

BIOSTATISTICS RESIDENT WEBINAR #1: INTRODUCTION TO BIOSTATISTICS FOR CLINICAL SETTINGS



Rady
Children's
Health

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2025



Requirements vs. Know-how

- Series of webinars to address:
 - Requirements for exams
 - Actual research and professional development
- Embed gaining expertise on requirements into research/QI experience
- Both QI and research are feasible; CHOC provides opportunities
- Train up as a Young Investigator
- Learn how to identify good QI questions
- Patient/family first
- Collaborate with a Biostatistician



Revised ACGME REQUIREMENTS-patient safety and health care quality

-Analyze practice using QI methods

-Implement changes with goals of improvement

-Patient Safety

- reporting*
- contribute to root cause analysis*
- risk reduction efforts*

-Quality Improvement- use data to

- improve systems of care*
- reduce disparities*
- improve patient outcomes*
- participate in new initiatives*
- professional development efforts*

Virtual “one-month” rotation –Biostatistics for QI

- See QI as an opportunity to improve efficiency and effectiveness in a clinical setting
- Gain an understanding of QI Science
- Learn how to ask the right question –best questions derive directly from clinical experience
- Draft a short QI protocol to guide your effort
 - A strong protocol easily translates into strong study and a strong manuscript
 - Avoid a protocol to collect data.
- Master the literature on the general topic area
- Design data collection and data analysis strategy
- Write up and present results
-

Section 1:Improvement Science



Tools

- SMART aims (Specific, Measurable, Actionable, Relevant, Time-based)
- Collaborate as a team (Be inclusive)
- PDSA-plan, do, study, act
- Process control tools
- Structured experiments
- Natural experiments
- Implementation Science



WHAT: SMART AIMS

- Reduce OR time (Laparoscopy)
- Reduce time-to-discharge from NICU (e.g. PAL)
- Reduce hospital infection rate

HOW:

Utilization of a new procedure

WHO: CHOC pediatric surgeons

WHEN/UNTIL: January, 2026 (after surgeons are trained to June 2026 (time to perfect procedure))

WATCH: adverse events (complication rate)

ASSESS: 6 months prior (old procedure) compared to 6 months after (new procedure)

Experiments-

Structured Example: Dr. Golden's medical error initiative

- Reduce medical errors through improved training
- Design an experiment that tests pedagogies to ensure consistency across interpretation of medical error

Natural examples:

- Recent change in ICU procedure to reduce time-to-discharge
- Use of a new instrument to improve diagnosis
- Change patient pain monitoring guidelines

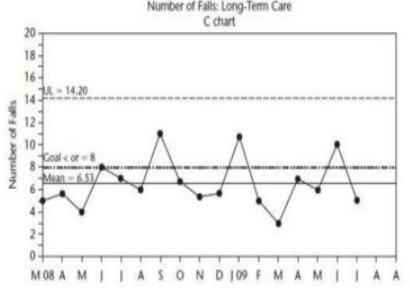
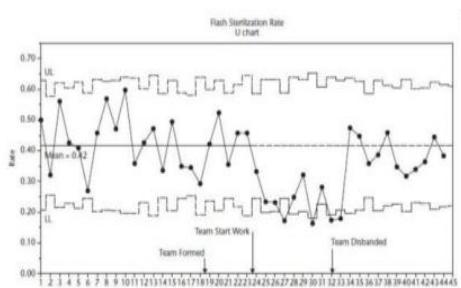
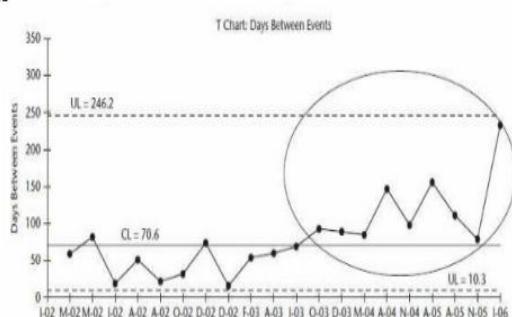
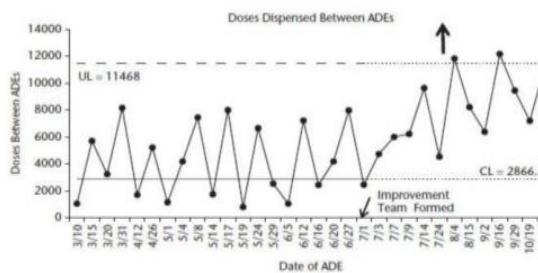
At CHOC/Rady

- Current approach is “control process”
 - Collect data pre/post to hit a benchmark
- Transitioning to include structured and natural experiments



Control Process- looking at process change over time

Resource:
Control-Chart-Overview.pdf

<p>Count Data (How many defects?)</p> <p>C Charts: displays the count of event/defect per a constant sample size</p> <p>Note: Each item can have more than one event/defect (1 staff member-multiple needlesticks, 1 patient - multiple falls)</p> <p>Examples: Number of needlesticks per month Number patient falls per nursing unit Number of missing handoffs per shift Number of coding errors per each group of 10 patient charts</p>	<p>C Charts</p> 	<p>U Charts</p> <p>U Charts: displays the count of events/defects per a varying sample size.</p> <p>Note: Each item can have more than one defect (1 medication order can have multiple errors, 1 surgical tray can have multiple missing instruments)</p> <p>Examples: Number of Errors/medication orders Number of Missing Instruments/surgical trays Number of employee accidents/hours worked Number of complaints/admissions Number of CLABSI/patient days</p> 
<p>Rare Events (How Often)</p> <p>T Chart: Time Between Rare Events</p> <p>T-Charts counts the time between rare events</p> <p>Examples: Days between wrong site surgeries Days between cardiac arrests Days between patient falls</p> 	<p>G Chart: Units Between Rare Events</p> <p>G-Charts counts the units between rare events</p> <p>Examples: Number of surgeries between wrong site surgeries Number of dispensed doses between fatal medication errors Number of admissions between patient falls</p> 	

Experiments-

Structured Example: Dr. Golden's medical error initiative

- Reduce medical errors through improved training
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Natural examples:

- Recent change in ICU procedure to reduce time-to-transfer-to-floor
- Use of a new instrument to improve diagnosis
- Change patient pain monitoring guidelines

Implementation Science- Complementary to QI

- QI
 - Practice-oriented
 - Problem-driven
 - local, specific problems
 - rapid, iterative changes
- Implementation Science
 - Adopt, adapt and scale proven interventions
 - Integrate research findings into routine practice
 - Change policy for generalizable impact.
 - intervention-driven
 - aims to generate knowledge about how to successfully implement innovations in diverse contexts.

Example: TOAST

TOAST (Targeting **O**besity in **A**dole**S**cents with **T**echnology).

Purpose: To develop and deploy an evidence-based intervention incorporating a novel digital mobile mental health application, CBT-TO (Cognitive Behavioral Therapy, Teen Obesity), and assess both the implementation strategy and the effectiveness of the intervention in a sequential platform trial.

Impact: Leverages advances in technology to scale a public health intervention in teen obesity:

Section2:Introducing Biostats for QI and Research



Biostats Consulting and Mentoring for Young Investigators

- Provide general research/QI education
- Assist you with the tools that you need
- Offer guidance on your QI project
- Support your development as an investigator
- Collaborate on design, data collection, analysis and publication



PAWS/Directory/Research/Research Consults and Service Requests/Biostatistical Consulting

Training Up to Key Skills

Phase 1-Conceptualize

Collaboration

Asking the right question

Review research literature

Select the right research design

Phase 2 –Collect/Analyze

Supervise data collection/collection

Guide analysis of data for publication

Phase 3-Draft

Produce results

Build tables

Build figures

Draft deliverable

Experiential Learning Goals: Be able to....

- **Provide leadership on the project**
- **Be an effective collaborator (communication, problem-solving)**
- **Draft and IRB (with support and collaboration)**
- **Identify available data**
- **Operationalize your central hypothesis**
- **Identify appropriate methods**
- **Plan/supervise data collection**
- **Interpret results**
- **Draft up results**

Is your question QI or Research



QI provides an *opportunity* to learn about or improve a process, a patient outcome, a program or clinical practice. QI is designed to promote improvements *in situ*.

Research, by contrast, must meet ethical and scientific standards; it is designed to protect the safety of patients, to generalize beyond the institution and make a contribution to more efficient and effective clinical practice.



Where Does Your Project Fit?

If all three statements go one-way then path is clear. In doubt? Call ORC.



Is It Research?

Submit To ORC/IRB

For Review

Intent
Intent of project is the contribution of generalizable knowledge of scientific and medical communities

And

Design & Scope
Project is designed as a systematic investigation (e.g. defined research plan/protocol) with results meant to apply to institutions outside CHOC

And

Publication
Specific Intent to publish project results in scientific journals for purposes of contributing generalizable knowledge

Is It QA/QI?

Intent
Intent of project is to learn about, or improve, a CHOC process, program, or clinical practice as part of the CHOC QA program

And

Design & Scope
Project may or may not be designed as a systematic investigation, with results meant to be directly applicable to a CHOC program, process, or clinical practice

And

Publication
No intent to publish, or presentation of project described as QA/QI attributed to the CHOC Research program (e.g. not described as 'research')

No Submission to ORC/IRB Required

Self Determination

Study and Clinical teams can self-assess and determine on their own if their project qualifies as QA/QI. Only if the study/clinical team is in doubt, or needs a formal letter of determination from ORC, do QA/QI style projects need to be submitted to ORC for review and a formal determination.

How to ask a good QI question

CHOC CHILDREN'S RESEARCH INSTITUTE | INFO SHEET NO. 3 (12/09/21)

How to find (or frame) a clinical research question

As attractive as it is to go fishing in our electronic health records on patient diagnoses and conditions, clinical research does not begin with data collection; it always begins with a question. This info sheet describes how to craft a good clinical research question. We cover the three critical elements of a good research question: 1) the question has not been fully addressed in the research literature; 2) the question can be answered by empirical data; and 3) the answer will affect how we treat our patients.

Drill Down From a Topic to a Research Question

	EXAMPLE	SOURCES
Topic	Pain management via gabapentin, fentanyl, or cryoanalgesia?	-Anecdotal clinical experience -Hot topics at conferences
Broad Question	Does gabapentin assist with managing surgical pain?	-Articles -Abstracts -Posters
Specific Question	What is the role of gabapentin as a pre-surgery treatment?	Journal articles

How do I find a good topic area that will lead to a good research question? The key to finding a good research question is to stay close to your clinical expertise and experience. The farther away investigators stray from their own expertise, the more work and risk they take on. Stay up on abstracts from conferences and medical journals in your field. Better yet, find and read journals with the highest impact factor to get a sense of what questions are being published in top journals.

How do I find a gap in the research literature? Oftentimes, investigators presume that because their specific question has not been asked and addressed in research literature, then there is a gap in clinical knowledge. However, this is not often the case. A narrowly defined search in the research literature may yield nothing but when the search is broadened, lots of interesting items may pop up. The simplest example is adult vs pediatrics—often there is a good amount published on adults for the topic which should be a guide to studying the topic in children. Published case reports can also be used to describe our current understanding of the topic. Finally, retrospective analyses from administrative data bases or summaries of patient records at other hospitals should help inform the state of the art on the topic.

JOURNAL IMPACT FACTOR

What is a journal's impact factor? The impact factor is a score assigned to a journal based on its readership and how frequently the articles in its pages are cited. The higher the impact factor, the more widely read and cited the articles.

Four Steps to a Comprehensive Literature Review

Literature reviews are daunting. Where do I start? How do I know I have found everything? What is an annotated bibliography? After performing hundreds of literature reviews, I have found that there is a more efficient and effective strategy than spending hundreds of hours annotating articles.

This info sheet describes four steps to a comprehensive literature review, useful for almost any article you may want to publish. One caveat: This is not a description for a Research Synthesis/Meta-Analysis, which requires a more formal approach and typically a librarian to assist. In this infosheet, I describe the 4 main steps to a comprehensive literature search: 1) exploring the main findings; 2) confirming main findings; 3) drafting for purpose; and 4) synthesizing results.

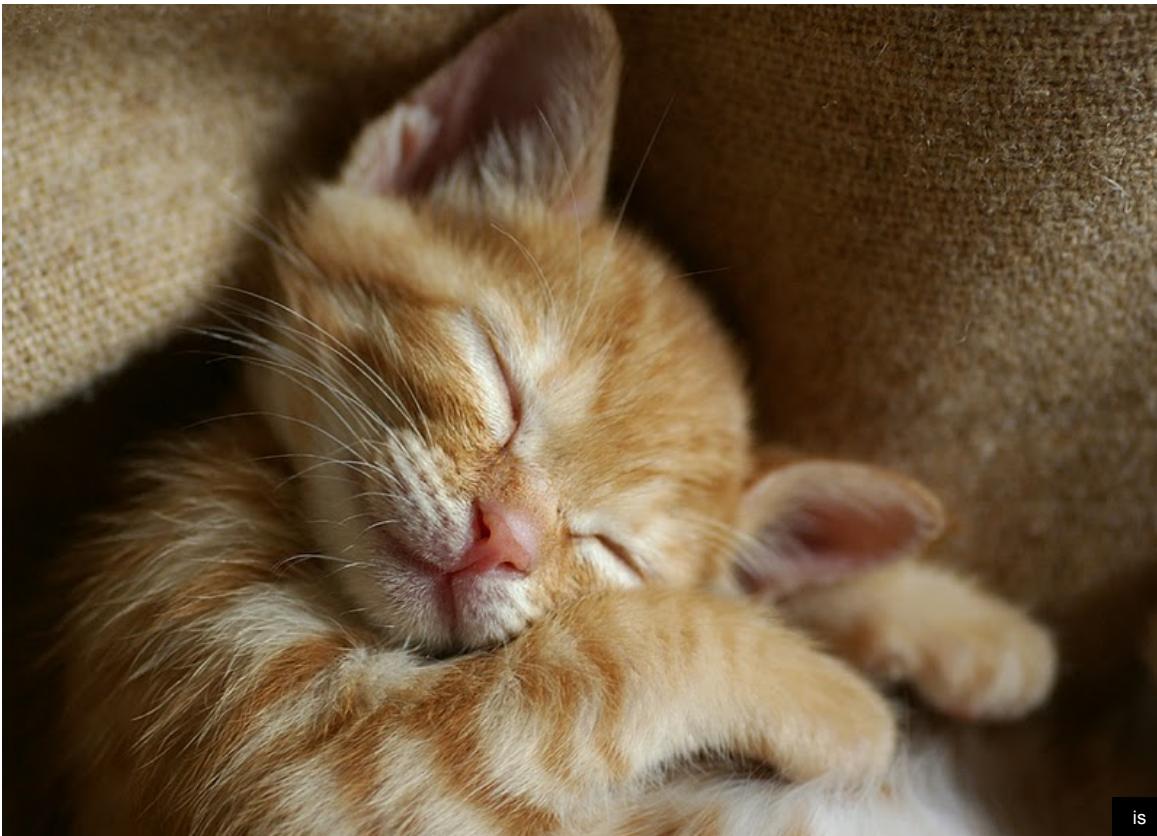


What will your study contribute? You are a contributor to a larger set of questions, but you are also contributing just one study—what does it add? What needs to happen for this question to be resolved definitively? Better data, more rigorous methods? Probably, but unless you are proposing an RCT, what are you really offering the research literature? How will your study truly bridge the research gap you have identified?

- Don't assume that just because your exact question has not been addressed, it is important to research. It may not have been researched for a very simple reason, i.e., already answered.
- Don't assume that a new data set is enough. If you want to move beyond asking the same question using different data, you must move beyond replication; you have to find the gap.
- The single purpose of your literature review should be to develop a narrative from existing literature that clearly identifies the research gap.

Finding the gap- A new database will work for publication but it's the shallow end of scholarship, basically replication. Almost any literature review you perform in clinical research should produce a combination of case reports, case series, retrospective studies and perhaps an analysis using a large admin database. This literature is international so do not discount the research from other countries. Deep literatures have multiple US studies, RCTs and syntheses completed. Deepest literatures have multiple RCTs and multiple research syntheses performed by Medical consortia and associations. Just because you are in a deep literature doesn't automatically mean there is not a gap—it will just take more work to find it.
If you are in a deep literature, then focus on the

Matching questions to design (checklist!)



- Generate multiple ideas on how to answer your question (backups)
- Pick 1-2 more feasible ways to phrase the question (ensure impact)
- Replication or Original?
 - Who else has answered this question?
 - Adding something new?
 - Is the data base a good fit?
 - Is a natural experiment possible?
 - What is the best design so far? Why?

Collecting Data

- **External Validity**- will you be able to generalize beyond the data? QI is not designed for this
- Develop a collection plan or requirements for an extraction
- Ensure variables collected represent the underlying concepts you are trying to measure (**internal validity**)
- Develop a quality control plan (training, supervision, automatic controls, audits)
(Reliability)
- **Replicability** –can another resident continue if you graduate?

Information entropy-information decreases as you move from continuous to discrete measurement

REDCap Data Dictionary (CODEBOOK)

REDCap®

Logged in as lsayrs | Log out

My Projects

REDCap Messenger

Project Home and Design

- Project Home · Codebook
- Project status: Development

Data Collection

- Survey Distribution Tools
 - Get a public survey link or build a participant list for inviting respondents
- Record Status Dashboard
 - View data collection status of all records
- Add / Edit Records
 - Create new records or edit/view existing ones

Show data collection instruments

Applications

- Calendar
- Data Exports, Reports, and Stats
- Field Comment Log
- File Repository
- CHOC REDCap Requests

Reports

- All Data (up through 4/9/21)
- All Data (after 4/12/21)
- Role Data 4/12-19/21
- Role Data 4/20-27/21
- Role Data 4/28-5/4/21
- Role Data 5/6-13/21
- Role Data 5/14-21/21
- Other Outpatient Area
- Other Outpatient Area (copy)
- KS
- All data Export
- "Other" Answers
- Role, Location & Child Data
- Needs
- Occurred
- Prevented
- Education & Time Data
- Licensure Evaluation, Needs and Occurred
- Child Description
- Child Description Both A&B
- Financially Quantifiable Data
- Role Data CHA

CHOC Children's

CHOC Children's Orange County

CCMT: Edited PID 767

Project Home Codebook

The Codebook is a human-readable, read-only version of the project's Data Dictionary and serves as a quick reference for viewing the attributes of any given field in the project without having to download and interpret the Data Dictionary. Note: Checkbox fields have their coded values displayed both in the format defined by users in the Online Designer/Data Dictionary as well as in the extended format seen in data imports and exports (i.e., field__code).

Print page

Data Dictionary Codebook

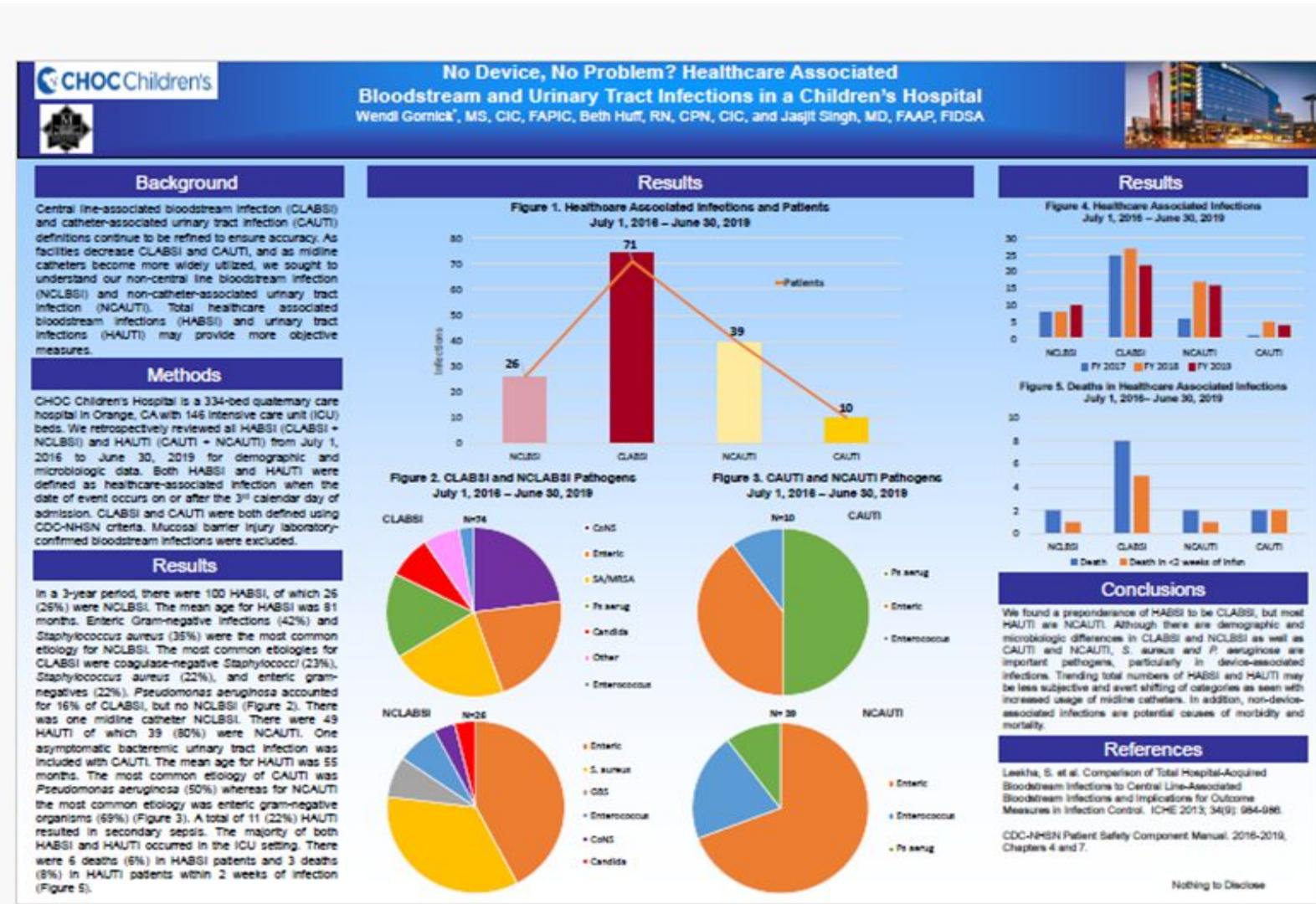
Instrument: Care Coordination Measurement Tool (care_coordination_measurement_tool) Enabled as survey Collapse

#	Variable / Field Name	Field Label Field Note	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)																		
1	record_id	Record ID	text																		
2	date	Date of encounter	text (date_mdy), Required																		
3	mrn	MRN <small>7 digit MRN without letters</small>	text (number, Min: 0000000, Max: 9999999), Required																		
4	patient_name	Patient name <small>Last name, First name</small>	text																		
5	staff_type	Staff type	radio, Required <table border="1"><tr><td>9</td><td>Care Coordinator- LVN</td></tr><tr><td>1</td><td>Care Manager Assistant</td></tr><tr><td>2</td><td>Care Manager- LVN</td></tr><tr><td>3</td><td>Care Manager- RN</td></tr><tr><td>8</td><td>Clinic LVN</td></tr><tr><td>4</td><td>Clinic RN</td></tr><tr><td>5</td><td>Medical Assistant</td></tr><tr><td>6</td><td>Patient Care Coordinator</td></tr><tr><td>7</td><td>Social Worker</td></tr></table>	9	Care Coordinator- LVN	1	Care Manager Assistant	2	Care Manager- LVN	3	Care Manager- RN	8	Clinic LVN	4	Clinic RN	5	Medical Assistant	6	Patient Care Coordinator	7	Social Worker
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3	Care Manager- RN																				
8	Clinic LVN																				
4	Clinic RN																				
5	Medical Assistant																				
6	Patient Care Coordinator																				
7	Social Worker																				



Before you start your data analysis...

Example: CLABSI and CAUTI



Example: Improving Family Management

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Pediatric Educational Discussion Scenarios: Reflect, Inspire, Support, and Empower (PEDS-RISE)—A Difficult Patient Encounter Video Scenario

Celine Payne, Hillary Zieve, MD, Candice Taylor Lucas, MD, MPH, Negar Shekarabi, PsyD, Monisha Vasa, MD, Varu Reddy, MD, Kelly Bauer, Behnoosh Afghani, MD*

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Abstract

Introduction: Difficult patient encounters can lead to burnout and stress in health care workers. Limited training exists to teach residents communication and coping skills needed for dealing with difficult patient encounters. **Methods:** We developed a 1-hour virtual video-case scenario workshop to teach communication skills and coping strategies to first-year pediatric residents. The workshop consisted of a short video-case scenario, which was developed in collaboration among ambulatory pediatricians and a hospitalist. The case scenario was followed by guidance from a psychologist and psychiatrist. As part of the workshop, the facilitator provided the residents an opportunity to self-reflect during and after reviewing the case scenario. The effectiveness of the workshop was evaluated using a pre- and post-assessment survey. **Results:** All 64 first-year pediatric residents completed the pre- and postworkshop surveys. Before the workshop, only 22% of residents stated familiarity with coping and communication strategies for handling difficult patient encounters. Pre- and postworkshop surveys demonstrated statistically significant increases in the residents' self-perceived comfort in using strategies to communicate with distressed patients, their ability to identify the need for a debriefing session for themselves or a colleague, and their ability to hold a debriefing session for a junior colleague. **Discussion:** Our results suggest that video-case scenarios in combination with facilitated reflection serve as a model to enhance resident training by teaching them skills needed to communicate with patients in difficult situations and helping them cope with distressing events. Such case scenarios may be further applied to other fields of health care.

Keywords

Four steps to transition any quality improvement project to research

CHOC investigators are actively engaged in all sorts of *research-like* activities. Some investigator-led activity is considered process or quality improvement (QI), while other activity is indeed research. What is the difference and why does it matter if I'm engaged in one over the other?

This info sheet describes: 1) how investigators can recognize when they are doing QI under the guise of research; and 2) how to transition a QI project into research for greater impact.



QI provides an *opportunity* to learn about or improve a process, a patient outcome, a program, or clinical practice. Since it is not designed for dissemination outside of CHOC, it is considered low risk and low impact. QI is not designed to move medicine forward but simply to promote improvements *in situ*; it is not required to meet rigorous scientific standards; it does not use patient information and, as a result, does not require approval from the Institutional Review Board (IRB).

More and more, a hybrid has evolved. Researchers are investigating quality questions under the guise of research. Ruled "exempt" by the IRB, these projects are expected to yield publishable results. However, publishing takes QI out of the original intent of QI and brings it into the realm of research. Despite its new classification of some QI as research, the IRB typically does not impose rigorous scientific standards on exempt projects and frequently affords the investigator a great deal of leeway on executing the study. This trend in exempt research for quasi-QI projects has opened up research to many more clinicians who might not otherwise engage with the process. On the other hand, these *research-like* projects still take resources to execute and may not have the anticipated impact.

Although publishable, *research-like* studies (quasi-QI projects) may not be eligible for the highest impact journals. Why? Often these studies lack the scientific rigor required of high-impact journals or do not address critical clinical questions. Only research can support the development of new clinical guidelines and/or disseminate new treatments, procedures, protocols and algorithms—things high-impact journals care about. Only research can assist in setting or revising treatment standards for a medical specialty—what specialty journals care about. Only research will move what CHOC does inside our institution to the world outside CHOC. As more and more investigators engage in quasi-QI, it benefits CHOC and investigators alike to transition these projects to research endeavors. Here are four simple steps to assist in making the transition:

Step 1: Turn the question away from you and toward the patient. Investigators often choose quality questions because they are driven by their own experience and frustrations with hospital and

Table of Comparisons-matched cohort design

Table 1. Demographic and clinical characteristics of pediatric patients diagnosed with non-perforated appendicitis and treated with laparoscopic or TULAA procedures

Patient clinical characteristics N=505	LA N=233 N(%), Median[IQR]	TULAA N= 272 N(%), Median[IQR]	p-value
Gender			
Male	150 (64.7)	155 (57.0)	0.08
Female	82 (35.3)	117 (43.0)	0.08
Age	9.76[7.71-13.47]	10.63[8.19-13.67]	0.17
Weight (kgs?)	37.85[27.48-56.48]	39.15[27.55-52.18]	0.16
BMI	19.93[17.02-25.05]	19.27[16.26-22.12]	0.005*
Length of Stay (days)	1.00[1.00-2.00]	1.00[1.00-1.00]	0.28
Pain Score (high)	4.00[2.00-6.00]	6.00[3.00-7.00]	0.001*
Surgery Time	29.00[22.25-38.50]	27.00[21.00-33.00]	0.43
Antibiotics			
Cefoxitin	196(84.10)	245(90.10)	0.05*
Clindamycin			
Cef/Flagyl	6(2.60)	3(1.10)	0.23
Ampicillin	22(9.40)	16(5.90)	0.14
	2(0.90)	5(1.80)	0.33

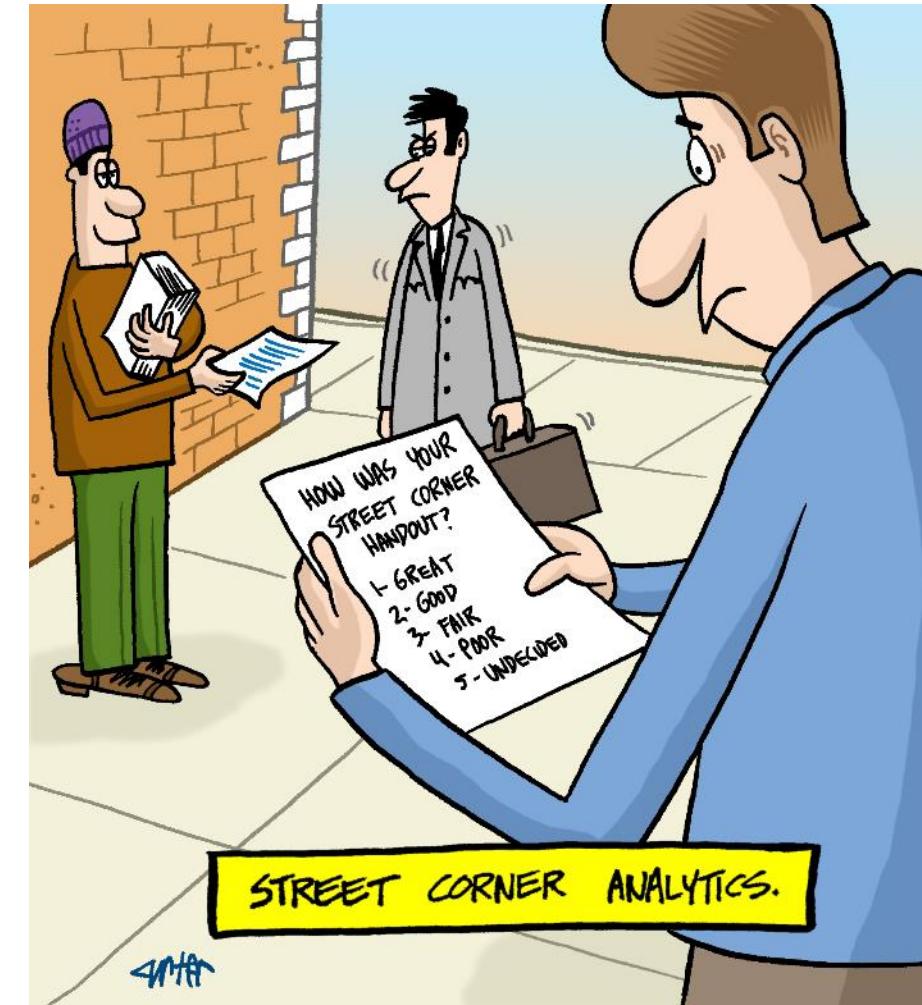
Resident Attendees-

Please take 5 minutes to provide feedback on this talk. Your responses will improve content and target support CHOC residents need for research and QI.

<https://redcapweb.choc.org/surveys/>

Use code:

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For biostatistical consulting services, please go to our PAWS Researcher page

<http://paws/index.php/researchers/research-resources/#biostat>

For any other questions, collaboration or consulting, please feel free to contact me directly at Lois.sayrs@choc.org or 714-509-7279





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Or contact me directly for questions, collaboration
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602-525-0173(C)

