

Working Group on Ophthalmic Standards

Ophthalmic Standards Information Kit

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*...facilitating the exchange of medical
information in eye care environments*

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Introduction and Overview

The American Academy of Ophthalmology has organized a Committee on Medical Information Technology to help fulfill its mission of achieving accessible, appropriate and affordable eyecare for the public. The Committee's purpose is to foster the development of information technologies that improve the accessibility, quality and efficiency of ophthalmic medical and surgical practice. Its activities encompass two general areas: *computer-based patient record systems* and *telemedicine*.

To facilitate these information technology advances in ophthalmic practice, the Committee has focused on the development of standards for information exchange in ophthalmic environments (clinical, educational and research). Three areas of standards development have been identified: (1) terminology; (2) essential minimal data sets; and (3) digital imaging. The Committee's work is using existing standardization efforts wherever possible, focusing on areas of direct impact to eye care.

A common clinical ophthalmic reference terminology is being developed in collaboration with the College of American Pathologists' Systematized Nomenclature for Human and Veterinary Medicine (SNOMED) and the Kaiser Permanente/Mayo Clinic Convergent Medical Terminology (CMT) Project. SNOMED is a leader in clinical terminology development, and the AAO is now a Liaison Member of the SNOMED Editorial Board. An overview of the proposed Convergent Ophthalmic Terminology is detailed in Part 4.

Digital imaging standards are developed at a global level through the Digital Imaging and Communications in Medicine (DICOM) Standards Committee. DICOM has evolved from the American College of Radiology-National Electrical Manufacturers' Association (ACR-NEMA) Standard, which originally developed the DICOM Standard for use in radiology. In 1996, the DICOM Standards Committee was reorganized and opened to all specialties involved in medical imaging. The AAO has been an active member of the DICOM Standards Committee since that time, and currently serves as the Secretariat for DICOM Working Group 9 (Ophthalmology).

These terminology and imaging standards form the foundation for minimal clinical data sets, based on the AAO Preferred Practice Patterns, Ophthalmic Procedure Assessments and NEON Outcomes. The Committee believes that by developing these key elements of a medical information infrastructure industry's resources can focus on creating applications that facilitate the exchange and communication of patient information in our clinical practices.

Acknowledgements

The work of the Committee and the Working Group is challenging and inspiring. I want to express my appreciation to the many people at the Academy who have supported our efforts: Dunbar Hoskins, the Board of the Academy, Richard Abbott, Andy Schachat, Jane Aguirre, Scott Burg, David Noonan, Don McFerrin and his development staff. A special acknowledgement to Flora Lum - her diligence, drive for excellence and quiet confidence often led us to achieve our goals. I thank the members of the Committee for volunteering their valuable time and effort. My appreciation to the many people associated with collaborating projects and SDOs: Dean Bidgood, Keith Campbell, Kent Spackman, Karen Kudla, and Diane Aschman. My appreciation to my Chairman at the University of Oklahoma's Department of Ophthalmology, David Parke, for his tolerance of my frequent absences travelling on behalf of standards efforts; to Scott Sigler, Bob Small and my fellow physicians at the McGee Eye Institute for their willingness to serve our patients when I wasn't there; my thanks for the support of all my colleagues at the Center for Telemedicine. I also appreciate the evolving partnership with our ophthalmic industry partners, especially the efforts of our European and Japanese colleagues – for without industry's participation we have no products.

Finally, I want to thank my dear wife Betsy and our three wonderful children. Standards work is a “globetrotting” experience and their love and support has been instrumental to my role in any of this work, much of it done away from home.

P. Lloyd Hildebrand, MD
Chair, Medical Information Technology Committee

The American Academy of Ophthalmology

The American Academy of Ophthalmology is the largest national membership association of ophthalmologists - medical eye doctors who provide comprehensive eye care, including medical, surgical and optical care. More than ninety percent of practicing U.S. ophthalmologists are Academy members, and more than five thousand international ophthalmologists are International Members.

The Academy evolved as part of the American Academy of Ophthalmology and Otolaryngology (AAOO), which was founded in 1896 primarily to provide continuing education to eye, ear, nose and throat doctors. The American Academy of Ophthalmology was incorporated as an independent organization in 1979 when the AAOO was divided into separate academies for each specialty. It is a Minnesota non-profit corporation.

The American Academy of Ophthalmology is an association of ophthalmologists dedicated to helping the public maintain healthy eyes and good vision. Its main goals include programs, products and services to ophthalmologists and the patients they serve. The mission of the American Academy of Ophthalmology is to achieve accessible, appropriate and affordable eye care for the public by serving the educational and professional needs of the ophthalmologist.

AAO Information Statement on Standard-setting Activities in Health Care (Draft)

Executive Summary

Standardization of imaging and terminology is a critical part of the infrastructure for providing quality health care. It will create a common platform that can provide a basis for comparison and communication among the different entities within the field of health care. Standards will bring confidence to the physician and hospital-user community that different brands of products will conform at the least to a minimum level of performance and safety. The health care industry will reap benefits as well, because standards will reduce excess costs that otherwise would have to be spent on defining product specifications and service requirements. International standards will facilitate the availability of products and help create a global market.

The interests and needs of ophthalmologists can be best served by establishing global standards to govern the communication of images and data, which increasingly will be done in digital formats for speed, accuracy, and convenience. Communication of data needs to be accurate and reliable, yet this is difficult to accomplish in settings that use multiple different proprietary devices. There currently is no easy way to exchange digital image data from one vendor's equipment to another's without creating a custom interface. Similarly, "common" terminology is not used uniformly across medicine, and there is no easy way to compare results on like conditions and to differentiate between dissimilar conditions with data collected in computer-based patient records.

A digital imaging standard will permit users to communicate readily, no matter what specific technology they use, and a system of globally agreed ophthalmologic definitions can be applied through it. Such common terminology will permit accurate communication even if alternative words or phrases are used to refer to the same clinical entities. The Digital Imaging and Communications in Medicine (DICOM) standard is recognized in the United States and throughout the world as the medical imaging standard, and the Systematized Nomenclature of Human and Veterinary Medicine (SNOMED) is recognized here and abroad as the most comprehensive medical terminology for describing clinical care situations. The American Academy of Ophthalmology is committed to supporting and working with these entities to assure that these standards reflect the needs and interests of ophthalmology and eye care.

Background

DICOM was initiated by the American College of Radiology and the National Electrical Manufacturers' Association, but was opened up in 1996 to other medical specialties and vendors. 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. 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 communication and storage of images from modalities such as CT, MR, PET, nuclear medicine, ultrasound, x-ray, digitized film, video capture and digital cameras. This standard has been implemented for a number of medical products already, and it is supported by industry and professional societies in the United States, as well as internationally by the Committee European de Normalization (CEN) and the Japanese Industry Association for Radiation Apparatus (JIRA).

SNOMED is increasingly adopted as a standard nomenclature, based on its comprehensive scope and content as a clinical reference terminology. The SNOMED International classification system contains 11 separate modules with more than 144,000 terms and term codes included in the system and has been partially or completely translated into ten languages.

The Academy can have a far-reaching impact if it lends its influence on resources to encourage standard-setting activities. Standards will provide a common platform of terminology, content, and communication for information about patients, and they will allow ophthalmologists to exchange data and learn from each others' experiences. 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 is a seamless interface that allows for the communication and comprehension of data between two parties. The most effective way to do this is to work with other specialty groups and industry, within established national and international standard-setting bodies, namely with DICOM and SNOMED.

The Working Group on Ophthalmic Standards

On June 22, 1998 in Amsterdam, the American Academy of Ophthalmology convened an open organizational meeting for a new Working Group on Ophthalmology Standards to focus on issues related to standards for ophthalmic imaging and digital communications. The Academy believes that the interests and needs of industry, ophthalmologists and their patients are best served by establishing global standards governing the communication of images and data. A digital imaging standard permits users to communicate readily, no matter what specific technology they use. The Digital Imaging and Communications in Medicine (DICOM) standard is recognized throughout the world as the medical imaging standard. To date, however, there has been little interface of ophthalmic industry with this standard. The establishment of this Working Group provides a formal mechanism for input into and creation of standards that are responsive to the needs of industry, users and patients.

There were a total of 30 participants, representing various vendors, ophthalmologists, ophthalmic photographers and academic medical centers. The morning session of the initial meeting was informational, with discussions of the DICOM, other standards efforts and the ophthalmic industry's interest and potential role in these standard-setting activities. The afternoon session focused on planning and organizing a working group of ophthalmologists and industry representatives. Ultimately, it was agreed that to advance patient care and to enable exchange of information, it would be best for industry and ophthalmologists to work together to create standards.

The group will be focusing on the standards development activities related to digital imaging and terminology in eye care. The Working Group is formally recognized within the DICOM Committee structure as Working Group 9 (Ophthalmology). As part of DICOM, it follows well-defined and formal procedures that are similar to other standard development organizations. The Working Group 9 is responsible for maintaining the DICOM standard and creating extensions which address the imaging and communication needs in eye care. It is also expected that this Working Group will function in other standard development activities outside of DICOM, such as in the development of a standard terminology and interaction with groups such as SNOMED. In this group, no commercial topics shall be acted upon or even considered. Membership in this Working Group is separate from membership in the DICOM Standards Committee.

The co-chairs elected at the initial meeting in Amsterdam are: P. Lloyd Hildebrand, M.D., Chair, Medical Information Technology Committee, American Academy of Ophthalmology; and Rainer Waedlich, President, ifa Systems. The American

Academy of Ophthalmology will serve as the Secretariat, performing administrative functions, coordinating meetings and meeting the requirements of the DICOM procedures for Working Groups. The Secretariat's administrative functions are handled by Flora Lum, M.D., Director of Quality and Clinical Care, American Academy of Ophthalmology, P.O. Box 7424, San Francisco, CA 94109-7424, phone (415) 561-8592, fax (415) 561-8533 and e-mail flum@aao.org. The website is located at: <http://157.142.192.42/iota.htm> . Communications to the group and interested parties will be done using online methods (website and the listserver) as much as possible.

Working Group Procedures

Scope

As a Working Group under the structure of DICOM, Working Group 9 is responsible for:

- Σ the definitive content specifically related to ophthalmic imaging and image related information (such as reports) and applications in the DICOM standard;
- Σ the extension of the DICOM standard with respect to ophthalmic imaging applications of visible light, ultrasound, and infrared imaging of the eye; visual field evaluation, and topography of ocular structures (e.g., corneal topography, retinal topography, optic nerve head imaging); and
- Σ assisting the DICOM on technical, engineering, quality assurance and safety issues related to imaging of the eye.

As a independent association, it is responsible for:

- Σ consulting, reviewing and developing other standards related to information technology needs in ophthalmology, e.g., terminology, telemedicine, and for representing ophthalmic industry to standard-setting organizations such as HL7, JIRA, and CEN.

Meeting Held

The initial organizational Working Group 9 meeting was held at the International Congress of Ophthalmology in Amsterdam on June 22, 1998. Additional meetings in 1998 are scheduled for September 21 in Berlin and November 6 in New Orleans.

Proposed Work Items

Digital imaging of the eye is playing a larger role in the care of patients with diabetic retinopathy and other ocular diseases. There is currently no standard for the image format or the report structure for these applications that allows communication and exchange of information. The American Academy of Ophthalmology wish to promote the exchange and communication of information through the DICOM standard for consistency within the rest of medicine, where many specialties have been working with DICOM.

Specific activities of the Working Group include:

A. Extensions to the existing DICOM standards to address the following ophthalmic imaging applications:

- Σ Ultrasound
- Σ Fluorescein angiography
- Σ Indocyanine green angiography
- Σ Ocular blood flow measurements
- Σ Visual fields
- Σ Laser tomography imaging

As its initial work items, the Working Group will create a supplement and Service Object Pair (SOP) Class derived from Supplement 15: Visible Light Image (VL) for stereoscopic retinal imaging; and create a supplement and a Service Object Pair Class based on the Information Object Definition derived from supplement 23: Structured Reporting for interpretation of Visible Light images for the management of patients with diabetic retinopathy

B. Demonstrations of the DICOM standards in ophthalmic imaging standards for visible light, ultrasound, structured reporting and use of these standards in telemedicine applications

C. Demonstrations of established standards in terminology for exchanging patient care data

Membership Roster

Membership from the Secretariat (AAO), vendors in the ophthalmic imaging, computer-based records, telemedicine, digital communications and related industries and other interested individuals.

Name of Secretariat

The American Academy of Ophthalmology will be the official Secretariat for Working Group 9. Flora Lum, M.D., Director of Quality and Clinical Care, will function as the Secretariat's Staff Manager.

Officers

The Working Group shall select a chair or co-chairs. Other officers may also be selected. The officers and members need not be members of DICOM. Co-chairs selected, as representatives from each of the user and vendor communities are: P. Lloyd Hildebrand, M.D., Chair, Medical Information Technology Committee, American Academy of Ophthalmology; and Rainer Waedlich, President, ifa Systems.

Dues

Members are requested to pay dues to pay for the associated administrative and meeting costs. Dues are determined annually based on an annual budget and operating plan. Dues are collected and administered by the Secretariat.

Procedures

Formation and Review

The formation (and later disbandment) of the Working Group requires approval by a majority vote of the DICOM Committee and appropriate notice to those who have interest in the activities of DICOM. The scope and duties delegated as a Working Group shall be approved at the time it is formed. Subsequent changes in scope or duties shall also require DICOM Committee approval.

Meetings

Calling of meetings

Meetings may be held as decided upon by the members or the (co) chair(s). Meetings shall be open to all members and others having a direct and material interest.

Prohibition of commercial topics

No commercial topics shall be acted upon or even considered. To avoid the most sensitive areas, there shall never be a discussion of the following at meetings: current or future prices or components thereof, including

- Σ discounts, rebates, and credit terms
- Σ price list or procedures for coordinating price changes;
- Σ sales or production quotas;
- Σ allocation or division of territories of customers among manufacturers, distributors or retailers;
- Σ boycotting any party or denying any party access to markets, products, product inputs, or information;
- Σ identified individual company statistics, market shares, inventories or merchandising methods
- Σ commercial practices, warranties, guarantees, or the particular terms and conditions of sales, including credit, shipping and transportation arrangements, or
- Σ anything dealing with “arm-twisting,” trade abuses, or excluding or controlling competition.

Conduction of meetings

All meetings shall be conducted in such a manner that all members are afforded an adequate opportunity to present their views. All opinions shall be considered before actions are voted upon. The chairperson(s) shall undertake this responsibility with the assistance of the Secretariat’s staff.

Discussions shall be confined to technical, engineering and safety factors. Commercial considerations (warranties, guarantees, etc.) are not proper issues and shall not be considered. Since the DICOM Standard is voluntary, there must be no agreement to adhere to it or any discussions as to when members will begin to offer products conforming to DICOM.

The Secretariat shall ensure that minutes of all meetings are clear, complete and accurate with regard to the actions which were taken and the justification for those actions.

There shall be no conversations off the record at the meeting. If comments are not appropriate for recording, they shall not be brought up at meetings.

Meetings shall be adjourned when it is over in all respects and not simply in name. Informal rump sessions are not part of meetings and should not be held.

Membership

Appointment

Members and the Sponsoring Organizations of this Working Group will be appointed by the DICOM Committee. A request for membership shall be addressed to the Secretariat, and shall indicate:

1. the applicant's direct and material interest in the DICOM Committee's work
2. the applicant's qualifications and willingness to participate actively;
3. the interest category of the applicant (vendors, bio-medical professional organizations, vendor associations, standards developing organizations, government agencies)
4. the name of the representative (and alternate, if desired)

Maintenance of membership

If any member or alternate of the Working Group is not present for three consecutive meetings of the working group, membership will cease. After the second consecutive meeting not attended, the secretariat shall notify the member that membership in the working group will cease after the next meeting, if the member is not present. Membership may be reinstated by action of DICOM.

Membership Roster

The secretariat shall maintain a current and accurate roster and shall distribute it to the members at least annually, and otherwise on request.

The roster shall include: the name, chair(s), Sponsoring Organizations, and names and addresses of all members.

Responsibilities of the Secretariat:

The Secretariat for the Working Group shall:

- Σ work closely with NEMA (National Electrical Manufacturers' Association) for proper conduct and documentation of subgroup activities, and coordinate with other standard-setting bodies as appropriate.
- Σ oversee the subgroup's compliance with the procedures of the DICOM Standards Committee
- Σ provide a secretary to perform administrative work including: meeting arrangements, notices, agendas, minutes and other records
- Σ perform other administrative functions as required; and
- Σ following the meeting procedures of the DICOM Standards Committee.

Convergent Ophthalmic Terminology Project

The purpose of the Convergent Ophthalmic Terminology project is to develop a comprehensive reference terminology for use in computer-based systems in ophthalmology. In essence, a major deficiency in the progress of ophthalmic computer-based systems, including computer patient record systems, is the lack of a standard dictionary or reference set of terms. Without this common understanding, it is difficult, to communicate, exchange, compare and analyze information from different settings in a meaningful way. Physicians will use different terms to mean the same entities, or the same terms to mean different entities. For clinical trials to be successful, investigators must have a common understanding of what various terms for disease conditions and clinical measurements mean.

Developing this common foundation of ophthalmic terms, with definitions, cross-references to similar or related terms, and with codes that map terms into a larger medical terminology dataset (as is done in SNOMED-RT), will greatly enhance the exchange and comparability of information collected through computer-based systems. In addition, it should help researchers and academicians to find and analyze information. Indeed, the foundation of a standardized terminology is so important that Kaiser Permanente postponed the development of a computer-based patient record to focus on the priority of terminology development and have spent millions of dollars building the Convergent Medical Terminology project.

The entire scope of standardizing medical terminology is enormous and very complex in the details. Fortunately, ophthalmology is relatively well delimited, compared with other fields in medicine. Therefore, with the experience, methodology and software tools already developed for terminology by Kaiser Permanente- Mayo Clinic Convergent Medical Terminology Project, and the clinical domain experts within ophthalmology, this project is feasible and reasonable in scope. Vital links and relationships have been established between the Academy and leading national organizations such as the DICOM Standards Committee, the SNOMED Editorial Board, the College of American Pathologists and Kaiser Permanente.

This project would be accomplished by two primary means. New information technology and sophisticated software will enable a logical, standardized and efficient approach towards the definition and modeling (refining the definition of terms and identifying similar or related terms) of terms, and developing consensus on these definitions. This strategy builds on the same tools and approach taken by the national leaders in medical terminology development, allowing the Academy's effort

to be incorporated into both the Convergent Medical Terminology Project and the SNOMED terminology, which is the most widely adopted medical terminology for computer-based systems. This approach also allows many individuals at different sites to work on the project simultaneously. This allows the developers to rely on the clinical knowledge and expertise of subspecialty trained ophthalmologists at different academic and practice sites across the country to assist in defining ophthalmic terms and identify their relationships to related and similar terms (a process called modelling).

Introduction to DICOM

Current Status of DICOM

The DICOM Committee is the de-facto international development organization for standards in medical imaging. This has been achieved through the strong involvement of both manufacturing and professional user organizations.

DICOM was developed in close cooperation between the imaging industry - represented by vendors from many countries as well as global companies, and the user community - represented by such professional organizations as the American College of Radiology (ACR), the American College of Cardiology (ACC), and the European Society of Cardiology. While it is not an official international (ISO, IEC) standard, it is a de facto international standard. Support for the DICOM Standard is a requirement in virtually all tenders for imaging equipment, whether in Asia, Europe, or the US. DICOM is currently in clinical use by hundreds of hospitals worldwide.

DICOM has expanded its scope from radiology and cardiology imaging to include visible light imaging (e.g., pathology, endoscopy, ophthalmology), imaging-related therapy (radiation therapy), reporting about findings, and information exchange at the boundary between imaging systems and information systems. In 1996, the DICOM Committee was reorganized to include all groups involved in medical imaging, and the AAO joined the Committee at that time.

Effective standardization of medical imaging

Two fundamental characteristics of medical imaging are that it:

- Σ involves a relatively small number of vendors, all with a global market presence, accustomed to working together, often for regulatory purposes, in regional or international vendor organizations such as NEMA, COCIR, and JIRA; and
- Σ has users who are members of a relatively small number of large and active professional national or international organizations, such as ACR, ACC, ESC, ADA, and CAP.

For these reasons, the DICOM Committee operates globally at an international level, through these organizations, as well as through individual vendors and users.

DICOM began as a standardization effort in the United States, through the efforts of NEMA and ACR. From the start, however, imaging vendors based outside the US have been directly involved, including Siemens, Philips, Toshiba, and Agfa to name just a few.

The DICOM Committee also has a long history of close cooperation with other standards organizations. This cooperation has led to new additions to DICOM as well as ensuring compatibility between DICOM and other standards, particularly with respect to sharing the same information model. Key examples of this are joint work include with:

- Σ CEN TC 251, to develop the Modality Worklist and Storage Commitment Supplements to DICOM;
- Σ JIRA, to develop the multi-byte character sets in DICOM;
- Σ MEDIS-DC, to develop of the Type 2 Common Standard for medical images on exchange media;
- Σ IEC 62C WG1, to develop radiotherapy objects; and
- Σ ISO JTC1 SC 29, to develop JPEG 2000 image compression for medical images.

Structure of the Committee:

The governing body is the DICOM Committee, composed of members from user organizations, vendor organizations, government agencies, and other standards developing organizations. There are currently 36 members (including 7 bio-medical professional organizations and 24 manufacturing companies).

The DICOM Committee and its Working Groups follow a formal and well-defined procedure that is consistent with that of other standards development organizations. The procedures define a rigorous review and balloting process. The DICOM Committee itself meets four times per year to discuss strategy, priorities, new standardization activities, relation to other standards organizations, financial issues, publications, and demonstrations.

Individual Working Groups perform the development of extensions and the maintenance of the standard. Currently there are 17 active Working Groups:

1. Cardiac and Vascular Information
2. Digital X-Ray (including Dental X-Ray)
3. Nuclear Medicine
4. Compression
5. Exchange Media
6. Base Standard (technical oversight assuring the Standard's consistency)
7. Radiotherapy
8. Structured Reporting
9. Ophthalmology
10. Strategic Planning
11. Display
12. Ultrasound
13. Visible Light
14. Security in Medical Imaging
15. Digital Mammography
16. Magnetic Resonance
17. 3-D Imaging

Official, voting Working Group members (or the organizations they represent) are not required to be members of the DICOM Committee and there are no membership dues or other mandatory fees associated with being a working group member.

The current version of the standard, DICOM 98, incorporating all currently balloted supplements and corrections, has just been submitted for printing (2300 pages) following a thorough review process. For the first time, a trial of electronic publication is underway, with the release of a draft of the 1998 edition.

Working Group Membership Application Form

Name	
Position/Title	
Company/Organization	
Address	
Country	
Telephone	
Fax	
Email Address	
Direct and material interest in digital imaging and communications standards	
Qualifications and willingness to participate in working group activities	

Please submit to Flora Lum, M.D., Director of Quality and Clinical Care, American Academy of Ophthalmology, P.O. Box 7424, San Francisco, CA 94120-7424, Fax (415) 561-8533 and e-mail: flum@aao.org.

