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Methods in Quality Improvement for Clinical and Academic Projects



Objectives

This session will prepare you for the EPIQ workshop and address:

- What is QI and what isn't QI
- How QI projects are organized
- Addressing project ethics
- Analyzing and presenting data
- Planning for publication

UNDERSTAND

DECIDE

SHARE ACT

EPIQ		10 Steps Workbook	
Steps	Tool	Instruction	
Sector for the sector	5 Whys	Make a short list of 3 to 5 things you would like to improve and pick one. Have your facilitator ask 5 whys to "scope" the problem down to a manageable size.	
iii An the tag	Force field analysis	Select your team members relevant to your problem from step 1. Use the force field analysis to ask what the driving and restraining factors are. Use the force field analysis to make sure that your team is complete?	
	Fishbone	Use the fishbone to identify possible root causes for your problem. Identify two or three causes that your team member feel that they can tackle.	
	Feasibility tool	These 2 or 3 root causes lead to possible interventions. Use the feasibility tool to select the intervention that is most practical for your team. Remember that you want a quick success - so select wisely.	
Sig the heats	Process map	Map the process that you wish to improve <u>as it is currently</u> <u>happening</u> . Choose a start and end-point first then fill in the gaps. Once done, ask yourselves how you might improve the process and create a second map.	
	SMART indicators	Select and define at least one process indicator and one outcome indicator from your process map. Both indicators should be "SMART". You may wish to select one or more balancing indicators .	
	EPIQ Aim form	Complete the EPIQ Aim form with a clear title, aim, and indicators. The rationale may be completed later with best available evidence. Do not forget to identify the dimensions of quality that are being targeted.	
	Engagement tool	For the engagement tool , draw a table describing where your team, families, administrators, or community are with respect to readiness on the scale of being unaware to awareness, planning, acting, or maintenance. Discuss how you will engage them using	
	EPIQ Change form	Complete the EPIQ Change form (<i>aim-plan-do-study</i>). You cannot complete act except for planning a date.	
	Run charts	Plan how you will present your results —to your team, administrators, families, other sites.	

What is Quality Improvement?

 Quality improvement is a process of identifying and <u>measuring</u> a problem, setting an improvement <u>aim</u>, and testing and learning from <u>multiple</u> changes, <u>knowing</u> whether progress is being made, and <u>striving</u> to reach the aim

- My own definition

What is Quality Improvement?

- The science of using measurement to understand and improve the performance of a system
- In healthcare, quality improvement refers to systematic and continuous actions that lead to measurable improvement in health care services and the health status of targeted patient groups

Quality Improvement, Health Resources and Services Administration, 2011



Model for Improvement

What are we trying to accomplish?

How will we know that a change is an improvement?

What change can we make that will result in improvement?





www.ihi.org

QI Involves Systems

• "The System" = how things are done now



Adapted from Donabedian, 1980

"Every system is perfectly designed to get the results it gets." - Paul Batalden, IHI

Terminology

- <u>Quality Improvement</u> is the purposeful measurement of a process and analysis of change with the goal of improving an outcome
- <u>Quality Assurance</u> is the process taken to provide confidence that a satisfactory outcome will result
 - Alberta Evidence Act (S.9) uses the term "Quality Assurance" to describe activities that "study, assess or evaluate the provision of health services"

How is QI different from research?

	Research	Quality Improvement
Purpose	Discover new knowledge	Use knowledge to fix a problem
Starting point	Hypothesis	Aim
Strategy	Interventions planned a priori	Tests of change inform next steps
Ethics Review	Performed by a research ethics board	Performed according to local guidelines (ARECCI in Alberta); REB confirms exempt
Variation and Bias	Reduced by using inclusion and exclusion criteria, randomization	Reduced by standardizing processes, so that change can be detected
Sample size	Calculated to ensure power to detect a meaningful difference; study ends when enrolment met	Focus on gathering enough information to reliably measure; project ends when aim is met (or when you declare defeat)
Analysis	Occurs after data collection complete or at a defined interim analysis; often utilizes hypothesis testing	Occurs in an ongoing manner throughout tests of change; often utilizes run charts or control charts
Reporting standards	Determined by study type (e.g. CONSORT for clinical trials)	SQUIRE 2 guideline (Standards for Quality Improvement Reporting Excellence)

Primary Purpose

You would like to reduce the median time to treatment of pain in your ED, currently 30 minutes, and decide to test if a nursing directive to provide analgesics at triage can produce a statistically significant change.

You compare time to analgesia before and after the order set change using a t-test.

Research or QI?

Primary Purpose

You would like to reduce the median time to treatment of pain for limb injury in your ED from 30 minutes to 15 minutes.

You work with your team to identify possible changes and decide to begin with a nursing directive for analgesia to be given in triage.

You create a chart to measure your progress toward the 15 minute aim.

Research or QI?

Your primary purpose is QI if:

- You are doing it to directly attempt to fix a local problem
- The work is valuable regardless of publication
- Your team is willing to do more than one thing to address the problem
- You're not simply trying to conclude whether or not one thing worked

Imagine you have finished your research project. What problem can you address with this new knowledge?

Write a problem statement for the QI project you could design after finishing your research.

QI ETHICS: ARECCI

- A pRoject Ethics Community Consensus Initiative
- Created in 2003 by representatives from Alberta REBs, regional health authorities, and Alberta Health and Wellness
- Recognition that all projects involving individuals and their health records can involve risk
- Standard process to review projects according to primary purpose (research or quality) and level of risk



Our impact

ARECCI helps project leads to address and mitigate ethical risks through decision support tools, training opportunities and project ethics consultation.

ARECCI decision support tools

ARECCI decision support tools consists of two complimentary tools to assist project sponsors.



1. <u>The ARECCI Ethics Screening Tool</u> and 2. ARECCI Guideline Tool.

These tools have been co-developed and validated. They help determine:

- 1. level of risk of your project,
- 2. types of ethical risks, and
- 3. appropriate type of ethics review.

Each tool aids in the identification of ethical areas of concern.

.aihealthsolutions.ca/arecci/screening/53405/57b7c82942408be27294e8b0fc64cdfa





Your score is 19. The project involves Somewhat More Than Minimal Risk and should be reviewed by a Second Opinion Reviewer.

Questions that affected your final score:



LINEAR BUILD

Save
Print
E-mail
Feedback

Next »

Score

0.1

6 mil 1

-

4. HOW WILL YOU MAXIMIZE BENEFITS AND MINIMIZE OR MITIGATE THE ETHICAL RISKS IN THE PROJECT?

POINTS TO CONSIDER

- How will your organization and participants benefit from the project?
- What are the risks identified by the *ARECCI Ethics Screening Tool* and how will you minimize and mitigate them?
- What are the risks of not doing this project?
- Will your organization tolerate the risks that remain in your project?

Describe the benefits to participants and to your organization.

ARECCI Ethics Guidelines:

Instructions

Usefulness of Knowledge

Method or Approach

Participant Selection

Risks & Benefits

Respecting Rights

Informed Consent

Conclusion

What about Implementation Science?

- IS = the study of methods to promote uptake of evidence into practice
- Both IS and QI share goal of improving quality
- QI has the primary purpose of fixing a quality gap and may be shared for others to learn from
- IS has the primary purpose of developing knowledge about evidence implementation that will apply beyond the local quality gap

Bauer et al. BMC Psych 2015. Intro to IS for the non-specialist.

What is "QI Research"?

- Efforts to build knowledge that add to understanding the science of quality improvement
- Examples
 - What contextual factors or strategies support improvement?
 - What factors contribute to successful spread?
 - Is an improvement project generalizable?
 - (This would be an example of implementation science.)

How is QI conducted?

- 1. Identify the Problem
- 2. Form a Team
- 3. Consider Ethics
- 4. Understand the Problem
- 5. Set the Aim
- 6. Plan the Change
- 7. Measure the Change
- 8. Repeat Cycle as Needed
- 9. Sustain Success

10. Share

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The problem statement

- Identify an area where a quality gap exists
 - Ideal conditions for QI success:
 - Solid evidence to inform a standard of care
 - Accessible data
 - Gap between current and desired practice
 - Motivation to change/improve
 - Resources to match scope of project

ACH ED example

- Review of data on all children presenting with limb injury over a one-year period
 - 20% were given a pain score at triage
 - 32% received medication for pain during their visit



The problem statement: which is best?

- Pain in the emergency department is undertreated.
- Only 20% of children with limb injury receive a pain score upon ED arrival because the electronic record is not user-friendly.
- For children presenting to the ED with acute limb injury, 20% receive a documented pain assessment at triage.

Reflection

- Think about your project for this course.
- What is your primary purpose?
- If it is to learn something new, how will the knowledge solve a future problem?
- Write an imaginary problem statement that could be used by someone in the future who wants to improve quality with your new knowledge.

Forming a Team

- You need a team when...
- The task is complex, and no one person has the knowledge, skills, and experience to implement a solution.
- Change will require commitment and cooperation across units or disciplines.
 - Discuss team membership with leadership and include members from all groups who will need to participate in a change

Consider Ethics

- Think again about your primary purpose
- Are you mostly trying to fix a local problem or mostly trying to learn something that you can share?
- If fixing a local problem, probably QI
- Proceed with ARECCI process
- Contact REB to confirm exemption
 - Send protocol, ARECCI screening tool document, ARECCI guidelines document, and copy of Second Opinion Review letter if obtained

Understanding the Problem

- You will learn many tools for understanding the problem in the EPIQ workshop
 - 5 Whys
 - Force Field Analysis
 - Fishbone Diagram
- One other that may be helpful is a Failure Mode and Effect Analysis (FMEA)
- No right tool as long as you understand your problem before trying to solve it

FMEA diagram

- Outlines steps in process
- Indicates potential failures
- Identifies potential solutions



Process: Pediatric limb injury pain assessment and treatment at triage



Setting Your Aim



Example:

We will increase the proportion of patients with limb injury who receive analgesic medication at triage from 32% to 40% within 6 months.

What is wrong with these aims?

- We will improve care of children with pain within 6 months.
- We will increase the proportion of patients with limb injury who receive analgesia by 50% within 6 months.

Return to your problem statement.

Write a SMART aim for your imaginary future QI partner who will use your research to improve care.



Planning the Change: Key Driver Diagrams



Source: The Illustrated Guide to Quality Improvement by Sonia Sparkles, NHS Foundation Trust https://qi.elft.nhs.uk/qi-illustrations/
KEY DRIVER DIAGRAM: Improving pain treatment



Green shaded = what we have begun working on

How are you feeling?



Let's work together to reduce pain. We can help by:

- helping kids rate their pain
- providing pain medicine
 - ask about no-needle options
- using comfort positions for procedures
- offering items on our comfort menu

Kids can help by:

• talking to us - ask questions and let us know what we can do for you

Grown-ups can help by:

- letting us know if your child isn't comfortable
- providing distraction, reassurance, a soothing voice, or a loving touch
- ask about how to support your child during a procedure



Our commitment to comfort:

We'll do our best to promote comfort by helping to lessen pain and anxiety. Please let us know what we can do to help.

Alberta Children's Hospital

Comfort Menu

- Medicine for pain
- Numbing cream before needles
- Ice pack
- Warm blanket
- Wheelchair
- Splint
- Something to watch
- Something to play with

Alberta Health

Services



Is your child having a needle?



It takes **at least** 30 minutes to work. If we forget, remind us early!



Alberta Health

Services

Please ask if **Numbing Cream** (Maxilene® or Ametop®) is right for your child.

Our goal is to use numbing cream <u>BEFORE ALL POKES</u> For IV starts & blood work

(as long as your child doesn't need their IV or blood work right away).



AHS Commitment to Comfort[®]

Measuring Change



• QI saying of uncertain attribution

4 Types of Measures

• Outcome measures

- Are changes leading to improvement of the end result?
- Are we reducing pain with our pain management?

Process measures

- Are the parts and steps in the system functioning as planned?
- Are we giving pain medication earlier?
- Structure measures
 - Do we have necessary structures in place?
 - Do we have an appropriate analgesia care guideline?

4 Types of Measures

- Balancing measures
 - Are changes designed to improve one part of the system causing new problems in other parts of the system
 - Can be structure, process, or outcome
 - Are we increasing ED waiting time by adding pain treatment steps to the triage process?

Before/After Studies



Did your project result in a change?

Pain study example

- Pain scale signs were created to determine whether this would result in more patients receiving analgesia during their ED visit
- In the week prior to the intervention, 16.6% met the target; one month after the intervention, 44.4% met the target
- Was the intervention a success?



"Premature pizza party error"

- M. Siska, CCHMC

Proportion of patients receiving analgesia



Week

Data over time



Run Charts and Control Charts

- How do we know if variation is not random?
- How do we look at QI data and identify non-random changes, if monitoring in real time rather than using traditional statistical methods at the end of the project?

Run Chart

Limb Injury Pain Scores at Triage



Run Charts and Control Charts

- Statistical Process Control introduced by Walter Shewhart at Bell Labs in 1920's
- Described "common cause" and "special cause" variation
 - Common cause is variation due to chance
 - Special cause is variation beyond what is expected by chance
- Allows surveillance for nonrandom change

Types of variation

- Common Cause Variation
 - Random
 - Not explainable
 - Do not waste time investigating
- Special Cause Variation
 - Non-random
 - May be explained
 - Consider investigating

Special Causes

<u> </u>	

 6 or more consecutive points either *all* above or below the median

Trend

 5 or more consecutive points all going up or all going down

Run

- A series of points in a row on one side of the median
- May have too many or too few for number of data points

Astronomical

- Not a statistical observation
- Logically obvious that a data point is unlike any of the others

Run Charts



Run Charts



Need to refer to a table for expected number of runs for number of data points

Control Charts



Control Chart Zones



SPC: "Special Causes"

	any point above +3 σ	3 o Upper Control Limit
	2 out of the last 3 points above +2 σ	a -
	4 out of the last 5 points above +1 σ	2 .
	8 consecutive points above center line Center Line 8 consecutive points below center line	
	4 out of the last 5 points below -1 σ	20
	2 out of the last 3 points below -2 σ	
	any point below -3 σ	3 of Lower Control Limit

6 consecutive points trending up or down 14 consecutive points alternating up and down

Children 4-17 with limb injury receiving >1 dose analgesia



Increase from 32% to 44%

Combining Control Charts Analysis with Statistical Analysis

- Remember primary purpose is to reach the aim
- Significance of change is of secondary importance
 - May still matter if deciding whether to sustain and spread
- Interrupted time series can evaluate change over time
- Measures slope and intercept of line before and after designated time
- Accounts for underlying trends

Kontopantelis E et al Regression based quasi-experimental approach when randomisation is not an option: interrupted time series analysis *BMJ* 2015;350:h2750

Interrupted Time Series



Rate of change of the ٠ proportion of patents receiving analgesia in the ED increased at the beginning of the improvement phase and was sustained through the sustainability phase (p < 0.05).

Pre Post

Sustainability Planning

- Measurement
 - What measurement will continue?
- Ownership
 - Who will be in charge?
- Communication and Training
 - How will people be kept informed?
- Hardwiring Change
 - How can the right actions be made easy?
- Assessment of Workload
 - How will impact on workload be managed?



A Framework for Spread



IHI, 2006

Test Scale-Up

- Aim: To form a quality improvement collaborative among the 3 Calgary general ED's to :
 - Improve the proportion of children receiving analgesia for limb injuries from 23% to 40%
 - Reduce the median time to analgesia from 89 minutes to < 60 minutes



Test Scale-Up

- Interventions
 - Quality improvement collaborative (QIC)
 - Project leads taught QI skills, shared resources
 - Interdisciplinary teams at each site
 - Physicians, nurses, orthopedic technicians
 - Each site developed key driver diagrams, set aims, planned tests of change (PDSA cycles)
 - Monthly QIC meetings to share learnings





Median Triage to Analgesia Minutes





Full Scale

- 97 ED's invited, 36 accepted
 - All geographic zones
 - 40% of pediatric ED visits in Alberta



Full Scale

Process measures

- For patients 0-12 years of age undergoing phlebotomy
 - Proportion receiving topical anesthetic cream
- For patients 0-16 years of age with a fracture
 - Proportion with a documented pain score
 - Proportion who receive analgesic medication
 - Median time to analgesia

Balancing measures

• Length of stay, opioid use



Methods



Small Multiples: Topical Anesthetic



Topical Anesthetic Provided with Lab Tests Children 0-12 years June 2016 - May 2018



N = 2910

Median Minutes to Analgesia Children 0-16 with Fracture (June 2016 – June 2018)



Balancing Measures



SQUIRE 2.0 Guidelines

- Developed in 2008, updated in 2015, by a consensus panel of QI publication experts
- Gives authors a framework upon which to structure a QI manuscript
- The same framework can also be instrumental in project design
- Goal is to support high-quality writing about improvement efforts

http://squire-statement.org
SQUIRE 2.0 Guidelines

Title and Abstract	
<u>1. Title</u>	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)
<u>2. Abstract</u>	 a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions
Introduction	Why did you start?
<u>3. Problem</u> Description	Nature and significance of the local problem
<u>4. Available</u> <u>Knowledge</u>	Summary of what is currently known about the problem, including relevant previous studies
<u>5. Rationale</u>	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work
<u>6. Specific</u> <u>Aims</u>	Purpose of the project and of this report
Methods	What did you do?
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)
<u>8. Intervention(s)</u>	a. Description of the intervention(s) in sufficient detail that others could reproduce itb. Specifics of the team involved in the work

Model for Improvement What are we trying to accomplish? How will we know that a change is an improvement? What change can we make that will result in improvement? Act Plan Study Do

Summary

- Quality improvement is a process of identifying and <u>measuring</u> a problem, setting an improvement <u>aim</u>, and testing and learning from <u>multiple</u> changes, <u>knowing</u> whether progress is being made, and <u>striving</u> to reach the aim
- Always be clear on your primary purpose
- QI projects measure progress over time
- Methods exist to guide project design, sustaining change, and share learnings

Questions?



