High Country Nuclear Medicine Conference
Clinical Decision Support, the Good, the Bad and the Ugly
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SNMMI’s History

• Founded in 1954
• The largest international scientific organization dedicated to nuclear medicine and molecular imaging and therapy
• A multi-disciplinary organization
  – More than 18,000 physicians, scientists, pharmacists, and technologists
  – Industry and other partners interested in the diagnostic, therapeutic, and investigational uses of molecular imaging and therapy agents, instrumentation and techniques
A Look at the SNMMI Strategic Plan

Goal A: Advance the development and approval of nuclear medicine and molecular imaging technologies

Goal B: Facilitate and support the availability and clinical utilization of nuclear medicine and molecular imaging technologies

Goal C: Increase appropriate utilization of radionuclide therapy

Goal D: Advance and promote quality, value, and safety of molecular imaging and nuclear medicine

Goal E: Support and enhance the professional workforce and environment
Goal D:
Advance and Promote Quality, Value, and Safety of Molecular Imaging and Nuclear Medicine
*NEW* Evidence and Quality Department

• New Department Created and Staff Hired
  – Sukhjeet Ahuja, MD, MPH, Director of Evidence and Quality
  – Julie Butt, Associate Manager, Evidence and Quality

• Focus and Goals of New Department
  – Evidence Generation and Gathering
  – Guidelines and Appropriate Use
  – Possible Molecular Imaging Registry
  – Interaction and Partnership with Other Organizations
  – Education and Training
• Guidance Oversight Committee (GOC) Initial Goals:
  – AUC – Appropriate Use Criteria
  – CPG – Clinical Practice Guidelines

• GOC has identified several high volume procedures in Nuclear Medicine to develop AUCs
  – Bone scintigraphy in malignant disease
  – Hepatobiliary scintigraphy in abdominal pain
  – Ventilation/Perfusion imaging in pulmonary embolism
  – FDG-PET for re-staging malignant disease

• Collaborating with EANM to develop joint guideline for Ra-223 for metastatic prostate cancer
• Quality Committee Goals:
  − Define ‘Quality’ in imaging – developing a white paper on defining quality in imaging, based on IOM standards
  − Maintenance of PQRS Measure (currently the only measure available for NM)
    − PQRS measure # 147
      − Measure Title - Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy
  − Develop new measures for Quality in Nuclear Medicine
  − Explore the development of registries in Nuclear Medicine
    − Registry on the variability of administered dose in Nuclear Medicine
  − Explore funding opportunities related to the Quality Initiatives in Nuclear Medicine
    − PCORI (Patient Centered Outcomes Research Institute) Funding
    − HHS Funding – Transforming Clinical Practice Initiative
    − Federal Funding – AHRQ Grant
    − Patient Advocacy Groups/Other Societies/Organizations – E.g. Alzheimer’s Association
5 Goals Specific to the Quality Enterprise

**Evidence Generation**
- Modeling
- Registry or PBRN
- Clinical Trials Network
- Systematic Review
- CMTP Workshop

**Training & Education**
- How to be an Investigator
- Scientific Curriculum
- Fellow Training

**Guidelines & Measurement**
- Develop Performance Measures
- Develop Appropriate Use Criteria

**Policy & Reimbursement**
- Reimbursement Strategy

**Awareness**
- SNMMI Website
- Renewed PR Work
- Leverage JNM Success
- Stakeholder Engagement
- International Engagement
- Define MI

**Overarching Goal**
Enhance the Value of Nuclear Medicine & Molecular Imaging
What are Appropriate Use Criteria (AUC) and why are they needed?
- Medicare Sustainable Growth Rate (SGR)
Medicare Sustainable Growth Rate (SGR)

• On March 31, 2014, Congress passed the “Protecting Access to Medicare Act of 2014” (H.R. 4302)
  – Tied advanced diagnostics imaging services – physician reimbursement to AUC
  – Advanced Diagnostic Imaging Services (ADIS) are defined as diagnostic magnetic resonance imaging, computed tomography, nuclear medicine (including positron emission tomography), and other diagnostic imaging services specified by the Secretary in consultation with physician specialty organizations and other stakeholders.

• Congress debated a permanent SGR fix during the year-end spending debate

• The current Act does not expire until March 31, 2015
"Protecting Access to Medicare Act of 2014" (H.R. 4302)

- The new law:
  - Directs the Secretary of HHS to launch (by 2017) a program that encourages the use of appropriate use criteria for advanced diagnostic imaging services (ADIS)
  - Ordering professionals (OP) will have to consult AUCs via a clinical decision support tool prior to ordering ADIS, for help in determining whether an exam is clinically appropriate for a patient’s condition

- AUC’s can only be created or endorsed by national medical specialty societies or other provider-led entities
  - Provider-led entities – for example, physician groups
  - This term is used to exclude insurance companies, patient advocacy groups and others like that

- By November 15, 2015, in consultation with stakeholders, the Secretary will choose which AUC’s will be included in the program
Objective: Identify patients who will most appropriately benefit from a procedure, thus resulting in a more effective and equitable allocation of healthcare resources.

Must be created or endorsed by national medical specialty societies or other provider-led entities

Must have stakeholder consensus

Must be scientifically valid & evidence-based

Must be based on publicly available studies that are published and reviewable by stakeholders
AUC Development – Summary

• According to the Institutes of Medicine (IOM) recommendations:
  – The process for creating each evidence based guidance document like AUC includes finding evidence, rating evidence, rating recommendations, creating evidence tables, grading evidence, creating decision flow chart, writing process and language, producing evidence profiles, and finally disseminating the end product

• IOM strongly recommends collaborating with other stakeholders:
  – From the inception of the process to produce multidisciplinary clinical guidance documents (group of 9-15 subject matter experts and partners from referring communities)

• Very labor and cost intensive process:
  – Can cost tens of thousands dollars (approx. $75K) and take 6-12 months for each AUC
SNMMI Prioritization of AUC Topics

• Prioritize
  – highest volume nuclear medicine procedures based on the CMS data

• Conduct an environmental scan
  – of existing clinical guidelines and AUCs (developed by other organizations)

• List high volume nuclear medicine procedures lacking appropriate AUCs
  – (where nuclear medicine is disadvantaged but evidence exists that will contradict existing non-evidence-based AUCs)
• The GOC has formed four AUC working groups for these topics and the committee chair has identified subject matter experts to lead these working groups
• To create a multi-disciplinary, evidence based guidelines, the society has reached out to other specialty societies like American Society for Clinical Oncology (ASCO), American Society for Radiation Oncology (ASTRO), American College of Physicians (ACP), American College of Hematology (ACH), and American Academy of Family Practitioners (AAFP) to participate in the development of AUCs
• The society has also contracted with Avalere, an industry leader in the field of healthcare policy, to assist with the AUC development process
• Aggressive timeline for AUC development
  - Anticipated completion of four AUCs by September 30, 2015
  - Once developed, there is a five year window to revise AUCs
Appropriate Use Criteria - Issues

Delivery of AUCs – Clinical Decision Support (CDS) Mechanism
“Protecting Access to Medicare Act of 2014” (H.R. 4302)

- Directs the Secretary of HHS to launch (by 2017) a program that encourages the use of appropriate use criteria for advanced diagnostic imaging services (ADIS)
  
- Ordering professionals (OP) will have to consult AUCs via a clinical decision support mechanism prior to ordering ADIS, for help in determining whether an exam is clinically appropriate for a patient’s condition

- In addition to the private sector and medical specialty organization’s clinical decision support mechanism, a clinical decision support mechanism will be established by HHS
  
  • It could be an existing clinical decision support tool of another organization or could be created de novo by HHS
Delivery of AUC – Clinical Decision Support Mechanism

- Requirements for the Clinical Decision Support Mechanism
  - The mechanism determines the extent to which an applicable imaging service ordered is consistent with the applicable AUC.
  - The mechanism generates and provides to the ordering professional a certification or documentation that documents that the qualified clinical decision support mechanism was consulted by the ordering professional.
  - In the case where there is more than one applicable AUC for an applicable imaging service, the mechanism indicates the criteria that it uses for the service.
  - The mechanism is updated on a timely basis to reflect revisions to the specification of applicable appropriate use criteria.
  - The mechanism performs other functions such as a requirement to provide aggregate feedback to the ordering professional.
Appropriate Use Criteria - Timeline

• June 2014
  – Starting in June 2014, the National Guidelines Clearinghouse follows the more rigorous standards for Guideline development (including AUCs) set forth by the IOM

• As of today
  – Other organizations, like ACR, have hundreds of AUCs, some covering nuclear medicine and a delivery mechanism called ACR Select
  – SNMMI has one AUC on Amyloid and four in pipeline to be developed next year; no delivery mechanism

• November 2015
  – Deadline for the HHS secretary to ‘deem’ or approve AUC, to be delivered by a clinical decision support mechanism

• January 2017
  – All referring/ordering physicians required to consult AUCs via an approved CDS mechanism prior to ordering any ADIS
Questions Related to AUC

• How will evidenced based medicine be defined since some societies develop clinical guidance documents (AUC) by consensus?
  – It would help if ‘evidence-based’ was better defined as there is a wide variation in the methods to develop AUC. Many societies have used consensus based approach in the past whereas the newer guidelines, including the ones developed by SNMMI, are closely following the Institute of Medicine (IOM) recommendations for clinical guidance document development.

• Does CMS have the authority to institute a phased approach in implementing the AUC program? If so, how to determine which ADIS would be included initially?
  – CMS needs to determine whether it has the authority to institute a phased approach for the implementation of this program. It can be based on evaluating the extent to which AUC program is adopted for specific imaging procedures, the availability of applicable AUC, the trends in the utilization of that service as well as “buy-in” by the providers, including the referring community.
  – The society supports the approach of implementing this program initially for modalities with increased utilization over last decade.
Questions Related to AUC – continued

• What criteria should CMS use to determine whether there is a need for update or review? How do societies deal with disseminating updates to AUC?
  – Societies need clarity on how the new AUC, as well as its revisions/updates, will be included in the program on an ongoing basis. Developing and updating AUC can be a very resource and time-intensive process. Therefore, we recommend that updates and reviews should be mainly based upon significant changes in the evidence (published scientific literature) used to develop AUC.

• What should CMS do in the event there are more than one AUC- should they apply only one? What is CMS’ position on conflicts in AUCs?
  – It is conceivable that there could be more than one AUC for a particular imaging modality, developed by two separate medical specialty societies, using separate processes and ‘evidence-based’ criteria. Assuming both AUC are ‘deemed’, would it be okay to use one or the other to order an ADIS?
  – Sometimes, there are differences in how the AUC are defined or constructed. For example, you may have some AUC for a specific imaging modality or you may have some that address the condition and then provide rankings for different imaging modalities.
  – If the AUC indicate that more than one imaging modality is appropriate for a condition, the society supports that the imaging physician should have the ability to decide the imaging modality in consultation with the ordering physician.
Questions Related to CDS Mechanism

• What criteria should CMS use to provide a free clinical decision support mechanism to smaller societies or other providers not utilizing an established EMR and CDS mechanism?
  – As PAMA legislation stipulates, in addition to the private sector and medical specialty organization’s clinical decision support mechanism, a support mechanism will be established by HHS and will be offered for free
  – CMS needs to provide clarity on whether an existing mechanism, developed by either the private sector or a medical specialty society, can be made available for free or whether the free mechanism will be newly developed
  – CMS also needs to provide clarity on whether all approved clinical decision support mechanisms will incorporate all ‘deemed’ or approved AUC regardless of copyright issues
  – If newly developed, in order to provide full functionality for this free mechanism, it should have the complete list of deemed or approved AUC developed by all medical specialty societies and other provider led entities
  – This mechanism should be comparable to other clinical decision support mechanisms in that it should provide user feedback and data on physician ordering behavior as well as information on outliers. This information is critical for follow-up physician education
  – This mechanism should have flexibility and interoperability to be able to transfer data from varied electronic medical record systems
  – This mechanism should be developed in easy and user-friendly format. If this mechanism is developed as a website or web-based application, it should also be made available for mobile devices like iPads and other tablets
  – CMS should provide a training program as well as customer service support for this mechanism
Questions Related to CDS Mechanism – continued

• **How will this clinical decision support mechanism be implemented?**
  – If this free clinical decision support mechanism is a web-based system, would it require the rendering physician to attach ‘paper authorization’ with clinical decision support number in order to document that an AUC was consulted?
  – How would the harmonization of different CDS mechanisms work?

• **How will CMS reconcile conflicting AUC in proprietary clinical decision support mechanisms?**
  – This goes back to the issue of providing rendering physician the final say in deciding which AUC to consult if there are conflicts in proprietary clinical decision support mechanism, as long as the AUC consulted are deemed or approved.
Summary Recommendations

• Better define ‘evidence-based’ as there is a wide variation in the methods to develop AUC. Need to understand what criteria will be used in “deeming” AUC

• AUC updates and reviews should be mainly based upon significant changes in the evidence (published scientific literature) used to develop AUC

• If the AUC indicate that more than one imaging modality is appropriate for a condition, the society supports that the rendering physician should have the ability to decide the imaging modality in consultation with the ordering physician

• All approved clinical decision support mechanisms should incorporate all ‘deemed’ or approved AUC regardless of copyright issues
Questions? Comments?

Please feel free to contact me, or Dr. Sukhjeet Ahuja, if you have additional comments or questions.

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