The ACADEMY
for Radiology & Biomedical
Imaging Research

Advancing Innovation in Imaging Science

**Advancing the Diagnostic Cockpit of the Future:
An Opportunity to Improve Diagnostic Accuracy and Efficiency**

A Partnership Between the Academy for Radiology & Biomedical Imaging Research
and the National Institute of Standards and Technology (NIST)

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In December 2017, the Interagency Working Group on Medical Imaging (IWGMI) within the Committee on Science, National Science and Technology Council, identified "advancing high-value imaging" as the key theme to achieve more efficient and effective health care, a greater impact on research, and better health outcomes. This theme is supported by four interlocking objectives that should guide Federal Research & Development:

1) Standardization/interoperability of image acquisition, annotation management, storage and transfer;
2) Application of advanced computation and machine learning to medical imaging;
3) Acceleration of the development and translation of new, high-value imaging techniques; and
4) Promotion of best practices in medical imaging.

These objectives form the foundation for a framework of tools that can support both clinical practice and research: the "**diagnostic cockpit**." The diagnostic cockpit is a future-state digital platform that will aggregate, organize and simplify medical imaging results and patient-centric clinical data, helping clinicians become the "diagnostic pilots" of the future in detecting disease early, making accurate diagnoses, driving image-guided interventions, and ultimately improving the downstream clinical management of patients.

The Academy for Radiology & Biomedical Imaging Research (The Academy) has been at the forefront of advocacy and policy on behalf of the medical imaging community for more than 20 years. It advocates for federal research funding, pushes for changes in policy issues critical to imaging researchers, and promotes technical advances that can improve diagnostics and patient care. The Academy was the catalyst that led to the creation of the IWGMI and it is now leading the effort to maintain momentum resulting from the IWGMI report. The Academy hosted a symposium and a workshop, in conjunction with NIST, to address two of five high

priority action items resulting from The Academy's scientific symposium *Building the Diagnostic Cockpit of the Future*, held in September 2017, and from the resulting white paper *(link).*

The symposium convened a diverse community to explore ways the imaging community could build the diagnostic cockpit, and the white paper was an important touchstone to frame the priorities. The most recent workshop with NIST focused on:

1. Developing (or promoting existing) national standards for encoding and quantification of data from multiple diagnostic sources including, but not limited to, imaging, pathology, genomics, laboratory and electronic medical records. These standards would be a step towards the functional goal of data interoperability that could be validated using national registries/databases (e.g., with a standard self-describing registry interface).
2. Creating an environment that facilitates continued cooperation and participation across government agencies, industries, and academia in a safe, neutral, pre-competitive space. Analogously, cooperation and cross-training amongst physicians from multiple diagnostic specialties were recognized as essential.

The workshop convened experts from medical imaging, pathology, cardiology, oncology, artificial intelligence and her communities, as well as representatives from 9 government agencies and 15 industry manufacturers. The workshop had three breakout sessions that attendees rotated through, each focused on a different aspect of the cockpit. the need for common use cases for various validated diagnostic cockpit components was identified as a priority.

Each breakout session addressed a different aspect of the diagnostic cockpit:

1. Defining the scope of the product (what data is possessed now and what can be done with it);
2. Moving from qualitative to quantitative findings, and the need for standardization; and
3. Environmental factors (workflow, billing, patient and provider perspectives).

Common themes emerged across the three groups and are summarized here.

First, there are the highly pragmatic questions of what data is currently accessible and what can be done with that data in the short term. It is important to understand the roles of the diagnostician as a data aggregator, interpreter, and synthesizer, and the ways in which the diagnostic cockpit could enable and enhance those activities. This type of tool will help shift the "art" of diagnostics to the "data science" of diagnostics, leading to repeatable and portable clinical results from downtown Tokyo to rural Zaire. Stepwise creation of the diagnostic cockpit should start with a tool to aggregate and visualize all case-relevant information before developing advanced analytics and self-learning.

There are a number of relevant data streams to identify, gather, and collate including imaging data, radiology test results including, but not limited to, standardized clinical scoring (such as LI-RADS, BI-RADS), processed or derived images (perfusion, tractography, etc.), lab measurements, synoptic pathology reporting in cancer, claims data and ICD10 codes. Each of these sources has its own storage and communication standard (e.g., DICOM) and while it might be tempting to unify these, working to adopt a common ontology among them would be

far more achievable to ensure semantic interoperability. The use of structured reporting being developed will help accelerate this effort in the RSNA and ACR.

The main challenge in the aggregation of these data sources is ownership and access. There are multiple entities across the healthcare enterprise (radiology, pathology, EMR vendors, imaging vendors, etc.) seeking to access data out of their natural control. With the current fragmented stewardship of diagnostic data, it may be difficult to identify the stakeholder that will drive aggregation in the provider community. The entire concept of a diagnostic cockpit relies on access to and aggregation of all relevant information.

To overcome barriers to aggregating existing data, an effort should be launched to create several open-access, exemplar datasets through collaboration across multiple clinical institutions and driven by government bodies to ensure public availability. Each dataset would contain all relevant data including imaging exams, reports, labs, pathology, and patient history and outcomes. In addition to establishing the data and technical standards, the resultant aggregated data can stimulate the development of the analytics that represents the next layer of the cockpit.

There was general consensus on the need for quantitative metrics for performing discrete measurements in a given study or gauging therapeutic response. These metrics are used not only by the physician reading the imaging study (e.g., radiologist, cardiologist) but also by a host of users interacting with the data downstream (e.g., oncologists, surgeons, pathologists, industry trials). The problems today are three-fold:

1. Lack of standardized measurements and techniques for rapidly and accurately performing volumetric measurements. RECIST and other 2D measurements, while widely used as the standard of care today, are tedious (manual), have notable interobserver variability, and are often not graphically documented. The linkage from measurement in the report to the image and the annotation of the measurement is of great value to the downstream users and also speeds up the comparison review for future studies for that patient.
2. Lack of a standard interchange mechanism for structured measurement data as documented in the interpreting physician's report. While there are structured measurement data available from the modality devices (DICOM SR), there is no similar process used to capture the final values, including metadata the reader has made or accepted as part of the interpretive process. Enhancing the report output could take several forms but requires a consensus path.
3. There is a need for more standardized reference studies such as: the NCI and NIH (e.g., The Cancer Imaging Archive from the NCI/NIH); phantoms that provide reference standards for metrology (e.g., those for MR studies by NIST and commercial vendors), the synthetic Digital Reference Objects (DROs) from RSNA / QIBA. However, there needs to be made available an archive of images acquired with these phantoms/ studies from a variety (vendors and modalities) of devices to provide simplified comparison and speed validation of new image quantification technologies (such as AI) and submission of applications for devices to the FDA.

Advancing these ideas to commercialization and use by the medical imaging community will require coalition efforts across industry, academia, standard organizations and the imaging societies, including SIIM, HIMSS, ACR, AAPM and other accrediting bodies.

In addition to quantitative data, there is an urgent need for a concisely summarized presentation of data gathered across multiple systems (e.g., EMR, HIE). Relevant data include but are not limited to: lab values pertinent to the current exam, relevant surgical and nursing notes, latest physical exam notes, standardized genomic data, relevant pathology and biopsy data, prior imaging study reports, measurements and other annotations/ metadata, and medications. The types of data required vary by specialty and the desire for personalization of the data presentation.

Rapid query mechanisms for source data (such as HL7 FHIR) must be adopted, as should AI and NLP processing, extraction of summary data with an easy means of drilling down into the source of the summarized data to gauge the context and validate the summarization, and a means of importing summarized data into the current report or note. Development of diagnostic cockpits (DX CP) need to be interoperable, perhaps based on disease and condition and with the intention of being utilized by the entire spectrum of the care team. A number of dashboard building blocks need to be created with well-defined APIs applications (application programming interfaces) to facilitate the creation of a more complex cockpit. To support this, common data elements will need to be defined, similar to information captured in the DICOM standard. For example, the creation of an open-source data set that can be employed to develop DX CP tools will ensure that there is a uniform, standard set of data from which different manufacturers and researchers can develop and test a product that end users (physicians) can also test and provide feedback.

Finally, there is the need to consider two additional key issues: 1) the practical impact of this influx of data on the end user; and 2) the impact of AI (artificial intelligence) on payer pathways and the need for proactive approaches (e.g., what happens to the professional component when a computer reads a mammogram). Data management standardization is a necessary prerequisite to help accelerate AI from an analysis perspective. Disparate systems with data transfer, especially where handwriting and retyping is involved are inhibitors to progress, not to mention error prone, inefficient and resource intensive. Dashboards are required for tracking and feedback of performance, validation of information, and co-registration of images and data. They must be tailored to the task, populate the report for rad final impressions that accomplish the tailoring, and improve efficiency while maintaining diagnostic accuracy (triage, stress on users, eliminate "*tediosity*").

Action Items:

The Academy will create a diverse task force to continue this effort.

1) The task force will work to identify a neutral third party (what NEMA was to DICOM) to validate de-identification, manage the dataset(s), and ensure interoperability.
2) The neutral third party will lead an effort to collect 100 complete datasets (imaging, labs, pathology, reports, patient records, etc.) from each of 10 different institutions in the areas of hepatocellular carcinoma (HCC), coronary artery disease, and prostate cancer. *(…continued next page)*

3) The task force and Academy leadership will create a compendium of existing standards.
4) The task force and Academy leadership will work to further refine the core functional requirements of the diagnostic cockpit.
5) Additionally, the task force and Academy leadership will work to identify potential funding sources for any initiatives that stem from this effort.

Multi-Society Effort

The Academy will lead an effort to create a compendium of standards from existing standards (e.g., ACR Registry of Standards and Interoperability), to avoid duplication, utilize existing resources, and ensure transparency amongst and between diagnostic research communities. This effort will require buy-in and participation of numerous imaging societies. Options include the utilization of "connectathons" at technical meeting (HIMSS and SIIM), and polling society Executive Directors.

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