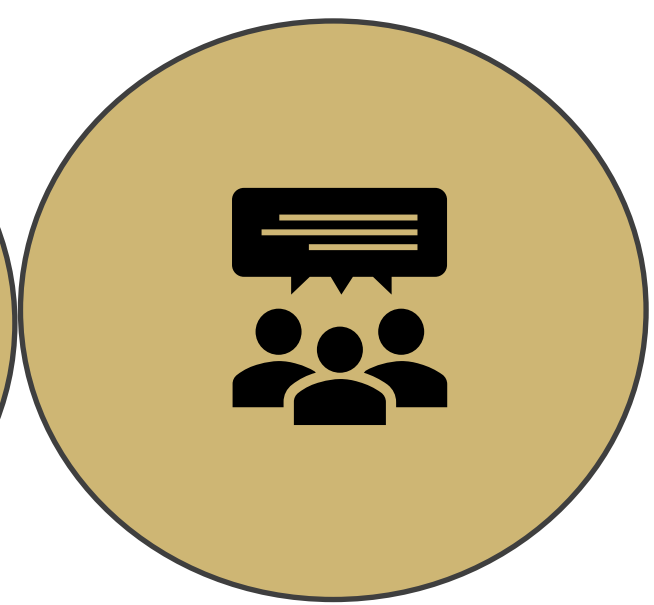


Writing a QI Manuscript



QI Grants

QI and the IRB



Faculty Q&A


zoom

Quality and Safety Academy
UNIVERSITY OF COLORADO **ANSCHUTZ MEDICAL CAMPUS**

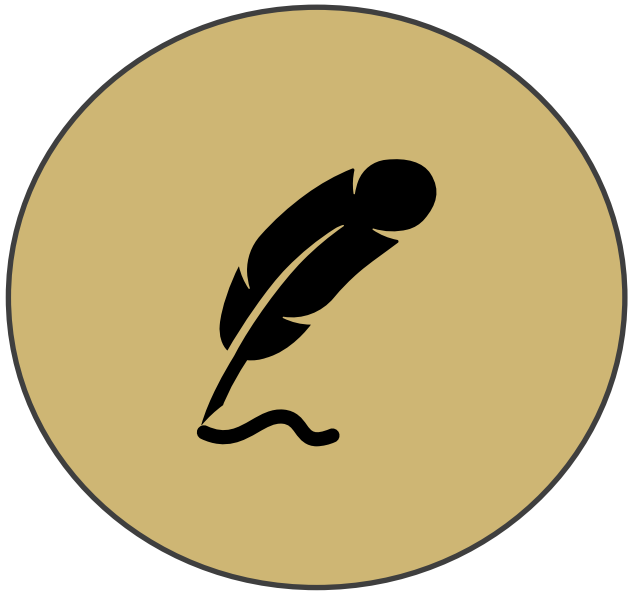
Fellows Series

Foundations of Patient Safety

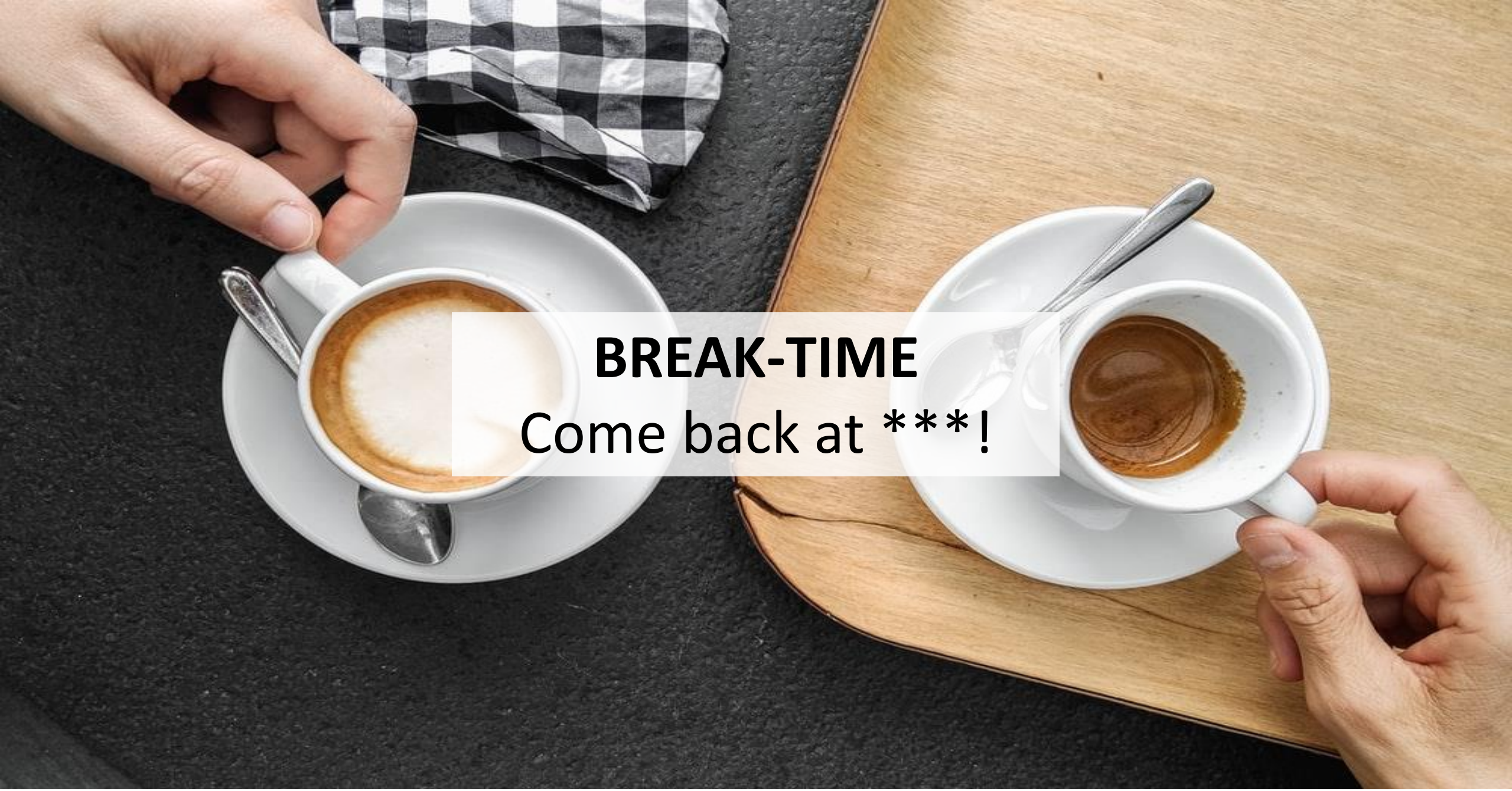
QI Basics for Project Work + Change Management

Making QI Academic

No Disclosures



Writing a QI Manuscript


BREAK-TIME
Come back at ***!

QI Grants

National

Hint: “Innovation”

Agency for Healthcare Research and Quality

Improving quality of diagnostic processes
Call for proposals open Jan 2021

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

QUALITY IS OUR IMAGE

American College of Surgeons

Inspiring Quality: Highest Standards, Better Outcomes

Local

uchealth

UCH CEPS Small Grant Program

Children's Hospital Colorado

CHCO COEPS Small Grant Program

1. Spell out the need for the grant = WHY
2. Sell yourself/your team = WHO
3. Eliminate jargon from your grant application = SIMPLE
4. Be a good storyteller = STORY
5. Ensure your solutions/interventions are clear AND feasible = WHAT
6. Ensure your budget makes sense = DUH, but really.
7. Recruit an objective reviewer.
8. Pay close attention to details.

Adapted from: firespring.com/solutions-for-nonprofits/12-quick-tips-for-better-grant-writing

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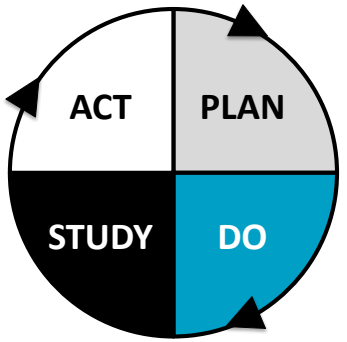

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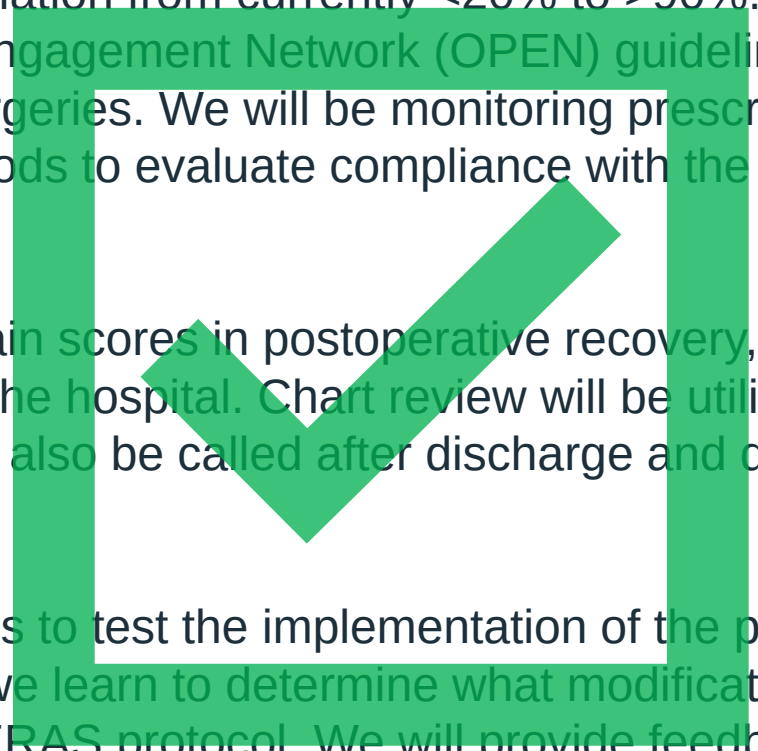
Project Aim: Clearly state the project's overarching goal(s) and the specific objectives for accomplishing these goals. An aim statement should address HOW MUCH improvement (e.g.,baseline measure and targets) and by WHEN (e.g. w/in 12 months).

GRANT PROPOSAL #1

The aim of this project is to implement ERAS protocols for patients undergoing colon surgery at the University of Colorado Anschutz Medical Campus within 12 months. Our goals are to increase the use of multimodal pain management in this patient population from currently <20% to >90%. Furthermore, we aim to improve compliance with Opioid Prescribing Engagement Network (OPEN) guidelines to >90% from our current compliance rates of 50% for colon surgeries. We will be monitoring prescribed analgesics in the preoperative, intraoperative, and postoperative periods to evaluate compliance with the ERAS protocols and with OPEN guidelines for opioid prescriptions.

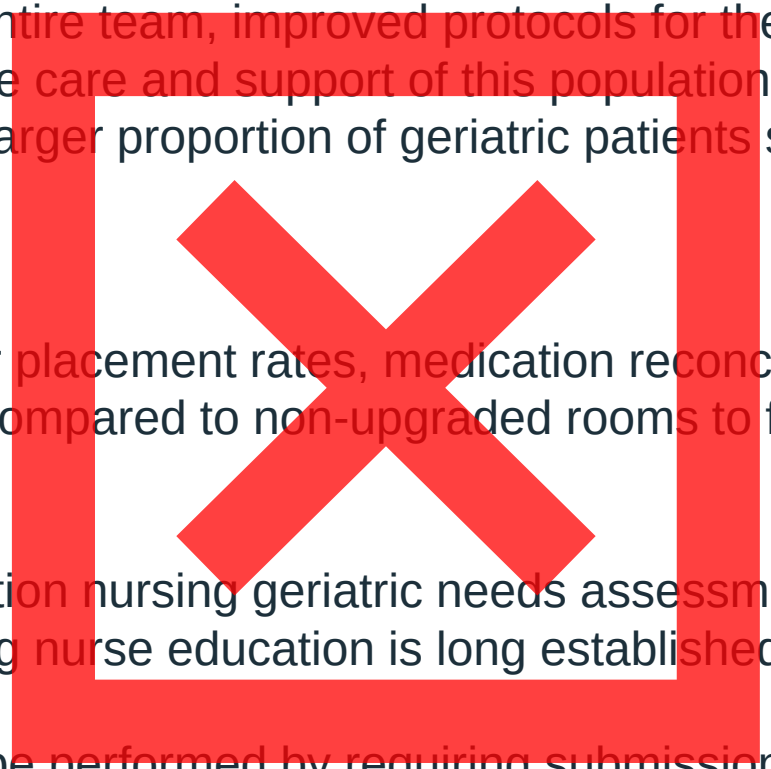


We will also be evaluating patients' pain scores in postoperative recovery, throughout inpatient stay, and at 48 hours after discharge from the hospital. Chart review will be utilized to evaluate pain scores while patients are hospitalized. Patients will also be called after discharge and questioned about pain score and medication use.

We will complete multiple PDSA cycles to test the implementation of the pathways, evaluate compliance with pathway components, and use what we learn to determine what modifications should be made to the pathways and the process to further refine the ERAS protocol. We will provide feedback to the multi-disciplinary team at the study step of each PDSA cycle and will generate a monthly report of prescribing practices which will be available to providers and will be presented monthly at the Colon Surgery Research Meeting.

GRANT PROPOSAL #2

The primary goal is to improve the quality of care given to geriatric patients treated at UCH. We seek to expand the knowledge base of our entire team, improved protocols for the treatment of elderly patients, and a physical environment optimized to the care and support of this population. In concert, we will launch a geriatric consult our unit, allowing a larger proportion of geriatric patients seen to receive their care in an outpatient setting.



We will also track falls, foley catheter placement rates, medication reconciliation rate, and restraint use. Rates in upgraded geriatric rooms can be compared to non-upgraded rooms to further assess the impact of this intervention.

We will perform pre- and post-education nursing geriatric needs assessment to assess the impact of the education. This process for assessing nurse education is long established in our department.

Tracking of physician education will be performed by requiring submission of CME certificates.

GRANT PROPOSAL #3

The goal of this project moving forward is to continue to collect data, perform statistical analysis of our data set and create a predictive model that will further aid in disposition decision making. Our early data review indicates that patients with longer surgery time and higher intraoperative transfusion requirements are more likely to require an ICU admission.

Additionally, members of our team hypothesize that intraoperative coagulation scores may also predict ICU admission. We need further statistical analysis by a statistician to evaluate our hypotheses. Once we have statistical analysis and we have created a predictive model, we will need time to test the model. In the last 16 months, we have decreased ICU admissions from 58% (ICU stay of more than 3 days 41%, ICU stay 2 days or less 17%) to 36% (ICU stay of more than 3 days 23%, ICU stay 2 days or less 13%).

Our next step will be to work with a statistician to determine the key clinical factors that predict the need for an ICU admission post operatively.

Once we have identified these factors, we will create a predictive model and present that model to our for input. We will work together to agree on a predictive model and implement that model. With the creation of a predictive model, we aim to decrease the ICU stays of 2 days or less to less than 10% post-op. Once implemented, we will need at least 9-12 months of data collection with the predictive model to have an adequate data set to compare to our current baseline data.

QI and the IRB

Learning Objectives

1

Describe differences and similarities between QI vs. Research

2

Recognize when an IRB application should be submitted for a project

3

Identify institutional specific considerations for QI

"QI is an integral part of good clinical practice and is designed to bring about ***immediate improvements*** in health care in ***local settings***.

In contrast... Human subjects research is not a necessary, integral element of good clinical practice… human subjects research aims to **generate new, generalizable**, and **enduring knowledge about health**."

Grady, C. *Ann Intern Med* 2007

	Human Subjects Research (HSR)	Quality Improvement
Purpose	Designed to contribute to generalizable knowledge	Designed to implement knowledge, assess/improve process or program within an institution compared to established standards
Design		
Benefits		
Risks		
Participant Obligation		
Goal		
Analysis		
Dissemination of results		
IRB		

- Is this efficacious? Research
- How can I apply this effective intervention consistently? QI
- Are patients randomized into intervention groups? Research…?
- Is there a new treatment? Research
- Is there deliberately delayed feedback of data in order to avoid biased interpretation of data? Research

- Does the project involve individuals with no ongoing commitment to the local institution? Research

- Is there greater than minimal risk to the patient as a result of the intervention? Research

There is overlap between the two

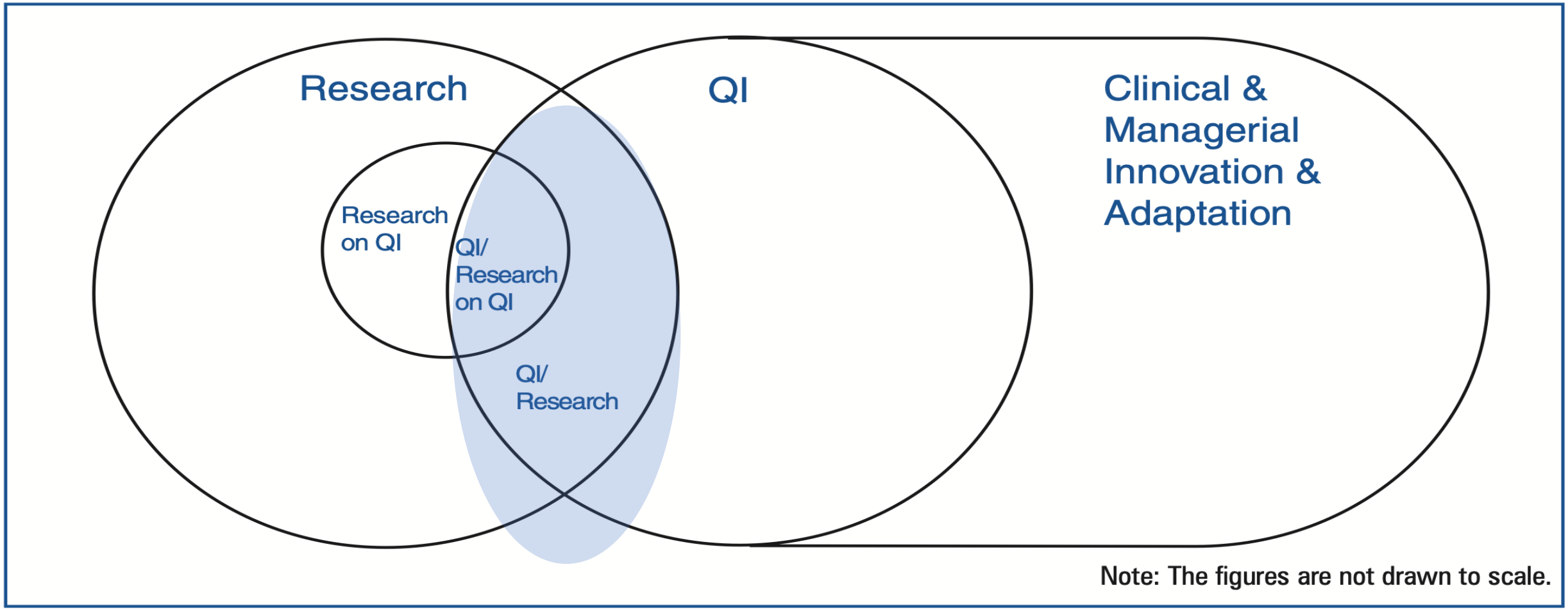


Figure 1.

What does “generalizable” mean?

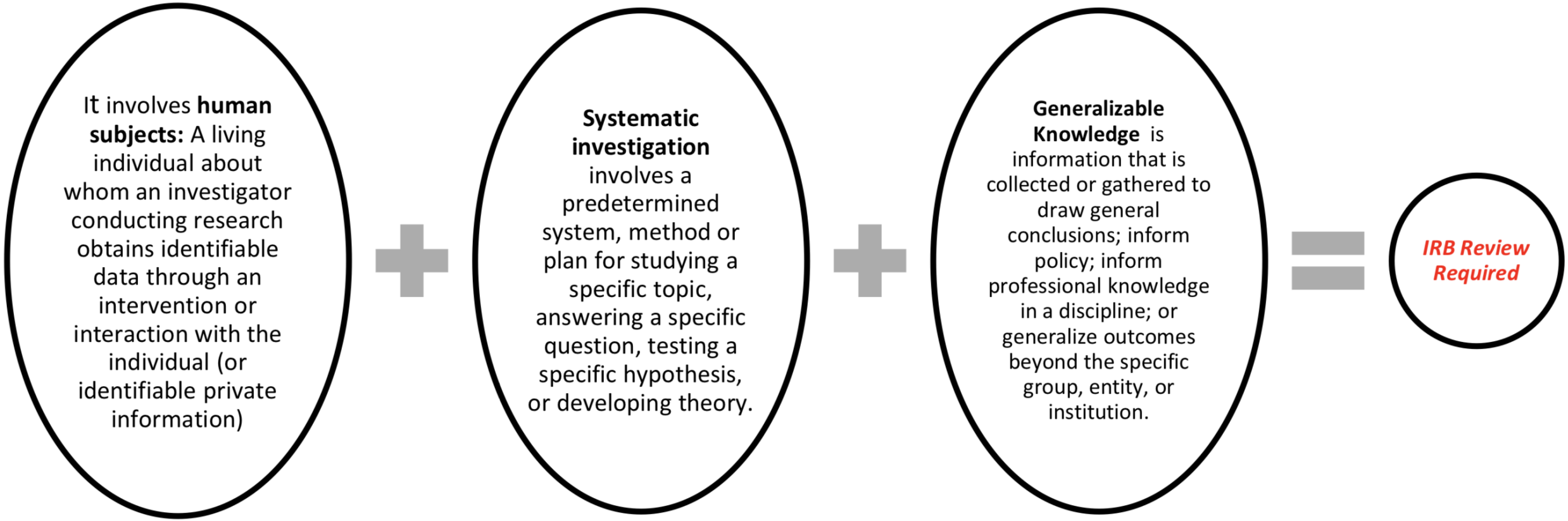
Sometimes the intent is to focus on a local institution, but the knowledge generated can be applied elsewhere (Hastings Report)

- If QI project designed scoped to be narrow
  - Not research

- If QI project is designed to improve local care and produce knowledge that could be used other places
  - QI + Research

Projects considered “research” **MUST** be approved by an IRB

Am I conducting human subjects research?



If an activity meets the definition of human subject research under 45 CFR 46.102(d), then HHS regulations apply, and IRB review is required.

Colorado Multiple Institutional Review Board **(COMIRB)**

"To protect human research participants' rights and welfare and to facilitate ethical research."

University of Colorado Anschutz Medical Campus

Children's Hospital Colorado

Department of Veterans Affairs

uchealth

DENVER HEALTH est. 1860 FOR LIFE'S JOURNEY

Do I need an IRB in order to publish QI?

Office of Human Research Protections (OHRP) response:

"Planning to publish an account of a quality improvement project does not necessarily mean that the project fits the definition of research; people seek to publish descriptions of non-research activities for a variety of reasons, if they believe others may be interested in learning about those activities. Conversely, a quality improvement project may involve research even if there is no intent to publish the results."

OHRP QI FAQ's http://www.hhs.gov/ohrp/policy/faq/quality-improvement-activities/index.html

Categories of submission responses from IRB

- Not HSR: The QI project is NOT research
  - IRB submission only for formal determination from IRB that it is not research
  - Subsequent publication should clearly state that it is QI and not research
- Not HSR: The QI project IS research, but no human subjects are involved
- Exempt: The QI project is research, but meets one of the exempt criteria under the regulations
- Non-exempt: Expedited vs. Full Board. The QI project IS research and does not meet exempt or not HSR criteria

*This study was approved by the Human Subjects Institutional Review Board (HSIRB) of the University **** and was exempt from patient consent. The work was deemed a* ***quality improvement project and NOT a study on human subjects.***

The study met the criteria for exemption from ethics review

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

Case 1:

In critically ill adult patients, early mobilization with physical therapy has been shown to reduce delirium, hospital length of stay and in one study mortality.

- AN plans to study the effect of a standing ICU PT order with the goal to increase the proportion of patients seen by physical therapy on HD#1 from 30% to 60% over the next 6 months.

- She additionally plans to track duration of mechanical ventilation, hospital length of stay, and mortality for these patients.

- Additionally, as it is more difficulty for patients with delirium to work with PT, she intends to treat half of the patients with Haldol and assess whether those patients are able to work with PT more frequently.

Case 2:

There are no standardized and validated thromboprophylaxis risk tool established in the pediatric population. Despite this, local venous thromboembolism (VTE) prophylaxis guidelines exist at most major pediatric tertiary care centers

- JL performs an analysis and finds that the hospital VTE prophylaxis recommendations are only followed 55% of the time. She assembles a team to increase adherence to the recommendations to 80% in the next 4 months

- During this time, a 6 yo patient has an intracranial bleed while on recommended enoxaparin prophylaxis. JL would like to revamp the current prophylaxis guidelines to only recommend prophylaxis in children $\geq$ 12 yo

- She is not sure if this will increase the rate of VTE in the < 12 yo age group. To study this, she develops a fixed protocol with the goal to study local VTE rates in age groups before and after this change. She now intends to publish the results since the pediatric VTE body of literature is lacking.

Other QI regulating agencies on campus

Denver Health	Quality Improvement Review Committee (QuIRC)
University	COMIRB No additional procedures needed
VA	COMIRB Contact Dr. Genet D'Arcy (Barbara.D'Arcy@va.gov) for QI project approval Dr. Tyler Miller (Tyler.Miller@CUAnschutz.edu), Director of QI for Hospital Medicine available for general guidance
Children's Colorado	Organizational Research Risk and Quality Improvement Panel (ORRQIP)

When in doubt, contact the IRB

Faculty Q&A