Value-Driven Imaging Practices

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Disclosures

- I do **not** have a financial interest, arrangement or affiliation, including receipt of honoraria or expenses from a commercial organization, that could have a direct impact in the subject matter of my presentation.
Objectives

• After attending the presentation, participants will be able to:
  
• 1. Discuss the definition of value and ways that it can be derived;

• 2. Explain methods to improve value in imaging;

• 3. Propose additional techniques that could develop value in imaging.
Quality and Value

• Importance of Quality:
• Quality is critical to good practice.
• Value cannot exist without Quality
Quality

• Quality is never an accident. It is always the result of intelligent effort. – John Ruskin

• Quality – Absolute and universally recognizable, a mark of uncompromising standards and high achievement. – Walter Shewhart
National Quality Strategy (US)

- 3 Goals:
- Better care
- Improve the health of the US population
- Affordable care
QI, QA, QC

- Quality Improvement
- Quality Assurance
- Quality Control
Quality Improvement

• Definition:

• Quality Improvement (QI) is a formal approach to the analysis of performance and systematic efforts to improve it.
Quality Improvement (QI) - Aims

• Safety – avoidance of harm
• Effective – prevention, diagnosis and treatment based on scientific knowledge, avoidance of underuse and overuse
• Efficient – avoidance of waste and excess cost
• Equitable – provide care that is consistent in quality
• Patient-centered – respectful of and responsive to individual patient preferences, needs and values
• Timely – reduce delays
• Promote effective communication and coordination of care
• Promote best practices
• Promote more affordable quality of care
• Plan-Do-Check-Act (PDCA)
• (Also known as Plan, Do, Study, Act [PDSA]):
• A four-step process for quality improvement:
  • Plan what to evaluate
  • Do it
  • Study results
  • Act on findings, make changes if necessary
• 3 types of QI:
• **Administrative** — appropriate use criteria, patient satisfaction, timeliness of reporting, completeness of documentation
• **Technical** — image quality, adequacy of patient prep, radiation dose optimization, therapy results
• **Interpretive** — report accuracy, interobserver/intraobserver variability, correlation

Reference: Mary Beth Farrell
Quality Assurance (QA)

- Quality Assurance describes how an organization or department knows that it is doing its job correctly.
- QA is a process that examines dept. outcomes and promotes continuous improvement.
- QA is an overall program of quality.
- QA in medicine includes quality of care to patients, appropriateness of diagnosis and treatment, and the level of patient satisfaction.
- QA is required by The Joint Commission (US)
Quality Control (QC)

• Quality control (QC) refers to tests that confirm adequate equipment performance of equipment or radiopharmaceuticals. These tests are used to identify problems of equipment or radiopharmaceutical performance.

• These tests are performed regularly - commonly daily, weekly or monthly.

• QC is one part of QA.
Quality in Nuclear Medicine

- General Principles in NM:
- Practice High Quality NM – high quality studies, well-performed
- Reports of studies are accurate and timely
- High standards of practice
- Know NM technology, physics, protocols, elements of quality
Quality in NM

- Radiation safety and patient safety
- High quality of instrumentation, including QC
- High quality of radiopharmaceuticals, including QC
- Provide education and continuing education
“Effective communication is a critical component of diagnostic imaging.”

Quality patient care depends on timely transmission of study results.

Effective communication:
- Promote optimal care and support referring clinician
- Satisfy need for timeliness
- Minimize risk of communication errors

Ref: ACR Practice Parameter for Communication of Diagnostic Imaging Findings
Reporting (ACR and SNMMI)

• PURPOSE:

1. Document in the medical record information from the exam or procedure

2. Transmit information (esp. answering the clinical question) to referring clinicians in a timely manner

3. Provide appropriateness, necessity and performance of the procedure for correct coding and billing
Quality/Value in NM

- Serve needs of referring clinicians –
- Answer clinical questions
- Produce useful reports
- Be available
- Bring in new studies for subspecialists
- Identify clinical champions of NM, and keep them happy by providing accurate reports and good service.
• Attend tumor boards and multidisciplinary conferences. Make sure NM studies are presented properly.

• Serve as the imaging investigator in research projects of clinicians.
Quality/Value in NM

- Be a source of pride for department –
- Innovation – new clinical studies, publish
- Be a center of quality
- Contribute to the greater radiology community
- Be collegial and a team player
  - A. Facilitate scheduling, esp. of multiple studies
  - B. Invite non-NM radiology colleagues to be involved in research or QI projects
- C. Be a good citizen in the dept.
Quality/Value

• Best practices:
• Policies, procedures and protocols, including Procedure Guidelines (parameters [ACR], standards, [SNMMI])
• Appropriate Use Criteria (AUC)
• Accreditation of your practice
• QI and QA
• QC, including acceptance testing
Value

• Value = Cost

• Value = Benefit/Cost

• Value = Quality + Service
  Cost
Value – Nuclear Medicine and the NM Physician

- Value - Support and promote Quality
- Appropriate use of NM/MI studies for specific clinical indications/problems
- Use procedure standards as guidelines of good practice.
- Implement Appropriate Use Criteria (AUC)
Value

- Leadership
- Integrity – honesty and high ethical standards, includes fairness
- Vision
- Planning – chart the course – plan for future needs
- Communication, motivating others
- Respect, honor, personal courage
Value

- Quality of Practice -
- Credentials of chief and faculty
- Appropriate use of NM/MI for specific clinical indications/problems
- Provide high quality studies - procedure guidelines and appropriate use criteria, accurate and timely reports, with recommendations for further studies when appropriate
- Introduce new state of the art studies
Value

• Quality of Practice (mainly academia) -
• Provide high quality training for residents, fellows, medical students and others
• Encourage students to pursue a career in NM/MI
• Operationalize value driven practice – e.g., implement procedure standards (guidelines), AUCs, high quality imaging, QI, QA, QC, accurate and timely reports, accreditation of your practice.

• Support maximizing reimbursement - not only correct coding, but utilization of higher value studies when appropriate.
Value

• Be a valuable resource for the department, institution and the field of NM/MI

• Provide useful input to society (SNMMI, ACR, etc.) Congress, government agencies such as NRC, FDA, DOE, CMS
• Research (academia)
• Provide research in department
• Invite colleagues, including referring clinicians, to participate
• Develop new tracers for diagnosis and/or Targeted Radionuclide Therapy
Approval of New Agents

• **Axumin™**
  - Blue Earth Diagnostic’s [F-18]Fluciclovine – Axumin™ was approved on May 27, 2016 for PET imaging of in men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen (PSA) levels following prior treatment.

• **NETSPOT™**
  - AAA’s [Ga-68]DOTATATE – NETSPOT™ was approved on June 1, 2016 for PET detection of neuroendocrine tumors in adult and pediatric patients.

• Currently working on [Ga-68] PSMA for primary and biochemical recurrent prostate cancer and a regulatory solution for F-DOPA

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*SNMMI Clinical Trial Network (CTN) facilitated the approval of new PET imaging agents*
• Lutetium-177 dotatate (Lutathera) has recently been approved for treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETS).
• PET/CT is the single most sensitive and accurate modality in many malignancies, for diagnosis, identification/evaluation, staging and re-staging, detecting residual or recurrent disease, monitoring response to therapy, and evaluating prognosis

• It is already vital for directing therapy in oncology, and will be critical in the use of radionuclides (including theranostic agents) for therapy
Value/Future of NM

- Nuclear medicine will demonstrate quality and value to referring physicians, patients and the public, and especially radiologists, by providing precision medicine and personalized care. Current and new tracers will be used to precisely characterize disease. This will be especially true for malignancies.
In addition to advances in diagnostic and therapeutic radiopharmaceuticals, including theranostic pairs, we will also see advances in instrumentation, including whole body PET.

Currently, we are seeing advances in diagnosis, staging/re-staging, monitoring therapy and surveillance.
Evidence for Renaissance II: Theranostics

Combination of therapeutic & diagnostic

Present/Future

- FDA approved and CMS reimbursed as Netspot®
  Lutathera® approval soon

- Not yet FDA approved and CMS reimbursed

PSA 425 ng/ml before, PSA 17 ng/ml after

Present/Future

Courtesy of: Johannes Czernin, MD
Moving Forward...Alpha Radiation Therapy - the Coming Revolution

Alpha-radiation therapy with Actinium-225 labeled PSMA

\[ ^{225}\text{Ac-PSMA-617} \text{ for PSMA-Targeted } \alpha\text{-Radiation Therapy of Metastatic Castration-Resistant Prostate Cancer} \]

Curing the incurable!

8/2015
PSA = 294 ng/ml

9/2015
PSA = 419 ng/ml

2/2016
PSA = 3.5 ng/ml

4/2016
PSA < 0.1 ng/ml

Courtesy of: Richard Baum, MD
THERANOSTICS — THE FUTURE OF CANCER TREATMENT

Cancers will be classified by **molecular phenotypes**
Organ site → secondary classification

Molecular phenotypes will be determined by **molecular pathology** and by **molecular imaging** studies (PET, SPECT, MRI, optical) using **cancer type specific probes**.

**Treatment will be targeted specifically against the tumor**

**PRECISION MEDICINE**

Neuroendocrine tumors and prostate cancer are a **paradigm** for this approach as molecular radiotherapy is applied based on molecular features (i.e. somatostatin receptor/PSMA expression) of tumors and not primarily based on the organ of origin of the tumor.
• Provision of targeted radionuclide therapy will be utilized, unique to each patient, which will include alpha- and beta- emitters, many as theranostic pairs, some as radiolabeled antibodies, probably in combination with each other and probably with other modalities, such as immune modulation, radiation therapy, chemotherapy or possibly viral infections. I expect advanced versions of PERCIST criteria will be utilized to characterize the metabolic response to therapy.
In the near future, based on biologic characteristics of tumors, we will be seeing increasing use of predictive and prognostic markers, assessing therapeutic response and focused surveillance/screening.

Ref: Lalitha Shankar, NCI
Targeted (precision) radionuclide therapy will target various enzymatic pathways and cell-surface receptors, including clonal variations. These therapies will also rely on precise dosimetry.
Value/Future of NM

- These new tracers, especially theranostic pairs, will provide solid evidence of efficacy, quality, and value, and will be fully incorporated into clinical guidelines, such as NCCN. These techniques will produce better outcomes for patients, with much less morbidity.
I predict that the development of new PET tracers and new targeted radionuclide therapies will be critical for the evaluation and treatment of malignancies, as these will provide much more precise management and therapy for many patients, with much less morbidity and much better patient outcomes.