Developing and Implementing Appropriateness Criteria and Imaging Referral Guidelines: Where are we and where are we going?

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Co-Chair, ACR Task Force on Clinical Imaging Decision Support
Chair, ACR Appropriateness Criteria Oversight Committee
Why is there a need for imaging referral guidelines/appropriateness criteria?

- Overuse of imaging
- Inappropriate use
- Increasing costs
- Radiation exposure

December 11, 2012
Reasons for Inappropriate Imaging

- Patient expectations and demands for imaging
- Concerns of liability exposure if diagnosis is delayed
- Conflict of interest presented by physician ownership of imaging equipment (self-referral)
- Lack of specific guidance from Radiologists (and other imagers)
- Lack of knowledge by ordering physicians and other providers (increasing number of exams ordered by non-physicians)-e.g., “customary practice”
Patient Expectations

- Patients expect their doctor to “do something”
- Not unique to imaging — expectations to get a prescription — antibiotics for viral illnesses (such as common cold)
- Patients often disconnected from costs of their care
- Elite athlete gets immediate imaging for injuries, why shouldn’t I? Vendors even market to patients!
- “A good doctor” would get an x-ray/CT/MRI
Mass. Medical Society 2008 Investigation of Defensive Medicine

- Liability Premiums = $26,000,000,000/year
- 2000% increase vs. 1975
- Annual growth rate = 12%, 4x inflation
- 83% of physicians practiced defensive medicine
- Defensive Practice:
  - Imaging:
    - Plain x-rays 22%
    - CT 28%
    - MR 27%
    - US 24%
  - Other:
    - specialty referral/consult 28%
    - laboratory studies 18%
    - hospital admission 13%
- 28%: Liability concerns affected their care of patients “a lot”

December 11, 2012
Fear of Lawsuits Influences Care From Most Orthopedic Surgeons: More than 95 percent said they ordered unnecessary tests, referrals and hospitalizations to protect themselves.

Of 2000 Orthopedists surveyed, 96% (1214) reported they had practiced defensive medicine by ordering scans, laboratory tests, specialist referrals or hospital admissions mainly to avoid possible malpractice claims. On average, 24 percent of all ordered tests were for defensive reasons.

Using the American Medical Association's billing codes as a reference point for costs, researchers determined that orthopedic surgeons spent nearly $8,500 per month -- nearly a quarter of their total practice costs -- on defensive medicine, adding up to an average of nearly $102,000 per doctor each year. Given the 20,400 practicing orthopedic surgeons in the United States, this amounts to $173 million per month and $2 billion annually nationwide.

M Sethi, Vanderbilt, AAOS Annual Mtg
2-9-2012
Lack of Knowledge by Referring Clinicians

- Most physicians want to do the right thing for their patients
- Medical imaging is increasingly complex
- Best imaging practices can change rapidly – CT for pulmonary embolus, noncontrast CT for renal stones, PET/CT for cancer imaging
- Physicians can’t possibly keep up with all areas of medicine
- Non-physician practitioners provide increasing amounts of care, and they order imaging studies
Cancer Screening Among Patients With Advanced Cancer

**Context**  Cancer screening has been integrated into routine primary care but does not benefit patients with limited life expectancy.

**Objective**  To evaluate the extent to which patients with advanced cancer continue to be screened for new cancers.

**Conclusion**  A sizeable proportion of patients with advanced cancer continue to undergo cancer screening tests that do not have a meaningful likelihood of providing benefit.

Camelia S. Sima, MD, MS; Katherine S. Panageas, DrPH; Deborah Schrag, MD, MPH

doi:10.1001/jama.2010.1449
Access To MRI Scanners May Be Linked To Rate Of Unnecessary Back Surgeries.

*Bloomberg News* (10/15, Ostrow) reports, "Patients with low back pain may undergo more unnecessary surgery if they have greater access to magnetic resonance imaging machines," according to a study in the journal Health Affairs. The authors noted that "the number of MRI machines tripled in the US to 26.6 machines per one million people in 2005," an increase that "is raising the cost of treating lower back pain."

According to *HealthDay* (10/14, Preidt), the study showed that "if all Medicare patients with new-onset lower back pain lived in areas with the least MRI availability in 2004, there would have been 5.4 percent fewer lower back MRIs and nine percent fewer back surgeries."

Notably, "two-thirds of the MRI scans that appear to result from increased availability happened within the first month of onset of back pain," *AuntMinnie.com* (10/15). But, "clinical guidelines recommend delaying MRI use until four weeks after onset," during which time most low-back pain patients show spontaneous improvement."
Variation in Use of Head CT by Emergency Physicians

Unadjusted head CT ordering per physician:
- range 4.4% to 16.9% overall,
- 15.2 to 61.7% for atraumatic HA

Conclusion: ER Physicians vary significantly in use of head CT, even after adjusting for variables.


December 11, 2012
Some 30 Percent Of Canadian Diagnostic Procedures Deemed "Inappropriate."

"As many as 30 percent of diagnostic imaging procedures are inappropriate or contribute no useful information, a joint report by the Canadian Association of Radiologists (CAR) and the Canadian Government-established Health Council of Canada (HCC) concluded."

The "association especially emphasized the role of family practice physicians in ordering unessential tests," stating that they "are overwhelmed with heavy caseloads and continuously changing technologies and imaging guidelines." Thus, "CAR is currently redeveloping its Diagnostic Imaging Referral Guidelines, originally produced in 2005, to reflect evolving technologies and considerations surrounding these guidelines to provide physicians with support in ordering the most appropriate diagnostic imaging exam."
Rising Costs in Medical Imaging

- Diagnostic imaging is the fastest growing component of medical expenditure in the United States, with an annual growth rate of 9% (through 2009). This rate is more than double the rate of general medical procedures (4.1%)
- This growth is primarily due to high-tech procedures
- High-tech procedures usually = high cost procedures
- CMS reported 25% increase in “advanced imaging” from 2003 to 2004
- “Nothing suggests a 25% increase in medical imaging is appropriate.” - Former CMS Administrator McClellan

December 11, 2012
Radiology procedure volume fell 5.4% in 2010 compared to 2009 among the three private payers that contributed data to the survey: Aetna, Humana, and United Healthcare.

2010: 1,185 radiology procedures per 1,000 insured individuals in 2010, 2009: 1,253 procedures per 1,000 insured individuals.

Radiology was the only loser in outpatient procedure volume, with decreased by 2.7%:
- 400 procedures per 1,000 insured in 2009 to 389 in 2010.

Use of diagnostic testing (i.e., laboratory and pathology services) increased by 2.4%
- Ancillary services grew 0.6%
- 'Other categories' segment grew 5.9%.

ACR Assistant Executive Director for Government Relations and Health Policy Cynthia Moran said imaging is among the slowest-growing physician service expenditures. Said Moran, "Imaging is not a primary driver of healthcare costs, but it is a primary tool for saving and extending lives."

December 11, 2012
What are the reasons for concern?

NCRP Report No. 160, Ionizing Radiation Exposure of the Population of the United States

<table>
<thead>
<tr>
<th>Category</th>
<th>Early 1980s</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collective effective dose (person-Sv)</td>
<td>835,000</td>
<td>1,870,000</td>
</tr>
<tr>
<td>Effective dose per individual in the U.S. population (mSv)</td>
<td>3.6</td>
<td>6.2</td>
</tr>
</tbody>
</table>

- Evidence suggests overuse of imaging, worldwide.
- Overuse and inappropriate use occur.
- Population radiation exposure is increasing.
- Use of diagnostic ionizing radiation.

Early 1980s:
- Background (83%)
- Occupational / industrial (0.3%)
- Consumer (2%)
- Medical (15%)

2006:
- Background (50%)
- Occupational / industrial (0.1%)
- Consumer (2%)
- Medical (48%)
Collective effective dose as a percentage for all exposure categories in 2006, according to NCRP report no. 160 (1). (Schauer D A, Linton O W Radiology 2009;253:293-296)
### Table 3. Medical Imaging Procedures with Largest Contribution to Cumulative Effective Dose.*

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Average Effective Dose</th>
<th>Annual Effective Dose per Person</th>
<th>Proportion of the Total Effective Dose from All Study Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial perfusion imaging</td>
<td>15.6†</td>
<td>0.540</td>
<td>22.1</td>
</tr>
<tr>
<td>CT of the abdomen</td>
<td>8</td>
<td>0.446</td>
<td>18.3</td>
</tr>
<tr>
<td>CT of the pelvis</td>
<td>6</td>
<td>0.297</td>
<td>12.2</td>
</tr>
<tr>
<td>CT of the chest</td>
<td>7</td>
<td>0.184</td>
<td>7.5</td>
</tr>
<tr>
<td>Diagnostic cardiac catheterization</td>
<td>7</td>
<td>0.113</td>
<td>4.6</td>
</tr>
<tr>
<td>Radiography of the lumbar spine</td>
<td>1.5</td>
<td>0.080</td>
<td>3.3</td>
</tr>
<tr>
<td>Mammography</td>
<td>0.4</td>
<td>0.076</td>
<td>3.1</td>
</tr>
<tr>
<td>CT angiography of the chest (noncoronary)</td>
<td>15</td>
<td>0.075</td>
<td>3.1</td>
</tr>
<tr>
<td>Upper gastrointestinal series</td>
<td>6</td>
<td>0.058</td>
<td>2.4</td>
</tr>
<tr>
<td>CT of the head or brain</td>
<td>2</td>
<td>0.049</td>
<td>2.0</td>
</tr>
<tr>
<td>Percutaneous coronary intervention</td>
<td>15</td>
<td>0.043</td>
<td>1.8</td>
</tr>
<tr>
<td>Nuclear bone imaging</td>
<td>6.3</td>
<td>0.035</td>
<td>1.4</td>
</tr>
<tr>
<td>Radiograph of the abdomen</td>
<td>0.7</td>
<td>0.028</td>
<td>1.1</td>
</tr>
<tr>
<td>CT of the cervical spine</td>
<td>6</td>
<td>0.020</td>
<td>0.8</td>
</tr>
<tr>
<td>CT of the lumbar spine</td>
<td>6</td>
<td>0.018</td>
<td>0.7</td>
</tr>
<tr>
<td>Chest radiograph</td>
<td>0.02‡</td>
<td>0.016</td>
<td>0.7</td>
</tr>
<tr>
<td>Thyroid uptake</td>
<td>1.9</td>
<td>0.016</td>
<td>0.7</td>
</tr>
<tr>
<td>Intravenous urography</td>
<td>3</td>
<td>0.014</td>
<td>0.6</td>
</tr>
<tr>
<td>CT of the neck</td>
<td>3</td>
<td>0.014</td>
<td>0.6</td>
</tr>
<tr>
<td>Cardiac resting ventriculography</td>
<td>7.8</td>
<td>0.014</td>
<td>0.6</td>
</tr>
</tbody>
</table>

* Average effective doses for these imaging procedures are based on data from Mettler et al.10
† Calculation of the average radiation dose for myocardial perfusion imaging with the use of single-photon-emission CT relied on dose coefficients from a detailed review of radiation dosimetry of specific cardiac radiopharmaceuticals,17 median injected radiopharmaceutical doses (millicuries) from the guidelines of the American Society of Nuclear Cardiology,19 and distributions of the use of various protocols in the United States.20
‡ This dose is the effective dose for a posteroanterior study of the chest.
Patient Safety

What might the upper estimate of risks be?

• **Lifetime** risk of fatal cancer from effective dose of 10 mSv from 1 CT or 1 nuclear medicine study is $\sim 1/2000$ or 0.05 %*.

• 60 million CT scans and 20 million nuclear medicine scans *annually* in US might cause up to 40,000 fatal cancers.

U.S. FDA website

December 11, 2012
Cancer risks associated with external radiation from diagnostic imaging procedures.

The 600% increase in medical radiation exposure to the US population since 1980 has provided immense benefit, but increased potential future cancer risks to patients. Most of the increase is from diagnostic radiologic procedures.

To reduce future projected cancers from diagnostic procedures, we advocate
1. the widespread use of evidence-based appropriateness criteria for decisions about imaging procedures
2. oversight of equipment to deliver reliably the minimum radiation required to attain clinical objectives
3. development of electronic lifetime records of imaging procedures for patients and their physicians
4. commitment by medical training programs, professional societies, and radiation protection organizations to educate all stakeholders in reducing radiation from diagnostic procedures.

Linet MS, NCI

Patient Safety

Goal:

• To maximize the benefits of performing medical imaging and radiological procedures to outweigh any risk of harm to patients from radiation exposure
  – Eliminate poor imaging (repeated procedures)
  – Eliminate inappropriate utilization of medical imaging and radiological procedures (wrong procedure ordered)
What Can We Do?

• Radiologists must act as consultants to their referring clinicians
• Best examination may depend on local equipment and expertise
• We can’t monitor every order before the study is done
• Recognized criteria could help guide selection of proper examination (ACR Appropriateness Criteria®)
• Integration into Radiology Information Systems could help steer to appropriate imaging request
Valid Clinical Imaging Referral Guidelines

• Require high-quality, reproducible methodology
• Must be regularly updated and widely accepted
• **Difficult and expensive to achieve!**
Ideal Clinical Imaging Guidelines

• Evidence-based supplemented by expert opinion
• Produced by experts in imaging, referring clinicians and users
• Consistent, transparent methodology
• Updated regularly (e.g., q 2 years)
• Widely accepted: by radiologists, referrers, health authorities, patients
• Readily available/accessible: on-line, in the HER as part of a CPOE or DSS

December 11, 2012
ACR Appropriateness Criteria®

Developed to provide data-based guidance to requesting physicians, radiologists, and radiation oncologists, in making initial decisions about diagnostic imaging and therapeutic techniques.

December 11, 2012
ACR Appropriateness Criteria®

• Based on best-available clinical data

• Intended uses:
  1. Education
  2. Clinical decision guidance:
     In a specific situation, if the clinician is considering an imaging study, what study (or studies) are most likely to provide the necessary information?

December 11, 2012
EXPERT PANELS

Diagnostic

- Breast Imaging
- Cardiac Imaging
- Gastrointestinal
- Musculoskeletal
- Neurologic Imaging
- Pediatric Imaging
- Thoracic Imaging
- Urologic Imaging
- Vascular Imaging
- Women’s Imaging
EXPERT PANELS

Therapeutic

- Interventional Radiology
- Radiation Oncology:
  - Bone Metastases
  - Breast
  - Brain Metastases
  - Gyn (new)
  - Head & Neck (new)
  - Hodgkin’s Lymphoma
  - Lung
  - Prostate
  - Rectal/Anal
EXPERT PANEL COMPOSITION

• Chaired by acknowledged expert
• +/- 12 members
• Broad representation
  – Geographic
  – All imaging modalities
  – Academic/community practices
• Participation from non-radiologic specialty societies
INVolvement of other Specialties

• ACR formally invites other specialty societies to send representatives to panels
• Over 60 physicians from more than 19 societies now serving
• Example: Thoracic Imaging Panel includes
  • Society of Thoracic Surgeons
  • American College of Chest Physicians
SELECTION OF CLINICAL CONDITIONS

- Disease prevalence
- Economic impact of the condition
- Potential for morbidity/mortality
- Potential for improved care
- Sufficient number and quality studies to allow valid conclusions to be drawn

*Pertinent variations developed to encompass the entire spectrum of each condition*
CRITERIA DEVELOPMENT

- Review scientific literature
- Consensus (i.e., modified Delphi methodology) used to reach conclusions based on systematic assessment of available data
- Biennial topic reviews
CRITERIA DEVELOPMENT

Panelist selected as Topic Author

- Formally reviews and selects available literature
- Based on selected articles, develops narrative of topic
- Develops clinical scenarios/variants with relevant imaging modalities
- Review by panel chair, then review and voting by all panel members
CRITERIA DEVELOPMENT

Evidence table
- Summarizes most important articles
- Indicates type of article
- Rates article based on quality of study and quality of data
- Becomes basis of developing the narrative for each clinical condition
CRITERIA DEVELOPMENT

Consensus-Building Process

- Modified Delphi technique
- Three voting rounds
- Consensus defined as 80% agreement

Decisions based on scientific evidence AND experience.
## Category Name and Definition

### Diagnostic Procedures

<table>
<thead>
<tr>
<th>RATING</th>
<th>CATEGORY NAME</th>
<th>CATEGORY DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>7, 8, or 9</td>
<td>Usually appropriate</td>
<td>The study or procedure is indicated in certain clinical settings at a favorable risk-benefit ratio for patients, as supported by published peer-reviewed scientific studies, supplemented by expert opinion.</td>
</tr>
<tr>
<td>4, 5, or 6</td>
<td>May be appropriate</td>
<td>The study or procedure may be indicated in certain clinical settings, or the risk-benefit ratio for patients may be equivocal as shown in published peer-reviewed, scientific studies, supplemented by expert opinion.</td>
</tr>
<tr>
<td>1, 2, or 3</td>
<td>Usually not appropriate</td>
<td>Under most circumstances, the study or procedure is unlikely to be indicated in these specific clinical settings, or the risk-benefit ratio for patients is likely to be unfavorable, as shown in published peer-reviewed, scientific studies supplemented by expert opinion.</td>
</tr>
<tr>
<td>Unrated</td>
<td>No Consensus</td>
<td>Either high quality, relevant clinical studies are not available or are inconclusive, or expert consensus could not be reached regarding the use of this study/procedure for this clinical scenario.</td>
</tr>
</tbody>
</table>
RRL (Relative radiation Level)

- Established by Committee of physicists and radiologists
- Compiled introduction describing basic methods and rationale
- Reviews all available literature
- Rates relative patient dose for each specific exam
- Pediatric dose in general = adult RRL + one
- Reviews and updates ratings for each release.
# SAMPLE VARIANT TABLE

## Clinical Condition:
**Low Back Pain**

**Variant 2:** Low velocity trauma, osteoporosis, and/or age >70.

<table>
<thead>
<tr>
<th>Radiologic Procedure</th>
<th>Rating</th>
<th>Comments</th>
<th>RRL*</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRI lumbar spine without contrast</td>
<td>8</td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>CT lumbar spine without contrast</td>
<td>6</td>
<td>MRI preferred. CT useful if MRI contraindicated or unavailable.</td>
<td>☢☢☢</td>
</tr>
<tr>
<td>X-ray lumbar spine</td>
<td>6</td>
<td></td>
<td>☢☢</td>
</tr>
<tr>
<td>NUC bone scan targeted</td>
<td>4</td>
<td></td>
<td>☢☢☢</td>
</tr>
<tr>
<td>MRI lumbar spine without and with contrast</td>
<td>3</td>
<td>Usually accompanied by plain film myelogram.</td>
<td>O</td>
</tr>
<tr>
<td>CT myelography lumbar spine</td>
<td>1</td>
<td>Usually done in conjunction with CT.</td>
<td>☢☢☢</td>
</tr>
<tr>
<td>X-ray myelography lumbar spine</td>
<td>1</td>
<td></td>
<td>☢☢</td>
</tr>
</tbody>
</table>

**Rating Scale:** 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate

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*Relative Radiation Level*
Innovations for Improving Guidelines: View from the ACR
Challenges to the use of imaging in the US

• Inappropriate use, for many reasons
• Attempts at external controls add cost+delay: Radiology Benefit Managers, Insurance company hurdles and constraints
• Guidelines in format usable in EMRs are limited, inconsistent, arbitrary, hard to use.
Challenges to the ACR Appropriateness Criteria

1. Usability of guidelines: format, scope
2. Availability in electronic format
3. Buy-in needed: Users individually,
   Health-care organizations
   EMR vendors
   Other medical societies
   Patients
4. Process for creation, revision, addition, validation
Current ACR Effort: Creation of a useable clinical imaging/referral guideline decision support tool

• ACR Select-collaboration with National Decision Support Company
• Content is ACR Appropriateness Criteria, supplemented as needed
• Content as a fixed data-base will be sold by NDSC
• Content owned by ACR. Cannot be altered by users
• Continual updating, validation based on data, and consultation between users and the ACR
Aim of ACR Select

• Serve as on-line CDS tool, to improve the appropriate use of imaging-decrease inappropriate exams, decrease unnecessary radiation exposure

• Through feedback from users, continual improvement of the coverage, usability and validity of the ACR AC

• Through analysis of use by individuals, groups and healthcare organizations, collect and analyze data on utilization and utility of imaging

• Eliminate unnecessary hurdles
ACR Select

• Sold to vendors of CPOE/ EMR systems
• Sold directly or secondarily to health care organizations or DSS creators
• Key considerations are:
  1. Highest quality content
  2. Methodological soundness,
  3. Ongoing feedback with users and vendors,
  4. Sound, web-based, user-friendly IT format
# Current VARIANT TABLE

**Clinical Condition:** Acute Chest Pain — Low Probability of Coronary Artery Disease

<table>
<thead>
<tr>
<th>Radiologic Procedure</th>
<th>Rating</th>
<th>Comments</th>
<th>RRL*</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-ray chest</td>
<td>9</td>
<td></td>
<td>☢</td>
</tr>
<tr>
<td>SPECT MPI</td>
<td>8</td>
<td>If a cardiac etiology is suspected.</td>
<td>☢☢☢☢</td>
</tr>
<tr>
<td>CTA coronary arteries</td>
<td>7</td>
<td>If a cardiac etiology is suspected.</td>
<td>☢☢☢☢</td>
</tr>
<tr>
<td>MRI heart with stress with or without contrast</td>
<td>7</td>
<td>If local expertise is available. See statement regarding contrast in text under “Anticipated Exceptions.”</td>
<td>O</td>
</tr>
<tr>
<td>CTA chest (noncoronary)</td>
<td>6</td>
<td>Useful in ruling out other causes of chest pain such as aortic dissection, pulmonary embolism, pneumothorax, pneumonia.</td>
<td>☢☢☢</td>
</tr>
<tr>
<td>US echocardiography transthoracic</td>
<td>6</td>
<td>If cardiac etiology is suspected.</td>
<td>O</td>
</tr>
<tr>
<td>US echocardiography transesophageal</td>
<td>6</td>
<td>If cardiac etiology is suspected. To exclude aortic dissection if MDCT and/or MRI are nondiagnostic.</td>
<td>O</td>
</tr>
</tbody>
</table>

**Rating Scale:** 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate  | *Relative Radiation Level |

*Relative Radiation Level
For DSS

• Exam: CT
• Clinical Condition: Chest pain, low prob. ACS
• Rating: CT chest  6
  CTA coronaries  7
  SPECT MPI  8
  CXR  9
  US-TTE  6
  US-TEE  6
Challenges/Goals

• Guidelines must be based on sound methodology
• Guidelines are difficult and expensive to produce and maintain
• There is a need for imaging referral guidelines, in useable form
• Such decision support must be comprehensive, user-friendly, relevant and interactive