Registries in Cardiology: The Good, The Bad and The Ugly

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Patient Registries

- Patient registries have been defined as “an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves a predetermined scientific, clinical, or policy purpose(s).” In brief, a patient registry is a collection—for one or more purposes—of standardized information about a group of patients who share a condition or experience
- Patient registries are additional or supplemental data sources. Registries use existing or contributed clinical data to provide information on “real world” practice and the effectiveness of treatments and procedures, and are to be distinguished from randomized controlled trials or scientific experiments that cannot measure real-life experience, in some cases, to the same degree.

Gliklich R, et al. AHRQ 2010
Berger M, et al. 2012
Workman TA. AHRQ 2013

Aims (The Good) of Medical Registries
What Works Today

- Identification of met and unmet clinical needs
- Prospective observation of populations (clinical profiles, co-morbidities, natural history) and settings (technology, costs)
- Use (prescription, assumption, dosing) and effectiveness of drugs and procedures
- Evaluation of current diagnostic–therapeutic processes and their comparative effectiveness
- Incorporation of/adherence to Guideline recommendations and impact of their application
- Long-term safety of recommended treatments (rare, unexpected drug/ device-related events)
- 'Natural' temporal dynamics of the use of diagnostic and therapeutic tools (off-label use, declining use, time for incorporation of new tools)

Tavazzi L. Eur Heart J 2014;35:7-9

Aims (The Good) of Medical Registries
What Works Today

- Identification of responders/non-responders to therapeutic drugs/ procedures
- Clinical profiles of low risk patients with incident events, and high risk patients not undergoing any event (outliers)
- Epidemiology of ‘uncertainty’ (new research hypotheses, better elaboration of recommendations in the Guidelines, focus on relevant new educational material and initiatives)
- ‘Avoidability’ studies (focusing on what should not be done)
- Source of cohorts for case–control studies
- Systematic information: results/costs of individual vs. teams Rare diseases
- New procedures (TAVR, WATCHMAN) – can expedite approval, and post-marketing data can assess performance and alter indications

Tavazzi L. Eur Heart J 2014;35:7-9

Limitations "The Bad"of Medical Registries

What is Missing, Broken or Does Not Work Today

- Proper Clinical Question: Risk factors, Treatments, Outcomes
- Across Patient Settings: Inpatient, Outpatient, Home
- Accuracy, Completeness of Data
- Can Data be Risk Adjusted?
- Size, Power for Sub-analyses and Duration of Follow-up
- Can One Go Back and Edit Data to Improve Accuracy?

Important National Arrhythmia Registries

- NCDR
  - ICD
  - Pinnacle AF
  - AF Ablation (Safari)
- Watchman
- AHA AF GWTG
- PCORI: Patient Centered Outcomes Research Initiative
  - "A **patient registry** is an organized. system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves a predetermined scientific, clinical, or policy purpose(s)."

Ongoing AF OAC Registries

- GARFIELD –AF: Global Anticoagulant Registry in the FIELD
- ORBIT-AF: Outcomes Registry for Better Informed Treatment of Atrial Fibrillation
- GLORIA-AF: GLObal RegIstry on long-term oral Anti-thrombotic treatment in patients with Atrial Fibrillation
- PINNACLE-AF (NCDR)

- Post Marketing Surveillance
  - XANTUS: Xarelto on Prevention of Stroke and Non-central Nervous System Systemic Embolism in Patients with Non-valvular Atrial Fibrillation

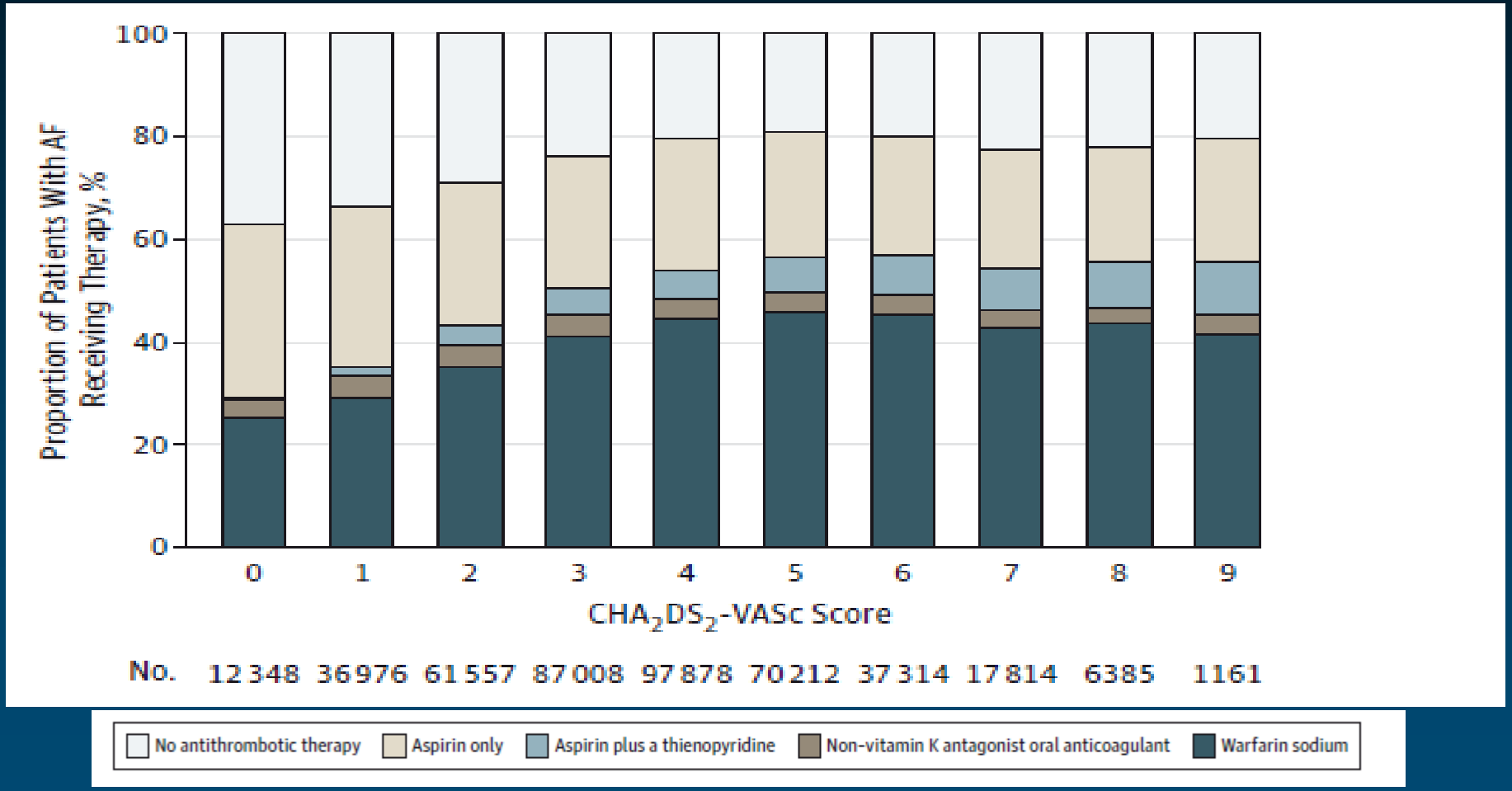
Many Patients with NVAF Do Not Receive Appropriate Anticoagulation

- TTR with warfarin[1]
  - Usual care: ≈30% to 60% vs. ≈50% to 80% with anticoagulation management service
- PINNACLE-AF Registry[2]
  - 57.2% with NVAF at high risk for stroke on guideline-recommended OACs
- ORBIT-AF Registry
  - 1/3 of rhythm-controlled patients not on systemic anticoagulation (only 12% had a contraindication)[3]
  - ≈40% on oral anticoagulants also on aspirin with no apparent indication[4]
- GARFIELD Registry[5]
  - 2 in 5 low-risk patients receive OACs against guideline recommendations (40% with CHA_2DS_2-VASc score of 0 received and OAC (32.4% VKA and 7.6% NOAC)

ORBIT AF, Outcomes Registry for Better Informed Treatment of Atrial Fibrillation (ORBIT-AF); TTR, time in therapeutic range

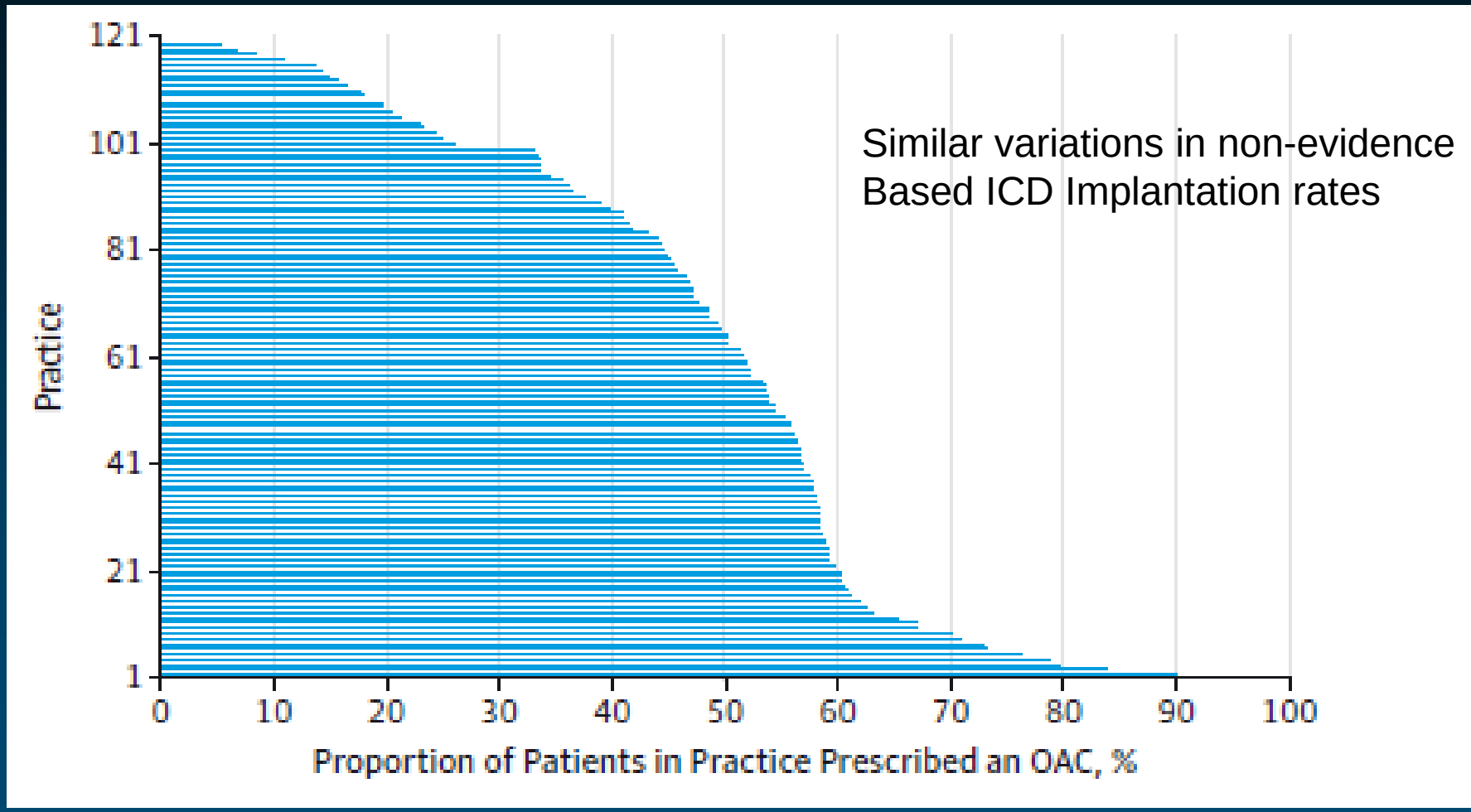
1. Ansell JA. Available at: http://excellence.acforum.org/sites/default/files/Patient%20Self%20Testing%20Presentation.pdf. Accessed July 14, 2014.
2. Jacobovitz S. *Am Coll Cardiol*. 2014;64(2):226-228. 3. ACCEL: Probing the ORBIT-AF Registry. Available at: www.cardiosource.org/en/News-Media/Publications/CardioSource-World-News/2013/October/ACCEL-Probing-the-ORBIT-AF-Registry.aspx/ . Accessed July 3, 2014. 4. Steinberg BA et al; for the ORBIT-AF Investigators and Patients. *Circulation.* 2013;128(7):721-728. 5. Bassand JP, Goldhaber SZ, Camm J, et al. 'Truly low-risk' patients with newly diagnosed non-valvular atrial fibrillation at risk of stroke: 1-year outcomes from the GARFIELD-AF Registry. Poster session presented at the ESC Congress 2014, Barcelona, Spain.

CHA_2DS_2-VASc and OAC Use: Pinnacle Registry



Hsu et al JAMA Cardiol 2016;1:55-62

Variation in OAC Rx Across Practices "The Bad"



Hu JC, et al. JAMA Cardiol 2016;1:55-62

Possible Reasons for Inappropriate Overuse or Underuse of Therapy

- Acceptance of the therapy is still evolving – data is too new
- Guidelines recommending therapy/test not consistent or evidence based
- Lack of education
- Data is inaccurate – IT issues, chart fleas, care providers
  - Bad data in – bad data out (Data from our ENDEAVOR study suggests that not having active AF as a real problem can by itself reduce OAC use in registries by >15%)
- Local resource issues – inadequate number of specialists, lack of capital equipment, local payer issues
- Referral, physician or patient selection bias

Data Assurance/Quality Control Provide Confidence in Findings

- Assessments of data quality (e.g., abstracted from verifiable source)
- Adherence to source verification procedures and data collection and recording procedures for completeness and consistency
- Completeness (minimized missing/out of range values)
- Data consistency across sites and over time
- Evaluation of on-going training programs for data collection and use of data dictionaries at participating sites
- Evaluation of site and data monitoring practices
- The use of data quality audit programs

National Arrhythmia Registries: "The Ugly" to Professional Societies, Clinicians and Hospital Systems

- How accurate is the data in the registries?
  - Inaccurate data may lead lower or better than reality report cards
- Cost - Who is going to pay for them?
- How will the data be used to reward/punish ?
- Unintended consequences – fines, malpractice suits, risk aversion
- Will societies feel the wrath of their membership?
- Can the registries be improved over time?

Medical Registries: "The Ugly"

- "Although the concept of measuring outcomes is now firmly embraced, risk-adjustment methods, the dissemination of outcomes data, and the incentives for healthcare providers and healthcare systems to improve outcomes remain contested."
- "public reporting may encourage physicians and hospitals to exaggerate the severity of illness … and avoid high-risk patients who may benefit the most from treatment. Inadequate risk adjustment may lead to inaccurate designations of providers as high or low quality.
- "publicly reported data are often complex and present challenges for proper interpretation. Successful public reporting will require optimizing data collection, risk adjustment, and data presentation so as to avoid these unintended consequences"

Wasfy, JH, et al. Circulation 2015;131:1518-1527

Unintended Consequences “The Ugly” of Medical Registries

- “In a healthcare landscape that continues to stress quality and cost, patient registries used to monitor safety and track outcomes are now being used in new ways: as decision-making aids, risk-adjustment tools, and alternatives to public reporting requirements.”
- "The unintended consequence of [fining doctors] is people will avoid operating on patients who might really benefit from surgery but who have higher complication rates.“
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S Firth. Medpage Today

Pew Charitable Trust Recommendations

- For registries to fulfill their potential, all stakeholders—especially clinicians, hospitals, FDA, and manufacturers—must work together to:
  - Streamline registry data collection by limiting data fields, using standardized definitions, and integrating information from other sources—in particular, electronic health records and claims—to reduce the time and cost of reporting.
  - Make information about registry governance, operation, and financing publicly available.
  - Ensure that regulators, providers, patients, and manufacturers have access to registry findings in order to make evidence-based decisions.
  - Disseminate registry findings to the public to facilitate informed decision-making.
  - Gain clarity, particularly from federal agencies, on the interpretation of privacy and human subject protection laws for registries.
  - Develop viable funding models to ensure the sustainability of registries.

National Medical Registries: Short and Long-Term Solutions

- The FDA, CMS, Insurers, Professional Societies, Medical Industry, Hospital systems and providers need to work together to prioritize which registries should be done and in what order
- Pilot registries may limit overcommitting to large registries
- Analysis of outcomes should be done with appropriate caution, clinical and statistical validity
- Registries must have the size, power, accuracy and be editable leading to accurate information that has value
- EMRs needs to share accurate data (e.g. PCORI)
- Registries should be part of a health system's CQI and resourced accordingly