Incorporating QI Into Practice

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Objectives

• **Introduce** the PDSA model for change as an example of one QI methodology

• **Incorporate** the PDSA model into your pediatric office setting

• **Integrate** results of PDSA cycles into actual clinical practice

• Discuss **IRB** issues with QI vs. research
What is PDSA

- Common sense approach to change and improvement
  - Three fundamental questions, which can be addressed in any order
- It is not complicated
- Manageable – big ideas tested on a small scale
- Cycles happen quickly
  - allows for successive cycles and sustainable change
- Guides the test of a change to determine if the change is an improvement

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The PDSA Cycle for Improvement

**Act**
- What changes are to be made?
- Next cycle?

**Plan**
- Objective
- Questions/predictions
- Plan to carry out the cycle (who, what, where, when)
- Plan for data collection

**Study**
- Complete the analysis of the data
- Compare data to predictions
- Summarize what was learned

**Do**
- Carry out the plan
- Document problems and unexpected observations
- Begin analysis of the data

Source: Nolan
Repeated use of the cycle to TEST changes

Changes that result in Improvement

Big Idea

Time

Source: D. Berwick
PDSA in Practice

Practical

• Time crunch in practice – pressure to see more
• Research experience
• Personal interest
PDSA in Practice

Doable

- 1-2 week cycles
- Immediate results
- Repeat cycles
PDSA in Practice

Straightforward

• No expensive equipment
• Measurement tools (few needed)
• No IRB (unless plan to present outside)
PDSA in Practice

Applicable

• Across specialty interests
• Required by American Board of Pediatrics for MOC
QI vs. Research

Navigating the Slippery Slopes and The Gray Areas While Staying in Compliance With the OHRP
Data collection:

- Number of catheter-related bloodstream infections
- Number of catheter-days
- Data aggregated into quarterly reports of number of infections per 1000 catheter-days
- Infection rates compared between baseline, during implementation, and after implementation
• Findings:
  – Median (mean) rate of catheter-related infection:
    • 2.7 (7.7)/1000 catheter-days at baseline
    • 0 (2.3)/1000 catheter-days at 3 months after intervention
    • 0 (1.4)/1000 catheter-days 18 months after intervention
The Results of this QI Effort:

- Reduced catheter-related infections after implementing the procedures/checklists
- National acclaim for the project leader
- Publication in New England Journal of Medicine
- Investigation by the federal Office of Human Research Protection (OHRP)
- Conclusion by the OHRP that the Johns Hopkins IRB was incorrect in exempting the “study” from IRB review or informed consent
- Suspension of the trial by the Johns Hopkins IRB
When Does QI Become Research?

• **Research:**
  – Systematic investigation
  – Includes development, testing, and evaluation
  – *Designed to develop or contribute to generalizable knowledge*
  – Implies a knowledge-seeking enterprise that is independent of routine medical care
    • *People should be able to choose whether or not they participate in research*
When Does QI Become Research?

- **Quality Improvement**
  - An ongoing process undertaken as a consequence of health care providers’ responsibility to serve their patients interests
  - Integral to, not independent of, clinical care
  - Designed to bring about immediate improvements in care
  - Employs evidence from research and practical experience
  - Often requires repeated modifications as experience accumulates
  - As a general rule, QI projects are likely to present minimal risk to participants
What is the IRB Role with Regard to QI?

• The IRB is charged with the responsibility of protecting human research subjects, including workers, without impeding Quality Improvement activities

• Patient rights to privacy must be maintained as well
What is the IRB Role with Regard to QI?

- Determine whether a project constitutes human subjects research
- Determine whether a project is exempt from IRB review
- Provide expedited review for projects that qualify
- Determine whether informed consent can be waived
- You can make the IRB’s job easier by knowing the criteria
Human subjects research covered by 45 CFR 46:
- Designed to develop generalizable knowledge
- Involves living people
- Involves private information

http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c2
Some types of research that may be exempt from review:

- Conducted in commonly accepted settings
- Surveys, interviews, observations
- Existing data
- Examines public benefit or service programs

http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c2
For expedited review:
- Minimal risk
- Not classified research
- Identification of subjects would not put them at risk of liability
- Meets specific criteria outlined by OHRP

http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c2
To waive informed consent:

- Minimal risk
- Does not compromise patient rights
- Impractical to do with consent
- When appropriate, notify subjects with written statement

http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c2
The Slippery Slope

• As the discipline of QI becomes more advanced, there is a natural progression in terms of complexity, size, and scientific rigor of the projects.

• A successful QI project may generate some knowledge that can benefit other/larger cohorts.

• Publication in the peer reviewed medical literature may ultimately result in improved quality for more people, but may also change the perception of the project from QI to research.
Important Questions

• Can QI research be ethical without obtaining informed consent?
  – For most QI projects, interventions are evidence-based, with a goal of improving safety or outcome
  – Interventions can be implemented as part of clinical care without measuring outcome
  – In many QI projects, the greatest “risk” to the patients may be the time and effort required to go through the informed consent process
Important Questions

• Is IRB review appropriate for most QI projects?
  – Needing IRB review of every QI project would likely discourage important QI initiatives
  – The nature of QI is to change with each iteration; IRB would need to review each time the “study” changed—impractical, if not impossible
  – Most IRB’s are not equipped to review every QI project
What About HIPAA?

- Protected Health Information (PHI) as defined under HIPAA cannot be disclosed except for certain exceptions.
- Among these are:
  - Waiver by an IRB under certain conditions
  - A preparatory review for the purposes of research (under certain conditions)
  - Use for treatment, payment, and health care operations
- QI (but not research) is included in “health care operations”
What To Remember

• In most circumstances, QI projects can (and should) be done without IRB review

• Some exceptions:
  – Greater than minimal risk
  – The expectation *a priori* that the project will generate generalizable information or will be published
  – The project involves a vulnerable population
Keys For Success

- Communicate beforehand with representative from IRB
- Recognize goals that may change the perception of the QI project
  - Publication
  - Presentation (outside your institution)
Next steps

• Brainstorm with your team Quality projects that might benefit your patients or improve the delivery of the care.

• If you find the project falls into addressing access or BMI these will qualify for certification through the SC QTIP program.

• Other project ideas may be able to receive MOC part 4 credit from the ABP as a group project. See ABP website for information.
Design the project using the attached work sheets and do at least 3 cycles (Baseline plus 2 change cycles) and graph the results with the description of the process and send those to Francis Rushton for feedback and he will be able to certify them for MOC part 4 or have you modify to be able to receive credit.
Let's Brainstorm Ideas!