Clinical Networks: IT for Radiation Oncology

# Designing a QA program for one's clinical IT environment

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### QA test areas for IT

- Data Integrity
- Data Quality
- Logical Consistency
- Application Functionality
- Configuration

# QA frequency

- ATP: test functionality, configuration
- Updates: test functionality, configuration and data integrity
- Per patient, per plan: data integrity, logical consistency, data quality
- Per treatment: data quality, delivered vs planned, data integrity
- WHENEVER DATA OR THE SYSTEM HAS AN OPPORTUNITY TO CHANGE, intentionally or otherwise

Clinical
Workflows Show
Where Data can
Change and the
Checks Involved

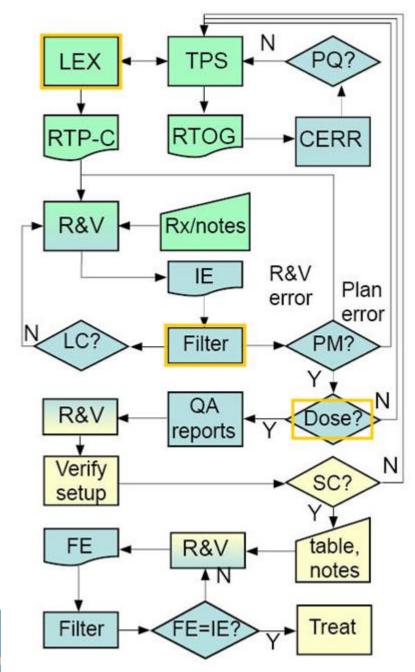
**Physicists** 

**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.





Departm

Radiation Oncology

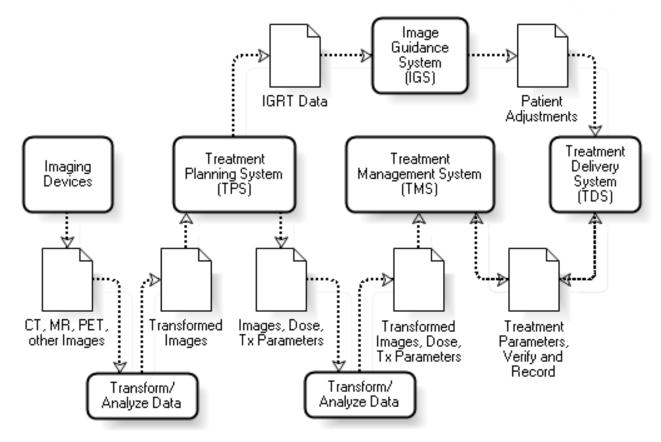
### Risk Assessment

- How do you decide which tests to run?
- What are the risks associated with the event that changes the system or the data?
- •TG-100
- Especially important when there is no established practice

### Environments

- Single Database:
  - Eclipse + Aria + Varian Linac
- Distributed Databases: e.g.
  - Pinnacle + Mosaiq + Elekta Linac,
  - Pinnacle + Aria + Varian,
  - Eclipse + Mosaiq + Varian.

### Distributed system data flow

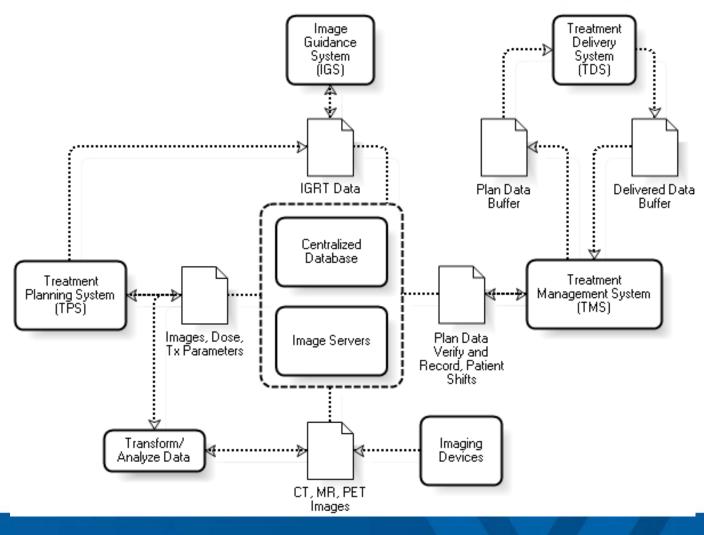


**Redundant data living in many places**: INFORMATION should match. (Data might be stored in different forms but mean the same thing.)

### Centralized DB dataflow

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

(watch out for caching and locking!)



### Data Integrity

- Treatment Plan Parameters
- Fractionation Schedule
- Prescriptions / Orders
- Documents
- Patient Notes / Alerts
- Other communication tools in your EMR/TMS/OIS

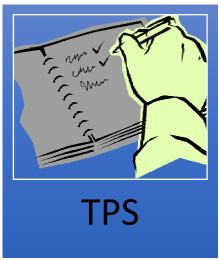
#### Manual check of items

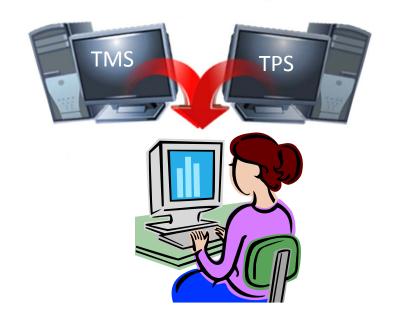
Potential automation depending on environment



# Manual vs Automated Check of Plan Data



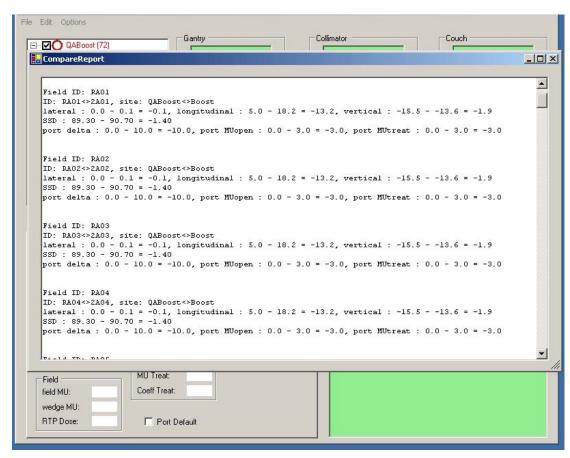




Manual Comparison of Printouts or Screens

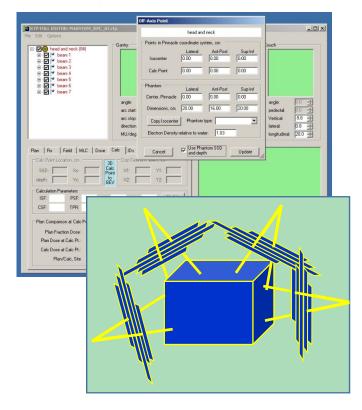
Software Compares Data Sources

# Plan Integrity After Data Transfer

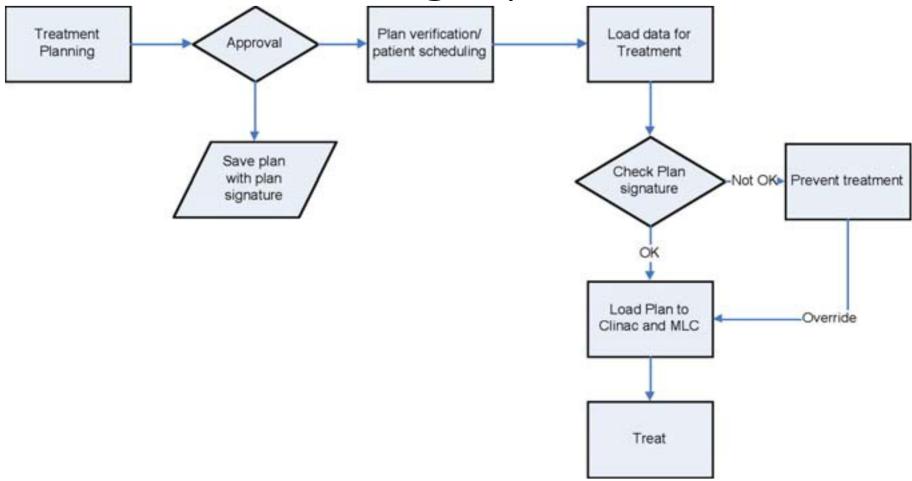


Plan data to treatment data comparison Pinnacle vs Mosaiq, In-house software UIOWA

#### **IMRT 2D Dose Calculation**



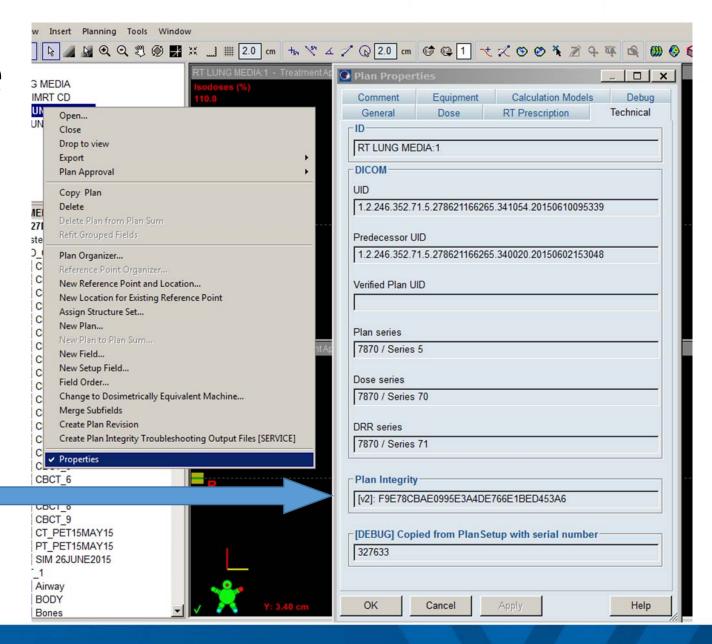
# Varian Plan Integrity Check



Joakim Pyyry, "Treatment Plan Data Integrity Check – A White Paper," Varian Medical Systems, 9/08



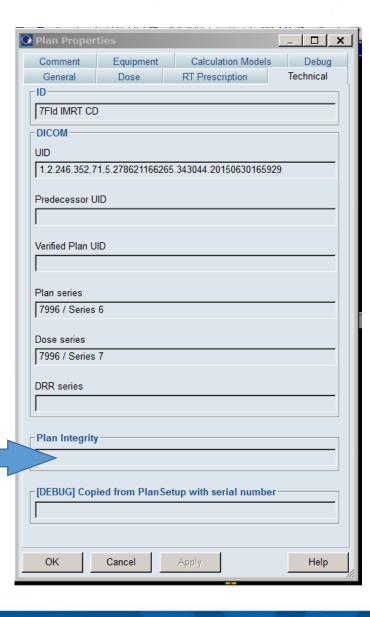
### Example



### Plan Revisions

- Can have the same Plan Integrity Check Value
- Example of retired plan with only a change in the number of fractions.

# Unapproved plans

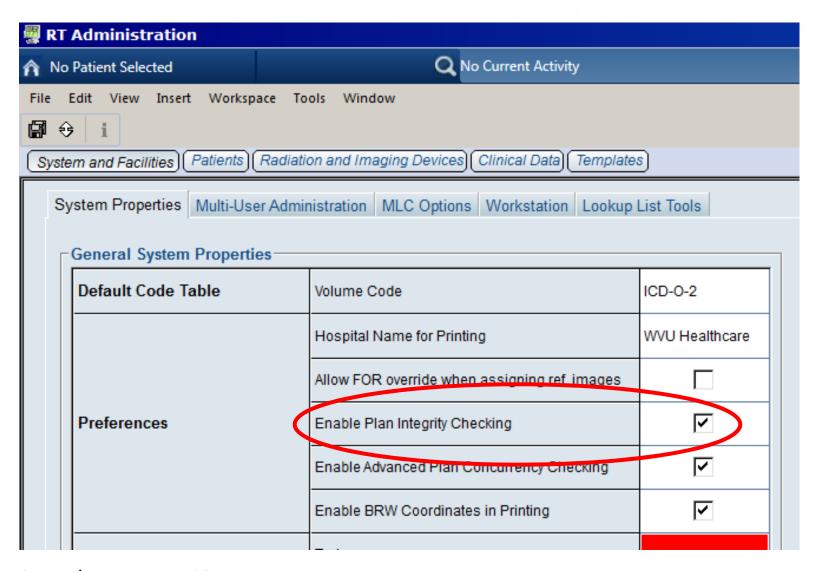


# Varian/Aria/Eclipse Plan Integrity

- This check ... is applied any time the approved plan is opened by an application, or after any transfer of data from one application to another (e.g., data transfer from Varian system database to 4D ITC).
- MD5 cryptographic hash function (128 bit hash).
- The full functionality is only available if the feature has been activated in both ARIA and 4D ITC (/TrueBeam).
- Enable the "Secondary Channel Integrity Check" / Treatment Plan Data Integrity

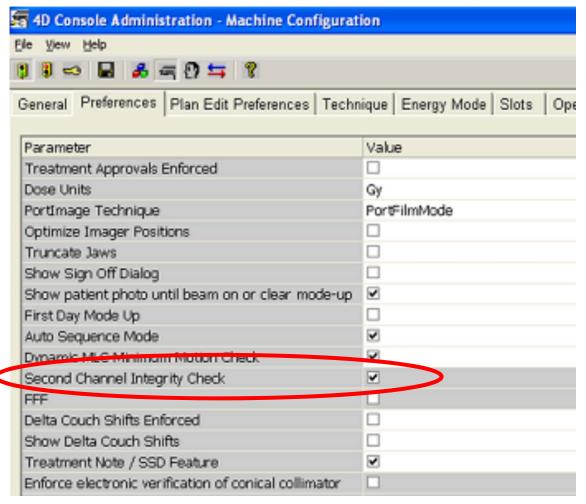
Joakim Pyyry, "Treatment Plan Data Integrity Check - A White Paper," Varian Medical Systems, 9/08





Eclipse /Aria 8.5 and later





4D ITC 8.3 and later. On TrueBeam: System Administration: Treatment Tab: Clinical General Preferences Panel: Secondary Channel Plan Integrity Check: YES. See the Varian User Manuals for further information.

### Modules that check plan integrity?

- Based on the white paper, they most likely are:
- Treatment Preparation
- Plan Parameters
- 4D ITC / TrueBeam when moding up.
- Any Varian Application that reads the plan parameters from the DB.

### Items included in check

- Every Treatment Beam in an Approved Plan
  - MU (in 0.1MU), modality
  - applicators, blocks, compensators, wedges, boluses
  - MLC leaf position boundaries
  - Control Points
    - Index
    - Dose rate
    - X and Y jaw positions
    - MLC leaf positions
    - Gantry, Collimator, Couch angle
    - Isocenter position
    - Meterset weight

Joakim Pyyry, "Treatment Plan Data Integrity Check – A White Paper," Varian Medical Systems, 9/08



### Items not included in check

- Fraction Dose (although implicitly included through MU)
- Number of Fractions
- Information in the Prescribe Treatment Module
- Couch vrt, Ing, lat; tolerance table
- Gated treatment flag
- Machine
- Tx Orientation
- SSD (implicitly; can recalculate)
- Plan Scheduling, Appointment Scheduling
- Reference Points
- MANUAL CHECK OF DATA INTEGRITY

### What if the DB gets corrupted?

- The Plan Integrity Value is stored in the DB for each approved plan.
- It could get corrupted itself.
- How would you know if the plan was intact, or the plan integrity value was intact or both?
- Store the Plan Integrity Value somewhere?
- What event would change the DB?
- Risk Analysis/Error Scenarios

### Other environments?

- Perhaps do a Dicom Export of the approved Plan from the planning system, transfer to the TMS, Dicom Export from the TMS, and compare.
- Perform MD5 on the Dicom Exports?
- Compare the MD5 values?
- Problem Even if the plan data is exactly the same, if the formats are slightly different, this will not match (e.g. number of digits, MU = 5.4 vs 5.40)
- IMRT QA? For 3DCRT manual check?
- Deliver the treatment and use Dynalog comparison software
- Use other commercial software for 2<sup>nd</sup> calc checks on delivered data, e.g. Mobius.



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winmd5.com/ ▼

WinMD5 is a freeware for Windows to allow user to calculate MD5 hash or checksum for files, and verify a download.

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Jan 28, 2014 - To generate or verify a hash, you simply browse to the file of choice, select either MD5 or SHA-1, and click either Copy to generate the hash or ...

#### Hash Tool - Calculate File Hashes - DigitalVolcano

www.digitalvolcano.co.uk/hash.html -

Hash Tool by DigitalVolcano Software. Easily calculate file hashes - MD5, SHA-1, SHA-256 and more.

#### MD5summer - Win MD5 file hash utility - SourceForge

sourceforge.net/projects/md5summer/ -

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Apr 16, 2013 - MD5summer - Win MD5 file hash utility 2013-04-16 17:10:27 free download. ... Get project updates, sponsored content from our select partners 4.2 Stars - Files - Support

#### HashMyFiles: Calculate MD5/SHA1/CRC32 hash of files

www.nirsoft.net/utils/hash\_my\_files.html -

HashMyFiles is small utility that allows you to calculate the MD5 and SHA1 hashes of one or more files in your system.

#### Md5Checker

getmd5checker.com/ ▼

MD5 checksum (MD5 hash) is a type of digests of files. ... To calculate MD5 checksum for publishing: File distributors and software authors can use Md5Checker ...

#### MD5 Checker - A Utility Program to Generate and Check ...

www.georgejopling.co.uk/md5check/md5check.html -

Jan 17, 2013 - MD5 Checker - A Utility Program to Generate and Check MD5 Hashes.

#### 10 Tools to Verify File Integrity Using MD5 and SHA1 Hashes

www.raymond.cc > Home > Software ▼

A couple of the popular hash algorithms are MD5 and SHA1 and you will ... What is needed is a utility to calculate a hash value using the same algorithm. Simply ...

#### Hash Generator: All-in-one Tool to Generate Hash MD5 ...

securityxploded.com/hashgenerator.php -



### Data Quality

- Important for standardized processes
- Improves workflow
- Improves communication
- Enables automation
- Enables Reliable Data Mining

# Missing Data, Erroneous data

Age	Height	Weight, lbs
50	5'6"	145
6		150
27	6′ 1″	
		22

# Data Structure Naming (TG263)

- Consistency within the department?
- Consistency with external clinical trials?

```
Structures
                                                                                37
                                                                       wire
.Where(s=> s.HstryDateTime > new DateTime(1980, 6, 30))
                                                                       wire air
.GroupBy (s => s.StructureId.Trim() )
                                                                       wire body 1
.Select(s => new {s.Key, number = s.LongCount ( ) })
                                                                       wire in
.OrderBy(s=> s.Key)
                                                                       wire out
.Count()
                                                                       wire-air
                                                                       wire-body 1
Result: 8,189 different structure Ids!
                                                                       wire-in
Issues: Variable spelling, abbreviations, punctuations, case
                                                                       wire-new 1
                                                                       wire.
sp cord
                                                                       wire2
sp. cord
                                                                       wire3
spinal cord
                                                                       wire4
                                                                                 1
spinal cord
                  506
                                                                       wires
```

### What can you do about it?

- Policy / convention
- QA is manual check structure names
- Use templates, structure sets
- DEVELOP DEPARTMENT STANDARDS

### Other examples

- Entering Diagnoses and attaching to a course
- Putting the right information in treatment notes (e.g. start dates)
- Anything else that a human enters that could possibly be used in a query
- ....
- Risk is variable, depends on the error and what clinical operations it affects

### 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

### Application Functionality - I

- When you turn on features, do they really work?
- End to end tests
- Typically put a patient through all systems that touch the feature(s) being tested.
- Simple Example: when you approve a plan, and the plan integrity check is enabled, does the plan integrity value appear in the properties?

# Application Functionality -II

- Complex Example: How do you verify that you get a warning if the plan integrity value has changed?
  - What did the vendor do?
  - Do you just take their word for it?
  - Can you directly change an item in the database and trigger the warning? (remember jumpers on boards for linac interlock tests?)
- IN GENERAL this functionality has been tested by the vendor prior to release.
- LOCAL PRACTICE the use of a function in a way the vendor did not anticipate can cause issues! Test the system in the context of your practice. This is the value of the end-to-end test.

### Configuration

- System Administration, preferences
- MANUAL Check
- SYSTEM WIDE ERRORS if incorrectly configured
- QA:
  - Independent second check by a user qualified to make judgments on the suitability of the configuration
  - End to end testing

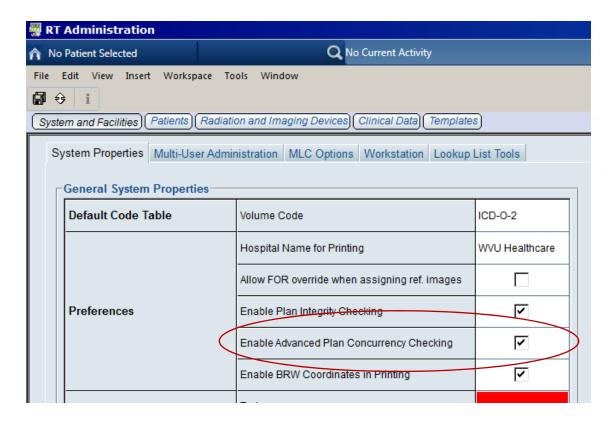
### Example Configurations

- VERY CRITICAL: COORDINATE SYSTEMS
- Is it IEC 1217? Is it a Varian version of IEC? Is it native? Is it a hybrid?....
- Very Critical: Machine configuration (motion limits, exclusion zones, energies, dose rates, etc.)
- Very Critical: Interlocks and safety related preferences.

### Commissioning

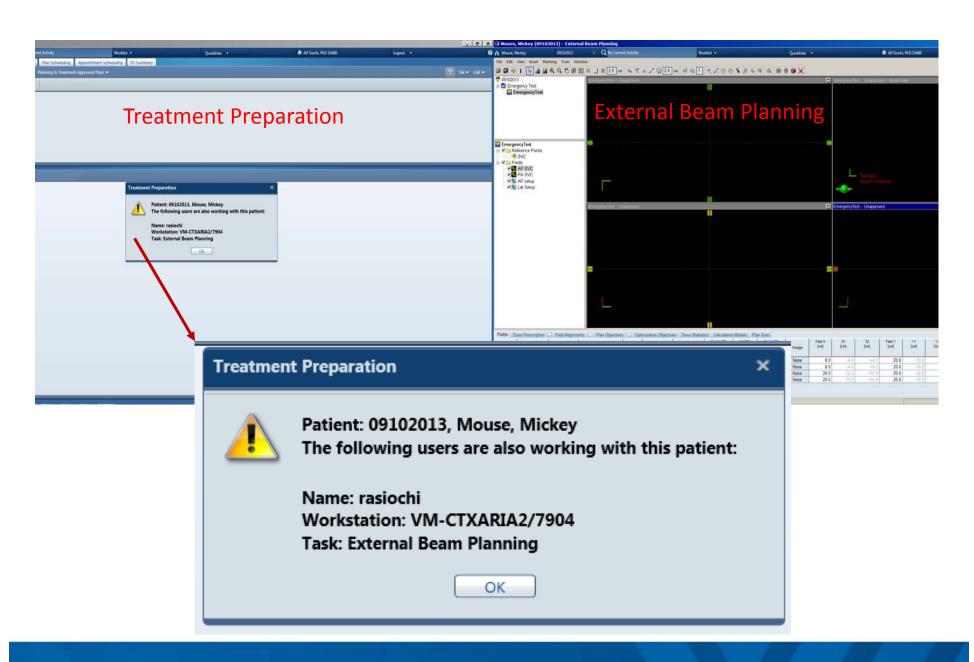
- Typically Configuration of applications and network connections
- End-to-end testing
- Other functionality testing, e.g. Concurrency

### Concurrency Configuration

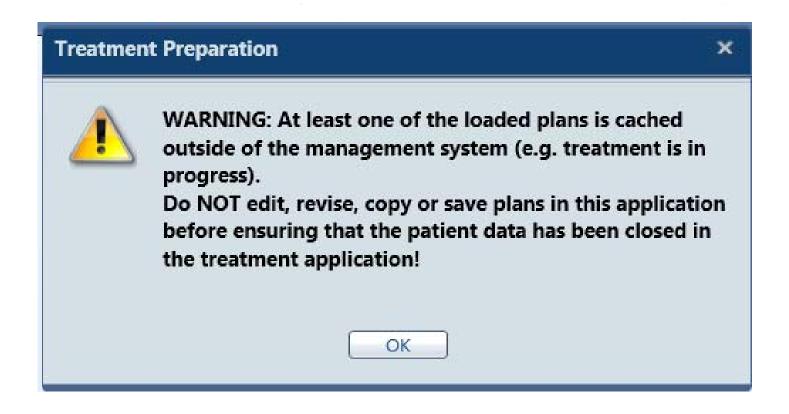


## Concurrency Testing

- Characterization test, not just functionality.
  - What does the manual say will happen? (functionality)
  - What actually happens? (characterization)
- Open the same plan for the same patient in two different applications / modules / workstations
- Try with the same user, different user
- What messages do you get?



# With a Plan Moded up on Truebeam, Right after starting the Treatment Preparation application:



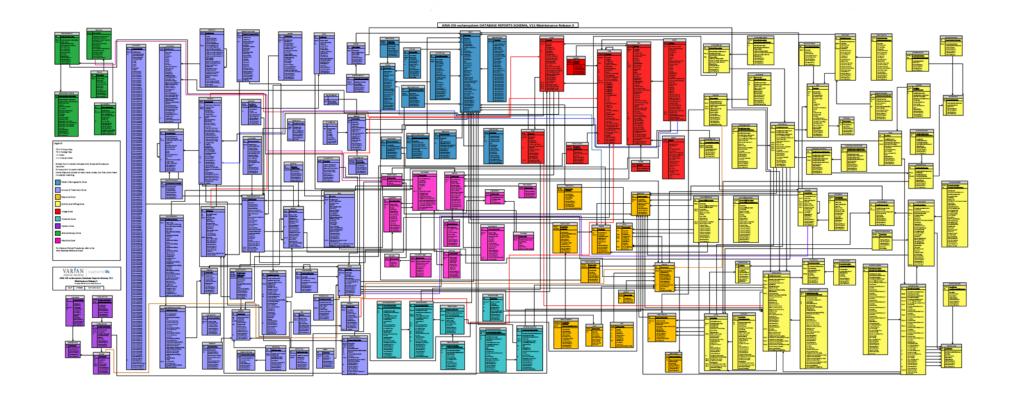
# Error/Warning Messages

- Characterization testing
- Hard to do
- Need to Keep a running log
- Investigate and eliminate the cause
- Reduce the number of Error/Warning messages in your process.
- Have a planned response to the messages.
  - If a treatment is in progress, and you get the warning about the cache, what should you do?
  - Policy: Close the application without editing anything. If you want to work on a plan other than what is under treatment, verify with the treatment machine first.

#### CASE STUDY

- Update to ARIA, Maintenance release
- NO ATP is specified by the vendor
- What is the risk, and what tests should we do?
- Only Practice Management will be touched, they say. (What do they mean by this?)

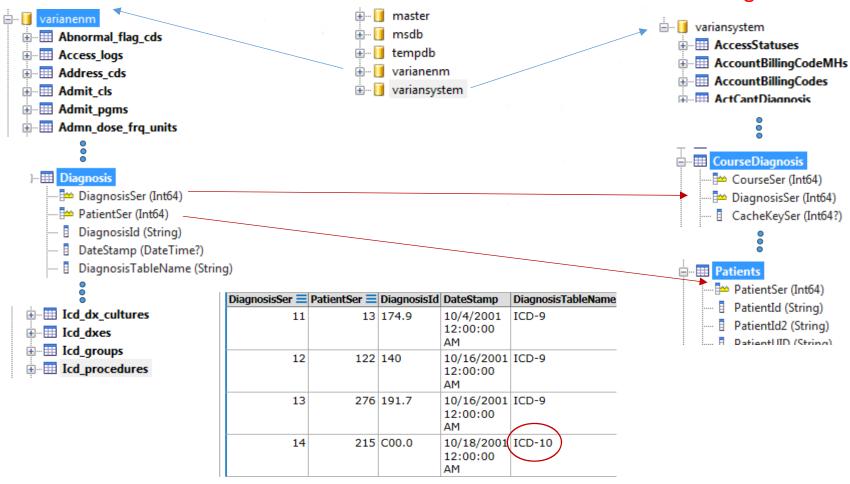
## ARIA OIS variansystem DB



Did they mean a different section of this DB, called variansystem?

### ARIA SQL SERVER

## Or did they mean a different, but related or "linked" DB altogether?



## One Suggestion for testing

- End to end test of registering a new patient (phantom), scan, import CT, plan, schedule, treat.
- Shortcuts? Just use an existing phantom, plan, schedule, treat.
- Question: Is it okay not to test the new patient registration? What about importing the CT?
- Vendor answer: This is only for ICD-10. It does not affect eclipse. However I don't know what tables in the DB will be updated.

## Problem: Is an end-to-end enough?

- End-to-end: Checks functionality.
- What about data integrity?
- Patient on treatment before and after the update?
- I HAVE PERSONALLY SEEN LOST DATA ON A DB MIGRATION. ALL PATIENTS COULD BE AFFECTED. (fortunately it was not the plan data).
- END-TO-END ON A SINGLE TEST PATIENT WILL NOT CATCH THIS PROBLEM.

# What is a DB migration?

(1) Backup Old DB.

(2) Run Migration Script.

(3) Test New DB.

New DB Schema

#### Old DB Schema

Column Name	Values
Name	Mr. Alpha Beta
Date of Birth	2001-01-01

Column Name	Values
Salutation	Mr
First	Alpha
Last	Beta
Birth Year	2001
Birth Month	January
Birth Day	1
Phone number	

#### What Data is at Risk?

- What do they mean only the practice management part is affected?
- ICD-10: affects Diagnoses.
- Diagnoses are linked to patients.
- Potentially linked to Courses.
- Courses in a plan exist in another DB.
- YOU COULD LOSE THE LINKS BETWEEN DATABASES, if you lose the data in the DB being updated.
- Plan data unlikely to be affected, but should be checked.



## Plan of Action – I Pre-upgrade

- Before the upgrade make a list of:
  - Critical Patients: under treatment, being planned
  - Application configuration settings (screen shots)
- For each critical patient:
  - Store the plan integrity check
  - Record the prescription, screen shot of documents list, journal notes, patient alerts, number of fractions treated, fractions remaining to treat...

## Plan of Action II – after the upgrade

- For each critical patient:
  - compare their post upgrade data to their pre upgrade data
  - mode them up (or open in Treatment Preparation) to verify plan integrity.
- verify configuration settings
- do an end-to-end test with a fake patient.
- If there are issues, be prepared to roll back to the old version.

#### Comments

- The plan of action is only responding to the upgrade event.
- In this QA, we checked data integrity and functionality.
- This QA will not fix the following problems:
  - Logical consistency among data elements
  - Quality of the data
  - These require manual checks on a per-patient basis. Should be part of the plan check and chart check.
  - Since no event triggers the need for this check, it is not an issue for the upgrade. These will be caught as part of normal clinical operations.

## Case Study II

- LANTIS to MOSAIQ upgrade
- Not only a change to the DB
- Also a major shift to functionality

## Changes

- User Interface is very different.
- Database Schema is very different. More tables.
   More fields in existing tables.
- Functionality is very different. To treat a patient, you need more data for that patient.

## QA is not enough

- Used a Simulator of the system
- Developed and trained to new workflows
- Determined how patient data needed to be transformed
- Snapshots of configurations, exports of machine files, exports of patient treatment data prior to update

## After the update

- After the update, process each patient under treatment to complete the missing data. This involved Dicom Image Exports for existing treatment plans.
- Export the patient treatment data and compare against the pre-update data.
- Perform end to end tests for all new functionality.
- Expert Users present at each treatment machine at Go-Live

# Other QA/Commissioning

- Network speed (ping)
- Routing configuration has it changed (tracert)
- Are there things that IT should be doing routinely to check the health of the network? Are they doing it for you?
- Network change events need to be informed when IT is planning changes (new servers, dns changes, IP address changes, topology, firewalls, host intrusion prevention, etc.)

#### Trace Route

```
Administrator: C:\Windows\system32\cmd.exe

Microsoft Windows [Version 6.1.7601]
Copyright (c) 2009 Microsoft Corporation. All rights reserved.

C:\Users\rasiochi>tracert nt-aria1

Tracing route to Final destination
over a maximum of 30 hops:

1 27 ms 2 ms 4 ms 2 (1 ms 1 ms 1 ms) 1 ms 2 (1 ms) 1 ms (1 ms) 1 ms 4 (1 ms) 1 ms (1 ms) 4 (1 ms) 4 (1 ms) 4 (1 ms) 4 (1 ms) 5 Final destination

Trace complete.

C:\Users\rasiochi>
```

a separate run gives different times, even for the same route:

1 2	30 m 1 m		ms ms	10 <1	
3	<1 m	is <1	ms ms	(1 (1	ms

Tracert is really meant for determining the route, not the speed (use ping instead).

## Ping

```
_ D X
Administrator: C:\Windows\system32\cmd.exe
Microsoft Windows [Version 6.1.7601]
Copyright (c) 2009 Microsoft Corporation. All rights reserved.
C:\Users\rasiochi>ping nt-aria1
                     Destination IP address
Pinging
                                                           ] with 32 bytes of data:
                                 bytes=32 time<1ms TTL=61
bytes=32 time<1ms TTL=61
Reply from
Reply from
                                 bytes=32 time<1ms TTL=61
Reply from
                 address
Reply from
                                 bytes=32 time<1ms TTL=61
Ping statistics for IP address:

Packets: Sent = 4, Received = 4, Lost = 0 (0% loss),
Approximate round trip times in milli-seconds:
     Minimum = Oms, Maximum = Oms, Average = Oms
C:\Users\rasiochi>
```

## Audits - annually

- Disaster Recovery Plan
- Business Continuity Plan
- Network Architecture

## Summary: General Principles

- Map the data flow in your department.
- Understand where and when all the opportunities for changes to the data can occur.
- Know where your data is stored, and how that storage can change. A lot of this will be in your DB.
- Design QA tests that are appropriate to the planned changes (e.g. ATP, Commissioning, Upgrades).
- Design QC tests that catch unplanned changes or errors in data entry and/or transfer.

## Summary: Topics to test

- Quality Assurance on the system
  - Functionality, use end-to-end test
  - Data Integrity, use before and after comparisons
  - Configuration, use a second check
- Quality Control of patient data
  - Data Integrity, before and after comparisons
  - Logical Consistency and Data Quality initial plan check, new patient rounds, and weekly chart check