Kaiser Permanente & IEC 80001-1
Digital OR-Endoscopy Case Study

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Healthcare Environment – Why do I care?

- **Regulatory:** Build it, deploy it, manage it right
  - IEC 80001-1: due for release in 2010 and adoption by FDA, reconnecting biomedical devices to the IT network, and resulting Risk Management (RM) challenges; desires to maintain network:
    - Safety
    - Effectiveness
    - Data and system security
  - IEC 80001-1 addresses RM:
    - definitions
    - responsibilities
    - documentation requirements

- **Accreditation:** The Joint Commission
  - Example: Encouraging Digital OR-Endoscopy (DOR-Endo) increased surveillance by designating Endo as “diagnostic device” in 2010
What are Kaiser Permanente’s perceived risks and planned Risk Management activities for DOR-Endo?

- **Risks:** Safety, Effectiveness, and Security
  - How to measure and improve
- **Response:** first we will describe this Case Study

**Stakeholders for the DOR-Endo Case Study:**

- Clinical (Physicians, Nurses, other Equipment Users)
- Information Technology
- Clinical Technology (CT, aka Clinical Engineering)
DOR-Endo
Kaiser Permanente definition

Meets wide-spread and diverse Clinical Needs
- Surgical sub-specialties with different clinical requirements; see Appendices.
- Volume: Kaiser Permanente has over 20 hospital deployment sites for DOR-Endo in 4 hospital regions. Every hospital (36) has either DOR-Endo and or stand-alone Endo via OR Towers & Carts, increasingly bringing High Definition image viewing and integration with EHR capabilities to all surgical locations.

Image Optimization
- Get the best clinical image on OR monitor(s) to optimize surgery

Image Management/Integration
- Manage the flow of information before, during after the surgical procedure, both with DOR-Endo biomedical equipment and external systems

Deployment
- Assess, train, deploy, and maintain – CT and IT in partnership with Clinicians (Operational leaders, surgeons, nurses) and Suppliers, etc. to assure best life-cycle use of biomedical equipment and systems
Hospital IT Infrastructure

- In the OR, most biomedical devices are attached to the enterprise network
- Readily accessing prior or storing current Images (from PACS) and discrete clinical data (from EHR) for better clinical outcomes

DOR-Endo Integration

- Digital Operating Room - Endoscopy (DOR-Endo)
  - **Enhances** dedicated image capture and control equipment
    - Not just connecting equipment, also configuring and ensuring best possible utilization by clinicians
  - **Enhances** workflow capability – e.g., patient safety, prior images, etc. – by connecting DOR to external systems via enterprise network. Contributing factors:
    - PACS and KP EHR
    - Kaiser Permanente Garfield Innovation Center / Lab allows Simulation / Testing
    - Wireless coming in 2011
Integration
Clinician perspective

Means ....

- **Clinical performance**: “Direct connection"
  - Simulation in Garfield Center in safe environment
  - Get it right before system gets to patient
  - Enhance clinical workflow with IT/CT technology enablers

And/Or ....

- **Integration on the IT network level** (next slide)

And/Or ....

- **Operational Issues**:
  - Introduce into the Kaiser Permanente New Facilities planning & implementation
  - Deploy this equipment into the KP delivery system
  - Fleet manage inventory as appropriate, e.g., transfers between facilities if needed
  - Locally manage equipment through life-cycle
Integration
IT/CT perspective

Means ....

- Image capture and control within OR
  - Optimize how devices are connected, configured, utilized
  - External clinical systems to and from OR
    - EHR and PACS-centric

And/Or ....

- Data and system security

And/Or ....

- Establish and implement IT standards
  - increase predictability, reduce variation, simplify, testing
  - Collect metrics to manage this environment
  - Utilize Garfield Innovation Center OR demonstration space for testing
Digital Operating Room
Visible Light Flowchart

- **Endoscope** (VL Image Source) → **DICOM Wrapper** (aka Middleware) → **PACS** (VL Server)

- "Jump" from EHR to Middleware for patient demographic validation for images; allowing clinical encounter to begin.

- Middleware creates HL-7 message to KP EHR noting VL Images available on PACS.

- **KP EHR**

Operation Room Environment
External Systems
Safety

IEC 80001-1

Acquire the right stuff
- Kaiser Permanente participation in the MD PnP MDFIRE contract group to ensure desired integration features acquired initially

Set and deploy consistent standards – IT/CT
- Simulation at Garfield Center to validate match of clinical requirements and Supplier products
- Going beyond connection to configuration, & utilization
- Identify relevant standards re deploying DOR-Endo

Collect metrics to match Safety environment
- Well defined to allow consistent measurement, eg,
  - Ensure equipment tuned to give optimal images for surgeons
  - Ensuring right images and right patients correlated during, post-surgery
  - Images stored for appropriate clinical length of time for later comparison
- Clear roles, responsibilities, and quality improvement (QI) follow-up activities after measurement
Effectiveness

IEC 80001-1

- People know and do the right thing; applying technology enablers appropriately
  - Initial training and continuing education
  - Standards followed

- Measure impact of technology on outcomes
  - Well defined to allow consistent measurement, eg
    - Like VCRs, DOR-Endo: don’t use it right, don’t get what you want
    - Technology more complex to use than ever before – eg, are our nurses and doctors trained initially and ongoing to optimally make use of the equipment to improve quality of care
    - How HD is your HD? Can clearer HD images help get quality outcome
  - Clear roles, responsibilities, and quality improvement (QI) follow-up activities
Data and system security

IEC 80001-1

Biomedical devices and systems are increasingly connected to the IT network to create, store, access electronic data

Enterprise IT systems are not, typically, designed around the requirements of biomedical devices and systems in regard to security. Some metrics include:

- No unauthorized access to patient information on network versus memory sticks
- Understand equipment operation so no unauthorized loss of important patient information, eg, don’t erase what’s on the image management system gathered during a particular procedure

Biomedical device and system vendors have not consistently designed security for their systems to enable consistently secure functionality

This leads to considerable issues / inconsistencies in providing adequate security

Strategy a work in progress to address the above issues.
Risk Management Summary, Part 1
Within KP DOR-Endo

Structure: OR department “COO” assumes RM responsibility

- To ensure a safe, effective, and secure medical IT network
- Coordinate between different departments and external vendors
  - Ordering, purchasing, inventory, deployment, installation, training, testing, etc.
- Assisted by IT and CT relevant local managers
  - IT and CT can escalate local issues as appropriate
  - 24/7 troubleshooting numbers both internal and external
- Device vendors provide documentation to the hospital OR COO and team that will allow them to safely place the devices onto the hospital’s IT network, eg,
  - Intended use of the medical device and the network
  - Required characteristics and configurations of the network
    - known incompatibilities or constraints
    - test criteria and protocols, known possible failure modes, system reliability statistics, and other data relevant to the performance of the network
  - Technical/operational specifications
  - Security requirements
  - Instructions for establishing proper connections.
Process: **Kaiser Permanente Roles and Responsibilities**

- **DOR-Endo Standards (must do’s) & Templates (how to’s)**
  - “Think” national, empower locally
    - via National OR Oversight Body to Hospital OR
  - Include Safety, Effectiveness, and Security metrics as guidance to local hospitals
    - conduct regular QI activities as response to ongoing measurements

- **Service level/responsibility agreements (eg, contracts) are created:**
  - With appropriate parties, for DOR-Endo, the medical or IT vendors involved, the information needed to build / sustain a medical IT network, and the responsibilities of each stakeholder.
  - Responsibility agreements can exist for particular projects and/or for the maintenance of a medical IT network.

**Outcomes:** **Measure and take corrective action to improve**

- Improved communications, transparency, & operational efficiencies
- Ultimately lead to a safer environment for the patient.
Appendices

Image Optimization (slide 16)
2010 DOR-Endo Testing at Garfield Center with 7 surgical sub-specialties:
General Surgery, Gyn, Urology, Head & Neck, Orthopedics, Vascular, Thoracic

Image Management-IM (slides 17-18)
DOR-Endo IM Info from January 2010 FDA Interoperability Conference:
Kaiser Permanente DOR-Endo Case Study presentation

DOR-Endo Deployment Challenges (slide 19)
Subjective DOR-Endo Evaluations:
Kaiser Permanente uses physicians and nurses with “Wet” or “Dry” operative field models to review:
- Resolution/clarity of image on monitor, light illumination, depth of field, field of view, and ease of use

Objective DOR-Endo Measurement:
Kaiser Permanente uses test equipment to review:
- Image clarity (color accuracy, illumination / brightness, HD monitor Resolution), depth perception, field of view, zoom

Supplier DOR-Endo Pre-Sets:
- Kaiser Permanente making best use of empirical optimization of various equipment involved for specific clinical presentations, eg, CCU, Camera Head, Lens, Monitor, Light Source & light cord
DOR Image Management
Clinical Requirements Part 1

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, etc.)
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.
Clinical Technology and DOR-Endo Deployment Challenges

- Biomedical device (BD) field (DOR-Endo) rapidly changing
  - Endo images stored on PACS; image management to improve workflows

- Demand for BD-KPHC integration results in partnerships & ↑ expectations for all from the KP governance structures
  - Includes OR Departments, KP CT, KP-IT, and equipment Suppliers

- Typical/emerging OR department requirements/expectations
  - New hospital planning
  - High Definition upgrades; replacements of DOR and/or Endo; Exceptions
  - Fleet management of existing DOR-Endo inventory between facilities
  - Ongoing internal service of equipment along with Suppliers
  - Integration of equipment with PACS & Kaiser Permanente’s EHR
  - The Joint Commission (June 2010): noted tighter accreditation requirements as “Endoscopes now considered diagnostic equipment”.
Questions?

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