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**The Academy for Radiology and Biomedical Imaging Research's
Coalition for Imaging & Bioengineering Research (CIBR)'s**

Research Roundtable Discussion

Monday, May 15, 2023

Washington, DC

Summary

Mobile Imaging for Cancer to Reach Underserved or Immobile Patients

Discussion Leads: [Q.Y. Ma, PhD, CEO Time Medical System Corporation](#)
[Christian Eusemann, PhD, Vice President, Research and Innovation,](#)
[Collaboration Officer, Siemens Medical Solutions](#)

This opening discussion topic focused on strategies to address cancer screening in underserved populations, with a particular focus on using mobile imaging centers (vans, trucks, trailers, etc.) to provide service in the community.

As an example, Dr. Ma presented a program his company is launching in collaboration with Memorial Sloan Kettering Cancer Center to deploy mobile MRI units to offer breast cancer screening. The program will rely on artificial intelligence (AI) assistance and telemedicine to interpret the studies. The vision is to grow the program to the point where it can provide screening to 20,000,000 women annually.

Attendees discussed various considerations for and challenges to relying on mobile imaging and remote interpretation. These considerations may vary for those designed to address issues in remote rural areas vs. underserved communities in urban areas.

A major need for programs such as these is a plan for how to handle patients identified by a mobile screening program as in need of further diagnostic assessment and/or treatment. Barriers include lack of access to such services and inability to afford co-payments. In many cases patients can be lost to follow-up because they cannot be located to inform them of their results. Having partners in the targeted communities may help with rates of participation as well as successful follow-up.

These challenges are common to all types of mobile cancer screening programs (e.g., lung cancer screening, colonography, etc.). The method for prioritizing which cancer screenings programs to pursue is not clear. In many cases screening does not offer a good business case for the institution supporting it, unless the patients seek out follow-up and care in the sponsoring medical center.

There are also questions about the appropriate use of AI in these programs. Can AI be used to rule out normal studies, allowing humans to focus on the studies in need of greater diagnostic skill and judgment? It was noted that the [Mammography Quality Standards Act and Program \(MQSA\)](#) mandates that all screening studies be interpreted by a human. Attendees agreed that there may be a role for AI algorithms in prioritizing the queue so that questionable results are interpreted more quickly. Other AI applications may be able to handle patient scheduling or identify where to bring the mobile units.

It was also observed that many medical imaging devices have significant power requirements. Because of this problem, it is not unusual to find that mobile imaging units are operating in close proximity to hospitals, which defeats the purpose of seeing patients in the community. Low field MRI scanners can be employed, but the algorithms that refine the medical images can also amplify imaging artifacts.

Further, workforce shortages in imaging are already being experienced. Radiologic technologists are already in high demand. Identifying trained staff to travel with the mobile units to collect the studies can be a significant problem. There is also often a requirement that the person driving the mobile unit be a licensed truck driver. This, too, can be a personnel challenge.

Increasing screening services to individuals in medically underserved areas is a sociologic challenge that technology alone will not be able to solve. Essential changes to enable success may include:

- Building mechanisms in the payment system to fund the services
- Recognizing that the solutions will be different in rural vs. urban areas
- Building in strategies for improved follow up by losing fewer patients
- Bolstering the imaging workforce

Regulation in Artificial Intelligence (AI) and Imaging

Discussion Leads: [Judy Wawira Gichoya, MD, MS, Assistant Professor, Emory University School of Medicine](#)
[Qi Duan, PhD, Program Director, Division of Health Informatics Technologies, National Institute of Biomedical Imaging and Bioengineering](#)

The FDA classifies approved medical devices into three categories, Classes 1, 2, and 3, based on the level of perceived risk and the regulatory controls therefore deemed necessary. New AI algorithms seeking approval may be placed in different classes when used for different clinical questions. AI algorithms do not require FDA approval when serving supportive/administrative functions or promoting wellness. Some algorithms can be considered through the 510K mechanism, requiring only demonstration of substantial equivalence to a previously approved device. Software-assisted medical devices have been seeking de novo approval as well as 510K approval since the 1990's. Software in medical devices can be Class 2 in some contexts and Class 3 when used in other, specific ways.

In January 2021, the FDA released “[*Artificial Intelligence and Machine Learning Software as a Medical Device Action Plan*](#).” This was followed in September 2022 with a final guidance, “[*Clinical Decision Support Software*](#),” and in April 2023 with draft guidance, “[*Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning-Enabled Device Software Functions*](#).” Each of these informs readers about the process of gaining regulatory approval for AI algorithms.

One barrier to developing, validating, and regulating AI algorithms is the protections around access to medical records. This is true not only in the context of regulation but in meeting the NIH mandate for public data-sharing by their funded investigators. Patients can access their own data and put them into the public domain, but investigators and data control boards are bound by significant privacy restrictions that limit algorithm development.

Another problem to be alert to when developing, evaluating, and deploying algorithms is the bias that can be “baked in.” This risk was acknowledged in a joint statement by the Bureau of Consumer Financial Protection, the Department of Justice, the Equal Employment Opportunity Commission, and the Federal Trade Commission, entitled “[*Joint Statement on Enforcement Efforts Against Discrimination and Bias in Automated Systems*](#).” Such biases have been demonstrated in publicly used large language models, particularly ChatGPT, but have also been identified in algorithms deployed for use in medical settings. Potential users must be aware of the biases associated with algorithms they are considering deploying, weighing the potential, albeit biased information they can gain against the effect those biases may have on clinical decision-making. It may be a valid choice to deploy an algorithm with known flaws, provided the users are aware and believe that some information is better than none. Dr. Gichoya observed that the system needs to incentivize people to look for and correct bias in clinical algorithms.

The field of AI is a fast-moving domain, resulting in a good chance that the regulatory process may take enough time that the algorithm has become obsolete by the time it is approved. There may be a need for an independent body to consider and “approve” new algorithms.

Using Real World Evidence to Support Device Approval

Discussion Leads: Robert Ochs, PhD, *Director Office of Health Technology (Radiological Health), Food and Drug Administration*

[Brad Bower, PhD, Data and Technology Advancement National Service Scholar, National Institute of Biomedical Imaging and Bioengineering](#)

Real world data are gleaned from routinely collected information about patient health status and/or health care, such as electronic health records, insurance claims registries, etc. When these data are analyzed, they may yield real world evidence (i.e., information about the use and benefits vs. risks of medical products and devices). Examples include observational studies based on systematic analysis of an existing dataset and prospective studies designed around clinical information documented as part of patient care.

Consideration of real-world data opens the door to more diverse datasets than ones generated by controlled clinical trials. It can also provide information about medical situations where clinical studies are not possible, practical, or ethical. It can be less burdensome than performing randomized controlled clinical trials and allows regulators to assess devices based on their real-life clinical performance.

The FDA can potentially use real world evidence to approve new indications, advise on clinical trial designs, and provide information to supplement controlled trials. Post-market monitoring of real-world data can inform safety communications, clinical guidelines, and reimbursement decision-making.

Regulatory requirements for approval and continuing use must be based on scientific evidence that is valid. As such, use of real-world evidence can only occur when evaluators are confident that the data were accurately and reliably captured for the question under consideration.

To support the systematic collection of real-world data, the NIH is creating a data ecosystem, currently comprising more than 130 data repositories, both domain-specific and general. The NIH data sharing policy for funded research promises to enrich and expand this ecosystem, which can be used to support AI algorithm development and validation.

An imaging-focused example of one of these repositories is the [Medical Imaging and Data Resource Center](#) (MIDRC), a collaborative program of imaging societies housed at the University of Chicago and funded by the NIBIB. MIDRC comprises curated images with accompanying clinical data and annotations. It is subdivided into an Open Discovery Data Commons and a smaller, sequestered dataset. The Open Data Commons is publicly available for creation and testing of algorithms and also has a library of existing algorithms and software tools. The sequestered data can be made available to investigators for a specific, pre-identified purpose. MIDRC was launched shortly before the onset of the COVID-19 pandemic and adopted COVID-19 diagnosis and management as its first use case. It is now beginning to prepare for expansion to a new clinical use case.

NIBIB is also working to establish the *Sustainable Ecosystem for AI in Medicine* (SEAM), based on a NIBIB-initiated, private partnership initiative in partnership with all of NIH and the FDA. It aspires to “democratize” access to vetted data for algorithm development and validation and to build a library of regulatory science and medical device development tools to support product development and validation, as well as post-market surveillance.

For this and similar efforts to succeed, it will be necessary to transition to a clinical investigation system where the generated data is tokenized/deidentified up front, as the time of its entry into the research record. Because the establishment of these repositories and libraries is so expensive and labor-intensive, both private and public funding will be required. The estimated cost of new use cases is \$3,000,000 to \$5,000,000 each.

A rate-limiting factor is the need for human curation and annotation. The question is how to foster innovation without requiring this labor-intensive process?

Areas of opportunity for research are routinely enabling the connectivity and inter-operability of clinical information through early tokenizing and making sure that clinical studies generate well curated datasets. An important need for the clinical setting is to educate the healthcare system providers not to use AI algorithms “off label” (i.e., for an application other than its validated use).

Update on [Advanced Research Projects Agency for Health \(ARPA-H\)](#)

[Ileana Hancu, PhD, is a newly minted program manager at ARPA-H](#), joining two other colleagues. ARPA-H is modeled after the Defense Advanced Research Projects Agency, a part of the Department of Defense. ARPA-H was established with the mission of accelerating better health outcomes for everyone. Launched in March 2022, its Director, Dr. Renee Wegrzyn, has begun to establish its small footprint in Washington DC with the recruitment of program managers tasked with getting its first projects up and running.

ARPA-H has released its first Open Broad Agency Announcement (BAA) calling for ideas for disruptive solutions to difficult clinical questions and barriers. ARPA-H is intended to create radical change and to be more flexible and empowered than many research agencies. Programs will be directed by the Program Managers, and targeted calls for proposals will be issued to accompany the BAA.

All ARPA-H staff, including the Director, and all funded projects are time-limited, with a horizon of six years or less (eight years for the Director). Projects will have aggressive milestones and will be terminated if the milestones are not met or if research results do not support the hypothesized solution. At the conclusion of the ARPA-H support period, successful projects will be spun out to other agencies or to industry so they can be sustained and implemented.

The four broad areas of focus for ARPA-H currently are:

- Health Science Futures—expanding what’s technically possible
- Scalable Solutions—reaching everyone quickly through rapid scalability, access, and affordability
- Proactive health—keeping people from becoming patients
- Resilient systems—developing mechanisms to enhance system stability and reliability

Interested investigators with proposed solutions to challenges in one of those areas are encouraged to submit a three-page proposal following the format available on the ARPA-H website. Promising ideas will result in the submitter being invited to develop a formal proposal and project budget. ARPA-H will work to connect investigators and process supporters in service of program goals. Broad cooperation will be encouraged and enabled.

ARPA-H will have three centers, from which their staff will branch out, supporting multiple programs. The first center, federal stakeholders, and operations have been established in Washington DC. A search is underway for geographic locations for the other two envisioned centers, customer experience and investor catalysts.

All parties are strongly encouraged to monitor ARPA-H communications for new program announcements as they are released and to submit all proposed projects.

Roundtable attendees were encouraged to email any questions to Dr. Hancu at ileana.hancu@arpa-h.gov, message her through the ARPA-H website, [or follow her on LinkedIn](#).

Questions on the above summary or this Research Roundtable discussion can be directed to the Academy’s Executive Director, Renee Cruea, MPA, rcruea@acadrad.org.

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