1. Buying Imaging Equipment for Interoperability and Compliance: Beyond DICOM
2. Informatics for the Acceptance Testing of Imaging Equipment

For patient service, safety and regulatory compliance, the quality control of image and image information needs to extend beyond the scanner console to encompass the entire imaging chain. Imaging physicists are often the ultimate quality control professionals and technology experts that are responsible for equipment selection and testing. To aid in these tasks, this session is designed to provide the clinical physicist with practical awareness and tools for equipment selection and acceptance testing that promotes interoperability throughout the imaging chain, protecting image and information quality for smooth clinical operation and patient safety.
Buying Imaging Equipment for Interoperability and Compliance

Beyond DICOM

Alisa Walz-Flannigan, Ph.D. DABR
Mayo Clinic, Rochester, Minnesota
Walzflannigan.alisa@mayo.edu

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Traditional Medical Physics Responsibility

I. Evaluation and selection of new equipment
II. Contracting for new equipment/systems
III. Acceptance Testing and Quality Control Measurements and Reporting
IV. Patient Safety/Dosimetry
V. Clinical optimization/Innovation
Equipment Evaluation and Selection

- Radiologist Assessment of clinical utility
- Usability (technologist or radiologist interface)
- Physics Assessment (image quality/patient safety)
- Financials (business needs)
  - Workflow/Dataflow
  - Support
  - Interoperability
  - Security/Compliance

Connectivity Review
Aligning reality of stakeholder expectation with technical solutions before you buy.
The work of radiology is accomplished by a team of professionals:

- **Radiologist**
- **Technologist**
- **Physicist**
- **Vendor**
- **Administrator**
- **Engineering**
- **IT/ PACS Administrator**

Pictures from Toshiba, Invivo, Nordic Neurolabs and Volcano promotional material.
Connectivity Review

**SCOPE:**
For the evaluation or purchase of any new and unique (of a substantively different product or software version) **image creator or modifier** that will integrate with the electronic environment

Relevant to both **ACQUISITION MODALITIES** and **POST-PROCESSING SOFTWARE**
Connectivity Review

A. Workflow/Dataflow
B. Support
C. Interoperability
D. Security/Compliance
A. Workflow/DataFlow:

How is it used and what data flow is triggered?
B. Support

Sample of Support related questions:

A. Is it a strategically aligned purchase?
   - Is this an enterprise convergence application?
     - *supporting many different vendors for the same type of system makes support harder*

B. Clinical Use? FDA Approval? Replacing existing system?
C. Installation plan? Who, What, Where, When?
D. Business Associate Agreement?
E. Do images need to be saved?
F. Interacts with the RIS?
G. Reported on by Radiologists
H. Hardware Break/fix SLA?
I. Application Break/fix SLA
C. Interoperability Assessment

**Resources:**
- DICOM Conformance Statement
- IHE integration Statement
- Sample Images
- Vendor Implementation Notes/Manuals
- Site Specific Interoperability Questionnaire

And/or

- On-site trial
DICOM Conformance Statement (DCS)

A document standard that provides:

• Description of how an application entity implements the DICOM standard
• Describes this in a standard format which facilitates comparison

Despite these documents being a standard form for describing a standard, there can be variation in how useful or readable a DCS is.
Limitations:

“The integration of any device into a system of interconnected devices goes beyond the scope of the DICOM 3.0 standard and this conformance statement when interoperability is desired. The responsibility for analyzing the applications requirements and developing a solution that integrates the Agfa equipment with other vendors’ systems is the user’s responsibility and should not be underestimated.

In some circumstances it might be necessary to perform a validation to make sure that functional interoperability between the Agfa equipment and non-Agfa devices works as expected. The user should ensure that any non-Agfa provider accepts responsibility for any validation required for their connection with the Agfa equipment.” from Agfa DICOM Conformance Statement
IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical need in support of optimal patient care.

IHE integration profiles describe a workflow and agents in that workflow. For example, the Post-Processing Workflow provides worklists, status and result tracking for post-acquisition tasks, such as Computer-Aided Detection or Image Processing.

Has the equipment or software been validated for all of the relevant integration profiles?
IHE Integration Profile

EXAMPLE: Post-Processing Workflow

Limitations of utility:
1) Your workflow matches the IHE workflow
2) Every other system in the profile has also been validated for its role
Interoperability Questionnaire

Other questions for vendors that might not be identifiable in the DICOM DCS or IHE profiles.

What matters to your practice?
Where have you been burned?

Sample Concerns:

- Does the system utilize wireless connections?
  - What is its function (between subparts of system or between the unit and institutional electronic environment?)
  - Encryption?
  - Can wired and wireless be used simultaneously?
- Does it use lossy compression or is that an option? What compression options are available?
- Do image transfers happened in background or foreground?
Interoperability Questionnaire

Sample Concerns, continued:

• When DICOM data elements or image data are modified what of the following are changed? Study, series, or instance UID.
• How are DICOM associations managed when transmitting images?
• How are temporarily-unavailable (off-line) DICOM Store destinations managed?
• Do image transfers from the modality or the workstation occur in the foreground or in the background?
• If post-processing software, is hardware provided? Video card? Display?
Sample Images

1. Assign them to a test order and put it into your electronic environment
2. Use a tool kit to assess conformance with the DICOM standard
   - From David Clunie
   - DICOM Viewer/Validator Software
On-site Trial

Try before you buy

Sample images

- Are not fed by your ordering or information systems.
- Do not allow variation in workflow operations on the modality

It is not possible to trial every system.
Sometimes vendors can provide modality emulators.
D. Security and Compliance

Take a look at the

ACR–AAPM–SIIM PRACTICE GUIDELINE FOR ELECTRONIC MEDICAL INFORMATION PRIVACY AND SECURITY

Know the regulations with Electronic Protected Health Information (ePHI)

- HIPAA
- HITECH
D. Security and Compliance

HIPAA/HITECH in a nutshell:

Security Rule:
- Ensure the confidentiality, integrity, and availability of all e-PHI they create, receive, maintain or transmit
- Identify and protect against reasonably anticipated threats to the security or integrity of the information
- Protect against reasonably anticipated, impermissible uses or disclosures;
- Ensure compliance by their workforce
D. Security and Compliance

Concern for any device connected to a network architecture:

- Maintainable OS
- Uses an antivirus or are otherwise protected from malware and viruses, i.e., vendors must provide a robust and regular maintenance plan.
- May need to be protected from pushing unvalidated patches to imaging equipment.

Know your network/information security policies!
Patients Put at Risk By Computer Viruses

By CHRISTOPHER WEAVER

The Food and Drug Administration is warning makers of heart monitors, mammogram machines and myriad other medical devices that their gear is at risk of being infected with computer viruses that can endanger patients.
Connectivity Review - Summary

Pull together all the information discussed to make sure it’s self-consistent and do-able.
Involve major stakeholders to get their perspective

A. Workflow/Dataflow
B. Support
C. Interoperability
D. Security/Compliance
Summary

A connectivity review provides forethought to implementation.

Two Uses for the review:

1. **Are we buying the right system?** Can it do what we expect it to do?

   And/or

2. **For the purchase that is coming**
   - What is it going to take to make it work?
   - Assess issues and estimate effort and allocate resources before we have patients waiting.
Role for physicists:

As a technical advisor to imaging equipment purchases, physicists have an interest in making sure the questions in a connectivity review are addressed and they may be integral in getting many aspects addressed.