It's About the Process: A Quality Undertaking

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Disclosures

- I have no financial or otherwise disclosures or conflicts of interests that are relevant to this presentation.
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Quality Improvement & Patient Safety

The Topics

- Understand the Purpose of Quality Improvement in Healthcare
- Understand the Steps of a Quality Improvement Project
- Appreciate the Difference in Significance and Data Display in Quality Work
- Understand the Difference between Research Studies and Quality Projects

Quality Improvement & Patient Safety

The Topics

AKA:

- Remembering the Why
- Steps of a QI Project
- A Difference in Significance
- Blurred Lines in Scholarly Activity

REMEMBERING THE WHY

WHY QI?

Well Defined Process to Improve Systems in *All* Industries

- Customer Service
  - Hotels, Restaurants, etc.
- Technology Services
- Business Strategies
- Others, etc.

Motel 6
Red Roof Inn

Courtyard
Hilton Garden Inn

Ritz Carlton
Waldorf Astoria

WHY QI?

Types of Quality Initiatives:

- Safety
- Effectiveness
- Timeliness
- Efficiency
- Equitability
- Patient/Customer Centeredness

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WHY QI?

Medical Focus:

- ***Quality***
- ***Safety***
- ***Equality***

Johns Hopkins, Baltimore MD

Mayo Clinic, MN, AZ, FL

Every Patient Deserves the Same Level of Care Regardless of What Hospital / Clinic They Go To

BAMC, San Antonio, TX

EXPECTATION VS REALITY

2000
"To Err Is Human"
↓
2025

Limited to No Training in QI, but Expected to Know How to Lead Projects

Expectation from Licensure Boards to Maintain License

Expectations from Leadership to Optimize Quality Domains

Expectations from **Patients** to Maintain Quality, Safety, Equality Care

EXPECTATION VS **REALITY**

"Less *Regulated*"

↓

More Individual Responsibility

If done wrong, risk safety

If done wrong, risk license

HIPAA Requirements must be understood

Not Research, but confusion leads to unsafe research studies

ACGME REQUIREMENT

"Graduate medical education develops physicians who focus on excellence in delivery of safe, equitable, affordable, quality care; and the health of the populations they serve."

- ACGME – Common Program Requirements

II.B.2.b) demonstrate commitment to the delivery of safe, equitable, high-quality cost-effective, patient-centered care; (Core)

Background and Intent: Patients have the right to expect quality cost-effective care with patient safety at its core. The foundation for meeting this expectation is formed during residency and fellowship. Faculty members model these goals and continually strive for improvement in care and cost, embracing a commitment to the patient and the community they serve.

We are responsible for building this foundation so the burden of teaching and instilling this is on us as Teachers, Mentors, & Advisors.

REMINDER

Quality Improvement is NOT Research

	Research	Quality Improvement
Purpose	Proof of effectiveness	Sustained improvement
Data Collection	Gather enough data to authoritatively study for effect and control for all known confounders	Gather just enough data to inform improvement, and only collect data on 1–2 confounders (i.e., balancing measures) as needed
Method	One large test with a fixed hypothesis; control bias as much as possible	Rapid sequential tests with a hypothesis that changes as learning takes place; no effort to control bias
Results Evaluation	Pre- and post-assessment	Regular assessment with run charts

HOW TO ERROR PROOF A SYSTEM

The *Idea* and *Overall Mentality* of Quality Improvement stems from the fact that "To Err is Human."[1]

Focus on Safety and Quality Care for Patients

Addressing:

- Morbidity / Mortality
- Cost / Eliminating Waste

At the System / Process Level

HOW TO ERROR PROOF A SYSTEM

The *Quality Chasm Report* was developed to help better Classify Quality Initiatives

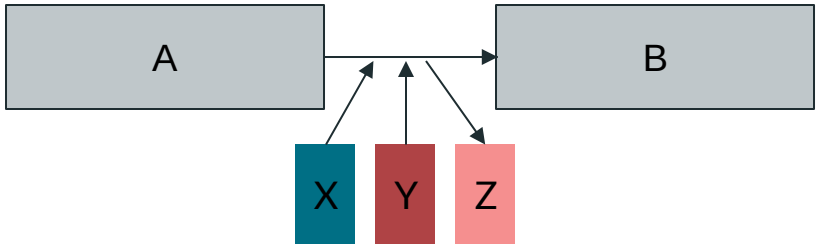
Foci:

- Safety - Avoiding injury to patients from care intended to help
- Effectiveness - Provide the appropriate level service based on scientific knowledge
- Timeliness - Reduce wait times and harmful delays for patients and providers
- Efficiency - Avoiding waste (e.g., equipment, supplies, personnel, ideas, energy)
- Equitability - Equal treatment for all
- Patient-centeredness - Respectful of and responsive to individual patients

HOW TO ERROR PROOF A SYSTEM

When approaching something you have found needs improvement, you must:

- Appreciate the System
- Understand the Theory of Knowledge
- Understand Variation
- Appreciate the Psychology/Human Behavior Component



STEPS OF A QI PROJECT

This is the Way.

To ensure appropriate QI methodology, follow these steps in order

1. Observe a Problem.
2. Prove it is a Problem.
3. Understand / Investigate the Problem.
4. Gather Baseline Data About the Problem.
5. Develop an AIM statement / SMART goal.
6. Define all measures.
7. PDSA → Gather and Assess Data.
8. Implement and Share Results.

WHAT IS / IS NOT QUALITY IMPROVEMENT

KEY CONCEPT(S)

A single change in process, teaching, method, etc. is NOT Quality Improvement.

Quality Improvement requires continuous steps of changes (minimum: 3-5).

Comparing a before and after change is NOT Quality Improvement.

Quality Improvement follows TRENDS, it does not compare anything, rather observe over time changes that occur and how you respond to these changes is the process of QI.

- Having a solution to a problem that does not exist is NOT quality improvement. -

The Quality Improvement Process is about fixing a problem that is leading to unequal care, quality, safety, or equality.

WHERE TO START?

Quality
Safety
Equality

Find The Problem

Quality Improvement Projects are developed when a **Gap** in One of the Foci is noted.
(e.g., safety, effectiveness, timeliness, efficiency, equitability, patient centeredness)

In other words - You find a project by finding (aka observing) a problem.

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GAP → WHAT MAKES THEM NOT EQUIVALENT

There is a Demonstrable **Gap** in Care / Process/ Procedure / etc.

WHERE TO START?

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GAP → WHAT MAKES THEM NOT EQUIVALENT

There is a Demonstrable **Gap** in Care / Process/ Procedure / etc.

The GAP must be MEASURABLE - Having a **Measurable** Way to Follow the Effect of Change (a means to track and visually show the effect the change had)

WHERE TO START?

Quality
Safety
Equality

Prove The Problem

Once a Measurable GAP is identified, you must **JUSTIFY** why this is in fact a problem that needs to be fixed.

- Find the support to change - aka the *justification* for your project*
  - Benchmarking - Use best practice guidelines, or the "benchmark" of standard of care to support need for change in areas not met
    - Using a published article to support safe practice alternative demonstrating improvement in patient safety / care
  - Technology - New developments can have support and data showing it helps with efficiency, automation, new abilities
    - WARNING: Can be bad if make system more vulnerable to internet, isn't reliable, etc.
  - Creative Thinking - Attack boundaries or limitations imposed by routine thought processes regarding the issue
    - Utilizing different perspectives, outside thoughts, work with other departments for new idea, etc.
  - *Change Concepts - A great way to approach and find ways to improve a process
    - Made up of 72 prompts for ideas under 9 subheadings focusing on processes when addressing QI foci.

WHERE TO START?

Quality
Safety
Equality

Understand The Problem

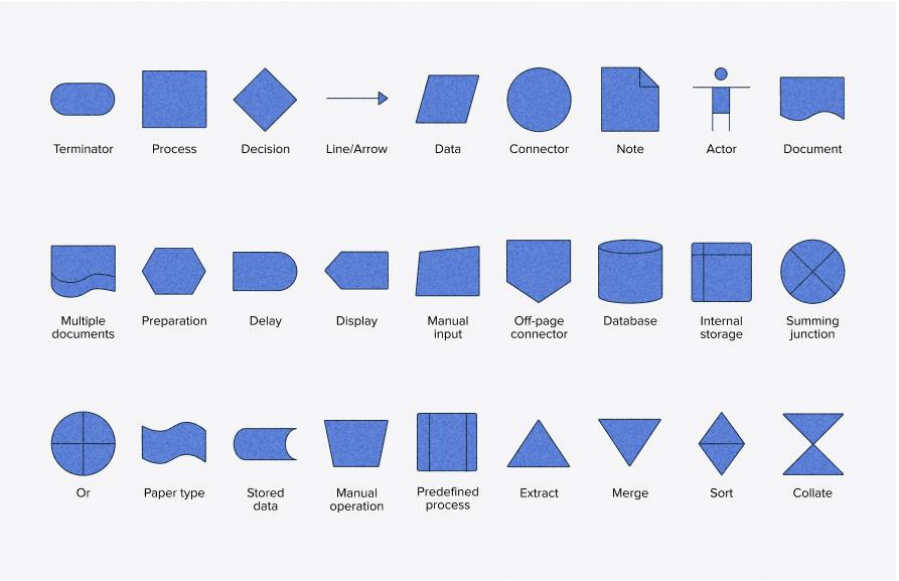
Once a Measurable GAP is identified, and you have Justified why it is a problem worth fixing, you must **Understand** the problem.

- Assess the current process / system and investigate it! How do you get to the observed deficiency in quality? What steps are involved and influenced by the process?
  - This can be done in a variety of different ways including using Flowcharts, Process Maps, Cause analysis (Ishikawa (fishbone diagrams), , etc.)*
    - You learn how to complete these by doing the actual process in question and / or gathering information from everyone involved in getting to the endpoint that you believe is not at standard (a Gap).

UNDERSTANDING THE PROCESS

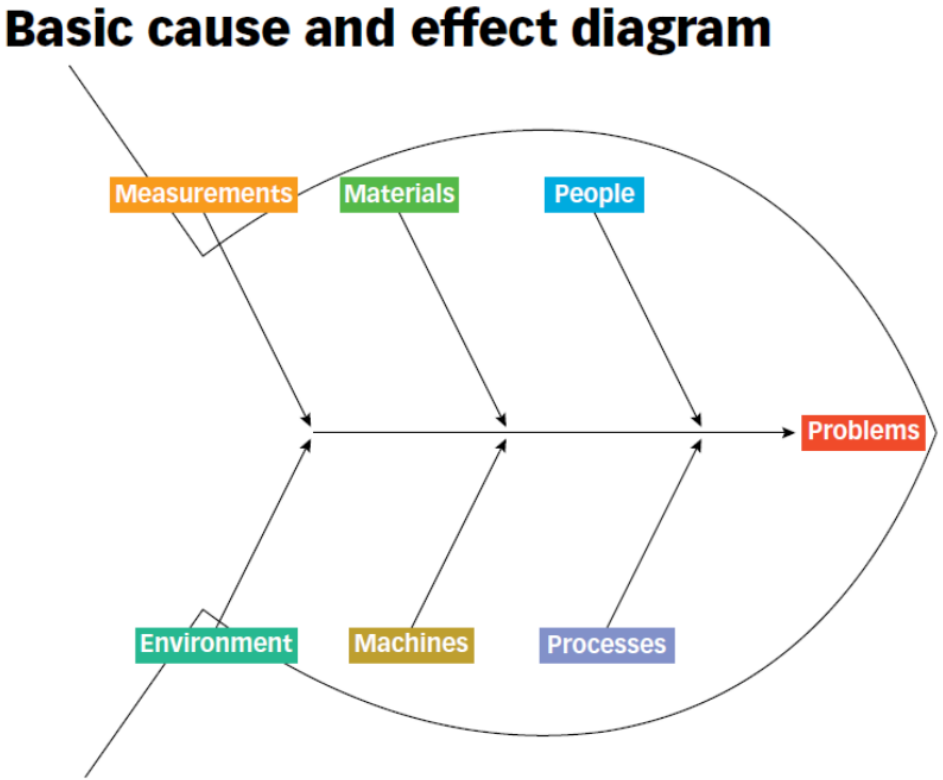
- Flowchart
  - General Basic Layout of a Workflow → A complex process in manageable steps
- Process Map
  - Detailed, Sequential Process Outline Including Input, Actions, & Outputs → Identify areas of Optimization
- Ishikawa Diagram
- Pareto Chart

Flowchart / Process Map Symbols



UNDERSTANDING THE PROCESS

- Flowchart
- Process Map
- Ishikawa / Fishbone Diagram
  - What Causes lead to the GAP (*Effect*) Identified?
- Pareto Chart



UNDERSTANDING THE PROCESS

- Flowchart
- Process Map
- Ishikawa / Fishbone Diagram
- Pareto Chart
  - 80:20 Rule → Focusing on what is causing the majority of the problems 80% of the time would yield the greatest impact on your outcome

Figure 1: Pareto Chart, Customer Complaints

Figure 2: Pareto Chart, Document Complaints

https://asq.org/quality-resources/pareto#Examples

MODEL FOR IMPROVEMENT

Quality
Safety
Equality

Six Sigma / Lean Mentality

Once a Measurable GAP is identified, you have Justified why it is a problem, and you Understand the problem - then you must: **Set your aim, develop measures, identify changes that you will test.**

- What are we trying to accomplish? → AIM
- How will we know change is working while still doing the right thing to get there in the safest way? → Measures
- What change can we make that will result in improvement? → PDSA
- Apply and implement changes.

MODEL FOR IMPROVEMENT

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Developing an Aim Statement / SMART Goal

- Your AIM must include the answers to:
  - **How good?**
  - **By when?**
  - **For whom / what?**
- Remember, your AIM must be meaningful and measurable / trackable
  → This is why you had to do the previous steps.

SPECIFIC	MEASURABLE	ACHIEVABLE	RELEVANT	TIME-BOUND

SMART goals help keep you focused and on track with a realistic view and timeline.

MODEL FOR IMPROVEMENT

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Define All Measures

How will we know change is working while still doing the right thing to get there in the safest way?
→ We must clearly define how we are going to measure the improvement and monitor / track the change.

- **Outcome Measures**: What are we ultimately trying to monitor? (1-2)
- **Process Measures**: Are we doing the right things to get there? Are we causing more problems we need to fix? (3-5)
- **Balancing Measures**: Are the changes introducing problems making the Initiative no longer worth the effort? (1-2)

After identifying all measures, you must decide how exactly are you going to calculate the measurement you have defined. (e.g., percentage, score, average)

MODEL FOR IMPROVEMENT

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PDSA Cycles

Change (and in turn each PDSA cycle) requires two things to be able to be successful.

Needs to have **MEANING** → Data needs to show the impact of the change.

Needs to be **MEASURABLE** → Deliberate and Specific.

- PDSA – A rapid methodology to test a change, learn from it, apply and revise. It is a way to fine tune success. It is also an acronym:
  - Plan → Plan how you are going to test a change
  - Do → The actual process of implementing the change
  - Study → The post-change implementation "debrief" assessing results in comparison to what was predicted to happen with the change
  - Act → this is is next step that is required with the change, to maintain it, etc.
    - A process to determine if a change should be: **adapted, adopted, or abandoned***

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PDSA Cycles

Determining size & scale:

- Think *Small* to start! ← This is to minimize risk as every change in a system has inherent risk to it and what it will effect. When dealing with people and patients, high risk for little reward is not going to be an authorized cycle process. This also can help buy-in!
  - **Changing Scale**: X5 Rule - multiply the number of testing scenarios by five each round.
  - **Changing Scope**: Do not forget to apply your change in different settings (e.g., using experience providers, inexperienced providers, etc. → this may change your outcomes so important to do at smaller scale)
    - These changes can be done in parallel or additive, but be sure to start small for both.
- Good Rule of Thumb: ~40 samples is good for pre-data.
  - Consider **Sampling** for Large Populations

MODEL FOR IMPROVEMENT

Quality
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Key Concept

Too Many Changes at Once is NOT helpful.

It does not allow for identification of what worked or did not work. This is why it is critical your PDSA cycles and QI projects only make a single change at a time.

Remember - we want to be efficient and minimize waste in this process. So making many changes all at once does not actually help if perhaps only 1 change was necessary and the others are just extra waste.

Practical example of this issue: You give a kid 10 different medications/supplements/treatments at once and they feel better. In some instances this is necessary for safety, but from a QI standpoint - if the goal of your project was to make the kid better - did you succeed? Sorta. You met your goal/objective, but you can not say you know how. Additionally, you have done 10 things instead of 1, so you have introduced extra processes/steps/meds and all of these have their own risk and cause/effect outcomes.

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TEAM Approach

Guidance and Consideration before the first PDSA Cycle:

- Who is responsible for data collection?
- How often it is collected? (What is the timeline of your PDSA cycle definition)
- What are the sources? (e.g., chart review, messages, etc.)
- What is Included/Excluded? (Use the work you did in Step 6 for this!)
- How is data collected? (e.g., manually, log, automatic, etc.)

MODEL FOR IMPROVEMENT

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TEAM Approach

A quick aside about forming your team. Quality Improvement requires a diverse group of team members. Ideally, at least one member of each part of the process of your objective is involved. Having input, accountability, and buy-in at every level is important and makes implementing change easier.

Defining roles is important early in this process. So things like determining who is going to submit the project for exemption, who will gather data at the set times, who will write up the results, maintain the project, lead the project etc. must also be considered and made clear early on in your project.

MODEL FOR IMPROVEMENT

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Understanding Variation - Determining Significance

- A Key to Assessing your Data is understanding the difference between Common Cause and Special Cause Variation.
- Run Charts have rules that can help us determine this.

 Common Cause Variation	 Special Cause Variation
Inherent to the system or process	Not inherent to the process design
Due to regular, natural, or ordinary causes	Due to irregular or unnatural causes
Affects all the outcomes of a process	Affects some but not necessarily all aspects of the process
Results in a "stable" process that is predictable	Results in an "unstable" process that is not predictable
Also known as *random* or *unassignable variation*	Also known as *non-random* or *assignable variation*

A DIFFERENCE IN SIGNIFICANCE

Time Period 1 = 79%

Time Period 2 = 86%

Significantly Improved! Right?

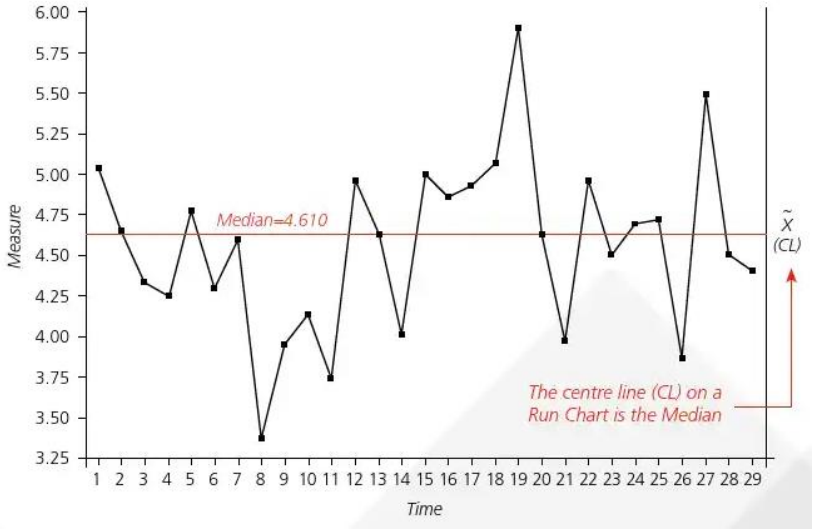
A DIFFERENCE IN SIGNIFICANCE

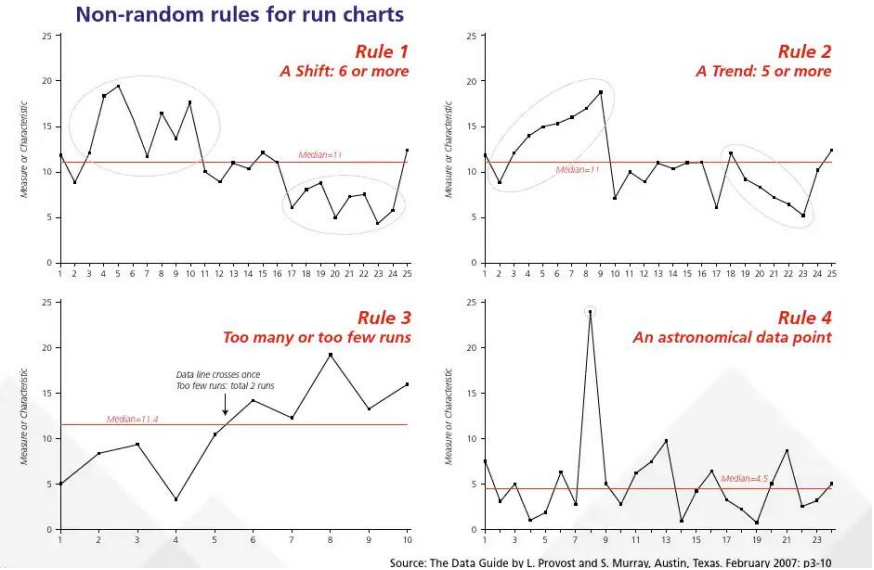
Time Period 1 = 79%

Time Period 2 = 86%

A DIFFERENCE IN SIGNIFICANCE

Run Chart → The Rules are the Significance.





https://www.england.nhs.uk/improvement-hub/wp-content/uploads/sites/44/2017/11/A-guide-to-creating-and-interpreting-run-and-control-charts.pdf

MODEL FOR IMPROVEMENT

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Implement & Share Results

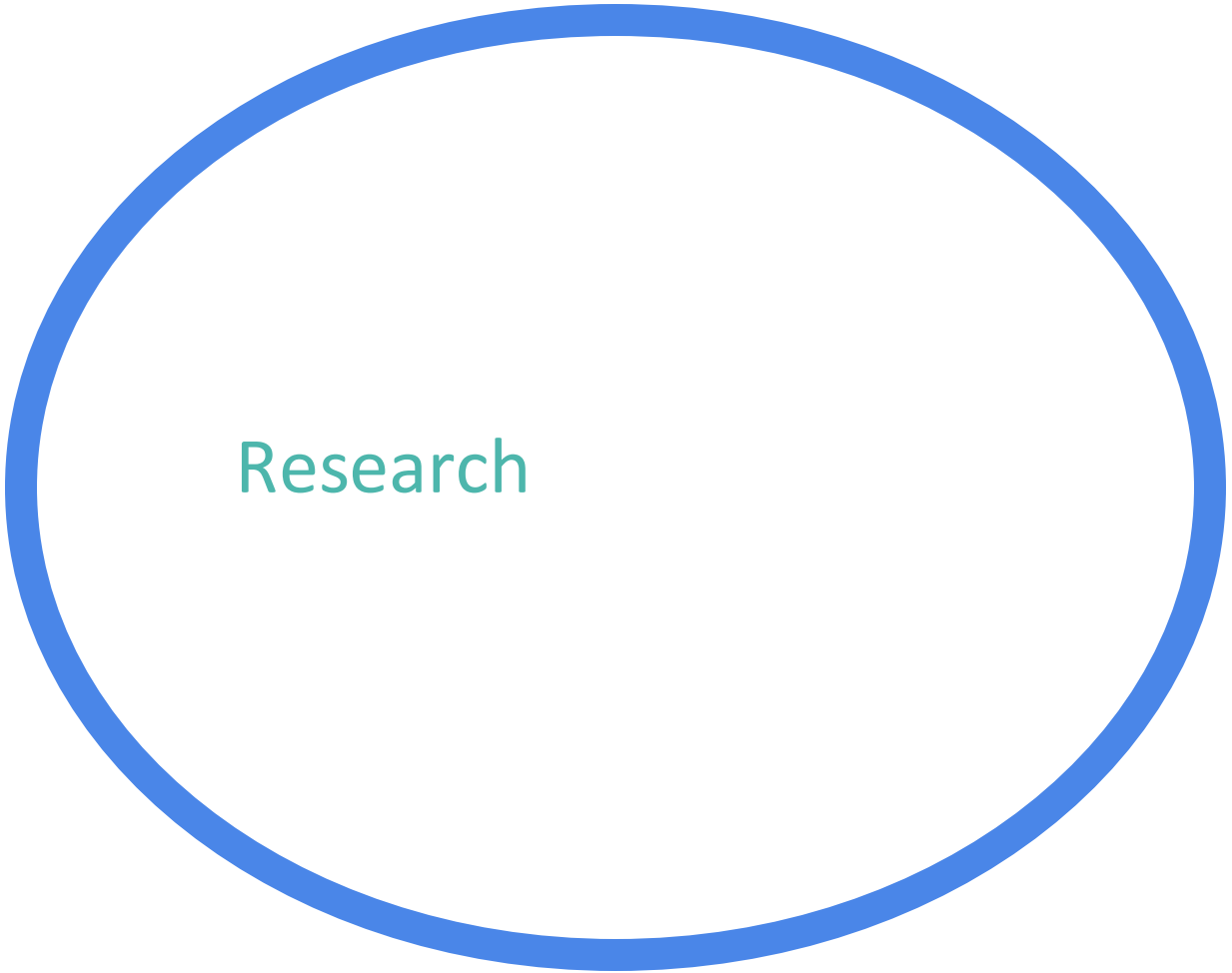
- Once you go through at least 5 PDSA cycles, after all the previous Steps of the QI process, and/or your outcomes have either been reached/maintained/changed/optimized → it is time to implement your changes as standard practice and share your results!
- Remember, the goal of QI is to have a process that can be widely spread and used by all to improve the outcome you found needed improvement.
    - As a reminder, it is a continuous process, not focused on results, but about the *process* & *trends*. This is a different way of thinking and writing and **SQUIRE 2.0*** is your friend when it comes to sharing your results and ultimately publishing your work.

Key Concepts

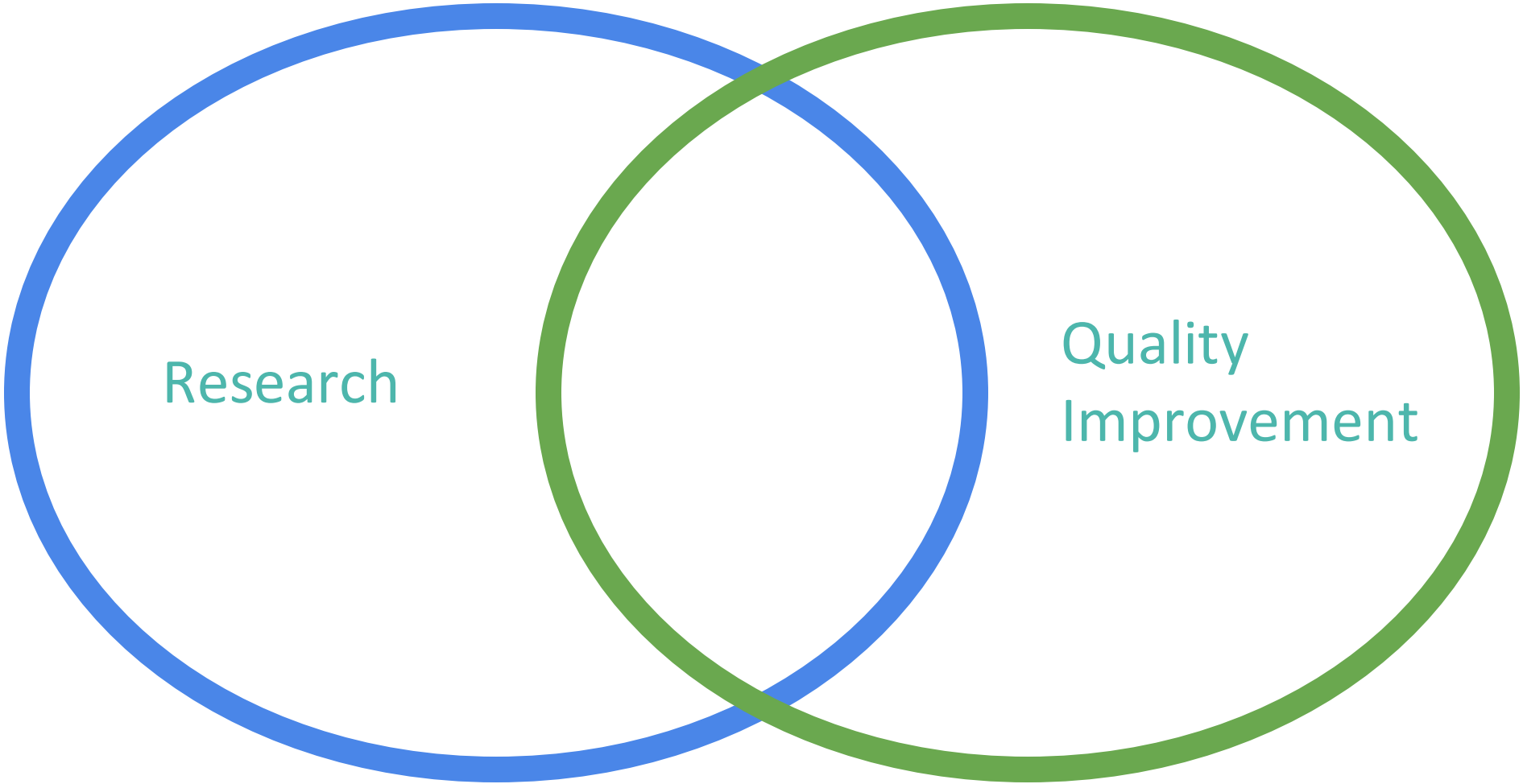
Summary

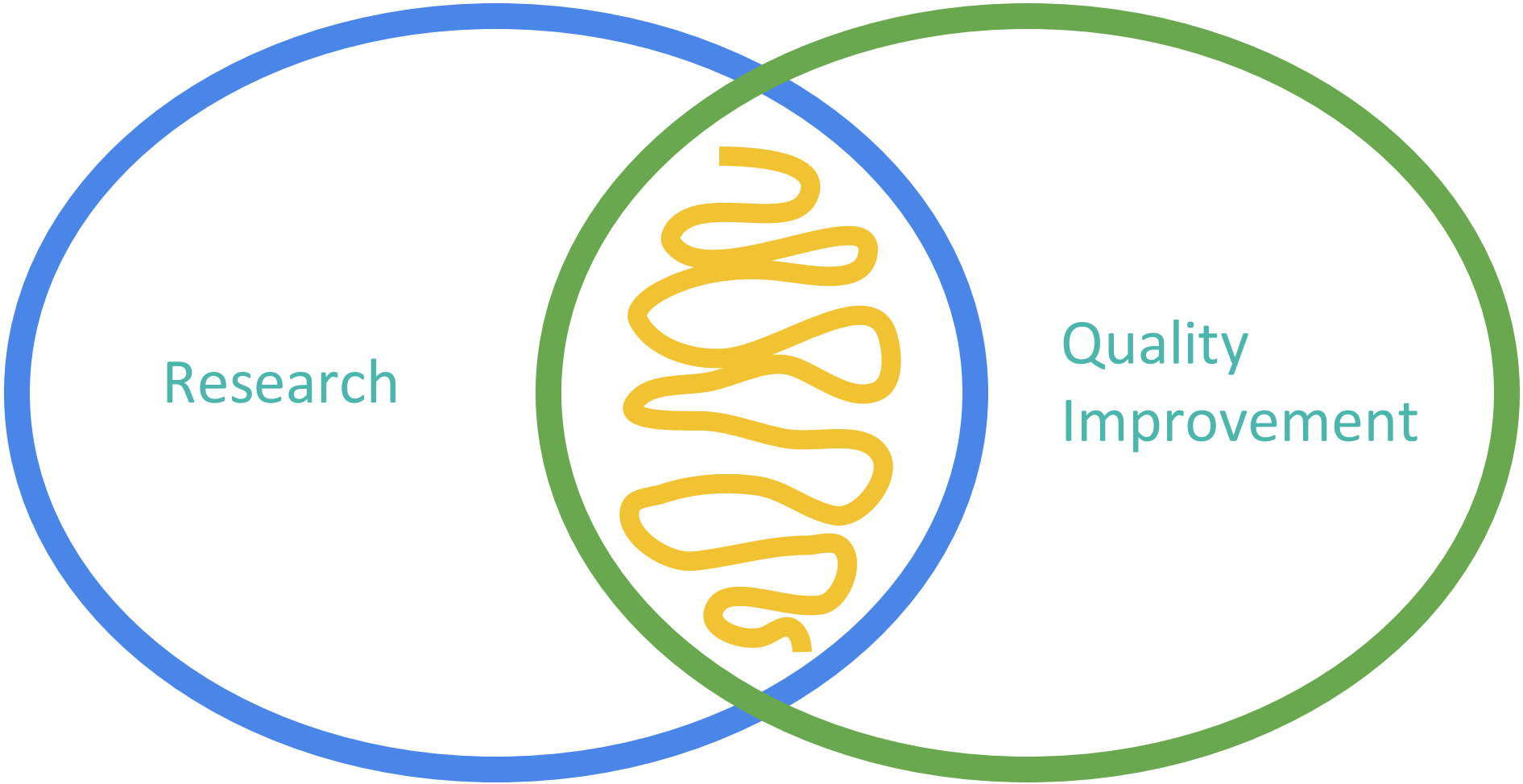
- Find a Gap
- Justify It as a Problem
- Appreciate the System and Find the Reasoning and Effects of the Process (Data Display)
- Develop an AIM / SMART Goal
- Define Your Measures
- Perform PDSA Cycles
- Gather, Present, And Interpret Your Data
- Share Your Data for All to Learn

BLURRED LINES IN SCHOLARLY ACTIVITY

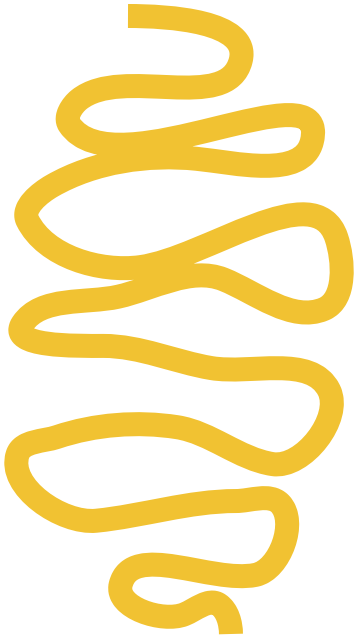

Research


Quality
Improvement


Research
Quality Improvement


Research
Quality
Improvement

Similarities / Overlap



- Systematic Investigation and Carefully Designed Project
- Analysis of Data
- New Intervention
- Present/Publish Data

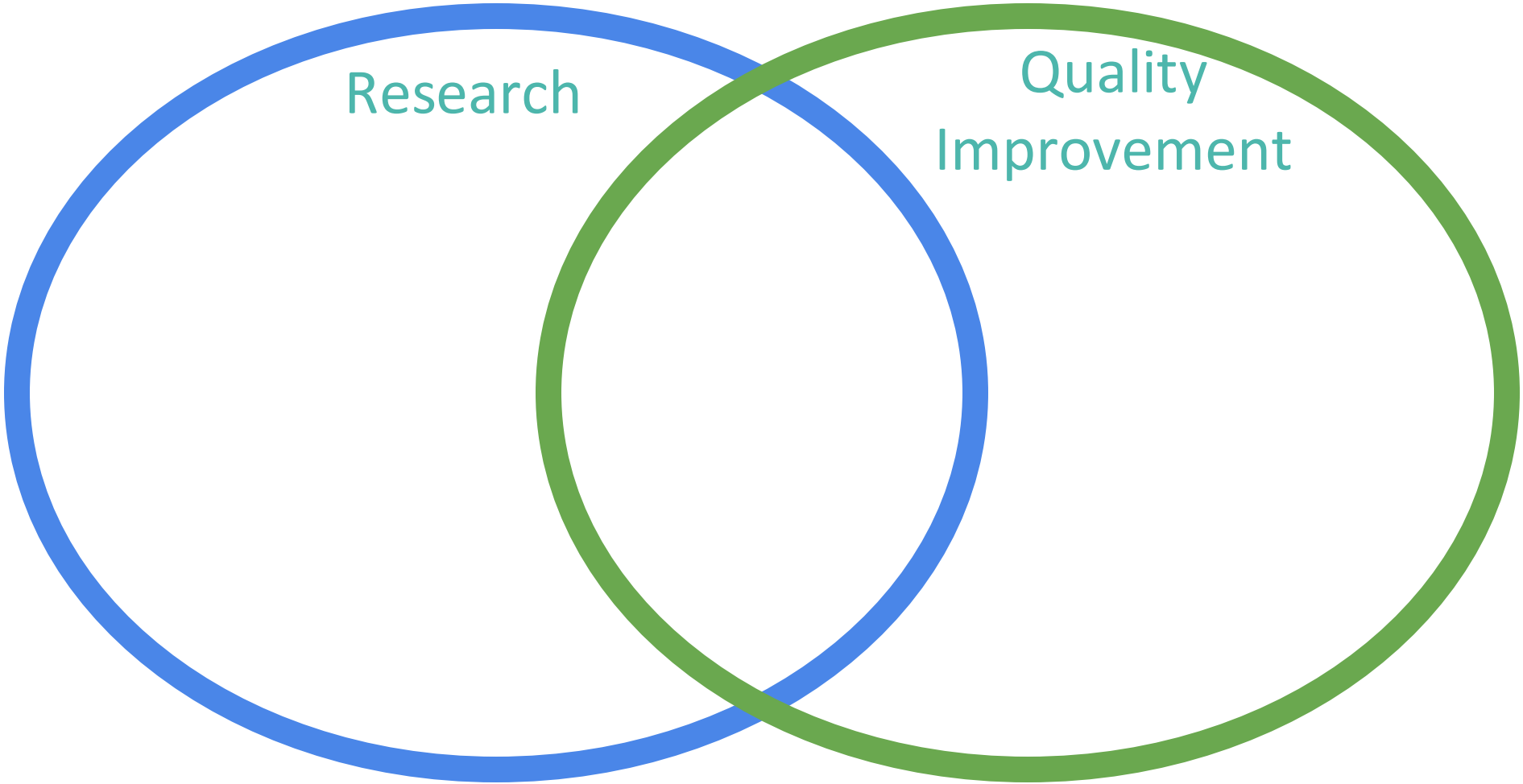
Differences

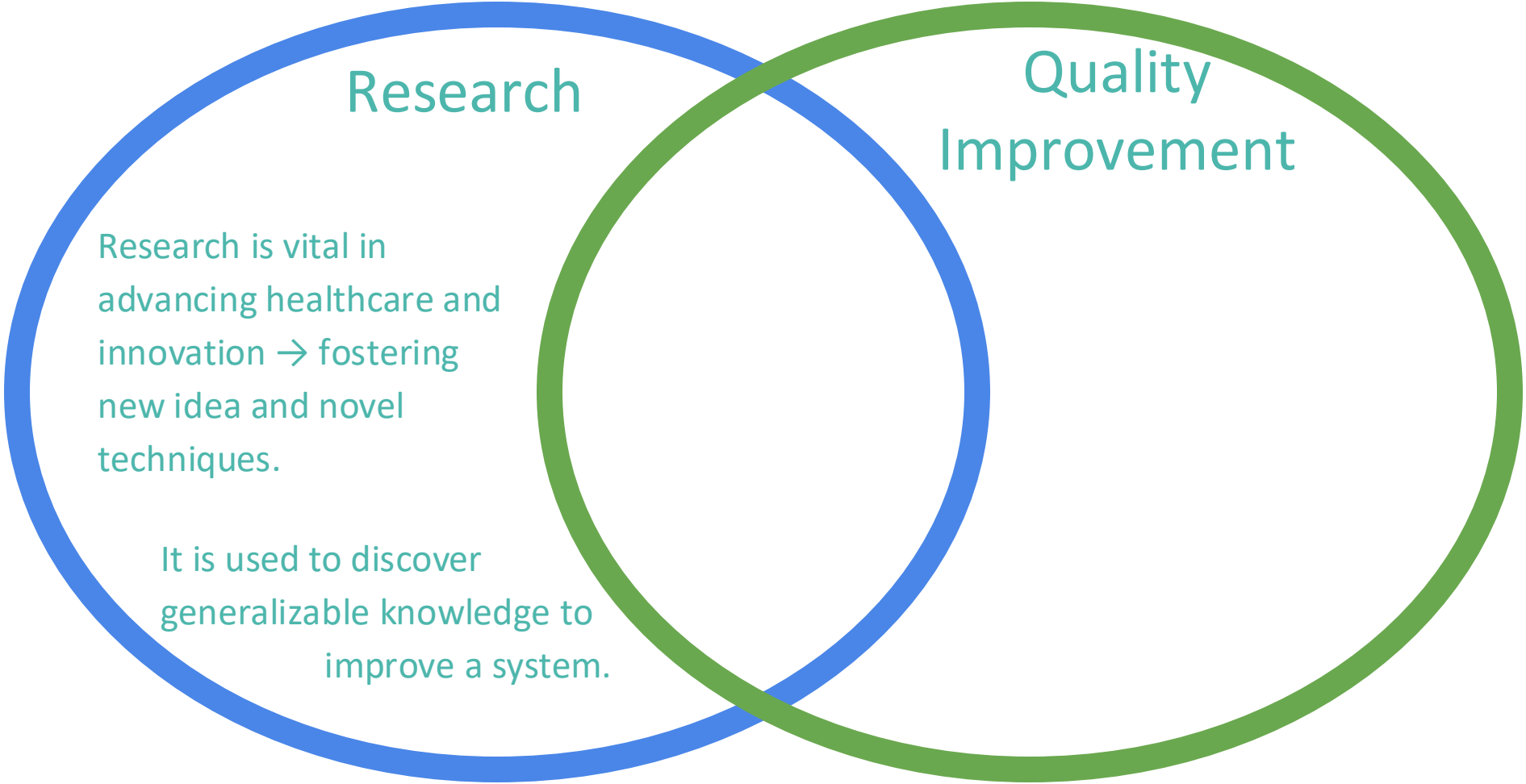
- QI flexible, changes, employ and respond to PDSA cycles
- Data analysis for workforce monitoring and safety
- Focus on safety, efficiency, cost effectiveness, etc.
- Proven elsewhere and accepted practices
- Focused on our population to serve their needs
- Directly benefit the immediate local implementation
- No increased risk of care
- Local focus applicability
- Reviews for permanently adopting a new practice and procedure

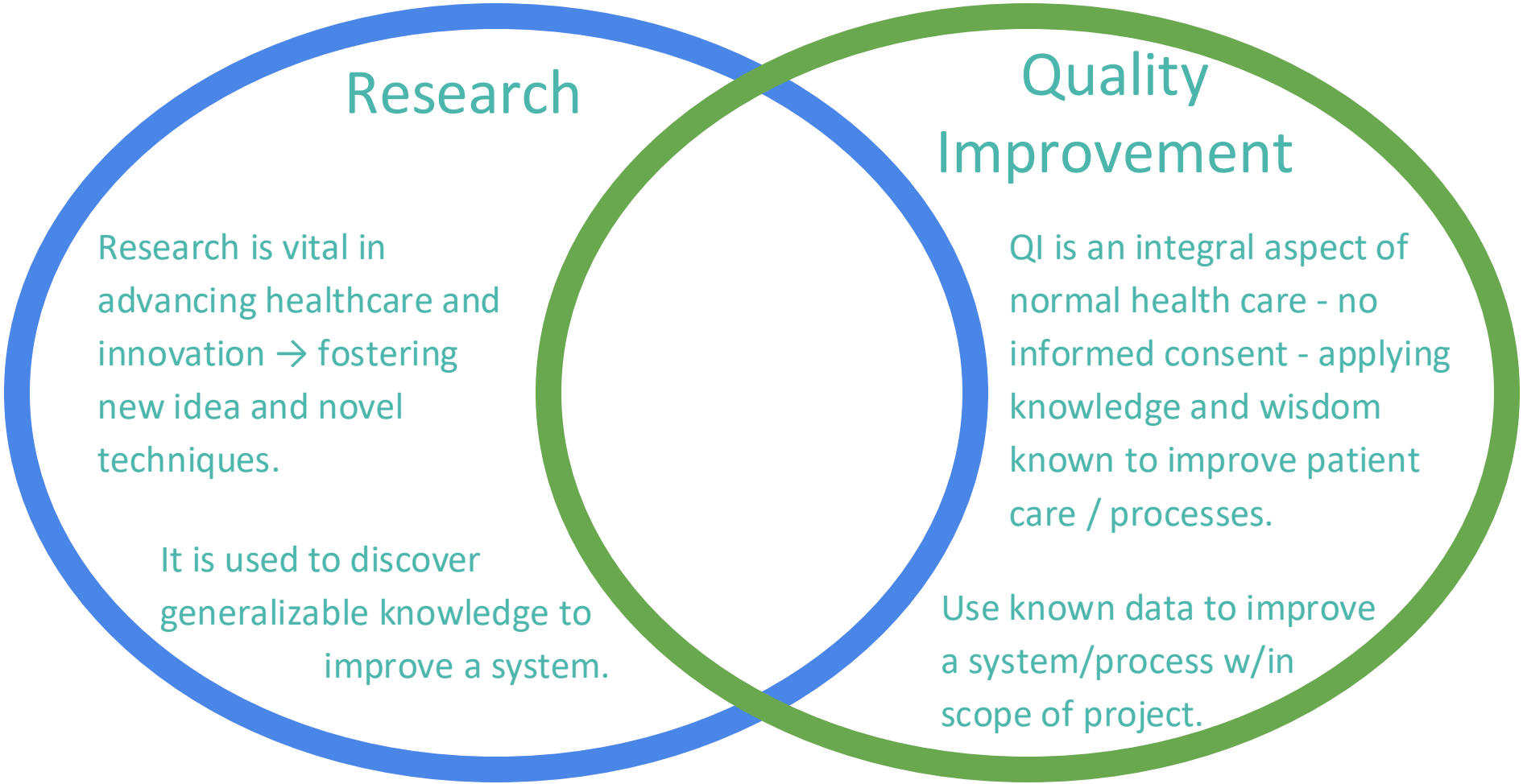
Quality Improvement

Differences - Simplified

- Flexible
- Safety Focus Monitoring
- Accepted Practice / Standard of Care Adjustment
- Tailored for Scope of Location of Implementation
- No question of improvement / No Risk (proven)
- Goal for new SOP / Standard Practice


Research
Quality
Improvement


Research
Quality Improvement
Research is vital in advancing healthcare and innovation → fostering new idea and novel techniques.
It is used to discover generalizable knowledge to improve a system.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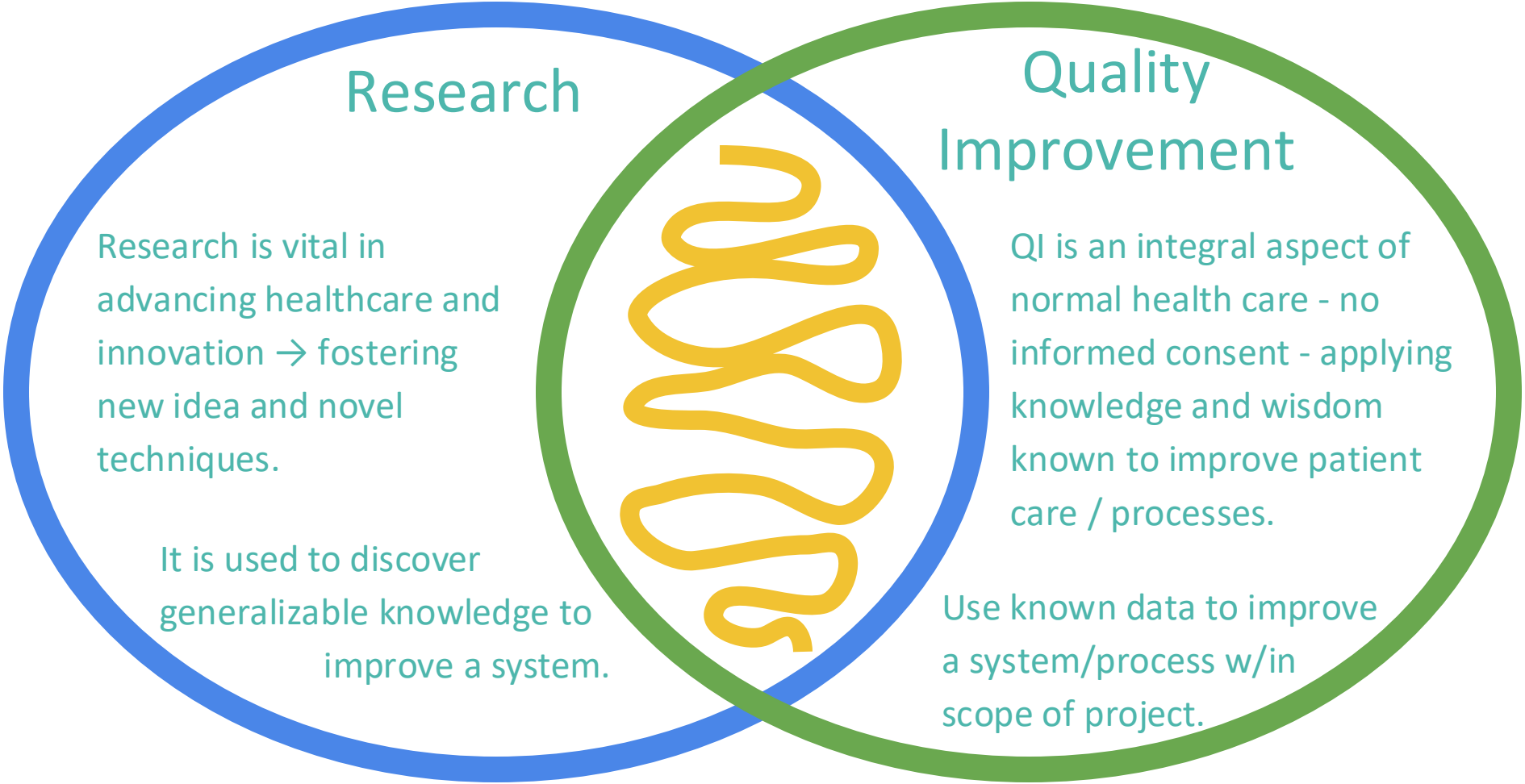
Quality Improvement
QI is an integral aspect of normal health care - no informed consent - applying knowledge and wisdom known to improve patient care / processes.
Use known data to improve a system/process w/in scope of project.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Use known data to improve a system/process w/in scope of project.

Similarities / Overlap from Data

Research = Discovery

Quality Improvement = Application

When these two aspects blend → the same data can be used, but IRB approval must be obtained for the Discovery portion or "analysis" if you are "assessing" a response to a change rather than "trending" an outcome over time.

- Implementing a new process and analyzing the data / response → Need IRB
- Implement new approach for goal of improvement not otherwise studied/proven → Need IRB
- New tool or quality assessment measurement → Need IRB
- Patient data use to develop new treatment guideline → Need IRB

Presentations & Publications

SQUIRE 2.0:

Don’t forget to cite it.

Quality Improvement

Never use the terms:
Analyzing, Assessing, Comparing

Use the terms:
Trending, Ensuring Safety, Evaluating efficiency / appropriateness over time

Presentations & Publications

SQUIRE 2.0:

Don't forget to cite it.

Quality Improvement

Data Display and Significance:

Common Cause vs. Special Cause Variation ← Run/Control Charts

https://pubmed.ncbi.nlm.nih.gov/38271315/ → *p* value pitfalls in QIPS

	Research Study	QI Project
Intent	Designed to develop, not generally to implement knowledge	Apply known solutions to a focused problem or process, typically related to cost, productivity, or quality
Design	Systematic, methodological approach to the scientific process	Less rigorous methodology, often involves a Plan-Do-Study-Act test of change
Setting	Single or multisite settings	Most often, a single setting and situation
Benefit	Greater scientific community and clinicians	Subjects involved in the QI project and the institution where the project was conducted
Generalizable findings	Yes	No
Oversight	Institution, IRB, government, and funding agencies responsible for the project	Institution where the project is being conducted
Subject risk	Variable, risks, and benefits	None or minimal
Informed consent	Requires informed consent	No informed consent
IRB required	IRB always required	IRB typically not required
Ethical justification	Ethically justified by weighting risks to individual vs societal benefits from the development of new knowledge	Considered an expectation by society for clinical practice to continuously improve
Dissemination plan	Publication and presentation reported as the IRB-approved research study	Internal communication, publication, and presentations reported as the QI work
(Gregory 2015)		

Quality Improvement & Patient Safety

The Topics

- Remembering the Why
- Steps of a QI Project
- A Difference in Significance
- Blurred Lines in Scholarly Activity

Quality Improvement & Patient Safety

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AKA:

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- Understand the Difference between Research Studies and Quality Projects

Thank You!