

#### **Disclosure Statement of Financial Interest**

Affiliation/Financial Relationship	Company
Consultant	Abbott Laboratories (paid to the institution), Abiomed (spouse), Boston Scientific, CardioKinetix (paid to the institution), Cardiovascular Systems Inc, Medscape, Siemens Medical Solutions, Spectranetics, The Medicines Company, Roivant Sciences Inc, Volcano Corporation
Research Funding to Institution	AstraZeneca, Bayer, Beth Israel Deaconess, BMS, CSL Behring, Eli Lilly/DSI, Medtronic, Novartis Pharmaceuticals, OrbusNeich
Equity, <1%	Claret Medical, Elixir Medical
Executive Committee	Janssen Pharmaceuticals, Osprey Medical
Advisory Board Funding to Institution	Bristol-Meyers Squibb
DSMB membership paid to the institution	Watermark Research Partners



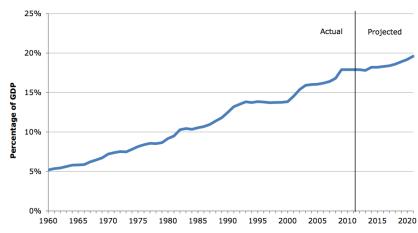




#### Introduction

- Medical development has resulted in improved survival but has also increased costs
- This higher cost has led to greater regulations to reduce spending and reimbursement
- There is an imperative need to improve the utilization of diagnostic and therapeutic tools in the most cost-effective fashion

#### National Health Expenditures as a share of GDP in the US, 1960-2021



Source: Centers for Medicare and Medicaid Services.







#### What is AUC?

Set of individual criteria that present information in a manner that links a specific clinical condition or presentation, one or more services, and an assessment of the appropriateness of the service.

<u>Main objective</u>: Identify patients who will most benefit from a procedure and those who will not, resulting in a more effective and equitable allocation of resources.

'The right patient receives the right test at the right time'.







Evidence from randomized trials and other sources

Expert consensus

#### Clinical Practice Guidelines

#### Performance Measures

Performance measures are derivatives of clinical practice guidelines that focus on critical recommendations and are constructed to be measurable with a numerator and denominator.

#### Appropriate Use Criteria

Appropriate use criteria are a derivative of clinical practice guidelines in which information is presented in clinical scenarios and used for benchmarking performance.

Common goals to: 1) increase use of effective diagnostic testing and therapeutic treatments, 2) decrease use of unnecessary or potentially harmful testing and therapy, 3) improve patient outcomes and 4) reduce costs

Ward, R. P. (2012). Journal of the American Society of Echocardiography, 25(6), 599-602.



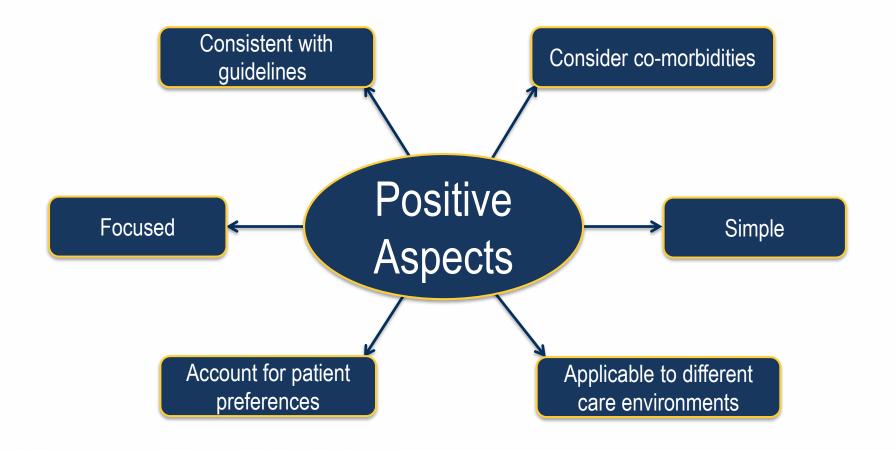


### Why we need AUC?

- Clinical practice guidelines were created to assist physicians in practicing evidence-based medicine, but in 2004, on the basis of mounting evidence of unexplained geographic variation in use and increasing cost and regulatory pressures, the American College of Cardiology decided to create a new category of standards, appropriate use criteria (AUC).
- Healthcare reform has yielded an unprecedented focus on improving valueadded care

VOLUME of service → VALUE of service







### **Potential Impact of AUC**

- Establishment of partnership among clinicians and payers
- Education of clinicians regarding their practice habits
- Emphasis of clinical indications to drive testing
- Facilitate reimbursement for "appropriate" and "maybe appropriate" indications
- Support for review and reduction of "rarely appropriate" indications
- Help bend the cost curve



## **Timeline of AUC in Cardiology**

Indications for radionuclide imaging

Indications for cardiac CT and MRI, echocardiography and cardiac catheterization

Indications for TEE, peripheral vascular US and physiological testing, ICDs, CRT, and coronary revascularization

2005 2012 2018







# **AUC Organizational Structure**

AUC Task Force	<ul> <li>At least 7 ACC members from various cardiovascular disciplines</li> <li>Oversight body for evaluation, development and implementation of AUC</li> </ul>
Writing Group	<ul> <li>Selected by the task force from multiple societies and diverse organizations</li> <li>Group of experts in the discussed technique, responsible for writing the AUC</li> </ul>
Review Panel	<ul> <li>Selected by the task force and provide feedback to the writing group</li> <li>The only 'external review' before voting on appropriate use of specific technology</li> </ul>
Rating Panel	<ul> <li>Typically made of 13 – 17 individuals</li> <li>Group of professionals responsible of rating each clinical scenario</li> <li>Balance between specialists using the technique and referring clinicians.</li> </ul>



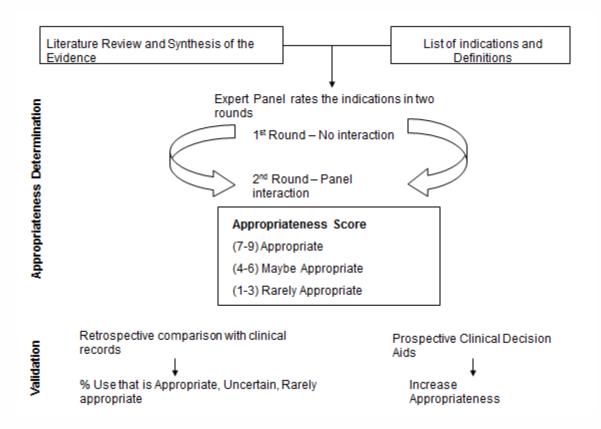


## **Relationships with Industry**

- ACC tracks relevant industry relationships for all its members.
- Writing groups chaired by a member with no relationship with industry.
- No more than 50% of **rating panel members** may have relevant relationship with industry.







Fitch, K. (2017). The RAND/UCLA Appropriateness Method User's Manual. 2001. Santa Monica, CA: RAND Corporation.





## **Rating of Indications**

- 7-9: Appropriate (A) test for specific indication
  - Test is generally acceptable and is a reasonable approach for the indication
- 4-6: Maybe Appropriate (M) or unclear if appropriate for specific indication
  - Test may be generally acceptable and may be a reasonable approach for the indication
- 1-3: Rarely Appropriate (R) test for specific indication
  - Test is **not** generally acceptable and is **not** a reasonable approach for the indication

AUC Task Force identifies a topic for new AUC and defines scope of work

Nominations for writing group and rating panel members solicited and received

Writing group members identified and they develop scenarios, assumptions and definitions aided by literature review and guideline mapping

External review of developed scenarios with subsequent revision as needed

First round of ratings performed without interaction among the raters

Ratings tabulated and analyzed for variation

Second round of ratings developed during face-to-face meeting of rating panel

Ratings finalized with additional limited round of ratings if needed

Text of manuscript completed and subject to external and internal review

AUC manuscript published

Ward, R. P. (2012). Journal of the American Society of Echocardiography, 25(6), 599-602.





## **AUC Focused Updates**

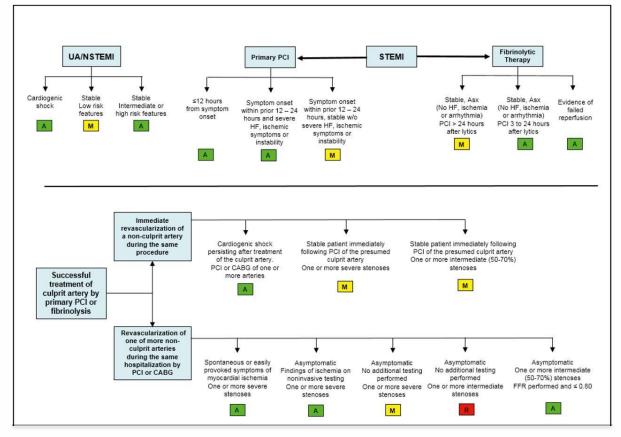
- Yearly revision for possible updates by the original writing group
- Update or revision of guidelines usually lead to partial or complete revision of AUC
- Initial AUC members are required by ACC policy to be involved in review for at least 5 years after publication





#### **Example**

Flow diagram for the determination of appropriate use of PCI in patients with ACS



Patel, M. R., 2017. Journal of the American College of Cardiology, 69(5), 570-591.





## **Application of AUC**

- Excellent for ongoing review of one's practice using the criteria will help guide a more effective, efficient, and equitable allocation of healthcare resources, and ultimately, better patient outcomes
- In situations where there is substantial variation between the appropriateness rating and what the clinician believes is the best approach for a specific patient, further considerations may be appropriate.

#### **Obstacles**

- Although evidence should be the foundation for the development, modification, and endorsement of AUC, we recognized that not all aspects of a criterion will be evidencebased, and that a criterion does not exist for every clinical scenario.
- As currently proposed, if this regulation is fully integrated into the practice of medicine, the consequences will be time-consuming documentation processes that impose substantial costs on physician practices already suffering from rising overhead.



### Implementation and evaluation

- AUCs are published in leading journals and on ACC websites; subject to updates
- Used as a major parameter in imaging laboratory accreditation; more accreditation institutions will adopt it in the future

The **Protecting Access to Medicare Act**, passed by Congress in 2014, included a provision requiring all advanced diagnostic imaging services, excluding echocardiography, to undergo an appropriate use criteria (AUC) consultation prior to the completion of the imaging service in order to receive payment approval from the Centers for Medicare and Medicaid Services (CMS).

The AUC Program mandates that ordering professionals must consult with AUC through a clinical decision support mechanism (CDSM) for all Medicare patients receiving applicable advanced imaging care.







# Positive effect since adoption of AUC

- One-half of nuclear cardiology laboratories used AUC (survey done 6 years after the publication of first AUC).
- Lower procedural volume appear to be correlated with AUC publication.
- Significant decrease (50%) in non-acute PCIs procedures, from the Cath/PCI Registry (national registry).

Desai NR et al., JAMA Intern Med. 2015; 175:1988–90. Arbel Y et al. Am Heart J. 2016;175:153–9. Kline KP et al. J Am Coll Cardiol Img. 2017;10:824–5. Tilkemeier P. J Nucl Cardiol. 2012;19: 1170–5.



### **Limitations of AUC**

- Appropriate use criteria are intended to assist patients and clinicians, but are not intended to diminish the acknowledged difficulty or uncertainty of clinical decision making and cannot act as substitutes for sound clinical judgment and practice experience
- They identify common clinical scenarios—but they cannot possibly include every conceivable patient presentation.

## **Continuing Improvements**

- The refinements to AUC methodology reflect the ACC's continued commitment to adapting and responding to the ever-evolving needs of cardiovascular practice.
- Over time, the College and AUC Task Force will continue to focus on reflecting the evolution of contemporary practice patterns and accruing scientific evidence, while remaining steadfast in their aim of ensuring patient-centered, professional stewardship of technology application within cardiovascular medicine.

#### **Conclusions**

- Medical development has resulted in improved survival but has also increased costs.
- AUC helps identify patients who will most benefit from a procedure and those who will not, resulting in a more effective and equitable allocation of resources.
- We need AUC because healthcare reform has yielded an unprecedented focus on improving value-added care



#### **Conclusions**

- AUC documents have been successfully adapted into processes of clinical care (education, accreditation, and quality improvement programs).
- AUC is providing better healthcare with substantial reduction in unnecessary costs.
- AUC serves as a guiding tool, final decision to be taken based on each patient's goals.

