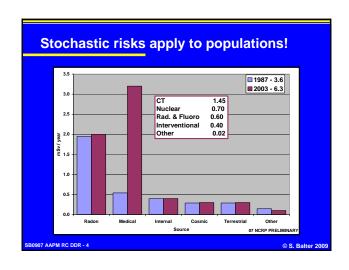


Why record patient imaging dose? To help determine the safety of a proposed diagnostic procedure. To help determine the safety of a proposed interventional procedure. For departmental QA. To make contributions to standards of practice.

What to tell a patient? • A version of this talk was recently presented to 15 experts participating in an international standards meeting on diagnostic imaging (IEC62b). • During the discussion 3 participants asserted that a patient's past high-dose radiation history is itself a sufficient reason to forbid the performance of new examinations. This seems to have been based on the assumption that the occupational dose limit is also the patient dose limit.





Should not have any influence on the decision to order a diagnostic procedure.

Justification

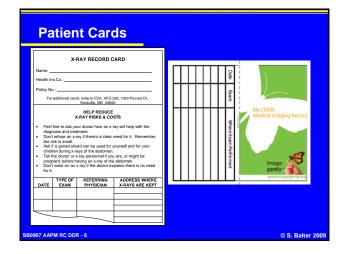
Dose data contributes to the quality process (e.g. guidance or reference levels)

Optimization

Medical use of radiation is specifically excluded from dose limits.

Past medical imaging history

- Facilitates avoidance of unnecessary
 - Access to findings and/or images.
 - Clinical judgment must be applied regarding utility of old study relative to the patient's current medical condition.
- Old images/reports might supply baseline information needed to better define or interpret the new study.



Individual Patient Radiation Record (IPRR)

- Logical record describing radiation related patient information.
 - New term introduced here.
- Value
 - To the patient
 - To the health-care system
 - To society
- Physical realization is a separate issue.
 - DICOM provides some standards

IAEA Smart Card Project

- "Although medical exposure of patients constitutes over 95% of exposure of the world population from non-natural radiation sources, there is no methodology to keep a record of the long-term exposure of the individual patient.
- One of the main reasons for this is that no dose limits exist for patients.
- The right of the patient to information about his/her radiation exposure is becoming increasingly
- In the absence of such methodology, there is a dark area about long-term radiation effects in children undergoing high dose interventional procedures."

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Smart Card Project

- "Achieve consensus standards for recording of patient exposure;
- Develop a methodology for achieving long term records of patient exposure using off-line and on-line methods of data handling, transfer and management;
- Develop guidelines, norms, disclaimers, manuals and regulatory frameworks with regard to security issues;
- Develop a system for cumulative recording at both patient and central levels.

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Capabilities of imaging equipment

- Physical transmission chambers
 - Integrated or Accessory
 - Can provide P_{KA} and K_{a.r}
- Values of the X-ray settings
 - Any generator capable of calculating tube loading can calculate K_{a,r} Local calibration is needed
- Mechanical configuration
 - Collimator (PKA)
 - **Gantry (Beam entry vectors)**
 - Table [patient geometry] (Dincident)

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Dose report data elements

- Actual dose "measurements"
- Technical settings of equipment
- Irradiation geometry
- Patient and procedure data
- Image links

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DICOM Image Headers

- Usually only contain information about their images.
- Few mandatory requirements for including dosimetric data from any modality.
- Information that is supplied usually varies from model to model and is often in private fields.
- No dose information is saved if there are no images to carry a DICOM header.

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MPPS Dose Reports

- · Has been available for more than a decade.
- A transient message that is usually lost when patients are 'deleted' from imager.
- Requires tight linkage to RIS for electronic transfer
- Usually provides exam level summary dose data
- Contents vary by make and model.

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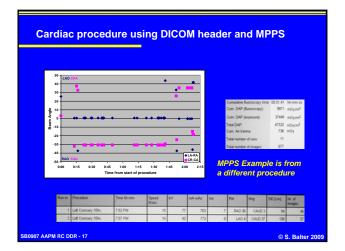
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Interventional Dose Reconstruction

- DICOM headers of stored images
 - Timestamps
 - Partial imaging geometry
 - Frame counts (often confused by stored fluoro runs)
 - Some technical factors
- MPPS report
 - Exam level summaries of dosimetric data
 - Total fluoroscopic time
 - Total frame count (often confused by stored fluoro runs)

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High dose interventional procedures

- The MPPS-DICOM header is not always sufficient for dose reconstruction.
 - No information on fluoroscopy use.
 - No information regarding missing images.
- Further detailed information is often available in the imaging equipment's log files.
 - No patient information is available.
 - Intended for problem solving by service engineers.
 - Usually at an individual irradiation level.
 - Typically overwritten in days to weeks after recording.

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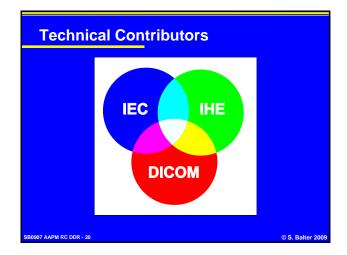
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Improved dose reporting

- Need recognized by DICOM and IEC
- DICOM supplement 94
 - Defines dose related attributes for projection radiography and fluorscopy
 - Introduces the Radiation Dose Structured Report
 - Describes logical transport
- IEC PAS 61910-1
 - Defines two compliance levels
 - Specifies minimum RDSR contents for each level.
- Implementation by IHE radiation profile.

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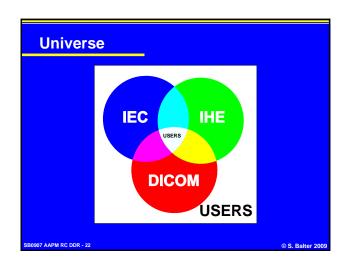


Responsibilities

- Contents of dose data objects (via IEC)
 - User Communities
 - Regulators (?)
- Logical formats
 - DICOM, IEC, IHE
- Physical transport
 - IEC, DICOM
- Logical transport, "display" and analysis
 - IHE, User communities

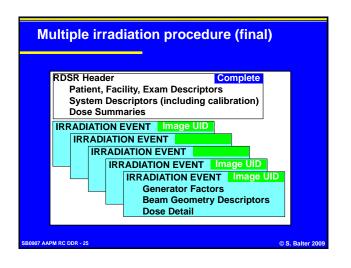
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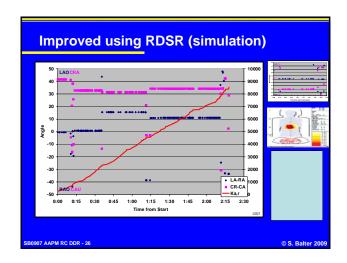
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IHE in One Slide IHE helps vendors implement & test functions that span multiple systems Profiles are implementation guides how to use existing standards to address a specific problem scenario Connectathons are test events managed testing of Profile implementatio IHE helps users purchase & integrate multi-system solutions list required IHE Profile support in RFPs

Padiation Dose Structured Report DICOM object that is designed to be handled independently from any images. Although generally in the same study folder Object will be managed & transported like other DICOM objects (e.g. store in PACS, query/retrieve, put on CD, USB, etc) Organization is Attribute: Value pairs as defined in DICOM Expandable format with all public fields. Near real-time streaming is included in the specification. No discussion about "display"





IEC PAS 61910-1

- Focus on fluoro guided interventions.
- Two compliance levels available based on expected doses for normal use.
- X-ray generator is the data source.
- Specification includes both network and "sneaker-net" data transfer.
- · Date/time stamps are missing.
- Will evolve into an IEC standard.

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Level 1: Equipment where the estimated maximum cumulative Air Kerma for any examination (study) is expected to be less than two (2) gray (Gy) for all normal uses Level 2: Equipment where the estimated maximum cumulative Air Kerma for any examination (study) is expected to be more than two (2) gray (Gy) for any normal use The defining dose is the cumulative dose for a complete examination at the interventional reference point defined in IEC 60601-2-43 (for equipment capable of measuring Air Kerma at this point or The equipment manufactures estimate of the cumulative dose for a complete examination at the closest point to the X-ray source where the patient's skin might be placed

Not limited to digital images

- The RDSR is a DICOM object that is independent of any stored images
- Valid RDSRs can be generated by equipment used to produce stored or not-stored analog or digital images
- IEC specifies that 500 RDSRs be stored in the imaging equipment (downloaded locally or via a network).

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Extensibility

- The present set of standards is applicable to all forms of projection radiography (except mammography and dental) (Sup 94).
- Mammography extension to DICOM is already available (CP 687).
- CT extension to DICOM is available (Sup 127).
- Container is also suitable for other modalities.
 - Dental
 - Nuclear Imaging
 - Images for Image Guided Radiation Therapy

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Known issues

- Time stamps (missing)
 - Corrected via CP 963
- Intersection of the X-ray beam with the patient.
 - There is no accepted standard unambiguously defining the geometry of external radiation beams relative to patients.
 - The present radiation therapy system is obsolescent (even for radiation therapy)
 - A consensus standard is being investigated.

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Inputs for IHE Radiation Profiles?

- RDSR
- Pseudo RDSR
 - Compatibility needs to be suitable for an IHE Dose Reporting Actor to process and 'display' the data set.
 - Automated stripping of DICOM headers
 - Screen scraping
 - Manual data entry

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Data accuracy and consistency

- Procedure Lexicon
- Accuracy of reported procedure names and descriptions in individual exams.
- Accuracy of demographic data
- Accuracy of dosimetric data
- Missing data

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How much to capture?

- Stochastic risk to an individual
- Stochastic risk to the population
 - Collect info on every procedure
 - Sampling
- Deterministic injury potential
 - Collect data on every type of procedure where injury is possible
- Quality Assurance
 - Collect everything (for local use)

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Consumers of Data

- Quality management
- Research community
 - Generate reference levels
 - Estimate population risks
- Policy makers
- Individual providers (potential tissue reactions)
- Individual patients ???

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What might be done with data

- Individual facility QA
 - Verify conformance with DRLs or interventional guidance levels.
 - Investigate trends and "outliers"
- Manage individual patients who have had procedures or procedure sequences that might produce deterministic injuries.
- Baseline for epidemiology

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Quality control and patient dose audit is a challenge for digital radiology

- Different image quality for different clinical tasks can be selected ... but patient doses need to be known.
- The objective is to avoid unnecessary patient doses; doses which have no additional benefit for the clinical purpose intended.
- Image quality can be compromised by inappropriate levels of data compression and/or post-processing techniques.

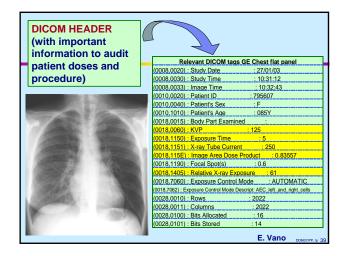
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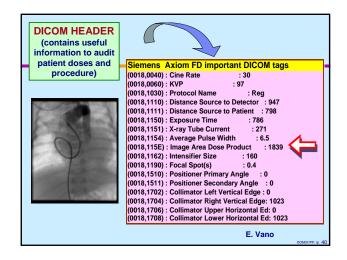
OM07/PP, lp

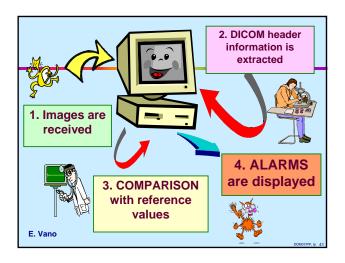
Experience with real time patient dose and quality control using DICOM Headers

- The pilot system allows auditing different parameters depending on contents of the DICOM header.
- DICOM contains information which currently is not restricted to only doses. Data on relevant parameters of the diagnostic or interventional procedures are also provided.
- The system for QC on line is working at the San Carlos University Hospital in Madrid from 1999.
 After several upgrades it is now a valid platform for practically all digital modalities in a full digital radiology department with 350,000 examinations per year.

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What are the audited parameters? Patient entrance dose (entrance air kerma). Dose area product (collimation). Radiographic technique (e.g. appropriate kVp). Appropriate use of the AEC. Appropriate breast compression in mammography. Flat panel detector temperature. Number of series, number of images per series, kV, mA, ms and total number of images per procedure. Exposure index and postprocessing parameters (for CR). Repeated images (retakes). Image quality (basic evaluation).

Next Steps

- Mammography RDSR
- Integration with CR DR
 - These readers "know" the patientAssociated generators do not

 - Many to many associations exist between generators and readers
- **Computed Tomography**
- User community to define key dosimetric quantities.
- **Nuclear Imaging**
 - Essential if meaningful population data or epidemiological results are to be expected.
 - User community to define key attributes and dosimetric quantities.

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Integration with radiation therapy

- Common coordinate system needed to describe the patient and the geometric relationship between the patient and external beams of radiation.
- **Dose recording**
 - DICOM RT Dose handles therapeutic doses.
 - How is the dosimetry for the images used for image guided therapy documented?
 - RDSR might be developed into an interesting DICOM object for reporting all delivered doses in a common framework.
- Reciprocal needs
 - Radiation therapy dose distribution by interventionalists.
 - High-dose interventional dose distribution for radiotherapy treatment planning

