What is the evidence that structured data collection & care delivery leads to better outcomes? Lessons Learned from Get with the Guidelines-Stroke

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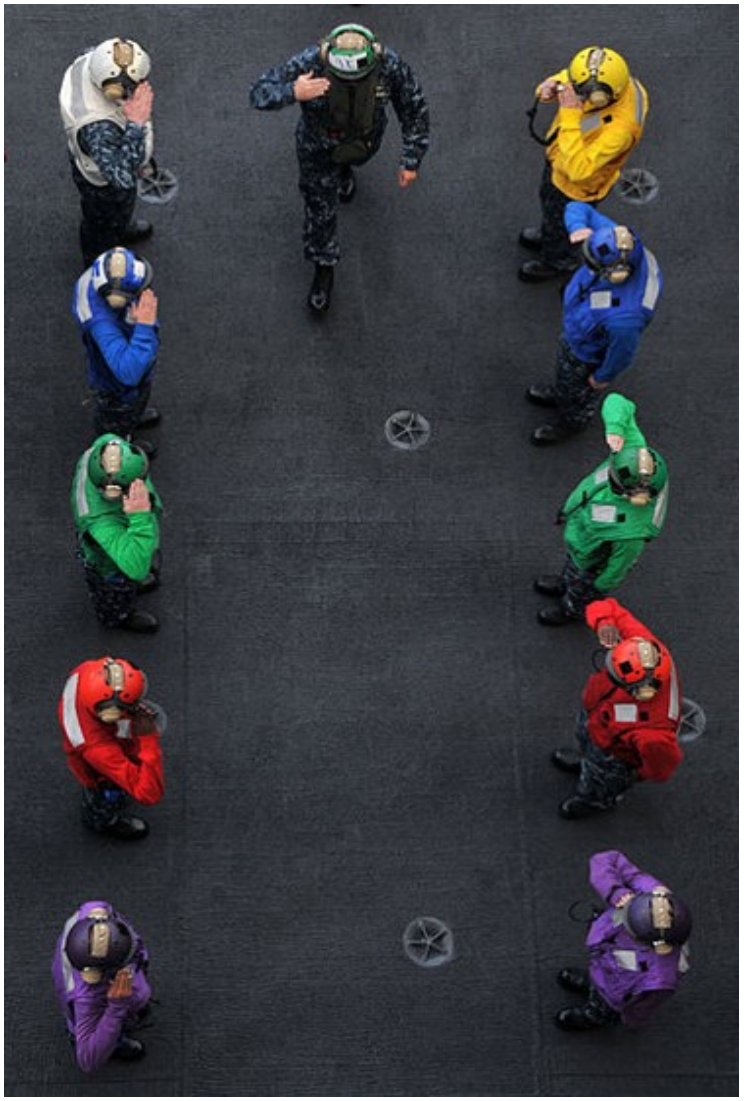
Disclosures

- Chair, AHA GWTG Stroke CWG
- Expert Consultant/Grantee
  - Massachusetts Dept of Public Health
  - CDC Paul Coverdell Acute Stroke Registry
  - PCORI
  - NINDS SPOTRIAS/StrokeNet
  - Joint Commission Stroke Measure Development
  - Yale CORE (a CMS measure vendor)
  - National Quality Forum

Every Sailor/Function is Color Coded Safety is Everyone's Job

Yellowshirts

The Aircraft Handling Officer (ACHO), commonly known as the "Handler," is responsible to the Air Boss for planning and controlling all aircraft movement on the flight and hangar deck, including the coordination of aircraft elevator runs. This person directs the update of the aircraft spotting and maintenance status boards to reflect the current status of all embarked aircraft. The Handler also coordinates flight- and hangar-deck spotting with the squadron maintenance liaison-officer, aircraft intermediate

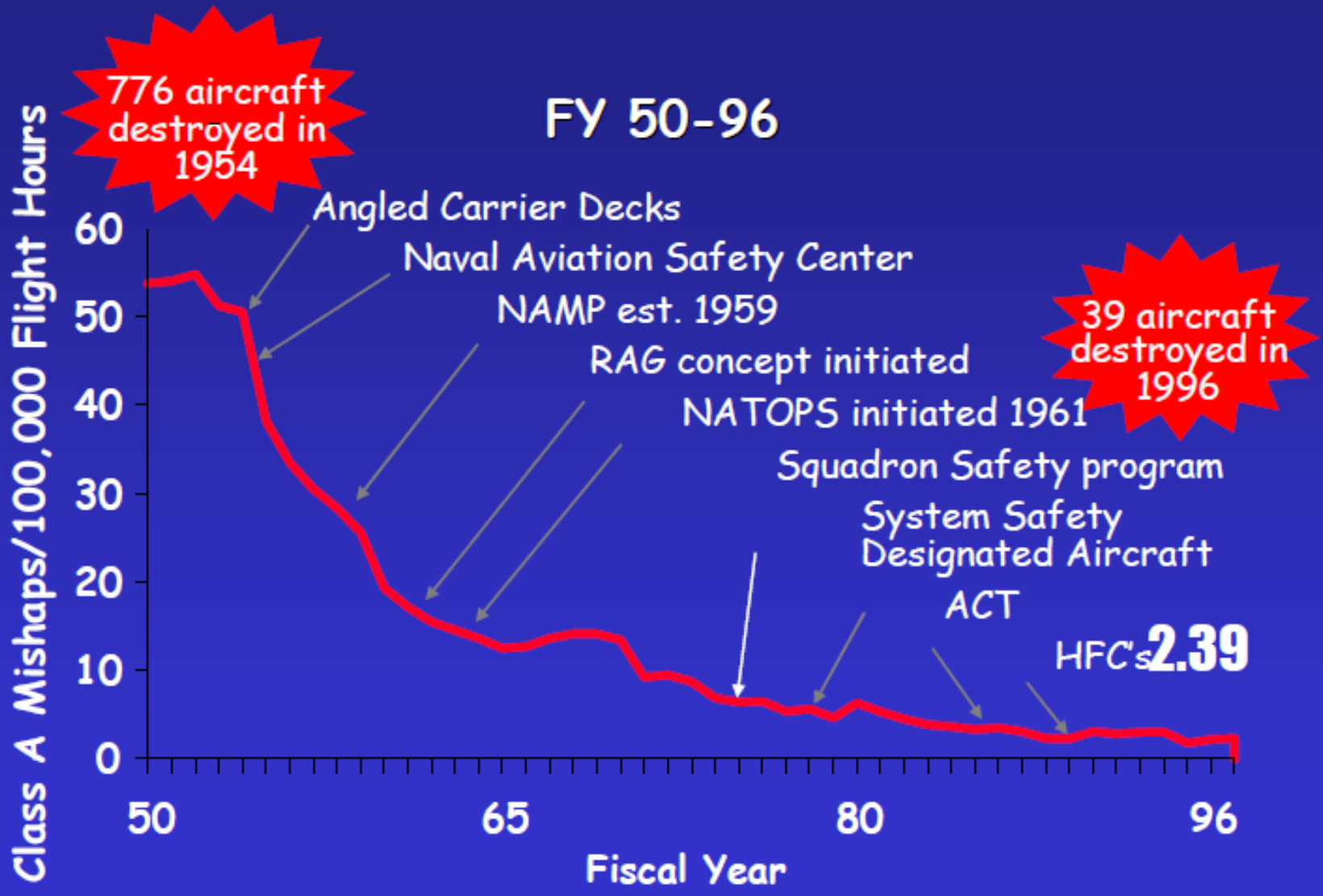


The Do's of Flight Deck Safety

1. Know your absolute limits. Fatigue is deadly.
2. Wear a complete and proper flight-deck uniform when working on the flight deck. This includes:
   A. Cranial, properly marked with reflective tape and with approved goggles and sound attenuators attached.
   B. Mk-1 life preserver. Make sure your float coat is maintained in accordance with current PMS standards.
   C. Flight-deck safety boots. Steel toe, non-slip soles.
   D. Flight-deck jersey. Sleeves rolled down.
   E. Gloves.
3. Be FOD-free. Remove and properly stow jewelry, pens, note pads, etc. before entering the flight deck.
4. Always enter the flight deck from the island.
5. Keep your head on a swivel.
6. Watch out for your shipmates.
7. Know and support the ship's FOD program.
8. Participate in FOD walkdown.
9. Take part in all flight-deck drills.
10. Know the location of the nearest firefighting equipment.
11. Know how to operate firefighting equipment.
12. If you see something wrong or unsafe, tell your supervisor or a yellowshirt immediately.
13. Comply with direction provided by supervisors and yellowshirts.
14. Never approach a turning helicopter without permission from the LSE. Approach from the forward quadrant only in plain view of LSE and aircrew.
15. Always assume that an aircraft is running if the cockpit is manned.
16. Extend your arm in front of your body when walking in front of jet intakes or behind jet exhaust if you are unsure the aircraft is running. This precaution is especially important at night.
17. Know aircraft danger areas.
18. Help out when aircraft are being pushed by hand.
19. Properly stow power cables, tools, and aircraft-handling equipment when they are not being used.
20. When told to clear the flight deck for an emergency, do so immediately.
21. STAY ALERT!

http://www.public.navy.mil/navsafecen/Documents/media/flight%20awareness/FlghtDckAware_amphib_05.pdf

NAVAL AVIATION MISHAP RATE



"What if we don't change at all ...
and something magical just happens?"

From Science to Implementation: A reluctant embarkation

- AHA raises funds to promote scientific enquiry
- AHA becomes a trusted source of scientific information on heart disease and stroke
- AHA convenes experts to create consensus guidelines and publishes these periodically
- Timescale of changes in patient care is glacial
- In 2000, AHA commits to measuring and reducing events and CVDS risk by 2010, and thereby invokes a necessary evolution

Ellrodt AG. Synthesizing Lessons Learned From Get With The Guidelines: The Value of Disease-Based Registries in Improving Quality and Outcomes. Circulation.2013 Oct 28.

To remain relevant, guidelines must no longer be kept in binders

"To prevent underutilization or disparities in the use of therapies recommended in national guidelines, the guideline development and distribution process should recognize and incorporate strategies for increased implementation"

2007 AHA Guidelines for Prevention of Stroke in Patients with Ischemic Stroke or Transient Ischemic Attack

To you, the leaders of Epilepsy

- "Between the health care we have and the care we could have lies not just a gap, but a chasm"–
  - *Institute of Medicine, 2001*

- You can actually change the world of epilepsy, even if you don't make a profound clinical or laboratory discovery, but by finding ways to ensure that the care that is *actually given* to all patients is the care *we all wish were given*.

Committee on Quality of Health Care in America, Institute of Medicine. Crossing the quality chasm: a new health system for the 21st century. 2001

Data Collection

- Included for each hospitalization:
  - Demographics
  - medical history
  - initial head CT findings
  - in-hospital treatment, and events
  - Discharge treatment and counseling
  - Discharge destination
- Concurrent collection encouraged for real-time QI intervention with decision-support during hospitalization

GWTG Program Description

- GWTG uses chart abstraction of clinical data elements into a web-based platform that supports offsite, database server functions
- Case ascertainment is either concurrent using clinical criteria or retrospective based upon coding
- Process measures are divided into *achievement (performance) measures and quality measures*, with *reporting and descriptive measure reports*
- *Achievement* measures have the strongest supporting evidence, strongest link between the process and health outcomes and, ideally endorsement by the National Quality Forum (NQF). These measures drive the Performance Achievement Award recognition program of GWTG
- *Quality* measures are supported by strong evidence but not as robust as that supporting *achievement measures*. Useful for testing candidate measures

Heidenreich PA. American Heart Journal. 2009;Oct;158:546-553

How to create measures

- Prior literature review
- Expert opinion
- Harminization
- Surveys with ratings
- Pragmatism
- Field testing
- Reflecting a range of performance
- Recognized by awards for achieving success
- (When to retire a measure?)

www.heart.org/quality

The Birth of Science

Picking the Right Measures

- Selecting which potential measures to endorse should involve considering the interpretability, actionability, and feasibility of implementing each measure.
- Interpretability reflects the degree with which a practitioner is likely to understand what the results mean and can take action if necessary
- Actionability is the degree to which a practitioner can influence the quality of the care being delivered by the health system
- Feasibility addresses whether the required data can be typically abstracted from patient charts through easily implemented prospective or retrospective data collection systems or from national registries/databases that are readily available

Adding Rigor

TABLE 1. Summary of Performance Measure Development

Task	Description
Phase I: Constructing Measurement Sets:	
Task 1: Defining the target population and observational period	Develop a clear, concise, and implementable definition of the sample (eg, adults more than 29 years of age, discharged alive with a principal diagnosis of heart failure (ICD-9: 398.91, 402.01, 402.11, 402.91, 428.0, 428.1, 428.9), with a length of stay of at least 1 day, excluding patients with an AMI in the previous month continuously enrolled for 6 months after discharge.
Task 2: Identifying dimensions of care	Explicitly define each aspect of care that should be quantified to ensure a valid assessment of the most meaningful aspects of care. Potential dimensions include diagnosis, risk stratification and patient education, treatment, self-management, and reassessment of patient's health status.
Task 3: Synthesizing and reviewing the literature	Review published literature (including guidelines and other performance measurement systems) with a team of clinicians and researchers with expertise in meta-analysis.
Task 4: Defining and operationalizing potential measures	For each measure, determine which data sources are available and define the data elements needed to construct it (including period of care).
Task 5: Selecting measures for inclusion in the performance measures set	Present information based on tasks 1–3 to writing group and other relevant individuals, and put in place a formal mechanism to decide upon the measures that will be selected for inclusion.
Phase II: Determining Measure Feasibility:	
Definition of sample	Calculate sensitivity and specificity of selection criteria whenever possible. Document sources of case attrition (eg, medical record never sent, not continually enrolled, died during period of care). Develop an algorithm to assign patients to providers (eg, primary care provider, specialist) and validate the accuracy of the algorithm.
Feasibility of measures	Report validity, reliability, and completeness of collected data. If chart abstraction is used, then interabstractor reliability needs to be measured; if patient survey is used, then item and unit nonresponse must be measured. Data lags in identifying and surveying patients need to be assessed.
Phase III: Measuring Performance:	
Determining reporting unit	Determine at what level information will be reported (eg, physician-level data will typically require longer accrual period, even if only for internal monitoring).
Determining number and range of measures	Cost constraints may dictate how many measures can be measured. For quality improvement, how many measures will be evaluated and/or whether a combined measure is necessary will need to be determined.
Evaluating Performance	*Caution*: To determine whether a provider has "improved" care over time or whether a provider is sufficiently different from others, a sample size calculation that incorporates the relevant statistical features of the "test" (within- and between-provider variability, size of test, significance of test) should be undertaken.

ICD indicates International Classification of Diseases; AMI, acute myocardial infarction.

ACC/AHA Methodology for the Selection and Creation of Performance Measures for Quantifying the Quality of Cardiovascular Care

Name of Measure:					
Clinical Rationale:					
Numerator:					
Denominator:					
Measure:					
Rate this measure on the following criteria	**Disagree**		**Moderate Agreement**		**Agree**
	1	**2**	**3**	**4**	**5**
Useful in Improving Patient Outcomes					
1. **Evidence-based:** The scientific basis of the measure is well established.	1	2	3	4	5
2. **Interpretable:** The results of the measure are interpretable by practitioners.	1	2	3	4	5
3. **Actionable:** The measure addresses an area that is under the practitioner's control.	1	2	3	4	5
Measure Design					
1. **Denominator:** The patient group to whom this measure applies (denominator) is clinically meaningful.	1	2	3	4	5
2. **Numerator**: The definition of conformance for this measure is clinically meaningful.	1	2	3	4	5
3. **Validity:** The measure appears to measure what it is intended to (face validity).	1	2	3	4	5
a. The measure captures most meaningful aspects of care (content validity).	1	2	3	4	5
b. The measure correlates well with other measures of the same aspect of care (construct validity).	1	2	3	4	5
4. **Reliability:** The measure is likely to be reproducible across organizations and delivery settings.	1	2	3	4	5
Measure Implementation					
1. **Feasibility:** The data required for the measure is likely to be obtained with reasonable effort.	1	2	3	4	5
a. The data required for the measure is likely to be obtained at reasonable cost.	1	2	3	4	5
b. The data required for the measure is likely to be obtained within the period allowed for data collection.	1	2	3	4	5
Overall Assessment					
Considering your assessment of this measure on all dimensions above, rate this measure overall for inclusion into the ACC/AHA Heart Failure Performance Measurement Set.	**Do Not Include**		**Could Include**		**Must Include**
	1	**2**	**3**	**4**	**5**

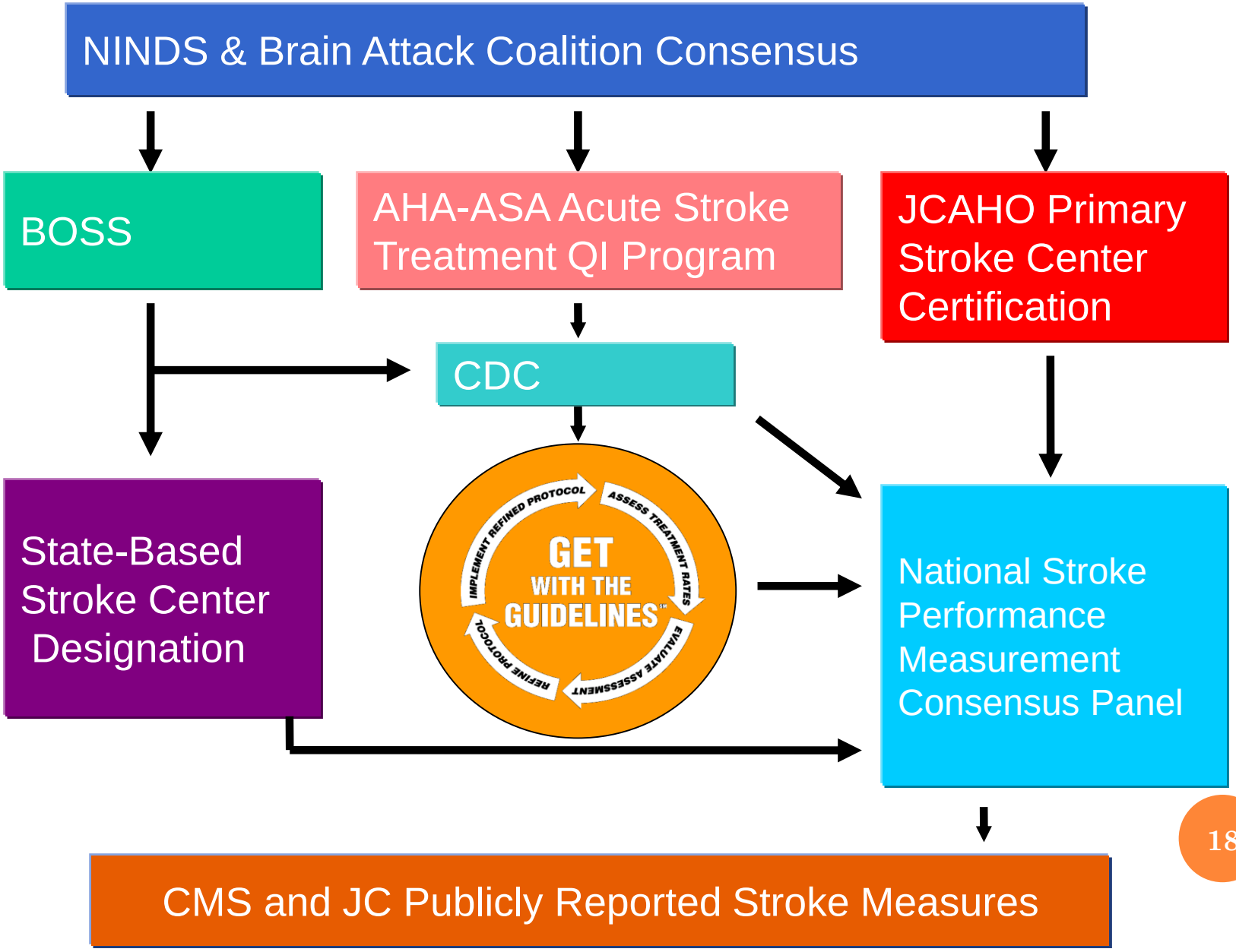
Attribute of Performance	**Considerations**
Useful in Improving Patient Outcomes	
1. **Evidence-based:** The scientific basis of the measure is well established.	This can be confirmed by explicit reference to a published clinical practice guideline.
2. **Interpretable:** The results of the measure are interpretable by practitioners.	This is your assessment of the degree with which a provider can clearly understand what the results mean and can take action if necessary.
3. **Actionable:** The measure addresses an area that is under the practitioner's control.	This is your assessment of the degree with which a provider is empowered and can influence the activities of the health care system toward improvement.
Measure Design	
1. **Denominator:** The patient group to whom this measure applies (denominator) is clinically meaningful.	Depending upon intended use of the measure, the data source, any inclusion or exclusion criteria, and sampling frames are explicit. These criteria used must be clinically meaningful. An algorithm for determining the denominator may be present.
2. **Numerator:** The definition of conformance for this measure is clinically meaningful.	The numerator may be specified using either explicit or implicit criteria. These criteria used must be clinically meaningful. An algorithm for determining the numerator may be present.
3. **Validity:** a. The measure appears to measure what it is intended to (face validity). b. The measure captures most meaningful aspects of care (content validity). c. The measure correlates well with other measures of the same aspect of care (construct validity).	This can be confirmed by your judgment of the clarity and comprehensiveness of the measure. For those measures that have been actually tested for validity, you may see indications of specific testing such as comparisons with the results of other methods, criterion or gold standard validity testing, and criterion validity testing. There may also be documentation that the health care construct underlying the measure is associated with important health care processes/outcomes.
4. **Reliability:** The measure is likely to be reproducible across organizations and delivery settings.	This can be confirmed by specific tests undertaken by the measure developers. For those measures that have been actually tested for reliability, you may see indications of types of reliability testing such as test-retest reliability, inter-rater reliability, data accuracy checks, and internal consistency analyses. If the measure has not been used in practice, indicate the degree of likelihood that it is reproducible.
Measure Implementation	
1. **Feasibility:** a. The data required for the measure is likely to be obtained with reasonable effort. b. The data required for the measure is likely to be obtained at reasonable cost. c. The data required for the measure is likely to be obtained within the period allowed for data collection.	From your perspective, the required data can be typically abstracted from patient charts or there are national registries or other databases readily available. For those measures actually being used, there is information on the data collection approach and the system required to support the measure.
Overall Assessment	
Considering your assessment of this measure on all dimensions above, rate this measure inclusion in the ACC/AHA AMI Performance Measurement Set.	Consider a balance in the continuum of care. Consider overall purpose of the measurement set and the intended user.

John A. Spertus et al. Circulation. 2005;111:1703-1712

Background: Stroke QI

- Key interventions exist to improve health outcomes in stroke patients, but many evidence-based therapies are not provided
- Prior to 2000, little systematic effort was applied to improving acute stroke care.
- In the past 15 years several organizations have promoted changes in care delivery
- Emphasis on
  - Reduce disparities in care
  - Increase adherence with delivery of IV tPA
  - Prevention of in hospital complications
  - Improve secondary prevention of stroke

Stroke Quality Improvement History



Seeking Consensus: I'd like to teach the world to sing, in perfect harmony

Table 1. US-Based Organizations Currently Involved in Stroke-Related QI Programs and Initiatives

Organization	Program(s)	Description
The Joint Commission (TJC)	Primary Stroke Center Certification Program[2]	Identifies centers that make exceptional efforts to improve patient outcomes, including demonstrated compliance with clinical guidelines such as the AHA/ASA
Centers for Disease Control and Prevention (CDC)	The Paul Coverdell National Acute Stroke Registry[3]	A surveillance system for acute stroke designed to support system improvements and elimination of disparities of care
American Stroke Association (ASA)	GWTG Stroke Program[4]	A hospital-based quality improvement program targeting patients with acute stroke and emphasizing commitment with the most current care guidelines
American Medical Association (AMA)	Physicians Consortium for Performance Improvement (PCPI)[5]	The consortium partners with physician groups to provide physician leadership for performance measure development and maintenance
American Academy of Neurology (AAN)	Stroke quality initiatives and endorsement of measurement sets[5,6]	Participates in the work of the PCPI and partners on the CARE (Carotid Artery Revascularization and Endarterectomy) Registry (part of the National Cardiovascular Data Registry); both emphasize performance measurement compliance as a QI tool
Veterans Administration (VA)	Stroke Quality Enhancement Research Initiative (QUERI)[7]	Facilitates translation of research results into improved clinical care and systems efficiencies within the VA system
National Quality Forum (NQF)	National consensus standards for measuring and reporting quality[5,8]	Supports a consensus process for developing national standards for measuring and reporting healthcare provider performance
National Committee for Quality Assurance (NCQA)	Heart/Stroke Recognition Program[9]	Evaluates and recognizes physician compliance with secondary prevention measures
Centers for Medicare and Medicaid Services (CMS)	PQRI[10]	PQRI is an incentive pay for reporting program for health professionals
	RHQDAPU	RHQDAPU is an incentive pay-for-reporting program for hospitals

Reeves et al. Devt of stroke performance measures. Stroke. 2010;41:1573-1578.

ID	Performance Measure	CDC[3]	AHA/GWTG[4]	TJC[2]	NQF[8]
1	Deep vein thrombosis (DVT) prophylaxis	Ischemic	Ischemic*	Ischemic	Ischemic
	Nonambulatory patients should start receiving DVT prophylaxis by end of hospital Day 2	Hemorrhagic	Hemorrhagic* TIA*	Hemorrhagic	Hemorrhagic
2	Discharged on antithrombotic therapy	Ischemic	Ischemic*	Ischemic	Ischemic
	Patients prescribed antithrombotic therapy at discharge	TIA	TIA*		
3	Discharge on Anticoagulation for patients with atrial fibrillation	Ischemic	Ischemic*	Ischemic	Ischemic
	Patients with atrial fibrillation discharged on anticoagulation	TIA	TIA*		
4	Thrombolytic therapy administered	Ischemic	Ischemic*	Ischemic	Ischemic
	Patients with acute ischemic stroke who arrive at the hospital within 120 minutes (2 hours) of time last known well and for whom intravenous tissue plasminogen activator was initiated at this hospital within 180 minutes (3 hours) of last known well				
5	Antithrombotic therapy by the end of hospital Day 2	Ischemic	Ischemic*	Ischemic	Ischemic
	Patients who receive antithrombotic therapy by the end of hospital Day 2	TIA	TIA*		
6	Discharged on cholesterol-reducing medication	Ischemic	Ischemic*	Ischemic†	Ischemic†
	Patients with LDL >100, or LDL not measured, or on cholesterol-reducer before admission, who are discharged on cholesterol-reducing drugs	TIA	TIA*		
7	Dysphagia screening	Ischemic	Ischemic	Ischemic	X
	Patients who undergo screening for dysphagia with a simple valid bedside testing protocol before being given any food, fluids, or medication by mouth	Hemorrhagic	Hemorrhagic	Hemorrhagic	
8	Stroke education	Ischemic	Ischemic	Ischemic	Ischemic
	Patients or their caregivers who were given education or educational materials during the hospital stay addressing all of the following: personal risk factors for stroke, stroke warning signs, activation of EMS, need for follow-up after discharge, and medications prescribed	Hemorrhagic TIA	Hemorrhagic TIA	Hemorrhagic	Hemorrhagic
9	Smoking cessation	Ischemic	Ischemic*	Ischemic	X
	Patients with a history of smoking cigarettes who are, or whose caregivers are, given smoking cessation advice or counseling during hospital stay; a smoker is defined as someone who has smoked cigarettes anytime during the year before hospitalization	Hemorrhagic TIA	Hemorrhagic* TIA	Hemorrhagic	
10	Assessed for rehabilitation				
	Patients who are assessed for rehabilitation	Ischemic Hemorrhagic	Ischemic Hemorrhagic TIA	Ischemic Hemorrhagic	Ischemic Hemorrhagic

Summary Measures

- Composite Performance
  - Denominator: The sum of all care opportunities across all patients
  - Numerator: all care opportunities fulfilled
    - partial credit for improvements
    - Population based opportunity measure
    - All measures and patients equally weighted

- "All- or- none" or "Defect-Free" Measure
  - Denominator = number of patients eligible to receive at least 1 of the 7 individual interventions
  - Numerator = number of patients who receive all of the care for which they were eligible
    - No partial credit, harder to move the needle
    - The patient is the unit of analysis and within-hospital clustering can be modeled

Ref CMS Premier Hosp QI Demonstration Project

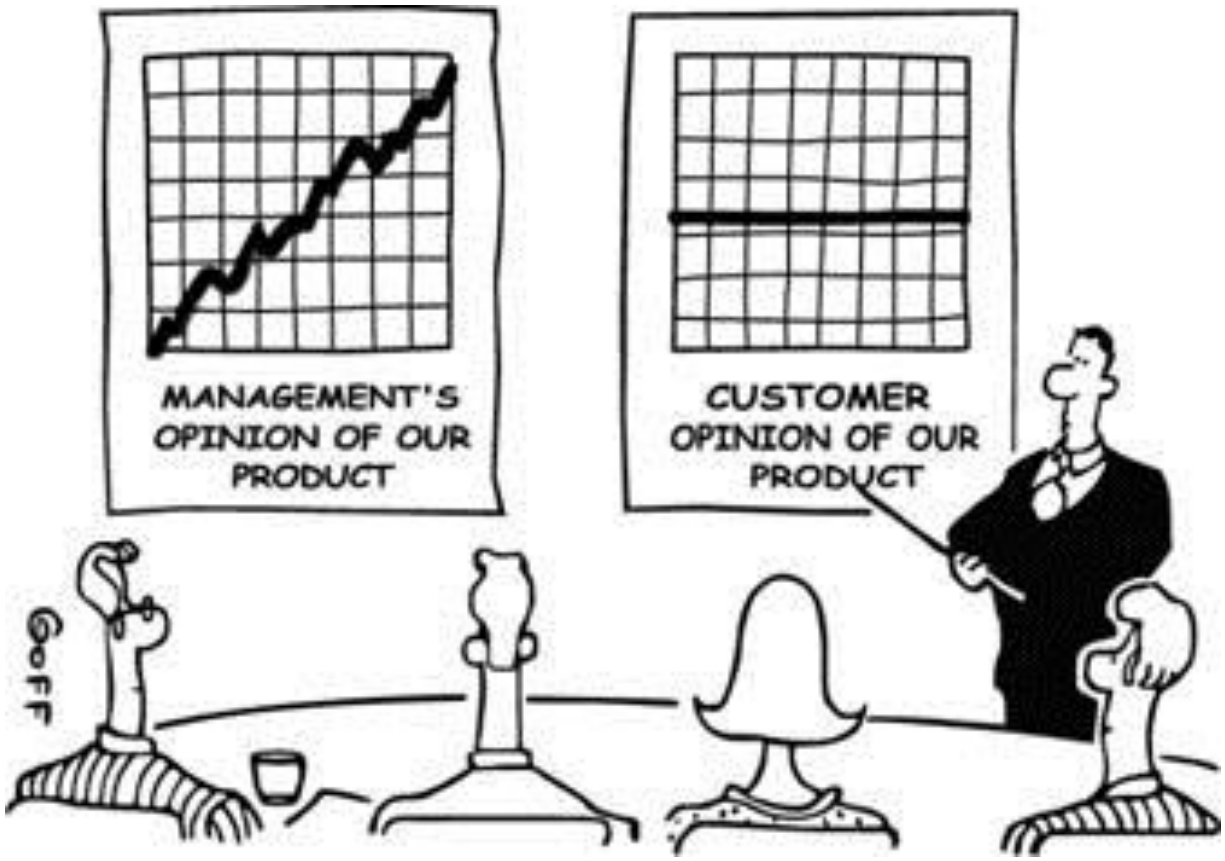
Outcome Dimensions

- Temporal
  - Inpatient, 30 d, 90 d, 1 yr
- Type
  - event rates (death, re-hosp, recurrence)
  - Change in health behavior (adherence, use of 911)
  - Discharge destination, ambulation, functional status
- Disparities
  - Race, age, gender, geography, SES

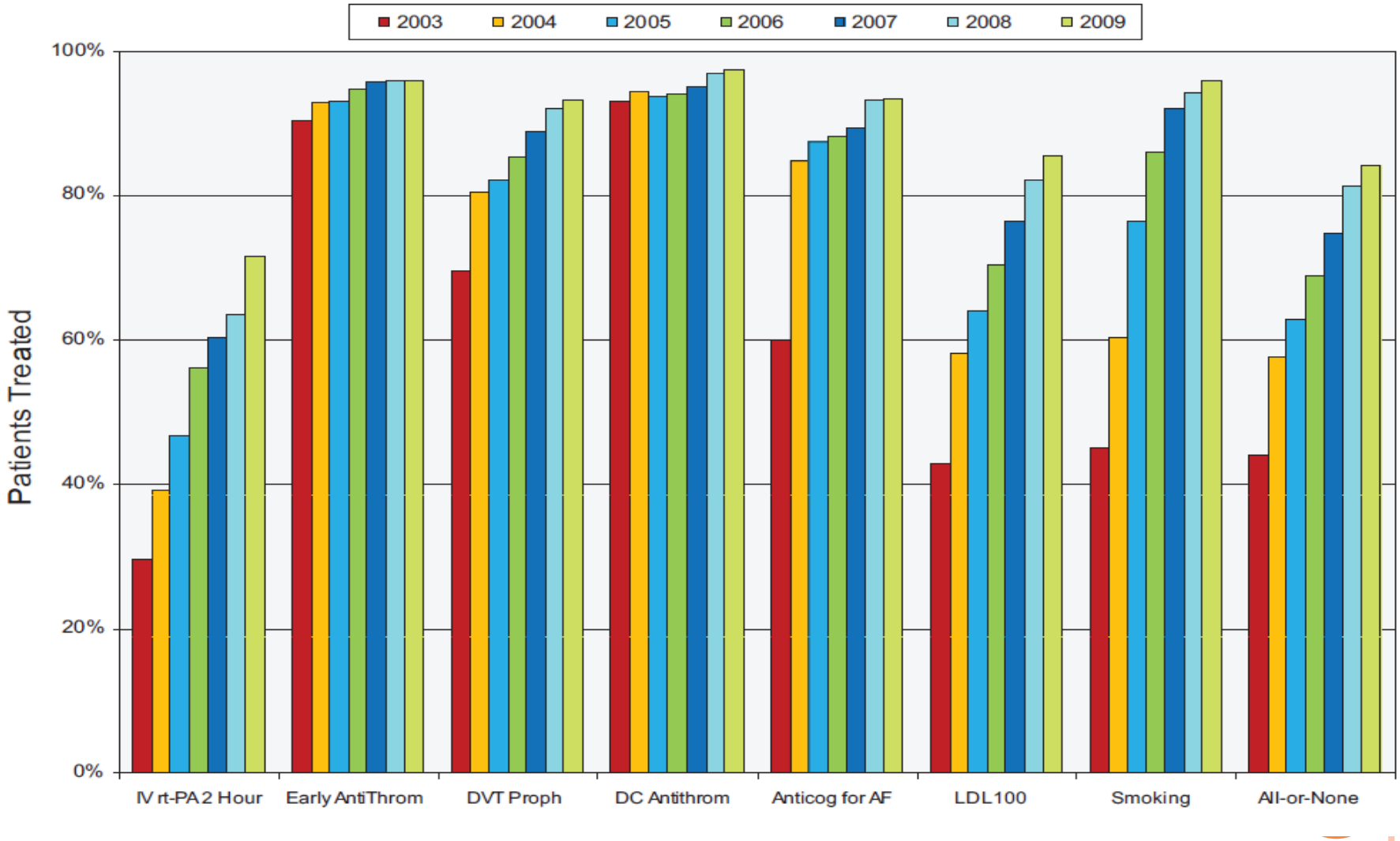
Hospital Participation

- GWTG is a voluntary program
- CMS collects and reports data on all US hospitals
- Desire to improve care compared with peers is a primary motivator in QI programs
- Desire to avoid penalties is a primary motivator in value-based risk contracts
- When participation in QI programs is aligned with reporting to public or professional entities, greater change occurs
- Recognition is important

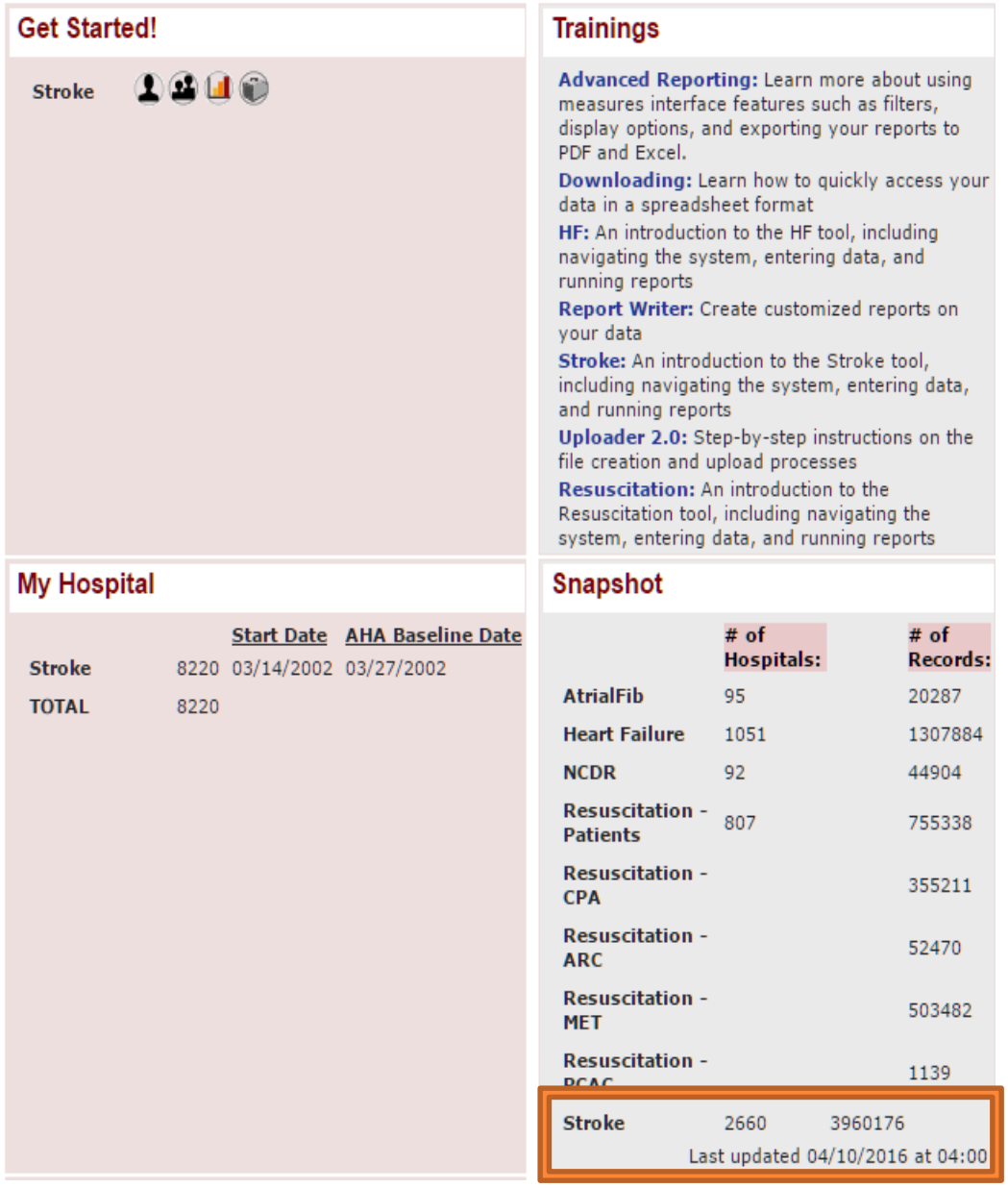
We Often Rate Ourselves Higher Than Our Actual Performance



Aim High: You can achieve multiple goals Simultaneously



Fonarow et al. Characteristics, performance measures, and in-hospital outcomes of the first one million stroke and TIA admissions in GWTG-Stroke. Circ Cardiovasc Qual Outcomes. 2010 May;3(3):291-302.



The Tipping Point:

- 525,306 new cases entered in 2015
- ~800,000 US strokes in 2015
- ~52% of all strokes in US in 2015 were captured in GWTG-Stroke
- 2,635 US hospitals have participated to date
- 3.96M encounters entered since 2001

Potential Data Sources

- Sources
  - Administrative Claims
  - Registries
  - EHR
  - Controlled Cohorts
  - RCT
  - Hybrids
- Quality v. Cost
  - Audits, Surveillance
  - QI Registries
- Prospective vs Retrospective Case Ascertainment and Data Collection

Data Validity

- An audit using central re-abstraction of GWTG-Stroke data suggests that hospitals of all types and sizes are accurately reporting their data without a bias toward overestimating their own performance.[1]
- Hospital reported improvement in care is driven by real changes rather than changed documentation or judgments of eligibility.[2]

1. Xian AHJ 2012;163:392-398.
2. Reeves Circulation. CVQO. 2011;4:503-511

American Heart Association. | American Stroke Association. Learn and Live.

GET WITH THE GUIDELINES.

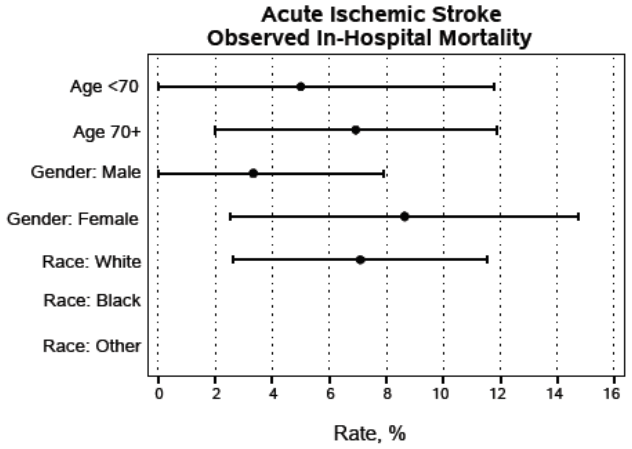
GWTG-Stroke In-Hospital Mortality Report: October 2013

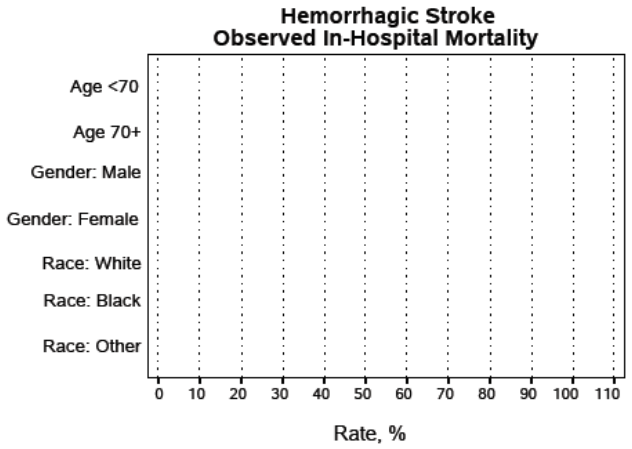
Site 1013

* Confidential Information *

Duke Clinical Research Institute

	Site[1]		Region[2]	Nation[3]
	Last 12 mo	Overall	Last 12 mo	Last 12 mo
Acute Ischemic Stroke				
Number of Cases	150	1406	57618	235568
Number of Risk Model Eligible Cases[4]	141	1308	50105	201056
Observed Mortality Rate[5]	6.4%	4.1%	5.4%	4.5%
Lower 95% confidence limit	2.3%	3.1%	5.2%	4.4%
Upper 95% confidence limit	10.4%	5.2%	5.6%	4.6%
Risk-Adjusted Mortality Rate[5]	5.6%	3.4%	5.3%	4.8%
Lower 95% confidence limit	2.6%	2.6%	5.1%	4.7%
Upper 95% confidence limit	10.3%	4.4%	5.5%	4.9%
Acute Ischemic Stroke - NIHSS Recorded				
Number of Cases	136	909	44160	178433
Number of Risk Model Eligible Cases[4]	129	847	38136	151882
Observed Mortality Rate[5]	5.4%	4.0%	5.1%	4.1%
Lower 95% confidence limit	1.5%	2.7%	4.8%	4.0%
Upper 95% confidence limit	9.3%	5.3%	5.3%	4.2%
Risk-Adjusted Mortality Rate[5]	4.4%	3.1%	4.5%	4.1%
Lower 95% confidence limit	1.8%	2.2%	4.3%	4.0%
Upper 95% confidence limit	8.7%	4.3%	4.7%	4.2%
Intracerebral Hemorrhage Stroke				
Number of Cases	9	130	8799	37108
Number of Risk Model Eligible Cases[4]	9	80	6164	25080
Observed Mortality Rate[5]	-	38.8%	27.1%	25.6%
Lower 95% confidence limit	-	28.1%	26.0%	25.0%
Upper 95% confidence limit	-	49.4%	28.2%	26.1%
Risk-Adjusted Mortality Rate[5]	-	32.2%	27.8%	28.2%
Lower 95% confidence limit	-	23.3%	26.6%	27.6%
Upper 95% confidence limit	-	41.8%	28.9%	28.8%
Subarachnoid Hemorrhagic Stroke				
Number of Cases	2	34	2815	12969
Number of Risk Model Eligible Cases[4]	2	15	1283	5957
Observed Mortality Rate[5]	-	33.3%	26.0%	23.9%
Lower 95% confidence limit	-	9.5%	23.6%	22.8%
Upper 95% confidence limit	-	57.2%	28.4%	25.0%
Risk-Adjusted Mortality Rate[5]	-	23.7%	28.1%	27.3%
Lower 95% confidence limit	-	8.4%	25.5%	26.1%
Upper 95% confidence limit	-	43.9%	30.8%	28.5%





FOOTNOTES

[1]Report eligible site should have at least 10 cases submitted in GWTG-Stroke in last 12 months with admission date in 01Oct2012-30Sep2013.

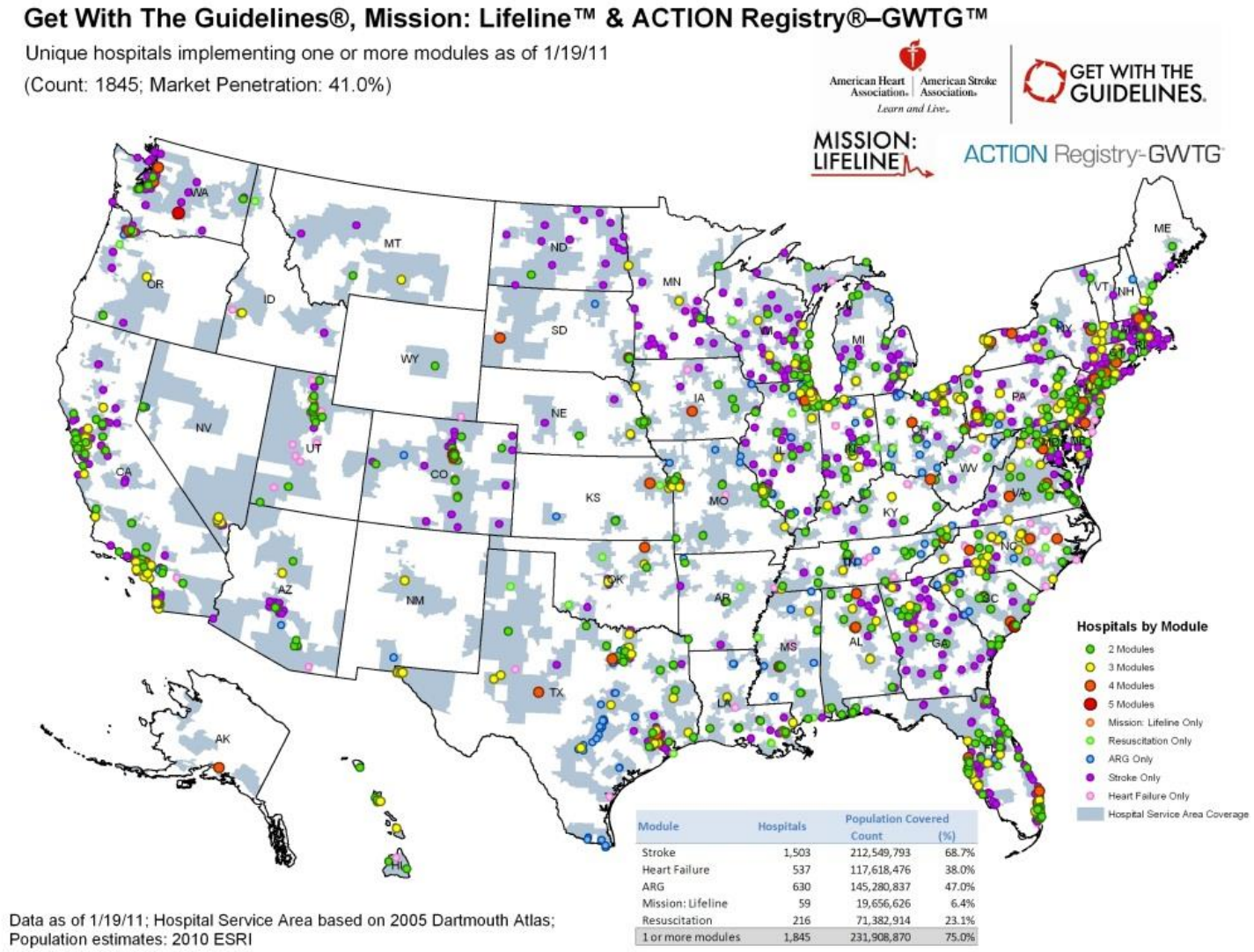
[2]All cases in your site's U.S. Census region.

[3]All cases in GWTG-Stroke.

[4]Excludes: transfer from another hospital, IV tPA at an outside hospital, not admitted as inpatient, discharge disposition is missing or acute care facility.

[5]If number of eligible cases >=10.

Incidence vs. Access to Care



Are Race and Ethnicity Confounders in Stroke Quality of Care?

- The burden of stroke is higher in black and Hispanic patients, and risk factors of DM and HTN more common
- Stroke occurs at an earlier age in black and Hispanic patients, and both the prevalence and age-standardized mortality due to ischemic stroke are higher in black patients compared with the general population
- The quality of care for hospitalized stroke patients has been shown to vary across different socio-demographic groups

Substantial changes with risk adjustment: is stroke type an unmeasured confounder?

Table 5. Unadjusted and Adjusted ORs With 95% CIs for Race/Ethnicity Differences in Clinical Outcomes

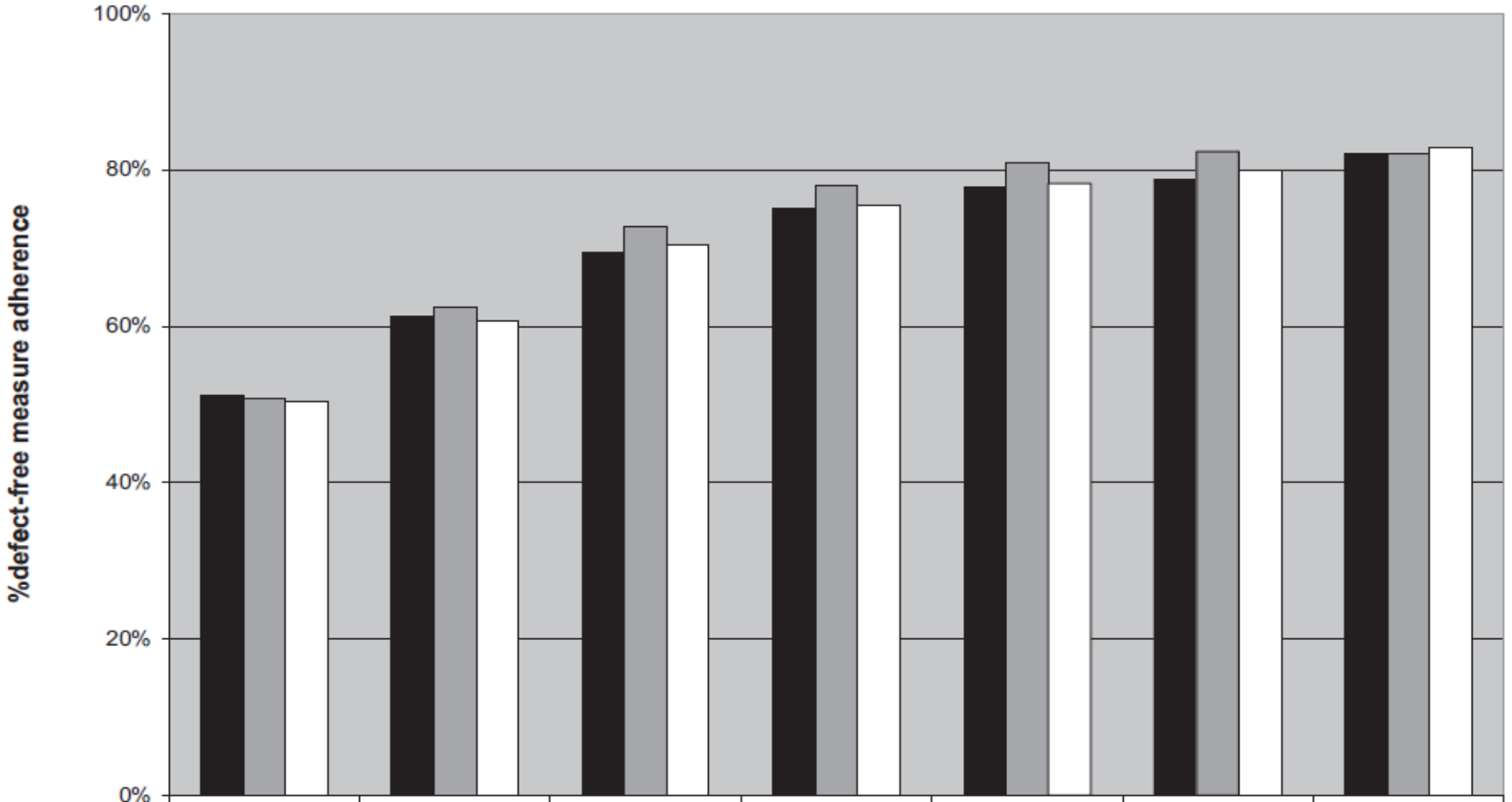
		Unadjusted		Adjusted for Patient* Characteristics		Adjusted for Patient* and Hospital† Characteristics	
Outcome	Race/Ethnicity	OR	95% CI	OR	95% CI	OR	95% CI
In-hospital mortality	B vs W	0.71	0.68–0.74	0.93	0.89–0.97	0.90	0.85–0.95
	H vs W	0.80	0.75–0.85	0.96	0.89–1.02	0.95	0.88–1.02
Discharge home	B vs W	1.17	1.15–1.19	0.86	0.85–0.88	0.83	0.81–0.86
	H vs W	1.41	1.37–1.45	1.15	1.11–1.18	1.13	1.08–1.18
Length of stay >4 days	B vs W	1.38	1.35–1.40	1.49	1.46–1.52	1.31	1.28–1.35
	H vs W	1.26	1.22–1.30	1.34	1.30–1.39	1.16	1.11–1.20

Models were also adjusted for calendar time and time in program. B indicates black; H, Hispanic; and W, white.

*Adjusted for patient characteristics of age, sex, body mass index, and prior medical history of atrial fibrillation, stroke/transient ischemic attack, coronary heart disease or myocardial infarction, carotid stenosis, diabetes mellitus, peripheral vascular disease, hypertension, dyslipidemia, or smoking.

†Adjusted for hospital characteristics of geographic region, number of beds, annual stroke volume, academic vs not, and percentage of minority stroke patients treated.

Exploring Disparity: I have a dream



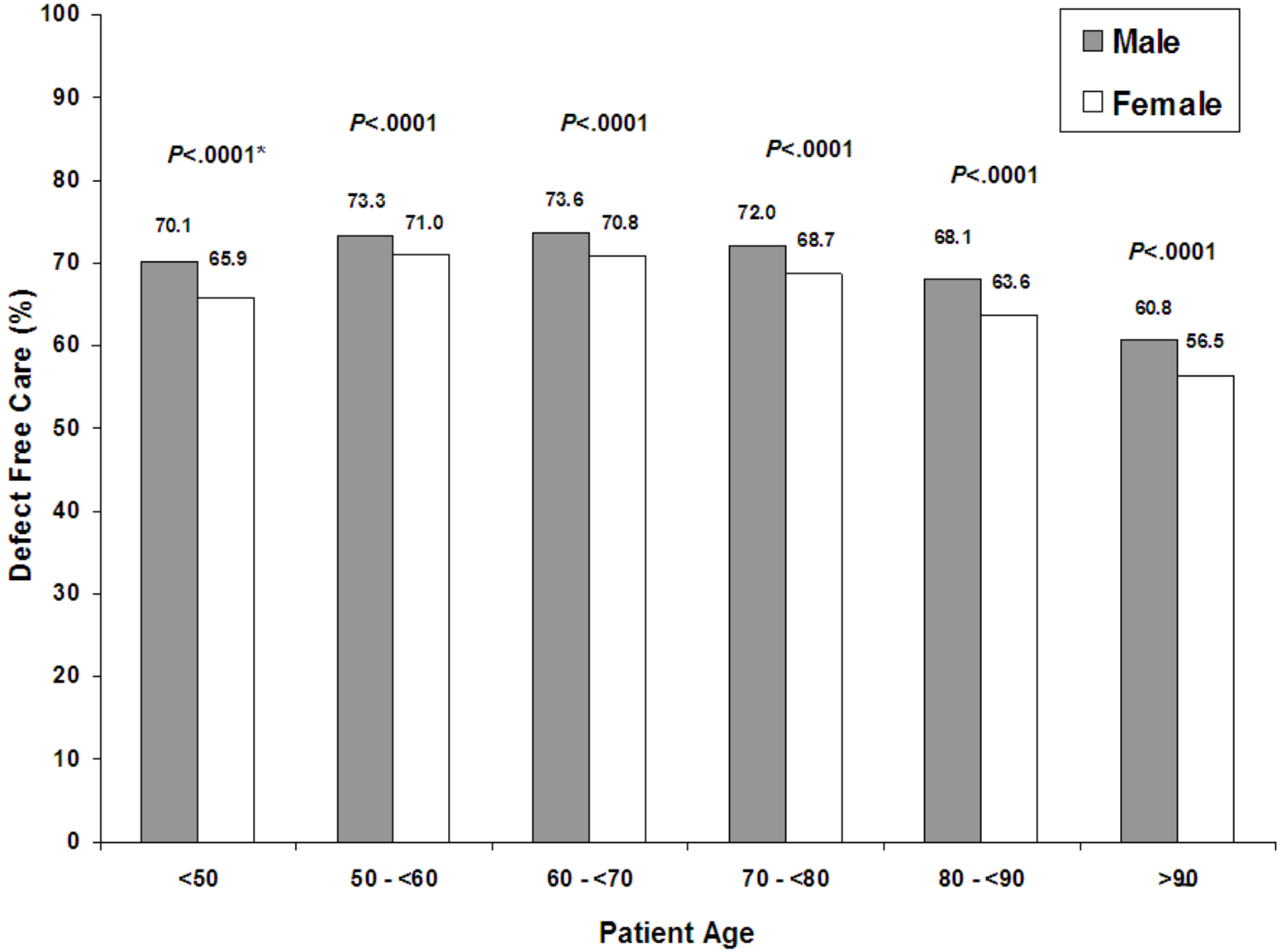
	Baseline	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Black	51%	61%	70%	75%	78%	79%	82%
Hispanic	51%	62%	73%	78%	81%	82%	82%
White	50%	61%	70%	75%	78%	80%	83%

Schwamm et al. Race/Ethnicity, Quality of Care, and Outcomes in Ischemic Stroke. Circulation. 2010;121:1492-1501

Gender Differences

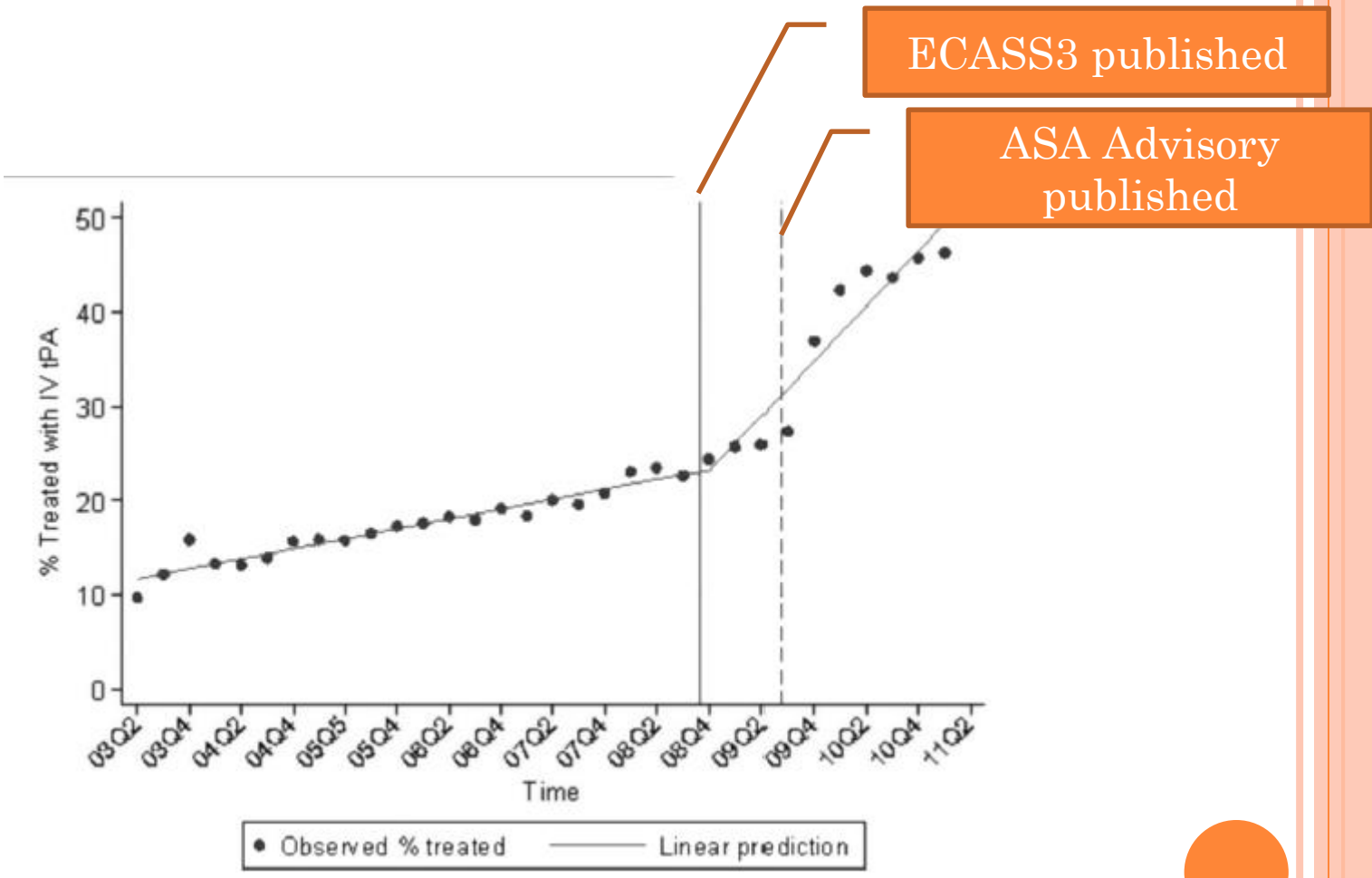
- Because women have a longer life expectancy, more stroke events occur in women than in men
- Women have higher stroke mortality in the oldest age groups and worse functional outcomes following a stroke than men
- This gender gap will increase dramatically over the next decade based on demographic trends
- These differences remain after adjustment for baseline differences in age and stroke risk factors

Unadjusted analysis showing gender effect at every age bracket



Extra! Extra! Read all about it: Bidirectional Communication

The trends over time of eligible patients arriving by 3.5 hr and tPA by 4.5



Messe´et al. Use of tPA Before and After Publication of ECASS3 in GWTG. Circ Cardiovasc Qual Outcomes. 2012;5 (epub)

Hurry up and wait: The Golden Hour Paradoxical Relationship between Onset to Door and Door to Needle in >30,000 AIS pts

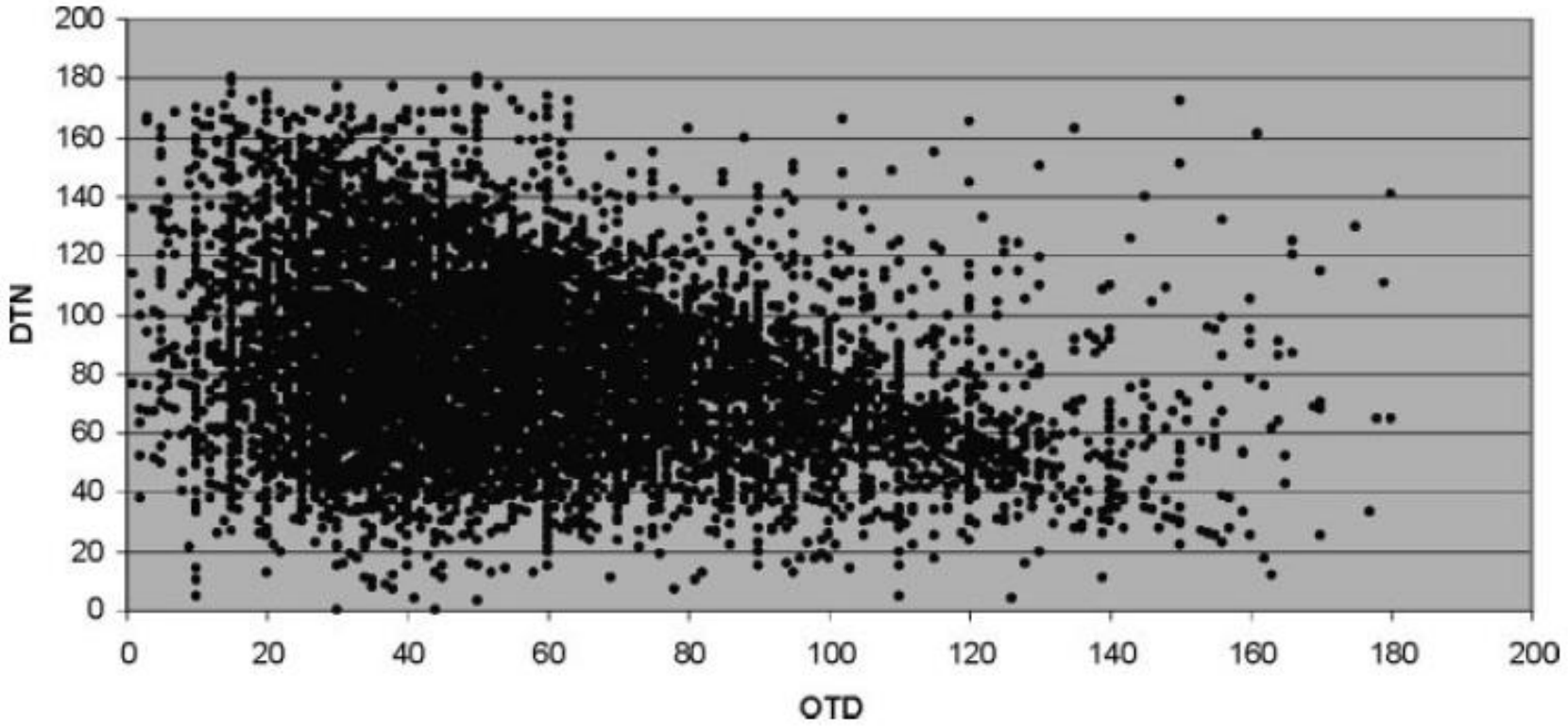
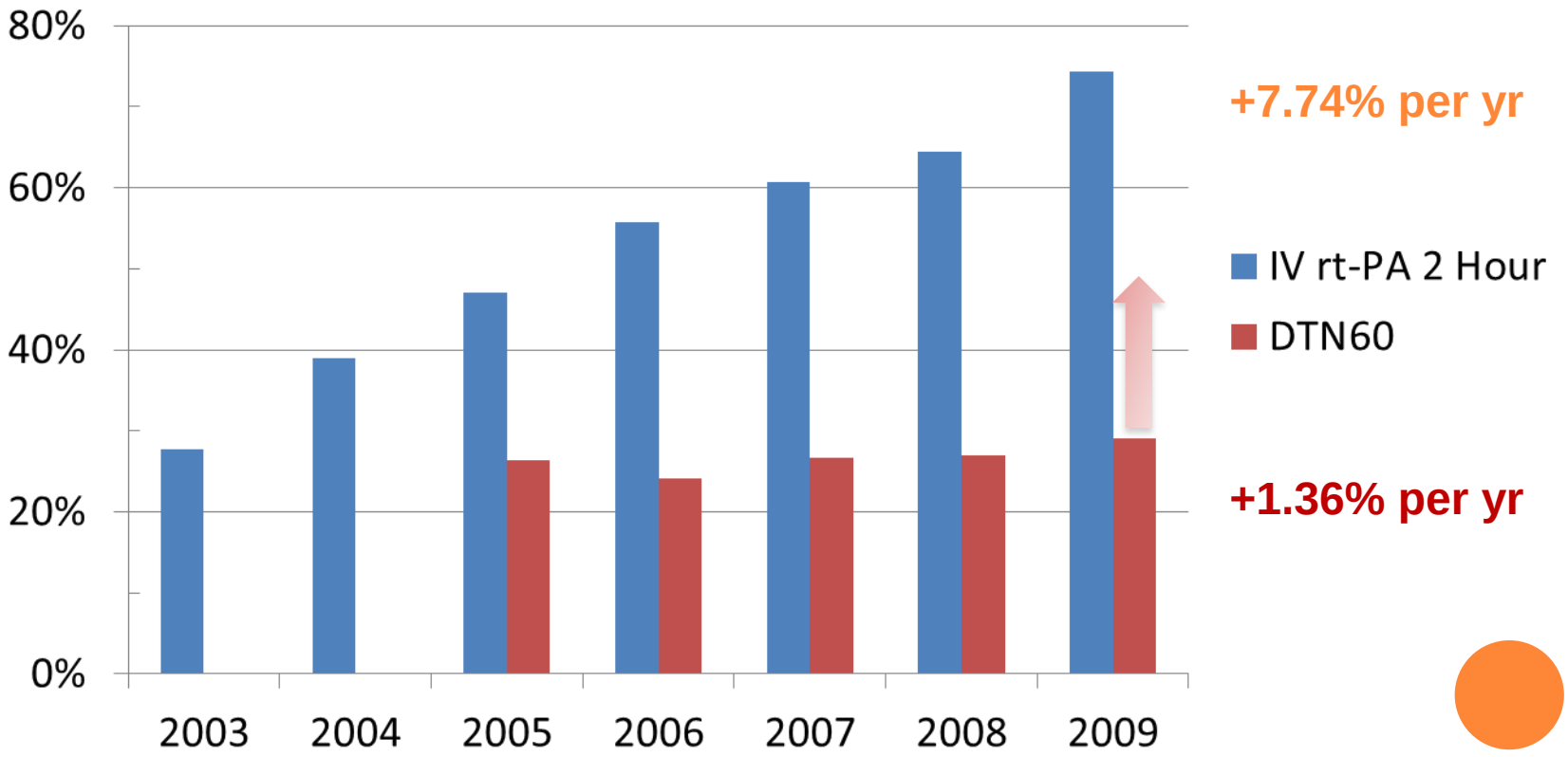


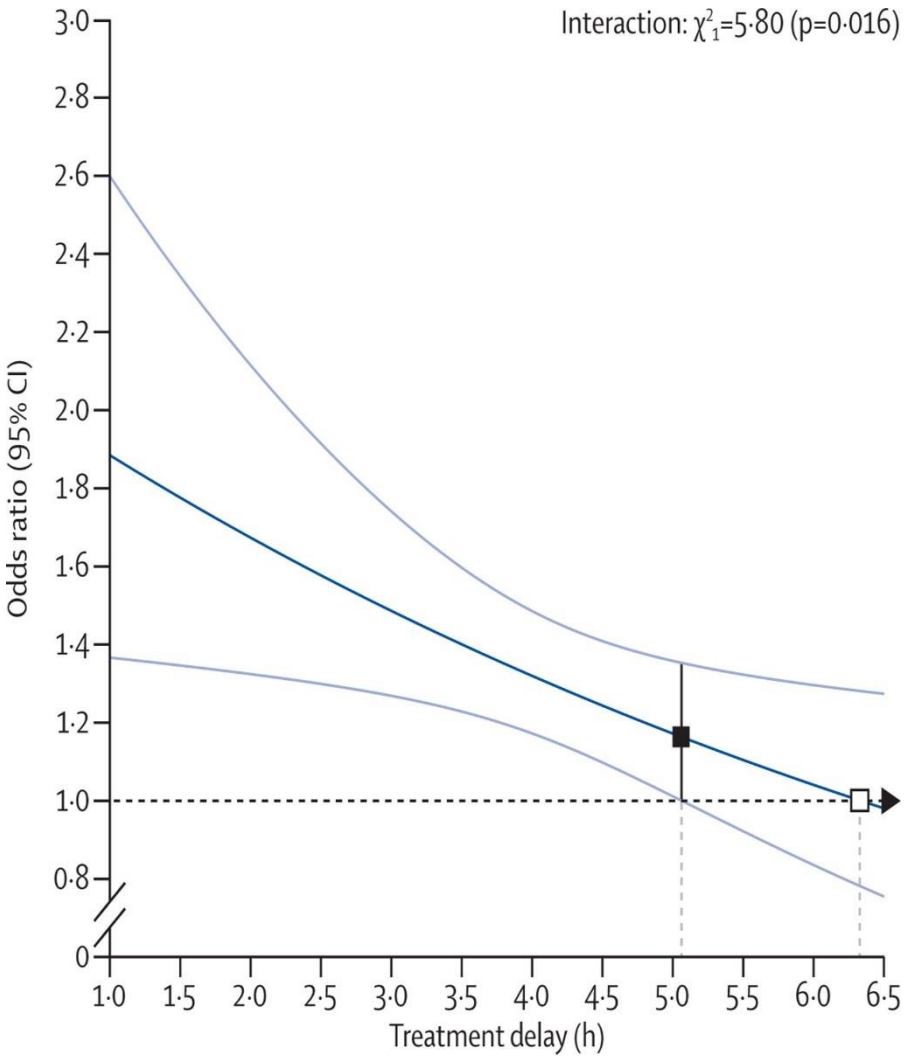
Figure 1. Relation of OTD to DTN times among all ischemic stroke patients treated within 3 hours with IV TPA (n=11 883). Mean ± SD OTD time was 56.3 ± 28.5 minutes and DTN time, 84.1±129.0 minutes. The correlation coefficient was -0.30.

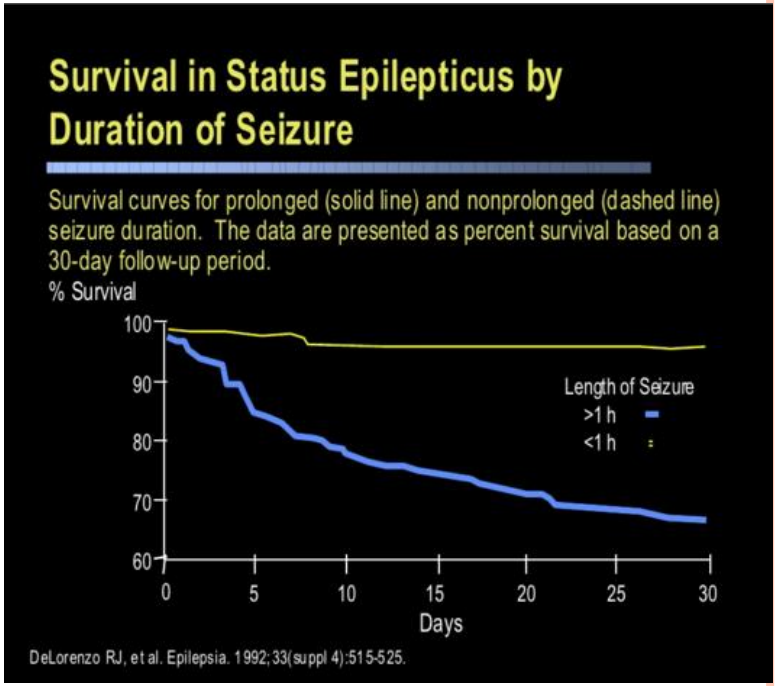
Improvements Over Time in the Use of IV tPA but not in Timeliness



Unadjusted raw data on Jan 30, 2012

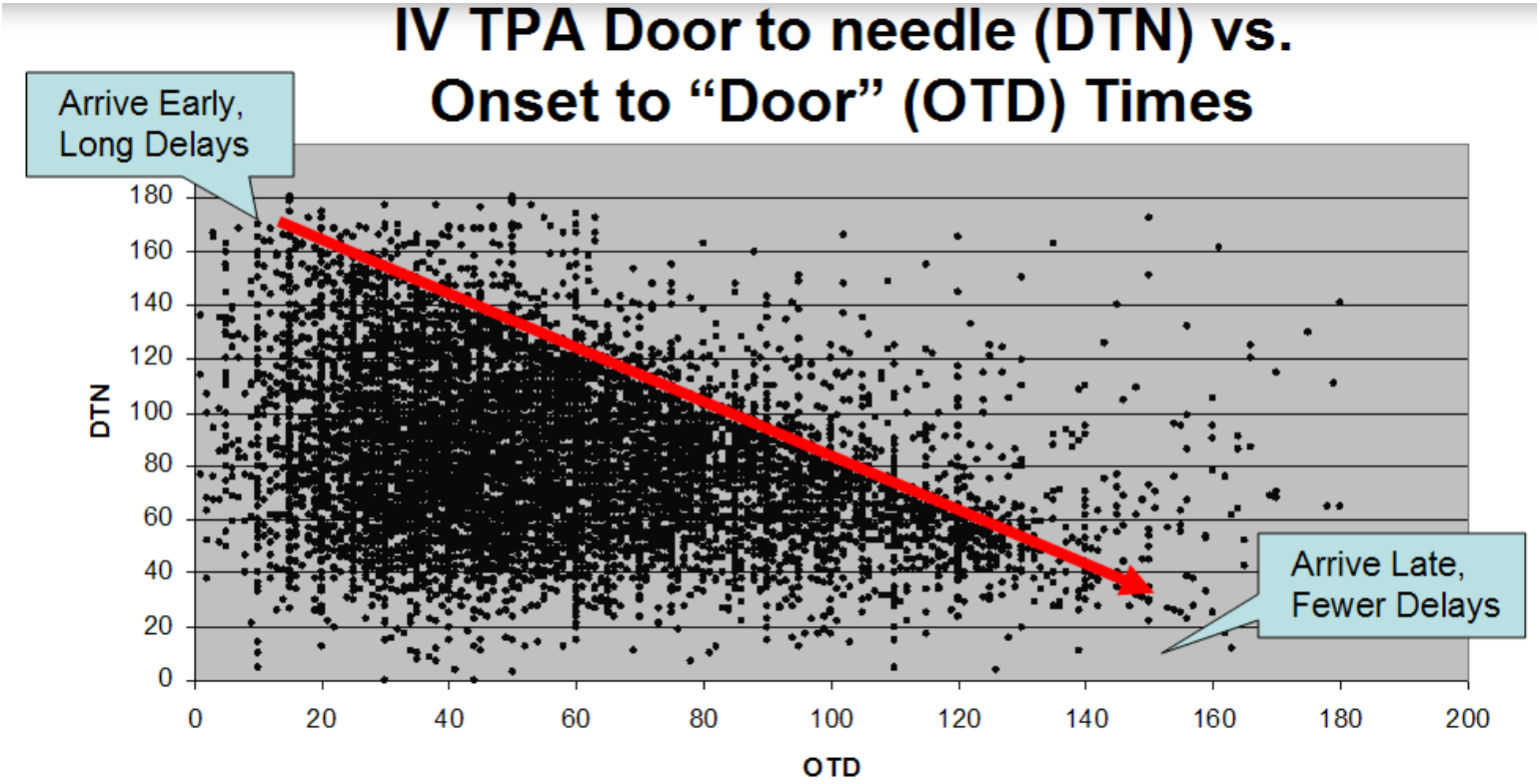
Time-Benefit of IV tPA in Acute Stroke





Emberson. Stroke Thrombolysis Trialists' Collaborative Group. Lancet. 2014 Nov 29;384(9958):1929-35

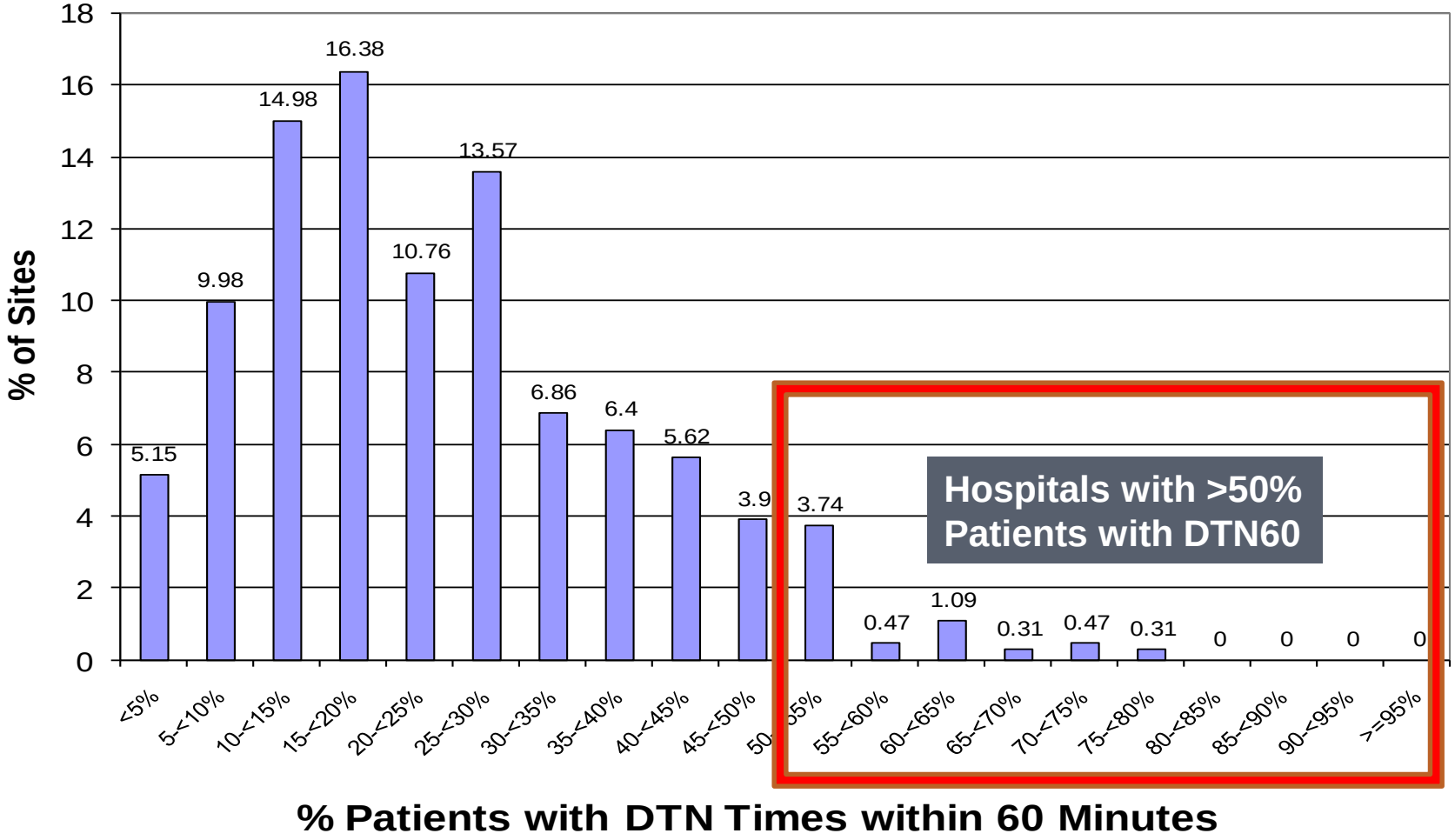
The Early Bird Gets a Slow, Cold Worm



- Mean DTN in all 12,545 IV TPA patients: 86 ± 42 min
- **Longer mean DTN in golden hour patients (90.6 vs. 76.7 min, p < 0.0001)**

Saver. Stroke. 2010;41:1431-1439

Hospital Variation in % of tPA Patients with DTN Times ≤60 min



Fonarow GC et al. Circulation. 2011;123:750-758. Among hospitals with at least 10 tPA patients (N=641)

"This really is an innovative approach, but I'm afraid we can't consider it. It's never been done before."

DTN60: The Early Bird Special

Table 5. Unadjusted and Adjusted ORs for Clinical Outcomes in Patients With Door-to-Needle Times ≤60 Minutes Compared With Those With Door-to-Needle Times >60 Minutes

	Unadjusted			Adjusted*		
Outcome	OR	95% CI	*P*	OR	95% CI	*P*
Mortality	0.78	0.69–0.88	0.0001	0.78	0.69–0.90	0.0003
Discharge home	0.96	0.90–1.04	0.3331	0.98	0.91–1.07	0.7130
Discharge home or acute rehabilitation	1.10	1.02–1.19	0.0146	1.07	0.98–1.17	0.1277
Ambulatory at discharge	1.01	0.94–1.09	0.8085	1.03	0.95–1.13	0.4848
Length of stay (≤4 d)	1.00	0.93–1.07	0.9902	0.98	0.91–1.05	0.4982
Symptomatic ICH	0.84	0.73–0.97	0.0182	0.88	0.75–1.02	0.0886
Systemic hemorrhage	0.82	0.61–1.11	0.2046	0.81	0.59–1.13	0.2171
Any tPA complication	0.90	0.81–1.00	0.0455	0.91	0.81–1.02	0.1148

ICH indicates intracranial hemorrhage.

*Variables included in multivariable models were sex, race, prior medical history of atrial fibrillation, stroke/TIA, coronary heart disease or myocardial infarction, carotid stenosis, diabetes mellitus, peripheral vascular disease, hypertension, dyslipidemia, smoking, NIHSS (continuous), arrival mode, arrival time on-/off-hours, onset-to-door time (continuous), hospital characteristics of geographic region, academic, primary stroke center, bed size, and annual number of strokes. No major differences were observed when the models were constructed using the more complete cohort of patients (n=24 284) with or without recorded NIHSS.

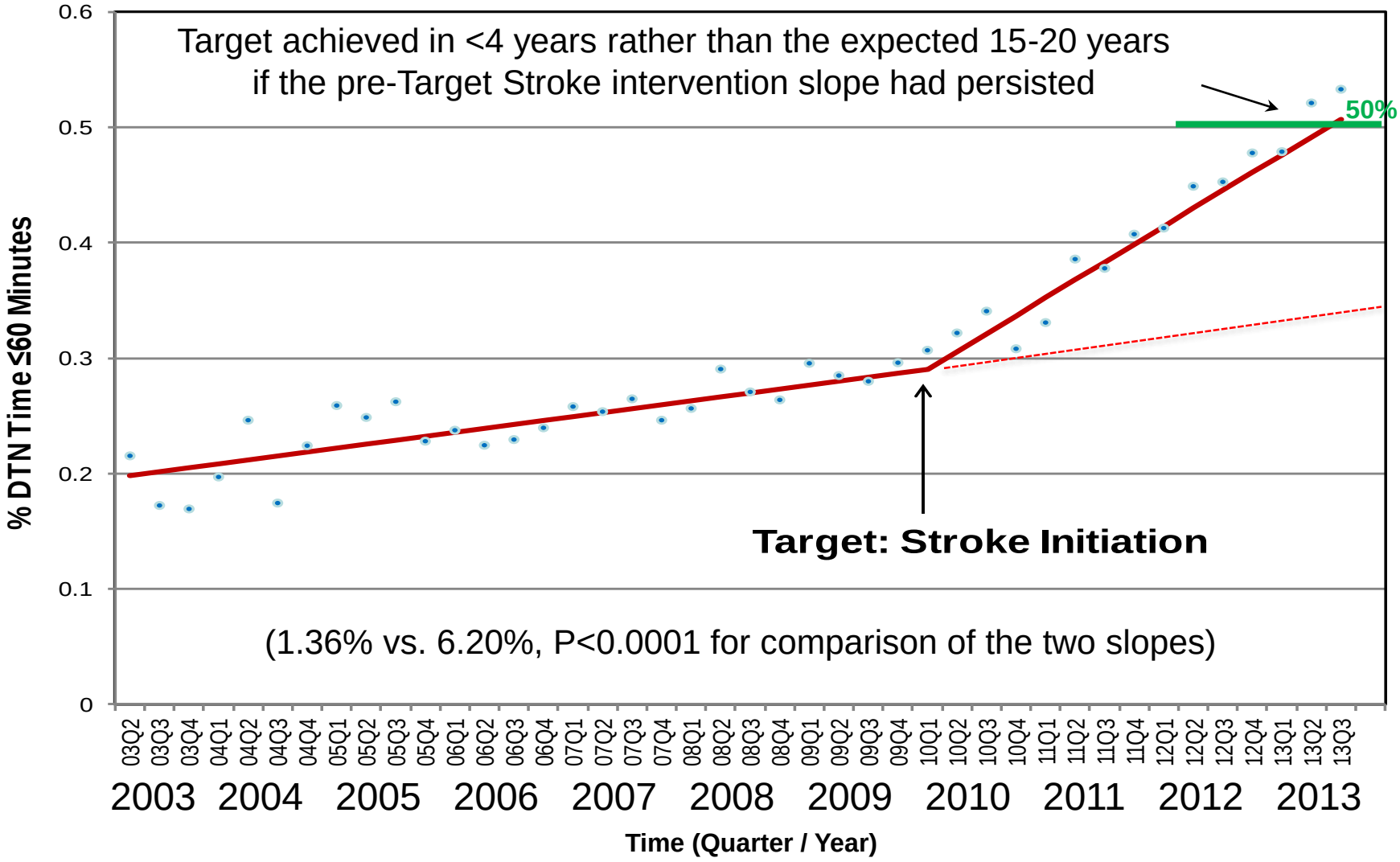
Fonarow et al. *Circulation. 2011;123:750-758*

The Door-to-Needle Bundle

1. Hospital pre-notification by Emergency Medical Services
2. Rapid triage protocol and stroke team notification
3. Single call/paging activation system for entire stroke team
4. Use of a stroke toolkit containing clinical decision support, stroke-specific order sets, guidelines, hospital-specific algorithms, critical pathways, NIH Stroke Scale and other stroke tools
5. Rapid acquisition and interpretation of brain imaging
6. Rapid laboratory testing (including point-of-care testing) if indicated
7. Pre-mixing tPA medication ahead of time for high likelihood candidates
8. Rapid access to intravenous tPA in the ED/brain imaging area
9. Team-based approach
10. Rapid data feedback to stroke team on each patient's DTN time and other performance data

Fonarow GC, Smith EE, Saver JL, Reeves MJ, Hernandez AF, Peterson ED, Sacco RL, Schwamm LH. Improving door-to-needle times in acute ischemic stroke: the design and rationale for the American Heart Association/American Stroke Association's Target: Stroke initiative. Stroke. 2011;42(10):2983-2989.

Increase in the % of Patients with DTN 60 Pre vs. Post Target Stroke



Original Investigation

Door-to-Needle Times for Tissue Plasminogen Activator Administration and Clinical Outcomes in Acute Ischemic Stroke Before and After a Quality Improvement Initiative

Gregg C. Fonarow, MD; Xin Zhao, MS; Eric E. Smith, MD, MPH; Jeffrey L. Saver, MD; Mathew J. Reeves, PhD; Deepak L. Bhatt, MD, MPH; Ying Xian, MD, PhD; Adrian F. Hernandez, MD, MHS; Eric D. Peterson, MD, MPH; Lee H. Schwamm, MD

IMPORTANCE The benefits of intravenous tissue plasminogen activator (tPA) in patients with acute ischemic stroke (AIS) are time dependent and guidelines recommend a door-to-needle (DTN) time of 60 minutes or less. However, studies have found that less than 30% of US patients are treated within this time window. Target: Stroke was designed as a national quality improvement initiative to improve DTN times for tPA administration in patients with AIS.

OBJECTIVES To evaluate DTN times for tPA administration and the proportion of patients with times of 60 minutes or less before and after initiation of a quality improvement initiative and to determine whether potential improvements in DTN times were associated with improvements in clinical outcomes.

DESIGN, SETTING, AND PATIENTS The Target: Stroke initiative disseminated 10 care strategies to achieve faster DTN times for tPA administration, provided clinical decision support tools, facilitated hospital participation, and encouraged sharing of best practices. This study included 71 169 patients with AIS treated with tPA (27 319 during the preintervention period from April 2003-December 2009 and 43 850 during the postintervention period from January 2010-September 2013) from 1030 Get With The Guidelines–Stroke participating hospitals (52.8% of total).

MAIN OUTCOMES AND MEASURES The DTN times for tPA administration of 60 minutes or less and in-hospital risk-adjusted mortality, symptomatic intracranial hemorrhage, ambulatory status at discharge, and discharge destination.

RESULTS Measures of DTN time for tPA administration improved significantly during the postintervention period compared with the preintervention period as did clinical outcomes.

	Study Period		Adjusted Odds Ratio (95% CI)	*P* Value
	Preintervention (n = 27 319)	Postintervention (n = 43 850)		
tPA DTN time, median (IQR), min	77 (60-98)	67 (51-87)		< .001
tPA DTN time ≤ 60 min, % (95% CI)	26.5 (26.0-27.1)	41.3 (40.8-41.7)		< .001
End of each period	29.6 (27.8-31.5)	53.3 (51.5-55.2)		< .001
Improvement in tPA DTN time ≤ 60 min, % per year (95% CI)	1.36 (1.04-1.67)	6.20 (5.58-6.78)		< .001
In-hospital all-cause mortality, %	9.93	8.25	0.89 (0.83-0.94)	< .001
Discharge to home, %	37.6	42.7	1.14 (1.09-1.19)	< .001
Independent ambulatory status, %	42.2	45.4	1.03 (0.97-1.10)	.31
Symptomatic intracranial hemorrhage within 36 h, %	5.68	4.68	0.83 (0.76-0.91)	< .001

CONCLUSIONS AND RELEVANCE Implementation of a national quality improvement initiative was associated with improved timeliness of tPA administration following AIS on a national scale, and this improvement was associated with lower in-hospital mortality and intracranial hemorrhage, along with an increase in the percentage of patients discharged home.

JAMA. 2014;311(16):1632-1640. doi:10.1001/jama.2014.3203

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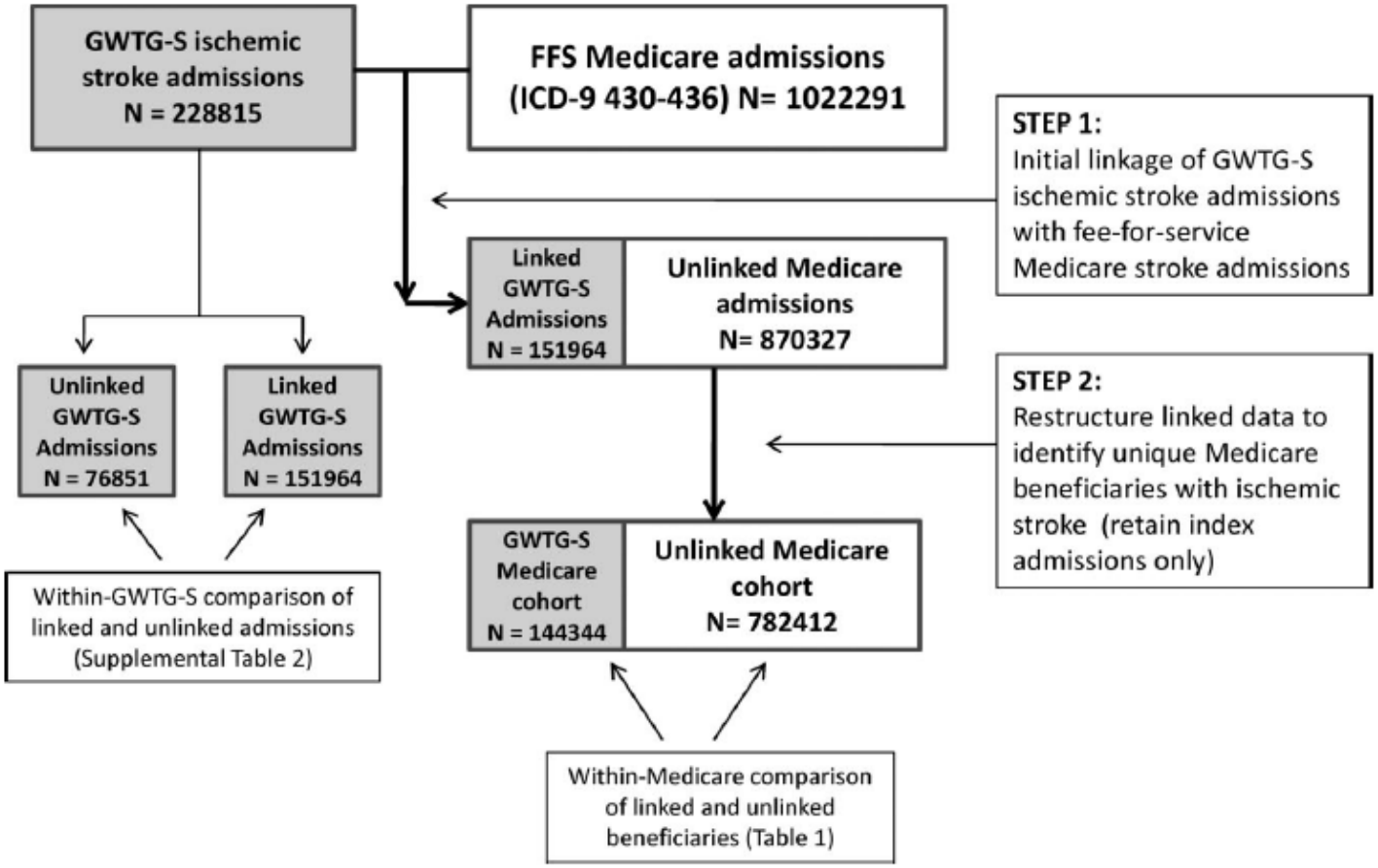
- 18,238 more patients treated with tPA
- 977 additional lives saved
- 5,883 patients with reduced long-term disability based on discharge destination

A Match Made in Heaven: Linkage to External Datasets for Representativeness and Outcomes



Reeves et al. Representativeness of the GWTG–Stroke Registry. Stroke. 2012; 43

Patients in GWTG-S appear representative of Medicare FFS as a whole

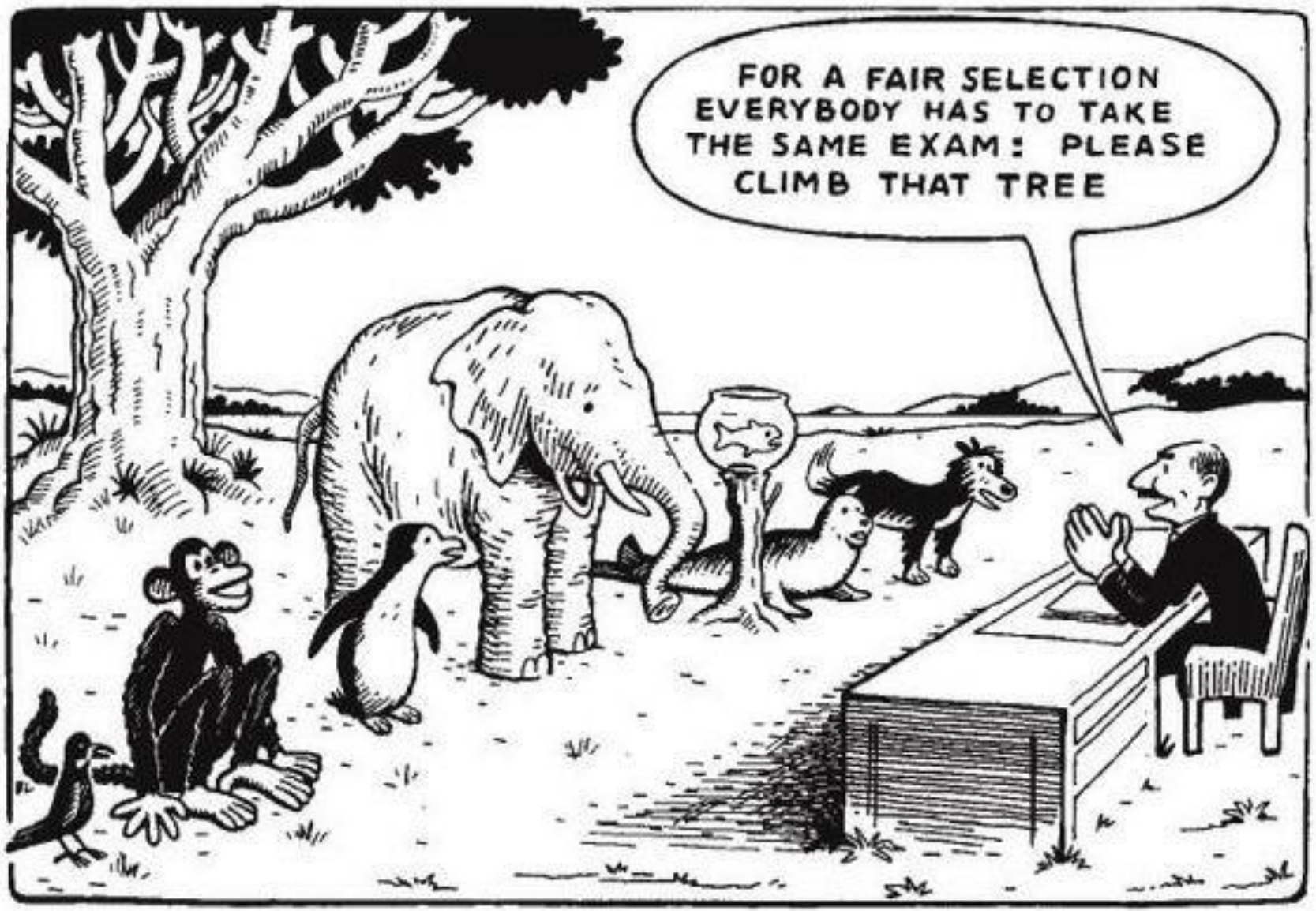
Table 3. Comparison of Length of Stay, Discharge Home, and In-Hospital Mortality Between Linked GWTG-Stroke and Unlinked Medicare Beneficiaries Hospitalized With Acute Ischemic Stroke

Variable	All Medicare Ischemic Stroke Beneficiaries (N=926 756)	Linked GWTG-Stroke Medicare Cohort (N=144 344)	Unlinked Medicare Cohort (N=782 412)	Absolute Difference	Adjusted Results‡ OR	95% CI	*P*
Clinical outcome							
Mean LOS (SD)*	6.5 (5.1)	6.5 (4.9)	6.5 (5.1)	0.0	0.99	0.98–1.00	<0.001
Discharge home	37.9%	37.9%	38.0%	0.1	1.01	0.99–1.03	0.52
In-hospital mortality†	6.9%	6.3%	7.0%	0.7	0.85	0.82–0.88	<0.001

GWTG indicates Get With The Guidelines; LOS, length of stay; SD, standard deviation; OR, odds ratio; CI, confidence interval.
*Calculation of LOS was based on 876 629 patients because patients transferred in or transferred out were excluded (N=50 127).
†Calculation of in-hospital mortality was based on 894 601 patients because patients transferred out were excluded (N=32 155).
‡Multivariable model estimates adjusted for patient and hospital characteristics.

Reeves et al. Representativeness of the GWTG-Stroke Registry. Stroke. 2012; 43

Let's Rank Everyone On Mortality!



Public Policy Impact: Initial Stroke Severity Explains Most Variation in Stroke Mortality

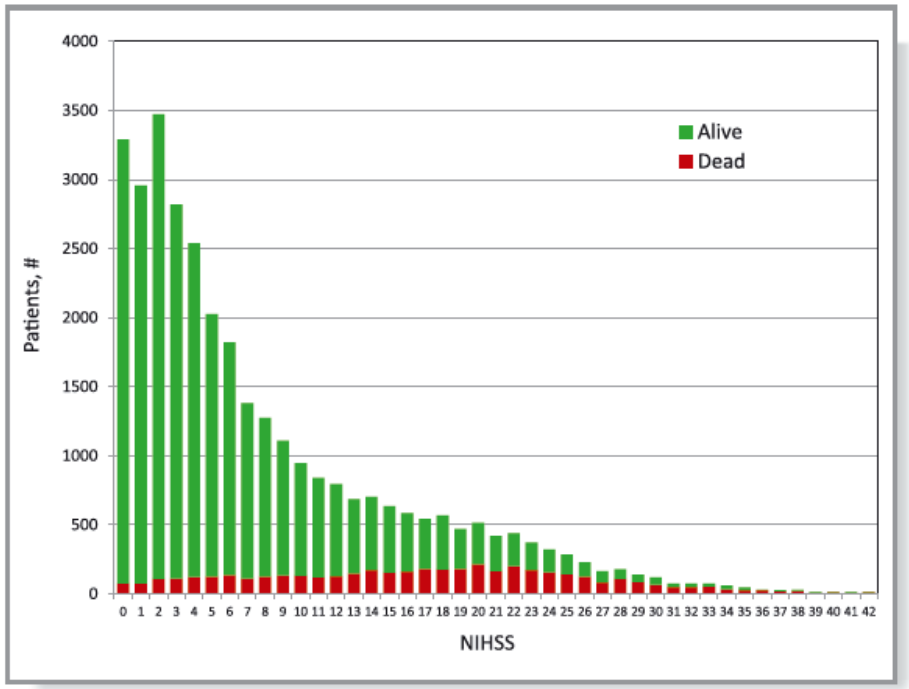


Figure 1. Distribution of NIHSS scores among Medicare beneficiaries in GTWG-Stroke hospitals with acute ischemic stroke patients alive at 30 days are shown in green and patients dead by 30 days shown in red. NIHSS indicates National Institutes of Health Stroke Scale; GWTG, Get With The Guidelines.

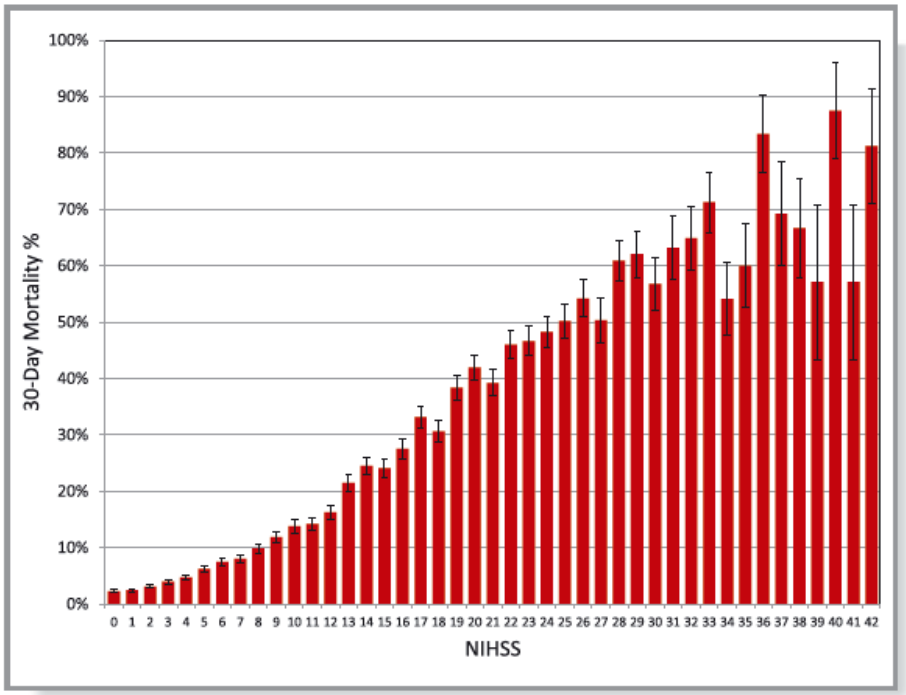
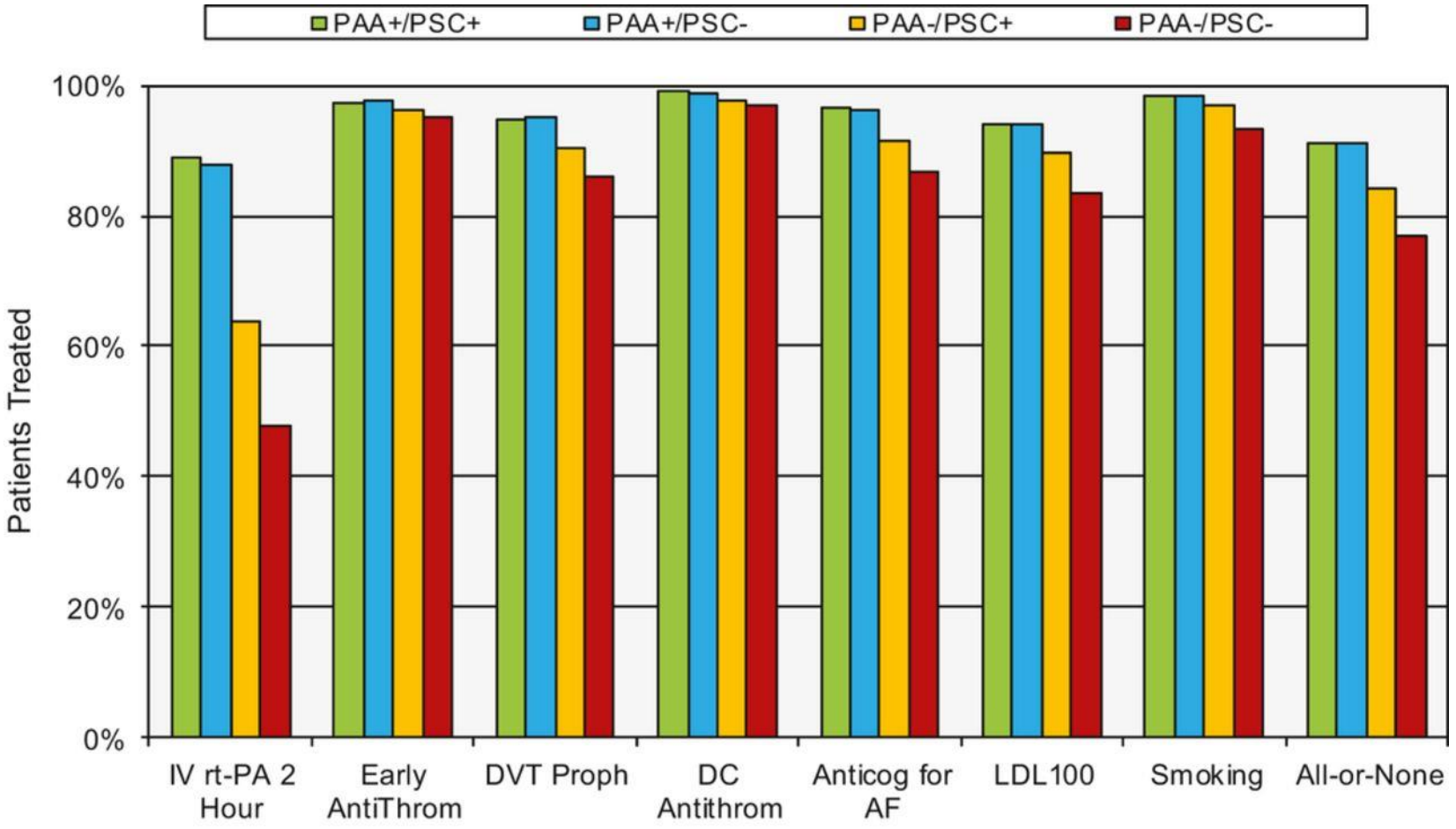


Figure 2. Acute ischemic stroke 30-day mortality rates by NIHSS. Standard error bars are displayed. NIHSS indicates National Institutes of Health Stroke Scale.

Fonarow et al. Relationship of National Institutes of Health Stroke Scale to 30-Day Mortality in Medicare Beneficiaries With Acute Ischemic Stroke. JAHA 2012

Quality is More than a saying on a billboard… Structure vs. Performance

Performance measure conformity by hospital PAA status (BG vs. YR) compared to PSC certification status



Fonarow G C et al. J Am Heart Assoc 2013;2:e000451

American Heart Association | American Stroke Association

Lessons Learned

- **Perfect is the enemy of good**
  - data validity/completeness vs. breadth of cases and real world practice
- **Many paths, one journey**
  - align measures for greater success
- **Whole is greater than the sum of the parts**
  - linkage to external data sources, e.g., state and national claims data
- **Great power = great responsibility**
  - focus on clinically meaningful (rather than statistically significant) robust measures that have minimal confounding and a clear message

Thank You For Your Attention