The ACADEMY for Radiology & Biomedical Imaging Research

Advancing Innovation in Imaging Science

Building the Diagnostic Cockpit of the Future:
An Opportunity to Improve Diagnostic Accuracy and Precision

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The Academy for Radiology & Biomedical Imaging Research (The Academy), has a mission to advocate for federal support of medical imaging research at the National Institutes of Health and across government agencies. Each initiative that the Academy undertakes and supports is directly linked to this mission. This paper describes several initiatives led by the Academy to pursue its mission:

1. After leading the initial effort to create the Interagency Working Group on Medical Imaging (IWGMI) within the White House Office of Science and Technology Policy (2015), the Academy currently serves as its primary advocate and maintains the momentum for its continued efforts.
2. Host an interdisciplinary scientific symposium on the Diagnostic Cockpit of the future, as described herein (2017).
3. Co-sponsor a workshop with the National Institutes of Standards and Technology (NIST) (2018).

This innovative advocacy effort has involved convening multiple government agencies, industry partners, academic radiology leaders, and experts from other subspecialties such as cardiology, pathology, neurology and genomics, to address pressing challenges and opportunities faced by the imaging research community. This work elevates the profile of medical imaging technologies, ensures that its value and impact are broadly recognized, facilitating collaborations, highlights our position as content experts, and provides the critical voice of the imaging community in the future of molecular diagnostics and precision medicine.

When advocating for federal funding, it is critical for the Academy to illustrate initiatives that proactively address challenges within the imaging research community. For example, the establishment of the IWGMI has generated collaborations amongst multiple federal agencies that can collectively enhance the development and impact of imaging research. These results will enable the Academy to more effectively advocate for additional federal investments into medical imaging research.

National organizations have pointed out that errors and imprecision in medical diagnosis are important contributors to poor patient outcomes (Kohn LT, et al, 2000; Richardson WC et al, 2001; Balogh EP, et al, 2015). Many of these

diagnostic errors in imaging include: (1) ordering of the wrong imaging test; and (2) misinterpretation of imaging test findings. The results of these medical errors typically include delays in definitive diagnosis.
In 2018, technology improvements and new care delivery paradigms create the opportunity to improve diagnostic performance, reduce errors and develop the concepts of precision medicine. A 2017 'pre-publication' from the National Academy of Medicine (NAM, formerly the Institute of Medicine) elaborated on the potential of advanced imaging and diagnostic biomarkers for addressing these goals, stating, "The recent dramatic technologic improvements in imaging, pathology, molecular diagnostics and information technology/data sciences can promote improved and more precise diagnoses…the critical elements for the growth and development of precision medicine" (Dzau VJ et al, 2017). Other papers have highlighted the critical importance of information technology in the effort to improve diagnosis for precision oncology (Ghasemi M, et al, 2016; Singer J, et al, 2017)

By integrating their knowledge and data, healthcare professionals from different disciplines could maximize the advantages of the unprecedented advances in diagnostic technologies and information technology to optimize diagnostic accuracy and precision, thus enabling informed and targeted therapeutic decisions. However, to date, the full potential of such "integrated diagnostics" has not yet been achieved. Obstacles to capitalizing on this potential appear to include: limited dissemination of valuable diagnostic technologies to all areas of the country; siloed, offline electronic health records; paucity of readily available data analytic tools; variability in data inputs and outputs; and lack of coordinated efforts to improve diagnostics across clinical, academic, governmental, and commercial stakeholders.

This paper describes initiatives taken by the Academy for Radiology and Biomedical Imaging Research (the Academy) to catalyze the realization of the full potential of integrated diagnostics.

Background:

In the past two decades, the magnitude and impact of medical errors made in the US have been identified as an important public health problem as well as a challenge for health policy and systems specialists. NAM has played a high profile role among many national organizations in the effort to identify and reduce such errors.

Diagnostic error is a subcategory of medical error. In a landmark NAM publication, 'Improving Diagnosis in Health Care' (Balogh EP, et al., 2015), the organization's Committee on Diagnostic Error in Health Care provided an extensive assessment of the extent of such errors and of their etiologies, and also suggested systematic and practical remedies.

The report had three major themes and other pertinent observations, as summarized in its Preface (emphasis added):

> *"…diagnosis is a collaborative effort. The stereotype of a single physician contemplating a patient case and discerning a diagnosis is not always true; ……. The complexity of health and disease and the increasing complexity of health care demands collaboration and teamwork among and between health care professionals, as well as with patients and their families."*

The report concluded by identifying 8 major national goals for improving diagnosis and reducing diagnostic error (Exhibit 1).

Exhibit 1

Box 9-1
Goals for Improving Diagnosis and Reducing Diagnostic Error

- Facilitate more effective teamwork in the diagnostic process among health care professionals, patients, and their families
- Enhance health care professional education and training in the diagnostic process
- Ensure that health information technologies support patients and health care professionals in the diagnostic process
- Develop and deploy approaches to identify, learn from, and reduce diagnostic errors and near misses in clinical practice
- Establish a work system and culture that supports the diagnostic process and improvements in diagnostic performance
- Develop a reporting environment and medical liability system that facilitates improved diagnosis by learning from diagnostic errors and near misses
- Design a payment and care delivery environment that supports the diagnostic process
- Provide dedicated funding for research on the diagnostic process and diagnostic errors

The Academy for Radiology and Biomedical Imaging Research fully supported the findings and recommendations of all the NAM reports on diagnostic error, and sought ways to further their objectives (Cruea RL and Meltzer CC, 2017). Due to the Academy's familiarity with the introduction and continuous innovation of advanced technology in medical imaging, we are well situated to serve as a convener of stakeholders committed to moving the needle on diagnostic accuracy through the integration of medical imaging and other key forms of patient information.

Therefore, the Academy facilitated three important initiatives (described more extensively in the next section of this paper): first, the creation of a federal Interagency Working Group on Medical Imaging (IWGMI) that, while focusing primarily on imaging, also seeks to leverage promising technologies from a wide variety of federal agencies that could improve diagnosis; second, the sponsorship of a national symposium on "Building the Diagnostic Cockpit of the Future"; and third, coordinating follow-up and collaborative advocacy activities.

Step 1. The Interagency Working Group on Medical Imaging

Multiple federal agencies are involved in efforts to improve medical diagnostics, and also contribute to medical imaging research. However, their efforts are often siloed and could be enhanced through collaboration. Agencies like the National Institute for Biomedical Imaging and Bioengineering (NIBIB), the National Institute of Standards and Technology (NIST), the National Science Foundation (NSF), and the Department of Energy (DOE) support technology development proposals for imaging research. Other agencies, including the National Institute of Neurological Disorders and Stroke (NINDS), the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute on Aging (NIA), the Department of Defense (DoD), and the Department of Veterans Affairs (VA) take the tools created by NIBIB and apply them to translational research. In addition, the Food and Drug Administration (FDA), Centers for Medicare and Medicaid Studies (CMS), Environmental Protection Agency (EPA), Department of Energy (DOE), and the Department of Commerce (DOC) all have divisions to approve, regulate, and define market conditions for delivering imaging to patients. Given these agencies' diverse constituencies, complementary roles, and economic significance, a strategic need to coordinate and accelerate imaging research across the federal government was identified. The Academy supported the formation of the IWGMI as a vehicle to accelerate the sharing of the collective knowledge of these agencies and optimize the investments of federal resources.

As a result, in 2015, the IWGMI was created, led initially by co-chairs Roderic I. Pettigrew, PhD, MD, Director of the NIBIB, and Richard Cavanagh, PhD, Director of Special Programs Office at NIST. More than a dozen Federal Agencies were invited to participate in the Working Group. Members of the IWGMI represented the following agencies:

Centers for Medicare and Medicaid Studies (CMS)
Department of the Treasury
National Institutes of Health
Federal Bureau of Investigation
Food and Drug Administration
Office of Management and Budget
Department of Energy
Department of Defense
National Aeronautics and Space Administration
National Science Foundation
National Institute of Standards and Technology (NIST)

The IWGMI held several listening sessions that included a wide variety of stakeholders from academia, industry and patient advocacy and produced a final report that was recently released to the public (Pettigrew R, et al, 2017).

One key take-away from the IWGMI listening sessions was that there were striking similarities between constructs used to approach important national problems and those used in medicine. To cite some specific examples, Figure 1 demonstrates similarities in the cardinal functions performed in medicine and in national security, emphasizing a step-wise approach to evaluation of risk, early detection or diagnosis, precision in characterizing a target, and implementing a solution.

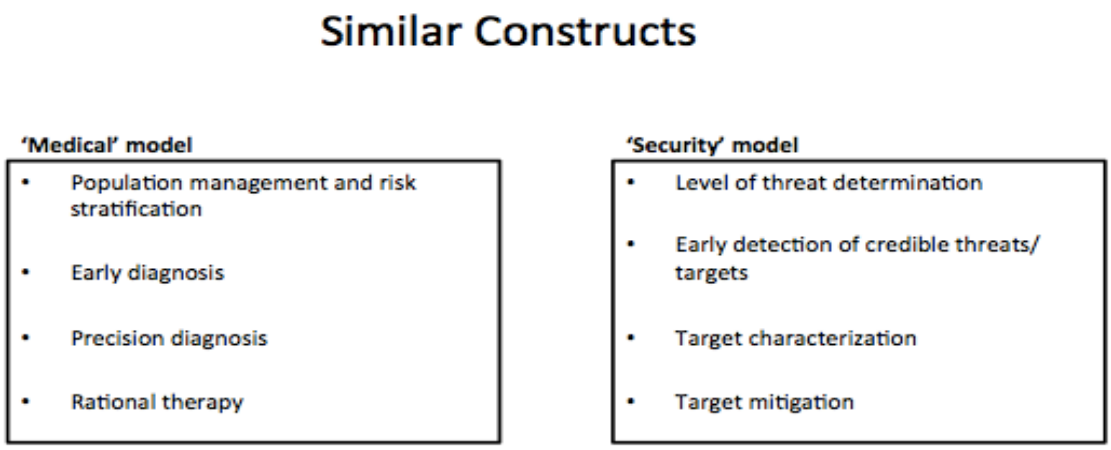

Figure 1.

Another observation was that most of these federal agencies have developed technologies for their own purposes that could be translated for use in medical diagnostics and therapeutics. For example, security-related agencies have developed and optimized tools for subtle signal detection in complex backgrounds as well as for harmonization of data from multiple sources; surveillance agencies, such as Homeland Security, have developed sophisticated pattern recognition tools (eg facial recognition); and exploratory agencies, such as NASA, have developed remote sensing technologies that can analyze the material and chemical components of distant objects.

In aggregate, the IWGMI report reflects that a consortium of government, industry and academic leaders could foster technology cross-fertilization and promote collaborations to advance breakthroughs in medical diagnostics, now and in the future. The Academy took the initiative to continue momentum towards this effort and organized and sponsored the presentation of a national symposium on "Building the Diagnostic Cockpit of the Future."

The "Cockpit" is a metaphor for a physical or virtual location where data from multi-disciplinary sources can be harvested, combined, and then presented, with a large overlay of data analytics, to a team of diagnosticians. Specific short-term objectives would be to first build a prototype of the Diagnostic Cockpit and then assess its ability to enhance diagnostics and improve communication of the associated information to physicians and patients.

Step 2. Symposium on "Building the Diagnostic Cockpit of the Future"

The Academy convened a scientific symposium on "Building the Diagnostic Cockpit of the Future" in Bethesda, Maryland on September 17-18, 2017, which brought together more than 100 invited experts from the imaging and biomarker community, cardiology, pathology and urology -- across government, industry and academia -- to collectively consider the variables involved in the eventual construction of a prototype Diagnostic Cockpit of the future.

The Symposium agenda had three major components. The first was to hear presentations from physicians who would be key active consumers of the integrated, quantitative diagnostic information that would be the output of the Diagnostic Cockpit. Medical oncologists, neurologists, cardiologists, and others provided a 'wish list' of capabilities, including the content and style of the integrated diagnostic report as well as means for effective communication to referring physicians. The second included presentations from physicians who would constitute the Cockpit 'Crew'. These included radiologists, pathologists and molecular diagnostics experts, who addressed the potential value, opportunities, and challenges in developing integrated diagnostic systems. The third focused on multidisciplinary, small-group working sessions that garnered input from all Symposium attendees to identify the 'state of the art' in the domains of risk stratification, early disease detection, precision diagnosis, and rational therapy, and to prioritize next steps in construction of a prototype Cockpit.

The resulting worklist of high-priority tasks that would facilitate the creation of the Cockpit included:

1. Develop national standards for the encoding and quantification of data from multiple diagnostic sources, including imaging, pathology, genomics, laboratory and electronic medical records. These standards would be a step towards the functional goal of data interoperability as well as creation of national registries/databases.
2. Catalog available data analytic methods that could be applied to a robust Cockpit. These could include tools for computerized pattern recognition; combination of data from multiple, disparate sources; improved visualization; and remote sensing, among others. It was noted that valuable capabilities developed at governmental agencies such as DOD, FBI, NASA, and Homeland Security could be translated into a medical context.
3. Develop advanced data analytic and artificial intelligence tools that can aid human observers in complex diagnostic decision making.
4. Develop an information technology and data visualization environment that can aid human observers to understand and interpret complex data.
5. Create an environment that facilitates continued cooperation and participation across government agencies, industries, and academia in a safe, pre-competitive space. Analogously, cooperation and cross-training amongst physicians from multiple diagnostic specialties were recognized as essential.
6. Catalyze the construction of a prototype of a multi-disciplinary Diagnostic Cockpit as proof of concept for a system that optimizes the diagnostic process.

Step 3. Follow-up on the Symposium

Symposium participants expressed enthusiasm about pursuing the development of a prototype Diagnostic Cockpit. A variety of paths forward can be considered, including:

- Identify multiple partners, including foundations and professional societies, to share expertise, resources, and perspectives, with the Academy remaining as a convener. This initiative is currently underway…NIST and the Academy will co-sponsor a symposium regarding development of inter-operable standards for diagnostic data, and will later assist NIBIB in sponsoring a symposium regarding how to optimize the development of artificial intelligence tools that can facilitate more accurate and precision diagnoses.
- Encourage the extension of the IWGMI Charter and/or coordinate federal agency leaders to take ownership of this initiative where appropriate.
- Work with NIH leadership to support creating a model of the Cockpit with inter-institute cooperation.
- Support private-public partnerships in developing standards for data collection, data reporting, and interoperability to reduce technology barriers.
- Solicit engagement from the National Academy of Medicine/National Academy of Sciences, as the proposed initiative is responsive to their healthcare improvement agenda.
- Develop a public communication plan to achieve greater visibility and accountability across stakeholder groups, including patients, physicians, industry colleagues, governmental officials, legislators, and payers.

Summary:

Unprecedented opportunities exist to improve the accuracy and precision of medical diagnoses and thus advance the goals outlined by NAM. To catalyze progress, recent activities of the Academy, the IWGMI and a consortium of government, industry and academics resulted in an endorsement of the concept of a "Diagnostic Cockpit of the Future" as a (metaphorical) tool—one that can integrate diverse technologies and solutions towards improved diagnostic accuracy and precision. Achieving this vision will take great energy, perseverance and cooperation, and we urge the members of the Academy and the broader medical imaging community to participate actively in this effort.

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