TG201: Quality Assurance of External Beam Treatment Data Transfer

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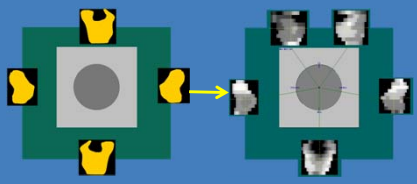
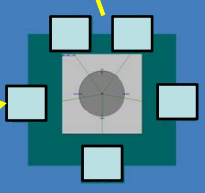
Rationale



Increased Complexity

NY Times Report: No MLCs for 3 fractions



TG 201 Charge

- Recommend radiotherapy processes that are robust in the presence of data transfer errors, and
- Recommend procedures that reduce the likelihood of a mistreatment due to data transfer error.

Outline

1. Data Transfer Concepts
   a) DICOM, HL7
   b) File Systems
   c) Databases
2. Models of Data Flow
   a) Distributed
   b) Centralized
   c) Examples
3. Fault Tree Analysis for Data Transfer – Design of ROBUST RT PROCESSES

Outline-II

4. Data Transfer Matrix
   a) Subsystems in Rad Onc
   b) Example Matrix
   c) Testing (to reduce likelihood of data transfer error)
5. Quality Assurance and Control Basics
   a) Principal concepts: Physical Integrity and Logical Consistency
   b) ATP and Commissioning
   c) Annual
   d) Patient QC

DICOM, HL7

- Primary protocols in a hospital setting
- TCP/IP
- DICOM-RT: RT treatment data
- HL7: Admissions, Discharge, Transfer, labs, billing….

Information vs Data

- Data are associated with attributes
- There should be enough attributes to be unambiguous

Value	attribute	information
99	?	?
	age	A very old person
	Code number	Maxwell Smart's sidekick?
	Weight	May be light or heavy. Lbs or Kg?

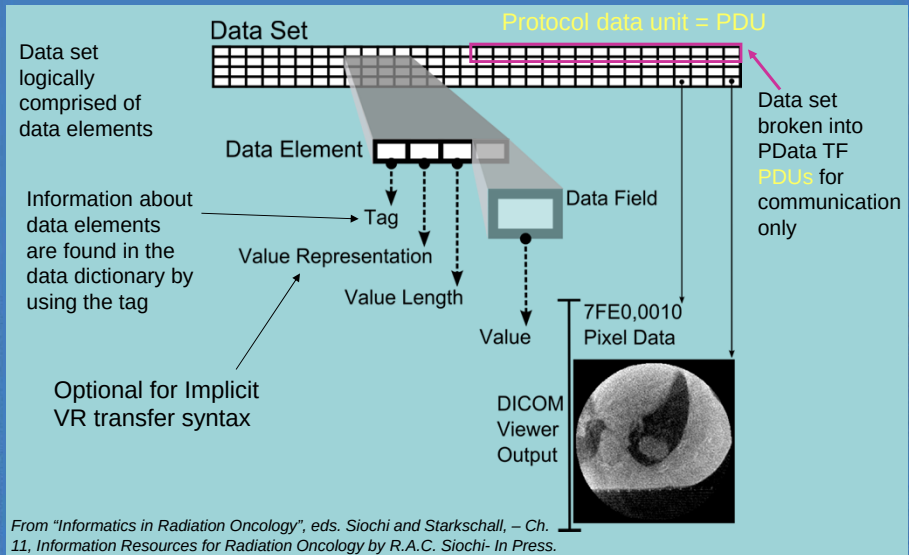
Attributes determined from:

- DICOM
  - Information Object Definition (IOD)
- HL7
  - message headers and expected record position within the message

DICOM Applications

- Picture Archiving and Communications System (PACS)
- DICOM-RT capable treatment planning systems, for export to R&V and IGRT systems
- DICOM from imaging systems to treatment planning systems

What gets transferred?



From "Informatics in Radiation Oncology", eds. Siochi and Starkschall, – Ch. 11, Information Resources for Radiation Oncology by R.A.C. Siochi- In Press.

Excerpt from a Data Dictionary

Group,Element:Item Name:VR:VM:RET(IRED)
≥
0010,1005:Patient's Birth Name:PN:1:
≥
0010,1030:Patient's Weight:DS:1:
≥
0010,2110:Contrast Allergies:LO:1-n:
≥
0028,0002:Samples per Pixel:US:1:
0028,0003:Samples per Pixel Used:US:1:
0028,0004:Photometric Interpretation:CS:1:
0028,0005:Image Dimensions:US:1:RET
≥
0028,0010:Rows:US:1:
0028,0011:Columns:US:1:
≥
7FE0,0010:Pixel Data:OW or OB:1:
FFFA,FFFA:Digital Signatures Sequence:SQ:1:
FFFC,FFFC:Data Set Trailing Padding:OB:1:
FFFE,E000:Item:NA:1:
FFFE,E00D:Item Delimitation Item:NA:1:
FFFE,E0DD:Sequence Delimitation Item :NA:1:

Value Multiplicity – The number of items in this data element, separated by "\" for character strings

Tag: Hexadecimal, 2 bytes each for group and element- unique identifier for the attribute

Value Representation (unsigned short)

A stream of words or bytes

From "Informatics in Radiation Oncology", eds. Starkschall and Siochi, – Ch. 11, Information Resources for Radiation Oncology by R.A.C. Siochi- In Press.

DICOM-RT Modules

- Designed to completely describe
  - Treatment Plan
  - Delivered Treatments
- References associated Images
- Some images may be the planning images (CT, MR) that were used for contouring
- Others may be RT Images (DRRs, portal images, CBCT).

Clinical DICOM Issues

- DICOM transfer of RT-Plan
  - TPS → R&V →IGRT systems
- If there is a problem with the transfer, how do you troubleshoot it?
- If you need to extract other information, what do you do?
- Need DICOM aware applications
- DICOM readers, viewers, editors
- DICOM servers

HL7

- Primarily for Hospital Information Systems
- Main issue for Rad Onc: demographics, scheduling, billing.
- Synchronize hospital data with Rad Onc Information System / EMR/TMS (e.g. Mosaiq, Aria)

Example HL7 message

```
MSH|^~\&|CLOVERLEAF|UIHC|LANTIS|UIHC|201301081413||BAR^P01|62830_33_RE|P|2.3|||||ASCII
EVN|P01|201301081413|||JEG475
PID|1||05979249^^^IDX||DOE^JANE||19800302|F|||123 45TH ST^^MARION^IA^52302-1234^US
PV1|001
```

4 Segments in this message:
MSH = Message Header
EVN = Event type
PID = Patient Demographics
PV1 = Patient Visit Information

PID segment made of several fields
| separates fields
Sequence of fields determines the meaning
e.g. 5th field is the patient's name

HL7 Issues

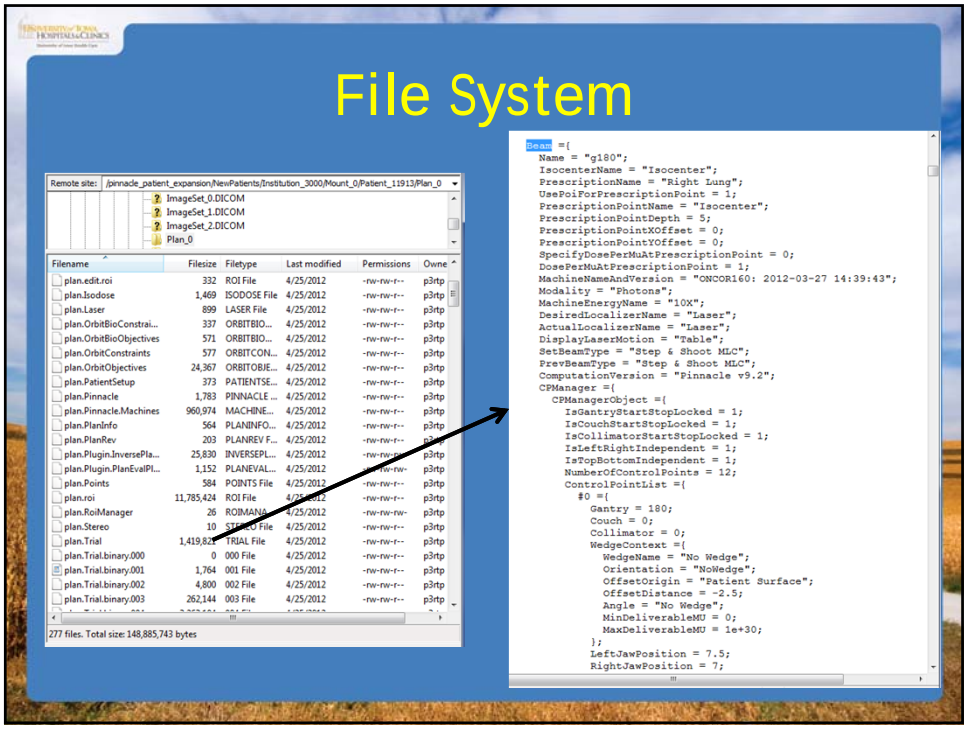
- Messaging System that should have
  - log of transactions
  - mechanism to verify uptime
  - On both sender and listener
- Example Error:
  - HL7 System down
  - lab results not sent
  - physician assumed labs OK
  - a patient died as a result.

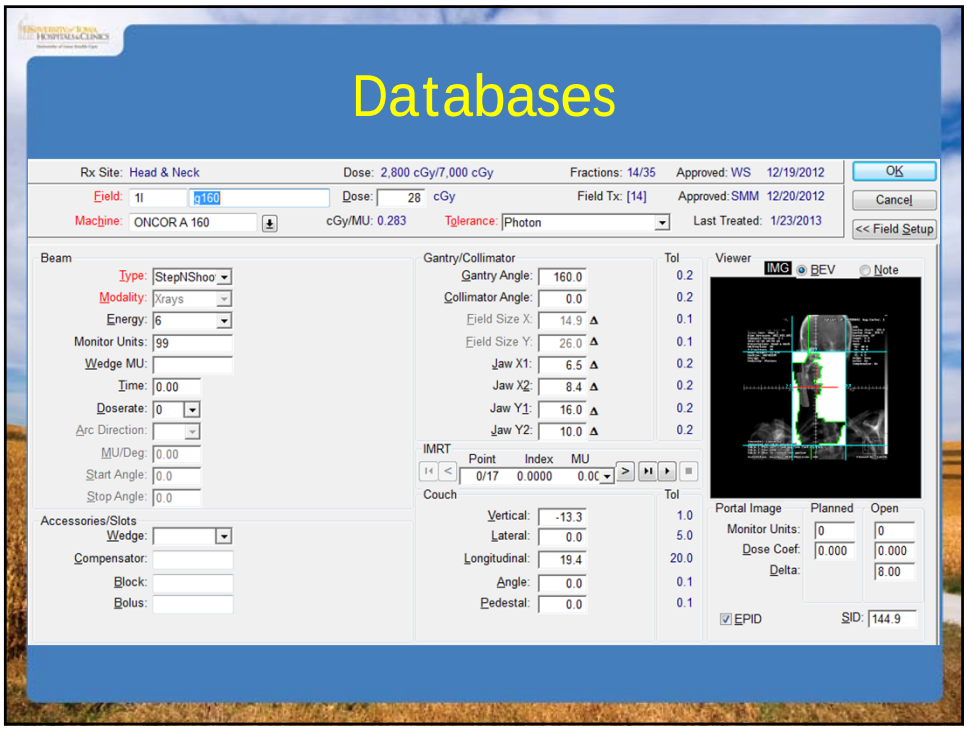
HL7 and Rad Onc

- Primarily demographics
- Name and Birthday are critical identifiers
- How do you know if you have the right patient?
- Verify patient registration in RO EMR with patient

Data Repositories

- Once Data has been generated or transported, where do they go?
- Folders / Files – directories on the hard drive
  - Example: Pinnacle plan.trial file holds all the treatment plan information
- Databases
  - Example: EPIC, MOSAIQ, ARIA


File System
Remote site: /pinnacle_patient_expansion/NewPatients/Institution_3000/Mount_0/Patient_11913/Plan_0
ImageSet_0.DICOM
ImageSet_1.DICOM
ImageSet_2.DICOM
Plan_0
Filename Filesize Filetype Last modified Permissions Owner
plan.edit.roi 332 ROI File 4/25/2012 -rw-rw-r-- p3rtp
plan.Isodose 1,469 ISODOSE File 4/25/2012 -rw-rw-r-- p3rtp
plan.Laser 899 LASER File 4/25/2012 -rw-rw-r-- p3rtp
plan.OrbitBioConstrai... 337 ORBITBIO... 4/25/2012 -rw-rw-r-- p3rtp
plan.OrbitBioObjectives 571 ORBITBIO... 4/25/2012 -rw-rw-r-- p3rtp
plan.OrbitConstraints 577 ORBITCON... 4/25/2012 -rw-rw-r-- p3rtp
plan.OrbitObjectives 24,367 ORBITOBJE... 4/25/2012 -rw-rw-r-- p3rtp
plan.PatientSetup 373 PATIENTSE... 4/25/2012 -rw-rw-r-- p3rtp
plan.Pinnacle 1,783 PINNACLE ... 4/25/2012 -rw-rw-r-- p3rtp
plan.Pinnacle.Machines 960,974 MACHINE... 4/25/2012 -rw-rw-r-- p3rtp
plan.PlanInfo 564 PLANINFO... 4/25/2012 -rw-rw-r-- p3rtp
plan.PlanRev 203 PLANREV F... 4/25/2012 -rw-rw-r-- p3rtp
plan.Plugin.InversePla... 25,830 INVERSEPL... 4/25/2012 -rw-rw-r-- p3rtp
plan.Plugin.PlanEvalPl... 1,152 PLANEVAL... 4/25/2012 -rw-rw-rw- p3rtp
plan.Points 584 POINTS File 4/25/2012 -rw-rw-r-- p3rtp
plan.roi 11,785,424 ROI File 4/25/2012 -rw-rw-r-- p3rtp
plan.RoiManager 26 ROIMANA... 4/25/2012 -rw-rw-rw- p3rtp
plan.Stereo 10 STEREO File 4/25/2012 -rw-rw-r-- p3rtp
plan.Trial 1,419,82 TRIAL File 4/25/2012 -rw-rw-r-- p3rtp
plan.Trial.binary.000 0 000 File 4/25/2012 -rw-rw-r-- p3rtp
plan.Trial.binary.001 1,764 001 File 4/25/2012 -rw-rw-r-- p3rtp
plan.Trial.binary.002 4,800 002 File 4/25/2012 -rw-rw-r-- p3rtp
plan.Trial.binary.003 262,144 003 File 4/25/2012 -rw-rw-r-- p3rtp
277 files. Total size: 148,885,743 bytes
Beam ={
Name = "g180";
IsocenterName = "Isocenter";
PrescriptionName = "Right Lung";
UsePoiForPrescriptionPoint = 1;
PrescriptionPointName = "Isocenter";
PrescriptionPointDepth = 5;
PrescriptionPointXOffset = 0;
PrescriptionPointYOffset = 0;
SpecifyDosePerMuAtPrescriptionPoint = 0;
DosePerMuAtPrescriptionPoint = 1;
MachineNameAndVersion = "ONCOR160: 2012-03-27 14:39:43";
Modality = "Photons";
MachineEnergyName = "10X";
DesiredLocalizerName = "Laser";
ActualLocalizerName = "Laser";
DisplayLaserMotion = "Table";
SetBeamType = "Step & Shoot MLC";
PrevBeamType = "Step & Shoot MLC";
ComputationVersion = "Pinnacle v9.2";
CPManager ={
CPManagerObject ={
IsGantryStartStopLocked = 1;
IsCouchStartStopLocked = 1;
IsCollimatorStartStopLocked = 1;
IsLeftRightIndependent = 1;
IsTopBottomIndependent = 1;
NumberOfControlPoints = 12;
ControlPointList ={
#0 ={
Gantry = 180;
Couch = 0;
Collimator = 0;
WedgeContext ={
WedgeName = "No Wedge";
Orientation = "NoWedge";
OffsetOrigin = "Patient Surface";
OffsetDistance = -2.5;
Angle = "No Wedge";
MinDeliverableMU = 0;
MaxDeliverableMU = 1e+30;
};
LeftJawPosition = 7.5;
RightJawPosition = 7;


Databases
Rx Site: Head & Neck
Dose: 2,800 cGy/7,000 cGy
Fractions: 14/35
Approved: WS 12/19/2012
Field: 1I g160
Dose: 28 cGy
Field Tx: [14]
Approved: SMM 12/20/2012
Machine: ONCOR A 160
cGy/MU: 0.283
Tolerance: Photon
Last Treated: 1/23/2013
OK
Cancel
<< Field Setup
Beam
Type: StepNShoo
Modality: Xrays
Energy: 6
Monitor Units: 99
Wedge MU:
Time: 0.00
Doserate: 0
Arc Direction:
MU/Deg: 0.00
Start Angle: 0.0
Stop Angle: 0.0
Accessories/Slots
Wedge:
Compensator:
Block:
Bolus:
Gantry/Collimator
Tol
Gantry Angle: 160.0 0.2
Collimator Angle: 0.0 0.2
Field Size X: 14.9 0.1
Field Size Y: 26.0 0.1
Jaw X1: 6.5 0.2
Jaw X2: 8.4 0.2
Jaw Y1: 16.0 0.2
Jaw Y2: 10.0 0.2
IMRT
Point Index MU
0/17 0.0000 0.0
Couch
Tol
Vertical: -13.3 1.0
Lateral: 0.0 5.0
Longitudinal: 19.4 20.0
Angle: 0.0 0.1
Pedestal: 0.0 0.1
Viewer
IMG BEV Note
Portal Image
Planned
Open
Monitor Units: 0 0
Dose Coef: 0.000 0.000
Delta: 8.00
EPID
SID: 144.9

Database basics

- DB consists of Tables
- Table: consists of rows (aka records)
- Row: contains column elements (aka fields)
- Queries
  - E.g. how many patients had IMRT this month?
  - SQL (Structured Query Language)

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DB Tables

Primary Key must be unique

Field or Column Names define the table

T_ID	First	Last	MI	SSN	MRN	License
45	Alpha	Omega		123456789	123	abc
72	Primero	Ultimo	M	987654321	456	def
73	Alias	Omega		123456789	123	abc

Record (row)

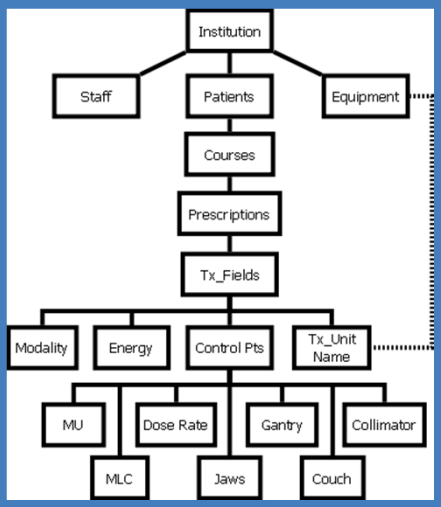
Field (column)

Typical Tables in an RT DB

In order to “incorporate” tables into other tables, foreign keys are used to point back to the related tables.

Here, each record in the Tx_Fields table consists of parameters that describe Linac settings. One of the parameters, control points, is a set of records in another table, with a “foreign key” that points back to the Tx_Field record to which it belongs.

DATA DICTIONARY – provides the definitions of the tables and the relationships among them.



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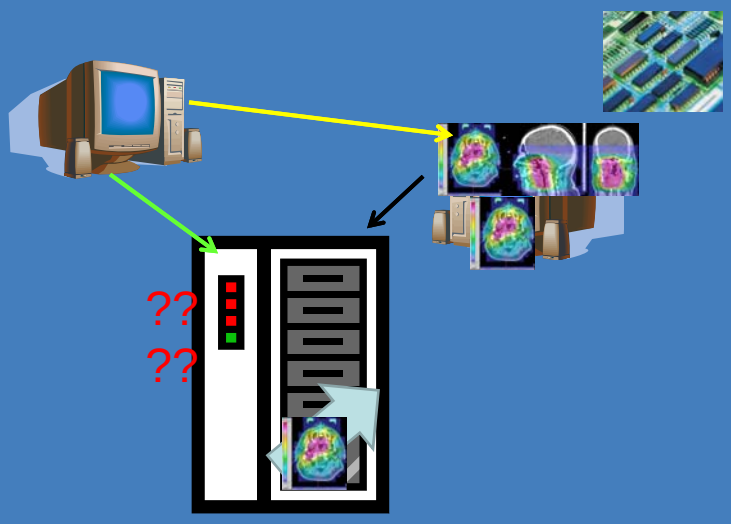
Caching



What the user sees vs the DB

- The users see a patient with a plan with multiple beams.
- Unfortunately, the actual DB schema may be quite different from vendor to vendor or version to version.
- Most likely, the DB sees multiple tables containing beams. Each beam is a record.
- Concurrency conflicts happen at the level of the DB record.

Locking

- Not a native ability of the DB engine
- Querying application should implement
- E.g. a field to indicate lock status
- Applications should check this field before allowing a user to work with the record.

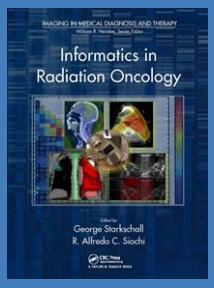
These basics help you to:

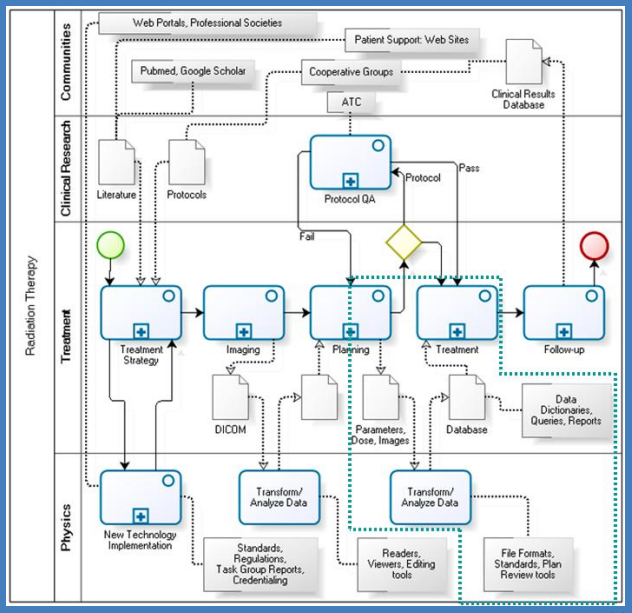
- Troubleshoot
- Design robust clinical workflows
- Design meaningful tests

Please read up on these concepts

Data Flow in RO

**Fig. 11.1 from Informatics in Radiation Oncology, G. Starkschall, R. Siochi, editors.*





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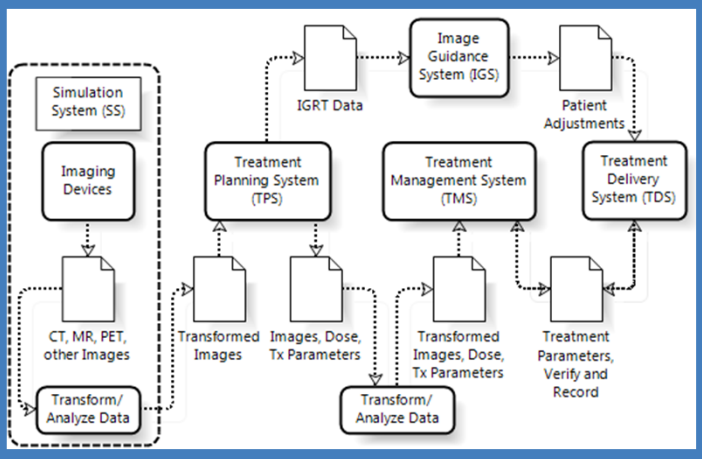
Distributed system data flow



Redundant data living in many places: INFORMATION should match. (Data might be stored in different forms but mean the same thing.)

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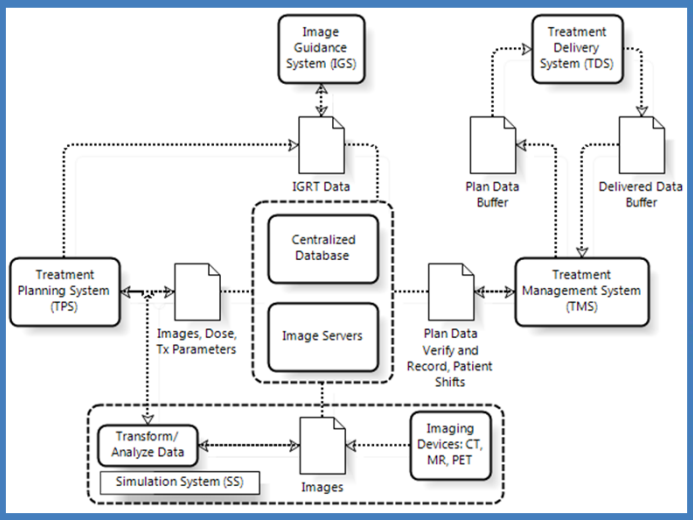
Centralized DB dataflow

Multiple applications accessing the same data at different times: They should synchronize!



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Examples

- Distributed
  - Pinnacle transfers RT plan to MOSAIQ
  - MOSAIQ transfers RT plan to Linac Console
- "Centralized"
  - Eclipse RT plan is created, using Aria to hold the RT plan database elements
  - …hybrid… still have to transfer to 4D ITC.

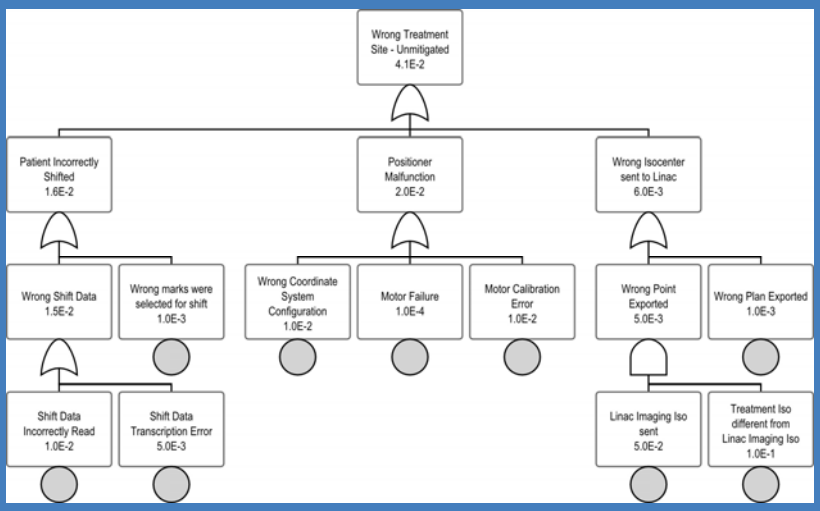
Why should it matter what I have?

- Centralized DB has to deal with concurrency, caching, locking.
- Distributed DB has to deal with storage synchronization
- Should be accounted for in
  - process design
  - testing

Robust Processes

- Understand the DB model before creating processes
- Design cycle:
  - Draft a process
  - Perform FTA, FMEA
  - Modify the process
  - Repeat until risk is acceptable

Fault Tree – Wrong Site



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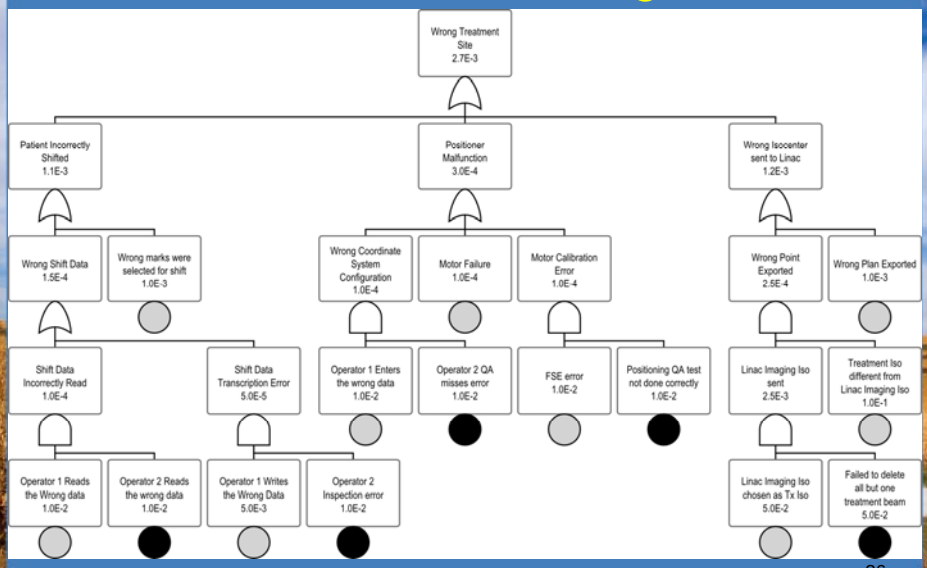
Fault Tree with Mitigations



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Clinical Interactions, paperless checks

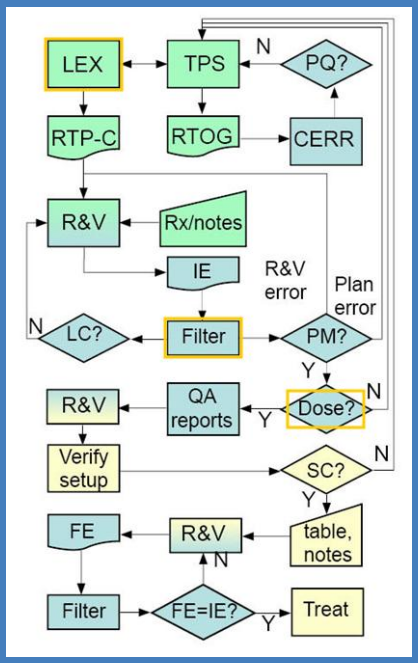
Physicists

Dosimetrists/Physicians

Therapists

In-House Software

Adapted from Fig 5. Siochi, et al. Radiation therapy plan checks in a paperless clinic, J. App. Clin. Med. Phys., 10(1):43-62.



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Data Transfer Matrix

- Table with 1st column containing source
- 1st row containing destination
- The cell at an intersection is the data to be transferred
- Helps one comply with recommendation II.A.2 of the TG201 Rapid Communication (check the entire chain of data transfers for a given patient.)

Typical elements of the matrix

- Simulation System (SS)
- Treatment Planning System (TPS)
- Treatment Management System (TMS)
- Treatment Delivery System (TDS)
- Image Guidance System (IGS)
- Picture Archiving and Communication System (PACS): The PACS allows for the electronic storage of images.
- Archiving System (AS): storage of a patient's entire treatment history.

Example Matrix

Table I: An example data transfer matrix. The row and column headers provide the source and destination subsystems, respectively. The matrix element at a row and column intersection contains the data to be transferred.

	Destination				
Source	SS	TPS	TMS	TDS	AS
SS		Images			Images
TPS			Plan, Images		Plan, Images
TMS				RT Plan-fields	Database backup
TDS			Recorded treatment		
AS	Images	Plan, Images	Database backup		

Testing

- Every cell in the data transfer matrix needs to be tested
- Some parts of tests could be used to test many cells (e.g. cells in the same row)
- Design efficient tests to exploit common features

Data matrix for centralized DB

- Pairs of applications in the matrix should be able to view the same thing
- Transfer of data amounts to Changing and Locking
  - Change a DB record using the source application in the matrix
  - Check that destination applications can't access the locked data.
  - Check that other INSTANCES of the source application can't access the locked data.

Other use of data transfer matrix

- How common are some data transfers
- Which ones have a significant impact on treatment
- Which ones are always in an end-to end test
- FMEA, clinical workflow design
- IT HELPS YOU UNDERSTAND YOUR SYSTEM

Quality Assurance and Control Basics

- **Principal concepts:**
  - **Physical Integrity**
  - **Logical Consistency**
- **ATP and Commissioning**
- **Annual**
- **Patient QC**

Principal Concepts

- Data Integrity
  - Are the bits and bytes intact?
  - Typically checked with a CRC
  - Were the transferred bits interpreted as the correct information?
- Logical Consistency
  - Are related pieces of information consistent with each other?

ATP and Commissioning

- ATP – typically done with the vendor
  - Might be limited to subsystem
  - Make sure to specify data transfer testing as part of the ATP at time of purchase
- Commissioning
  - Where data becomes information
  - Typically enter coordinate systems, preferences
  - Test data transfer matrix row for the subsystem

"Annual"

- Anytime a system is changed
- No change after a year?
  - test functionality/efficiency
- Combine several software updates on a deployment schedule if possible

Testing: Quality Assurance

- System Tests
- equipment meets specs
- Given input produces expected output

Can you really dial 999?

Part of Table II of the draft, QA items

5.	For virtual simulator: correct interpretation by the TPS of isocenter or initial reference marks used during the CT simulation.	1. Visually compare coincidence of radio-opaque markers and laser lines. 2. Visually check user origin on the TPS is passing through the three marks[15].
6. TPS to TMS/IGS/TDS	Validate plan constancy	1. Use the TPS plan lock feature if available. 2. Export plan to a separate file and perform a cyclic redundancy check at the time of plan completion; compare it with the value at the time of revalidation.
7.	Ensure the absence of systematic errors such as erroneous coordinate conversion or labeling.	Run test patients which represent all scenarios treated in the clinic and then manually inspect for discrepancies.
8.	Compare relevant values and DICOM information on the source and receiving systems.	1. Visually compare MLC shapes, treatment parameters (e.g. energy, beam directions), and images in the TMS against those in the TPS. This could be done using screen captures or print outs from the systems being compared.

Quality Control

- Inspects each service
- Or intermediate product
- Or items on an assembly line
- What we generally refer to mistakenly as QA in “patient-specific QA”

Testing: Quality Control

Data Transfer QC

- Done for every patient
- Done for every transfer of data
- Check for Logical Consistency and Data/Information Integrity.

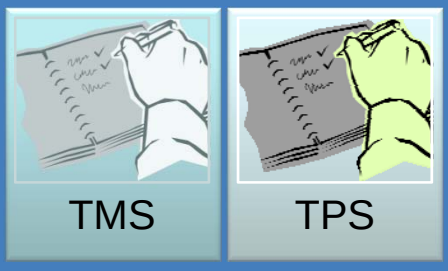
Part of Table III of the draft – QC items

Description	Method
1. Integrity of images transferred from imaging systems to planning systems should be checked for image quality and patient demographics.	Manual inspection of on-screen data or printouts.
2. Treatment plan parameters, including isocenter and setup information, across all systems.	1. Visual review 2. Automated review where possible
3. Perform patient-specific verification of treatment parameters in the treatment database to ensure that they match those in the treatment plan, including all control points in a delivery sequence.	A control-point-by-control-point comparison can be done through graphical comparisons, dose map, or fluence profile comparisons.
4. The transfer of coordinate system-dependent data (images, dose, and treatment parameters).	Visual review for proper orientation and registration
5. Independent MU checks should be performed on the data that gets downloaded to the treatment delivery system.	Numerical comparison
6. Manual entry into TMS: Examples: number of treatment sessions per week, or per day, session or daily dose limits, field names, tolerance tables, setup instructions and verification image	Visual review by a second user, i.e. not the person that entered the information

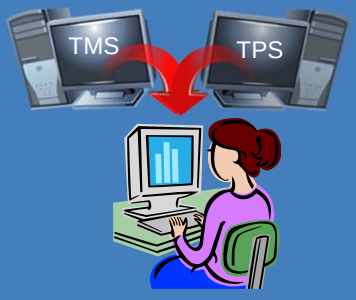
Information Integrity

- Generally a manual check
- Some places have automated systems

Manual vs Automated Check



Manual Comparison of Printouts or Screens



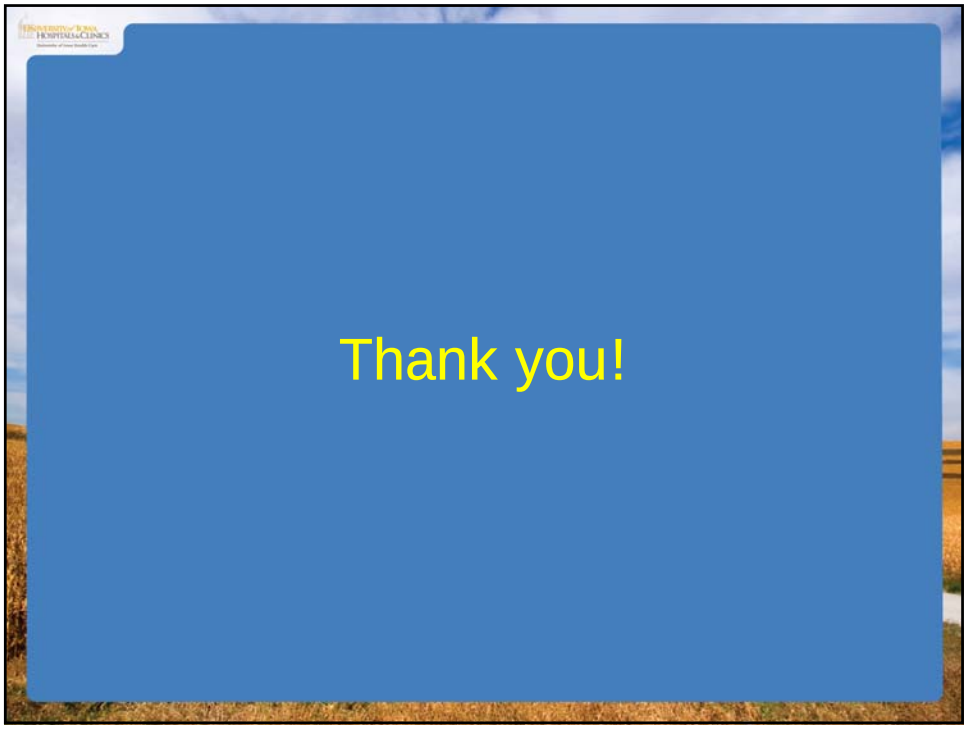
Software Compares Data Sources

Logical Consistency

- Mostly manual process
- Can be automated to some extent
- Example: a prescription calls for a treatment using 6x, but there is a 10x treatment beam within the prescription

Recommendations to the RT community

- Development of automated comparison tools
- Reduce manual data entry
- Enter data once correctly, automatic transfers/sharing of data
- IHE-RO response: QAPV


Thank you!