Choosing a QI/KT topic

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Today’s session

• To recognize differences between QI and clinical trial research
• To understand considerations for choosing a QI topic
• To understand how to formulate a QI question
• Review some funding sources
• Group exercise and discussion
Review of Quality Improvement/Knowledge Translation and differences between QI and clinical trial research

What is Knowledge Translation?

“T2” Translating research into practice:
   – ensuring new treatments & research knowledge
     actually reach the patients or populations for whom they are intended
       and
     are implemented correctly (JAMA 2008;211-3)

GOAL: improvement in patient care and patient outcomes
QI vs. clinical trial research

**Phase I, II, III trial goals:**
- Safety
- Efficacy
- Effectiveness
- Comparative effectiveness

**QI goals:**
- Enhance implementation of effective therapies
- Change clinician behavior → improvement in patient care and patient outcomes
- Improve care process/delivery system

**Major difference:** QI is implementation of what has worked in controlled trial to real life setting—thinking through and understanding the mechanisms of action and processes critical.

Both are systematic but purpose of research is to develop *generalizable knowledge* while purpose of QI is to implement to *directly* benefit system, setting, or program

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**How does QI differ from research?**

Both research and quality improvement are systematic investigations that may involve human participants but they differ in important ways. The table below is based on information adapted from The Ethics of Using QI Methods to Improve Health Care (Quality and Safety link is external)

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Human Subjects Research</th>
<th>Quality Improvement</th>
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<tbody>
<tr>
<td>Designed to develop or contribute to generalizable knowledge</td>
<td>Designed to implement knowledge, assess a process or program as judged by established/accepted standards</td>
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| Starting Point | Knowledge-seeking is independent of routine care and intended to answer a question or test a hypothesis | Knowledge-seeking is integral to ongoing management system for delivering health care |

| Design | Follows a rigid protocol that remains unchanged throughout the research | Adaptive, iterative design |

| Benefits | Might or might not benefit current subjects; intended to benefit future patients | Directly benefits a process, system or program; might or might not benefit patients |

| Risks | May put subjects at risk | Does not increase risk to patients, with exception of possible patients' privacy or confidentiality of data |

| Participant Obligation | No obligation of individuals to participate | Responsibility to participate as component of care |

| Endpoint | Answer a research question | Improve a program, process or system |

| Analysis | Statistically prove or disprove hypothesis | Compare program, process or system to established standards |

| Adoption of Results | Little urgency to disseminate results quickly | Results rapidly adopted into local care delivery |

| Publication/Presentation | Investigator obliged to share results | QI practitioners encouraged to share systematic reporting of insights |
**JHM IRB QI Determination**

(https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/102_2a.html)

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<thead>
<tr>
<th>Human Subjects Research</th>
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<th>Quality Improvement (QI)</th>
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<td><strong>Purpose</strong></td>
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<td>Generally not externally funded</td>
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<td><strong>Benefits</strong></td>
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<td>Compare program, process or system to established standards/best practices</td>
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<td><strong>Adoption of Results</strong></td>
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<td>Intent to utilize results locally (e.g. for system enhancement)</td>
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**Implementation Science**

- We know that Knowledge Translation has been defined as a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically-sound application of knowledge to improve the health of persons, provide more effective health services and products and strengthen the health care system complex systems (Canadian Institute of Health Research, 2000)
- Implementation research/science falls under this umbrella and is the scientific study of “how” best to do KT/QI
- “Implementation research focuses on testing how interventions work in real settings and how to improve them. It also addresses any aspects of implementation that cover factors affecting implementation, processes of implementation, introduction of solutions into a health system, and promotion of sustainability”
Which is which?


- Gender, HIV-Related Stigma, and Health-Related Quality of Life Among Adults Enrolling in HIV Care in Tanzania. Parcesepe AM1,2, Nash D3,4, Tymejczyk O3,4, Reidy WS, Kulkarni SG3, Elul BS. AIDS Behav. 2019 Mar 30. [Epub ahead of print]


- Implementation of infection control best practice in intensive care units throughout Europe: a mixed-method evaluation study: A mixed-methods study of this scale with longitudinal follow-up is unique in the field of infection control. Hugo Sax, Lauren Clack, Sylvie Touveneau, Fabricio da Liberdade Jantarada, Didier Pittet and Walter Zingg. Implementation Science 2013 8:24

Overview of Methods for QI/KT

(Shojania Health Affairs 2005; Rubenfeld Cur Opin Crit Care 2004)

Weak:
- Passive education with Clinical Practice Guidelines, CME

Moderate or variable:
- Economic incentives
- Local opinion leaders
- Audit & feedback (better if high intensity A&F, low baseline adherence, and/or perception of credibility for reports) (Jamtvedt Qual. Saf. Health Care 2006; Fung Ann Int Med 2008; Shojania Health Affairs 2005)

Stronger:
- Reminders
- Multi-faceted program (combinations) (Oxman CMAJ 2005)

To understand considerations for choosing a QI topic
When choosing a topic and intervention understanding context is critical

“For us, the experimental paradigm constitutes a heroic failure, promising so much and yet ending up in ironic anticlimax. The underlying logic...seems meticulous, clear-headed, and militarily precise, and yet findings seem to emerge in a typically non-cumulative, low impact, prone-to-equivocation sort of way.”

(Pawson and Tilley, 1997 from Berwick, The Science behind clinical systems improvement, JHSPH lecture 2008)

Context + New Mechanism = Outcomes

\[ C + M = O \]

Sometimes what is called practice-based evidence

(Pawson and Tilley, 1997 from Berwick, The Science behind clinical systems improvement, JHSPH lecture 2008)
From Realistic Evaluation (Pawson & Tilley, 1997)

“In other words, programs work (have successful ‘outcomes’) only in so far as they introduce the appropriate ideas and opportunities (‘mechanisms’) to groups in the appropriate social and cultural conditions (‘contexts’).”

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From Realistic Evaluation (Pawson & Tilley, 1997)

“....(E)xperimentalists have pursued too single-mindedly the question of whether a program works at the expense of knowing why it works.”
The balancing act: Messiness

What if life were this simple?

X → Y

Is this more accurate?

X1, X3 → X3
X2, X4 → Y
X3, X5
The balancing act: Messiness

Probably more like this?

```
X_1 \downarrow \quad X_2 \quad X_4 \quad X_5 \quad X_5
R_1
X_2 \downarrow \quad X_4 \quad X_5
X_3 \downarrow
```

Numerous direct effects and indirect effects, interaction of $X_1$ and $X_4$ and $X_2$ and $X_5$

$R = \text{residuals or error terms that represent effects of variables omitted in model}$

(Barwick, The Science behind clinical systems improvement, lecture JHSPH 2008; Blalock et al, Causal models in social sciences, 1999)

So how do you go about starting a KT/QI project?
Recall the KT model for translation?

(Pronovost, Berenholtz, & Needham
BMJ 2008)
**Choice of Topic**

1. **Summarize the Evidence**

   - Basic elements (not necessarily linear)
     - Identification of broad QI/KT issue, gaps
     - Review relevant literature and critical appraisal
       - Identify the intervention(s) of interest
   - Formulation of specific (and SMART*) question
     - Aims & hypotheses
     - Conceptual framework

*SMART* (Specific, Measurable, Actionable, Realistic, and Timely)
Choosing a topic: Ideas

- Ideas emerge from...
  - Sentinel events
  - Patient Safety Reporting Systems
  - Surveys from quality assurance/certification agencies
  - Your own or another investigator’s research results
  - Your own or your team’s observations/concerns/experience
  - Risk management/malpractice claims
  - Changes in health care policy
  - Stakeholders, consumer advocacy groups
  - Innovations in other fields
- Usually starts vague and becomes more defined

Choosing a topic: IOM quality dimensions

- Safe
- Effective
- Patient-centered
- Timely
- Efficient
- Equitable
Choosing a topic: QI Gaps

- What is known already?
- Why is this question important and to whom?
  - Patients, families, providers, safety/compliance/regulatory agencies, local/federal policy makers
- Is there a gap between practice and known evidence based models, treatments, best-practice guidelines?
  - High vascular access-related blood stream infection rates in outpatient hemodialysis practices (outpatient)
  - High rates of catheter-associated blood stream infection prevention practices in ICUs (inpatient)
  - Transitional care planning/coordination for complex geriatric patient to prevent 30 day hospital readmissions (home-based, community)
  - Early anticoagulate therapy to prevent death in stroke patients (ED)
  - Overuse of antipsychotics in nursing home dementia patients (long term care setting)

Choosing a topic: Key factors

1. The size of the problem
2. Preventability
3. Effectiveness of intervention(s)
4. Benefits and harms
5. Intervention costs
6. Cost/benefit comparison
7. Feasibility
8. Acceptability
9. Sustainability

Choosing a topic: Organize your thinking

Use frameworks
  – Example: TRIP
    • To frame the entire QI process (initiation, implementation, evaluation of the overall quality improvement project)
  – Example: Structure-Process-Outcomes (Donabedian)
    • to frame the context and mechanisms and outcomes of the intervention

• What is the problem?
• Who is affected and how?
• What may work?
• How it may work?
• Where may it work?
• On what might it work, or not work?

1. Summarize the Evidence

• Basic elements (not necessarily linear)
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      • Identify the intervention(s) of interest
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    – Aims & hypotheses
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*SMART* (Specific, Measurable, Actionable, Realistic, and Timely)
Reviewing the Evidence

Identifying Evidence

• What is evidence-based healthcare?
  – The conscientious use of current best evidence in making decisions about the care of individual patients or the delivery of health services
  – Principles: (a) evidence alone is insufficient to make a clinical decision, (b) there is a hierarchy of evidence to guide clinical decision making

(Cochrane, 1999)
Identifying Evidence

- **Systematic Reviews and Meta-analyses**
  - PubMed, other medical and health care databases
  - Cochrane Collaboration
  - AHRQ Evidence-Based Practice Centers
  - White paper reviews
- **Professional networks**
- **Clinical Practice Guidelines**
  - CDC
  - Professional Societies

Read Auerbach et al.—The Tension between Needing to Improve Care and Knowing How to Do It—NEJM 2007

Scrutinizing the evidence

- **Grade the evidence**
- **Similar studies may differ by**
  - Design
  - Exposure definition/intervention composition, dose, timing, duration
  - What and how questions are asked (analyzed, interpreted and generalized)
  - Unit of analysis (specific elements under study)
  - Patient populations (disorder, inclusion/exclusion)
  - Outcomes (definition, followup time)
  - Settings, patient characteristics
  - Process variables (if reported)
  - Fidelity (how executed)
  - Adverse consequences
- **Always keep in mind that you need a balanced application of available evidence to your clinical issue, situation, or question**

Whether, how, and where the intervention has been effective
1. Summarize the Evidence

• Basic elements (not necessarily linear)
  – Identification of broad QI/KT issue, gaps
  – Review relevant literature and critical appraisal
    • Identify the intervention(s) of interest

• Formulation of specific (and SMART*) question
  – Aims & hypotheses
  – Conceptual framework

*SMART* (Specific, Measurable, Actionable, Realistic, and Timely)

Developing the aim of your project
Developing a Question: SMART

Specific: Who? (target) and What? (action)
Measurable: How much change expected?
Achievable: Can it be done given constraints/barriers?
Realistic: Problem addressed pragmatically?
Time-phased: Timeline?


Developing a Question: Example

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Outcomes</th>
<th>Population</th>
<th>Setting</th>
<th>Time frame</th>
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</thead>
<tbody>
<tr>
<td>Type, prominent component</td>
<td>Primary</td>
<td>Define targeted condition,</td>
<td>Hospital</td>
<td>Days</td>
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<td>Secondary</td>
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<td>NH</td>
<td>Weeks</td>
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<td>Criteria for defining?</td>
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<td></td>
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<td>Outpatient</td>
<td>years</td>
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</tbody>
</table>
Developing a Question: Example

- Starting aim
  - How can we reduce the rate of staff injuries resulting from workplace violence by residents in our nursing home?

- Refined aim
  - Could a staff educational program delivered to front line certified nursing assistants reduce the rate of staff injuries resulting from resident violence in our nursing home?

- Better (probably not Final) aim
  
  **Proven Intervention**

  Can implementation of the CARE behavioral training program can reduce rates of staff injuries resulting from nursing home resident violence by 50% at 3 months?

Framework: How it might work/
What to measure

To evaluate whether the CARE training program can reduce rates of staff injuries resulting from nursing home resident violence by 50% at 3 months.

Key point: to think through how the intervention may work and measure process if possible
More examples of specific objectives

SMART objective 1: By year two of the project, LEA staff will have trained 75% of health education teachers in the school district on the selected scientifically based health education curriculum.

SMART objective 2: By the end of the school year, district health educators will have delivered lessons on assertive communication skills to 90% of youth participants in the middle school HIV prevention curriculum 3 months.


2. Identify local barriers

• Understand the process and context of work
  – Walk the process
• Then organize the factors to make sure you address the critical ones
• Method to organize care quality factors
• SPO framework may be helpful
  – Factors fall into 3 inter-related categories
    • Structure: organizational, environmental, or staff resources of the setting where care is provided
    • Process: the actions or things that are done to and for the individual by caretakers or practitioners, how system works
    • Outcomes: endpoints, goals for care

(Donabedian, 1988, Sloane, Zimmerman, & Orgy, 2001)
3. Select performance measures

- Outcomes, process measures specific setting
- Identification of important variables (availability for measurement, valid, reliable)
- Timeframe—how would it take to observe change in outcomes? What is the ‘dose’?
Funding

Creativity and diversification
- Institutional
- Agency for Healthcare Research and Quality (AHRQ)
- Private donors
- Foundations (local and national)
  - e.g. Robert Wood Johnson Foundation
- PCORI
- NIH
- Centers for Disease Control
- US Department of Veterans Affairs
- Potential search terms:
  - Knowledge translation, implementation, translational research, diffusion, applied health research

Tetroe et al. Millbank Quarterly, 2008

Summary Points

- Quality improvement/knowledge translation is the implementation of best practices to improve care—may contain research elements/goals
- This type of systematic method can apply to any setting and any topic
- Using a structured framework for identifying an important topic, factors that impact the topic, and developing a specific aim is key to starting a successful project
Questions?

Group exercise and practice scenario:

Improving care quality for
Assisted Living residents
AL context

- Dramatic changes in the patterns of long-term care (LTC) use.
  - Between 1990 and 2002, the number of assisted living beds in the US increased by 97%, compared to a 7% increase in nursing home beds.
- AL has become linchpin in care continuum for elders with dementia and other mental health conditions like depression, anxiety, schizophrenia
- Philosophy based a mix of ‘social’ and ‘medical’ models of care
  - Independence, dignity, safety, autonomy, & minimize the need to move
- Huge variance in definition, services, programs, environments, case mix
- Many ALs lack adequate MH care elements
  - Symptom evaluation, mental health service expertise/knowledge, staff training, provision of non-pharmacologic approach, overuse of pharmacologic approaches
- Proliferation of programs specializing in dementia care
- No federal regulations like nursing homes, states regulate individually
- Stakeholders are closely examining quality of care and ways to improve care
Your teams tasks

• List out the problems addressed in the focus groups.

• Choose a specific quality improvement topic to focus

• Develop a specific research question for a QI project.
  – One question that incorporates intervention, setting, population, outcome.

• In developing the research question consider the following:
  – What makes this issue important?
  – Does the issue have a potential solution (will the question be answerable)?
  – What is a preliminary framework for how and why the QI project would work?
    • What are the factors that you would want to measure?
    • How the proposal quality improvement will help are the factors that you would want to measure.
  – What types of solutions could you consider (e.g. what would you search for when looking for EB)?
  – What additional information on prior to implementing the intervention?
  – What primary outcomes are you considering and how would you define them?

AL Directors say...

• Director 1: “Agitation and combative behaviors are huge concerns. We also have a lot of screaming, crying, and disrobing. I just came to work at Memory Meadows from a traditional Assisted living facility that did not specialize in Alzheimer’s disease and it feels like a whole different world...I’ve been surprised at how many long lasting mental illnesses that people have that have gone untreated...it’s been shocking to me.”

• Director 2: “I’m worried about our direct care staff skills in understanding and managing dementia and the behaviors. I think in some cases the company doesn’t recognize the need for the specialized training for caregivers. They’re so focused on meeting the states requirement for hours of training for dementia, and meeting the other state requirement like staff ratios, and the bottom line of course, that they lose sight of the actual care that Alzheimer’s and dementia residents need. So I think it’s difficult from our standpoint as executive directors to get them to recognize that this is a special area of care. These residents are different from someone who is incontinent or someone who just needs to help in the shower to make sure they don’t fall. You see a resident who was a great famous writer, and now they can’t remember how to put on their shirt. And the companies I don’t think recognize that or see the individual. It’s like taking them by the collar, shaking them. We’ve got to train these caregivers better.”
AL Director say...

- **Director 3:** "I think quality of care also has a lot to with where the family's going to meet you. We try to focus on resident-centered care as much as possible. Of course you know, you've got your constraints too because you can't have everybody eating dinner at varying different times but you know if today it's not a good time to eat at 5 o'clock, then ok that's fine. We can hold a plate and they can eat a little bit later or have a sandwich a little later. You know. So it's also having the family meet you on that same plane. I'll just give you an example of something that happened yesterday. I had a family member. His wife is 95 and he is 92 years old he lives out in the community and he drives. And she's had dementia for numerous years and she moved in 3 weeks ago. Yesterday he got upset because it was 2 o'clock in the afternoon and she wasn't laying down for a nap. He says "She's always taken a nap in the afternoon." Well she's been with us for 3 weeks and in 3 weeks timeframe she hasn't wanted to take a nap in the afternoon so, I'm sorry, you know we offer her the nap, we take her back to her room. But if she doesn't want to take a nap, that's ok. Well that was wrong. Well the reason she's not taking a nap is because she is not up all night like she was at home...she's sleeping better. So a large part of quality is also bringing the family to meet the resident where she is...the things that contribute to quality for the resident may not be what you or I or the family think it should be, you know. So yeah, I think it's about bringing the family to where we are because I can't tell you how many families have stood in front of me and been angry because their mom's in her housecoat at 12 noon.. well, so she didn't want to get dressed yet, you know."

- **Director 4:**
  - "The family thinks we can fix them. We're a dementia unit. We're assisted living. And that's why I brought her here cause you guys are the experts in this and you need to fix her. She did it at my house but that's different. She comes to a structured community that you guys say really works. Why isn't she fixed you know. We get that. They get frustrated."

Care staff say...

- **Staff 1:** "One of the biggest issues is that a lot of the residents are combative when they hit a certain level, especially fear of water. And once they escalate it's horrendous. It's a done deal. It's not about them hurting me, more or less of them hurting themselves or someone else."

- **Staff 2:** "Well, for me it would be also a behavior problems as a serious concern...because my concern would be how best can I help them without adding to the problem? How can you best diffuse the situation so that most of all you don’t hurt them or you don’t get hurt. That would be what I’m thinking about. Yet, I have not gotten there to figure that out."

- **Staff 3:** "I see issues at an even more basic level. Quality of care means to me that you give your best care such as making sure that you groom the hair, brush their teeth, if it calls for the shower, the shower, dressing them properly. Definitely letting them also help you in the care so that they can make those decisions such as what outfits they want to wear, what jewelry they want to put on, if he wants to put on his watch. Does he want to be shaved or not shaved? Does he want to use a straight razor as opposed to an electric razor?"
Care staff say...

- **Staff 4:** "One thing I think would help is if we had more structured activities. Like one-on-one activities to deal with their behavioral issues and to redirect them. To me it would be reaching back in their past and finding out some of the things that interested them such as painting, some of them like to paint, some of them love music. The other day one of the resident says, "I used to play the congas. I played all different kinds of drums." So when I brought it to the activities staff attention she said, “Oh, we’ll just give it a try.” And sure enough she was playing. I mean it just brought a smile to her face, the activities person’s face and definitely mine that we were able to reach back in her past and find something that she loved. Before she used to do a lot of yelling out. But now she’s been engaging in activities more it’s as though she has calmed down a lot. Other things to me is making sure that we have the tools and the variety around here to give them that kind of activity or that kind of time that they need to do certain things. First we need to learn more about what residents like and then have the tools on hand to help them get into activities."

- **Staff 5:** "Well, I think making sure we provide the proper medical treatment is important because we have residents with all kinds of medical diagnoses that and we need to make sure we have trained people within the facility to consistently give out proper meds or whatever it is needed. Also people don’t communicate well because things could be changing within the resident as time goes on. And it’s best that we communicate that to the nurse but sometimes I’m not sure if they take in consideration of what you’re saying about a resident or if that information makes it’s way to the residents doctor.’

Family members say...

- **Family 1:** “Along with looking for clean fingernails because I think that’s a telltale sign of the quality of care, I also observe how the staff interact with the residents...to see if I hear them talking gently, kindly, jokingly. And not just the nursing staff, but other workers as well like activities...when they gather residents groups and the interaction they have...do they interact and know them as individuals...there is so much turnover here that it seems like there are different staff every few months...now how can they get to know them?”

- **Family 2:** “I am troubled by the staffing ratio...I started having monthly meetings with the director to complain that having one aid for an entire floor is not enough. There just isn’t enough staff and for me I feel like they sometime overmedicate residents instead of using staff to try and manage their behaviors in better ways. I don’t want my mom zombieized...I don’t want to see her over-medicated and drugged out...”

- **Family 3:** “I find that the organization is not responsive... We want to partner with our loved ones’ care givers. We want to partner, we’re all in this together, yes? And I really want to partner and I sacrificed a great deal of time and treasure to have my husband here. But then when I send an email either sharing observations or requesting certain things I expect a response, sorry, you know? I think that’s just mannerly. So I have these lingering questions and I have to ask them again and again and again and again and it’s very frustrating.”
Your teams tasks

- List out the problems addressed in the focus groups.
- Choose a specific quality improvement topic to focus
- Develop a specific research question for a QI project.
  - One question that incorporates intervention, setting, population, outcome.
- In developing the research question consider the following:
  - What makes this issue important?
  - Does the issue have a potential solution (will the question be answerable)?
  - What types of solutions could you consider (e.g. what would you search for when looking for EB)?
  - What primary outcomes are you considering and how would you define them?
  - What additional information would you need prior to implementing the intervention?