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BY ELECTRONIC DELIVERY

Nahed El-Kassar, M.D., Ph.D.
Director Task Order Officer
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850

RE: AHRQ Draft Comparative Effectiveness Review on Imaging Tests for the Diagnosis and Staging of Pancreatic Adenocarcinoma

Dear Dr. El-Kassar:

The Medical Imaging & Technology Alliance (MITA) is pleased to submit comments on the Agency for Healthcare Research and Quality (AHRQ) draft comparative effectiveness review entitled Imaging Tests for the Diagnosis and Staging of Pancreatic Adenocarcinoma (“Draft Report”).¹ MITA has extensive knowledge of the substantial benefits afforded by medical imaging and radiation therapy to the health of Americans due to our role as the leading trade association representing medical imaging, radiation therapy, and radiopharmaceutical manufacturers. We support quality efforts that foster appropriate use of these technologies for the early detection, diagnosis, staging, therapy monitoring, and surveillance of many diseases.

Medical imaging encompasses X-ray imaging, computed tomography (CT) scans, diagnostic ultrasound, nuclear imaging (including positron emission tomography (PET)), magnetic resonance imaging (MRI), and related imaging acquisitions. Medical imaging is used to diagnose patients with disease, often reducing the need for costly medical services and invasive surgical procedures.² In addition, medical imaging equipment often is used to select, guide, and facilitate effective treatment, for example, by using image guidance for surgical or

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radiotherapeutic interventions. MITA’s members also develop and manufacture innovative radiotherapy equipment used in cancer treatment.

Our comments address three areas in the Draft Report: (1) imaging modalities have varied functions and uses in a clinical setting; (2) outcomes related to the use of imaging must be defined to reflect the unique contribution of imaging to clinical decisions; and (3) innovative, dose-lowering imaging technologies support quality care.

1) Imaging modalities have varied functions and uses in a clinical setting. As such, comparative analyses of modalities are of limited value, especially when removed from the particular clinical setting and circumstances of the individual patient.

Medical imaging includes multiple modalities and each modality provides unique and many times complementary value in better understanding the clinical situation. In fact, outside the context of a particular episode of clinical care, comparisons of modalities do not appropriately value the contribution of each modality to healthcare. Rather imaging modalities should be considered in the context of the information they add to the clinical situation and how they add value in establishing appropriate care for the individual patient. AHRQ acknowledges this in the Draft Report as “different imaging tests are believed to have utility in different circumstances (e.g., when suspicious of metastatic disease vs. localized disease) and a clear delineation of the relevant evidence would help guide clinicians and patients in choosing the most appropriate imaging test.”

Access to appropriate imaging is necessary to inform clinical decisions related to the proper diagnosis and treatment of disease. In order to better direct the optimal use of imaging, physician societies and other provider groups have developed appropriate use criteria and practice guidelines specific to individual clinical indications. These clinical decision-support tools are based on research and evidence, and aid physicians to determine the appropriate scans to be used for specific clinical indications.

The National Comprehensive Cancer Network (NCCN) has clinical practice guidelines on pancreatic adenocarcinoma. The guidelines outline considerations and approaches to care. For each stage of care, appropriate testing and treatment are outlined. In addition, imaging modalities are discussed. For example, triphasic CT provides “clear distinction between a hypodense lesion in the pancreas and the rest of the organ” but in some staging, endoscopic ultrasound can provide additional information “for patients whose CT scans show no lesion or who have questionable involvement of blood vessels or lymph node.” These guidelines appropriately acknowledge that clinical value of each imaging modality is determined by how it informs specific clinical care, not how it ranks in comparison to other modalities.

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MITA advocates the development and use of physician-developed appropriateness criteria to guide treatment decisions and training of hospital and imaging facility personnel who perform medical imaging exams. In order to provide optimal care and prevent medical errors, physicians and technologists must account for the patient’s individual needs. By providing proper training and adhering to these standards and initiatives, physicians can ensure that patients receive the life-saving benefits of medical imaging technology.

2) Outcomes related to the use of imaging must be defined to reflect the unique contribution of imaging to clinical decisions.

The Draft Report points to lack of studies on “patient-oriented outcomes”. In particular, the AHRQ states, “No included studies compared these tests for their subsequent impacts on patient management, survival, or quality of life.” This is cited as a gap in evidence. However, we offer that this is not a gap, but rather includes some endpoints which are inappropriate to evaluate diagnostic imaging in the context of patient care.

One consideration is that it is difficult to isolate the contribution of diagnostic imaging from the larger care paradigm, and in fact, due to the incremental value of diagnostic imaging within the delivery of healthcare, diagnostic imaging’s value outside the care paradigm would be of limited meaning. Models that attempt to extract diagnostic imaging from the care that it informs neglect to reflect the reality of healthcare delivery. In fact, in clinical practice, a patient may have multiple diagnostic tests, with additional value from each test used to inform the complex clinical decision process in unique and inimitable ways. In addition, some diagnostics tests are synergistic. For example, a PET scan may be ordered in follow up to a CT scan that shows small indeterminate lesions. Additionally, as the science of cancer staging progresses, diagnostic imaging may inform decision-making in concert with other tests including biomarker identification, genomic studies, and other assays.

A more appropriate endpoint for diagnostic imaging would be similar to that which AHRQ considers as “how patients were managed differently after different tests.” That is, changes in therapeutic management or stage reclassification are appropriate terminal points when considering the impact of diagnostic imaging on healthcare. A recent article on the topic suggests, “The outcomes, or endpoints, appropriate to assessing whether diagnostic interventions are reasonable and necessary are best characterized as “change in clinical management.” This is distinct from the outcomes, or endpoints, classically applied in assessing whether therapeutic interventions are reasonable and necessary.”

3) Innovative, dose-lowering imaging technologies support quality care.

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The Draft Report also points to radiation dose as a potential harm of CT and PET/CT.\textsuperscript{11} In recent years, innovative, dose-lowering technologies have limited dose while maintaining imaging quality. Due to lower dose and high clinical efficacy, the CT and PET/CT benefit-to-risk profiles have improved.

Dose efficiency and dose reduction have been important design considerations for CT for many years. The focus on these design considerations has grown and intensified in more recent years, and has yielded a variety of new and innovative hardware and software features that directly help physicians both reduce and monitor dose for CT exams. The CT industry has developed new features that enable both the dose to be displayed prior to scanning, and to alert operators to potentially higher than expected doses, as well as enabling electronic recording of the CT dose in the patient record. These features are important for both the patient as well as facilities, since they provide facilities with the ability to compare the dose of their CT protocols and establish optimized reference values.

The dose monitoring/reduction features described below play a significant role in helping to reduce the dose for CT exams, while maintaining diagnostic quality and the capability to report and record dose. For example:

- Automatic Exposure Control helps optimize dose for each patient for the given diagnostic task. This feature adjusts the exposure to use only what is needed to maintain a constant image quality. This feature is now standard on CT systems.
- Wider coverage detectors minimize the amount of x-ray that falls outside of the active detector region, thereby reducing dose to the patient without impacting image quality. Systems are now available in a range of wide coverage designs.
- “Shutter” modes block unused x-ray at the beginning and end of helical scans and therefore do not degrade image quality. This feature is now standard on many CT systems and is “built in” to each helical acquisition.
- Advanced electronics in data acquisition systems result in better imaging performance and less noise, thereby enabling equal performance at a lower dose.
- First generation CT iterative reconstruction results in a significant dose reduction potential, while maintaining diagnostic image quality, and is well suited to CTC studies. Iterative reconstruction is available on new systems and also as an upgrade to many installed base systems.
- More advanced second generation CT iterative reconstruction provides even further dose reduction potential, where some expert users are able to achieve some exams approaching 1 mSv levels for combined supine and prone CTC scans, while still maintaining diagnostic image quality. This feature is becoming widely available on new systems.
- The DICOM Dose Structured Report allows the exam dose to be electronically captured with the patient record. This feature is now standard on all new CT systems and has also been implemented on newer installed base systems.

MITA leads industry efforts to coordinate and establish standards to mitigate radiation dose. Adoption of these standards benefits patient dose. MITA’s approach builds upon existing manufacturer safety measures – including equipment safety standards, protocol development, quality and safety checks, provider education programs and physician-developed medical guidelines – to minimize radiation dose as much as possible, and to provide even greater degrees of coordination, transparency and reporting in the delivery of medical radiation. Recent examples of MITA standards which have addressed dose include:

- **NEMA XR 25-2010, Computed Tomography Dose Check.** This standard introduced two novel features to assist the imaging team in providing better patient care: dose notifications and dose alerts. Dose notifications are designed to provide a clear indication to health care providers when the parameters for a CT scan will result in a dose higher than the facility’s pre-determined dose threshold for routine use. Dose alerts are designed to prevent dose levels for a complete exam from exceeding pre-determined thresholds that are deemed excessive by the facility. This feature can be configured to prevent equipment operation. These protections help the operator and ultimately the physician to better understand dose implications of protocol choices, and should significantly reduce exposure due to inappropriate scan parameter settings.

- **NEMA standard XR 26 - 2012, Access Controls for Computed Tomography: Identification, Interlocks, and Logs.** This standard requires software features that ensure only an authorized operator can alter the controls of CT equipment. This industry-wide standard requires the institutionalization of administrative privileges, access levels, and the recording of clinical protocols to ensure safe and appropriate use.

- **NEMA standard XR 27 - 2012, X-ray Equipment for Interventional Procedures User Quality Control Mode.** This standard helps imaging facilities conduct quality testing and monitoring of X-ray equipment used for interventional procedures.

- **NEMA standard XR 29 - 2013, Standard Attributes on Computed Tomography (CT) Equipment Related to Dose Optimization and Management.** This standard, known also as MITA “Smart Dose”, is the fourth dose-related standard to be released by MITA since 2010. This standard includes four components:
  1. DICOM Dose Structured Reporting – This enables the recording of post-exam dose information in a standardized electronic format. This information can be included in the patient record, promoting the establishment of diagnostic reference levels, as well as facility dose management and quality assurance.
  2. Pediatric and adult reference protocols – These are a set of pre-loaded protocols on a CT system that serve as a baseline for a variety of clinical tests.
  3. CT Dose Check – CT Dose Check incorporates two features—dose notifications and dose alerts that can inform operators and physicians when dose exceeds established thresholds.
  4. Automatic Exposure Control (AEC) – AEC automatically adjusts the amount of radiation used based on the size, shape and composition of the patient, in order to achieve a specified level of image quality.
MITA appreciates this opportunity to comment on the Draft Report. We would be pleased to answer any questions you might have about these comments. Please contact me at (703) 841-3235 if MITA can be of any assistance.

Sincerely,

Gail Rodriguez, Ph.D.
Executive Director, MITA