AMERICAN ACADEMY OF OPHTHALMOLOGY®

Editorial

Joint American Academy of Ophthalmology and Association for Research in Vision and Ophthalmology Policy Statement: The Time for Digital Imaging Standards Implementation Is Now

Aaron Y. Lee, MD, MSCI - *Seattle, Washington*
SriniVas Sadda, MD - *Los Angeles, California*
Flora Lum, MD - *San Francisco, California*

The American Academy of Ophthalmology (AAO), representing more than 27 000 ophthalmologists worldwide, and the Association of Research and Vision in Ophthalmology (ARVO), representing more than 8000 eye and vision researchers globally, have joined forces to emphasize the importance of digital imaging standards for the advancement of research and clinical care. In the past, both organizations have issued statements calling for the implementation of imaging standards.[1,2] A new chapter of collaborations and coordination is opening, with the steps being set in motion from the May 10, 2022, National Eye Institute Ocular Imaging Workshop. More than 250 participants and 30 panelists, including representatives from the Veterans Administration, Department of Defense, National Eye Institute of the National Institutes of Health, United States Food and Drug Administration, and the Office of the National Coordinator of Health Information Technology discussed the benefits and barriers to the implementation of digital image standards for device and picture archiving and communications systems (PACS) vendors.

The use of standard formats for digital imaging is in the best interests of the ophthalmic community and the patients they serve…

The use of standard formats for digital imaging is in the best interests of the ophthalmic community and the patients they serve by allowing the field of ophthalmology and vision science research to progress along the path of improved electronic workflow, data interoperability, and novel artificial intelligence systems. The most fundamental benefits expected from standardization of digital imaging are not only economic reductions in the total cost of service delivery, but also the quality-of-care improvements. Improvements in clinical care include the ability to make timely and appropriate treatment decisions based on combining data from different imaging devices and the use of resources required to deliver that care. Plug-and-play compatibility and interoperable product alternatives should assist decision makers in selecting instruments, PACS, and so forth that work together seamlessly without the need for special customized efforts and costs for installation and support. Moreover, the ability to transport ocular imaging as part of the overall medical record as patients transition care from one provider to another will improve health care efficiency and result in better clinical management. Finally, full adoption of ocular imaging standards will enable a comprehensive analysis of large global datasets that can facilitate critical analysis in ophthalmic disease epidemiology and artificial intelligence algorithm development. Most radiology and cardiology devices already store raw data as per the Digital Imaging and Communications in Medicine (DICOM) standards, allowing digital workflow and delivery of images.[3] The AAO and ARVO believe that the ability to exchange information is critical and that this interoperability is based on a commitment to shared standards among vendors.

The lack of progress and broader engagement has been a source of frustration and has led to a gap in the development of new or revised DICOM standards in the past several years. Although awareness of DICOM in the vendor and user communities has heightened, many manufacturers still do not participate in the standard development process, nor do they use existing standards in their products. Companies are weighing the increased resource requirements to implement these standards against the perceived scarcity of market demand, a lack of willingness to pay a higher price for fulfilling these requirements, and the absence of current regulatory mandates requiring DICOM compliance. These factors often are cited as important reasons for not making the business decision to commit the required resources to complete DICOM implementation. Concerns also exist that DICOM conformance statements are not certified by any third party and do not reflect the true extent of implementation. The requirements of clinical users; pharmaceutical, biotechnology, and other funders of clinical trials; and government agencies (both users and regulators) for interoperability and compliance with the DICOM format will need to be articulated and crystallized for manufacturers to make modifications. Companies, too, should be more intentional and should focus on the clinical and research use cases for interoperability to meet the needs of their market better.

We believe that the collective community of clinicians, researchers, industry, and government agencies—regulatory and research oriented—is ready to take concrete steps forward to identify and address the gaps in standards implementation. The AAO and ARVO agree that this path forward is justified by patient safety considerations as well as quality-of-care concerns. A standards-based approach

https://doi.org/10.1016/j.ophtha.2022.07.034
ISSN 0161-6420/22

enhances quality: data will be less likely to be lost or unusable in the future, and the right data are connected to the right patient. Three major government agencies, the National Eye Institute, the Food and Drug Administration, and the Office of the National Coordinator of Health Information Technology, planned and convened the workshop and share a strong partnership and commitment to create the proper levers, benefits, and incentives to recognize manufacturers that implement DICOM standards. We believe that the establishment of these levers, benefits, and incentives for recognition is crucial for future success with a deeper buy-in from all stakeholders. This could be in the form of expanded global marketability, enhanced marketability to digital health companies, reduced time to market, recognition through voluntary certification or validation, enhanced ability for performing research, approaches to include interoperability standards in electronic health records that interface with PACS, or incorporation of user requirements into contracts. By implementing digital imaging standards broadly in ophthalmic imaging devices and PACS, the ophthalmic community collectively can build a better infrastructure for the future of digital eye care, clinical artificial intelligence systems, and eye and vision research, with all relevant data available at the point of care with portability across health care settings and the broad array of clinical and vision research environments.

Recommendations

The AAO and ARVO recommend the next steps to achieve the objectives of digital image standards adoption, with the first 2 steps already presented in the AAO's 2020 statement[1]:

1. Imaging device and PACS manufacturers provide machine-readable, discrete data for user-selected reports of ophthalmic imaging or functional testing.
2. Imaging device and PACS manufacturers use lossless compression for pixel or voxel data to encode the same raw data as used by manufacturers.
3. Manufacturers of imaging devices and PACS vendors provide their conformance statements to the AAO and ARVO to house in a single website for visibility and transparency.
4. The DICOM conformance statement website provides a forum for clinicians and researchers to comment on real-life implementation and to receive feedback to and from the manufacturers, and would provide education to clinicians and researchers on the benefits of standards implementation and include Request for Proposal language samples to specify DICOM standards in contracts and to articulate specific market needs to the manufacturers.
5. Imaging device manufacturers and PACS vendors provide timelines for when devices that are not yet DICOM compliant will adhere to digital imaging standards.
6. Imaging device manufacturers and PACS manufacturers join and become members of the DICOM Standards Committee as a demonstration of their commitment of resources and staffing to the standards development process.
7. Manufacturers agree that new products will adhere to applicable DICOM standards.
8. For outdated products that will not be compliant with DICOM standards, the manufacturers provide the open-source software for purchasers to extract their own data or provide file specifications for how to read the imaging data from proprietary legacy file formats.
9. Imaging device manufacturers and PACS manufacturers identify the inventory of DICOM standards implemented and reviewed to determine which standards are current, which standards need updating, and what imaging methods are not covered by current standards to be able to formulate new work items.
10. Imaging device manufacturers, PACS manufacturers, government agencies, clinicians, and researchers work together to define and secure the financial, staffing, and administrative resources needed to accomplish these updates and new work items.

Footnotes and Disclosures

Disclosure(s):

All authors have completed and submitted the ICMJE disclosures form.

The author(s) have made the following disclosure(s): A.Y.L.: Consultant — Genentech, Johnson & Johnson, Gyroscope, United States Food and Drug Administration; Financial support — National Institute on Aging and National Eye Institute, National Institutes of Health, Carl Zeiss Meditec, Santen, Regeneron, Microsoft, Research to Prevent Blindness, Inc, Lowy Medical Research Institute, Ryan Initiative for Macular Research; Lecturer — Topcon Corporation; Patent — ResMatch; Board member — American Academy of Ophthalmology, Collaborative Communities of Ophthalmology; Equity owner — Index Fund ETF: SPY

S.S.: Consultant — Amgen, Apellis, AbbVie/Allergan, Biogen, Boehringer Ingelheim, Jannsen, Nanoscope, Pfizer, Novartis, Bayer, Regeneron, Roche/Genentech, Oxurion, Astellas, 4dMT, Optos, Centervue, Heidelberg Engineering, Notal; Financial support — Carl Zeiss Meditec, Optos; Data Safety and Monitoring Committee or Advisory Board — Regeneron; Lecturer — Nidek, Heidelberg, Optos, Novartis, Biogen; Secretary — Macula Society; Trustee — Association for Research in Vision and Ophthalmology, IntRIS; Nonfinancial support — Topcon, Nidek, Centervue, Heidelberg, Carl Zeiss Meditec, Optos

SriniVas Sadda, MD, an editorial board member of this journal, was recused from the peer-review process of this article and had no access to information regarding its peer-review.

The American Academy of Ophthalmology Board of Trustees and the Association for Research in Vision and Ophthalmology Board of Trustees approved this statement in June 2022.

Correspondence:
Flora Lum, MD, 655 Beach Street San Francisco, CA 94109-1336. E-mail: flum@aao.org.

References

1. Lee AY, Campbell JP, Hwang TS, et al. Recommendations for standardization of images in ophthalmology. *Ophthalmology*. 2021;128:969–970.
2. Association of Research and Vision in Ophthalmology. Association of Research and Vision in Ophthalmology statement on data standards in ophthalmology. https://www.arvo.org/advocacy/updates/statements/; 2021. Accessed May 11, 2022.
3. Clunie DA, Dennison DK, Cram D, et al. Technical challenges of enterprise imaging: HIMSS-SIIM Collaborative White Paper. *J Digit Imaging*. 2016;29:583–614.