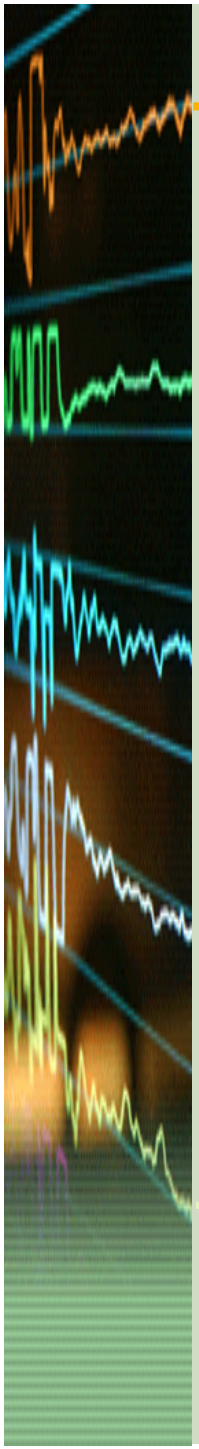

Workshop on Medical Device Interoperability

Session 2: Enterprise Issues

Digital Operating Room

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Sponsored by FDA/CDRH, Continua, and CIMIT

January 25, 2010

Overview

- Equipment Integration within Kaiser Permanente – Dr. Douglas Grey
  - Physician perspective
  - Interoperability/Integration approaches
- Safe & effective – Tom Judd & Tom McGrane
  - Digital Operating Room Image Management example
  - IT Perspectives
- Recommendations to FDA
  - How interoperability adds value for clinical workflow and patient safety
  - Aspects of this solution that should and/or should not be regulated by the FDA

KP Equipment Integration

What constitutes integration????

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The KP delivery system oversees integration/interoperability of Digital Operating Room (DOR) equipment on many levels through a governance structure:

- Integration of OR equipment on a "direct connection basis" - **clinical performance**
- Integration on the IT network level
- Integration of this equipment into the “Fleet"
- Integration of this equipment into clinical workflow of the OR
- Integration of this equipment into the KP New Facilities planning and deployment.
- Integration of this equipment into the KP delivery system

DOR Image Management

Clinical Requirements Part 1

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Pre-Op

- **Review of "key films"** (digital Visible Light-VL or Radiographic-Rad Images, eg CT, MRI, X-ray, Fluoroscopy, Ultrasound-US)
- **DOR room Presets** (system configured in a standardized way for clinical procedures)

Intra-Op

- **Image Display** (Real-time endoscopic VL, reference Rad images, and real-time Rad (Fluoro, US)
- **Image Capture** (for later annotation and storage as appropriate), including option for video capture for research or training purposes

Post-Op

- **Image Management** (VL, US, x-ray image editing, annotating, storage, deletion, inclusion in EHR Op Note, linking VL with Rad)

DOR Image Management

Clinical Requirements Part 2

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Other Image Management (IM) Issues

- Middleware (eg, patient demographics mechanism on IM "front-end", and annotation tool & PACS storage on IM "back-end")
- Linking wireless devices to network (best current example is the Ultrasound-US)

IM Role Definitions

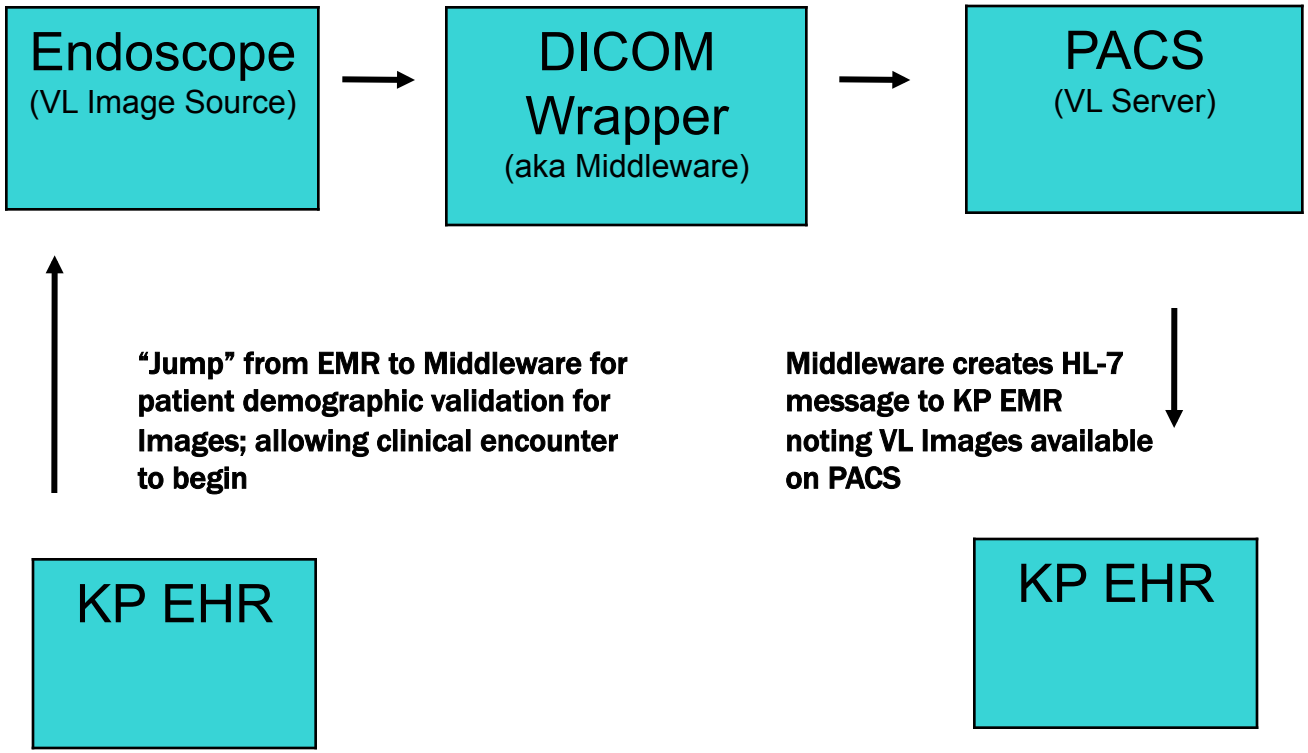
- eg Nursing (circulator, scrub, super user) and Physicians

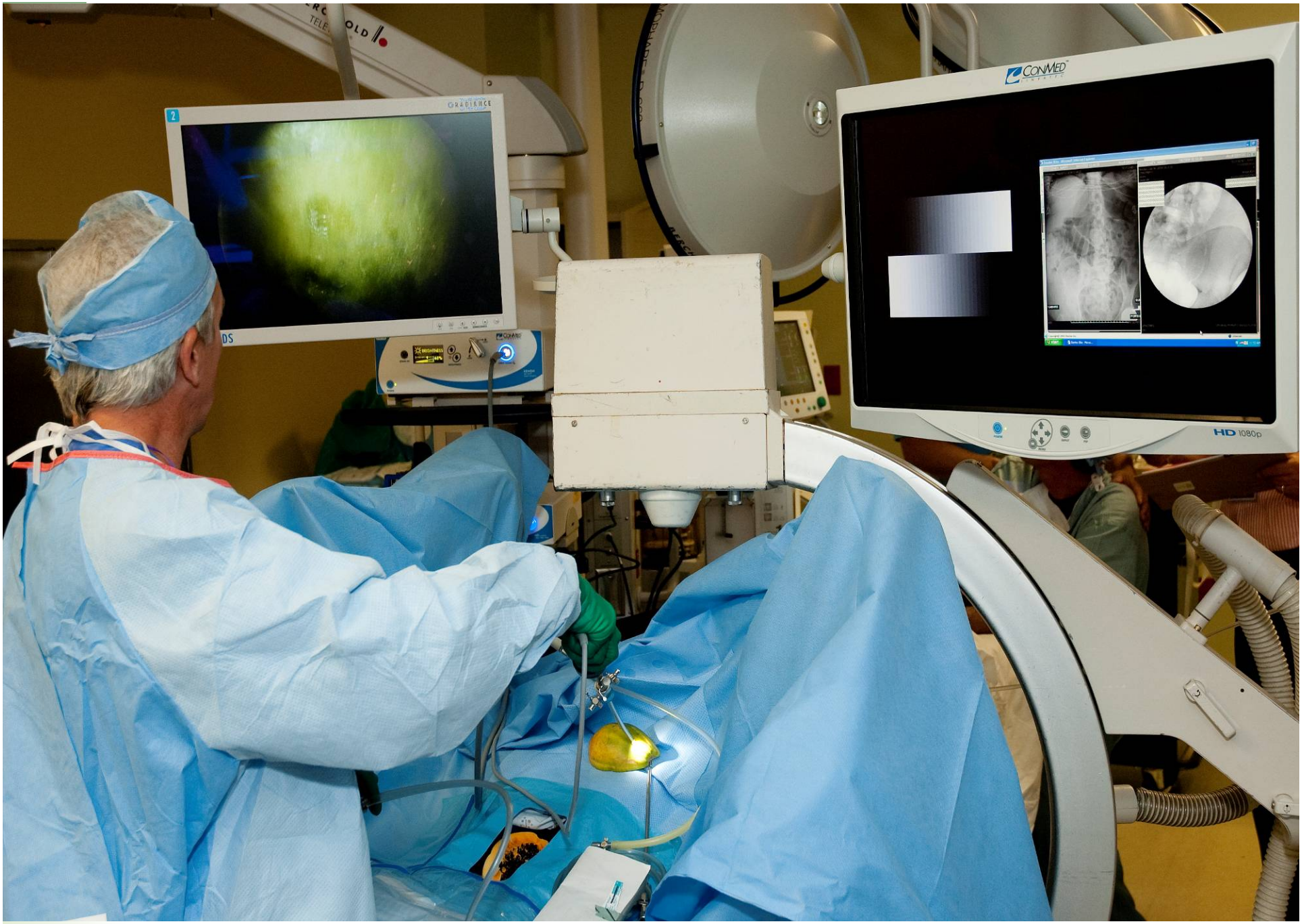
Virtual Visits

- IM in virtual clinic visits, for members/patients, with secure messaging links.

Digital Operating Room

Visible Light Flowchart

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IT Perspectives

- Medical Center IT Infrastructure
  - Collapsing existing standalone “Biomed” networks into enterprise-wide network
  - Most new devices will be attached to enterprise network
  - Readily accessing prior Images and discrete clinical data for better clinical outcomes (EHR)
- Where are the Problems
  - Regulations that conflict with “main stream” IT standards create 1-offs or result in not attaching those devices
  - IF regulations extend too far e.g., which malware version of software to be used, that becomes untenable for a large enterprise like KP to control (too many 1-offs)
  - IT needs to be able to respond quickly to protect devices with increasing cyber threats.
- Specific recommendations
  - Approvals take too long which can result in vendors bundling enhancements so they can get 1 FDA review–KP left waiting for available/needed enhancements
  - Regulations should not impede integration, Wireless is our current challenge
  - Understand and help us adhere to the Meaningful Use Rules

Recommendations

- A minimum of requirements should be defined by the industry suppliers and FDA
- KP will need to configure our own infrastructure, computing, servers, etc.
- KP is responsible for patient care
- KP is appropriate to be the final systems integrator

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Questions?

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