Road Map for Medical Imaging: Research and Development US National Science and Technology Council, December 2017

Interagency Working Group on Medical Imaging

Executive Summary

Medical imaging guides the course of much of patient care and is an essential element of biomedical research. From x-rays and ultrasound to computerized tomography (CT), functional magnetic resonance imaging (fMRI), and positron emission tomography (PET), medical imaging helps clinicians diagnose, treat, and understand a range of diseases and conditions, including cancer, cardiovascular disease, and neurodegenerative disorders.

The Federal government invests in medical imaging research and plays an important role in developing and deploying imaging technology that will help lengthen and improve the quality of American lives, open new areas of scientific discovery, and ensure the United States remain a global leader in medical innovation. The Interagency Working Group on Medical Imaging (IWGMI) coordinates these Federal investments and developed this roadmap for future medical imaging research and development (R&D) as required by the Senate committee report accompanying the Departments of Commerce and Justice, Science, and Related Agencies Appropriations Bill, 2015, S. Rep. No. 113-181, at 104-105 (2014).[1]

The IWGMI has identified "advancing high-value imaging" as an overarching theme for efforts to achieve better health outcomes and smarter health care spending through medical imaging. It has identified four objectives that should guide future Federal R&D activities in order to generate better value for patients from medical imaging and to optimize health care outcomes and reduce costs.

1. Standardize image acquisition and storage. Uniform data acquisition and storage standards will allow the creation of curated, trustworthy imaging databases that enable medical imaging research to capitalize on advances in big data and data sharing. There is broad consensus that advances in medical research and care hinge on a large data ecosystem to collect and organize vast amounts of data from patient studies and basic research. To be useful, imaging data must be trustworthy, able to be queried in a logical and consistent way, and accessible to those with a legitimate need. The first step in ensuring these criteria are met is to coordinate the development and adoption of standard operating procedures for collecting, annotating, and archiving medical imaging data. The second step is to establish approaches for curating, storing, and providing access to medical imaging data that has been verified and validated.

[1] *https://www.congress.gov/113/crpt/srpt181/CRPT-113srpt181.pdf*

2. Apply advanced computation and machine learning to medical imaging. Techniques such as artificial intelligence, machine learning, and deep learning offer considerable promise for medical imaging. Curated data sets can be used to develop and test algorithms for accurate and sophisticated machine-assisted analysis of images, identifying disease subtypes and correlations with known genetic and metabolic pathways. These new analytic approaches can help identify relationships that a human observer alone might never discover, helping improve diagnosis and suggesting optimal interventions and likely drug targets. Imaging data can be organized and presented in conjunction with other patient data in a comprehensive diagnostic "cockpit"—a future digital interface for medical teams to facilitate optimal and tailored management of each patient.

3. Accelerate the development and translation of new, high-value imaging techniques. Streamlined medical imaging techniques can provide quicker diagnoses and lower health care costs. Future research should aim to develop imaging protocols that decrease time in the scanner and improve work flow. These new protocols can be combined with quality improvements and appropriate use criteria initiatives to better target diagnostic tests for patients. Appropriate use criteria assess whether advanced diagnostic imaging is indicated for a particular clinical scenario and, when it is, in what combination diagnostic tests should be performed.

Make high value imaging more accessible. Reducing the cost of medical imaging equipment and increasing its portability can increase patient access to imaging for research, diagnosis, and treatment, particularly at smaller clinics and research centers.

Accelerate the translation of new technologies into the marketplace. Greater collaboration and knowledge sharing among Federal agencies during the development of new medical imaging technologies could accelerate the evaluation and approval of high-value, innovative technologies and accelerate their translation from the laboratory to the marketplace—from the bench to the bedside, in medical parlance. Improved coordination among Federal bodies on their related health care missions may reveal new ways to best leverage limited resources.

4. Promote best practices in medical imaging. Technology is driving innovation in clinical decision support, but new imaging practices will require education and training so that health care professionals employ value-driven approaches. Evolving analytical software systems and technologies for sharing medical imaging data will increase demand for new skills and training in the workforce. Priorities include disseminating knowledge about new imaging practices, developing competencies and operational skills for effective use of innovative technologies, and reorganizing workflows to improve the productivity of medical imaging operations as practices change.

These objectives provide a framework for prioritizing future medical imaging research and related Federal activities, as determined by the IWGMI based on information and perspectives gathered from the broad community of medical imaging stakeholders, including patient advocacy groups, academics, professional societies, industry, and government representatives.

Summary of Recommendations

1. Standardize image acquisition and storage

1.1. Develop and promote adoption of standards for collecting, annotating, and archiving clinical imaging data.

1.2. Coordinate public and private efforts to combine, archive, and disseminate clinical data from multiple diagnostic studies.

1.3. Establish an infrastructure that will provide validation and quality assurance for clinical imaging data.

2. Apply advanced computation and machine learning to medical imaging

2.1. Support focused artificial intelligence research and development for applications in medical imaging.

2.2. Establish a public-private forum to coordinate efforts and interests in the artificial intelligence and medical imaging communities.

2.3. Support the development of a diagnostic cockpit as both a clinical and research tool that integrates imaging data with other electronic medical data sets.

3. Accelerate the development and translation of new, high-value imaging techniques

3.1. Get to diagnosis more quickly and cost-effectively.

3.2. Make high-value imaging techniques more accessible.

3.3. Conduct regular outreach efforts to increase dialogue among Federal, academic, clinical, and industrial stakeholders on their respective roles, evidence-based research, trial design, and clinical translation of high-value techniques.

4. Promote best practices in medical imaging

4.1. Define methodologies that support dissemination of knowledge, competencies, and operational skills towards efficient use of innovative technologies.

4.2. Employ cost-effective, accredited tools that promote wider engagement of practitioner populations.

4.3. Establish best training practices and priorities for educational institutions to prepare students for success in health care research and delivery.

Agency R&D Interests.

Agencies can collaboratively support recommendations that fall within their designated missions.

	CMS	DOD	DOE	FBI	FDA	NASA	NIH	NIST	NSF
1.1					X		X	X	
1.2		X	X		X		X	X	X
1.3					X			X	
2.1		X	X	X	X		X	X	X
2.2		X	X	X	X		X	X	X
2.3	X	X	X		X	X	X	X	X
3.1	X	X			X	X	X		
3.2	X	X	X		X	X	X		
3.3	X	X	X	X	X	X	X	X	X
4.1	X				X			X	
4.2	X				X			X	
4.3		X			X		X	X	

Advancing High-Value Imaging: A Roadmap for Medical Imaging Research and Development

Medical imaging guides the course of much patient care and is an essential element of biomedical research. With modalities ranging from x-rays and ultrasound to computerized tomography (CT), magnetic resonance imaging (MRI), single-photon emission computed tomography, and positron emission tomography (PET), medical imaging helps clinicians diagnose, treat, and understand a range of injuries, diseases, and conditions, including cancer, cardiovascular disease, musculoskeletal complaints, and neurodegenerative disorders. As a measure of scale, 79 million CT scans, 39 million MRI scans, and 1.7 million PET scans were performed in the United States in 2015.[2]

The Federal government invests in medical imaging research and plays an important role in developing and deploying imaging technology to lengthen and improve the quality of American lives and to open new areas of scientific discovery. In response to the Senate committee report accompanying the Departments of Commerce and Justice, Science, and Related Agencies Appropriations Bill, 2015 [S. Rep. No. 113-181, at 104-105 (2014)],[3] in 2015, the National Science and Technology Council (NSTC) established an Interagency Working Group on Medical Imaging (IWGMI) co-chaired by the National Institutes of Health (NIH) National Institute of Biomedical Imaging and Bioengineering (NIBIB) and the Department of Commerce National Institute of Standards and Technology (NIST).

The IWGMI coordinates Federal investments in medical imaging research and development (R&D) and developed this roadmap. In developing the roadmap, the IWGMI solicited individual input from a range of relevant stakeholders from scientific and professional societies, industry, academia, and patient advocacy groups, and identified several emerging themes in medical imaging.

The IWGMI has identified "advancing high- value imaging" as the key theme for achieving 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 R&D: 1) standardize image acquisition and storage; 2) apply advanced computation and machine learning to medical imaging; 3) accelerate the development and translation of new, high-value imaging techniques; and 4) promote best practices in medical imaging.

These four interlocking objectives are the foundation for a concept and tool that can support both clinical practice and research: the "diagnostic cockpit." The diagnostic cockpit is a future digital interface that would organize and simplify medical imagingresults and help to interpret them in the context of related clinical data to support early detection of disease, precision diagnosis, image-guided interventions, and improved downstream clinical management of the patient.

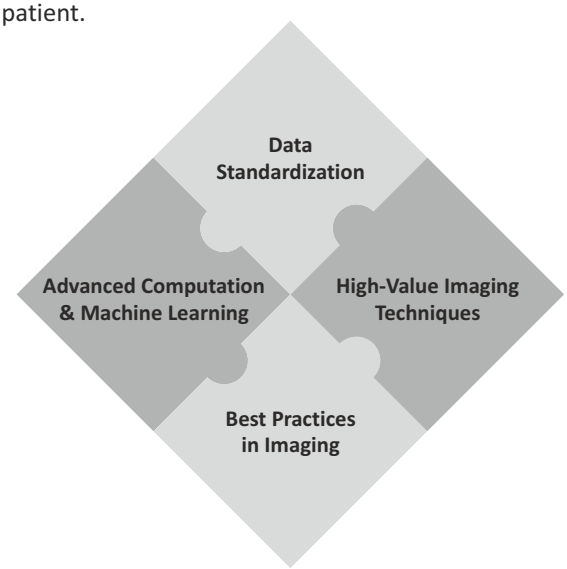

Figure 1. Four Objectives for Advancing High-Value Imaging

[2] *http://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT#*

[3] *https://www.congress.gov/congressional-report/113th-congress/senate-report/181*

Standardization of data acquisition and storage will make images more clinically usable and shareable across research and clinical care centers. Standardization will then focus the power of advanced computation on improving medical imaging. Application of artificial intelligence (AI) techniques, such as machine learning, will support more efficient and accurate diagnoses and assist clinicians and patients in shared decision-making by providing evidence-based, patient-specific recommendations. Improved interagency collaboration will accelerate the translation of advances in AI and other imaging and diagnostic technologies into clinical practice while maintaining high standards for evaluation of technical efficacy and clinical utility, enabling innovations to contribute more rapidly to better patient care. Finally, getting better, faster, and cheaper imaging technologies to the patient requires the adoption of recognized best practices by care facilities and research laboratories across the country, which can be achieved through workforce education and is predicated on clinician buy-in and leadership.

1. Standardize Image Acquisition and Storage

Improved standardization of image acquisition is needed to assure the comparability of quantitative imaging data so that changes in a patient's condition over time are measurable and comparable to observations from other patients. Standardization will allow imaging to better guide patient care and for medical images to potentially serve as “surrogate markers” to predict downstream patient health outcomes. This development in turn could reduce the duration, complexity, and cost of large clinical trials. Surrogate markers could similarly improve the efficiency of basic research which also relies heavily on medical imaging.

Standardized data coding, storage, and retrieval will improve the portability of a patient's health record and allow the creation of curated, trustworthy imaging databases that enable medical imaging research to leverage advances in big data and data sharing. Multiple NIH national health care activities, including the All of Us Research Programand key initiatives of the National Cancer Institute,have identified the benefits of a large data ecosystem in which data from clinical and basic research along with real patient clinical data from electronic health records (EHRs) are aggregated, organized, and made accessible for both machine and human analysis. Inclusion of quantitative imaging data would strengthen both initiatives.

The first step to achieving standardization is to coordinate the development and adoption of standard operating procedures for collecting, annotating, and archiving medical imaging data. The second step is to establish approaches for federating, storing, querying, and providing reliable access to medical imaging data. In addition, the data must be verified, validated, and secure to assure users of their integrity (i.e., that the data is trustworthy and accurate). Steps must also be taken to protect the data to assure patients that their private data are properly anonymized and stored securely without risk of compromise. Ultimately, the imaging data should meet the FAIR principles of being Findable, Accessible, Interoperable, and Reusable.

[4] *https://www.nih.gov/research-training/allofus-research-program*
[5] *https://www.cancer.gov/research/key-initiatives/*
[6] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4792175/*

Recommendation 1.1: Develop and promote adoption of standards for collecting, annotating, and archiving clinical imaging data.

Uniform procedures in image acquisition, incorporating accepted quality assurance and calibration protocols, will assure that imaging results are comparable from site-to-site, time-to-time, and patient-to-patient. Federal employees can play an important role in standards development and their participation should be encouraged consistent with Federal policy and agency priorities. For example, Federal employees have in the past worked with various bodies to develop guidelines and protocols for imaging studies that might serve as templates for further standardization of advanced imaging techniques, and current work at NIST aims to facilitate implementation of these guidelines by providing the measurement tools to demonstrate compliance. New and continued support of such activities should be encouraged, particularly in areas in which new technologies are entering clinical practice. Adoption of standard operating procedures (SOPs) for patient preparation, image acquisition, and data handling could be encouraged by funding agencies if studies that incorporate these activities were prioritized. Further, funding agencies should promote the clinical adoption of SOPs for the most common imaging procedures, including through outreach to professional societies. NIST and the NIH have experience in developing data standards and should work with external stakeholders to assure that the needs of the entire imaging community are met.

A consistent vocabulary with a standardized methodology is needed to interpret and annotate data. As the central coordinating body for clinical terminology standards within the Department of Health and Human Services (HHS), the National Library of Medicine should work with stakeholders to ensure the availability of a consistent vocabulary for annotating images. As the agency responsible for coordinating the development of documentary standards for data structure, transmission, and security, NIST should work to ensure that the annotated data sets are uniformly accessible.

Recommendation 1.2: Coordinate public and private efforts that combine, archive, and disseminate clinical data from multiple diagnostic studies.

The integration of clinical data with imaging data for more patient-centric analytics aligns with the Office of the National Coordinator for Health Information Technology[7] (ONC) initiative to ensure interoperability among digital health datasets maintained by health care organizations. The integration of various datasets should also include a definition of standards for usage and dissemination of lessons learned. Additionally, efforts to advance analysis of medical images could benefit from collaborations with national efforts to employ machine learning, such as Department of Energy (DOE) work to process large, complex datasets from experiments, simulations and observational facilities.

Federating existing medical imaging databases will promote innovation and provide a richer set of reference outcomes to guide patient care. The National Cancer Institute at NIH supports The Cancer Imaging Archive (TCIA),[8] a large archive of medical images of cancer accessible for public download, which could serve as a model for a federated medical imaging database. Under the All of Us research program, participants can share their EHR data through a pilot that leverages open standards to deliver data in a structured format with standardized vocabularies from disparate health records. This pilot could lend valuable expertise to efforts to federate imaging databases.

[7] *https://www.healthit.gov/newsroom/about-onc*

[8] *http://www.cancerimagingarchive.net/*

Refined standards for metadata and data formats are needed to enable cross-database communications and additional user resources. Tagging raw images could provide investigators with greater insight into the operational and situational conditions that generated the images.

Promoting coordination across Federal agencies and public entities could encourage barrier-free yet secure access to the data. Previous efforts like TCIA could provide valuable examples of how to balance the need for data encryption and access controls with ease of access for the user - particularly while databases under development contain personal health information. An additional source of guidance from ONC is A Shared Nationwide Interoperability Roadmap[9] developed to facilitate the secure, efficient, and effective sharing and use of electronic health information.

Recommendation 1.3: Establish an infrastructure that will provide validation and quality assurance for clinical imaging data.

For a federated database to be trusted (and therefore used), strict quality assurance and curation of the data are critical. Curation should include ensuring that reported quantities are traceable to appropriate national measurement standards and should verify the appropriateness and implementation of reconstruction and analysis methods. To support curation, encryption standards and digital and physical phantoms should be developed and adopted that meet the unique needs of clinical imaging data. New encryption standards are needed that enable easy access to the data and a mechanism to add additional patient-specific records to data sets (e.g., to correlate diagnostics, treatments, and outcomes), while simultaneously protecting the integrity of the data and hiding patient identities. Physical phantoms are objects with precisely known properties that can be scanned by an imaging device to test performance, accuracy, resolution, etc. They are needed to provide the basis for comparison among datasets through traceability to national standards.

Similarly, digital phantoms are datasets with precisely known properties that are needed to validate image analysis software and reconstruction/correction algorithms.

2. Apply Advanced Computation and Machine Learning to Medical Imaging

There is an opportunity to transform the current standard of medical care by applying artificial intelligence computational capacities such as machine learning and deep learning to the analysis of medical images. Curated data sets would serve as the basis for developing and testing algorithms for accurate and sophisticated machine-assisted analysis of images, correlation with disease subtypes, and linkage with genetic and metabolic pathways. These enhanced analytic capacities can help improve image acquisition and decision making toward diagnoses and suggest clinical interventions as well as drug treatment options. A diagnostic cockpit that combines imaging data in a digital interface with other patient data such as clinical, laboratory, and genomic findings would facilitate optimal and tailored management of each patient. Cumulatively, these computational processes will enhance clinical decision making and refine predictive analytics for wider support of health care delivery.

[9] *https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final- version-1.0.pdf*

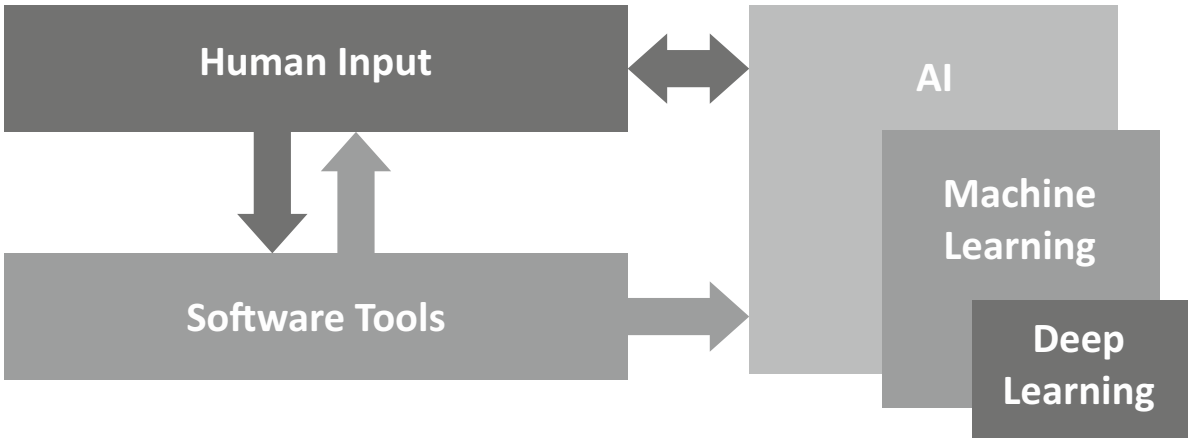

Figure 2. New Tools for Medical Imaging

The application of AI techniques to large, standardized databases is foundational for a concept the IWGMI enthusiastically supports: the diagnostic cockpit, a tool that would tie together diverse research efforts, timely data, and evidence-based approaches. Specifically, the medical imaging community must work with the medical informatics and clinical quality improvement and research communities to ensure that imaging is included in efforts to improve clinical decision support.

Inside the cockpit, emerging and novel multi-parametric computational and analytical methods, including deep machine learning, both supervised and unsupervised, would scrutinize large, standardized databases that combine patient-specific and population-based clinical, laboratory, genomic, demographic, and quantitative imaging data. With targeted investment in R&D, the cockpit could become a valuable tool for both clinical and research applications.

For the clinician, the diagnostic cockpit would:

- Assist the physician interpreting the imaging scan, e.g., through quantitative image analysis;
- Integrate the current scan result with results of all prior patient imaging and diagnostic tests, known patient-specific clinical and demographic data, and population-based data;
- Update individual patient risks and health priorities in real time;
- Present management options with probabilities grounded in evidence-based appropriate use criteria to better inform patient-doctor shared decision-making; and
- Prioritize and streamline the information presented to the physician in order to speed accurate diagnosis.

This next-generation clinical decision support would result in a "personalized," evidence-based guideline, attuned to the needs and values of the individual patient at hand.

In turn, researchers could employ this tool to efficiently generate numerous observational studies, which, through appropriate design and extremely large sample sizes, could approach the narrow confidence intervals and validity usually seen only in randomized controlled trials (RCTs). Although such studies would not render the RCT obsolete, they would have the advantage of stronger generalizability (the traditional weakness of RCTs). The strategies

underlying the diagnostic cockpit, in both its clinical and research dimensions, apply to and could help accelerate national health care activities such as All of Us and the key initiatives of the National Cancer Institute.

Recommendation 2.1: Support focused artificial intelligence research and development for applications in medical imaging.

AI technology is developing and maturing at a rapid pace. There have been considerable private investments in AI, with applications crossing many disciplines, including medicine. Still, strategically directed R&D funds could accelerate advances in AI that would directly support improved value in medical imaging. The relevant research efforts would also be furthered by the availability of federated databases (Recommendation 1.2) that could provide a wealth of past outcomes on whichto base predictions and prescriptions. In addition, participation of funding recipients in performance tests could help to benchmark progress and provide measured feedback on the current state-of- the-art. Funding agencies will contribute to shaping the future of medical imaging applications through support of the basic research needed to apply AI to image analysis.

Recommendation 2.2: Establish a public-private forum to coordinate efforts and interests in the artificial intelligence and medical imaging communities.

Innovative algorithms are required that can integrate logic, evolution, statistics, and neural network frameworks, similar to human thought processes. A public-private forum is recommended to bring together relevant participants to align efforts to develop standards for interoperability and effective information exchange regarding patient records. Expertise in pattern recognition in images and in machine learning should be sought with the aim of bringing lessons learned in related fields to bear on the challenges faced in AI-assisted clinical decision support. The IWGMI has opened discussions with the NSTC Machine Learning/Artificial Intelligence subcommittee of the Committee on Technology to plan such a joint forum.

Recommendation 2.3: Support the development of a diagnostic cockpit as both a clinical and research tool that integrates imaging data with other electronic medical data sets.

The diagnostic cockpit would integrate diverse data feeds in a single digital interface to allow imaging data to be analyzed in the fullest contexts possible. To maintain the most comprehensive analyses, the diagnostic cockpit must flexibly accommodate and ultimately suggest new and innovative diagnostic strategies. Advances in reconstruction algorithms, for example, enabled by increased computational capacity can now reduce a 45 minute MRI of the brain involving multiple types of scans to a few minutes without sacrificing quality or accuracy. This improvement is achieved by focusing on a few key scans and then shortening the image acquisition and processing times. For example, a 2014 study found that a condensed breast imaging protocol with 2 scans taking 3 minutes to acquire can be fully and accurately interpreted in 30 seconds.[10] This approach compares favorably to a conventional breast MRI of 8 scans taking 30 minutes or longer to acquire and interpret. With similar examples in cardiac and brain imaging protocols, the potential clinical and economic impacts of efficient protocols are significant.

[10] *https://www.ncbi.nlm.nih.gov/pubmed/24958821*

R&D into high-speed and highly efficient diagnostic protocols should be prioritized across multiple Federal agencies. The development of appropriate reconstruction algorithms (tailored to judiciously streamlined scanning protocols) will be critical and will ultimately enable drastic acceleration of clinical workflows, resulting in more efficient and cost-effective health care. The ideal diagnostic cockpit will assist in the development of streamlined protocols by analyzing which data are and are not critical to diagnoses, making connections that the human observer alone might miss.

3. Accelerate the Development and Translation of New, High-Value Imaging Techniques

Greater collaboration and knowledge sharing among Federal agencies during the development of new medical imaging techniques could accelerate the evaluation and approval of high-value, innovative technologies and accelerate translation from laboratory to market—from bench to bedside, in medical parlance. Better communication among Federal agencies can facilitate awareness of new studies or ideas and clarity about which agency is cultivating those areas of expertise. Improved coordination among Federal bodies on their related health care missions may reveal new ways to best leverage limited resources. Harmonizing Federal efforts to promote innovation and facilitate clinical evaluation of emerging imaging products will make for a more efficient journey through the multiple regulatory processes and translation into clinical practice. Ultimately, improved coordination should bring innovations to patients more quickly and at lower cost.

Currently, much research is conducted without sufficient consideration of commercialization potential or reimbursement concerns. Academic and industrial investigators often submit research proposals to funding agencies such as the National Science Foundation (NSF), the Department of Defense (DOD), or NIH without knowing what clinical trial designs and outcomes may ultimately be needed for Food and Drug Administration (FDA) approval or Centers for Medicare & Medicaid Services (CMS) reimbursement. The relatively narrow requirements for a biomedical research grant can differ from the broader evidence required to make policy decisions about regulation or reimbursement. Better coordination and education among academic and industry investigators, science funding agencies, FDA, and CMS could remove some of the barriers that slow the translation of useful products (including imaging) into clinical practice by harmonizing the needs of biomedical scientific research with evidence-based policymaking.

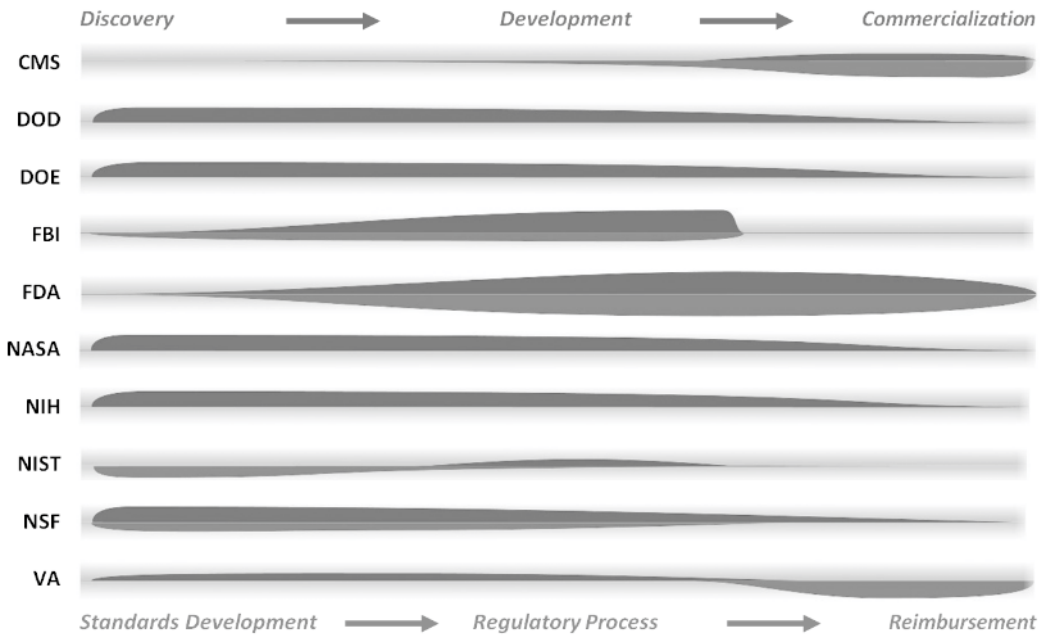

Figure 3. Select Federal Stakeholder Roles in Medical Imaging and Coordination Opportunities

To remove some of the barriers to translation, Federal agencies could better coordinate their different missions. Figure 3 highlights some of the opportunities for closer coordination among Federal agencies based on the overlapping roles they play in research and translation along the development pathway. The blue lines illustrate the R&D pathways from discovery through commercialization, and red the regulatory pathways from standards development through reimbursement, with the thickness of each line indicating the relative size of that agency's role over time. The graphic illustrates that DOD, DOE, the National Aeronautics and Space Administration (NASA), NIH, and NSF all fund basic and early-stage applied research that often provides the scientific discoveries underlying new imaging technologies and therefore should be well coordinated. NIH funds basic and clinical research to improve human health while NIST is simultaneously developing the data and measurement infrastructure—methods and standards—that enable the future clinical evaluations. FDA regulates new imaging technologies and develops evaluation strategies through research to support regulatory decision-making. CMS and the Department of Veterans Affairs are primarily payers for medical products and services. Note that FDA and CMS have different mandates reflecting different statutory authority making coordination key to successful translation of new imaging technologies. FDA thresholds are based on "safety and effectiveness," with a focus on technical and analytical validity. In contrast, the CMS threshold is "reasonable and necessary," with a focus on clinical utility that is supported by evidence in the peer-reviewed medical literature.

Recommendation 3.1: Get to diagnosis more quickly and cost-effectively.

Streamlined medical imaging techniques can arrive at the right diagnosis more quickly, lowering health care costs. Future research should aim to develop imaging protocols that decrease time in the scanner and

improve work flow. These new protocols may be combined with quality improvements and appropriate use criteria initiatives to better select optimal diagnostic tests for patients. Appropriate use criteria assess whether advanced diagnostic imaging is indicated for a particular clinical scenario and, when it is, in what combination diagnostic tests should be performed. These appropriate use criteria are embedded within the evidence-based, best practice care pathways that are incorporated and constantly improved inside the diagnostic cockpit. Research dollars can be more effectively directed to establish best practices and criteria for the appropriate use of medical imaging.

Recommendation 3.2: Make high-value imaging techniques more accessible.

Reducing the cost of medical imaging equipment and increasing its portability can increase access to medical imaging for research, diagnosis, and treatment purposes. In particular, more affordable systems will increase patient access to medical imaging at smaller clinics and research centers. Lower cost point-of-care systems, designed for the battlefield or emergency use, have already proven valuable in extending care to underserved populations. DOD, NIBIB, NASA, and others support research portfolios to develop lower-cost, lightweight MRI and portable ultrasound, an example of which is shown in Figure 4.[11] The same agencies have supported efforts in telemedicine, leveraging modern networking technologies to make world-class diagnostic capabilities accessible in the most remote settings. The drive towards increased accessibility will make systems smaller, cheaper, faster, and potentially better diagnostic tools.

Figure 4. A new pocket-sized, ultrasound imaging device developed with NIH/NIBIB support will help doctors more safely and easily perform epidural blocks and spinal taps.

Recommendation 3.3: Conduct regular outreach efforts to increase dialogue among Federal, academic, clinical, and industrial stakeholders on their respective roles, evidence-based research, trial design, and clinical translation of high-value techniques.

For newly developed technologies to have clinical impact, they must first navigate the regulatory and reimbursement approval processes. For recommendations 3.1 and 3.2 to ultimately improve the American health care system, the bench-to-bedside pipeline must be streamlined. The IWGMI has identified some areas where this goal can be achieved through improved interagency coordination, but a landscape analysis is needed to identify additional areas for improvement.

Some mechanisms for interagency coordination already exist (e.g., FDA-CMS parallel review), but a detailed analysis would assess where gaps exist or current programs could be bolstered.

Mechanisms such as an existing memorandum of understanding (MOU) among agencies allows experts to participate in discussions with manufacturers or other stakeholders during regulatory submissions when that adds value to the agencies or the private sector. For example, firms and/or CMS staff may benefit from CMS participation in FDA pre-submission discussions of a clinical trial for a new imaging product. Expanding on this concept, an MOU could be drafted to allow, for example, NSF, NIST, CMS, and FDA staff to participate in NIH concept or protocol reviews that build on a technology developed through an NSF grant. NSF could help clarify technical points in the grant application while NIST, CMS, and FDA could advise on studies that, if funded and conducted as designed or with some modification, could support FDA approval and CMS policy in the same trial.

Collaboration can build on existing relationships, facilitating sharing of experts among agencies through, for example, interagency personnel exchanges or the HHS Entrepreneur-in-Residence program.[12] The NSF-FDA Scholars-in-Residence program[13] is another mechanism to heighten awareness of the regulatory process for academic innovators. An expansion of this program could increase the opportunities for medical imaging technology developers to gain access and expertise in regulatory and reimbursement pathways through on-site collaboration and training.

Federal agencies should encourage their subject matter experts to participate in outreach and collaborative activities to support specific technology development needs. For example, in telemedicine applications, NASA could play a central role. In image recognition, processing, and data mining, NASA, the Federal Bureau of Investigation, NIST, and other agencies have expertise to share. DOE capabilities in advanced computing and data handling are already being used to accelerate discovery in cancer research and DOE contributions to developing biomarkers are helping facilitate disease detection.

[12] *https://www.hhs.gov/idealab/eir-program/*

[13] *https://www.nsf.gov/funding/pgm_summ.jsp?pims_id=5605*

4. Promote Best Practices in Medical Imaging

As standards and advancing technologies drive new imaging practices through a streamlined translational pipeline, the impact on health care will depend on their adoption by clinical practitioners. Technology is driving innovation in clinical decision support, but new imaging practices will require education and training so that health care professionals can maximize value to achieve optimal health outcomes, knowing which types of imaging studies are most effective and clinically relevant in different circumstances. In addition, evolving analytic software systems and technologies for sharing medical imaging data will increase demand for new skills and training in the workforce. Priorities include disseminating knowledge about new imaging practices, developing competencies and operational skills for effective use of innovative technologies, and reorganizing workflows to improve the productivity of medical imaging operations as practices change. In light of advances in medical imaging, a well-trained workforce is essential. Figure 5 illustrates a possible future for medical imaging.

	Referral	Scan	Interpretation	Next Steps
Current Practice	Driven by professional habit, time pressure, defensive medicine, networks	Lengthy techniques or imaging series	Qualitative: much information is discarded	Further imaging or surgical consultation
Future Possibility	Driven by evidence-based criteria for appropriate use	Faster, high-value techniques with shorter targeted protocols	Quantitative assessments: analytical tools mine image data for more useful information	Reduced need for further imaging: more timely and precise diagnostics and treatment

Figure 5. A New Paradigm in Medical Imaging

competencies and operational skills for effective use of innovative technologies, and reorganizing workflows to improve the productivity of medical imaging operations as practices change. In light of advances in medical imaging, a well-trained workforce is essential. Figure 5 illustrates a possible future for medical imaging.

Recommendation 4.1: Define methodologies that support dissemination of knowledge, competencies, and operational skills towards efficient use of innovative technologies.

Methodologies include, but are not limited to, outreach programs to professional societies and user populations to increase knowledge and operational skills, inclusion of knowledge metrics for professional/academic accreditation, and inclusion of appropriate use criteria for health care delivery reimbursement and research support. As clinical

workflows evolve to leverage innovations in imaging, the roles of practitioners will undergo seismic shifts. Outreach, especially to professional societies, will be essential to promoting acceptance of the changing roles of researchers, imagers/technicians, and requesting physicians.

Recommendation 4.2: Employ cost-effective, accredited tools that promote wider engagement of practitioner populations.

Evolving analytic software systems when applied to medical imaging, such as the recommended diagnostic cockpit and technologies for sharing medical image data, will increase demand for new skills and competencies in the workforce needed to effectively evaluate and utilize these new technologies. Professional societies can be an effective means of reaching the clinical community. Recipients of Federal research funds can also be encouraged to participate in continuing education programs, both as lecturers and as attendees. Similar participation by Federal employees with research, standards, and regulatory backgrounds should also be prioritized.

Recommendation 4.3: Establish best training practices and priorities for educational institutions to prepare students for success in health care research and delivery.

Projections for workforce growth of radiology technologists and MRI technologists are 12% and 14%, respectively, between 2016 and 2026.[14] This growth alone represents over 20,000 new jobs. The field of health information technicians is projected to add another 27,800 jobs during this time period.[15] Because workforce needs are changing rapidly with technology advances, these represent only a fraction of the new positions likely to be created.

Outreach to professional societies and institutes of higher education to establish best training practices and encourage their adoption should be prioritized. Diagnostic imaging technologists typically enter the field with an Associate's degree,[16] so it is critical to establish efficient communication with community colleges and professional societies to assure that the next generation of technologists are equipped with the diverse skill sets required by rapidly advancing medical imaging technologies.

Conclusion

To reach a goal of improved value in medical imaging research and practice, the IWGMI recommends adoption of standards for image acquisition and data handling, which will allow improved leveraging of advanced computation paradigms. Advances in artificial intelligence and deep machine learning will be critical to optimizing value and access to modern diagnostics. To improve translation of resulting innovations to clinical practice, the IWGMI recommends focused investment of research dollars and improved coordination among Federal agencies to streamline the bench-to-bedside pipeline. Finally, to assure full utilization of the most cost-efficient, high-impact innovations in medical imaging, the IWGMI recommends extensive outreach focused on promotion of best practices in imaging. In summary, the effective use of smaller, faster, and cheaper imaging technologies defines our vision for the future of medical research and practice. This document is intended to serve as a roadmap to guide and improve the coordination of Federal R&D efforts toward realizing this vision and ensuring America's global leadership in medical innovation.

[14] *https://www.bls.gov/ooh/healthcare/radiologic-technologists.htm#tab-6*

[15] *https://www.bls.gov/ooh/Healthcare/Medical-records-and-health-information-technicians.htm*

[16] *https://www.bls.gov/ooh/healthcare/diagnostic-medical-sonographers.htm*

List of Acronyms

AI	artificial intelligence
CMS	Centers for Medicare and Medicaid Services
CT	computerized tomography
DOD	Department of Defense
DOE	Department of Energy
DOTreas	Department of the Treasury
EHR	electronic health record
EPA	Environmental Protection Agency
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
fMRI	functional magnetic resonance imaging
HHS	Department of Health and Human Services
IWGMI	Interagency Working Group on Medical Imaging
MOU	memorandum of understanding
MRI	magnetic resonance imaging
NASA	National Aeronautics and Space Administration
NIBIB	National Institute of Biomedical Imaging and Bioengineering
NIH	National Institutes of Health
NIST	National Institute of Standards and Technology
NSF	National Science Foundation
NSTC	National Science and Technology Council
OMB	Office of Management and Budget
ONC	Office of the National Coordinator for Health Information Technology
OSTP	Office of Science and Technology Policy
PET	positron emission tomography
R&D	research and development
RCT	randomized controlled trial
SOP	standard operating procedure
TCIA	The Cancer Imaging Archive