Registry Growth and Sustainability: Opportunities and Challenges

CMSS Registry Summit

May 10, 2018
A little background on me

• (Newish) AAOS Director of Orthopaedic Registries

• Former President, Provider Solutions at FIGmd

• Former Director, Outpatient Registries at American College of Cardiology
Key questions

Can registry programs be made self-sustaining financially?

What are the revenue and mission opportunities beyond self-directed QI?
Registry Requirements

- Specially trained, dedicated staff for chart abstraction
- Compliance with continuously changing registry reporting requirements to reflect new science, measures, guidelines, research requirements, and devices
- MACRA – MIPS / APM and value based payment model compatibility
Structuring the registry enterprise

One registry or many to meet various stakeholder needs?

• RWE/passive, observational research

• Post-market surveillance and/or device tracking

• Clinical trials?!?

• Participation in MIPS
Every Case or Sampling?

How many cases do we need to...

• Measure guideline adherence?
• Report quality metrics?
• Identify potential safety signals?
Balancing comprehensiveness against the data collection burden
Clinical Data Registry: A Wordy Definition

A clinical data registry is an organized system that collects uniform data (clinical and patient-reported) to evaluate specified actions and outcomes for a patient population.

With the increasing usage of EHRs, registries have emerged as valuable solutions for harnessing the power of information technology to capture insights on real world patient care, guideline adherence, and safety signals.
“If you can’t measure it, you can’t improve it” ~ Drucker
Funding Models: Pick Your Poison

- Draw down reserves
- Charge members a user fee
- Pursue industry sponsorship
Current Usage Of Performance Reports In Practice QI Initiatives (2016)

- Over 4 out of 5 (84%) users that receive the PINNACLE Registry performance reports have indicated that they are using them to inform QI initiatives. Compared to last year, usage of PINNACLE Registry performance reports to inform QI initiatives has increased by 18 percentage points.

Q: Do you currently use the PINNACLE Registry performance reports to inform Quality Improvement (QI) initiatives at your practice? (n=70)
PINNACLE Registry User Fee (2016)

- 7 out of 10 (72%) of users are not able to assign a value. 1 out of 10 (10%) would assign $100-$150. Nearly 1 out of 10 (7%) would assign $150-$200 and another 1 out of 10 (7%) would assign $200 to $250.

Q: Considering the benefits of the PINNACLE Registry, such as meeting multiple federal reporting requirements, advanced customer support, dashboard reporting, access to quality improvement tools, etc., what value would you assign to these services if the PINNACLE Registry charged an annual fee? (n=129)
Q: What is the most important PINNACLE Registry participation benefit for you and your practice? (n=129)

- Participation in federal program requirements: 68%
- Submission for federal incentive programs, including PQRS: 61%
- Benchmarking your performance against national averages: 47%
- Receiving quarterly performance reports measuring your adherence to outpatient performance measures: 45%
- Access to quality improvement tools: 40%
- Preparing for value-based purchasing: 26%
- Using data for ACC-sponsored educational, PI-CME, and MOC: 16%
- Receiving a discounted rate from The Doctors Company for medical malpractice insurance coverage: 8%
- Contributing to novel scientific research production: 7%
- Other: 6%

Q: What primary feature of the PINNACLE Registry was the reason for your recommendation? (n=64)

- Participation in federal program requirements: 55%
- Submission for federal incentive programs, including PQRS: 23%
- Benchmarking performance against national averages: 8%
- Access to quality improvement tools: 5%
- Receiving quarterly performance reports measuring adherence to outpatient performance measures: 3%
- Preparing for value-based purchasing: 2%
- Receiving a discounted rate from The Doctors Company for medical malpractice insurance coverage: 2%
- Access to quality improvement tools: 3%
- Other: 6%
Clinical Data Registry: A Wordy Definition

A clinical data registry is an organized system that collects uniform data (clinical and patient-reported) to evaluate specified actions and outcomes for a patient population.

With the increasing usage of EHRs, registries have emerged as valuable solutions for harnessing the power of information technology to capture insights on real world patient care, guideline adherence, and safety signals.
What Registries Do

**Feedback:** Send monthly clinical performance reports to thousands of doctors, including rapid deployment of new metrics

**Insights:** Generate market insights, new hypotheses, and guidance for society programmatic offerings

**Research:** Show how care is managed for millions of real world patients; demonstrate value and effectiveness of interventions
Potential Sponsorship Benefits

• Expansion of Data Collection to Meet Your Needs
• Technical Workshops with the Registry Team
• Quarterly Sponsor Reports
• Ad hoc Analytic Queries
• Trial Modeling
• Novel Scientific Research
Expand Scope of Data Collection

New data elements or modules specific to disease states
Joint Technical Advisory Workshops

Collaborative workshops between registry and sponsor teams
• Review data elements selected by the registry Expert Panel
• Suggest data elements for future versions of registry for Expert Panel review
• Review performance measures and metrics
• Identify data linkages between registry and other sources of data
• Contribute ideas to research agenda
• Discuss database infrastructure
Quarterly Sponsor Reports

Work with registry team to design quarterly reports specific to data elements of interest for sponsor internal use

• Demographics of patients
• Comorbidities
• Events and History
• Medication use
• Lab values
• Performance measure rates
## Priority Access to Ad Hoc Queries

<table>
<thead>
<tr>
<th>Project ID</th>
<th>Topic</th>
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<tbody>
<tr>
<td>Ad Hoc 1</td>
<td>INR Value before Stroke Among patients on Warfarin</td>
</tr>
<tr>
<td>Ad Hoc 2</td>
<td>Aspirin Use by Practice and Patient Region, State and Zip code</td>
</tr>
<tr>
<td>Ad Hoc 3</td>
<td>AF Performance Measure Adherence and Medication Use by Region, State and Zip Code</td>
</tr>
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<td>Ad Hoc 4</td>
<td>Kidney Impairment and treatment, days from AF diagnosis to treatment</td>
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<tr>
<td>Ad Hoc 5</td>
<td>Trial Criteria Modeling</td>
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<td>Ad Hoc 6</td>
<td>Trial Site Recruitment</td>
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<table>
<thead>
<tr>
<th>State</th>
<th>PINN 160: Assessment of thromboembolic risk factors (CHADS2)</th>
<th>PINN 161: Chronic anticoagulation therapy</th>
<th>Count of patients in state with no therapy (No aspirin, No OAC)</th>
<th>Count of patients with aspirin and no OAC</th>
<th>Count of patients with aspirin + any OAC</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Numerator</td>
<td>Denominator</td>
<td>Mean</td>
<td>Std Dev</td>
<td>Numerator</td>
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<td>Alaska</td>
<td>285</td>
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<td>6.06</td>
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<td>Arizona</td>
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<td>Arkansas</td>
<td>1842</td>
<td>7695</td>
<td>22.34</td>
<td>27.3</td>
<td>3122</td>
</tr>
<tr>
<td>California</td>
<td>688</td>
<td>4801</td>
<td>16.21</td>
<td>20.08</td>
<td>2358</td>
</tr>
<tr>
<td>Colorado</td>
<td>1232</td>
<td>7568</td>
<td>8.89</td>
<td>15.39</td>
<td>3517</td>
</tr>
</tbody>
</table>
Support for Novel Scientific Research

• Publication of Research in top medical journals
• Promotion of Registry Research through member communication channels
• Formation of a dedicated Writing Group with expertise in registry
• Support for set number of abstract and manuscript submissions
• Joint commissioned manuscript projects with mutually agreed upon topics
Scope of PINNACLE AF Research

- AF and Native Americans (Jeong)
- Provider gender and appropriate OAC (submitted to AHJ)
- Differences in provider perception and performance in AF OAC (Glusenkamp, QCOR ‘12)
- Practice variation in Warfarin (AJC 2011)
- OAC in paroxysmal v. persistent AF (submitted to AHJ)
- Inappropriate OAC in low risk AF patients
- ASA Therapy in OAC
- OAC as a function of CVA Risk
- Use of NOACs
- Off-label Use of Novel Oral Anticoagulants in Patients
- Racial Disparities & OAC
- Uptake of NOACs
- Rates and Predictors of Warfarin vs. OAC treatment
- OAC in h HF with Preserved and Depressed Ejection Fractions
- Association between AC use and CKD
- Practice Variation in Antiplatelet and AC for Patients with Both AF and CAD
- TOAT use in AF Patients with Recent Coronary Artery Stenting
Research Pipeline: 12 AF Manuscripts in Preparation

Manuscripts

• Practice-level variation in warfarin use among outpatients with atrial fibrillation (from the NCDR PINNACLE program). Chan P. Am J Cardiol. 2011;108:1136–1140

Abstracts

• Practice Variation in Antiplatelet and Anticoagulation Therapy for Patients with Both AF and CAD (abstract accepted at AHA ’14)
• Use of Novel Anticoagulants (Dabigatran and Rivaroxaban) for Patients with AF (ACC’14)
• Inappropriate Oral Anticoagulation Use in Patients with AF but without Stroke Risk Factors (ACC’14)
• Uptake of Novel Oral Anticoagulants in Patients with Non-Valvular and Valvular AF (ACC’14)
• Prescription of Oral Anticoagulation in AF Patients Across the Spectrum of Stroke Risk (HRS’14)
• Predictors of Aspirin Versus Oral Anticoagulant Use in AF Patients At-Risk for Stroke (ACC’14)
• Relationship of Provider and Practice Volume to Performance Measure Adherence for Patients with AF, HF, and CAD (QCOR ’13)
• Differences in Anticoagulant Therapy Prescription in Patients with Paroxysmal versus Persistent AF (HRS ’13)
• Inappropriate Oral Anticoagulant Use in Atrial Fibrillation Patients with a Low Risk of Thromboembolism (ACC’13)
• Assessing Performance Perceptions and Realities in Outpatient Atrial Fibrillation Care. Glusenkamp (QCOR ’12)
• Outpatient Compliance with Performance Measures for AF: A Report of the first 14,000+ Patients from the American College of Cardiology’s IC³ (Improving Continuous Cardiac Care) Program. (ACC’10)
Prescription of Oral Anticoagulation in Atrial Fibrillation Patients Across the Spectrum of Stroke Risk: Insights from the NCDR® PINNACLE Registry

Jonathan C. Hsu, MD,1 | Thomas M. Maddox, MD, MSc,2 | Kevin Kennedy, MS,3 | David F. Katz, MD,4 | Lucas N. Marcoz, MD,5 | Anil K. Gehi, MD,6 | Minoo P. Turakhia, MD, MA,7 | Gregory M. Marcus, MD, MA8

From the 1University of California, San Diego, San Diego, California; the 2University of Colorado School of Medicine, Denver, Colorado; the 3Mid America Heart Institute, Kansas City, Missouri, the University of North Carolina, Chapel Hill, North Carolina; 4Stanford University, Palo Alto, California and the 5University of California, San Francisco, California; on behalf of the NCDR

Background

- Patients with atrial fibrillation (AF) are at a proportionally higher risk of stroke based on the accumulation of well-defined risk factors.
- It is unknown the extent to which prescription of oral anticoagulation (OAC) in real-world practice increases as the amount of risk factors increase.

Objective

- To determine the proportion of AF patients treated with OAC, antplatelet therapy, and no antithrombotic therapy across the spectrum of CHADS2 risk.
- To determine whether increased CHADS2 score was associated with an increased prevalence of OAC treatment.

Methods

- As a measure of stroke risk, we calculated the CHADS2 and CHA2DS2-VASc score of all outpatients with AF enrolled in the ACC NCDR PINNACLE Registry between 2008-2013.
- Using hierarchical modified Poisson regression models adjusted for patient, physician, and practice characteristics, we examined the association of an increased stroke risk score with prescription of OAC.

Results and Table 1

<table>
<thead>
<tr>
<th>CHADS2 Score</th>
<th>OAC</th>
<th>CHA2DS2-VASc</th>
<th>ASA</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-1</td>
<td>40%</td>
<td>50%</td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td>2-3</td>
<td>60%</td>
<td>40%</td>
<td>40%</td>
<td></td>
</tr>
<tr>
<td>4-5</td>
<td>80%</td>
<td>20%</td>
<td>20%</td>
<td>10%</td>
</tr>
</tbody>
</table>

Conclusions

- Each 1 point increase in risk score was associated with an increased odds of OAC compared to aspirin only prescription using both the CHADS2 (adjusted OR 1.10, 95% CI 1.17–1.18; p < 0.0001) and CHA2DS2-VASc (adjusted OR 1.18, 95% CI 1.15–1.18; p < 0.0001) scores. Overall, OAC prescription prevalence did not top 50%, even in high risk patients (Figure).

References

Use of Novel Oral Anticoagulants for Patients with Non-valvular Atrial Fibrillation: A Report from the NCDR® Pinnacle Registry

Nilay D. Shah*, Paul Chan*, Kency L. Gosh*, Lucas Marzec*, Henry H. Ting*
*Mayo Clinic, Rochester, MN; †St. Luke’s Health System, Kansas City, MO; ‡University of Colorado, Denver, CO on behalf of the NCDR

Background
The use of novel oral anticoagulants (NOACs) such as direct thrombin inhibitors and direct activated Factor X inhibition in routine clinical practice is not well described. We undertook this study to characterize the adoption patterns of use of NOACs in a sample of outpatient cardiology practices.

Methods
Data Source: NCDR Pinnacle registry. Population: Patient with non-valvular atrial fibrillation and CHADS2 score ≥ 2. Exclusion Criteria: CHADS score<1; prior cardiac valve surgery; not on warfarin due to a medical reason. Outcomes: Rates and types of anticoagulants used.

Time Frame: July 2009 through June 2012. Analyses: Descriptive and hierarchical logistic regression analyses to examine the use of any anticoagulants, warfarin, and NOACs. The last visit for each quarter for each patient was used for analysis (for those patients with more than one visit in a quarter).

Results
Overall, our analyses included a total of 178,207 unique patients with 268,820 outpatient encounters from 133 cardiology practices between July 2009 and June 2012.

Table 1. Descriptive Statistics, by year

<table>
<thead>
<tr>
<th>Year</th>
<th>Total</th>
<th>Age</th>
<th>Sex</th>
<th>Type</th>
<th>%</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>178,207</td>
<td>77.4 ± 10.4</td>
<td>58.6 ± 10.9</td>
<td>70.4 ± 10.6</td>
<td>56.3 ± 10.7</td>
<td>&lt; 0.0001</td>
</tr>
</tbody>
</table>

Table 2. Factors Associated with Receiving a NOAC

<table>
<thead>
<tr>
<th>Factor</th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (per 10 years)</td>
<td>0.84</td>
<td>0.83-0.85</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Male</td>
<td>1.06</td>
<td>1.04-1.09</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>CHADS score (per 1 pt)</td>
<td>0.91</td>
<td>0.90-0.93</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Syncope</td>
<td>0.97</td>
<td>0.95-1.01</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Prior stroke/TIA</td>
<td>0.57</td>
<td>0.54-0.60</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Comorbid status</td>
<td>1.05</td>
<td>1.03-1.06</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Medication - PPI</td>
<td>1.14</td>
<td>1.11-1.18</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Medication - MC</td>
<td>1.10</td>
<td>1.06-1.14</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Medication - Other</td>
<td>1.01</td>
<td>0.96-1.07</td>
<td>0.749</td>
</tr>
<tr>
<td>Any anticoagulant</td>
<td>1.01</td>
<td>0.96-1.06</td>
<td>0.350</td>
</tr>
</tbody>
</table>

Conclusion

- There was a gradual increase in the use of novel anticoagulants for the management of non-valvular atrial fibrillation.
- There were no significant changes in the rates of overall anticoagulation among this population.
- Younger individuals, males, and those with lower risk were more likely to receive a novel anticoagulant.
- Dual antithrombotic therapy was associated with a lower likelihood of receiving a novel anticoagulant.
- The predominant novel anticoagulant prescribed during this timeframe was dabigatran (in Q2 2012: 11.1% of the prescriptions were for dabigatran and 21.4% for rivaroxaban).
- A key limitation is that we did not evaluate the adoption of novel anticoagulants amongst individuals with low risk or prescribing that may occur in primary care practices.
- It is likely that the adoption of novel anticoagulants will accelerate as practitioners get more experience with the use of these agents.

This research was supported by the American College of Cardiology Foundation’s National Cardiovascular Data Registry (NCDR). The views expressed in the abstract represent those of the author(s), and do not necessarily represent the official views of the NCDR or its associated professional societies identified at www.ncdr.com. For more information go to www.ncdr.com or email ncdrresearch@accd.org
Research example: Two oral presentations at AHA.15 Scientific Sessions

November 8; 3:45 p.m.
Gender Differences in Use of Anticoagulant for Atrial Fibrillation: A report from the NCDR®

November 9; 6 p.m.
The Introduction of Novel Oral Anticoagulants Has Improved Overall Oral Anticoagulation Rates In Atrial Fibrillation: Insights from the NCDR PINNACLE REGISTRY
The Introduction Of Novel Oral Anticoagulants Has Improved Overall Oral Anticoagulation Rates In Atrial Fibrillation: Insights from the NCDR PINNACLE Registry

Lucas N Marzec, MD; Kensey L Gosch, MS; Paul S Chan, MD, MSc; Henry H Ting, MD; Nilay D Shah, PhD; Thomas M Maddox, MD
Rates of OAC and NOAC Use Over Time

![Graph showing rates of OAC and NOAC use over time.](image-url)
Patient Factors Associated with Overall OAC Use

<table>
<thead>
<tr>
<th>Factor</th>
<th>Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHADS-VASc (per 1 pt increase)</td>
<td>1.52 (1.49, 1.54)</td>
</tr>
<tr>
<td>Weight (per 23 kg increase)</td>
<td>1.34 (1.33, 1.35)</td>
</tr>
<tr>
<td>CAD</td>
<td>0.79 (0.78, 0.80)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>1.10 (1.08, 1.11)</td>
</tr>
<tr>
<td>Male</td>
<td>1.50 (1.47, 1.54)</td>
</tr>
<tr>
<td>Age (per 10 yr increase)</td>
<td>0.96 (0.94, 0.97)</td>
</tr>
<tr>
<td>Heart Failure</td>
<td>0.86 (0.84, 0.88)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.71 (0.70, 0.73)</td>
</tr>
<tr>
<td>Stroke/TIA</td>
<td>0.94 (0.91, 0.97)</td>
</tr>
<tr>
<td>PAD</td>
<td>0.61 (0.59, 0.62)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>0.70 (0.68, 0.72)</td>
</tr>
</tbody>
</table>
At the Core of Society Strategy

Why we invest

- Unique clinical information
- Enable performance measurement by physicians for physicians
- Support for novel scientific research production
- Scaled delivery of registry-driven quality improvement programs
Programmatic Uses for Registry Data

1. Provide performance reports to providers and CMS

2. Inform leadership discussions and strategic direction

3. Embed in branded Quality Initiatives
Practice Level Variation In Anticoagulation Performance Rates: 2013 Baseline

**National Summary Statistics**
Mean: 61.9%
Standard: ± 10.9

n= 138 practices  Full Year 2013
Sponsored QI programs can work together

- Clinical Registry
  - Feedback reports to clinicians
  - Quarterly sponsor reports and ad hoc

- QI Programs
  - Anticoagulation Initiative, AF Recognition program

- QI Tools
  - Quality Ambassador, mobile apps, checklists

- Education
  - (CME and MOC Part IV)

- Peer Reviewed Medical Literature
  - (Abstracts and manuscripts)

- Guidelines, Performance Measures, Decision Pathways

- Outcomes Research

- Real World Practice
Using registry data to examine barriers to stroke prevention in Afib patients

**Underdiagnoses** – NVAF unrecognized

**Under-treatment** – OAC not prescribed or continued for eligible patients

**Under-dosing** – low dosing of NOACs, suboptimal TTR, use of aspirin for high risk patients
Antithrombotic Therapy by Stroke Risk Score

CHA2DS2-VASc Score

- OAC and ASA
- ASA only
- OAC only
- None
Older patients more likely to receive low dose anticoagulants

<table>
<thead>
<tr>
<th>Display Element</th>
<th>75 mg dabigatran</th>
<th>150 mg dabigatran</th>
<th>15 mg Rivaroxaban</th>
<th>20 mg Rivaroxaban</th>
<th>2.5 mg Apixaban</th>
<th>5.0 mg Apixaban</th>
<th>No Antithrombotic (No Warfarin, Dabigatran, Rivaroxaban, Apixaban, ASA, clopidogrel, prasugrel, Ticagrelor)</th>
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<tbody>
<tr>
<td>Age (Means +/- SD)</td>
<td>81 (±8.70)</td>
<td>72 (±10.09)</td>
<td>79 (±9.02)</td>
<td>70 (±10.16)</td>
<td>82 (±9.27)</td>
<td>71 (±10.09)</td>
<td>72 (±13.14)</td>
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<tr>
<td>Gender</td>
<td></td>
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<td>15874</td>
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<td>2</td>
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<td>479</td>
<td>1294</td>
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<td>1055</td>
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<tr>
<td>State Specific Plan (non-Medicaid)</td>
<td>255</td>
<td>1897</td>
<td>938</td>
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<td>860</td>
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<td>None</td>
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<td>3602</td>
<td>1882</td>
<td>6561</td>
<td>1743</td>
<td>5801</td>
<td>7439</td>
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</table>
Getting Serious about QI

Moving from passive reports to targeted interventions

Deploying practice stratification and recognition program

Gleaming best tactics and tools from high performance groups

Sending a Quality Ambassador to low performance groups
The Preventing Preventable Strokes Program

**Phase 1**
• Q1-Q2 2015
• Define practice level variation
• Rank Pinnacle Registry practices based on anticoagulation performance rates.

**Phase 2**
• Q1-Q3 2015
• Analysis of clinical data from the Pinnacle-AF Registry
• Conduct interviews among a subset of Pinnacle Registry practices.

**Phase 3**
• Q3-Q4 2015
• Identify and develop new evidence-based quality improvement tools and best practices
• Align personalized physician- and practice-level reports with new and existing resources (TEAM-A).
• Recognize high-tier physicians through a newly developed Physician Recognition Program

**Phase 4**
• Q2-Q4 2015
• Deploy trained Quality Improvement (QI) Ambassador to assist practices in overcoming challenges in their own physician- and practice-level anticoagulant performance rate.

**Phase 5**
• Q4 2015-Q1 2016
• Analyze quantitative and qualitative data to observe changes in anticoagulation performance rates to determine the overall impact of the project.
National Summary Statistics
Mean: 66.8%
Standard: ± 9.7
Manual Data Entry or Vendor Supported  
** Requires Abstractor **

Extracted in raw form out of EMR  
** No Manual Intervention **

Data Entry

HIGH – poor or inconsistent data is rejected

VARIABLE – No data validation and dependent on how data is documented in EMR

Data Quality

Hospital Subscription Vendor Certification Fees

Free to physicians Industry / Sponsorship funded

Funding

In-Patient  VS  Out-Patient

AAOS
American Academy of Orthopaedic Surgeons
The Winning Equation
Questions