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# The I's Have It: Incorporating a QI Curriculum into Pediatric Residency Training

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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 curriculum
- ***Integrate*** results of PDSA cycles into actual clinical practice
- Discuss ***IRB*** issues with QI vs. research



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“an ethos of ongoing reflection for the purpose of improved quality of care for patients should permeate every aspect of training to reinforce the need for trainees to adopt this practice as a lifelong habit”

– *Companion Document Pediatric Program Requirements*



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Each residency program must document that residents acquire the skills to analyze and improve the quality of their practice.

- participation in QI activities
- Plan-Do-Study-Act cycle described by Berwick, et al provides a practical model

# What is PDSA



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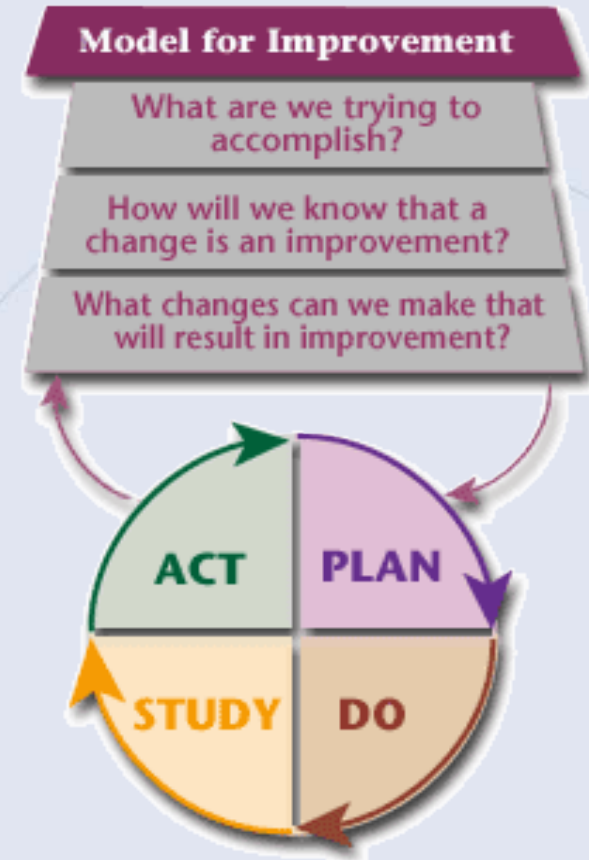
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- **Common sense approach to change and improvement**
  - **Three fundamental questions, which can be addressed in any order**
- It is not complicated
- Manageable – big ideas tested on a small scale
- Cycles happen quickly
  - allows for successive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



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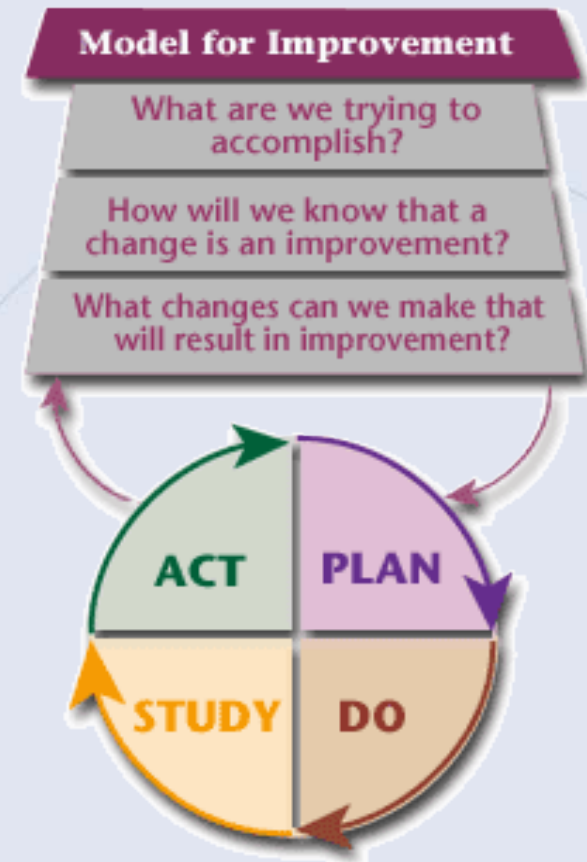
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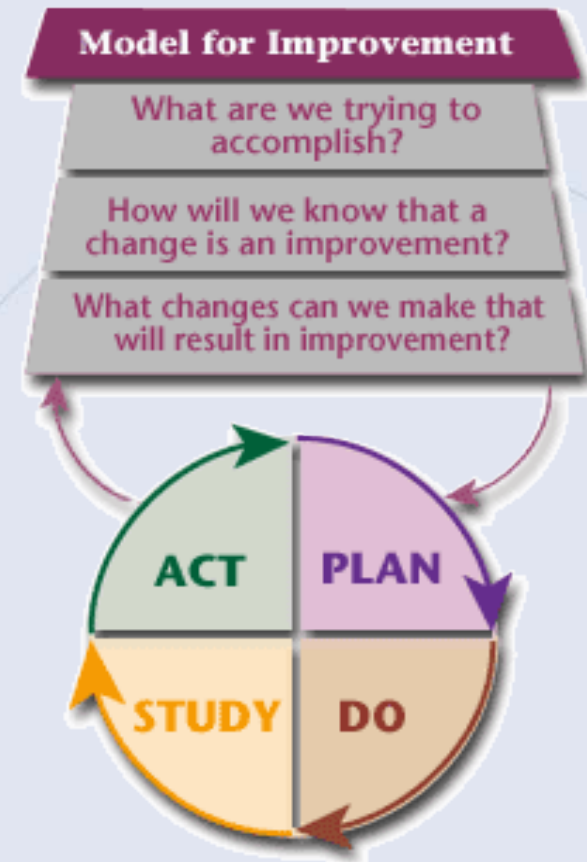
# What is PDSA



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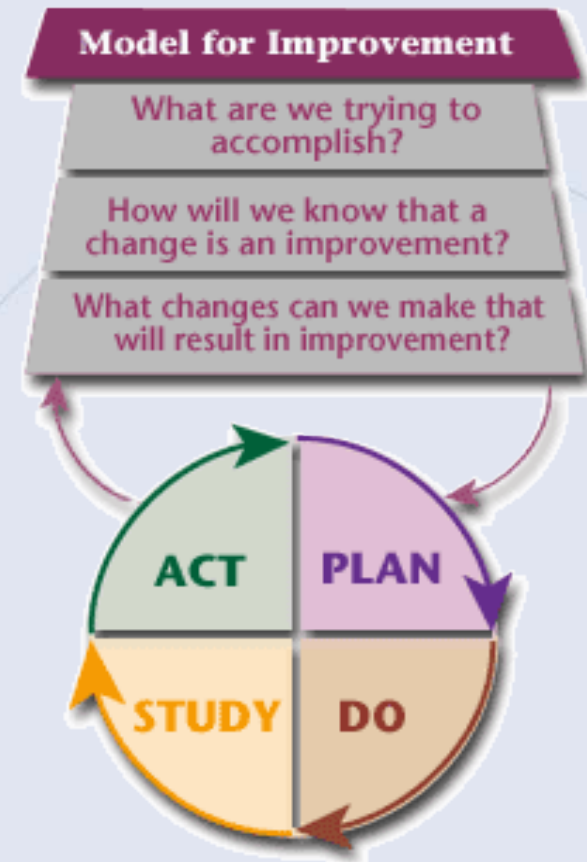
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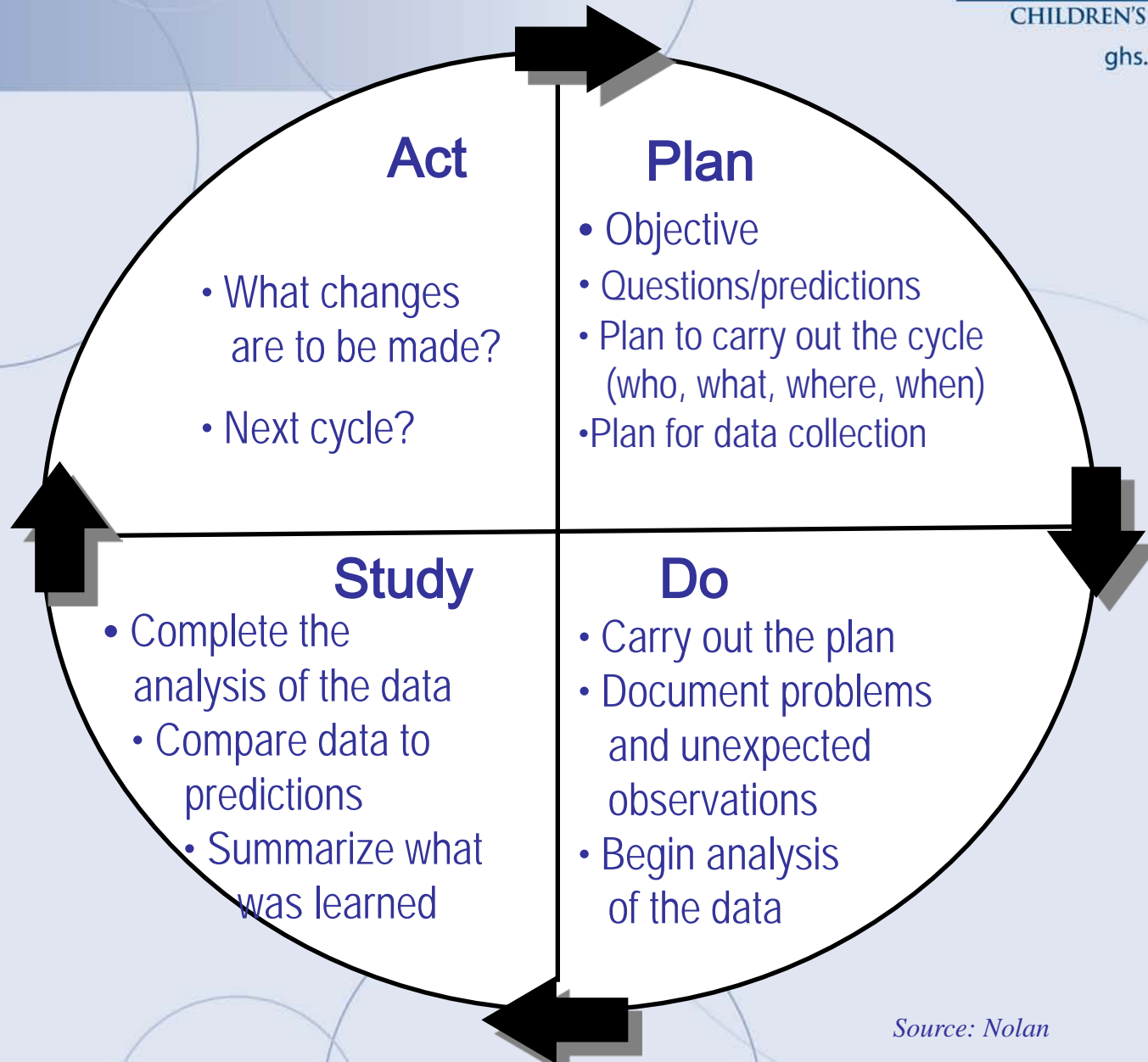


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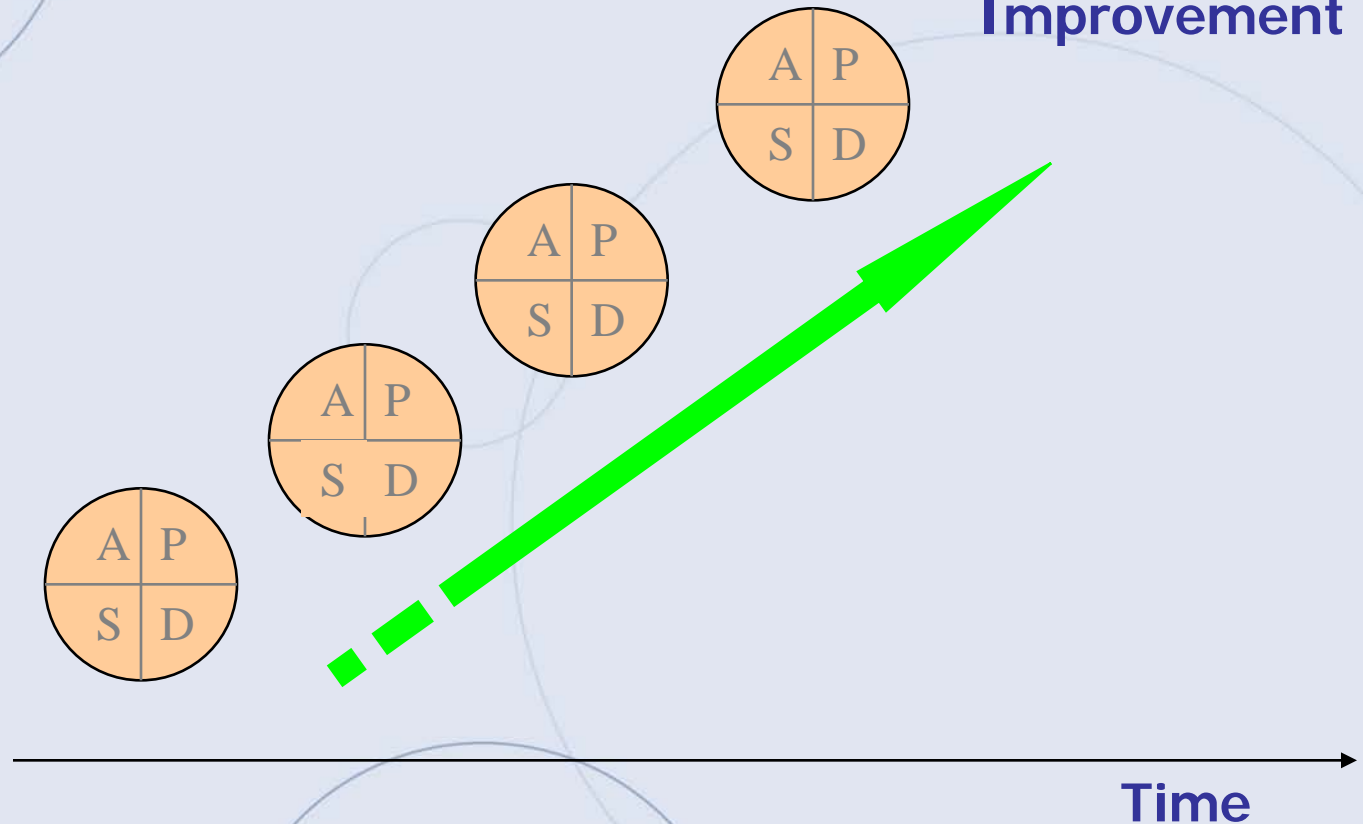
# The PDSA Cycle for Improvement



# Repeated use of the cycle to TEST changes

Changes that result in Improvement

Big Idea

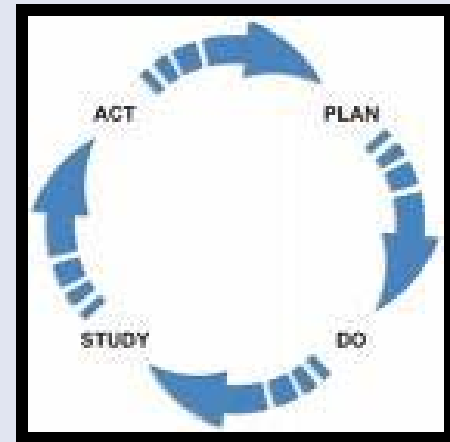


Source: D. Berwick

# PDSA in Residency

## Practical

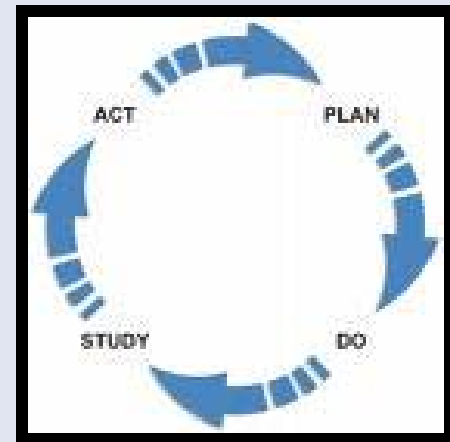
- Work hour limits
- Research experience
- Personal interest



# PDSA in Residency

## Doable

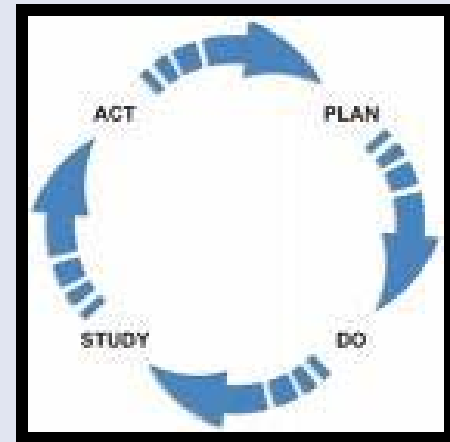
- 1-2 week cycles
- Immediate results
- Repeat cycles



# PDSA in Residency

## Straightforward

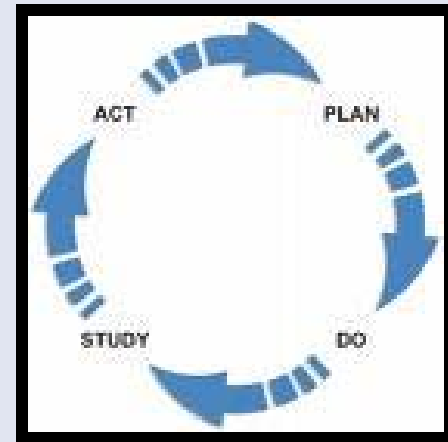
- No expensive equipment
- Measurement tools (few needed)
- No IRB (unless plan to present outside)



# PDSA in Residency

## Applicable

- Across specialty interests
- Required by ACGME
- Required by American Board of Pediatrics



# QI Curriculum History

## 2003



- Proposal: Development of a Senior Research Project
- For 2003-2004, limited to NICU/NBN, with subsequent expansion to other subspecialties
- Scope: Self-directed research on a pediatric medicine topic
- Purpose: Broaden understanding of evolving clinical practice issues
  - Utilize practice-based and evidence-based learning
  - Develop interpersonal communication skills needed for effective information exchange with health care professionals and ancillary staff
  - Gain experience in examining the impact that patient care issues have upon a larger health care system

# Senior Project Plan



- **Newborn Nursery Senior Resident Projects**
- Individual topics identified at start of year
- Resident-driven, while on nursery rotation
- Expectation of formal presentation to Nursery Committee
- Working group includes:
  - Senior resident
  - Nursery Director
  - Neonatologist
  - Nursing staff from Nursery and NICU
  - Other personnel as needed (social work, PT/OT)

# Senior Project Procedure



- Define current Nursery and NICU practice at GHS
- Identify any applicable guidelines or standards of care
  - AAP, CDC, ACOG
- Obtain related or similar protocols from other institutions
- Research applicable medical literature on the subject
  - Medical textbooks
  - Cochrane database
  - Web searches
- Obtain institutional data relating to the subject
  - Staff workload issues
  - Laboratory data
  - Billing information

# Senior Project Procedure

- Draft a unified hospital protocol or guideline for managing infants in both the NBN and NICU with relation to the subject
  - Utilize approved hospital template
  - Cite applicable resources
  - Circulate draft to appropriate persons for feedback
- Present draft to Nursery Committee
- Amend draft as required
- Assist with planning of educational and in-service issues
  - Clinical nursing staff
  - Practicing physicians
  - Residents

# Senior Project Plan



- Topics for 2003-2004:
  - Hypoglycemia screening
  - Hyperbilirubinemia screening
  - Tachypnea management
  - Infant feeding policies
  - High risk infant/drug screening
  - Circumcision policy
  - Sepsis screening
  - Premature infants in the level 1 nursery
  - Paternal education classes

# Completed Projects

- Pain control policy for newborns
  - Oral sucrose solution
  - Researched dosing and hospital cost
  - Defined painful procedures
  - Identified appropriate pain scale
  - Education for nursery staff
  - Facilitated product purchasing
  - Policy currently in use
  - Attitude change regarding pain control overall

# Completed Projects

- Hypoglycemia Screening Policy
  - Narrowed list of infants at risk
  - Eliminated universal glucose screening
  - Defined hypoglycemia, borderline, normal
  - Nursing protocol reduced physician calls
  - Overall reduced number of infants tested
  - Aligned Nursery and NICU definitions
  - Currently still in place

# Completed Projects



- Circumcision Policy
  - Emphasized AAP stance (neutrality)
  - Addressed mandatory issues not well-practiced
    - Pain control
    - Informed consent
    - “Time Out”
    - Documentation requirements on operative note
  - Recommended exclusions
    - Included medical conditions and age
  - Defined postoperative observation and care

# Completed Projects

- Newborn History and Physical Form
  - Replaced outdated form
  - Added new clinical information
    - Feeding method and mother's language
    - Maternal GBS status and antibiotics given
  - Documented
    - Intake information gathered
    - Daily progress notes
    - Specific discharge teaching provided
  - Formatted for barcoding and converted to e-Form
  - Currently in use

# Other Completed Projects



- Tachypnea Management Guideline
- Infants At Risk for Sepsis
- Management of Preterm Infants in the Level 1 Nursery

# Moving Forward



- Difficulty expanding to other areas without a willing mentor
  - Successful in clinic but less so in other areas
- Needed a formalized process applicable to all clinical areas of pediatrics
- Needed to incorporate quality improvement language and procedures
- Needed consistently measurable outcomes
- Anticipated new ABP requirements
- Desire to showcase resident work

# GHSUMC Experience



- QI teaching/projects begin 2006-2007
  - Basic instruction in PDSA to 3rd year class
  - Participation in SCDHEC training
  - All graduates complete PDSA cycles
    - Presented at Pediatric Grand Rounds
    - Sustained change documented

# GHSUMC Experience



- Smoking Cessation
- Obesity (BMI measurement)
- Post Partum Depression Screening
- Asthma Guidelines
- Formal Developmental Screening

# GHSUMC Experience



- QI teaching/projects continues 2007-2008
  - Incorporated into noon conference
  - Faculty mentoring for senior residents
  - All graduates complete PDSA cycles
    - Presented at Pediatric Grand Rounds
    - Continued sustained change
      - Longitudinal projects from previous year

# GHSUMC Experience



- QI teaching/projects continues 2008
  - Change from PGY 3 to PGY 2
    - further development of PDSA cycles to expand into broader scholarly work
  - Required presentation at SC chapter of the American Academy of Pediatrics annual meeting
  - Encouraged other outside presentations

# GHSUMC Experience



- QI teaching/projects continues 2008 - current
  - All residents complete PDSA or equivalent project and present at SCAAP
  - 2 projects presented at SCAHEC Research Symposium
    - 1st place in QI category
    - 3rd place in Original Research category
  - 3 projects invited to be presented at SCAAP CATCH meeting January 2009
  - 1 project accepted at National Meeting

# Continued Challenges



- Faculty understanding of the PDSA cycle change concept
- Sustainability of projects
- Seamless incorporation into curriculum



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# QI vs. Research

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

# An Example



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## *The* NEW ENGLAND JOURNAL *of* MEDICINE

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### An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU

Peter Pronovost, M.D., Ph.D., Dale Needham, M.D., Ph.D., Sean Berenholtz, M.D., David Sinopoli, M.P.H., M.B.A., Haitao Chu, M.D., Ph.D., Sara Cosgrove, M.D., Bryan Sexton, Ph.D., Robert Hyzy, M.D., Robert Welsh, M.D., Gary Roth, M.D., Joseph Bander, M.D., John Kepros, M.D., and Christine Goeschel, R.N., M.P.A.

# An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU



- In 2003, all Michigan hospitals with ICU's were invited to participate in a project to reduce the rate of catheter-related bloodstream infection in the ICU setting
- Involved implementing five evidence-based procedures recommended by the CDC:
  - Hand washing, full-barrier precautions during catheter insertion, cleaning skin with chlorhexidine, avoiding femoral site, removing unnecessary catheters
  - Procedures were reinforced by following a checklist

# An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU

- 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

# An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU

- 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

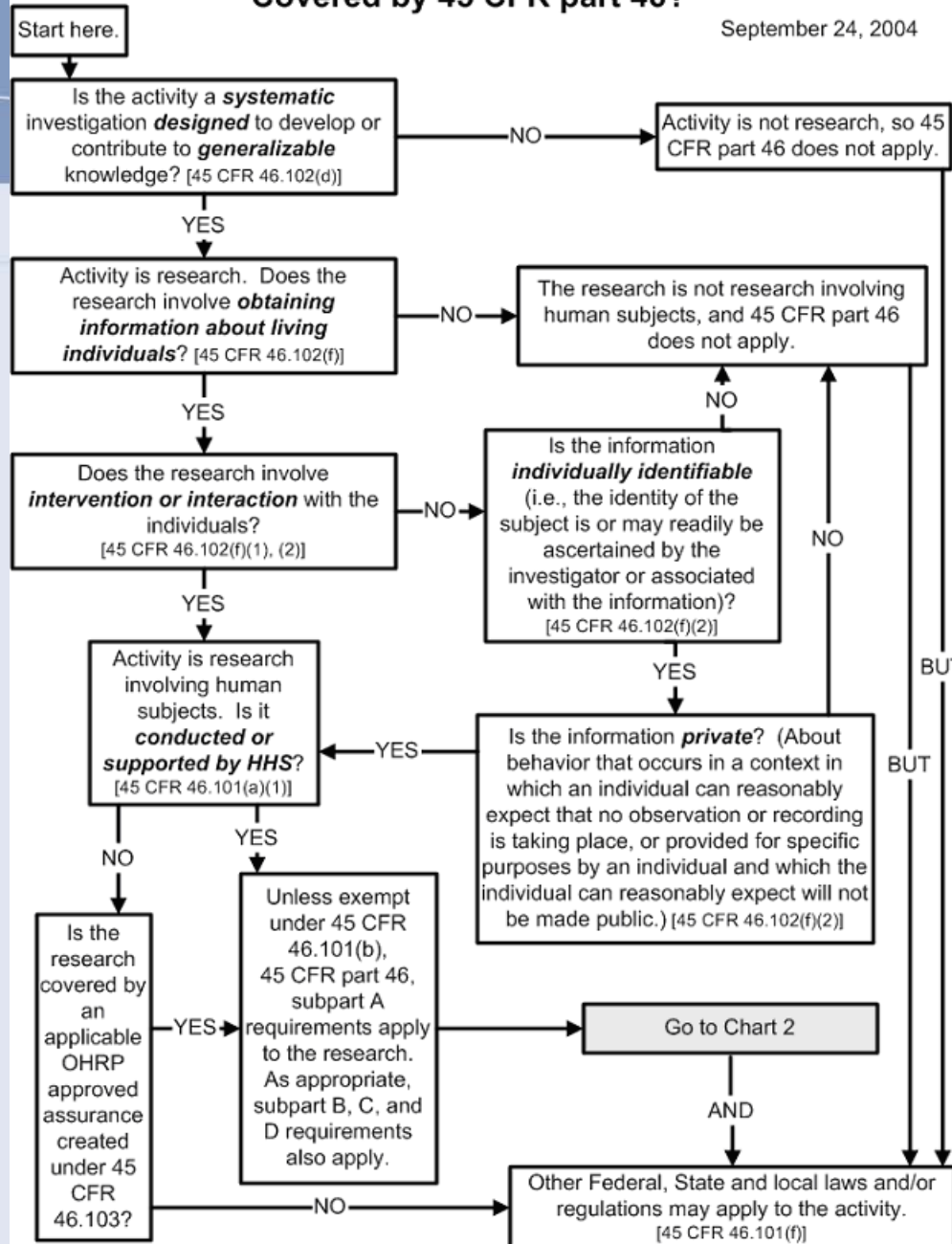
# What is the IRB Role with Regard to QI?



- 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

# Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

September 24, 2004



## 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>

## Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

From Chart 1

September 24, 2004

Has HHS **prohibited** exemption of the human subjects research?  
(All research involving prisoners, some research involving children.)

[Footnote 1 to 45 CFR 46.101(i), 45 CFR 46.401(b)]

NO

Will the **only**\*\* involvement of human subjects be in one or more of the following categories?

\*\* **"Only"** means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is **not** exempt.

Research conducted in **established or commonly accepted** educational settings, involving **normal education practices**?

YES

Exemption 45 CFR 46.101(b)(1) may apply.

Go to Chart 3

AND/OR

Research involving the use of **educational tests, survey procedures, interview procedures, or observation of public behavior**?

YES

Exemption 45 CFR 46.101(b)(2) or (b)(3) may apply.

Go to Chart 4

AND/OR

Research involving collection or study of **existing** data, documents, records, or pathological or diagnostic specimens?

YES

Exemption 45 CFR 46.101(b)(4) may apply.

Go to Chart 5

AND/OR

Research studying, evaluating, or examining **public benefit or service programs**?

YES

Exemption 45 CFR 46.101(b)(5) may apply.

Go to Chart 6

AND/OR

Research involving **taste and food quality evaluation** or **consumer acceptance studies**?

YES

Exemption 45 CFR 46.101(b)(6) may apply.

Go to Chart 7

NO

YES

No exemptions to 45 CFR part 46 apply. Provisions of 45 CFR subpart A apply, and subparts B, C and D also apply if subjects are from covered vulnerable populations.

Go to Chart 8



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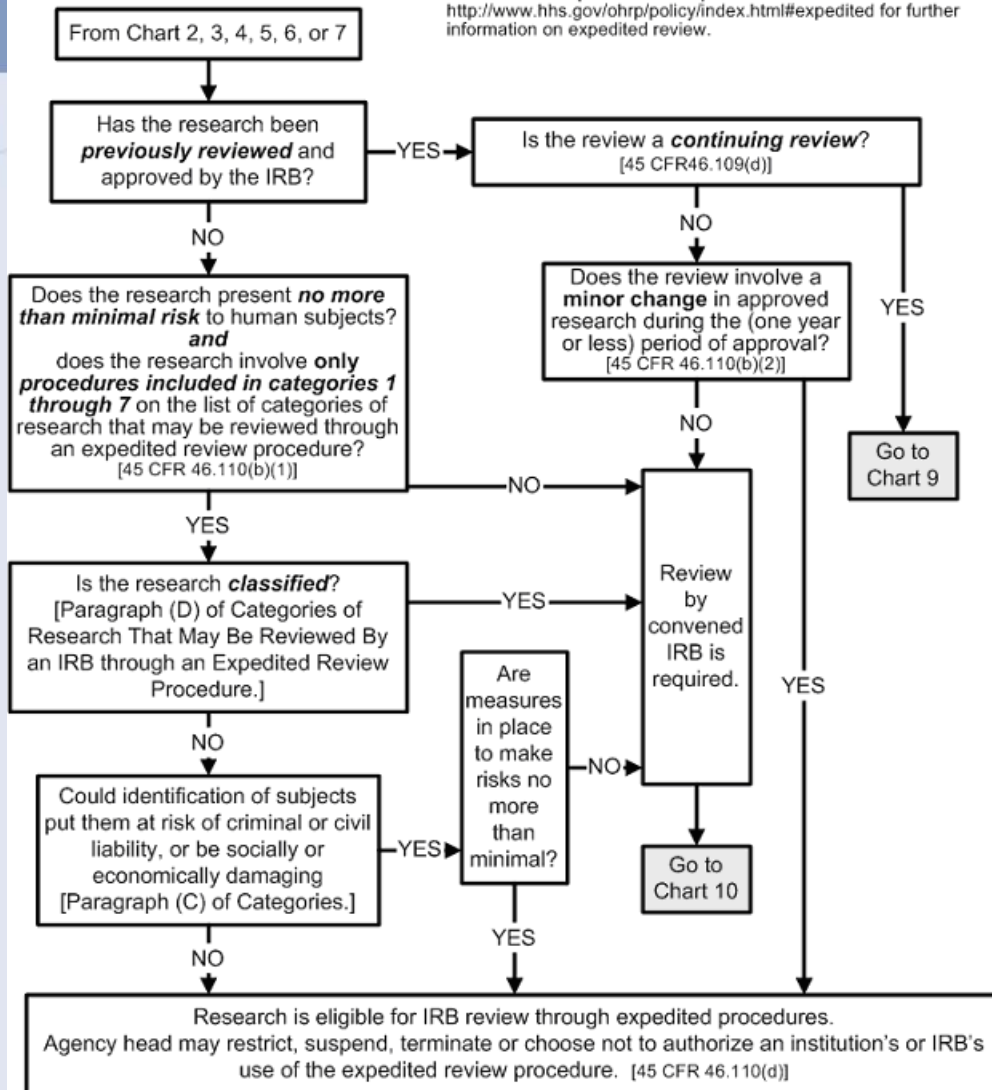
Some types of research that may be exempt from review:

- 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>

## Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?\*

\* Note: See expedited review categories and OHRP guidance on the use of expedited review procedures at <http://www.hhs.gov/ohrp/policy/index.html#expedited> for further information on expedited review.



September 24, 2004



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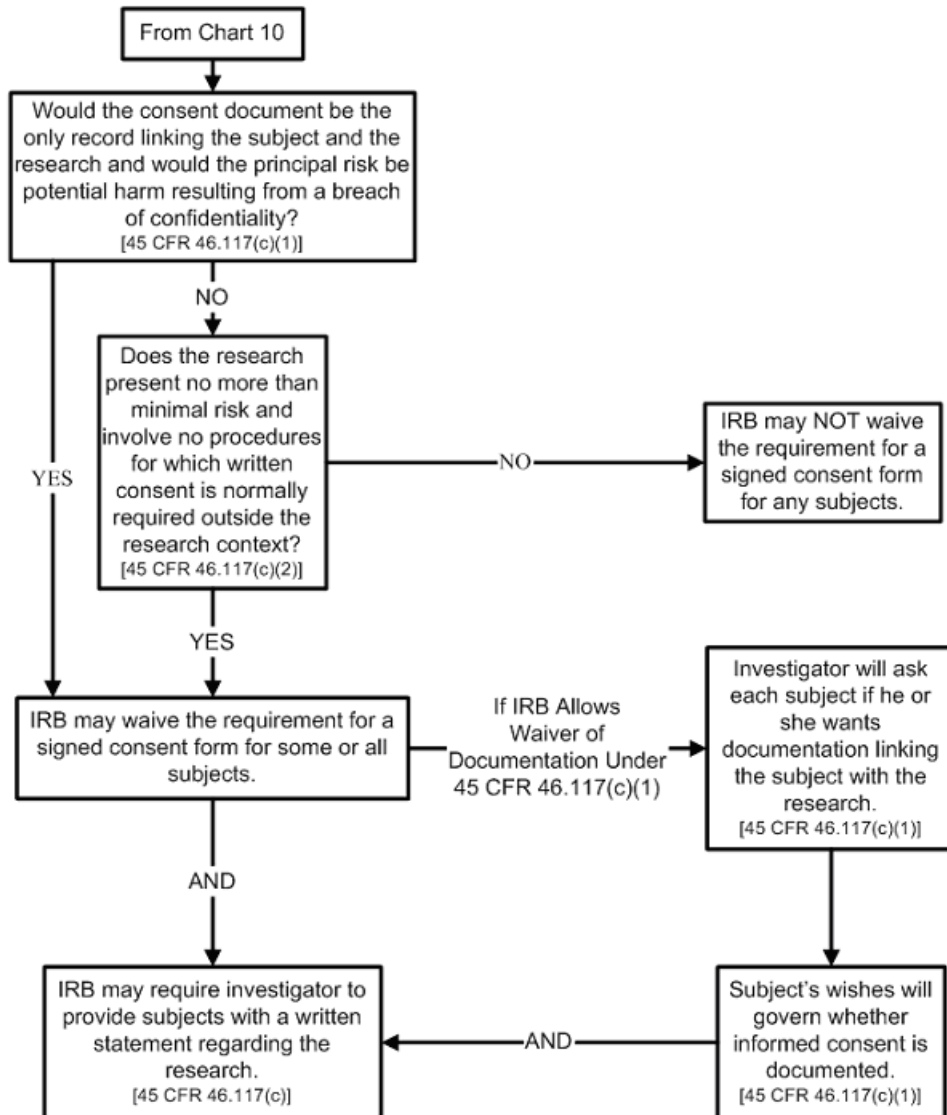
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For expedited review:

- 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>

**Chart 11: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?**



September 24, 2004

## 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



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# 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”

# Return To The Example:

What Could Have Been Done Differently?

- By the investigator:
  - The project could have been submitted as a research project rather than QI project
- By the JHU IRB:
  - Could have taken full or expedited review
  - Likely would have ruled that it met the conditions for waiving informed consent
- By the OHRP:
  - Recognizing earlier that informed consent was not necessary or feasible

# 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)
- Consider steps for consolidating any IRB submissions

# References



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- Office for Human Research Protections, U.S. Department of Health and Human Services. Code of Federal Regulations, Title 45, Part 46 (Protection of Human Subjects). <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101>
- Office for Human Research Protections, U.S. Department of Health and Human Services. Human subject regulations decision charts. <http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>
- Lynn J, et al. The ethics of using QI methods to improve healthcare quality and safety. Hastings Cent Rep 2006;36:S1-40

# Next Steps



- Quality Improvement collaboration with Levine Children's Hospital
- Continued Faculty Development on change concepts
- Recruitment of faculty mentors and champions of change

# Final Thoughts

- Teaching QI in residency provides young physicians skills they will need for maintenance of certification
- May improve pay for performance measures for faculty
- Better understanding of hospital quality measures in the academic setting