A24B24: Concurrent Mixed Methods in a National QI Project
Nothing to Disclose

Michelle Mann, Nila Sathe have no relevant financial or nonfinancial relationship(s) within the services described, reviewed, evaluated, or compared in this presentation.

Eva Kline-Rogers:
QUANTUM AF Advisory Committee
AC Forum Board of Directors

Sue Mashni:
QUANTUM AF Advisory Committee
Wolters Kluwer Advisory Committee
Learning Objectives

Learners will:

• Understand stroke prevention gaps in atrial fibrillation (AF), exemplified by the nationwide QUANTUM AF project
• Comprehend the limitations of traditional quantitative strategies and strength of mixed methods to evaluate quality improvement impact
• Discuss the direct application of mixed methods evaluation through the lens of the QUANTUM AF project
Speakers

Susan Marx Mashni, Pharm D, BCPS
Vice President and Chief Pharmacy Officer
Mount Sinai Medical Center, NY

Eva Kline-Rogers, MS, NP, AACC
Nurse Practitioner and Co-Director for Michigan Cardiovascular Outcomes Research and Reporting Program at the University of Michigan
Speakers

Michelle Mann
Principal, Program Management
Premier Applied Sciences

Nila Sathe, MA, MLIS
Director, Medical Evidence
Premier Applied Sciences
Agenda

- Understanding the QAF project
  - Premier
  - QUANTUM AF design

- Understanding using qualitative and quantitative data in QI work
  - Examples from related projects
  - QUANTUM AF as a case study

- Wrap up and summary
  - Tools to inform your process
Why Are You Attending This Workshop Today?
Premier as a Partner in QI Research
Significant footprint and scale

4,000 HOSPITALS AND HEALTH SYSTEMS

83% U.S. COMMUNITY HOSPITALS

165K OTHER PROVIDERS & ORGANIZATIONS

5,000+ AMBULATORY PRACTICE

ANALYZE DATA ON ~45% HOSPITAL DISCHARGES NATIONWIDE
Premier’s unique member model drives innovation

ALIGNMENT
• Members own ~60% of equity
• 10 health system board members
• Premier field force embedded in member hospitals

COMMITMENT
• Member owner average tenure ~19 years (82% at 10+ years)
• Members view Premier as strategic partner

CO-INNOVATION
• Co-develop solutions with members
• Committees composed of ~195 member hospitals
• ~1,400 hospitals in performance improvement collaboratives
Premier Applied Sciences™ offerings

**DATA**
Leveraging the Premier Healthcare Database
- Data extracts
- Data license

**INQUIRY**
Answering questions about past and current state
- Comparative effectiveness
- Outcomes research
- Market analysis
- Prospective registries
- Protocol modeling and feedback
- Surveys, interviews, and conversations

**INTERVENTION**
Aligning care with best practice
- Clinical trials of improvement interventions
- Evaluations (e.g. pre-post)
- Education
Premier QI Collaborative Approach

THIS IS HOW WE GET IT DONE

- **Measure** with defined metrics
- **Report** transparently
- **Share** best practice
- **Execute** collaboratively
QUANTUM AF Background
QUANTUM AF Structure

- Inception
- Design
- Execution

Janssen and Premier Research Teams
Janssen/Premier/Steering Committee
Premier/Steering Committee
# QUANTUM AF Steering Committee

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Affiliation</th>
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<tr>
<td><strong>Chris B. Granger, MD</strong> (Chair)</td>
<td>Professor of Medicine, Department of Cardiology</td>
<td>Duke University Medical Center</td>
</tr>
<tr>
<td><strong>Elaine M. Hylek, MD</strong> (Chair)</td>
<td>Professor of Medicine, Department of Medicine</td>
<td>Boston University School of Medicine</td>
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<tr>
<td>Mark Jay Alberts, MD</td>
<td>Physician-in Chief, Chief, Department of Neurology</td>
<td>Hartford Hospital</td>
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<tr>
<td>Kevin J. Anstrom, PhD, MS</td>
<td>Associate Professor, Biostatistics and Bioinformatics</td>
<td>Duke University Medical Center</td>
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<tr>
<td>Peter B. Berger, MD</td>
<td>Interventional Cardiologist</td>
<td>Independent Consultant</td>
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<td>Michael P. Dorsch, PharmD, MS</td>
<td>Clinical Associate Professor, College of Pharmacy</td>
<td>University of Michigan</td>
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<tr>
<td>Gregory J. Fermann, MD</td>
<td>Executive Vice Chairman; Director -Clinical Trials Center; Department of Emergency Medicine</td>
<td>University of Cincinnati College of Medicine</td>
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<tr>
<td>Susan Mashni, PharmD</td>
<td>Chief Pharmacy Officer</td>
<td>Mercy Health</td>
</tr>
<tr>
<td>Gerald V. Naccarelli MD</td>
<td>Bernard Trabin Chair in Cardiology, Chief of the Division of Cardiology, and Director of the Cardiovascular Center</td>
<td>Pennsylvania State University College of Medicine/Milton S. Hershey Medical Center</td>
</tr>
<tr>
<td>Eva Kline-Rogers, NP</td>
<td>Cardiovascular Nurse Practitioner</td>
<td>University of Michigan</td>
</tr>
<tr>
<td>Sean Pokorney, M.D., MBA</td>
<td>Cardiology Fellow</td>
<td>Duke University Medical Center</td>
</tr>
<tr>
<td>Kevin L. Thomas, MD</td>
<td>Assistant Professor, Clinical Cardiac Electrophysiology Division of Cardiovascular Disease</td>
<td>Duke University Medical Center</td>
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</table>
"Patients with atrial fibrillation at risk of stroke should receive oral anticoagulant therapy to decrease the incidence of stroke."

However...

APPROXIMATELY 1 OF EVERY 2 AFIB PATIENTS AT RISK OF STROKE DOES NOT RECEIVE GUIDELINE-DIRECTED ANTICOAGULATION FOR STROKE PREVENTION

84% of stroke patients with known history of AFIB were not treated with therapeutic anticoagulation prior to the stroke.

Is 60,000 Fewer Strokes Annually a Possibility?

• ~5 million Americans have AF
• ~3.25 million may be at risk of stroke
• ~1.63 million are likely untreated
• ~97,000 are likely to have a stroke
• ~60,000 strokes could potentially be prevented with appropriate anticoagulation therapy

Treatment Gap in Premier Hospitals

Which hospital is yours?

801 Premier Member Hospitals

Impact of Afib-related Strokes on Patients

Impact of Afib on Hospitals

AF ACCOUNTS FOR OVER 550,000 ED VISITS ANNUALLY

30-DAY READMISSION RATE FOR AF PATIENTS IS 18%

Clinical Trial of Improvement Intervention

QUANTUM AF overview – Unique partnership

Background
First and largest study of its kind to address an unmet medical need for hospitalized patients with AF who are at risk for ischemic stroke

Objective
Study will evaluate the effect of a structured hospital improvement program on oral anticoagulant (OAC) use in patients with AF

Design
20-month study involving approximately 60 hospitals in cluster-randomized research study

Outcomes
Determine whether the implementation of a hospital improvement program compared with standard hospital practice will improve the proportion of patients with AF appropriately treated with an oral anticoagulant

Secondary Outcomes
A number of additional outcomes will be examined –
• Effect of the program versus usual care on hospital readmissions
• Hospital characteristics predictive of improvement rates for OAC use
• Evaluate effect of specific program components on overall OAC use

Janssen Collaborates with Premier Inc. on Unique Study to Improve Stroke Risk Management among Hospitalized Patients with Atrial Fibrillation
The QUANTUM AF study will evaluate the impact of a hospital quality improvement program on the use of new guidelines to treat patients with atrial fibrillation (AF) at risk for ischemic stroke

TITUSVILLE, N.J., April 3, 2017 – Janssen Pharmaceuticals, Inc. (Janssen) today announced it has
AHA/ACC Guideline Components

• Evaluation of stroke risk

• Use of OACs to decrease incidence of stroke
  – Warfarin and four “DOACs” (direct oral anticoagulants)
  – NOT aspirin

• Use of shared decision-making

• Use of patient education on AF and anticoagulants
Study Methodology

• Cluster randomized
  – Hospitals randomized to QI Program arm or Usual Care (control) arm
  – Hospitals with IRB approval and executed clinical trial agreement roll into the study in groups of 10 or more
  – QI Program is the intervention being studied
  – Hospitals are the unit of randomization (and of the intervention)
  – Drug-agnostic approach

• Eligibility based on active Premier Data Platform participation and minimum patient volume threshold of 70 patients with AF/quarter.

• Sites randomized to the Usual Care arm will receive QI program materials upon request, following study completion
  – Benefit from the learnings of the QI Program arm
  – Expedite efforts in practice redesign
Timeline

20 Month Study Duration

(1 month)        (4 months)                        (15 months)
Prerandomization Phase

Preparatory Phase

Baseline Analysis done by Premier

-1                   1  2  3  4  5  6  7  8  9  10  11  12  13  14  15  16  17  18  19
QI Program Arm      QI Program Arm

Final Action Plan

Final Measurement Period

End of Study

Hospitals assigned to the Usual Care arm will not participate in the structured QI program but will continue with their standard hospital practice until the Final Measurement Period
## Where We Are Today

<table>
<thead>
<tr>
<th></th>
<th>Cohort A</th>
<th>Cohort B</th>
<th>Cohort C</th>
<th>Cohort D</th>
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<tbody>
<tr>
<td>Number of Hospitals</td>
<td>7</td>
<td>8</td>
<td>11</td>
<td>35</td>
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<tr>
<td>Phase</td>
<td>Implementation</td>
<td>Implementation</td>
<td>Implementation</td>
<td>Preparatory</td>
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<td>Completion Status</td>
<td>50%</td>
<td>30%</td>
<td>20%</td>
<td>5%</td>
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<td>Coaching Calls</td>
<td>6</td>
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<td>Webinars</td>
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<td>1</td>
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Qualitative and Quantitative Data in QI Projects
Qualitative vs. Quantitative Data

Quantitative Data

• Quantifies a phenomenon
• Data that can be counted or assessed on a numeric scale
  ❑ Baseline rate of OAC prescribing=56%
• Used to indicate “how many” or “what”
• Pros and Cons
  ✓ Provides descriptive, objective information
  ✓ Findings may be statistically but not clinically meaningful
  ✓ Data can be manipulated
  ✓ Often lacks interpretive information; may not provide whole picture

Qualitative Data

• Describes, categorizes, or explains a phenomenon
• Data from notes, observations, interviews, etc. often in narrative format
  ❑ Theme derived from interviews=Optimizing HIT. Example quote: “…. One of the things that [we] have been working with is ensuring that [the EHR] probably does a better job at optimizing decisions that are made. So for instance, the calculation of CHA₂DS₂-VASc scores and things like that probably should be automated...” [P1, physician]
• Can explain the “why” behind the what
• Pros and Cons
  ✓ Information not easily captured in quantitative data
  ✓ Nuanced descriptions of underlying factors from multiple perspectives
  ✓ Subjectivity--Influence of researcher perspective
  ✓ Small sample sizes can limit generalizability
  ✓ Time-consuming, complex analysis procedures
Example of a Recent Mixed Methods Study to Determine Barriers Associated with Integrating DOACS into Anticoagulation Clinics

Structure and function of anticoagulation clinics in the United States: an AC forum membership survey

Geoffrey D. Barnes¹ · Eva Kline-Rogers¹ · Christopher Graves¹ · Eric Puroll¹ · Xiaokui Gu¹ · Kevin Townsend² · Ellen McMahon² · Terri Craig² · James B. Froehlich¹

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ORIGINAL ARTICLE

Barriers to integrating direct oral anticoagulants into anticoagulation clinic care: A mixed-methods study

Geoffrey D. Barnes MD, MSc¹,² | Jennifer Acosta MPH² | Christopher Graves BA¹ | Eric Puroll BA¹ | Eva Kline-Rogers NP¹ | Xiaokui Gu MD, MA³ | Kevin Townsend PharmD, MSc³ | Ellen McMahon PhD³ | Terri Craig PharmD³ | James B. Froehlich MD, MPH¹

Res Prac Throm Haemost. 2018; 1-6
Rise of DOAC Use

2016 ACCP VTE Guidelines:
• DOAC favored over warfarin (Grade 2B)

AJM 2015;128:1300-1305
Chest 2016;149:315-352
Anticoagulation Clinics

• Where are we now?

• Where are we headed?

• How to maximize potential to benefit patients & health system?

• What are barriers to change?
Hands-On: Survey Questions

• Given this focus, what kinds of survey questions would you want to ask:
  – Focus: understanding how anticoagulation clinics are structured
  – Focus: understanding barriers to OAC use

For example: How many RNs are on staff in your clinic?
Methods

Online survey of Anticoagulation Forum members (N=159)

Providers who indicated knowledge of staff model, structure, and function contacted

Semi-structured In person interview (N=20)

Interview transcripts analyzed
Anticoagulation Clinic Staff Variability

Fig. 3  Staff Utilization by Anticoagulation Clinics. Clinics with multiple staff types are represented multiple times in this figure. NP/PA nurse practitioner/physician assistant
Clinical FTEs by Staff Type

Fig. 4 Number of Clinical FTE by Staff Type. Clinics may have multiple staff member types. Median number of full time equivalent staff calculated among clinics reporting use of that specific staff type. Error bars indicate interquartile ranges. FTE full-time-equivalents.
Fig. 5 Number of Patients Assigned to Clinical Staff. *FTE* full time equivalent
AC Forum Membership Survey

Type of INR

- Point-of-care is most common
- >70% use multiple types of INR
- 925 patients (IQR 400-2000)

Qualitative Analytic Approach

• Three step coding (categorizing) process:
  1) Several transcripts reviewed by PI and assistants – consensus on major themes. Code book developed using open coding with code names, meanings, and examples
  2) Coding team coded 2 transcripts – edits made and codebook modified in conjunction with the PI
  3) Two research assts coded remaining transcripts using the final codebook. All transcripts were coded using MAXQDA 12 software (VERBI Software GmbH, Berlin, Germany.

• Simplified approach can be incorporated into routine QI practice
  – *More in a moment...*
Results

FIGURE 1  Variation in anticoagulation clinic structure and associated barriers to integrating direct oral anticoagulant care. DOAC, direct oral anticoagulant; RN, registered nurse
Summary

• Anticoagulation clinics experience barriers to integrating DOAC care

• These barriers vary based on clinic size, model of care, and staffing

• Understanding barriers is key to implementing new, appropriate protocols

• Conducting both quantitative and qualitative research helps identify “gaps” and pragmatic interventions to close the gaps
How To Do It?
Effective Strategies to Reduce D2B Time: Example of “How”

Study finds six hospital interventions significantly reduce door-to-balloon times

Door-to-balloon times reduced by...

8.2 minutes
Having ED physician activate the cath lab

8.6 minutes
Providing real-time feedback to ED and cath lab staff

13.8 minutes
Using a single-call page system

14.6 minutes
Staffing a full-time attending cardiologist on site

15.4 minutes
Having EMS diagnose STEMI en-route to the hospital and alert the ED

19.3 minutes
Requiring cath lab staff to arrive within 20 minutes of being paged

Bradley EH, NEJM, 2006
Goal of SAMI – Surviving AMI

Create lasting change...

*Leadership, culture, and communication all linked with lower 30-day AMI mortality

Provider-led QI Works!

- Participation in provider-led quality improvement (QI) efforts can improve care:
  - BCBSM sponsored CQI Programs
  - ACC-GAP
  - NRMI
  - AHA GWTG; now GWTG-AF, others
  - CRUSADE – ACTION - CP

- Means of QI
  - Measurement and Feedback
  - Motivated local champions
  - Collaborative sharing of best practices
  - Continuous feedback with team members
How It All Connects...

Success Metric
- Change in OAC use at discharge

Assessment
- Little tracking of percent of OAC use

Tool
- EMR updated to include a metric
The Goal Is to Shift the Curve – There Will Always Be Outliers
Without data, you are just another person with an opinion.

- Deming
• Qualitative data, paired with quantitative data on change in outcomes of interest, can help shed light on:
  – Participant rationale (e.g., for medication adherence/non-adherence; for provider prescribing/non-prescribing)
  – Participant perceptions, knowledge, thoughts, attitudes, beliefs
  – Contextual influences (e.g., setting, team composition)

• In QUANTUM AF, qualitative data will illuminate:
  – Barriers and facilitators of OAC
  – Reasons for lack of appropriate OAC prescribing in patients with AF
  – Contextual factors underlying change in OAC rates (e.g., site champions; QI culture)
  – Team and intervention structures associated with change in OAC rates (e.g., involvement of nursing or pharmacy staff; access to residents)
Qualitative Data in QAF: Data collection

Multiple methods

• Sites identify gaps via chart review and develop action plans to address

• Coaching calls to discuss approaches and issues
  – Premier team facilitator—peer-to-peer discussion
  – Steering Committee “special guests” to review specific issues
  – Additional focus on specific topics raised by sites

• End of project surveys
  – Open and closed-ended questions
## Team Coordinators

<table>
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<tr>
<th>Cohort</th>
<th>PI Area of primary work</th>
<th>Study Coordinator Area of primary work</th>
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<tbody>
<tr>
<td>A</td>
<td>Neurology</td>
<td>Research Coordinator</td>
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<tr>
<td></td>
<td>Hospitalist</td>
<td>Research Coordinator</td>
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<tr>
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<td>Cardiac Electrophysiology</td>
<td>Nurse Practitioner</td>
</tr>
<tr>
<td></td>
<td>Cardiologist</td>
<td>Clinical Research Coordinator</td>
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<td>B</td>
<td>Hospitalist</td>
<td>Senior Research Coordinator</td>
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<tr>
<td></td>
<td>Internal Medicine</td>
<td>Senior Research Coordinator</td>
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<td>Quality Improvement</td>
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<td>C</td>
<td>Neurosurgery</td>
<td>Project Manager, Neuroscience Institute</td>
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<td>Cardiologist</td>
<td>Pharmacist</td>
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<tr>
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<td>Director Performance Improvement/Pediatrician</td>
<td>Quality Improvement</td>
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<td>Hospitalist</td>
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<tr>
<td></td>
<td>Cardiologist</td>
<td>Coordinator: Atrial Fibrillation and Heart Failure Clinics</td>
</tr>
</tbody>
</table>

- The Team Coordinator and Principal Investigator positions likely to have a significant bearing on the quality and progress of the QI program
Action Plan Focus – Cohort A and B

Number of Hospitals Addressing

- Assess Risk of Stroke: 8
- OAC prescribed at DC: 7
- OAC Therapy Education: 7
- Shared Decision Making: 1

Type of Solution

- Technology Solution: 6
- Education of Residents: 5
- Working with Coders: 1
- Cost Implications: 2
- Coordination of Care: 1
- Education of Patients: 1

Quantify Use of Anticoagulation to Improve Management of Atrial Fibrillation
Cohort A Barriers

Example Barriers

• Lack of documentation
  • No place to document risk score in EHR

• No one responsible for educating providers
  • Don't understand current knowledge base of residents

• Risk scoring not part of the current process/no one responsible
  • Ease of risk score calculation and education on guidelines

• Deferring OAC prescribing to PCP
Cohort A Barriers and Actions

Example Action Steps

- Provider education: falls, CHA$_2$DS$_2$-VASc, bleeding risks
  - Key myths and misperceptions about treatments
  - Document TYPES and NUMBERS of educational events/lectures
  - Use Premier tools

- EHR modifications
  - Build EHR data points towards CHA$_2$DS$_2$-VASc

- Modifying discharge processes to optimize documentation
Qualitative Research Methods

Understand problem and develop methods

Sampling and recruitment

Conduct and transcribe interviews

Coding and comparison

Report themes, trends, implications

Controls for subjectivity in the process:

- Sampling to ensure broad stakeholder representation
- At least 2 independent coders with multidisciplinary perspectives
- Iterative code development with team consensus—flexible refinement
- Constant comparison against the data
Analyzing Qualitative Information Group Exercise

• Review the handout: What kinds of codes would you apply?

• Example:

So we really want to increase documentation of patient education on all anticoagulation therapies.

What we wanted to do is leverage the use of our clinical pharmacists for that, because we also noticed that there was limited documentation of conversations with patients about anticoagulation therapy.

So, if the patient's on any of the oral anticoagulants, having those charts reviewed by pharmacy, and then education will happen at that time, then documenting that (QAF site study coordinator)

Potential codes:
- Improving documentation
- Leveraging pharmacists
- Patient education
Wrapping it all up: Integrating Qualitative Approaches in QI Projects
Incorporating Qualitative Approaches into QI

• How to apply qualitative analysis to further understand your process measures.

• How many people have worked on issues in hand washing? Do you feel you suffer from:
  – Lack of resources?
  – Culture issues?
  – Knowledge gaps?

• How would you know what place to start?
  – What kinds of questions would you ask qualitatively?
  – What kinds of quantitative data would you collect?
Incorporating Qualitative Approaches in QI

• Identifying qualitative data sources that can inform the issue or area
  – Institutional surveys with open-ended questions (patient/staff satisfaction, clinic surveys)
  – Workflow analyses (process map)
  – De novo surveys
  – Quick polls of staff
  – Discussions with floor or clinic leaders

• Understanding quantitative data that can speak to the issue
  – Quantitative surveys
  – Clinical data (e.g., pain scores)
  – Process-oriented data (e.g., turnaround times)
Summary: Key Factors for Integrating Qualitative Approaches

• Use qualitative approaches at outset to identify issues at ground level

• Use qualitative findings to help determine:
  – Influencing team structure
    • Matching team roles and team members
    • Stakeholders represented (e.g., pharmacy, nursing, support staff, physicians from relevant practice areas)
  – Optimal goals
    • Prioritizing key targets
    • Staging approaches
  – Behavior change mechanisms
Summary: Key Factors for Integrating Qualitative Approaches

• Provide insights into key metrics or initiatives

• Influence leadership thinking

• Combining qualitative input into QI projects can help to
  – Explore and inform issues, approaches, interventions
  – Provide additional insight into quantitative findings (the WHY or HOW behind the WHAT)
  – Serve as an evaluation mechanism for QI work
Summary: QAF Project

• QAF goal: Improve use of OAC in appropriate AF patients
  – Limited OAC use in AF patients despite well-known stroke risk and high burden of stroke

• QAF study is a novel example of integrating multiple methods of data collection into QI research
  – Randomized comparison of QI vs local care
  – Incorporates local QI approaches plus supportive education and coaching

• Mixed methods analysis incorporates quantitative change in OAC rates and qualitative data form coaching calls and other sources
  – Informs not only whether approaches worked to change rates but also which approaches and why
Questions?

- Handout includes data collection checklist (when you may want to use qualitative approaches) and sample questions that may be helpful

- Questions for presenters?

- Thanks for your participation!

```
1. DEFINING AND UNDERSTANDING THE PROBLEM OR ISSUE

<table>
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<tr>
<th>Statement</th>
<th>Rating (circle rating that best fits)</th>
<th>Notes/What I know so far</th>
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<tr>
<td>I understand I'm interested in addressing exists</td>
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<tr>
<td>Why the issue I'm interested in addressing exists</td>
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<tr>
<td>Potential underlying causes of the issue</td>
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<tr>
<td>Scope of the issue (e.g., an issue across the hospital, localized in one unit)</td>
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<td>Barriers/challenges to addressing the issue</td>
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<tr>
<td>Approach/strategies likely to help resolve the issue</td>
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<td>Which approach/strategies best fit the issue</td>
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<tr>
<td>Optimal trajectory of approaches/strategies to try</td>
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<td>Resources needed for approach/strategies</td>
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<tr>
<td>Who should be involved in the team to address the issue</td>
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<tr>
<td>Where best to position any interventions or approaches (e.g., begins in ED, begins in telemetry unit)</td>
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<td>Time required to implement and test approaches/strategies</td>
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<tr>
<td>What outcomes of the strategies used are important to track</td>
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<tr>
<td>How to measure changes in outcomes</td>
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<tr>
<td>What success would look like to stakeholders</td>
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Mostly 1s: Qualitative data collection is probably not necessary to get started. I have a good understanding of the context surrounding this issue and approaches to try to improve it.

Mostly 2s: Qualitative exploration would be very useful to help understand the issue. For example, who’s most affected, why is this happening, what can be done to try to fix this problem, who needs to be involved.

Mostly 3s: Some targeted qualitative exploration may be helpful to generate more information to fill in the gaps in my understanding.

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