



AMERICAN ACADEMY OF  
ORTHOPAEDIC SURGEONS

# Registry Growth and Sustainability: Opportunities and Challenges

CMSS Registry Summit

May 10, 2018

## A little background on me

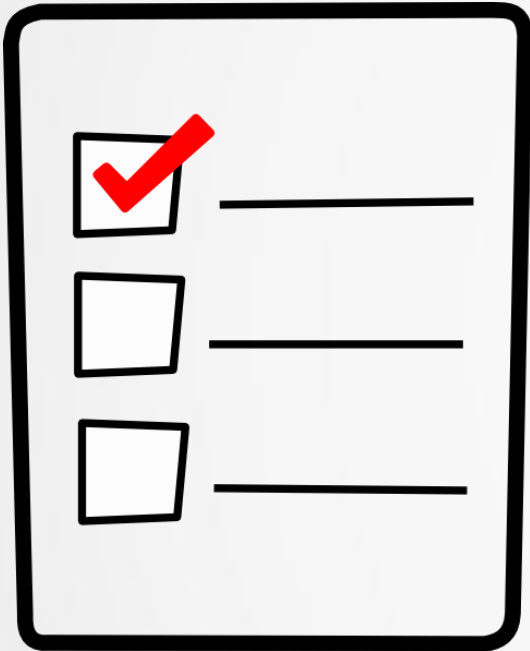
- (Newish) AAOS Director of Orthopaedic Registries
- Former President, Provider Solutions at FIGmd
- Former Director, Outpatient Registries at American College of Cardiology

## 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?

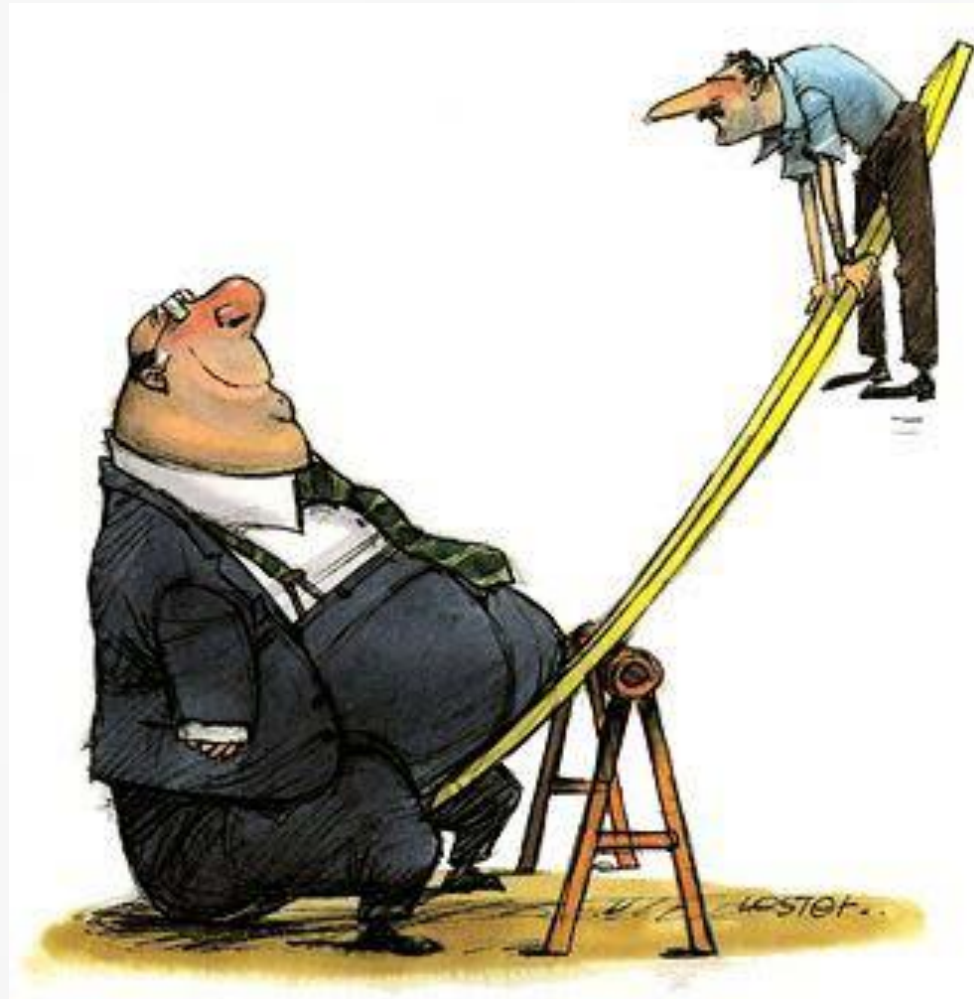
- RWE/passive, observational research
- Post-market surveillance and/or device tracking
- Clinical trials?!?
- Participation in MIPS

# 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



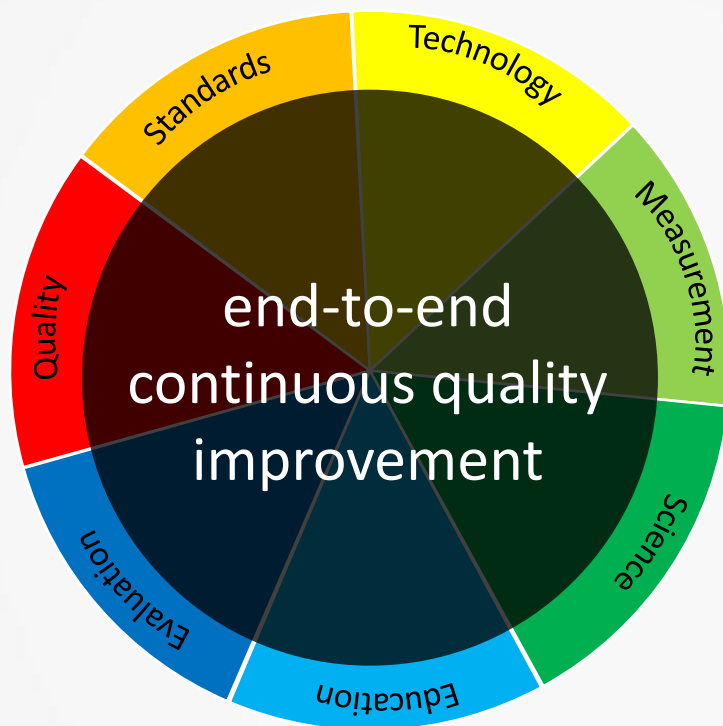
# Clinical Data Registry: A Wordy Definition

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.



# Quality Vision



## Registries

- component of a larger quality vision
- provide data to inform AAOS guidelines and test performance measures
- provide feedback to providers to continuously improve their practice and healthcare outcomes
- allow AAOS to define what quality means in a value-based system
- reduce the reporting burdens on physicians
- help inform gaps in knowledge or areas for further education

“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**

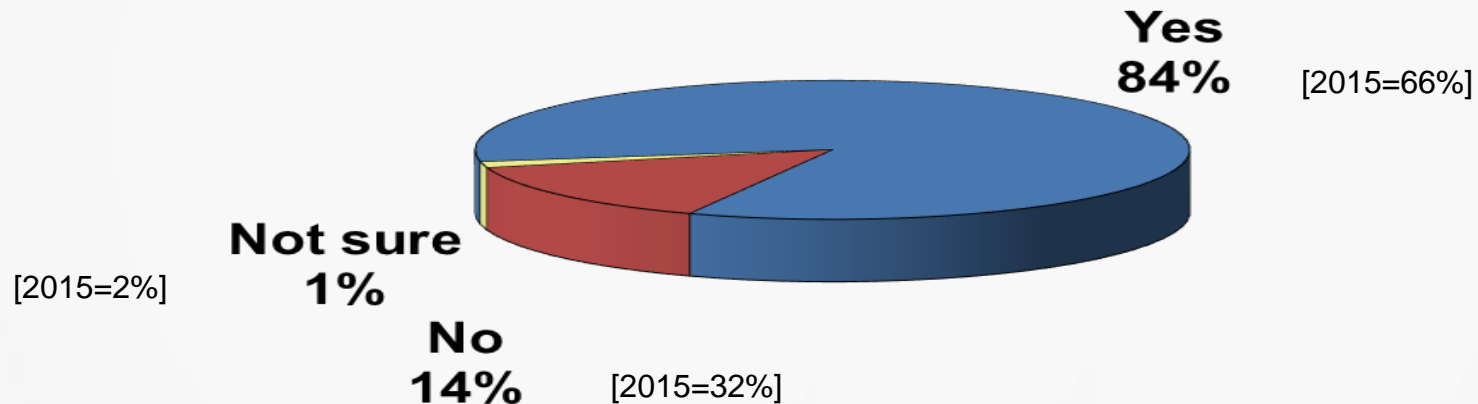


**Pursue  
industry  
sponsorship**



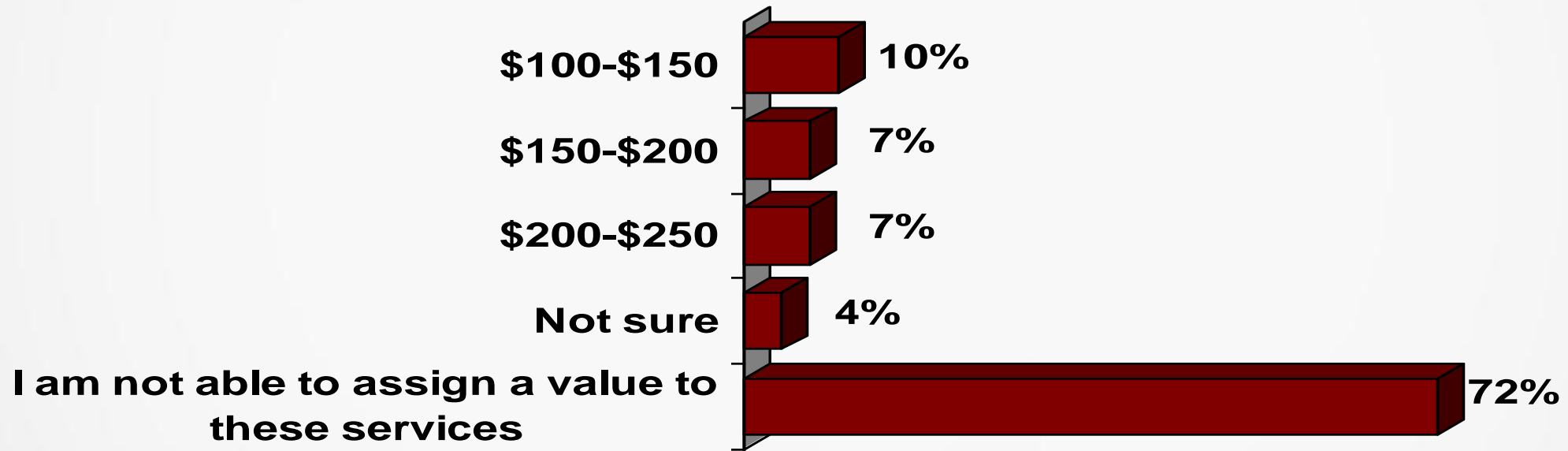
## Current Usage Of Performance Reports In Practice QI Initiatives (2016)

- 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.



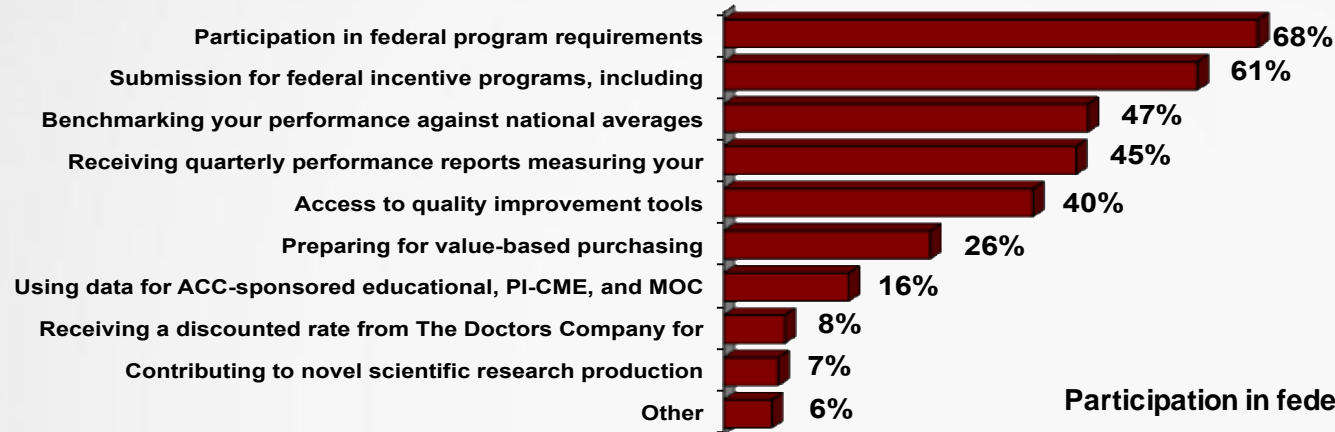
# PINNACLE Registry User Fee (2016)

- 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.

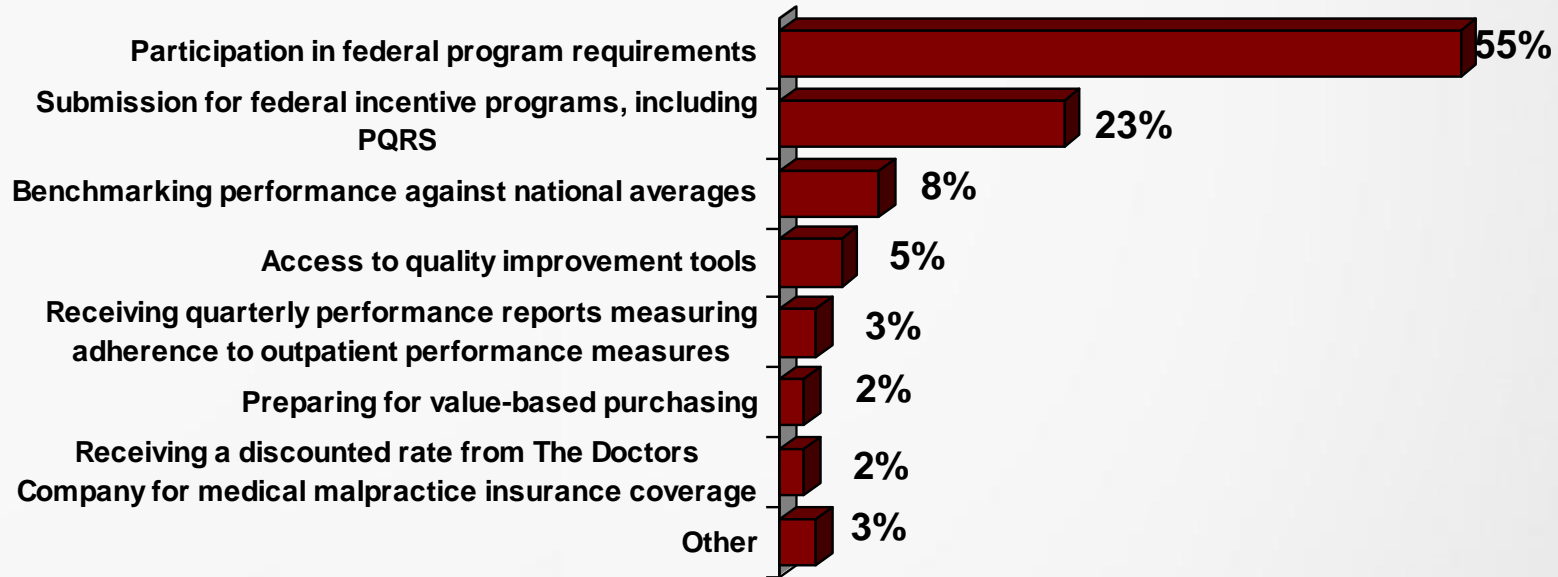


Q: Considering the benefits of the PINNACLE Registry, such as meeting multiple federal reporting requirements, advanced customer support, dashboard reporting, access to quality improvement tools, etc., what value would you assign to these services if the PINNACLE Registry charged an annual fee? (n=129)

# Most Important PINNACLE Registry Participation Benefit



## Primary Reason for Recommendation



Q: What is the most important PINNACLE Registry participation benefit for you and your practice? (n=129)

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

# 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

**PINNACLE Registry™** NCDR® PINNACLE Registry™ v1.2  
 Practice Innovation and Clinical Excellence Data Collection Form

MRN<sup>(100)</sup>, Encounter Date<sup>(100)</sup>, Practice ID<sup>(100)</sup>, Location ID<sup>(100)</sup>

Provider Name (Last, First MI)<sup>(100, 1541, 1542)</sup>, Provider NPI<sup>(100)</sup>

Patient new to the Practice<sup>(100)</sup>:  No  Yes

**A. PATIENT DEMOGRAPHICS**

Patient Name (Last, First MI)<sup>(100, 1541, 1542)</sup>, SSN<sup>(100)</sup>, Patient Zip<sup>(100)</sup>

Date of Birth<sup>(100)</sup>, Sex<sup>(100)</sup>:  Male  Female

Race: (Check all that apply)  White<sup>(100)</sup>,  Black/African American<sup>(101)</sup>,  American Indian/Alaska Native<sup>(103)</sup>,  Native Hawaiian/Pacific Islander<sup>(104)</sup>,  Asian<sup>(102)</sup>,  Hispanic or Latino Ethnicity<sup>(105)</sup>

Insurance Payers: (Check all that apply)  Private Health Insurance<sup>(100)</sup>,  Medicare (fee for service)<sup>(108)</sup>,  Medicare (managed care)<sup>(109)</sup>,  Medicaid<sup>(102)</sup>,  Military Health Care<sup>(103)</sup>,  State Specific Plan (non-Medicaid)<sup>(104)</sup>,  Indian Health Service<sup>(105)</sup>,  Non-US Insurance<sup>(106)</sup>,  None<sup>(107)</sup>

Payer ID<sup>(100)</sup>

**B. DIAGNOSES/CONDITIONS/COMORBIDITIES** (Check all that apply) Note: Indicate if the patient has a history of any of the following.

Coronary Artery Disease<sup>(100)</sup>,  Atrial Fibrillation/Flutter<sup>(102)</sup>,  Dyslipidemia<sup>(101)</sup>,  Diabetes Mellitus<sup>(101)</sup>,  Hypertension<sup>(100)</sup>,  Systemic Embolism<sup>(100)</sup>,  Peripheral Arterial Disease<sup>(100)</sup>,  Prior Stroke/TIA<sup>(100)</sup>

Unstable Angina<sup>(100)</sup>,  Heart Failure<sup>(100)</sup> → If Yes,  New diagnosis (within 12 months)<sup>(100)</sup>,  Stable Angina<sup>(100)</sup> → If Yes,  New diagnosis (within 12 months)<sup>(100)</sup>

**C. CARDIAC EVENTS** (Check all that apply) Note: Indicate if the patient has a history of any of the following.

Myocardial Infarction (any history of)<sup>(100)</sup> → If Yes,  Myocardial Infarction (within 12 months)<sup>(100)</sup>,  Coronary Artery Bypass Graft (within 12 months)<sup>(100)</sup>,  PCI - Bare Metal Stent Implant (within 12 months)<sup>(100)</sup>,  Cardio Valve Surgery (within 12 months)<sup>(100)</sup>,  PCI - Drug Eluting Stent Implant (within 12 months)<sup>(100)</sup>,  Heart Transplantation (within 12 months)<sup>(100)</sup>,  PCI - Other (non-stent) Intervention (within 12 months)<sup>(100)</sup>

**D. ENCOUNTER INFORMATION** Note: Complete only if assessed during today's encounter. If not assessed, leave blank.

Height:  in<sup>(100)</sup>  cm<sup>(100)</sup>, Blood Pressure<sup>(100, 101)</sup>, Weight:  lbs<sup>(100)</sup>  kg<sup>(101)</sup>, Patient unable to be weighed<sup>(100)</sup>, Heart Rate<sup>(100)</sup>, bpm

Tobacco Use<sup>(100)</sup>:  Never  Current  Quit within past 12 months  Quit more than 12 months ago

→ If Current or Quit within 12 months, Tobacco Type (Check all that apply):  Cigarettes<sup>(100)</sup>,  Cigars<sup>(100)</sup>,  Pipe<sup>(100)</sup>,  Smokeless<sup>(100)</sup>

→ If Current or Quit within 12 months, Smoking Cessation Counseling/Pharmacological Therapy Provided<sup>(100)</sup>:  No  Yes

Patient asked, during any previous encounter in the past 24 months, about the use of Tobacco<sup>(100)</sup>:  No  Yes

Advance Care Plan OR Discussion of Advance Care Plan Documented<sup>(100)</sup>:  No  Yes

**ANGINA SYMPTOMS AND ACTIVITY ASSESSMENT(S)** Note: Complete at least one to meet measure.

CCS Class<sup>(100)</sup>:  No angina  I  II  III  IV,  Other Tool/Method Used to Assess Angina Symptoms and Activity Completed<sup>(100)</sup>,  Seattle Angina Questionnaire Completed<sup>(100)</sup>

**HEART FAILURE ACTIVITY ASSESSMENT(S)** Note: Complete at least one to meet measure.

NYHA Class<sup>(100)</sup>:  I  II  III  IV,  Kansas City Cardiomyopathy Questionnaire Completed<sup>(100)</sup>,  Chronic Heart Failure Questionnaire from Guyatt Completed<sup>(100)</sup>,  Minnesota Living with HF Questionnaire Completed<sup>(100)</sup>,  Other Tool/Method Used to Assess Heart Failure Activity Completed<sup>(100)</sup>

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**PINNACLE Registry™** NCDR® PINNACLE Registry™ v1.3  
 Practice Innovation and Clinical Excellence Data Collection Form

MRN<sup>(100)</sup>, Encounter Date<sup>(100)</sup>, Practice ID<sup>(100)</sup>, Location ID<sup>(100)</sup>

Provider Name (Last, First MI)<sup>(100, 1541, 1542)</sup>, Provider NPI<sup>(100)</sup>

Patient new to the Practice<sup>(100)</sup>:  No  Yes

Encounter Reason<sup>(100)</sup>:  Atrial Fibrillation  Coronary Artery Disease  Diabetes  Heart Failure  Hypertension  Other Cardiac  Non-Cardiac

**A. PATIENT DEMOGRAPHICS**

Patient Name (Last, First MI)<sup>(100, 1541, 1542)</sup>, SSN<sup>(100)</sup>, Patient Zip<sup>(100)</sup>

Date of Birth<sup>(100)</sup>, Sex<sup>(100)</sup>:  Male  Female,  Patient Deceased<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy

Race: (Check all that apply)  White<sup>(100)</sup>,  Black/African American<sup>(101)</sup>,  American Indian/Alaska Native<sup>(103)</sup>,  Native Hawaiian/Pacific Islander<sup>(104)</sup>,  Asian<sup>(102)</sup>,  Hispanic or Latino Ethnicity<sup>(105)</sup>

Insurance Payers: (Check all that apply)  Private Health Insurance<sup>(100)</sup>,  Medicare (fee for service)<sup>(108)</sup>,  Medicare (managed care)<sup>(109)</sup>,  Medicaid<sup>(102)</sup>,  Military Health Care<sup>(103)</sup>,  State Specific Plan (non-Medicaid)<sup>(104)</sup>,  Indian Health Service<sup>(105)</sup>,  Non-US Insurance<sup>(106)</sup>,  None<sup>(107)</sup>

Payer ID<sup>(100)</sup>

**B. DIAGNOSES/CONDITIONS/COMORBIDITIES** (Check all that apply) Note: Indicate if the patient has a history of any of the following.

Coronary Artery Disease<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Heart Failure<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Atrial Fibrillation/Flutter<sup>(102)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Dyslipidemia<sup>(101)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Diabetes Mellitus<sup>(101)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Hypertension<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Peripheral Arterial Disease<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Unstable Angina<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Stable Angina<sup>(100)</sup> → If Yes,  New diagnosis (within 12 months)<sup>(100)</sup>,  Isochemo Vasoular Disease<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Peripheral Vasoular Disease<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Chronic Kidney Disease<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Chronic Liver Disease<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy

**C. CARDIAC EVENTS** (Check all that apply) Note: Indicate if the patient has a history of any of the following.

Myocardial Infarction<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Coronary Artery Bypass Graft<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  PCI - Bare Metal Stent Implant<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Cardio Valve Surgery<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  PCI - Drug Eluting Stent Implant<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Heart Transplantation<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  PCI - Other (non-stent) Intervention<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Cardio Therapeutic Procedure<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Systemic Embolism<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Cardioversion<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Minor Hemorrhage<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  CRT-D<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Intra-arterial Hemorrhage<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  LVAD<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Non-intra-arterial Major Hemorrhage<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  CRT<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  TIA<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  ICD<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  PTCA<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Isochemo Stroke<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Permanent Pacemaker<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Hemorrhagic Stroke<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy,  Vascular Complication<sup>(100)</sup> (requiring intervention) → Date<sup>(100)</sup> mm / dd / yyyy

**D. ENCOUNTER INFORMATION** Note: Complete only if assessed during today's encounter. If not assessed, leave blank.

Height:  in<sup>(100)</sup>  cm<sup>(100)</sup>, Blood Pressure<sup>(100, 101)</sup>, Weight:  lbs<sup>(100)</sup>  kg<sup>(101)</sup>, Patient unable to be weighed<sup>(100)</sup>, Heart Rate<sup>(100)</sup>, bpm

Body Mass Index Screen Performed<sup>(100)</sup> → Date<sup>(100)</sup> mm / dd / yyyy

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Atrial Fibrillation Recurrence → Date<sup>(100)</sup> mm / dd / yyyy,  Rate Control Therapy,  Atrial Fibrillation Symptom Frequency (severe) → Date<sup>(100)</sup> mm / dd / yyyy,  Rhythm Control Therapy

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New data elements or modules specific to disease states

# Joint Technical Advisory Workshops

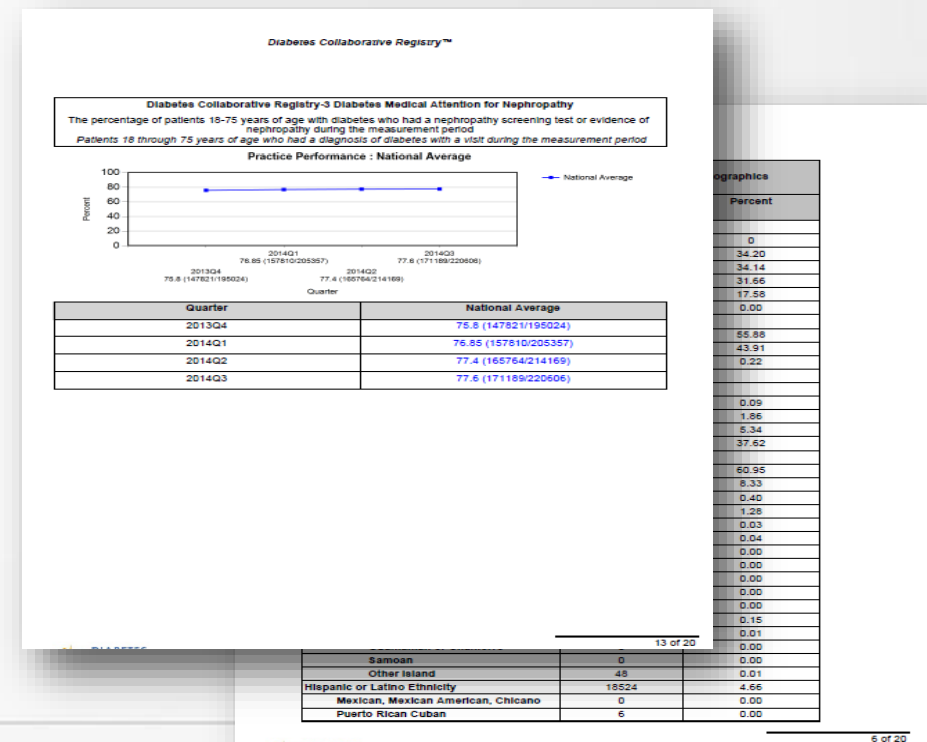
Collaborative workshops between registry and sponsor teams

- 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

Project ID	Topic
Ad Hoc 1	INR Value before Stroke Among patients on Warfarin
Ad Hoc 2	Aspirin Use by Practice and Patient Region, State and Zip code
Ad Hoc 3	AF Performance Measure Adherence and Medication Use by Region, State and Zip Code
Ad Hoc 4	Kidney Impairment and treatment, days from AF diagnosis to treatment
Ad Hoc 5	Trial Criteria Modeling
Ad Hoc 6	Trial Site Recruitment

State	PINN 160: Assessment of thromboembolic risk factors (CHADS2)				PINN 161: Chronic anticoagulation therapy				Count of patients in state with no therapy (No aspirin, No OAC)	Count of patients with aspirin and no OAC	Count of patients with aspirin + any OAC
	Numerator	Denominator	Mean	Std Dev	Numerator	Denominator	Mean	Std Dev			
Alabama	3029	6321	31.93	35.31	3431	5046	68.09	7.7	737	1944	1900
Alaska	285	4703	6.06	0	2027	3262	62.14	0	728	1870	1405
Arizona	11702	37576	25.8	35.07	16458	28570	57.94	10.07	7810	15361	8216
Arkansas	1842	7695	22.34	27.3	3122	5170	60.4	2.39	1029	3020	1982
California	688	4801	16.21	20.08	2358	3569	68.43	7.1	1317	1126	977
Colorado	1232	7568	8.89	15.39	3517	5089	58.32	18.53	805	2233	2896

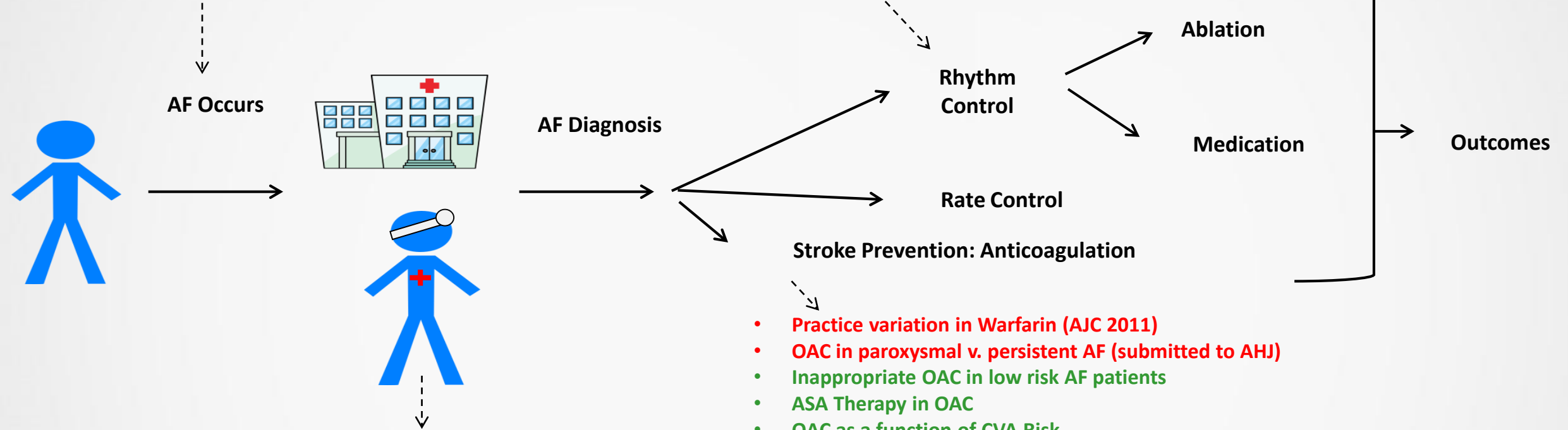
# Support for Novel Scientific Research

- 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)

- Predictors and disparities of rhythm control



- 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 IC<sup>3</sup> (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<sup>®</sup> PINNACLE Registry<sup>®</sup>

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 From the \*University of California, San Diego, San Diego, California; the †University of Colorado School of Medicine, Denver, Colorado; the ‡Mid America Heart Institute, Kansas City, Missouri; the §University of North Carolina, Chapel Hill, North Carolina; <sup>1</sup>Stanford University, Palo Alto, California and the <sup>1</sup>University of California, San Francisco, San Francisco, California; and 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.<sup>1</sup>

•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, antiplatelet therapy, and no antithrombotic therapy across the spectrum of CHADS<sub>2</sub> risk.

•To determine whether increased CHADS<sub>2</sub> score was associated with an increased prevalence of OAC treatment.

## Methods

•As a measure of stroke risk, we calculated the CHADS<sub>2</sub> and CHA<sub>2</sub>DS<sub>2</sub>-VASc score of all outpatients with AF enrolled in the ACC NCDR-PINNACLE Registry between 2008-2013.

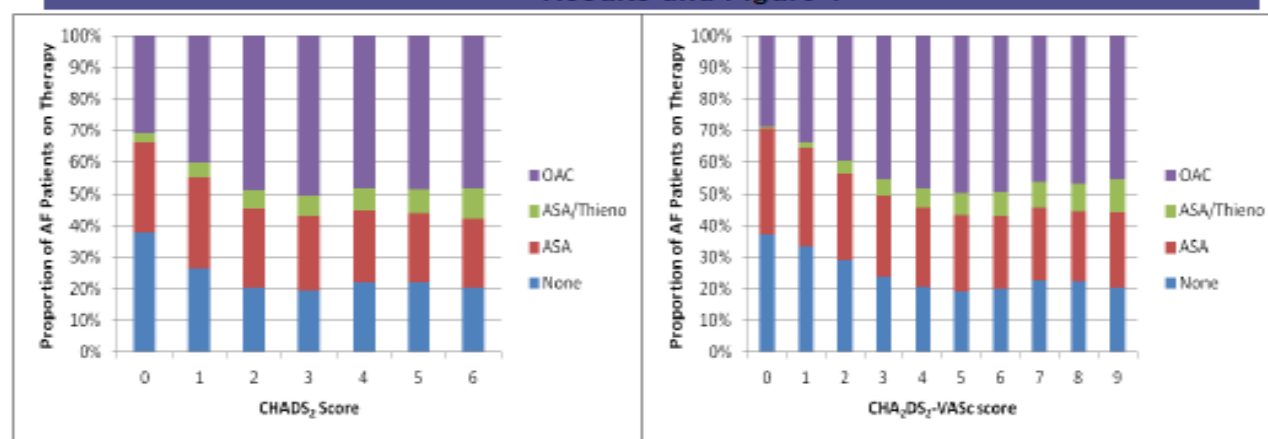
•Using hierarchical modified Poisson regression models adjusted for patient, physician, and practice characteristics, we examined the association of an increased stroke risk score with prescription of OAC.

## Results and Table 1

	Cohort n = 429,417
<b>Demographics</b>	
Age	71.31 ± 12.9
Sex	
Male	55.8%
Female	44.2%
Race	
White	93.2%
Black	5.7%
Other	1.1%
Region	
Northeast	13.5%
Midwest	28.2%
South	38.7%
West	19.6%
<b>Patient History and Risk Factors</b>	
Coronary artery disease	49.7%
Hypertension	76.8%
Unstable angina	1.0%
Prior systemic embolism	1.2%
Congestive heart failure	24.9%
Stable angina	6.4%
Dyslipidemia	55.2%
Peripheral arterial disease	8.5%
Diabetes	22.9%
Prior myocardial infarction	17.9%
Recent CABG	8.7%
<b>Practice Characteristics</b>	
Urban practice	86.7%
Average patient visits/year	36276.5 ± 27661.9

•Of 429,417 patients, 44.9% were treated warfarin or novel OACs, 25.9% were treated with aspirin, 5.5% were treated with combination aspirin/thienopyridine, and 23.8% were not treated with any antithrombotic therapy.

## Results and Figure 1



The distributions of specific therapies are shown for the cohort of AF patients as defined by both CHADS<sub>2</sub> (Panel A) and CHA<sub>2</sub>DS<sub>2</sub>-VASc (Panel B) scores.  
 AF = atrial fibrillation; ASA = aspirin; OAC = oral anticoagulant; Thieno = Thienopyridine.

•Each 1 point increase in risk score was associated with an increased odds of OAC compared to aspirin only prescription using both the CHADS<sub>2</sub> (adjusted OR 1.18, 95% CI 1.17-1.18; p<0.0001) and CHA<sub>2</sub>DS<sub>2</sub>-VASc (adjusted OR 1.15, 95% CI 1.15-1.16; p<0.0001) scores. Overall, OAC prescription prevalence did not top 50%, even in high risk patients (Figure).

## Conclusions

•In a large, real-world cardiac outpatient population, AF patients were more likely to be prescribed OAC therapy with accumulation of stroke risk factors. However, less than half of all patients at high risk for stroke were prescribed OAC.

## References

1. Gage BF, et al. Validation of clinical classification schemes for predicting stroke: results from the National Registry of Atrial Fibrillation. *JAMA*. 2001; Jan 13;285(2):266-70.

Disclaimer: Bristol-Myers Squibb and Pfizer Inc. are Founding Sponsors of the PINNACLE Registry<sup>®</sup>. Dr. Gregory M. Marcus receives speaker's fees from St. Jude Medical, is a consultant for InCardia, and receives research support from Baylis Medical, Cilentis, and Becton Dickinson Inc.

Disclaimer: This research was supported by the American College of Cardiology Foundation's National Cardiovascular Data Registry (NCDR). The views expressed in this 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](http://www.ncdr.com).

For more information go to [www.ncdr.com](http://www.ncdr.com) or email [ncdrresearch@ncdr.com](mailto:ncdrresearch@ncdr.com)



# Use of Novel Oral Anticoagulants for Patients with Non-valvular Atrial Fibrillation: A Report from the NCDR<sup>®</sup> PINNACLE Registry<sup>®</sup>

Nilay D. Shah<sup>‡</sup>, Paul Chan<sup>^</sup>, Kensey L. Gosch<sup>^</sup>, Lucas Marzec<sup>‡</sup>, Henry H. Ting<sup>‡</sup>

<sup>‡</sup>Mayo Clinic, Rochester, MN; <sup>^</sup>St. Luke's Health System, Kansas City, MO; <sup>‡</sup>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 inhibitors in routine clinical practice is not well described. We undertook this study to characterize the adoption and 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  $\geq 2$ .

**Exclusion Criteria:** CHADS score  $\leq 1$ ; 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 388,820 outpatient encounters from 103 cardiology practices between July 2009 and June 2012

Table 1. Descriptive Statistics, by year

	2009 n = 19524	2010 n = 69017	2011 n = 168704	2012 n = 131575	p-value
Age	77.4 ± 10.4	76.8 ± 10.9	76.4 ± 10.8	76.3 ± 10.7	<0.001
% Female	48.2%	48.2%	46.7%	46.3%	<0.001
Insurance					
None	2.8%	4.7%	5.4%	4.3%	<0.001
Private	48.3%	51.4%	53.8%	56.6%	<0.001
Public	48.9%	43.9%	40.8%	39.1%	<0.001
CHADS Score	2.5 ± 0.6	2.5 ± 0.6	2.5 ± 0.6	2.5 ± 0.6	<0.001
Comorbidities:					
Coronary artery disease	58.9%	60.8%	63.9%	66.2%	<0.001
Hypertension	93.8%	94.9%	96.0%	96.3%	<0.001
Unstable angina	1.8%	1.7%	1.9%	2.0%	<0.001
Systemic embolism	1.7%	1.5%	1.7%	1.9%	<0.001
Dyslipidemia	63.6%	67.4%	71.4%	74.0%	<0.001
Peripheral artery disease	11.8%	15.7%	22.3%	22.9%	<0.001
Diabetes	32.4%	36.6%	39.2%	39.6%	<0.001
Prior stroke/TIA	18.3%	22.0%	22.4%	22.7%	<0.001
Heart failure	47.3%	48.0%	48.7%	50.7%	<0.001
Stable Angina	8.0%	8.1%	9.6%	11.4%	<0.001
History of myocardial infarction	17.3%	19.4%	21.8%	23.1%	<0.001
Cardiovascular history in prior 12-months					
Myocardial infarction	9.2%	8.3%	10.0%	10.8%	<0.001
CABG	9.8%	8.2%	9.0%	9.6%	<0.001
PCI with bare metal stent	1.6%	1.8%	2.5%	2.8%	<0.001
PCI with drug eluting stent	7.7%	8.8%	8.0%	8.4%	0.921
PCI without stent	5.6%	4.5%	4.3%	4.7%	0.065

Figure 1. Treatment Rate and Uptake of NOACs by Quarter

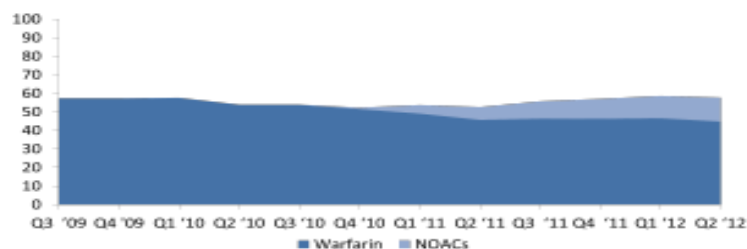
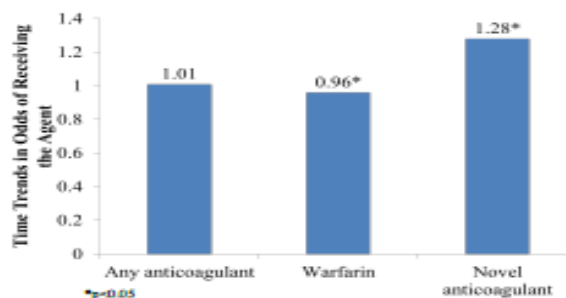


Figure 2. Adjusted Trend in Anticoagulation and Choice of Agent, 2009-2012



## 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 antiplatelet 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 2.1% 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

Table 2. Factors Associated with Receiving a NOAC

	Odds Ratio	95% CI	p-value
Age (per 10 years)	0.84	0.83-0.86	<0.0001
Male	1.06	1.04-1.09	<0.0001
CHADS score (per 1 pt)	0.91	0.90-0.93	<0.0001
Systolic embolism	0.95	0.86-1.05	0.323
Prior stroke/TIA	1.18	1.14-1.22	<0.0001
Commercial	1.18	1.14-1.22	<0.0001
Medicare - FFS	1.10	1.06-1.14	<0.0001
Medicare - MC	1.01	0.96-1.07	0.749
Medicaid	0.68	0.64-0.73	<0.0001
Dual antiplatelet use	0.53	0.51-0.56	<0.0001

PINNACLE Registry<sup>®</sup>

Bristol-Myers Squibb and Pfizer Inc. are Founding Sponsors of the PINNACLE Registry<sup>®</sup>.



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For more information go to [www.ncdr.com](http://www.ncdr.com) or email [ncdrresearch@acc.org](mailto:ncdrresearch@acc.org)

# Research example: Two oral presentations at AHA.15 Scientific Sessions



SCIENTIFIC 2015  
SESSIONS

**November 8; 3:45 p.m.**

Gender Differences in Use of Anticoagulant for Atrial Fibrillation: A report from the NCDR<sup>®</sup>

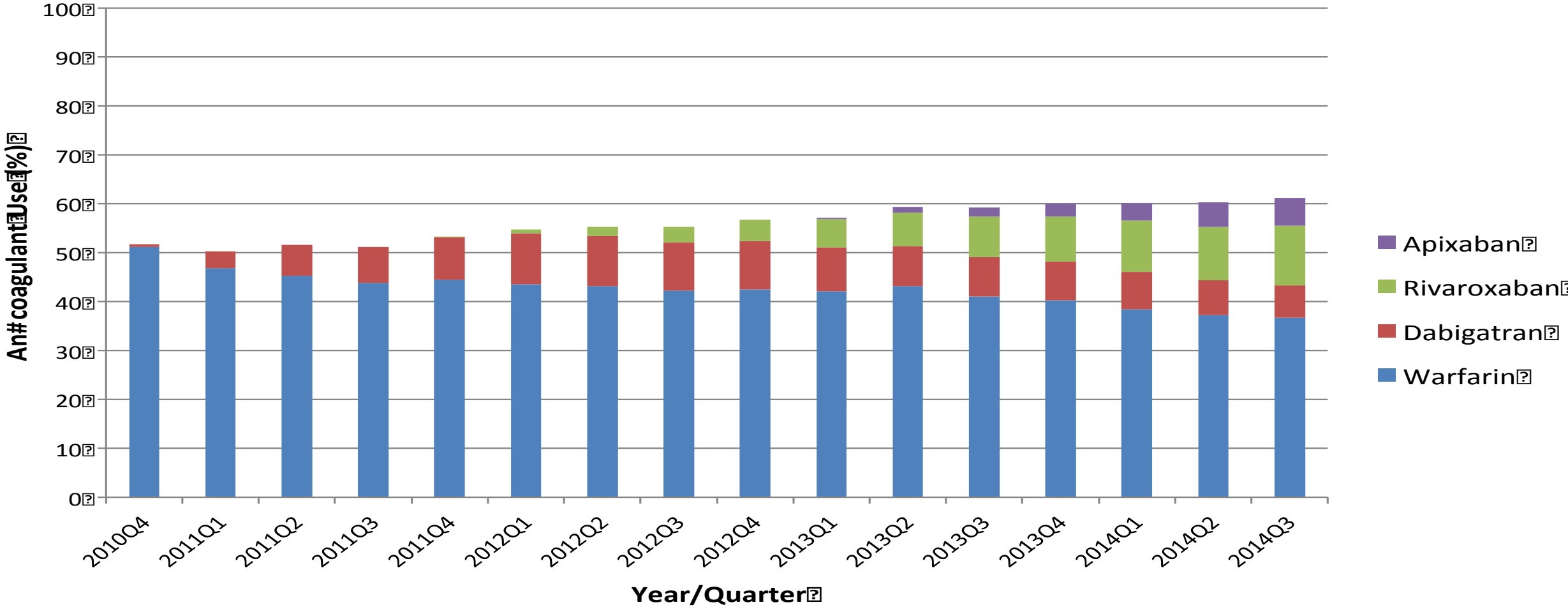
**November 9; 6 p.m.**

The Introduction of Novel Oral Anticoagulants Has Improved Overall Oral Anticoagulation Rates In Atrial Fibrillation: Insights from the NCDR PINNACLE REGISTRY

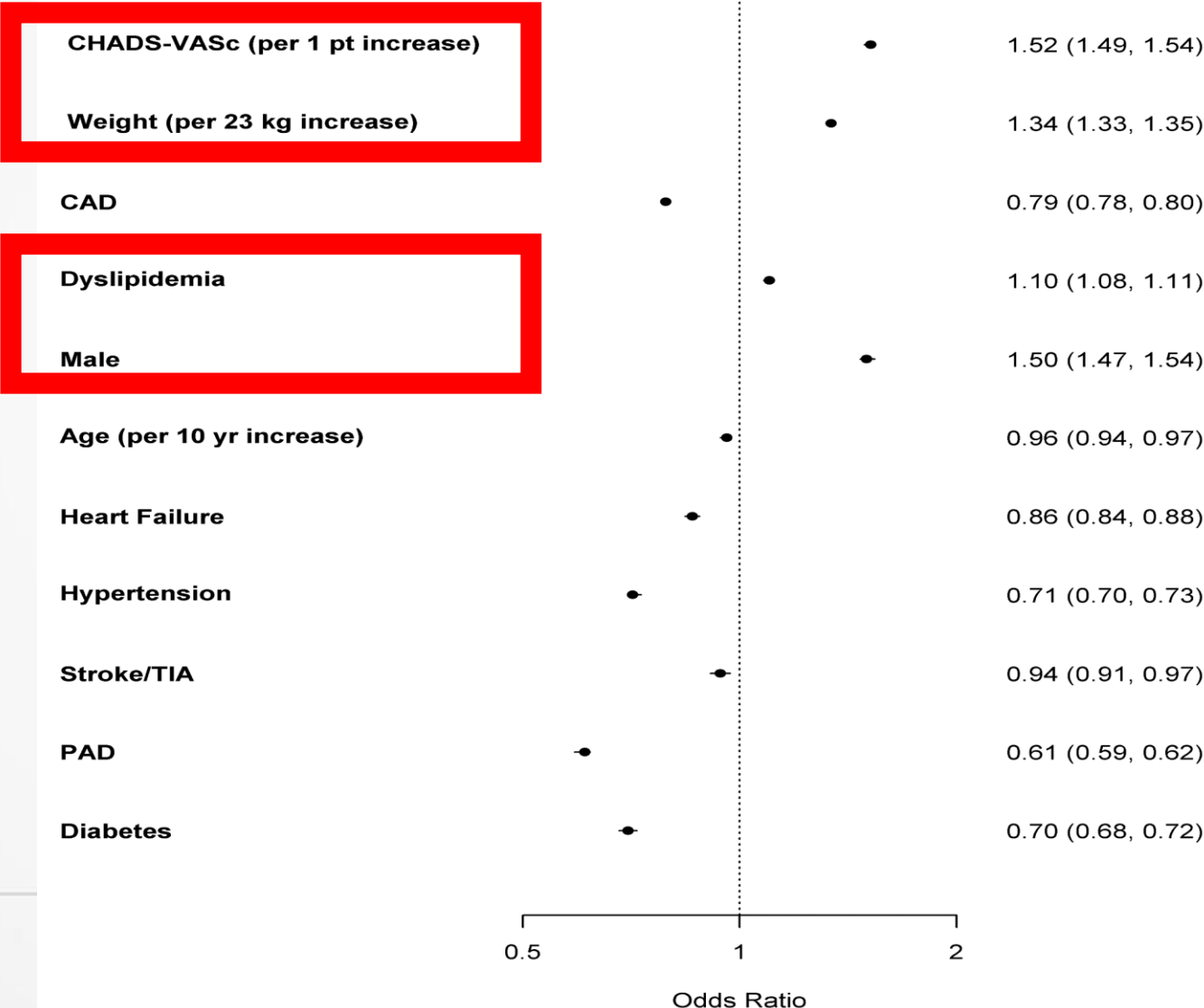
# The Introduction Of Novel Oral Anticoagulants Has Improved Overall Oral Anticoagulation Rates In Atrial Fibrillation: Insights from the NCDR PINNACLE Registry

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

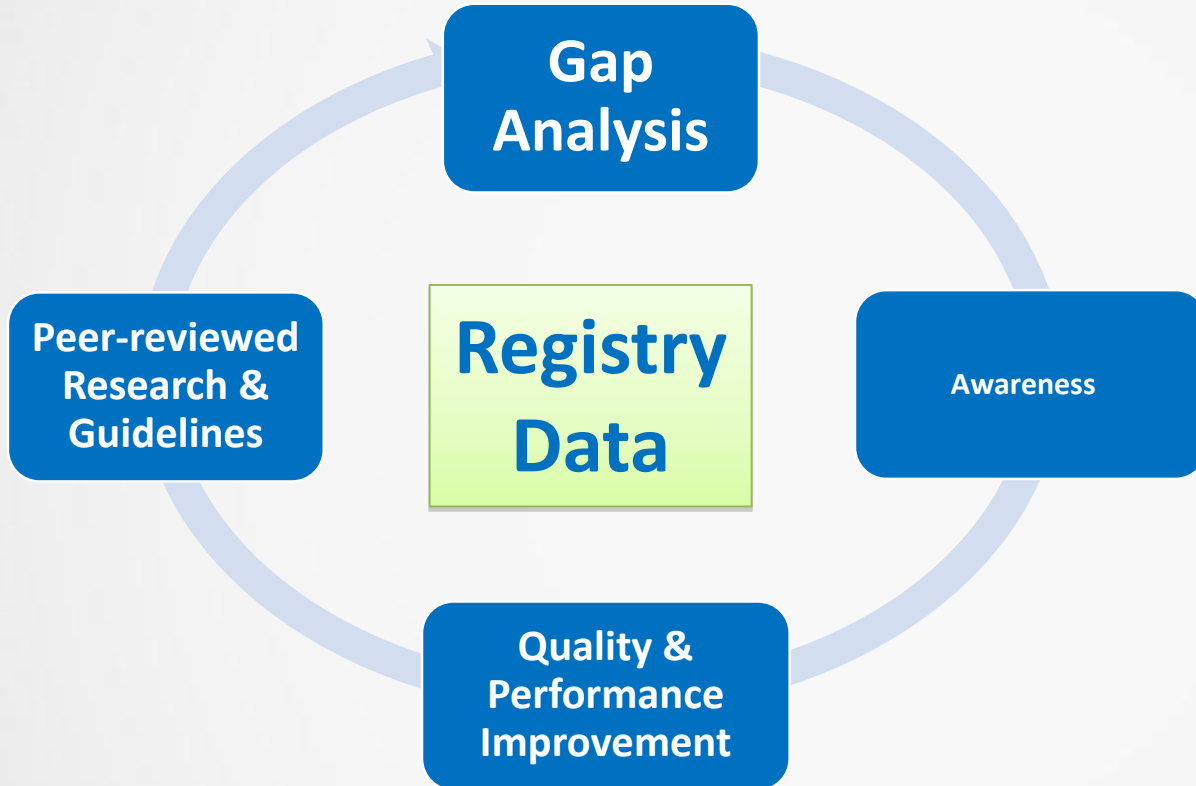
# Rates of OAC and NOAC Use Over Time



# Patient Factors Associated with Overall OAC Use



# At the Core of Society Strategy



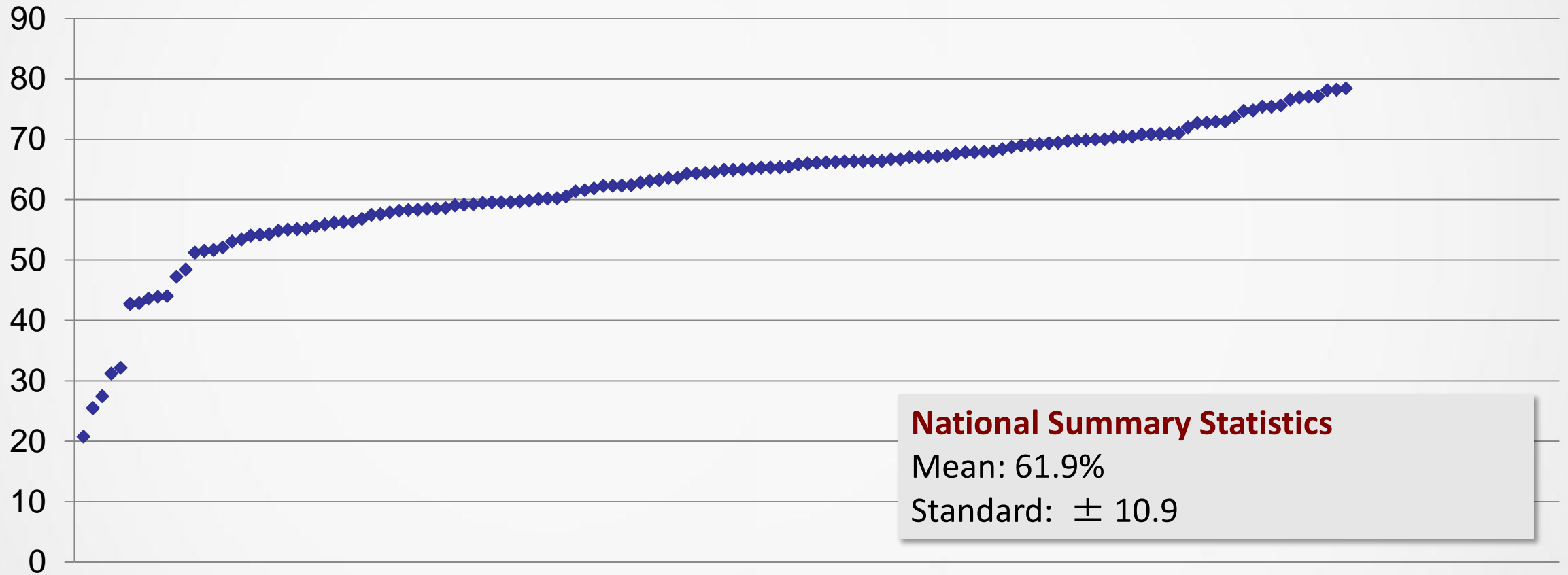
## Why we invest

- ✓ 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

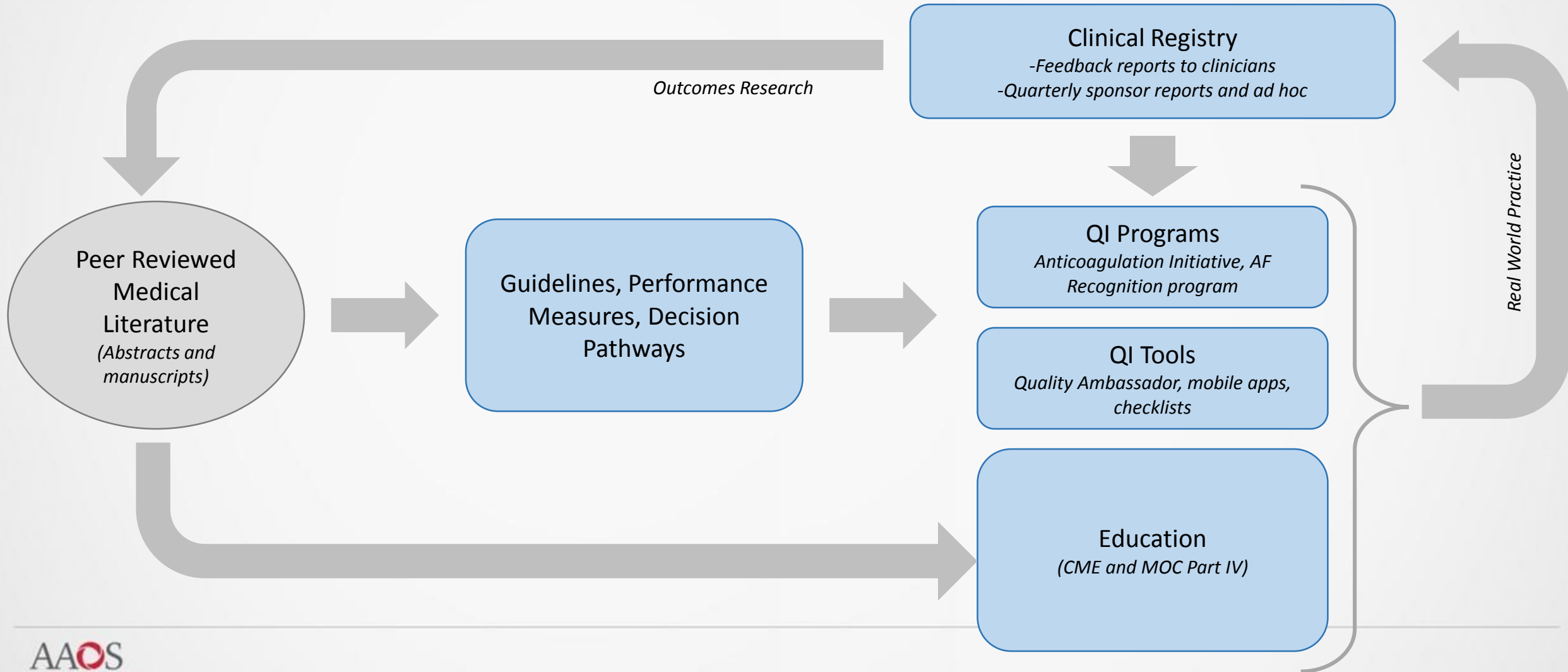
Mean: 61.9%

Standard:  $\pm 10.9$

n= 138 practices Full Year 2013



# Sponsored QI programs can work together



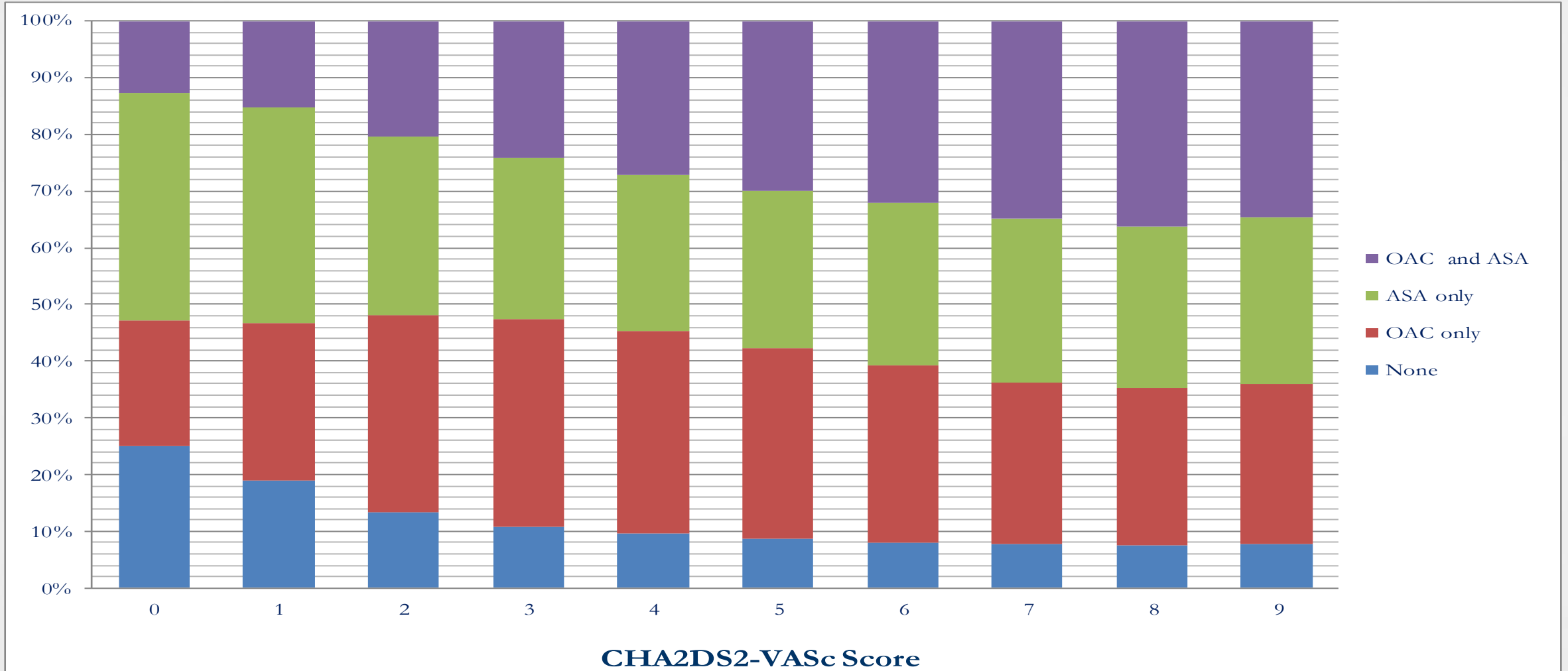
# Using registry data to examine barriers to stroke prevention in Afib patients

**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



# Older patients more likely to receive low dose anticoagulants

Underdosing AF patient characteristics							
Display Element	75 mg dabigatran	150 mg dabigatran	15 mg Rivaroxaban	20 mg Rivaroxaban	2.5 mg Apixaban	5.0 mg Apixaban	No Antithrombotic (No Warfarin, Dabigatran, Rivaroxaban, Apixaban, ASA, clopidogrel, prasugrel, Ticagrelor)
<b>Age (Means +/- SD)</b>	81 ( $\pm 8.70$ )	72 ( $\pm 10.09$ )	79 ( $\pm 9.02$ )	70 ( $\pm 10.16$ )	<b>82 (<math>\pm 9.27</math>)</b>	<b>71 (<math>\pm 10.09</math>)</b>	72 ( $\pm 13.14$ )
<b>Gender</b>							
Male	2055	15874	6412	30064	4769	22620	25379
Female	2407	8965	7679	18702	6569	15699	25718
Gender Missing	7	29	14	52	2	8	46
<b>Insurance Payer (more than one may be checked)</b>							
Medicaid	131	528	338	1063	296	771	1267
Medicare	1728	7999	5071	14036	4121	11306	13599
Private/commercial	2383	13698	7124	24990	5710	19089	24236
Military Helath Care	216	915	479	1294	384	1055	856
State Specific Plan (non-Medicaid)	255	1897	938	3710	860	2957	4433
None	658	3602	1882	6561	1743	5801	7439

# 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

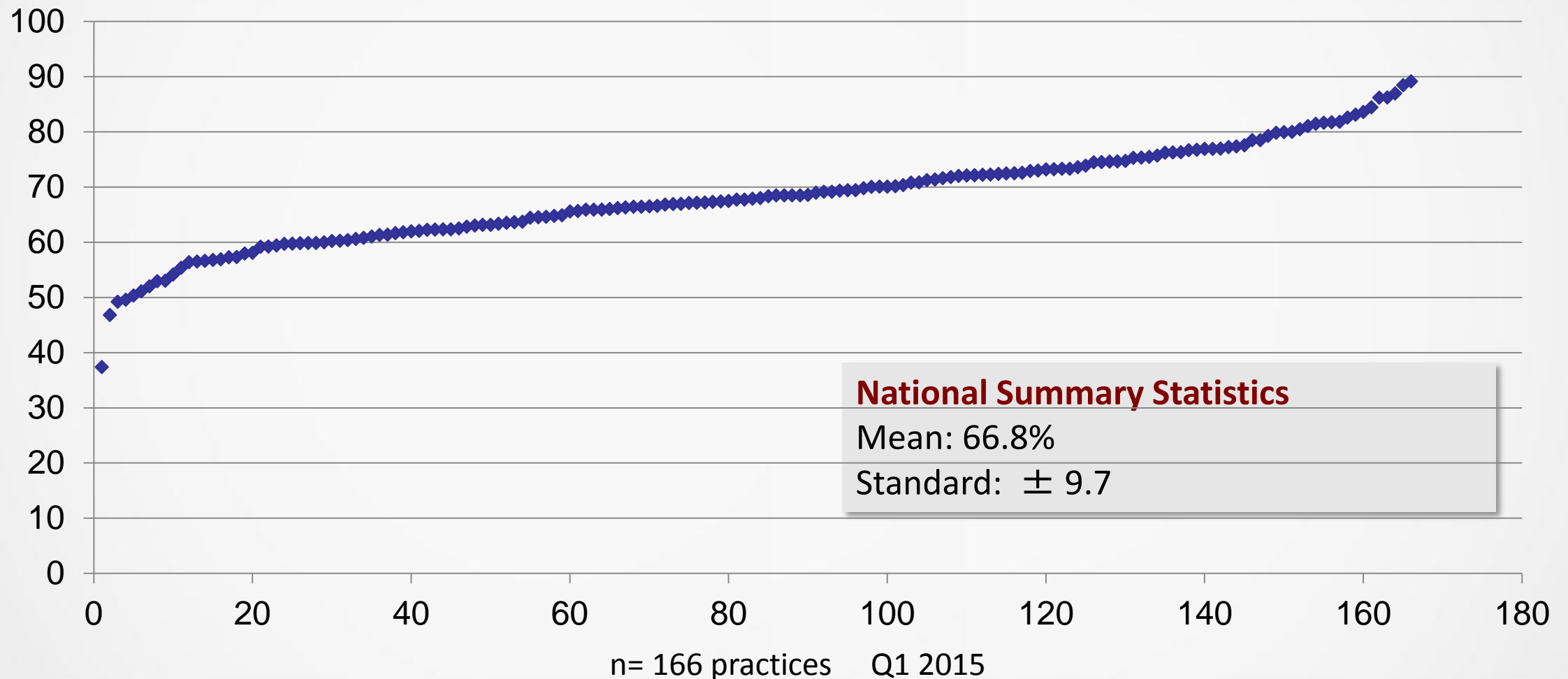
## Phase 4

- 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.

# Practice Level Variation In Anticoagulation Performance Rates: First Quarter 2015



Manual Data Entry or Vendor Supported  
\*\* Requires Abstractor \*\*

## Data Entry

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

HIGH – poor or inconsistent data is rejected

## Data Quality

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

Hospital Subscription  
Vendor Certification Fees

## Funding

Free to physicians  
Industry / Sponsorship funded



**In-Patient**

**VS**



**Out-Patient**



# The Winning Equation



+



+



=



# Questions