Evidence Based Medicine in Cardiac Imaging

Paolo Raggi, MD

No conflicts to disclose
“Well, Bob, it looks like a paper cut, but just to be sure, let’s get an echo.”
“I wanted to go to America so badly. All those years I read Harrison’s and the other textbooks......and the things they do, the tests they order...it’s like reading fiction. Money is no object. A menu without prices. But if you get there, it won’t be fiction. It will be true” (page 433)
Over the past several decades, advances in the prevention and treatment of cardiovascular disease have led to important declines in age-adjusted, cardiovascular-related mortality (1). At the same time, cardiovascular imaging has proliferated (2,3). A recent review of Medicare billing data revealed a doubling of expenditures on medical imaging, from $6.89 billion in 2000 to $14.1 billion in 2005, approximately one-third of this involved cardiovascular imaging (4). Medicare expenditures for diagnostic imaging have grown more rapidly than any other component of medical care (5). However, relatively few data link cardiovascular imaging to improved patient outcomes, and concern is growing that these tests have been adopted at extraordinary cost with insufficient evidence of benefit (6,7).
Trends in Echocardiography in ON

- The age- and sex-adjusted rates of echocardiography grew from 39.1 per 1,000 persons in 2001 to 59.9 per 1,000 persons in 2009, for an annual rate of increase of 5.5%.
- Repeat echocardiograms increased at a rate of 10.6% per year and accounted for 25.3% of all procedures in 2009 as compared to 18.5% in 2002.

Blecker S et al JACC Img 2013;6:515-22
Stress test was used before cataract surgery, knee arthroscopy, or shoulder arthroscopy in only 0.67% of Veterans Affairs patients and 2.14% of Medicare patients from February to December 2009, more than 2 years before the CW campaign was launched.

Hospital-Level Variation in Use of Cardiovascular Testing for Adults With Incident Heart Failure

Findings From the Cardiovascular Research Network Heart Failure Study

Steven A. Farmer, MD, PhD,*† Justin Lenzo, PhD,† David J. Magid, MD, MPH,‡ Jerry H. Gurwitz, MD,§‖
David H. Smith, RPh, PhD,¶ Grace Hsu, MPH,# Sue Hee Sung, MPH,# Alan S. Go, MD##††

CONCLUSIONS For patients with newly diagnosed HF, we did not observe widespread overuse of cardiovascular testing in the 6 months following incident HF hospitalization relative to existing HF guidelines. Variations in testing were greatest for assessment of ischemia, in which testing guidelines are less certain. (J Am Coll Cardiol Img 2014;7:690-700) © 2014 by the American College of Cardiology Foundation.
RESULTS

During the study period, 655,613 enrollees (68.8%) underwent at least one imaging procedure associated with radiation exposure. The mean (±SD) cumulative effective dose from imaging procedures was 2.4±6.0 mSv per enrollee per year; however, a wide distribution was noted, with a median effective dose of 0.1 mSv per enrollee per year (interquartile range, 0.0 to 1.7). Overall, moderate effective doses of radiation were incurred in 193.8 enrollees per 1000 per year, whereas high and very high doses were incurred in 18.6 and 1.9 enrollees per 1000 per year, respectively. In general, cumulative effective doses of radiation from imaging procedures increased with advancing age and were higher in women than in men. Computed tomographic and nuclear imaging accounted for 75.4% of the cumulative effective dose, with 81.8% of the total administered in outpatient settings.

CONCLUSIONS

Imaging procedures are an important source of exposure to ionizing radiation in the United States and can result in high cumulative effective doses of radiation.
Evidence-based medicine is the *conscientious, explicit, and judicious* use of the best current evidence in making decisions about the care of individual patients. (David L. Sackett, et al., BMJ 1996; 312:71)
Definition of EB Practice

Evidence-based practice is “a process of care that takes the patient and his or her preferences and actions, the clinical setting including the resources available, and current and applicable scientific evidence, and knits the three together using the clinical expertise and training of the health-care providers.” (Haynes et al., 2002)
Evidence Classification

Classification of Recommendations

- **Class I**: Conditions for which there is evidence, general agreement, or both that a given procedure or treatment is useful and effective.

- **Class II**: Conditions for which there is conflicting evidence, a divergence of opinion, or both about the usefulness/efficacy of a procedure or treatment
  - **Class IIA**: Weight of evidence/opinion is in favor of usefulness/efficacy.
  - **Class IIB**: Usefulness/efficacy is less well established by evidence/opinion.

- **Class III**: Conditions for which there is evidence, general agreement, or both that the procedure/treatment is not useful/effective and in some cases may be harmful.

Level of Evidence

- **Level of Evidence A**: Data derived from multiple randomized clinical trials
- **Level of Evidence B**: Data derived from a single randomized trial or nonrandomized studies
- **Level of Evidence C**: Consensus opinion of experts

Strong Evidence for Cardiac Drugs

- Beta blockers
- ACE-I and ARBs
- Antiplatelets agents
- Anticoagulants for A. Fibrillation
- Etc..

BUT

Do we have strong evidence for imaging?

AND

What is the evidence we are looking for?
Assessing Adherence to Medication Long-Term: Impact on MACE

Sameer Bansilal, MD, MS
Allison Freeman, MS, CHLP
Renee J.G. Arnold, PharmD

Adherence Levels and MACE (Hospitalizations per 100 Patient-years)

- Post-MI: Nonadherent (18.1), Partially Adherent (12.8), Fully Adherent (10.9)
- Atherosclerosis: Nonadherent (7.9), Partially Adherent (6.0)

Kary G. Wei, MD, PhD
Kesavan, PhD
Juliano, PhD
Kuster, MD, PhD
Is There a Problem with EBM?

• Over the past few decades a large body of evidence has been acquired

• But knowledge translation has been implemented very slowly

• Some estimates suggest a gap of 15-20 yrs between acquisition of E and KT*

*Balas EA et al. Yearbook of Medical Informatics 2000
Obstacles to Implementation of EBM
The Nature of Obstacles

- **KNOWLEDGE**
  The base of knowledge enormous and overwhelms professionals often leading to confusion

- **ATTITUDE**
  Recommendations generated by professional organization may be incomplete or conflicting creating resistance to implementation. Furthermore, physicians may feel that the guidelines do not reflect real practice

- **BEHAVIOUR**
  Even when physicians have accepted the evidence there are obstacle to implementing a new EB approach (reimbursement, non availability of imaging tools, pt’s preference etc.)
With Myocardial Viability

Probability of Death

Medical therapy (95 deaths)
CABG (83 deaths)

Years since Randomization

No. at Risk
Medical therapy  243  219  206  179  146  94  51
CABG  244  213  203  192  148  94  51
Do Physicians Follow EBM?

FDG viability

Mr. SA (University of Alberta Oct 2016)
AHA Scientific Statement

Approaches to Enhancing Radiation Safety in Cardiovascular Imaging

A Scientific Statement From the American Heart Association

Endorsed by the American Association of Physicists in Medicine, American College of Cardiology, American Society of Nuclear Cardiology, North American Society for Cardiovascular Imaging, Society of Cardiovascular Computed Tomography, and Society for Coronary Angiography and Interventions

Reza Fazel, MD, MSc, FAHA, Chair; Thomas C. Gerber, MD, PhD, FAHA, Co-Chair; Stephen Balter, PhD; David J. Brenner, DSc; J. Jeffrey Carr, MD, MSCE; Manuel D. Cerqueira, MD; Jersey Chen, MD, MPH; Andrew J. Einstein, MD, PhD, FAHA; Harlan M. Krumholz, MD, SM, FAHA; Mahadevappa Mahesh, MS, PhD; Cynthia H. McCollough, PhD; James K. Min, MD; Richard L. Morin, PhD; Brahmaghee K. Nallamothu, MD, MPH, FAHA; Khurram Nasir, MD, MPH; Rita F. Redberg, MD, MSc, FAHA; Leslee J. Shaw, PhD; on behalf of the American Heart Association Council on Quality of Care and Outcomes Research, Council on Clinical Cardiology, and Council on Cardiovascular Radiology and Intervention
<table>
<thead>
<tr>
<th>Step</th>
<th>Urgency</th>
<th>Cardiac condition</th>
<th>Type of surgery*</th>
<th>Functional capacity</th>
<th>Number of clinical risk factors*</th>
<th>ECG</th>
<th>LV echo†</th>
<th>Imaging Stress Testing‡</th>
<th>BNP and TnT</th>
<th>β-Blockers§</th>
<th>ACE-inhibitors§</th>
<th>Aspirin§</th>
<th>Statin§</th>
<th>Coronary Revascularisation</th>
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<td>Urgent surgery</td>
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<td>Elective surgery</td>
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<td>Low risk (&lt;1%)</td>
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<td>3</td>
<td>Elective surgery</td>
<td>Stable</td>
<td>Stable</td>
<td>Low risk (&lt;1%)</td>
<td>None</td>
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<td>4</td>
<td>Elective surgery</td>
<td>Stable</td>
<td>Stable</td>
<td>Intermediate (1–5%) or high risk (&gt;5%)</td>
<td>Excellent or good</td>
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<td>III C</td>
<td>III C</td>
<td>III C</td>
<td>IIb B</td>
<td>IIa C</td>
<td>I Cm</td>
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<td>I B</td>
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<td>5</td>
<td>Elective surgery</td>
<td>Stable</td>
<td>Stable</td>
<td>Intermediate risk (1–5%)</td>
<td>Poor</td>
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<td>III Cx</td>
<td>III Cx</td>
<td>I Ia C</td>
<td>I Ib B</td>
<td>IIa C</td>
<td>I Cm</td>
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<td>I Ib B</td>
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<tr>
<td>6</td>
<td>Elective surgery</td>
<td>Stable</td>
<td>Stable</td>
<td>High risk (&gt;5%)</td>
<td>Poor</td>
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<td>III Cx</td>
<td>III C</td>
<td>I Ia C</td>
<td>I Ib B</td>
<td>IIa C</td>
<td>I Cm</td>
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<td>I Ib B</td>
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Benefit of Pre-Op Revascularization

Exclusions:
* Left main disease
* Severe aortic stenosis
* LVEF < 20%

Coronary Artery Revascularization Prophylaxis (CARP) trial

### Most Common Indications for Inappropriate Tests

1. **Detection of CAD: Symptomatic; Evaluation of Ischemic Equivalent (Nonacute)**
   - Low pretest probability of CAD; ECG interpretable AND can exercise (I)

42. **Risk Assessment: Preoperative Evaluation for Noncardiac Surgery Without Active Cardiac Conditions; Intermediate-Risk Surgery**
   - No clinical risk factors (I)

   - Moderate to good functional capacity (greater than or equal to 4 METS) (I)

40. **Risk Assessment: Preoperative Evaluation for Noncardiac Surgery Without Active Cardiac Conditions; Low-Risk Surgery**
   - Preoperative evaluation for noncardiac surgery risk assessment (I)
Steps Taken to Remedy Deficiencies

- **PASSIVE DIFFUSION**
  Physicians acquire their own knowledge through educational material

- **HELP IS COMING**
  The literature is enormous and overwhelming; professional organizations developed guidelines and EB summaries

- **CASE MANAGERS**
  Personnel to help identify appropriate tests for the specific question

- **INFORMATIC REVOLUTION**
  Implementation of computerized ordering and reminders

- **THE CAROT AND THE STICK?**
  Reimbursement linked with application of EBM and guidelines
As of 2017, claims that do not include documentation that AUC criteria were consulted will not be paid by MEDICARE.

Documentation is the responsibility of the referring physician.

But

Payment is at risk only for the clinical team performing the test.

http://www.cardiovascularbusiness.com/topics/imaging/acc-examines-impact-medicare-changes-imaging
Effectiveness of Steps to Improve Practice of EBM

- EDUCATION VIA SEMINARS AND PRINTED MATERIAL
  Short lived effectiveness

- ELECTRONIC REMINDERS
  Mild improvement

- CASE MANAGERS
  Fair impact

- AUDITS AND FEEDBACK
  Limited impact

- FINANCIAL AND REGULATORY INTERVENTIONS
  Pay for performance and pay for participation
Steps Taken to Remedy Deficiencies

Probably the best approach is MULTIFACETED
Improvement Strategies

- Increasing knowledge and awareness of the AUC and guidelines and applying them to practice
- Better educating staff and physicians to keep them well informed on AUC
- More complete documentation and evaluation of patient (i.e. patient history & chart)
- Aiding both Cardiologists and referring physicians in improving their AUC performance
- Using tools (i.e. data collection sheet, PIM, AUC cards) to help track appropriate use
- Increasing the communication among physicians, nurses, and referring physicians
- Reviewing physician orders prior to test to ensure appropriate use
What is an “Appropriate” Procedure?

“an appropriate procedure in one in which the expected health benefit (reduced CV events, increased life expectancy) exceeds the expected negative consequences (mortality, morbidity, anxiety, pain, time lost from work) by a sufficiently wide margin that the procedure is worth doing, exclusive of cost”

RAND/UCLA methodology

What is “Appropriate” Imaging?

A test in which the expected incremental information, combined with clinical judgment, exceeds the expected negative consequences (radiation and contrast exposure, downstream testing etc.) by a sufficiently wide margin that the procedure is generally considered acceptable care and a reasonable approach for the indication

Hendel RC et al. JACC 2013;61:1305-17
Choosing Wisely Canada (CWC) and the Canadian Cardiovascular Society
Language is important

- This is about over-diagnosis, waste and harm
- This is not about cost savings (although there will likely to happen)
1. Don’t perform stress cardiac imaging or advanced non-invasive imaging in the initial evaluation of patients without cardiac symptoms unless high-risk markers are present.
   Asymptomatic, low risk patients account for up to 45 percent of unnecessary "screening." Testing should be performed only when the following findings are present: diabetes in patients older than 40 years old; peripheral arterial disease; or greater than 2 percent yearly risk for coronary heart disease events.

2. Don’t perform annual stress cardiac imaging or advanced non-invasive imaging as part of routine follow-up in asymptomatic patients.
   Performing stress cardiac imaging or advanced non-invasive imaging in patients without symptoms on a serial or scheduled pattern (e.g., every one to two years or at a heart procedure anniversary) rarely results in any meaningful change in patient management. This practice may, in fact, lead to unnecessary invasive procedures and excess radiation exposure without any proven impact on patients’ outcomes. An exception to this rule would be for patients more than five years after a bypass operation.

3. Don’t perform stress cardiac imaging or advanced non-invasive imaging as a pre-operative assessment in patients scheduled to undergo low-risk non-cardiac surgery.
   Non-invasive testing is not useful for patients undergoing low-risk non-cardiac surgery (e.g., cataract removal). These types of tests do not change the patient’s clinical management or outcomes and will result in increased costs.

4. Don’t perform echocardiography as routine follow-up for mild, asymptomatic native valve disease in adult patients with no change in signs or symptoms.
   Patients with native valve disease usually have years without symptoms before the onset of deterioration. An echocardiogram is not recommended yearly unless there is a change in clinical status.

5. Don’t order annual electrocardiograms (EKGs) or any other cardiac screening for low-risk patients without symptoms.
   There is little evidence that detection of coronary artery stenosis in asymptomatic patients at low risk for coronary heart disease improves health outcomes. False-positive tests are likely to lead to harm through unnecessary invasive procedures, over-treatment and misdiagnosis. Potential harms of this routine annual screening exceed the potential benefits.
Can Physicians Identify Inappropriate Nuclear Stress Tests? 
An Examination of Inter-Rater Reliability for the 2009 Appropriate Use Criteria for Radionuclide Imaging

Siqin Ye, MD, MS; LeRoy E. Rabbani, MD; Christopher R. Kelly, MD; Maureen R. Kelly, MD; Matthew Lewis, MD; Yehuda Paz, MD; Clara L. Peck, MD; Shaline Rao, MD; Sabahat Bokhari, MD; Shepard D. Weiner, MD; Andrew J. Einstein, MD, PhD

Background—We sought to determine inter-rater reliability of the 2009 Appropriate Use Criteria for radionuclide imaging and whether physicians at various levels of training can effectively identify nuclear stress tests with inappropriate indications.

Methods and Results—Four hundred patients were randomly selected from a consecutive cohort of patients undergoing nuclear stress testing at an academic medical center. Raters with different levels of training (including cardiology attending physicians, cardiology fellows, internal medicine hospitalists, and internal medicine interns) classified individual nuclear stress tests using the 2009 Appropriate Use Criteria. Consensus classification by 2 cardiologists was considered the operational gold standard, and sensitivity and specificity of individual raters for identifying inappropriate tests were calculated. Inter-rater reliability of the Appropriate Use Criteria was assessed using Cohen κ statistics for pairs of different raters. The mean age of patients was 61.5 years; 214 (54%) were female. The cardiologists rated 256 (64%) of 400 nuclear stress tests as appropriate, 68 (18%) as uncertain, 55 (14%) as inappropriate; 21 (5%) tests were unable to be classified. Inter-rater reliability for noncardiologist raters was modest (unweighted Cohen κ, 0.51, 95% confidence interval, 0.45–0.55). Sensitivity of individual raters for identifying inappropriate tests ranged from 47% to 82%, while specificity ranged from 85% to 97%.

Conclusions—Inter-rater reliability for the 2009 Appropriate Use Criteria for radionuclide imaging is modest, and there is considerable variation in the ability of raters at different levels of training to identify inappropriate tests. (Circ Cardiovasc Qual Outcomes. 2015;8:23-29. DOI: 10.1161/CIRCOUTCOMES.114.001067.)
Table 3. Inter-Rater Reliability and Proportion of Agreement (Overall, and Specific for Appropriate and Inappropriate Tests), by Training Level and for All Noncardiologist Raters

<table>
<thead>
<tr>
<th>Rater Groupings (Number of Raters)</th>
<th>Unweighted κ (95% CI)</th>
<th>Proportion of Agreement, All Indications (95% CI)</th>
<th>Proportion of Specific Agreement for Appropriate Indications (95% CI)</th>
<th>Proportion of Specific Agreement for Inappropriate Indications (95% CI)</th>
</tr>
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<tbody>
<tr>
<td>Interns (2)</td>
<td>0.61 (0.54–0.68)</td>
<td>0.79 (0.75–0.83)</td>
<td>0.88 (0.85–0.91)</td>
<td>0.52 (0.43–0.62)</td>
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<tr>
<td>Hospitalists (2)</td>
<td>0.63 (0.55–0.70)</td>
<td>0.81 (0.77–0.85)</td>
<td>0.87 (0.84–0.89)</td>
<td>0.57 (0.48–0.55)</td>
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<tr>
<td>Fellows (2)</td>
<td>0.37 (0.30–0.46)</td>
<td>0.66 (0.61–0.71)</td>
<td>0.76 (0.72–0.80)</td>
<td>0.48 (0.40–0.55)</td>
</tr>
<tr>
<td>All Noncardiologist raters (6)</td>
<td>0.51 (0.46–0.55)</td>
<td>0.74 (0.73–0.75)</td>
<td>0.83 (0.82–0.84)</td>
<td>0.52 (0.50–0.54)</td>
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Temporal Changes in Appropriateness of Cardiac Imaging

Ricardo Fonseca, MD, Kazuaki Negishi, MD, PhD, Petr Otahal, GDipSc, Thomas H. Marwick, MBBS, MPH, PhD
Change in **APPROPRIATE** Test Ordering

* Significant improvement
Change in **IN-APPROPRIATE** Test Ordering

* Significant improvement
Problems with AUC

• AUC’s are often a matter of consensus with a weak scientific basis

• As soon as a law is made an escape is found! (old Italian say), i.e.

• If a physician feels that he/she is judged on the basis of AUC he/she may use a dx that fits the AUC and not the real one to order the test
Problems with AUC

• Regional variations apply (see Alberta-Canada)

• Ultimately there is no proof of improved clinical care with the application of AUC criteria*

Cardiac EASE Clinic at the U. of AB

- Every patient referred for CP living over 1 hour away is submitted to a stress test and 2D echo before the cardiologist meets him/her

- The approach is practical but not aligned with AUC
Problems with AUC

• Regional variations apply (see Alberta-Canada)

• Ultimately there is no proof of improved clinical care with the application of AUC criteria

Cardiac Imaging in a Value-Based HCS

- The US health care system is shifting emphasis from productivity to value, whereby value is defined as outcome achieved per dollar spent.

- The economic role of cardiac imaging as a revenue generator is correspondingly changing to that of a cost center, requiring demonstration of value to justify support for its operations (value over volume).
Cardiac Imaging in a Value-Based HCS

<table>
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<tr>
<th>Preserve and Enhance the Relevance of Cardiac Imaging in a Value-Based Healthcare System</th>
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<tr>
<td>Create meaningful outcome measures, which demonstrate the value of imaging</td>
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<tr>
<td>Use these metrics to measure and improve imaging outcomes</td>
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<tr>
<td>Ensure that imaging expertise informs patient care</td>
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<th>Define the CV Imager of the Future</th>
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<tr>
<td>Redefine the cardiac imager based on level of expertise rather than number of modalities</td>
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<td>Define training goals for the new cardiac imaging expert</td>
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<tr>
<td>Define avenues for &quot;life-long&quot; competency</td>
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<tr>
<td>Optimally integrate the cardiac imaging expert into clinical practice</td>
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<th>Ensure Robust Innovation and Research in Cardiac Imaging</th>
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<tr>
<td>Identification of unmet clinical needs</td>
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<td>Collaborative academic and industry partnerships</td>
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<td>Dedicated training in innovation and research</td>
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<tr>
<td>Re-emphasize the value of scholarly activity</td>
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<td>Expand funding opportunities</td>
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<th>Maximize Imaging Information and Improve Outcomes</th>
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<tr>
<td>Define and reinforce minimal standards for image quality, structured data reporting and workflow for all modalities</td>
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<td>Measure and improve adherence to minimal standards</td>
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<tr>
<td>Connect imaging data and clinical data to outcomes using big data analysis</td>
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<tr>
<td>Facilitate implementation by removing barriers and incentivizing schemes</td>
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Cardiac Imaging in a Value-Based HCS

Potential solutions

• Use creative endpoints to prove the value of cardiac imaging (reduced admission/re-adm rate, increased compliance with EBM drugs, etc)

• Provide recommendations in the imaging reports about implementing best EBM interventions to improve outcomes

• Include imaging recommendations within various cardiac guidelines

Douglas PS et al. JACC Img 2016;9:1211-23
Cardiac Imaging in a Value-Based HCS

Potential solutions

- Defining and Reinforcing Minimal Standards for Imaging Quality, Structured Reporting and Workflow for all Modalities
- Creating Registries Linked to Clinical Database to Develop Big Data Repositories
- Connect Imaging and Clinical Data to Outcomes Using Big Data Analytics
- Facilitating Implementation by Removing Barriers and Incentivizing Schemes
- Maximizing Imaging Information and Outcomes

An early model: Michigan Cardiovascular Imaging Consortium

Douglas PS et al. JACC Img 2016;9:1211-23
Closing Considerations

• Despite the obstacles there is **optimism** for the future of imaging
• Barriers between modalities have been replaced by interest in **collaboration**
• Universal aspiration at **excellence** rather than status quo
• Unanimous call for “**more evidence**” to support imaging