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Recommendations for Standardization of Images in Ophthalmology

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Communication of image-based data needs to be accurate and reliable, yet this is difficult to accomplish in settings that use multiple proprietary devices and data storage processes. Currently, there is no easy way to exchange digital imaging data from one manufacturer's equipment to another's without creating a custom interface. Use of standards for digital image format is in the best interests of the ophthalmic community. The Digital Imaging and Communications in Medicine (DICOM) standard is recognized in the United States and throughout the world as the medical imaging standard, which includes a system of globally agreed upon ophthalmological definitions.

The American Academy of Ophthalmology believes that ophthalmic imaging device manufacturers should standardize image formats to comply with standards already established by the Academy in collaboration with manufacturers, including the following:

- Ultrasound (DICOM Supplement 5)

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- Ophthalmic photography devices (DICOMSupplement91)
- OCT equipment (DICOM Supplement 110)
- Keratometers and autorefractors (DICOM Supplement 130)
- Reporting of macular grid thickness and volume (DICOM Supplement 143)
- Optical biometry devices (DICOM Supplement 144)
- Visual field perimetry testing equipment (DICOM Supplement 146)
- Optic nerve head topography and retinal thickness mapping devices (DICOM Supplement 152)
- Corneal topography equipment (DICOM Supplement 168)
- Wide-field ophthalmology photography devices (DICOM Supplement 173)
- OCT angiography (DICOM Supplement 197)
- Key measurements in Encapsulated PDF (DICOM Correction Proposal 1811)

Adherence to standardization would advance the needs and interests of ophthalmologists, their patients, and the quality of clinical care by promoting interoperability, enabling the creation of comprehensive datasets for research and big data analyses, and developing algorithms for machine learning and artificial intelligence.

Background

The standardization of imaging data is a critical part of the infrastructure that will improve quality of care by creating a common platform that enables communication across physicians and institutions. Patients can obtain more efficient care when common standards are used to send images throughout the healthcare settings they visit. Establishment of standards will also enhance physician or end-user confidence as commercial entities conform to a clearly defined level of performance and, as consumers of these products, purchasing devices that adhere to these standards that comply with these criteria. The manufacturers reap benefits as well, because standards reduce excess costs that would have been spent on defining product specifications and service requirements. International standards also facilitate availability of interoperable products in a global market. Ultimately, payers and patients would benefit from more efficient communication and coordination of care, with possible lowered healthcare costs.

The 21st Century Cures Act, signed December 13, 2016 (Public Law No. 114-255), included provisions that encourage greater interoperability of electronic health records and to prohibit data blocking, but did not address medical imaging in Picture Archiving and Communications Systems (PACS) outside of electronic health record systems. The response to comments on the Cures Act notes the following about imaging: "…In the context of imaging, if the only EHI (electronic health information) stored in or by the product to which this certification criterion applies are links to images/imaging data (and not the images themselves, which may remain in a PACS) then only such links must be part of what is exported." Most ophthalmic practices store the actual images in PACS because of the need

for storage and archiving. The Academy believes that the raw images themselves together with the accompanying metadata should be included and that the native format of the PACS should support standardized DICOM format both for data sharing and in interoperability rules to promote medical image sharing, as well as in the US Core Data for Interoperability.

The DICOM standard is a detailed specification that describes a way to format and exchange images and associated information, such as the text describing the image, patient demographic information, the image capture protocol, and any relevant outputs of the imaging study (e.g., algorithmically derived measurements and the associated results). This standard applies to the operation of the interface that transfers data in and out of an imaging device. It relies on media devices and computer network connections that address the image communication and storage in technologies such as computed tomography, magnetic resonance imaging, positron emission tomography, nuclear medicine, ultrasound, x-ray, digitized film, video capture, and various cameras. This standard has been implemented in nearly every radiology, cardiology, and radiotherapy device and is supported by industry and professional societies, and internationally by the Committee European de Normalization and the Japanese Industry Association for Radiation Apparatus. This widespread adoption in radiology has revolutionized radiology practices by enabling digital patient workflow, empowering the sharing of large datasets, and creating enormous training sets for machine learning.

However, DICOM compliance is low for ophthalmic imaging technologies. Even so-called DICOM-compliant devices fail to meet DICOM standards with significant limitations, such as the embedding of patient identifiers on the image. In the past, the Academy has used its resources extensively to encourage standard-setting activities and to develop standards collaboratively with device manufacturers.

Recommendations

The Academy strongly encourages imaging device manufacturers and PACS manufacturers to implement existing DICOM standards. These are 2 specific examples of implementation that would benefit ophthalmologists:

1. Provide machine-readable, discrete data for user-selected reports of ophthalmic imaging or functional testing.
2. Use lossless compression for pixel or voxel data to encode the same raw data as used by manufacturers.

The Academy’s efforts are focused on making sure that medical technology is more relevant to the needs of the end user, the ophthalmologist, by ensuring that there is interoperability, that is, that there can be a seamless interface that allows the communication and comprehension of image data between 2 parties. Once ophthalmic imaging device manufacturers implement globally recommended standards, then the field of ophthalmology can rapidly progress along the path of efficient electronic workflow, interoperability, and artificial intelligence systems that will meet an increased demand for ophthalmic services to the public.

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