School of Medical Physics for Radiation Therapy: Dosimetry and Treatment Planning for Basic and Advanced Applications

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Record&Verify and Patient Information System

Eugenia Moretti
ASUIUD Udine
eugenia.Moretti@asuiud.sanita.fvg.it

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I do not endorse any products, manufacturers, or suppliers.

Nothing in this presentation should be interpreted as implying such endorsement

Agenda

- ♦ IT in RO
- ♦ R&V
- ♦ OIS
- ◆ QA

IT is vital in the process of cancer care

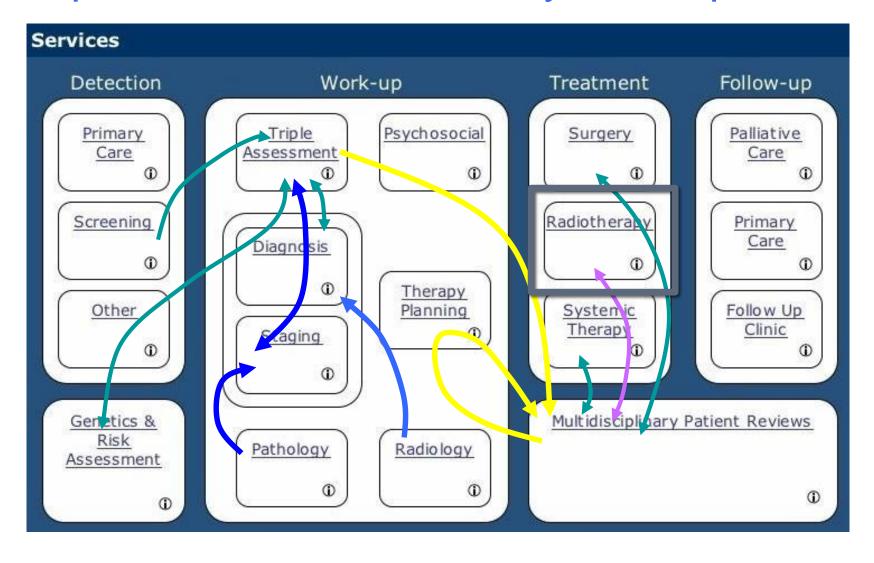
- Cancer care has changed
- ♦ Patients used to get either surgery, CT or RT...: it is common for patients to get combined therapies, 2 or all 3 of the above
- To perform diagnosis can be necessary to integrate different information
- To perform the therapy can be necessary to combine different information and so concerning the follow-up
- Integration of information: this has increased the <u>need for</u> (<u>computer</u>) <u>communication</u> between different departments within the hospital (or among hospitals)

Most health care processes involve continuously exchanging information

- Within the workgroup, to record and manage the care of individual patients
- Between specialized diagnostic and treatment departments, to request services and to report results
- Across organization boundaries between hospital doctors and community staff, to ensure continuity of care
- From the care provider to payers and regulatory agencies, for revenue and accountability



The process of care: RO is only one step



RO is a complex world

- ♦RO involves a complex set of sub-processes (mainly clinical, but very often: technological, physical) and accompanying workflow to evaluate, plan, deliver, and monitor patient treatments
- ♦The workflow includes a mixture of process steps requiring clinical decisions at many points, quality assurance checks along the way, on-line and off-line evaluations, and careful patient monitoring
- Computerized decision support is a fundamental component to a number of these phases

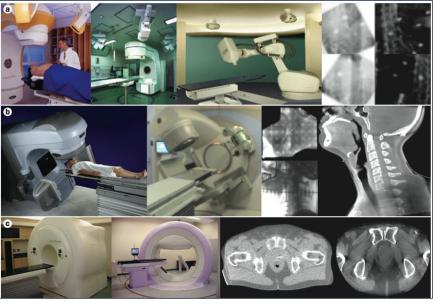
RO is a complex world

"The most important feature related to the complexity and sophistication of "new technology" is the <u>omnipresence of computers</u>"

[ICRP Preventing Accidental Exposures from new EBRT Technologies, 2009]

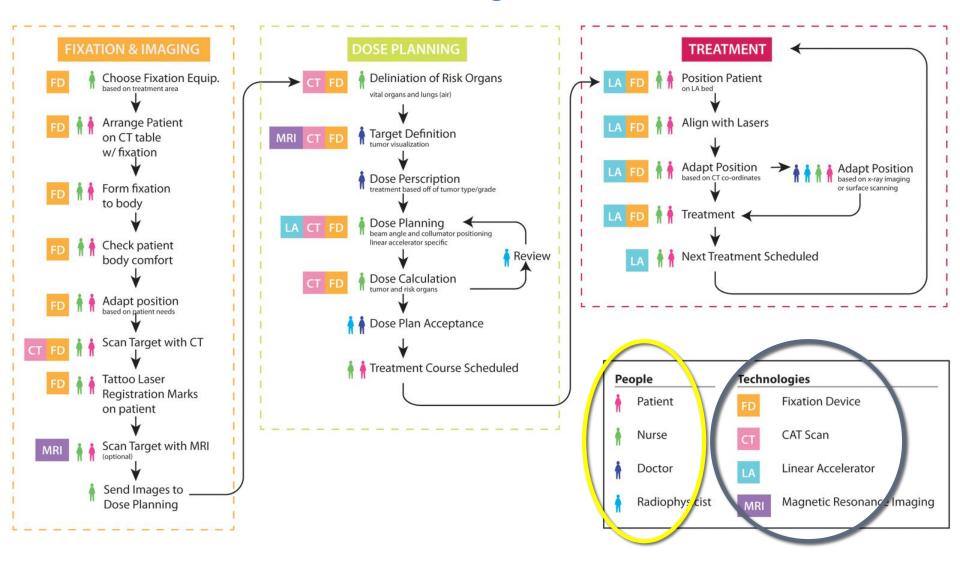
RO is "Computer-driven RT and software-based devices"

<...digital linacs, VMAT, SABR, 4DRT, ART, MRgRT..>



Jaffray, Nature, 201

Radiology Oncology workflow A multi-actor and technological environment



The Radiation Oncology staff

Radiation oncologist Medical Physicist Radiation Therapist "Dosimetrist" Nurse Secretary System Administrator (=Medical Physicist)

- Each of these operators can have access to the data with different rights
- Every their actions must be registered by the system of management of the whole treatment (*username*, *password*...*digital signature* to give legal values to the activities around the pt)

Record & Verify System

The software that checks the TX parameter (position of the couch, collimator, gantry, leaves positions, and any beam modifiers etc) before a treatment is given.

It **links** with the TPS or PIS and the control system of the linear accelerator or TDS (often the <u>R&V system</u> is part of the control system)

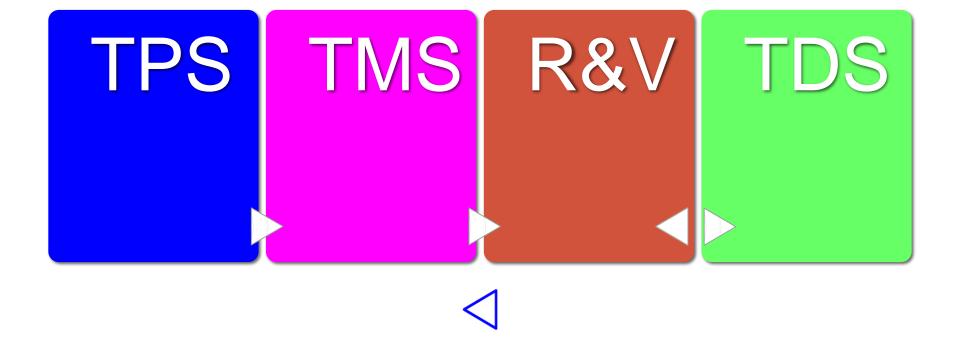
It has tolerance levels built into them. These allow some parameters to be allowable as long as they are within a certain range of the expected value. Different parameters have different tolerance levels (depending on the type of technique too)

A username/password entry so staff can authorize a TX

Patient Information System

The information infrastructure which is directly related to the planning (TPS), delivery (TDS), quality assurance, and archival of patient treatments

Interactions



R&V (V&R) functionality

- ♦ The R&V S Verifies and Records all aspects of each individual TX
- ♦ Each time the patient is treated, the linac requests the TX parameters from the R&V, sets the beam-defining devices, informs the R&V of its positions, and waits for the R&V to verify that the positions are within tolerance
- Once the linac receives the approval, it delivers the radiation and sends the delivered treatment information to the R&V so that it can record the dose (dose tracking) and treatment parameters that were used to treat the patient
- This process of downloading, verifying, treating, and recording is repeated for every single treatment field. There is also a transfer of images, structure sets, markers, other information ("this is the last fraction" bla bla)

Network infrastructure: robustness!!

It is important that the network infrastructure <u>efficiently handles the transfer of these large amounts of data</u>, otherwise patient treatment could be either delayed or compromised

The most common networks that an end user encounters are the LANs (Local Area Network). As implied by the name, LANs usually reside in a single building, in a complex of buildings or on a campus up to a few kilometers in size (less than 10 km). (12) They are mostly used to share resources (such as printers, files, internet connections, etc.) and exchange data among components of the local IT infrastructure (personal computers, workstations and servers). The other main attribute that discriminates LANs from other network types is the in-advance knowledge of all main network characteristics (size, physical layer technologies and topology). Both the small size and the in-advance knowledge of the main network characteristics make LANs simpler to design and manage when compared with other network types. LANs are common in Radiology and RO departments, and must have sufficient bandwidth for specialized services. In some cases 100 Mbps is insufficient for quality data transfer. These networks must also have high availability support mechanisms in order to archive and backup digital data that developed in order to support the plethora of different client and/or server systems throughout the hospital. Real-time treatment support requires an extremely high uptime for these networks, so the network architecture must be designed with alternative routes in case of failure. Medical physicists should be consulted when the systems are being designed.

Wireless networks have additional considerations. Current technology limits the transmission speed to approximately 140 Mbps, so these may not be suitable for some applications. Their operating frequencies (2.4 to 5 GHz) may also interfere with those of other RF systems, or the other systems (e.g. linac at 3 GHz) may cause problems for these networks. Finally, security policies for wired and wireless networks may be different and the impact of this on clinical systems must be discussed with the medical physicist.



Siochi et al.: RO IT resource management, JACMP, 2009

IT in RO (Siochi, 2011)

JOURNAL OF APPLIED CLINICAL MEDICAL PHYSICS, VOLUME 10, NUMBER 4, FALL 2009

Information technology resource management in radiation oncology*

R. Alfredo Siochi, ^{1,a} Peter Balter, ² Charles D. Bloch, ³ Harry S. Bushe, ⁴ Charles S. Mayo, ⁴ Bruce H. Curran, ⁵ Wenzheng Feng, ⁶ George C. Kagadis, ⁷ Thomas H. Kirby, ⁸ Robin L. Stern ⁹ Department of Radiation Oncology, ¹ University of Iowa Hospitals and Clinics, Iowa City, IA, USA; UT MD Anderson Cancer Center, ² Houston, TX, USA; Department of Radiation Oncology, ³ Washington University, Saint Louis, MO, USA; Radiation Oncology Dept., ⁴ UMass Medical Center, Worcester, MA, USA; Department of Radiation Oncology, ⁵ Rhode Island Hospital, Providence, RI, USA; Department of Radiation Oncology, ⁶ William Beaumont Hospital, Royal Oak, MI, USA; Department of Medical Physics, ⁷ School of Medicine, University of Patras, Rion, Greece; Global Physics Solutions/Univ. New Mexico, ⁸ Albuquerque, NM, USA; Department of Radiation Oncology, ⁹ University of California, Davis Health System, Sacramento, CA, USA. ralfredo-siochi@uiowa.edu

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The ever-increasing data demands in a radiation oncology (RO) clinic require medical physicists to have a clearer understanding of information technology (IT) resource management issues. Clear lines of collaboration and communication among administrators, medical physicists, IT staff, equipment service engineers, and vendors need to be established. In order to develop a better understanding of the clinical needs and responsibilities of these various groups, an overview of the role of IT in RO is provided. This is followed by a list of IT-related tasks and a resource map. The skill set and knowledge required to implement these tasks are described for the various RO professionals. Finally, various models for assessing one's IT resource needs are described. The exposition of ideas in this white paper is intended to be broad, in order to raise the level of awareness of the RO community; the details behind these concepts will not be given here and are best left to future task group reports.

Summary

- Radiation Oncology Informatics deals with
 - The IT infrastructure to plan and deliver radiotherapy and participate in clinical trials
 - The information science needed to analyze clinical data
 - The infrastructure to gather massive amounts of data
 - The improvement of clinical practice, safety, and quality

AAPM/COMP 2011 Vancouver



Infrastructure Summary

- · Computers with RT applications:
 - Treatment Planning System
 - Treatment Management System ("V&R")
 - Treatment Delivery System (Linac control console)
- Servers
 - DB servers
 - Web server
 - Wiki host server
- · Archiving and Backup
- Networks
 - Data transfers, e.g. DICOM: images and RT plans
 - Access to servers

At the very beginning, only the R&V (o V&R) systems

Record and verify systems (RVSs) were initially developed to reduce the risk of treatment errors, where the treatment parameters used for a given fraction were set manually and could differ from the 'prescribed' (or 'intended') parameters [IAEA, HHR No.7 2013]

"Programmable Electrical Medical System or subsystem including its associated peripherals, that is used to compare the set-up of a Radiotherapy Treatment machine to predetermined set-up conditions prior to the start of a proposed Radiotherapy Treatment and each Treatment session, and record actual Treatment sessions. It also provides a means of preventing the machine operation if the actual set-up is not the same as the pre-set intended set-up, within User defined tolerances."

IEC 62274 ed.1.0, «Safety of Radiotherapy RVSs», 2005

Afterwards.. not-only R&Vs but CCDTS



Int. J. Radiation Oncology Biol. Phys., Vol. 71, No. 1, Supplement, pp. S98–S102, 2008
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0360-30160085-see front matter

doi:10.1016/j.ijrobp.2007.05.089

QA FOR RT SUPPLEMENT

QA ISSUES FOR COMPUTER-CONTROLLED TREATMENT DELIVERY: THIS IS NOT YOUR OLD R/V SYSTEM ANY MORE!

BENEDICK A. FRAASS, PH.D.

Department of Radiation Oncology, University of Michigan Medical Center, Ann Arbor, MI

State-of-the-art radiotherapy treatment delivery has changed dramatically during the past decade, moving from manual individual field setup and treatment to automated computer-controlled delivery of complex treatments, including intensity-modulated radiotherapy and other similarly complex delivery strategies. However, the quality assurance methods typically used to ensure treatment is performed precisely and correctly have not evolved in a similarly dramatic way. This paper reviews the old manual treatment process and use of record-and-verify systems, and describes differences with modern computer-controlled treatment delivery. The process and technology used for computer-controlled treatment delivery are analyzed in terms of potential (and actual) problems, as well as relevant published guidance on quality assurance. The potential for improved quality assurance for computer-controlled delivery is discussed. © 2008 Elsevier Inc.

Computer control, Treatment delivery, Quality assurance, Intensity-modulated radiotherapy, Image-guided radiotherapy.

Computer-controlled treatment delivery (CCTD) process R&V is a part of the control system of the delivery process

"Quality Assurance of Radiation Therapy: The Challenges of Advanced Technologies" Dallas, TX, 20-22 febraury, 2007 [ASTRO, AAPM, NCI]

- It was the 1980s before the first commercial CCTD System, the Scanditronix MM50 Racetrack Microtron, became available. (..) incorporated a fully computerized control system, MLC, and photon and electron beams (to 50 MeV) flattened with CC-scanning
- (..) Modern RT is performed with CCDS which are electronically linked to the TPS
- (..) Random transcription errors, which invariably happen as human transfer information manually, are no longer the most important issue, as transfer are automated
- More important are the much less, but potentially more severe systematic errors, which can occur, especially in interface between systems

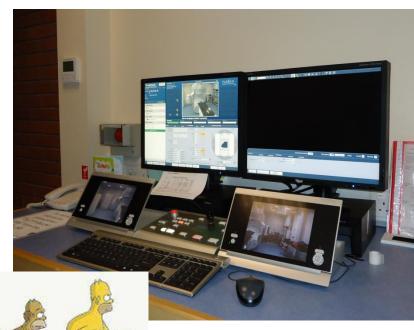
Control Console (R)evolution (TDS)

HOMERSAPIEN

1985

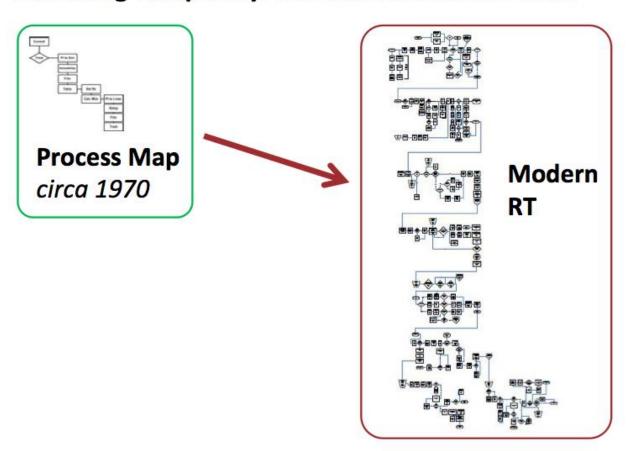
2010





The evolution of the process

Increasing Complexity: Increased Chance of Error?



Eric Ford, Future of Radiation Medicine, Feb 17, 2011, Scottsdale, AZ

TMS, RTIS, OIS, PIS and other acronyms

 R&VSs are 'medical devices' (...) evolved into complete <u>Radiotherapy</u> <u>Information Management Systems</u> that interface with <u>Imaging</u> <u>Systems</u>, <u>Treatment Planning computers (TPS)</u> and <u>Treatment</u> <u>Delivery Systems (TDS)</u> [IAEA, 2013]

TMS → **Treatment Management System**

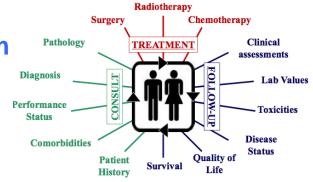
RTIS → Radiation Therapy Information System

DMS → **Data Mangement System**

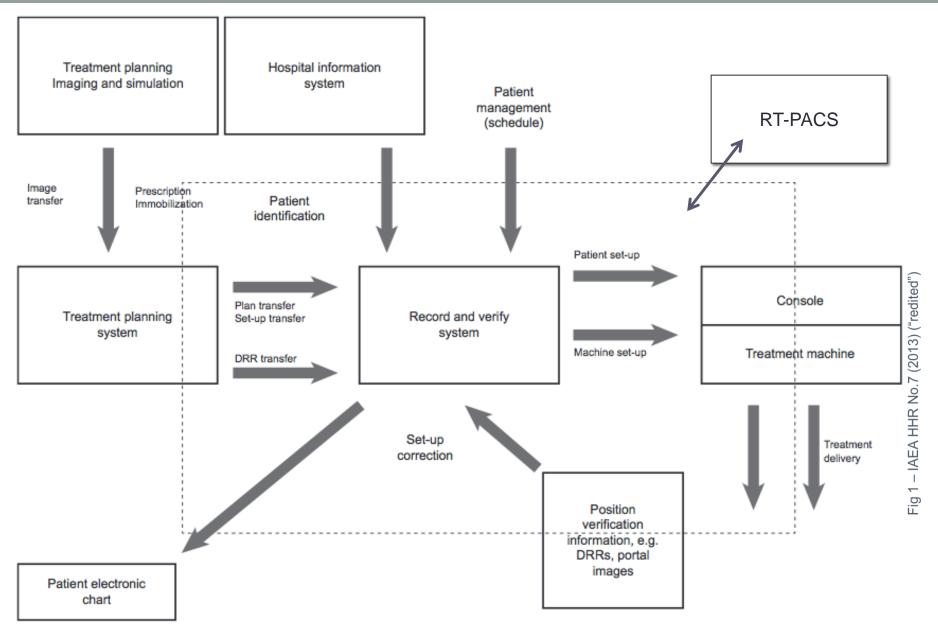
OIS → Oncology Information System

EMR → **Electronic Medical Record System**

EHR → **Electronic Health Record System**



• TMS is typically a combination of an OIS with R&VS [Siochi et al., JACMP, 2011]



R&V systems have evolved in DBs that include not only treatment machine parameters, but also scheduling, images, assessments, document import and Health Level 7 (HL7) support (Siochi et al., JACMP, 2009)

Today...the cloud

1980



≥ 2015



Computing Systems in RT New paradigms

Cloud Computing is "a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g. networks, servers, storage, apps and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction" (NIST, 2011)

Vision 20/20: Automation and advanced computing in clinical radiation oncology

Kevin L. Moore^{a)}

Department of Radiation Medicine and Applied Sciences, University of California San Diego, La Jolla, California 92093

George C. Kagadis

Department of Medical Physics, School of Medicine, University of Patras, Rion, GR 26504, Greece

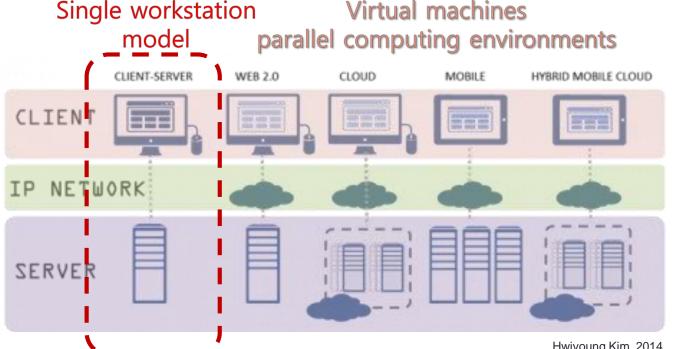
Department of Radiation Oncology and Molecular Radiation Science, School of Medicine, Johns Hopkins University, Baltimore, Maryland 21231

Vitali Moiseenko

Department of Radiation Medicine and Applied Sciences, University of California San Diego, La Jolla, California 92093

Department of Radiation Oncology, Washington University in St. Louis, St. Louis, Missouri 63110

Med Phys, 41(1), Jan 2014



Hwiyoung Kim, 2014

- Cloud-based service models
- Aggregate data analysis
- Parallel computation
- Automation

We're still here (1980's!)

Stratosphere of Cloud Computing



- CaaS = Communication As A Service
- SaaS = Service As A Service
- PaaS = Platform As A Service
- laaS = Infrastructure As A Service

Cloud Computing in RO - literature

Phys Med Biol. 2011 September 7; 56(17): N175-N181. doi:10.1088/0031-9155/56/17/N02.

Toward Real-Time Monte Carlo Simulation Using a Commercial Cloud Computing Infrastructure+

Henry Wangb, Yunzhi Maa, Guillem Pratxa, and Lei Xinga

^aDepartment of Radiation Oncology, Stanford University School of Medicine, Stanford 94305-5847

^bDepartment of Electrical Engineering, Stanford University, Stanford, California 94305

Abstract

Purpose—Monte Carlo (MC) methods are the gold standard for modeling photon and eltransport in heterogeneous medium; however, their computational cost prohibits their rout in the clinic. Cloud computing, wherein computing resources are allocated on-demand fro party, is a new approach for high performance computing and is implemented to perform a MC calculation in radiation therapy.

Methods—We deployed the EGSS MC package in a commercial cloud environment. Lai from a single local computer with Internet access, a python script allocates a remote virtua cluster. A handshaking protocol designates master and worker nodes. The EGSS binaries a simulation data are initially loaded onto the master node. The simulation is then distribute independent worker nodes via the Message Passing Interface (MPI), and the results aggreg the local computer for display and data analysis. The described approach is evaluated for pleams and broad beams of high-energy electrons and photons.

Results—The output of the cloud-based MC simulation is identical to that produced by t single-threaded implementation. For 1 million electrons, a simulation that takes 2.58 hour local computer can be executed in 3.3 minutes on the cloud with 100 nodes, a 47x speed-u Simulation time scales inversely with the number of parallel nodes. The parallelization ov



cent advances in ntially improved s a layer of abstr calculations are

Cloud Computing in Radiation Therapy

Kevin L. Moore, Ph.D., DABR

AAPM, Meeting 2014

Where discoveries are delivered."



ron n

PHYSICS IN MEDICINE AND BIOLOGY

Phys. Med. Biol. 58 (2013) 6525-6540

doi:10.1088/0031-9155/58/18/6525

Toward a web-based real-time radiation treatment planning system in a cloud computing environment

Yong Hum Na 1,2,3, Tae-Suk Suh 2, Daniel S Kapp 1 and Lei Xing 1

Department of Radiation Oncology, Stanford University, Stanford, CA 94305 USA
 Department of Biomedical Engineering, The Catholic University of Korea, Seoul, Korea

E-mail: yhna@stanford.edu

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Abstract

To exploit the potential dosimetric advantages of intensity modulated radiation therapy (IMRT) and volumetric modulated arc therapy (VMAT), an in-depth approach is required to provide efficient computing methods. This needs to incorporate clinically related organ specific constraints, Monte Carlo (MC) dose calculations, and large-scale plan optimization. This paper describes our first steps toward a web-based real-time radiation treatment planning system in a cloud computing environment (CCE). The Amazon Elastic Compute Cloud (EC2) with a master node (named m2.xlarge containing 17.1 GB of memory, two virtual cores with 3.25 EC2 Compute Units each, 420 GB of instance storage, 64-bit platform) is used as the backbone of cloud computing for dose calculation and plan optimization. The master node is able to scale the workers on an 'on-demand' basis, MC dose calculation is employed to generate accurate beamlet dose kernels by parallel tasks. The intensity modulation optimization uses total-variation regularization (TVR) and generates piecewise constant fluence maps for each initial beam direction in a distributed manner over the CCE. The optimized fluence maps are segmented into deliverable apertures. The shape of each aperture is iteratively rectified to be a sequence of arcs using the manufacture's constraints. The output plan file from the EC2 is sent to the simple storage service. Three de-identified clinical cancer treatment plans have been studied for evaluating the performance of the new planning platform with 6 MV flattening filter free beams (40 × 40 cm2) from the Varian TrueBeamTM STx linear accelerator. A CCE leads to speed-ups of up to 14-fold for both dose kernel calculations and plan optimizations in the head and neck, lung, and prostate cancer cases considered in this study. The proposed system relies on a CCE that is able to provide an infrastructure for parallel and distributed computing. The resultant plans from the cloud computing are

3694

VMAT Treatment Planning Using Cloud Computing

Y. Na, D.S. Kapp, Kim, T. Suh, and L. Xing; Stanford University,
Stanford, CA, The Catholic University of Korea, Seoul, Korea, Republic of
Korea

Purpose/Objective(s): Cloud computing is becoming increasingly used as a platform to improve the computational efficiency of radiation treatment planning processes. The purpose of this study is to develop a cloud-based VMAT dose optimization framework and evaluate the performance improvement of the new platform.

Materials/Methods: A cloud computing-based radiation treatment planning system (cc-TPS) associated with the type of virtual hardware specifications for the master and worker was developed for clinical treatment planning. Three de-identified clinical head and neck, lung, and prostate cases were used to evaluate the cloud computing platform. The de-identified clinical data encrypted with a 256-bit Advanced Encryption Standard (AES) algorithm were uploaded to Simple Storage Service (S3). After the Monte Carlo (MC) dose calculation and large-scale plan optimization, the output plan files were encrypted with the same algorithm in S3 to be downloaded to the user computer. Typical VMAT plans were generated for the three de-identified clinical cases to determine the quality of the treatment plans and computational efficiency. All plans generated from the cc-TPS were compared to those obtained with the PC-based TPS (pc-TPS). The performance improvement of VMAT treatment planning in this study was quantified as speedup factors and performance ratios (PRs). Speedup factor is defined as the ratio of computation time for MC dose calculation and treatment plan optimization with different number of workers in cloud. The PRs indicate the actual amount of performance improvement between the cc-TPS and the pc-TPS.

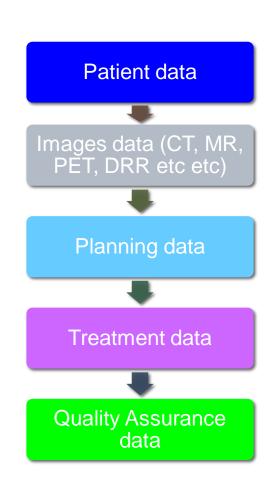
Results: The isodose curves of VMAT plans on both cc-TPS and pc-TPS were identical for each of the de-identified clinical cases. Speedup factors of the dose calculations and plan optimizations were improved up to 14.0-folder dependent on the clinical cases. The PRs were approximately 1 for both plans when the cc-TPS was used with only 1-worker. The PRs for both PAMT plans are 1.0 \leq PRs \leq 10.6 for the head and neck case, 1.2 \leq PRs \leq 13.3 for lung case, and 1.0 \leq PRs \leq 10.3 for prostate cancer cases.

Conclusions: The cc-TPS can dramatically improve the computational efficiency and infrastructure cost of VMAT planning while maintaining the high quality of treatment plan.

Author Disclosure: Y. Na: None. D.S. Kapp: None. Y. Kim: None. T. Suh: None. L. Xing: None.

RO manages, produces and shares a lot of different types of data







OIS needs to be connected with Hospital Information System HIS

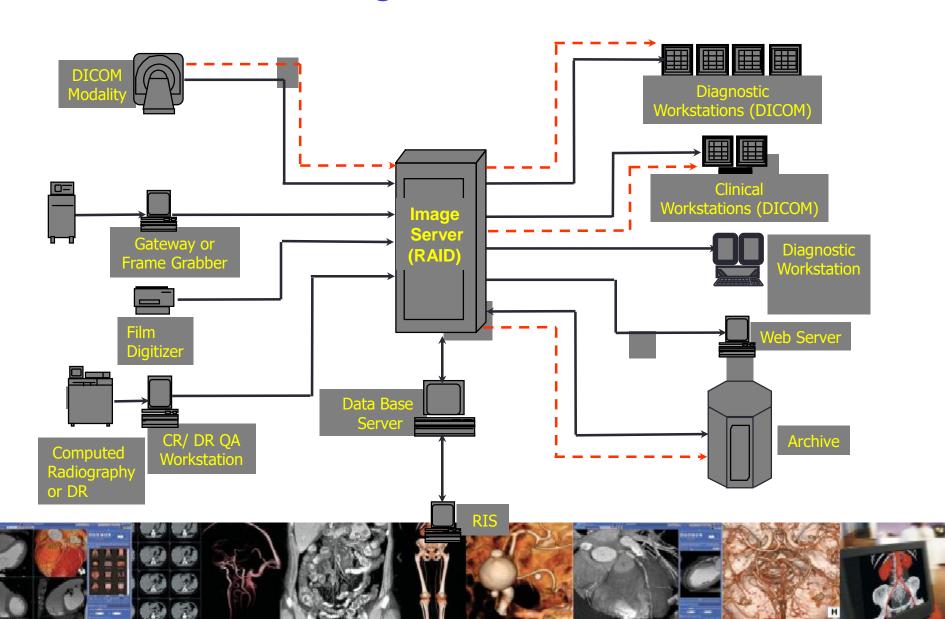
- Download Patient Registration or Demographics information (ADT)
- Upload Billing information
- Upload Radiation Oncology scheduling and treatment summary

Patients are typically registered in the HIS hospital-wide information system, which serves as a source of patient demographic, billing, and insurance information (USA)

The HIS also provides clinical, laboratory, and radiology information

The communication between the hospital and departmental system for registration, billing, and transcription, is usually **HL7 interface-based** (that is encoded using the **Health Level 7 HL7 standard**)

RO could be integrated into PACS-RIS



DICOM (Digital Imaging and Communications in Medicine standard)

- ♦ During the 1980s the need for simplification and standardization became apparent in order to ensure and maintain connectivity and interoperability of all pieces of equipment
- ♦ The medical equipment industry, represented by the National Electrical Manufacturers Association NEMA and the medical community, represented by the American College of Radiology ACR, joined forces to develop the Digital Imaging and Communications in Medicine standard (DICOM)
- ♦ The "winner" release was: DICOM v3
- ♦ DICOM was first developed to address connectivity and interoperability in radiology, but then it was extended to other modalities
- → During the RSNA conference in 1994, a meeting was held at which a clear need was expressed for standardization of the way radiotherapy data (such as treatment plans, doses and images) are transferred from one piece of equipment to another: ex. TPS (BRAND A) → LINAC (BRAND B)

DICOM3: basics (1)

- ♦DICOM v3.0 standard is large and consists of <u>16 different parts</u>, each part addressing a particular functional side of DICOM
- ♦ The standard defines fundamental network interactions such as:
 - Network Image Transfer: Provides the capability for two devices to communicate by sending objects, querying remote devices and retrieving these objects
 - ◆Open Media Interchange: Provides the capability to manually exchange objects and related information (such as a report). DICOM standardizes a common file format, a medical directory and a physical media. Examples include the exchange patient imaging study for remote consultation
 - ◆Integration within the Health Care Environment: Hospital workflow and integration with other hospital information systems have been addressed with the addition services such as Modality Worklist, Modality Performed Procedure Step, and Structured Reporting. This allows for scheduling of an acquisition and notification of completion

DICOM3: basics (2)

Data Element

- Unit of information, with defined data type and structure
- Standard elements are uniquely indexed by 'tag' and name (e.g. patient name, CT slice position, gantry angle)

Information Object

- Set of elements which together describe a physical entity, like a document (e.g. CT scan..)

♦ Service Class

- Action which can be performed on information objects to facilitate the network functionality (e.g. transferring data between systems, archiving to media, printing)

Service Object Pair (SOP)

 A defined action which can be performed on a particular object (e.g. CT image can be printed)

Multiplicity of data and RO-specific data

- Structures
- Plan (geometrical parameters, MU, position leaves, constraints, tolerances tables...)
- ♦ RT-DOSE
- ♦ DVHs
- Registration transform
- Radiobiological values
- Setup patient data
- ♦ IGRT/ART data
- Delivery data
- In-vivo dosimetry results
- Patient-QA summary
- (Clinical) decisions
- **♦** ...

DICOM-RT objects (1)

At the end of 1999, an ad-hoc Working Group, later to become **Working Group 7 defined 7 Radiotherapy DICOM Object**:

- RT Structure Set: containing information related to patient anatomy, for example structures, markers and isocenters. These entities are typically identified on devices such as CT scanners, physical or virtual simulation workstations or TPS
- RT Plan: containing geometric and dosimetric data specifying a course of TX and/or BT (e.g. beam angles, collimator openings, beam modifiers, and BT channel and source specifications)

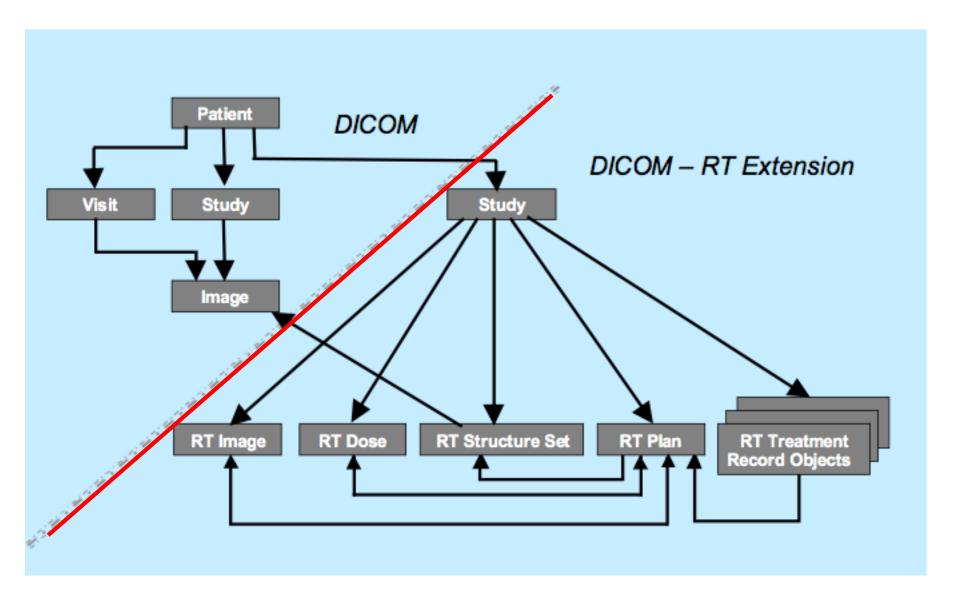
The RT Plan entity is created by a TPS before being transferred to a R&V system or treatment device

An instance of the RT Plan object usually references an RT Structure Set instance to define a coordinate system and set of patient structures

DICOM-RT objects (2)

- 3. RT Image: specifying radiotherapy images that have been obtained on a conical imaging geometry, such as those found on conventional simulators and portal images (EPID). It can also be used for calculated images using the same geometry, such as digitally reconstructed radiographs (DRRs)
- 4. RT Dose: containing dose data generated by a TPS in one or more of several formats: 3D dose data; isodose curves; DVHs; or dose points
- 567.RT Beams Treatment Record, RT Brachy Treatment Record and RT Treatment Summary Record: containing data obtained from actual RT treatments. These objects are the historical record of treatment and are linked with the other "planning" objects to form a complete picture of the treatment

Patient-data: Dicom and Dicom-RT



Dicom file

Representation of patient name element Physical encoding depends upon specified transfer / storage format

Preamble ((128 bytes)
------------	-------------

Prefix ("DICM")

Data Element 1

Data Element 2

Tag	Value Representation	Value Length	Value
(0010,0010)	PN	10	Joe Bloggs

• • •

Data Element n

e.g. Imaging: CT-planning (.dcm)

Tag	Attribute Name	VR	Value
(0002,0013)	ImplementationVersionName	SH	OFFIS_DCMTK_352
(0008,0008)	ImageType	CS	ORIGINAL\PRIMARY\AXIAL
(0008,0016)	SOPClassUID	UI	1.2.840.10008.5.1.4.1.1.2
(0008,0018)	SOPInstanceUID	UI	1.2.840.113619.2.22.287.35138.2431.3.19.20031117.200530
(0008,0020)	StudyDate	DA	20031117
(0008,0032)	AcquisitionTime	TM	100450.674
(0008,0060)	Modality	CS	CT
(0008,0070)	Manufacturer	LO	GE MEDICAL SYSTEMS
(0008,0080)	InstitutionName	LO	EDINBURGH CANCER CENTRE
(0018,0022)	ScanOptions	CS	HELICAL MODE
(0018,0050)	SliceThickness	DS	5.0
(0018,5100)	PatientPosition	CS	HFS
(0019,0010)	Proprietary Tag	LO	GEMS_ACQU_01
(0020,0032)	ImagePositionPatient	DS	-250.0\-250.0\25.0
(0020,0037)	ImageOrientationPatient	DS	1.0\0.0\0.0\0.0\0.0\1.0\0.0
(0020,1041)	SliceLocation	DS	25.0
(0027,0010)	Proprietary Tag	LO	GEMS_IMAG_01
(0028,0030)	PixelSpacing	DS	0.9765625\0.9765625
(0028,0100)	BitsAllocated	US	16
(0028,0101)	BitsStored	US	16
(0028,1050)	WindowCenter	DS	20.0
(0028,1051)	WindowWidth	DS	350.0
(0028,1052)	RescaleIntercept	DS	0.0
(0028,1053)	RescaleSlope	DS	1.0
(7FE0.0010)	PixelData	OWIOB	24\ff\24\ff\24\ff\24\ff\24\ff\24\ff\

RT-structure set (.dcm)

Tag	Attribute Name	VR	Value
(0008,0018)	SOPInstanceUID	UI	1.2.840.113619.2.832162544279.12377.1069165019.472
(0008,0060)	Modality	CS	RTSTRUCT
(0008,103E) SeriesDescription		LO	Adv Sim RT Structure Sets
(0008,1090)	ManufacturerModelName	LO	Advantage Sim
(0018,1000)	DeviceSerialNumber	LO	80e5ce97
(0018,1020)	SoftwareVersion	LO	5.0.13
(3006,0004)	StructureSetName	LO	prostate
(3006,0008)	StructureSetDate	DA	20031118
(3006,0009)	StructureSetTime	TM	144014.000
>ITEM 1	null	null	null
>(3006,0084)	ReferencedROINumber	IS	5
>(3006,002A)	ROIDisplayColor	IS	135\206\235
>>(3006,0016)	ContourImageSequence	SQ	null
>>>(0008,1155)	ReferencedSOPInstanceUID	UI	1.2.840.113619.2.22.287.35138.2431.3.19.20031117.200530
>>(3006,0042)	ContourGeometricType	CS	CLOSED_PLANAR
>>(3006,0044)	ContourSlabThickness	DS	5.0
>>(3006,0046)	NumberOfContourPoints	IS	73
>>(3006,0050)	ContourData	DS	12.207\-65.918\25.156\13.184\-64.941\25.156\19.043\-64.941\25.156\20.02\-65.918\25.156\
>(3006,0084)	ReferencedROINumber	IS	5
>(3006,0085)	ROIObservationLabel	SH	rt_fh
>(3006,00A4)	RTROIInterpretedType	CS	ORGAN

RT-plan (.dcm)

Tag	Attribute Name	VR	Value
(0008,0060)	Modality	CS	RTPLAN
(300A,0002)	RTPlanLabel	SH	final_beams
(300A,0006)	RTPlanDate	DA	20031119
>(300A,00B2)	TreatmentMachineName	SH	la4;1
>(300A,00B4)	Source-AxisDistance	DS	1000.0
>>(300A,00B8)	RTBeamLimitingDeviceType	CS	MLCX
>>(300A,00BC)	NumberOfLeafJawPairs	IS	60
>>(300A,00BE)	LeafPositionBoundaries	DS	-200.0\-190.0\-180.0\-170.0\-160.0\-150.0\-140.0\- 130.0\-120.0\-110.0\-100.0
>>(300A,00B8)	RTBeamLimitingDeviceType	CS	ASYMY
>>(300A,00BC)	NumberOfLeafJawPairs	IS	1
>(300A,00C0)	BeamNumber	IS	1
>(300A,00C2)	BeamName	LO	lant
>(300A,00C4)	BeamType	CS	STATIC
>(300A,00C6)	RadiationType	CS	PHOTON
>(300A,00CE)	TreatmentDeliveryType	CS	TREATMENT
>(300A,00D0)	NumberOfWedges	IS	0
>(300A,00E0)	NumberOfCompensators	IS	0
>(300A,00ED)	NumberOfBoli	IS	0
>(300A,00F0)	NumberOfBlocks	IS	0
>(300A,010E)	FinalCumulativeMetersetWeight	DS	100.0
>(0008,1150)	ReferencedSOPClassUID	UI	1.2.840.10008.5.1.4.1.1.481.3
>(0008,1155)	ReferencedSOPInstanceUID	UI	1.2.840.113619.2.832162544279.12377.1069165019.472

Dicom Conformance Statement

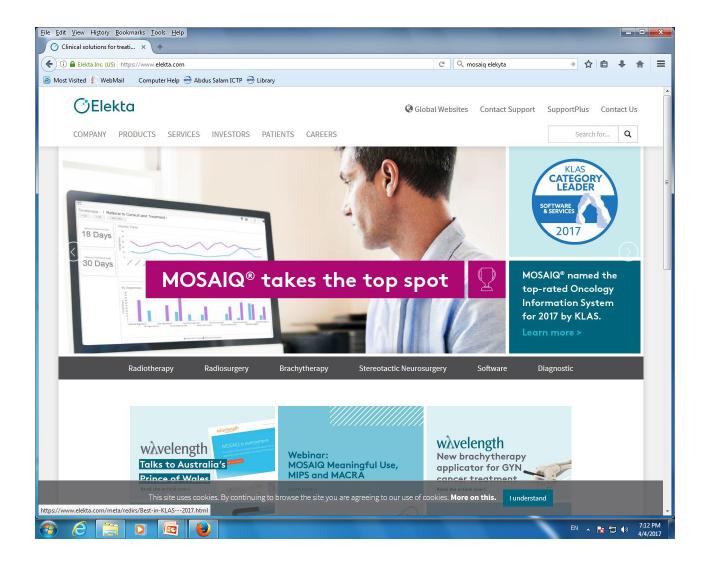
- The standard specifies that the manufacturer of any device claiming DICOM conformance shall provide a DICOM Conformance Statement that describes the DICOM capabilities of its medical equipment
- Conformance statements provide a foundation to determine connectivity and assess the potential inter-operability of two products, and in some cases identify potential problems
- It is not sufficient for a vendor to simply claim conformance to DICOM
- The statement "This product is DICOM" has even less meaning in the radiotherapy domain, in which inter-operability is a very complex issue
- For RT applications, it is usually not possible to determine interoperability a priory – this must be established through extensive testing

Storage

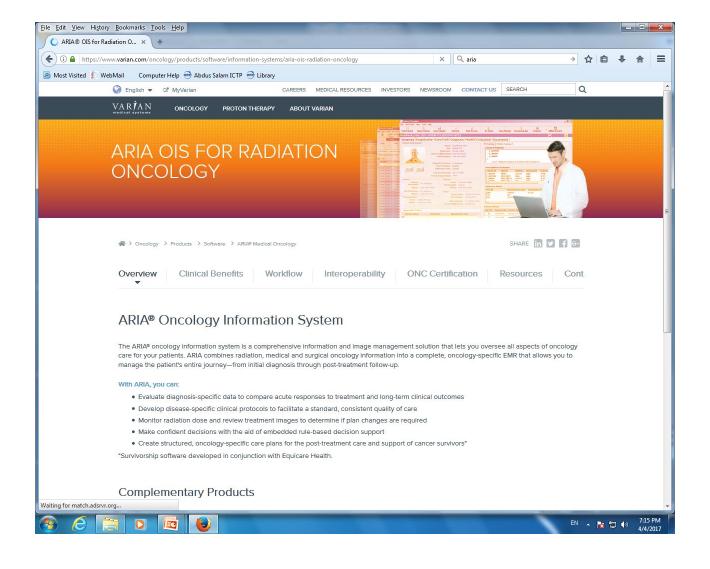
- RAID (Redundant Array of Inexpensive Disks) disks generally required
 - Can automatically make duplicate copy of all data, and alert user if one copy/disk fails before both copies are lost
- Backup servers are important too
- ♦ Ideal final archive:
 - ♦ RT-PACS
 - ♦ RT-Cloud
 - ..new IT solutions



The actors: Mosaiq (Elekta)



The actors: Aria (Varian)



The actors: Raycare (Raysearch)

RAYCARE – THE NEXT GENERATION OIS

Release dates

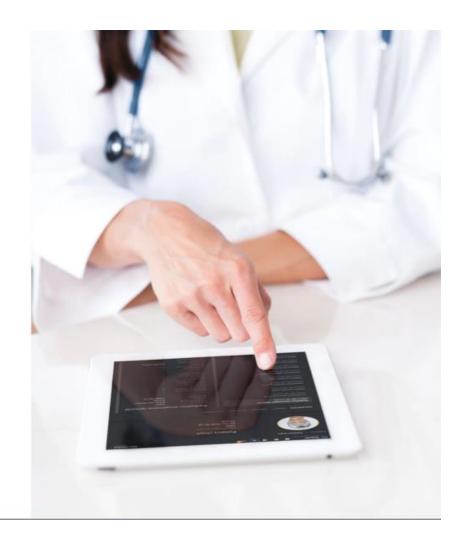
- A CE-marked version of <u>RavCare</u> 1 will be released mid 2017
- FDA clearance estimated by the end of 2017

Machine integration

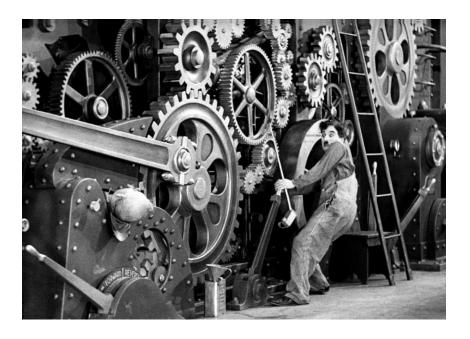
- Will support integration with all major hardware vendors
- Ongoing collaboration with Accuray

Technology

- Platform-independent web application with support for mobile devices
- Backend server running on Windows Server, SQL Server



QAIT: what does it mean?



QAIT (R&Vs) in RO - guidelines

- Many documents mentioned them
- Most recent and dedicated documents:
 - ♦ IAEA HHR No. 7 : 2013
 - Canadian Guidelines (Canadian Partnership for Quality in RT): 27 Jan 2017
- Key-words
 - "R&Vs-related errors" (systematic errors)
 - ♦ Data TX-transfer
 - Integrity
 - Logical Consistency
- → Not useful documents: not updated up

R&VS-related errors: "taxonomy"

- Data transfer: corrupted data or lack of registration or incorrect registration (criticism in software /network)
- Manual input
- Violation of approved procedures (override)
- Inconsistency followed a Plan-revision

Table	1.	R&V-related	radiotherapeutic	errors

Error	Origins	Contributing factors
Incorrect patient	Failure to positively identify patient	Accessing patient's R&V file before arrival Unfamiliarity with patient Inadequate staff communication
Incorrect data file	Entry of incorrect treatment parameters	Failure to verify R&V file data Manual R&V data entry rather than electronic data transfer Excessively liberal overriding privileges
Incorrect site	Treatment administered to incorrect volume	Excessively broad tolerance table allowances Nonfixed positioning device Ambiguous patient or positioning device markings Inadequate staff communication
Incorrect beam modification	Use of devices not recognized by the R&V system	Nonfixed treatment device Noninterlocked treatment device Ambiguous patient or treatment device markings Inadequate staff communication

Patton GA et al., Facilitation of Radiotherapeutic error by computerized R&Vs IJROBP., Vol. 56, No. 1, 2003

TABLE 1. TYPICAL ERRORS ENCOUNTERED IN DAILY USE OF RVSs

Error description	Possible origin
Incorrect setting of one treatment parameter (could remain undetected during whole treatment course) — critical for treatment time/MUs	(1) Error in manual input of reference parameters in the RVS
and for large errors in jaw setting (e.g. inversion of direction for an	(2) Incorrect data transfer
asymmetric field)	(3) Mix-up of automatic transfer and manual correction (doing the same corrections twice)
MUs calculated with wedge but treatment performed without wedge	Erroneous manual input of wedge type identification Automatic data transfer from TPS, but RVS fails to identify the presence of the wedge (e.g. after update of the RVS software)
MUs calculated for dynamic movement of the leaf (intensity modulated radiation therapy), but treatment performed with open static field	RVS software failure for unanticipated sequence of operations (more likely to occur after alteration of the initial plan)
Part of the treatment with incorrect parameters (e.g. MU, field size, MLC setting, gantry or collimator rotation, wedge filter)	(1) Incorrect manual modification of RVS data after treatment modification
	(2) Proper correction of the plan data after treatment modification but failure to transfer data back to the RVS, or software failure when updating the files
	(3) Discrepancy found at patient set-up followed by an override with new actual values taken as reference
	(4) Machine interruption followed by a loss of MUs already given or improper recovery of the data
Treatment of the wrong patient	Wrong patient file selected without verification of the consistency with actual patient (less likely if a photograph is displayed)
Treatment of the wrong site	Fixed patient position with respect to the table not ensured (no indexing) and/or information from table coding not used properly
Wrong number of fractions given	Incomplete or inappropriate field scheduling from the beginning or after treatment schedule alteration (e.g. cancellation of a session)

Note: MLC — multileaf collimator; MU — monitoring unit; RVS — record and verify system; TPS — treatment planning system.

QAIT - AAPM TG53 (1998)

♦ Data transfer

Numerous potential problems can develop during the **transfer** of treatment planning information from the RTP system to the paper chart, treatment machine, R&V system, or anywhere else. The issues listed in Table 3-23 must be considered as part of the QA for the planning process

Table 3-23. Data Transfer Issues

Plan information transfer by hand into a paper chart or record/verify system is prone to significant transcription error rates.⁷⁰

Blocks and compensators are made using information from the planning system. The physical blocks and compensators should be verified for correct size, shape, and placement in the treatment field. Verification should be performed for simple and complex shapes of modifiers associated with orthogonal and oblique fields.

MLC shape information is often transferred to (or from) the treatment machine from the planning system. This is clearly a critical quality assurance issue, and must be carefully verified and routinely checked.

Several QA considerations for automatic transfer of the complete set of plan information from the RTP system to the treatment machine or to its record/verify system have been discussed in detail in recent papers on a Computer-Controlled Radiotherapy System.^{64,65,73}

American Association of Physicists in Medicine Radiation Therapy Committee Task Group 53: Quality assurance for clinical radiotherapy treatment planning

Benedick Fraass^{a)}

University of Michigan Medical Center, Ann Arbor, Michigan

Karen Doppke

Massachusetts General Hospital, Boston, Massachusetts

Margie Hunt

Fox Chase Cancer Center, Philadelphia, Pennsylvania

and Memorial Sloan Kettering Cancer Center, New York, New York

Gerald Kutcher

Memorial Sloan Kettering Cancer Center, New York, New York

George Starkschall

M. D. Anderson Cancer Center, Houston, Texas

Robin Sterr

University of California, Davis Medical Center, Sacramento, California

Jake Van Dyk

London Regional Cancer Center, London, Ontario, Canada

(Received 15 December 1997; accepted for publication 4 August 1998)

In recent years, the sophistication and complexity of clinical treatment planning and treatment planning systems has increased significantly, particularly including three-dimensional (3D) treatment planning systems, and the use of conformal treatment planning and delivery techniques. This has led to the need for a comprehensive set of quality assurance (QA) guidelines that can be applied to clinical treatment planning. This document is the report of Task Group 53 of the Radiation Therapy Committee of the American Association of Physicists in Medicine. The purpose of this report is to guide and assist the clinical medical physicist in developing and implementing a comprehensive but viable program of quality assurance for modern radiotherapy treatment planning. The scope of the QA needs for treatment planning is quite broad, encompassing image-based definition of patient anatomy, 3D beam descriptions for complex beams including multileaf collimator apertures, 3D dose calculation algorithms, and complex plan evaluation tools including dose volume histograms. The Task Group recommends an organizational framework for the task of creating a QA program which is individualized to the needs of each institution and addresses the issues of acceptance testing, commissioning the planning system and planning process, routine quality assurance, and ongoing QA of the planning process. This report, while not prescribing specific QA tests, provides the framework and guidance to allow radiation oncology physicists to design comprehensive and practical treatment planning QA programs for their clinics. © 1998 American Association of Physicists in Medicine. [S0094-2405(98)03410-5]

Key words: treatment planning, quality assurance, 3D treatment planning

PREFACE

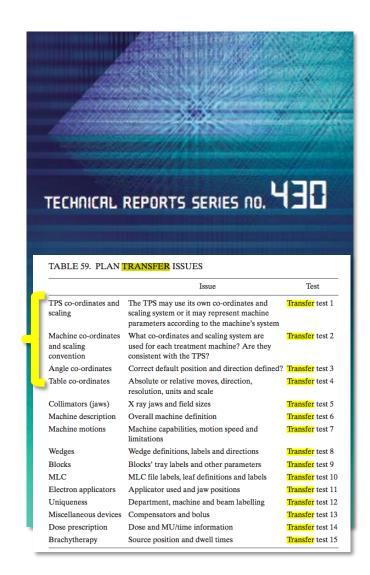
This document is the report of Task Group 53 of the Radiation Therapy Committee of the American Association of Physicists in Medicine (AAPM). The purpose of this report is to guide and assist the radiation oncology physicist in developing and implementing a comprehensive but viable program of quality assurance for radiotherapy treatment planning. This report is the first guidance on the topic of treatment planning quality assurance (QA) from the AAPM, although there are several related reports,' including the recent report from Task Group 40 on Comprehensive QA for Radiation Oncology. Further expansion of AAPM recommendations regarding treatment planning quality assurance is

likely after the radiation oncology community accumulates some experience with the approach recommended in this report.

In recent years, the increased complexity of the treatment planning process required to support such procedures as conformal radiotherapy has led to the need for a comprehensive set of quality assurance guidelines that can be applied to treatment planning systems that support this complex process. This Task Group has been charged by the AAPM to prepare this report recommending the scope and content of necessary quality assurance procedures and the frequency of tests, from acceptance testing, characterization and commissioning to routine quality assurance of clinical system use.

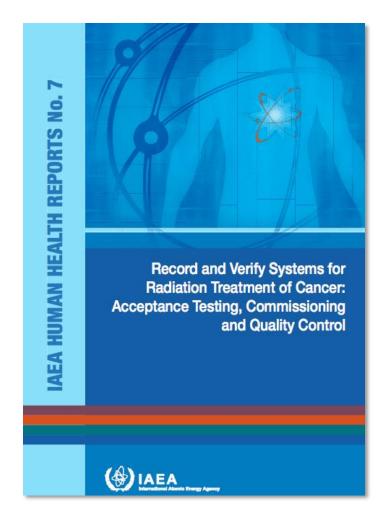
QAIT - IAEATRS No. 430 (2004)

- Output of the treatment planning information and transfer of that information to the patient chart and/or the treatment machine is an important aspect of the planning and delivery process that requires appropriate QA.
- Correct <u>transfer is critical</u> because any error or misinterpretation of information transferred from the TPS to the therapy machine (or chart) will <u>result in a systematic error</u> in all the treatment fractions that are delivered (..)
- ♦ If files are transferred across a network, it should be understood who transfers them (..)
- Although <u>direct transfer to patient management systems is very efficient</u>, it is also potentially dangerous if it leads to inadequate <u>review of data</u> before they are used to deliver a treatment. It is important to ensure that sufficient <u>redundancy checks</u> are in place.



QAIT-IAEAHHR No.7 (2013)

♦ Some of the tests performed at installation must be repeated regularly (acceptance tests and commissioning) as part of the local ongoing QC programmed and on each occasion where there is a possibility that some change has occurred in the treatment planning process



QA IT - Technical Quality Control Guidelines for Data Management Systems by Canadian Association of Provincial Cancer Agencies (CAPCA) (2017)

A comprehensive quality assurance program for a DMS should consider all of the separate components in the DMS, the exchange of data between components, and the procedures governing that exchange. Accordingly, the program could have three general categories:

- 1) Quality assurance of computerized systems: performance and functionality of each individual component in the DMS, data integrity within each component;
- Quality assurance of data exchange: data exchange between components in the DMS (multiple formats, multiple protocols); and
- 3) Quality assurance of procedures (including data entry and data interpretation).

Key features of a quality assurance program should include: assembling a multidisciplinary team with regular meetings and clearly established roles and responsibilities; project management of scheduled upgrades and systematic tracking and evaluation of hardware and software failures and issues, and subsequent root-cause analysis.

Canadian Partnership for Quality Radiotherapy

Technical Quality Control Guidelines for Data Management Systems

A guidance document on behalf of:

Canadian Association of Radiation Oncology

Canadian Organization of Medical Physicists

Canadian Association of Medical Radiation Technologists

Canadian Partnership Against Cancer

January 27, 2017

DMS.2017.01.01

www.cpgr.ca

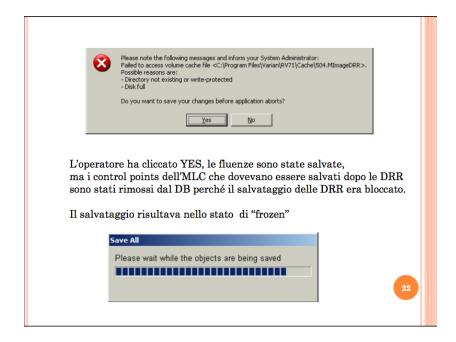




The N.Y. Times Radiation Boom







QAIT & safety

- Independent checking is a mainstay of error reduction from transcription and communication errors, but is subject to automaticity errors
- Modern <u>R&V systems reduce random</u> transcription errors, but <u>require QA</u> <u>regimens to prevent systematic errors</u>
- Protocol checklists will prevent the implementation of unauthorized plans

Radiotherapy Risk Profile Technical Manual WHO (2008)

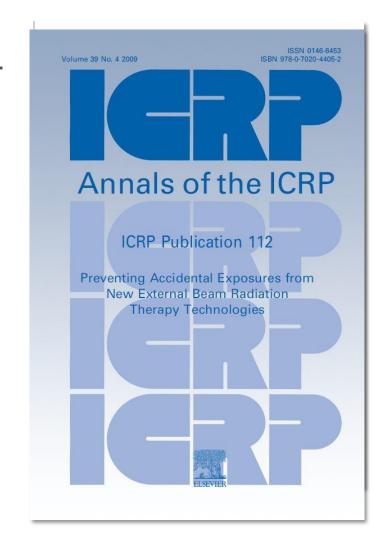


7. Treatment information transfer

Risks	Potential impact	Solutions
Incorrect identification of patient	High	ID check open questions, eliciting an active response as a minimum 3 points of ID Photo ID
Manual data entry	Medium	Automated data transfer In vivo dosimetry
Incompatible chart design	Medium	Clear documentation and
Illegible handwriting for manual transfers	High	protocols
No independent check	High	
Incorrect or inadequate data entry on 'record & verify' system	High	Independent checking
Ambiguous or poorly designed prescription sheet	High	Model prescription sheet
Sending unapproved plan	Medium	Protocol checklist
Failure to communicate changes in plans Incorrect number of monitor units, accessories, wedges	Medium High	'Record and verify' systems Independent checks In vivo dosimetry

QAIT & safety

- Clear <u>protocols</u> should exist for the use of <u>R&V systems</u> in assisting treatment set-up. The source documentation should be used by operators to confirm the patient set-up and the beam parameters set on the linear accelerator (..)
- Verification should be performed using active rather than passive procedures to reduce the risk of involuntary automaticity
- Prior to turning on the treatment beam, the key parameters of MUs, beam energy and beam modification should be verified and confirmed by both operators using the source documentation



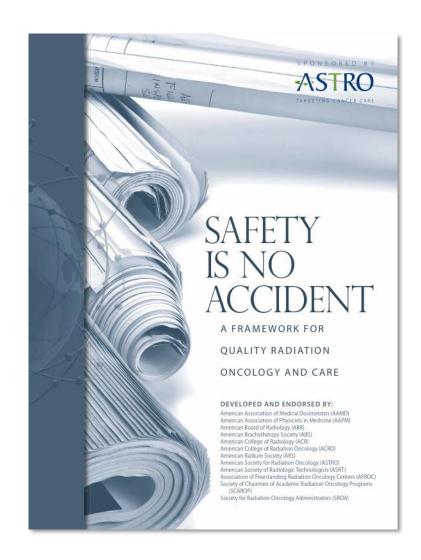
ICRP Publication 112 (2009)

QAIT & safety

Table 4.5. Treatment Management and Delivery System Issues

Safety/Quality Issue	Recommendations	Reference
Computer-controlled delivery	Acceptance test procedures for new software and/or control features should be designed to test software and control aspects of the system.	[59]
	Safety interlocks and new functionality should be tested in accordance with vendor documentation and testing information	TG35(1993)
Software upgrade testing	Routine updates of software for a computer-controlled machine should be treated as if it includes the possibility of major changes in system operation. All vendor information supplied with the update should be studied carefully, and a detailed software/control system test plan created.	[59]
	All safety interlocks and dosimetry features should be carefully tested, regardless of the scope of the changes implied by the update documentation.	ASTRO IHE
System interconnectivity	IHE-RO protocols	[81]

The <u>TMS</u> is one of the newest and most quickly evolving systems involved in radiation therapy. As such, the <u>QA program</u>, which should be associated with <u>safe use of the system</u>, is <u>less well-described and understood than almost any other system</u>



Astro (2012)

Database Rosis, Safron, RO.ILS

ROSIS – Record and Verify July 2007



Radiation Oncology Safety Information System

http://www.rosis.info

Feedback letter July 2007
SPOTLIGHT ON RECORD AND VERIFY

RECORD AND VERIFY

Record and verify systems (R&V systems), or check and confirm systems, have been a crucial part of the technological advancement in Radiation Oncology – enabling the delivery of more sophisticated and complex treatments. However, although the implementation of R&V systems has reduced some types of "random" mistakes, new risks were also introduced.^{1,2,3}

Many R&V-related mistakes arise during manual input of data. Reliance on computers often leads to operators trusting the information they contain – forgetting that the information could either be electronically corrupted, or that often the information has been manually input into the computer by a fallible human in the first place! Instances where much of the data is electronically transferred, but some is manually input can also give rise to a false sense of security.

As this data forms the basis of the patient's treatment, it is imperative that it is always correct. Approximately one-fifth of the reports in the ROSIS database related to incorrect data input into R&V systems, of which nearly half resulted in incorrect treatment delivery for at least one fraction. Other mistakes related to R&V systems were due to software / network problems, violations of approved procedure, or failure to update the R&V data with treatment changes.

Incident Report 453: Transcription Error: Wrong value input

http://www.clin.radfys.lu.se/queries/q_search_ID_new.asp?number=453

Some treatment parameters are to be introduced manually in the R&V system, even if others are transferred automatically from the TPS. One of the formers is the dose per field. Despite the fact that the dose calculation was correct a wrong dose per field has been introduced. The error has been detected by the physicist who checks all treatment parameters at the R&V system before treatment.

Incident Report 271: Transcription Error: Wrong value input

http://www.clin.radfys.lu.se/queries/q_search_ID_new.asp?number=271

Field input incorrectly onto Varis

Pt transfered from 1 unit to another to help reduce pts waiting times Field treated as 7 x 8 instead of 8 x 7 for 1 field only - corrected on 2nd field

Incident Report 201: Transcription Error: Wrong value input

http://www.clin.radfys.lu.se/queries/q_search_ID_new.asp?number=201

Linac 3 broke down - pt moved to different Linac for 1#. On ant s'clav field size treated incorrectly, length should have been 9.9cm treated at 8.9cm - input incorrectly - check process did not pick up as done at short notice and did not go through normal pretreatment system.

Incident Report 162: Incorrect data - ? due to error in electronic transfer http://www.clin.radfys.lu.se/gueries/q_search_ID_new.asp?number=162

A lung patient was treated with a 3-field technique. The prescribed gantry angles were 0, 167 and 209 degrees. At fraction no. 11 it is discovered that field 3 has been given in 249 degrees for all the previous 10 fractions. The gantry angle in the dose plan and treatment chart is correct, but wrong in the verification system. We use electronic transfer of data and we cannot rule out a transfer error although we have not been able to repeat it in

IAEA HHR No.7 - Background

- → J. Van Dyk, D. Georg, J.C. Rosenwald
- ♦ 29 references
- Although it is recognized that there are several risks of error related to <u>data exchange</u> between all these components (..), this report will not address these issues
- (..) Errors might be partially attributed to <u>a lack of appropriate human</u> <u>control</u>, <u>since it is perfectly clear that human and organizational</u> <u>factors are mostly responsible for accidents</u>
- (..) It has been further advocated that the radiation therapists, if not properly informed, could be naturally inclined to relax their attention due to an 'excessive reliance' on the system
- (..) Errors are also <u>often due to a lack of well defined workflow and procedures</u>. Some other errors might be due to problems in the system design or implementation

IAEA HHR No.7 - Goals

- ♦ To describe the acceptance tests and the commissioning process
- ♦ IEC 62274 ed.1.0 standard (2005)
- Since there is no existing descriptive document explaining what an RVS really is, this report also contains a short description of the database structure and the main functionalities currently encountered in most existing RVSs. This should help the reader to acquire a better understanding of the whole system
- This report will not address the details of the human and organizational aspects, which remain <u>fundamental</u> for the safe use of RVSs
- MPs with specialized RO physics training and practical clinical experience (+ computer specialists)

IAEA HHR No.7 - Acceptance/Commissioning/QC

- Unlike for a TPS, it is difficult for an RVS to <u>clearly differentiate</u> 'acceptance' testing from 'commissioning'. The reason is that an RVS 'sits' between the TPS and the treatment machines and that the main issues are related to safe interoperability between these pieces of equipment (..)
- ♦ At the time of acceptance, the RVS configuration must be consistent with data input from the local TPS and data output to the local treatment machines (..)
- ♦ The 'commissioning' process (..'all testing, data input and verification checks that are needed to get the system ready for clinical use'..), must be performed in conjunction with the final installation by the manufacturer and therefore <u>partly merged</u> with the 'acceptance'

IAEA HHR No.7 - Parametrization

1	Definition of the names of the machines, and for each of them, the attached modalities, energies and dose rates (MUs/min)
2	For each machine (and modality), identification of the internal variables used to describe all the mechanical parameters that will be verified or controlled, including a list of possible accessories (trays, MLCs, wedge filters, etc.)
3	For each parameter, definition of the allowed direction, range (minimum-maximum values) or related specificities (e.g. wedge position and orientation, allowance or not for remote automated set-up)
4	Preparation or verification of mapping tables ensuring a one-to-one match for each parameter between names, scales and orientations used by: (i) the TPS and RVS and (ii) the RVS and each treatment machine (including simulator)
5	Customization of data exchanges: definition of IP addresses of external devices, preparation of import/export filters according to the type of data to be exchanged (i.e. RTP Connect, DICOM and DICOM RT objects, patient identification medical records); definition of the paths for data archiving and retrieving
5	Definition of users' rights according to professional categories and departmental policy
7	Definition of tolerance tables according to the degree of accuracy expected for each different type of treatment (see Section 3.3.3)
8	Definition of various 'preferences' specific to each RVS and pertaining, for instance, to options for screen display, for printing, for management of patient schedules, etc.

IAEA HHR No.7 - Acceptance: type vs site

♦ Site tests

- Refer to those tests that are to be carried out by the installer and the user together to establish compliance with specified criteria, i.e. acceptability (..)
- Subset of the 'type tests'
- These tests should be repeated after installation of a new version of the software
- ♦ The tests will provide an educational opportunity (..) will demonstrate to the user that the results using the hardware and software as installed at the user's site are consistent with the type tests performed by the manufacturer at the factory

IAEA HHR No.7 - Acceptance tests (site)

TABLE 5. SITE TESTS PER IEC 62274 ed.1.0 [20]

Clause	Requirement		
4.2	Testing during installation	Yes	No
	The MANUFACTURER shall provide an installation test document as part of the technical description that includes a demonstration that the RVS performs according to the operational description provided in the ACCOMPANYING DOCUMENTS as required in Clause 5.		
	Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.		
	IAEA Note: Table 1 of clause 5 of IEC standard 62274 ed. 1.0 is a list of the types of document (instructions for use or technical description) that are required for each clause. This publication should be used as a replacement of table 1.		
6.1	RADIATION quantities	Yes	No
	All values of RADIATION quantities requested, displayed or printed shall include their units. Units of RADIATION should conform to the SI convention. Units (e.g., "monitor units" (MU)) describing dose delivery shall be consistent with those used by the TREATMENT machine.		
	Compliance is checked by inspection of the DISPLAY and output information.		
	IAEA Note: Incorporated in tests described in the Appendix to this publication.		
6.2	Date and time	Yes	No
	When the date is displayed or printed, correct interpretation shall not depend upon the OPERATOR's interpretation of format, and a DISPLAY of the year shall be in four digits.		
	Compliance is checked by testing and by inspection of the DISPLAY and output information.		
	IAEA Note: Incorporated in tests described in the Appendix to this publication.		
	When the time is requested, displayed or printed, it shall be represented on a 24-hour clock basis, or if a 12-hour clock is used it shall be unambiguously indicated whether it is a.m. or p.m. Measurements of time shall include units (hr, min, sec.).	Yes	No
	Compliance is checked by testing and by inspection of the DISPLAY and output information.		
	IAEA Note: Incorporated in tests described in the Appendix to this publication.		
	When time is entered, displayed or printed, each denomination of time shall be labelled. To	Yes	No
	prevent confusion with numbers, single-letter abbreviations of time denomination shall not be used (e.g., h, m, s).		
	Compliance is checked by testing and by inspection of the DISPLAY and output information.		
	IAEA Note: Incorporated in tests described in the Appendix to this publication.		
6.3	Coordinate systems and scales	Yes	No
	It shall be possible for the OPERATOR to perform all RVS functions with the scales and coordinates of RADIOTHERAPY TREATMENT EQUIPMENT displayed according to the IEC 61217 convention. If, in addition, any convention other than IEC 61217 is employed for scales and coordinates, the conventions shall be identified. The units shall be the same as are used in the RADIOTHERAPY TREATMENT EQUIPMENT.		
	Compliance is checked by testing and by inspection of the DISPLAY, output information and ACCOMPANYING DOCUMENTS.		
	IAEA Note: Compliance tests are described in the Appendix to this publication.		

TABLE 5. SITE TESTS PER IEC 62274 ed.1.0 [20] (cont.)

Clause	Requirement	Comp	Compliance?	
6.4	Protection against unauthorized use	Yes	No	
	Means shall be provided to prevent unauthorized changes. Where changes to the data are permitted by authorized persons, means shall be provided to prevent a person making changes he/she is not authorized to make.			
	Compliance is checked by testing and by inspection of the ACCOMPANYING DOCUMENTS and INSTRUCTIONS FOR USE.			
	IAEA Note: Compliance test (incorporated in tests described in the Appendix to this publication): create several authorized users with different levels of access (e.g. different for treatment prescription and machine configuration). Verify that each authorized user has no more than the level of access intended by the specified authorization.			
	Where network connection is permitted by the design, the following requirements apply.	Yes	No	
	 (a) Access to the RVS shall be provided only to EQUIPMENT or individuals who are authorized (for example, by a password under the control of the USER). 			
	Compliance is checked by testing and by inspection of the ACCOMPANYING DOCUMENTS.			
	IAEA Note: Compliance test (incorporated in tests described in the Appendix to this publication): if a network connection is provided, connect the RVS to the network and confirm that access to the RVS is limited to only authorized users; for example, those provided with a PASSWORD. Confirm that the RVS cannot be accessed from another computer on the network other than by an authorized user.			
	(b) Access to TREATMENT prescriptions and other data containing the PATIENT identification information through the network shall be restricted to prevent unauthorized access.	Yes	No	
	Compliance is checked by testing and by inspection of the ACCOMPANYING DOCUMENTS.			
	IAEA Note: Compliance test (incorporated in tests described in the Appendix to this publication): Confirm that the RVS cannot be accessed from any computer on the network, other than by an authorized user.			
6.6	Data acceptance	Yes	No	
	Means shall be provided such that the TREATMENT machine set-up data and other patient TREATMENT data shall be available for TREATMENT use only after the OPERATOR has acknowledged that they have been reviewed for correctness and completeness.			
	Compliance is checked by testing and by inspection of ACCOMPANYING DOCUMENTS.			
	IAEA Note: Compliance tests incorporated in the tests described in the Appendix to this publication.			
	Where design allows, machine set-up data and other patient TREATMENT data shall be reviewed or approved by entry of an authorized identification:	Yes	No	
	(a) any modification to the data shall result in invalidation of the authorized identification;			
	(b) after modification of the approved data a new authorized identification shall be required;			
	 (c) the RVS shall provide a means for preserving the history and the record of the authorized identification; and 			
	 (d) the INSTRUCTIONS FOR USE shall describe how these features are to be properly and safely used. 			
	Compliance is checked by testing and by inspection of ACCOMPANYING DOCUMENTS.			
	IAEA Note: Compliance tests incorporated in the tests described in the Appendix to this publication.			

IAEA HHR No.7 - Acceptance tests (site)

TABLE 5. SITE TESTS PER IEC 62274 ed.1.0 [20] (cont.)

Clause	Requirement Complian		liance?
6.7	Deleting and editing data	Yes	No
	Means shall be provided to restrict the ability to edit TREATMENT history data to persons who are authorized to earry out this function. A record of the change details shall be retained. The fact that the TREATMENT history has been modified shall be apparent to a person using it e.g., by a visual indicator.		
	Compliance is checked by testing.		
	IAEA Note: Compliance test incorporated in the tests described in the Appendix to this publication.		
6.8	Backing up data	Yes	No
	Means shall be provided for backing-up data onto a separate medium from the primary storage, such that it can be restored in the case of a failure of the primary data storage device.		
	NOTE Usually a backup provides a means to restore data in the case of system failure.		
	Compliance is checked by testing and by inspection of ACCOMPANYING DOCUMENTS.		
6.9	Archiving data	Yes	No
	Means shall be provided for archiving sets of data for long term storage, such that the data can be accessed at a later date.		
	NOTE Archiving is the process of moving or copying sets of data from the primary storage to a separate storage media. Standardizing the archiving process is highly desirable. By using established standards such as DICOM or HL7, archiving would be vendor and media independent.		
	Compliance is checked by testing and by inspection of ACCOMPANYING DOCUMENTS.		
7	TREATMENT machine set-up verification		
7.1	Prevention of TREATMENT	Yes	No
	The RVS shall provide a means by which the operation of the TREATMENT machine shall be prevented in the event that the machine set-up does not correspond to the prescribed data within prescribed tolerances.		
	Compliance is checked by testing.		
	IAEA Note: Compliance test incorporated in the tests described in the Appendix to this publication.		
7.2	Override	Yes	No
	If an override capability is provided, the USER shall:		
	acknowledge the override parameters; provide authorized identification.		
	The fact that an override has been made shall be recorded.		
	Compliance is checked by testing.		
	IAEA Note: Compliance test incorporated in the tests described in the Appendix to this publication.		
8	TREATMENT recording and reporting	Yes	No
	For each patient the RVS shall provide a means by which the OPERATOR can retrieve and report all recorded TREATMENT machine parameters used in the previous TREATMENT sessions.		
	NOTE The guides and contents of the record and report may be found in ICRU publications 50 and 62 for photon beam therapy and 58 for BRACHYTHERAPY.		
	Compliance is checked by testing.		
	IAEA Note: Compliance test incorporated in the tests described in the Appendix to this publication.		

TABLE 5. SITE TESTS PER IEC 62274 ed.1.0 [20] (cont.)

Clause	Requirement						Compliance?					
9	Accuracy						No					
	The MANUFACTURER shall state the accuracy of the RVS for all of the TREATMENT parameters recorded.											
	Compliance is chec											
	IAEA Note: This to parameters are rec described in the Ap											
This is to certify that version of the RVS software Software version												
produced by												
Name of manufacturer												
has passed the acceptance tests as described in Section 5 of, and in the Appendix to, the IAEA report on Record and Verify Systems for Radiation Treatment of Cancer: Acceptance Testing, Commissioning and Quality Control.												
Company representative Name Signature Date												
User/purchaser representative Name Signature Date												

[20] Medical Electrical Equipment — Safety of Radiotherapy Record and Verify Systems, Report IEC 62274 ed.1.0 (2005)

IAEA HHR No.7 - Site test: details

- ♦ A.1. GENERAL TESTS
 - Demographics pt data (4)
 - Treatment prescription and delivery (32)
 - ♦ Delete a pt from the RVs (2)
- ♦ A.2. END-TO-END TEST: FROM A TPS TO TDS WITH AN RVS (14)
- ♦ A.3. CONVERSION OF TREATMENT PLANS BETWEEN MACHINES
 - Conversion of TPlans between matched machines (2)
 - Conversion of TPlans between non-matched machines (4)

IAEA HHR No.7 - Site test: ..homeworks

- TRY to insert a patient with ID associated with another patient..
- TRY to access to the system as not authorized user..
- ♦ TRY to load @TDS WS an unproved plan..
- STOP the plan delivery, check MU, re-load the Treatment, ..
- ♦ TRY to override as not-authorized user...
- → TRY to delete a patient not yet delivered





IAEA HHR No.7 – Ongoing QC

TABLE 6. ONGOING QC OF RVSs

- Formal approval (electronic signature), by an authorized person, of each prescription, plan and beam entered or transferred to the RVS after comparison between the data stored in the RVS and the data output from the TPS, and complemented, by any formal document related to the treatment prescription
- 2 Critical review (preferably formalized) of the RVS data by the staff in charge of treatment delivery (radiation therapists) before the first fraction and after each treatment modification. Complementary information (e.g. information on patient positioning or use of special accessories) might be added to the RVS records at this step
- 3 Special attention during patient set-up and treatment delivery about any unexpected value or message displayed by the RVS, with emphasis on presence and orientation of accessories, MLC setting, MU values and beam and sessions sequencing
- 4 Special attention to alerts and any treatment modification, such as changes in beam parameters, number of fractions, dose per fraction, treatment schedule, replanning on another machine, etc.
- 5 Regular inspection (typically weekly), for all patients, of the recorded cumulative dose at the reference points (see Section 3.3.1.1) to check consistency with prescribed and expected dose values
- 6 Systematic closure of patient files by an authorized person immediately after the last session, with production of a summary of the main treatment characteristics used as a reference for and possibly transferred automatically to the medical record (e.g. site, dose, number of fractions, number of days between start and end of treatment)
- 7 Regular survey (typically daily) of all unexpected situations detected and recorded by the RVS, e.g. overrides or abnormal treatment terminations
- 8 Traceability of all encountered problems in log books and regular analysis of these problems to adapt procedures and training

Note: MLC — multileaf collimator; MU — monitor unit; RVS — record and verify system; TPS — treatment planning system.

IAEA HHR No.7: summary

- It takes into account the manual input data (outdated!)
- QC R&V data: chart-review based
- ♦ 3D-CRT oriented

Go



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Task Group No. 201 - Quality Assurance of External Beam Treatment Data Transfer

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Charge

- To recommend radiation oncology processes that are robust in teh presence of errors in electronic data transfers of treatment data.
- To recommend test procedures that prevent mistreatments due to corruption and/or misinterpretation of radiation therapy treatment data.

Chair



Ramon Alfredo Siochi Task Group Chair

TG201

Bylaws: Not Referenced.

Rules: Not Referenced.

Approved Start: 4/22/2010 Date(s) End: 12/31/2015



Committee TG201 Keywords:

- → Board of Directors [Status]
 - □ Science Council [Status]
 - Therapy Physics [Status]
 - Quality Assurance and Outcome Improvement SC [Status]
 - → Work Group on Information Technology [Status]

TG201 - Quality Assurance of External Beam Treatment Data Transfer

Still nothing

Preview report TG201 (JACMP, 2011)

- This report does not give descriptions of the various systems and the exchange of data among them. It is assumed that medical physicists who wish to implement these recommendations understand the systems in their clinic
- The purpose (..) is to provide clinics with a checklist and a diagnostic tool can help determine what data transfer related quality assurance steps to be implemented to make their radiation treatments safer

JOURNAL OF APPLIED CLINICAL MEDICAL PHYSICS, VOLUME 12, NUMBER 1, WINTER 2011

A rapid communication from the AAPM Task Group 201: Recommendations for the QA of external beam radiotherapy data transfer. AAPM TG 201: Quality assurance of external beam radiotherapy data transfer

R. Alfrede Siochi, 1th Peter Balter, ⁶ Chanies D. Bloch, ³ Lakshmi Santanam, ³ Kurf Bledgett, ⁶ Bruce H. Curran, ⁶ Martijn Engelsman, ⁶ Wenzheng Feng, ⁷ Jim Mechalakos, ⁶ Dan Pavord, ⁹ Tom Simon, ¹⁰ Steven Suttler, ¹³ and X. Ronald Zhu, ¹²

Department of Buildation Oncology: University of Ionas Hospitals and Chiefe, Iona (Inj. Id. USA: UT MD deuterron Cancer Center? Houston, TV, USA: Department of Buildation Oncology: Waitington University, Saint Louis, MO, USA: Department of Buildation Oncology: Waitington General Hospital, Plimburgh, Pl. USA, Department of Buildation Oncology: Real Information Hospital, Plimburgh, Pl. USA, Department of Buildation Oncology: Real Information Hospital, Plimburgh, Pl. USA: Department of Phenatherian Hospital, Plimburgh, Pl. USA: Buildation Oncology: New York Persistence and Respiral, New York, N. U.SA: Buildation Oncology: Visions Probest Hospital, Plimburgh, Pl. U.SA: Buildation Oncology: Visions Problem Hospital, Plimburgh, Pl. USA: San Nations Coroporation, Whilebourne, Pl. USA: Buildation Therapy, V. Medical Conter-VA Paget Sound Health Care System, South, Buildation Therapy, V. Medical Conter-VA Paget Sound Health Care System, South, Buildation Physics - Unit 1150, V. U.T. MD Anderson Cancer Center, Hospital, T. U.SA: Hospital Plimburgh, TX, USA: Plantiferd Science (Vision) and Paget Science (Vision).

Received 8 October, 2010; accepted 8 October, 2010

The transfer of radiation therapy data among the various subsystems required for external beam treatments is subject to error. Hence, the establishment and management of a data transfer quality assurance program is strongly recommended. It should cover the QA of data transfers of patient specific treatments, imaging data, manually handled data and historical treatment records. QA of the database state (logical consistency and information integrity) is also addressed to ensure that accurate data are transferred.

PACS numbers: 87.56.bd, 87.55.D, 87.55.Gh, 87.55.Qr, 87.55.T Key words: quality assurance, record & verify, treatment planning, DICOM, data transfer

I. INTRODUCTION

This rapid communication comes from a Task Group of the Working Group on Information Technology, TG 201: Quality Assurance of External Beam Treatment Data Transfer. Each nuthor listed five to ten QA and safety related recommendations based on their experience with particular models of treatment planning systems (TPS), treatment management systems (TMS, typically a combination of an occology information system with a verify and record system¹⁰), and external beam treatment units. The collective experience covers a broad range of manufacturers and combinations of systems: Varian Melcilles, ARIA, VARS, Clinacs) (Varian Melcille Systems, Palo Alto, CA), Philips Pinnacle (Philips Healibeare, Andover, MA), Elekia (Multi-Access, Lantis, Mosaid, Xio, Gammak/nife, linacs) (Elekia, Stockholm, Sweden), Siemens Innes (Siemens Medical Solutions, Malvern, PA), IBA (Elegium) and Histori (Tokyo, Japan)

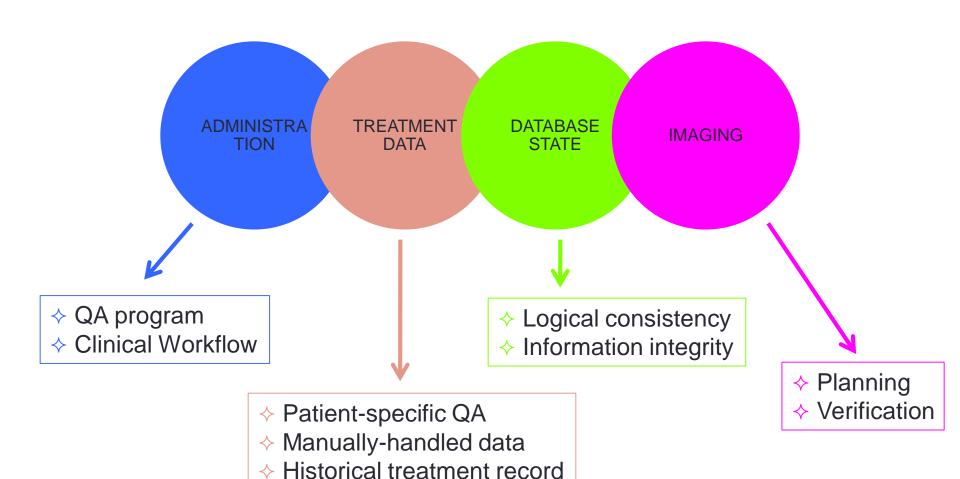
17

Corresponding author, R. Alfredo Sroch (TG201 Chair), Department of Radiation Oncology, University of Iowa. Hospitals and Cirica, 200 Hawkims Drive, Iowa City, IA 52242, USA; phone: 319-363-8079; tax: 319-566-1630 email: militade-olochilg. Jowan edu.

Preview report TG201

JOURNAL OF APPLIED CLINICAL MEDICAL PHYSICS. VOLUME 12. NUMBER 1. WINTER 2011

A rapid communication from the AAPM Task Group 201: Recommendations for the QA of external beam radiotherapy data transfer. AAPM TG 201: Quality assurance of external beam radiotherapy data transfer



Preview report TG201 - Administration



QA program

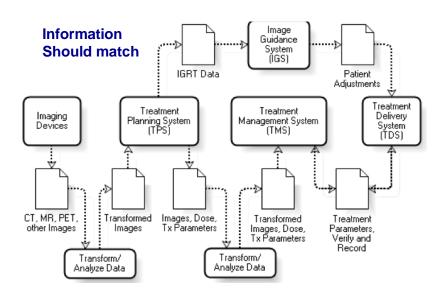
- A data transfer QA program should be established by a MP
 - MPs understand the flow of data (..) and are responsible for ensuring that the delivered Tx matches the physician approved plan
- ♦ Testing patient-specific Tx data transfer
 - Data Transfer complements measurements or independent calculations of dose distributions

	Target							
Source	SS	TPS	TMS	TDS	Archive			
SS		images						
TPS			plan +Images		images			
TMS				RT-plan	plan +Images			
TDS			record beam Tx		database backup			
Archive	images	plan +Images	database backup					

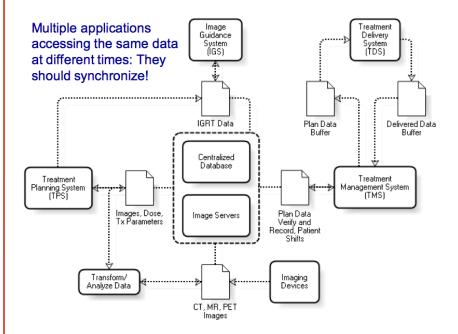
- Clinical treatment scenarios should be used for verifying the automated transfer functionality
 - ♦ Synchronize Hospital data (HIS) with RO-IS
 - → Log of transactions and mechanisms to verify uptime (both sender & listener)
- ♦ Periodic tests (benchmark cases), upgrades
- ♦ Evaluated by using benchmark cases with known data transfer problems
- ♦ Re-evaluated and, if necessary updated (mitigation process etc)

Know your own data flow

Distributed Data System



Centralized Data System



Environments

SINGLE DATA BASE

Eclipse + Aria + VARIAN linacs

DISTRIBUITED DATABASE: e.g.

Eclipse + Mosaiq + Varian Linac
Pinnacle + Mosaiq + Elekta Linac
MinMaestro+Monaco + Mosaiq + Elekta
Raystation+RayCare+Elekta linac

Preview report TG201 - Administration



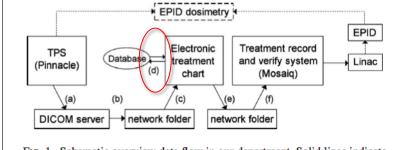
Clinical workflow

- ♦ A robust clinical workflow including checkpoints at all data exchange interfaces
 - ♦ Example: a secondary MU calculation by a different MP is one checkpoint TMS-TPS
 - ♦ Updated with new hardware, software or procedures
- Test DICOM compatibility as a part of commissioning (ATP) and documents work-arounds
- Warning and error messages should not be ignored. User should notify the physicist, investigate the message and documents their findings
 - ♦ A culture of "click through the warning messages" should be discouraged
- Items that are used in the TPS but that need to be manually entered or modified in the TMS should be included in a checklist to remind users to complete
 - ♦ Example: bolus
- Policies and procedures in place to handle treatments that are interrupted by network or software problems
 - ♦ This also in the case of a power outage

DATA TRANSFER (Med Phys, 2010)

♦IMRT PLAN

- ♦ Rectum ca
- ♦ 5 Gy x 7 fx
- ♦ IMRT S&S
- → 7 fields, 35 segments (10, 18 MV)
- ♦ 3D-EPID in-vivo dosimetry
 - \uparrow Y_{mean}=2.0;
 - → reconstructed @iso: 4.56 Gy vs 4.87 Gy from TPS (underdosage: 6.3%)



A. Mans, M. Wendling, L. N. McDermott, J.-J. Sonke, R. Tielenburg, R. Vijlbrief,

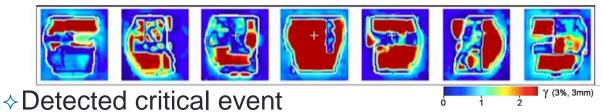
Department of Radiation Oncology, The Netherlands Cancer Institute-Antoni van Leeuwenhoek Hospital,

Catching errors with in vivo EPID dosimetry

B. Mijnheer, M. van Herk, and J. C. Stroom

Plesmanlaan 121, 1066 CX Amsterdam, The Netherlands

Fig. 1. Schematic overview data flow in our department. Solid lines indicate the route that the treatment plans follow (plan transfer steps are indicated with letters). Dashed lines indicate EPID dosimetry information transfer.



♦ 27 of 35 segments (control points) were corrupted

♦ Diagnosis

- ♦ Transfer (d): ETC → ETC Database
- Leaves&jaws were stored in separate tables: probably, one record containing leaves posotions was lost, causing asynchrony among leaves and jaws positions

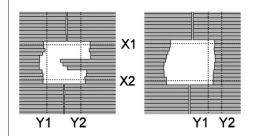


Fig. 3. Two examples of corrupted segments (control points) from a stepand-shoot IMRT plan. Due to a network transfer error, leaf positions of the next segment were used, while jaw positions were correct. MLC leaves are displayed in gray and jaw positions are indicated with dashed lines.

Reporting: MLC-corruption [IJRBP, 84(4), 2012]

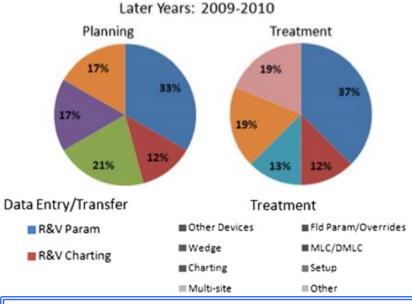
- ♦ Survey MSKCC: 2001-2010
- The MLC and IMRT technologies .. were not associated with a significant number of events (..). SMLC and DMLC events were uncommon, with only 5 reported
- 2 SMLC events both had a "human error" component
- → The 3 DMLC events (..) seemed to be software related. These events (..) all detected (..) at the machine, occurred when leaves incorrectly retracted to the open position at the start of treatment. All 3 were irreproducible, but one was eventually traced to a rare software problem known to the vendor but not to our clinical staff.
- (..) our own software, implemented in 2008, to verify proper delivery of IMRT fields daily through comparison of the planned and delivered leaf motion as recorded in accelerator log files (Varian Dynalog files). Any discrepancy is reported (..) by an email

Clinical Investigation: Safety

The Impact of New Technologies on Radiation Oncology Events and Trends in the Past Decade: An Institutional Experience

Margie A. Hunt, M.S.,* Gerri Pastrana, R.T.T., † Howard I. Amols, Ph.D.,* Aileen Killen, R.N., Ph.D., † and Kaled Alektiar, M.D. †

Departments of *Medical Physics, † Radiation Oncology, and † Quality of Care Initiative, Memorial Sloan-Kettering Cancer Center, New York, New York



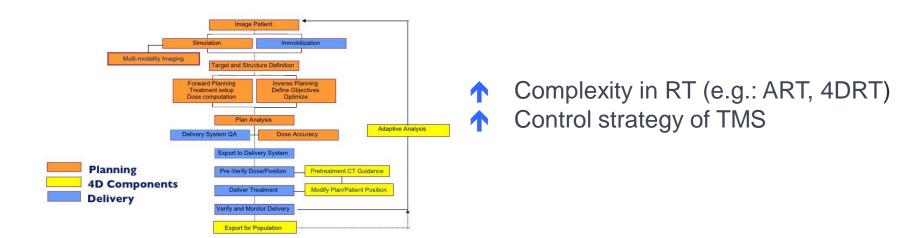
We believe that the changing role of R&V systems inherent in an EMR environment, the introduction of ever more complex technology, and the emergence of hypofractionated treatment paradigms may all lead to new types of errors, which may be even riskier than those we have encountered in the past.

Preview report TG201 - Administration



Clinical workflow

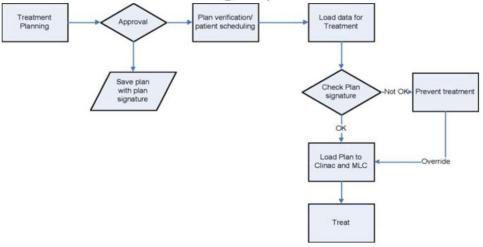
- Adopt a <u>change driven QA paradigm</u> and check the TMS when activities with the potential to change treatment data occur
 - ♦ If the prescription is changed after a plan is entered, an independent review should be done to ensure the plan is still appropriate.
 - ♦ A simple change, such as increasing the number of fractions, could cause critical structure tolerance doses to be exceeded.



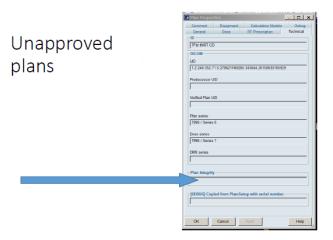
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TMS: Built-in check strategy: one example





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



TMS: Built-in check strategy: one example

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



Preview report TG201 – Treatment Data



- ♦ Patient-specific QA (QC!*)
 - ♦ Whenever possible, patient-specific QA of data transfer should be implemented on the <u>actual data that will be used for treatment</u>, rather than a copy of the data
 - ♦ QA mode
 - Unless the copy is compared to the original to ensure they are exactly the same, tests on the copy will only give you confidence to treat with the copy
 - ♦ Patient-specific verification of Tx parameters in the Tx DB to ensure that they match those in the plan, prior to Tx-approval
 - ♦ Checking a representative shape for a DMLC plan (e.g., CIAO) does not guarantee that the control points are correct → IMRT QA: control-point-by-control-point comparison!
 - ♦ The transfer of coordinate system-dependent data (images, dose, and Tx parameters) should be verified for proper orientation and registration
 - ♦ Non standard treatment geometries such as prone and/or feet-first
 - Independent MU checks performed on the data that gets downloaded to TDS
 - ♦ 3DCRT: AAPM TG114, Booklet Estro 10, software commerciali, altri TPS; IMRT, VMAT: letteratura

^{*} Point/Counterpoint Med Phys 40(7), 2013

Preview report TG201 – Treatment Data

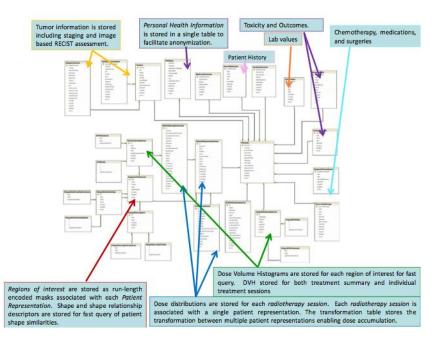


- Manually-handled data
 - Check items that are manually entered into TMS or imaging systems
 - ♦ E.g. n. fx per week or per day, dose limits, field name, TTables, setup info,IGRT schedules
 - Check items that are manually positioned for delivery (blocks, bolus..)
 - ♦ Some type of interlock mechanism or tagging system (e.g. barcodes) may be needed
 - ♦ Dedicated procedure for RT systems that are not directly tied into EMR/TMS
 - Amendments to a Tx plan should be recorded in the TMS or TPS and be independently verified
 - ♦ Example: couch attenuation
 - ♦ Check mechanisms that transfer clinical setup data (e.g., S, VS) to the TMS
- Historically treatment record
 - ♦ Dose tracking problems resolved prior to the next Tx delivery to ensure the proper operation of dose-based system functions.
 - ♦ Procedures to correctly track dose for situations that the TMS can not handle
 - ♦ Delivered Tx compared against the intended plan
 - ♦ In vivo portal dosimetry
 - to augment the weekly chart check (i.e., reviews of the TMS Tx history log) by searching for delivery parameters (including DMLC control points) that are out of tolerance
 - Patient's dose history

Preview report TG201 – Database State



- Logical Consistency
 - Check all related data in (TMS +TPS) for logical consistency. Inconsistent items should be corrected (conflicting information)
 - When checking a plan, MP should check the TPS and the TMS for unusual data or departure from the norm (New York Times accident docet)
 - ♦ Prescriptions, DRR
 - Verify that a Tx unit is compatible with the parameters in the TD database (beammatched machines included)
 - Mostly manual but automatic checks are work in progress



Preview report TG201 – Database State



- Information integrity
 - → Data transfer is meaningless if the data source are corrupted
 → Periodic QA (checksum approach)
 - When unintended changes to the Tx DB are discovered, this should be followed by a comparison of the affected data against the Tx plan prior to the next treatment of the field.
 - Scenarios exist where the treatment DB and its supporting files can be inadvertently changed (e.g. unintended unapproval during a weekly chart check, windows directories being rearranged, primary database fails and is not synchronized with the backup).
 - Security risk management (anti-virus, firewall, privacy) without compromising the TD's ability to treat correctly and efficiently
 - ♦ For RT-systems that use a single centralized DB, ensure synchronization between intended plan and delivery



Check that delivered plan = intended plan



QC: integrity of DB after upgrade TMS



- MCT: software home-made written by using Microsoft.NET technology (plan data XML format extracted)
- New plan compared to old plan
- Aria™ 8.9 → Aria™ 11:
 (warning: different platform:
 Sybase → MS SQL server)

JOURNAL OF APPLIED CLINICAL MEDICAL PHYSICS, VOLUME 14, NUMBER 6, 2013

Migration check tool: automatic plan verification following treatment management systems upgrade and database migration

Scott W. Hadley, $^{\rm a}$ Dale White, Xiaoping Chen, Jean M. Moran, Wayne M. Keranen

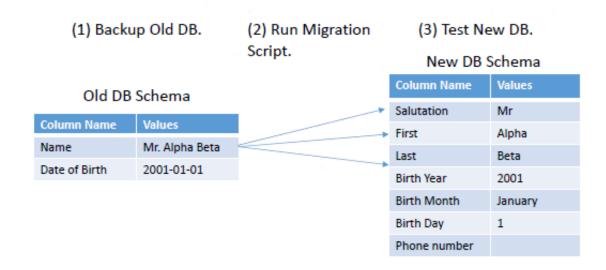
Department of Radiation Oncology Physics, The University of Michigan Medical School, Ann Arbor, Michigan. USA swhadley@umich.edu

Received 1 January, 2013; accepted 1 July, 2013

Software upgrades of the treatment management system (TMS) sometimes require that all data be migrated from one version of the database to another. It is necessary to verify that the data are correctly migrated to assure patient safety. It is impossible to verify by hand the thousands of parameters that go into each patient's radiation therapy treatment plan. Repeating pretreatment QA is costly, time-consuming, and may be inadequate in detecting errors that are introduced during the migration. In this work we investigate the use of an automatic Plan Comparison Tool to verify that plan data have been correctly migrated to a new version of a TMS database from an older version. We developed software to query and compare treatment plans between different versions of the TMS. The same plan in the two TMS systems are translated into an XML schema. A plan comparison module takes the two XML schemas as input and reports any differences in parameters between the two versions of the same plan by applying a schema mapping. A console application is used to query the database to obtain a list of active or in-preparation plans to be tested. It then runs in batch mode to compare all the plans, and a report of success or failure of the comparison is saved for review. This software tool was used as part of software upgrade and database migration from Varian's Aria 8.9 to Aria 11 TMS. Parameters were compared for 358 treatment plans in 89 minutes. This direct comparison of all plan parameters in the migrated TMS against the previous TMS surpasses current QA methods that relied on repeating pretreatment QA measurements or labor-intensive and fallible hand comparisons.

Upgrade TMS or a new TMS: transition: a critical point

What is a DB migration?



Preview report TG201 – Imaging



♦ Planning

- Check integrity of images transferred from Imaging systems to TPS (including image quality and patient demographics (name, ID).
 - Changes to images (e.g. bit-depth) but also to demographics information if they are entered multiple times
- ♦ The assignment of primary and secondary images for planning should be checked, specifically at the image registration stage

Verification

- ♦ The transfer of IGRT data from the TPS to the Tx unit's IGRT system should to be verified to ensure the correct points of interest are matched to the correct treatment sites, and that reference and treatment images are registered
- ♦ The transfer of imaging data from the TPS to the TMS should be verified to ensure that the TMS and the TPS display all images correctly

Maintenance as a part of QA program

- Backup, Archive
- Check DB log-files
- Remote monitoring service



Table 1: Change Management Quality Control Test Tables for general DMS similar to Figures A1-3.

Designator	Test	Performance						
DMS Data Links								
L1	Data transfer integrity	Complete						
L2	Data transfer integrity of images and imaging data	Complete						
L3	Data transfer integrity of electronic documents	Complete						
L4	Tests for failure	Complete						
L5	Soak or endurance testing	Complete						
DMS Components								
C1	Performance tests	Complete						
C2	Network tests	Compare to baseline						
C3	Security tests	Complete						
C4	Data integrity	Complete						
C5	Tests for failure	Complete						
C6	Machine readout checks	Complete						
C7	Data capture	Complete						
C8	General administrative checks	Complete						
Procedures								
P1	End-to-end testing	Complete						
P2	Review of clinical process maps	Complete						
P3	Contingency plan review	Complete						

C1 Performance tests

- A Test: Check accuracy of data transfer (using checksums, automated data transfer, redundancy checks, etc.) (see L1–L3 for details and suggested frequency).
- B Test: Monitor delay times (changes from baseline)

Suggested frequency: At commissioning and on an ongoing basis. Baseline values and thresholds should be established with the collaboration of the responsible IT personnel with input from vendors as appropriate.

C Test: Monitor available memory, CPU usage (set thresholds)

Suggested frequency: At commissioning and on an ongoing basis. Lack of available memory can have unexpected impacts on performance and could lead to errors in data integrity. Automated tools exist to monitor system resources and alert system administrators when an established threshold is reached. If automated tools are not available, close monitoring is required.

C2 Network tests

- A Test: Monitor DNS/DHCP allocation
 - Suggested frequency: At commissioning and quarterly.
- B Test: Monitor routing tables or routed and gated daemons.
- C Test: Connectivity tests (Digital Imaging and Communications in Medicine
 - [DICOM], Echo, ping checks) between DMS components
- D Test: Monitor functionality of required services (depending on operating system)
- E Test: Monitor network speed/resource allocation (time required to transfer large test data between servers or computers, lag in console display).

Suggested frequency C2 B–E: At commissioning, on an ongoing basis and during troubleshooting (of connectivity issues, for example). Baseline and threshold values depend strongly on the network design and infrastructure and should be established in collaboration with qualified IT personnel. Automated tools exist to monitor many aspects of network performance against established thresholds.

C3 Security tests

- A Test: Check for manufacturer security fixes (unless automatically provided by vendor).
- B Test: Maintain up-to-date list of applications, versions, patches, service packs, operating systems, etc.
- C Test: Maintain up-to-date anti-virus software.
- D Test: Adherence to pushed anti-virus and other policy settings for standard and non-standard computers.
- E Test: Appropriateness of virus scan settings on specific workstations and servers (real-time vs. scheduled for critical workstations and servers).
- F Test: Monitor user and system logs.
- G Test: Evaluate and monitor physical and network boundaries including firewall settings.
- H Test: Control user access permissions.
- I Test: Physical hardware checks.

P1 End-to-end testing

Test: Using carefully constructed, clinically relevant test cases, validate the complete clinical data chain from simulation to dose delivery. Test cases must be chosen to cover the full range of possible clinical situations.

Suggested frequency: At commissioning or following a change to any component of the DMS that is part of the routine clinical data flow. This type of testing is also valuable as part of the validation of a new treatment technique or, for some clinical protocols, as part of patient quality assurance. Regular end-to-end testing may be appropriate, especially in large systems with shared responsibility and management where changes to the DMS may occur without the responsible physicist's knowledge.

Note that end-to-end testing alone is not sufficient – though the test result may show an error, it will not necessarily identify the source or cause of the error. In addition, end-to-end testing relies on test case construction. Without full testing of data transfer integrity between components in the DMS as outlined above, it is entirely possible to miss errors that will later impact clinical data.

P2 Review of clinical process maps

Test: Review existing documentation of clinical processes and update to reflect changes to DMS system components, links and/or procedures. Ideally this test should be executed by a multi-disciplinary team responsible for the DMS quality assurance program.

Suggested frequency: Annually or following a change to a DMS component that is part of the routine clinical data flow.

"Manual" Chart-review (printout/screen)

+

Independent calculation



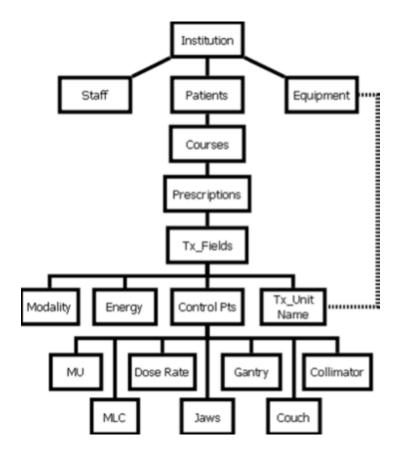
pre-Treatment verification:

Can we do it?
What is?
Is it enough?





RT: Complexity



"Manual" Chart-review (printout/screen)

+

Independent calculation



pre-Treatment verification:

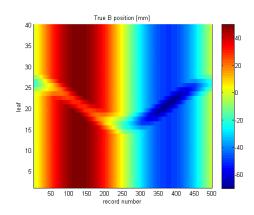
Can we do it? What is?



QA: New strategies

- Patient-specific QA each fx (Real Time)
 - In vivo EPID-dosimetry
 - Fluence measurement (Field Monitor)
 - Delivery system check (machine delivery log-file based)

•



http://www.wienkav.at/kav/kfj/91033454/physik/irohome.htm

"Manual" Chart-review (printout/screen)

+

Independent calculation

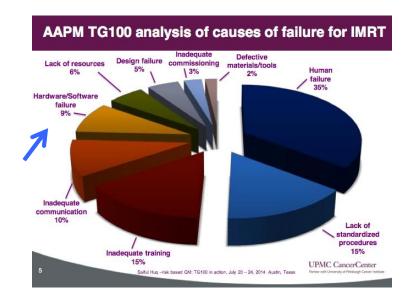


pre-Treatment verification:

Can we do it? What is?



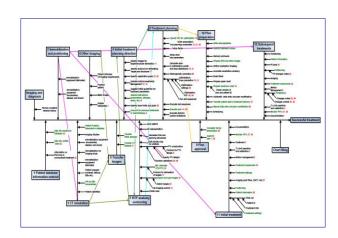
New approaches: TG100-like



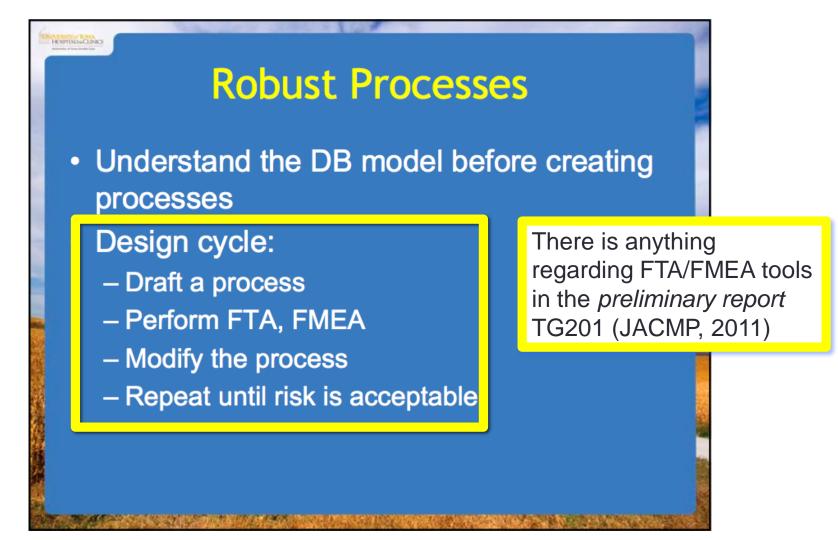
- Current QA guidance documents are based on prescriptive approaches evaluating technical performances of radiotherapy equipment
- There has been a growing recognition that quality and safety impairment arises from weakness in radiotherapy processes
- A good QM program should be process centric, prospective and risk based

An useful approach: FMEA - Failure Modes and Effects Analysis

- A Practical approach for improving Patient Safety: a semi-quantitative way to identify and give a priority to risks before they become errors
- AAPM (TG100) has decided to apply it to Radiation Oncology (after the New York times accident)
- The modus operandi is:
 - Study the workflow and create a process map
 - Identify weak points
 - Score each weak point
 - Rank and prioritize by score
 - Develop mitigation strategies



Design robust clinical workflows and meaningful tests



Incorporating the TG100 philosophy: risk analysis and error scenarios

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



"Manual" Chart-review (printout/screen)

+

Independent calculation



pre-Treatment verification:

Can we do it? What is?





Automation



"Classic" chart review (paradigm from AAPM TG40)

A number of operators review the various entries in the Rx chart. They should address the following items:

- Patient identification
- Initial physical evaluation of patient and pertinent clinical
- Treatment planning
- ♦ Signed and witnessed consent form
- ♦ Clinical assessment during Tx
- ♦ QA checklists

AAPM recommends that

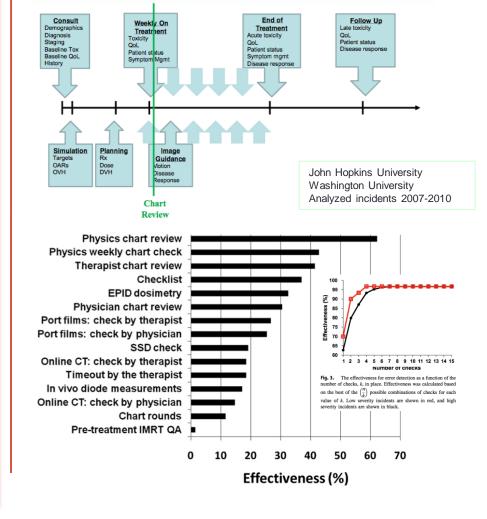
- → Before the third fraction following the start or a field modification (with SBRT, before 1st fx)
- Charts be reviewed at least weekly
- ♦ At the completion of Tx

Clinical Investigation: Quality Assurance

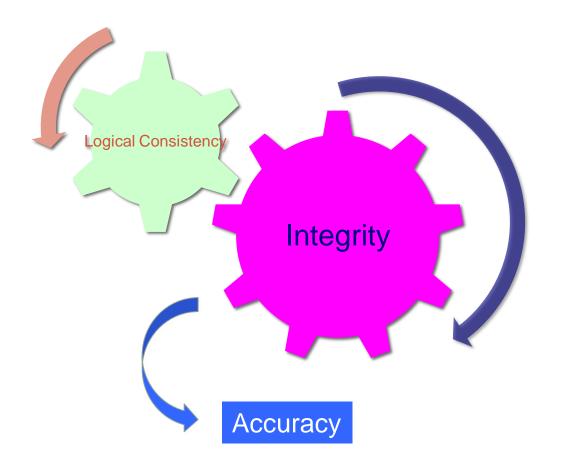
Quality Control Quantification (QCQ): A Tool to Measure the Value of Quality Control Checks in Radiation Oncology

Eric C. Ford, PhD,* Stephanie Terezakis, MD,* Annette Souranis,* Kendra Harris, MD,* Hiram Gay, MD, † and Sasa Mutic, PhD †

IJROBP, 84(3), 2012

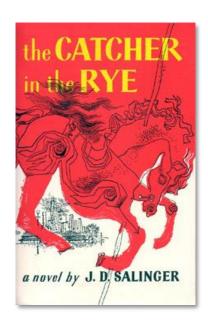


How to make "Chart review" more adequate/efficient and automatic?



Meta Check: Check squared (references)

- Azmandian F, Kaeli D, Dy J G1 et al., Towards the development of an error checker for radiotherapy treatment plans: a preliminary study, PMB 2007 52
- ♦ Ebert M A, Haworth A, Kearvell et al. Detailed review and analysis of complex radiotherapy clinical trial planning data: evaluation and initial experience with the swan software system RO, 2008 86
- ⇒ Siochi RAC, Pennington EC, Waldron TJ, Bayouth JE. Radiation therapy plan checks in a paperless clinic, J Appl Clin Med Phys, 2009 10(1)
- → Furhang EE, Dolan J, Sillanpaa J, Harrison LB. Automating the initial physics chart checking process, J Appl Clin Med Phys, 2009 10(1)
- → Yang D and Moore K.L., Automated Radiotherapy Treatment plan integrity verification, Med Phys, 2012; 39(3)
- → Yang D, Wu Y, Brame RS et al. Technical Note: Electronic chart checks in a paperless radiation therapy clinic, Med Phys 2012 39(8)
- → Halabi T and Lu HM. Automating checks of plan check automation, J Appl Clin Med Phys 2014; 15(4)
- → Dewhurts J M, Lowe M, Hardy J et al., AutoLock: a semiautomated system for radiotherapy treatment plan quality control, J Appl Clin Med Phys, 2015 16(3)



Siochi et al. (JACMP, 2009)

Electronic RT plan QA system (EQS): software modules with well documented processes and policies (3DCRT&IMRT)

→(1) Plan quality assessment: CERR (Computational Environment RT Research), an independent plan review program developed in Matlab; independent calculation of DVH from the RTOG plan data [Med. Phys. (5) 2003]

→ (2) TPS parameter export to R&V DB: LEX

reads the TPS data and creates an RTP-Connect file that can be imported into R&Vs DB (Visual Basic Net) performs a number of checks on the planning data to ensure that they are compatible with the requirements of the TDs and the R&V DB, flagging the user to fix any inconsistencies.

→ (3) Data integrity verification between R&V and TPS: RTP-filter

another (extra safety) in-house application reads the R&V data file (exported as RTP-Connect file) al R&Vs and compares it against TPS (Visual Basic 6.0)

RTP-Filter informs the user of any differences as well as any logical inconsistencies in the data. it also performs independent MU check and creates QA reports JOURNAL OF APPLIED CLINICAL MEDICAL PHYSICS, VOLUME 10, NUMBER 1, WINTER 2009

Radiation therapy plan checks in a paperless clinic

R. Alfredo Siochi,^(a) Edward C. Pennington, Timothy J. Waldron, John E. Bayouth

Department of Radiation Oncology, University of Iowa Hospitals and Clinics, Iowa City, IA 52242, U.S.A.

ralfredo-siochi@uiowa.edu

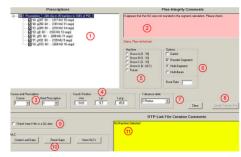


Fig. 1. Screen shot of LEX. The numbered areas correspond to the following descriptions: (1) Prescription and beam data are read directly from Pinnacle's data file; (2) The transfer software looks for conditions that do not follow our clinical practice; (3) Pinnacle has no provision for course or prescription number; the operator can select a course number and prescription number in order to create a unique ID for each beam; (4) Pinnacle has no fields for table position; the operator can edit the default values determined by LEX from the isocenter; (5) The Siemens ONCOR linear accelerators in our clinic have matched beam energies, so the operator must select a machine from the list; (6) The operator can choose to have the beams gated, re-order the segments in multi-segment beams to minimize the delivery time, and/or convert multi-segment beams into a series of individual beams to handle gated IMRT; (7) Pinnacle does not provide tolerance tables, so the operator must choose the proper one from the drop down list; (8) The button to create the RTPLINK file is disabled until all errors are cleared; this prevents the operator from sending incomplete data; (9) By checking the QA box, beams will be created that have a unique "QA" field ID; (10) These buttons control MLC options such as adding a 2 mm gap between closed leaf pairs that are blocked by the collimators; (11) Unresolved errors are displayed in this box. Once all the errors have been cleared, the button to create the transfer file is enabled.

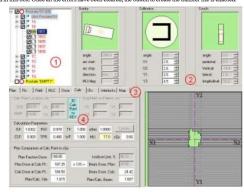


Fig. 2. Screen shot of the RTP-Filter. The numbered areas correspond to the following descriptions: (1) The prescriptions, beams and segments can be selected by the operator; (2) The position parameters (gantry, collimator, couch, MLC leaves) of each segment can be viewed in the panels in this section; (3) More information about the plan, the selected prescription, field and MLC, the dose, beam IDs, interlocks and intensity maps can be reviewed by selecting the appropriate tabs; (4) Pinnacle plan to LANTIS field comparisons are done when the user performs a dose calculation using the LANTIS data; calculation parameters for flash and effective depths can also be modified in this tab.

Siochi et al. (JACMP, 2009)

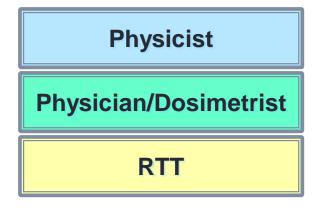
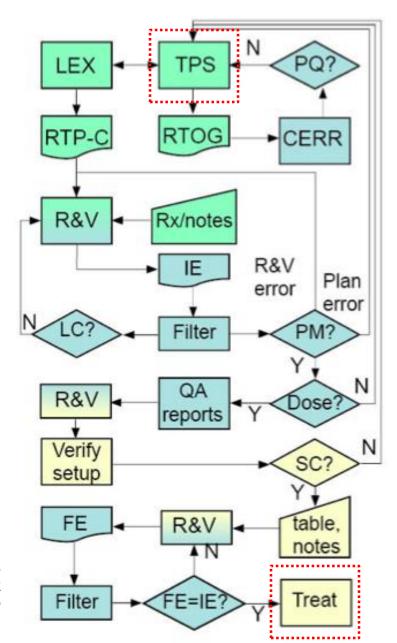




Fig. 5. An overview of the electronic plan check workflow. The workflow starts from the TPS and ends with the treatment. Rectangles = processes or software, diamonds = decisions, trapezoids = manual input, rectangles with curved bottom = files. The boxes are color coded by function: green = dosimetrists, blue = physicists, yellow = therapists. The abbreviations are as follows: TPS = treatment planning system (Pinnacle), LEX = in-house plan transfer software, RTP-C = RTP-Connect file, R&V = Record and Verify (LANTIS), Rx = Proceedings, R



Furhang et al. (JACMP, 2009)

JOURNAL OF APPLIED CLINICAL MEDICAL PHYSICS, VOLUME 10, NUMBER 1, WINTER 2009

Automating the initial physics chart-checking process

Eli E. Furhang, ^{1,a} James Dolan, ¹ Jussi K. Sillanpaa, ¹ Louis B. Harrison, ¹ Department of Radiation Oncology, ¹ Beth Israel Medical Center, 10 Union Square East, New York, NY, U.S.A. efurhang@chpnet.org

- Extracting the plan data from R&Vs, (after the approval, the fields are modified manually by RTT&MP to incorporate additional info: couch coordinates, field sequence, DR)
- Report was developed to extract diagnosis-prescription-plan parameters into excel spreadsheet; macro in Visual Basic guides the review process
- CHART CHECKING is divided into:
 - → (1) Intra-plan review: confirms diagnosis/prescription/plan correlation/accuracy of transfer of plan parameters and plan parameters self-consistency
 - → (2) Inter-plan Review: compares (Statistical Process Control formalism) the current plan to previous **similar cases** and **identifies outlying plan parameters**, potentially due to atypical circumstances or due to errors The category of similarity is according to diagnosis, anatomic site, laterality, delivery technique, fractionation scheme

IHE-RO: QA with Plan Veto

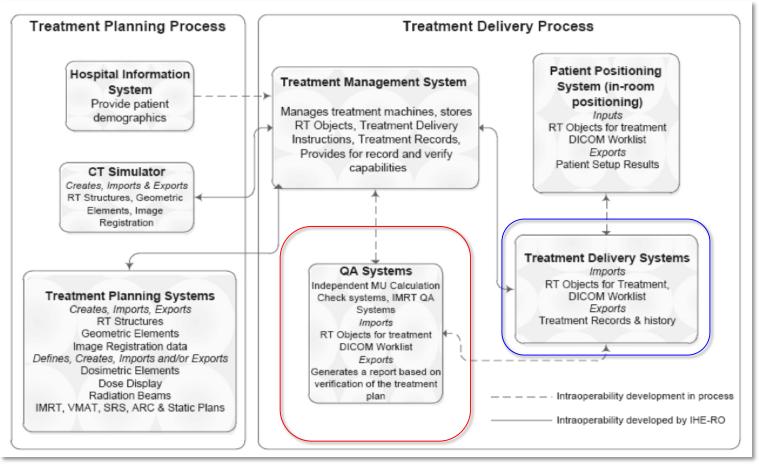
- ♦ IHE-RO has worked to develop an <u>automatic Quality Assurance with Plan</u> <u>Veto</u> (QAPV) integration profile, which would define communication standards and tools for verification of treatment data immediately before treatment
- The Quality Check Requester QCR QCR is TDS. It creates a Dicom Unified Procedure step item to request a QCP to perform a pre-treatment verification of treatment parameters and to validate them against the planned data
- → A Quality Check Performer QCP
 compare data sent from TMS to TDS with
 the approved plan data created by TPS
 and generates a <u>structured report</u>
 identifying any critical issues found.
- QCR is expected to trigger a veto of plan delivery if <u>critical problems are identified</u>



The IHE-RO (Integrating The Healthcare Enterprise Radiation Oncology) seeks to improve the interoperability of RO computer systems and share of information through coordinated use of established standard such as DICOM and HL7. [http://www.astro.org/ihero]

IHE-RO





QAPV - FMEA

- FMEA methodology is used to assess failures in accurate communication of DICOM RT plan parameters and estimate risk from possible failure modes due to errors in transferred data
- The probability of detection (undetectability) was established for scenarios with and without the use of QAPV
- The evaluated DICOM RT plan parameters were identified from DICOM RT plan export parameters in addition to the Advanced Radiotherapy Objects Interoperability IHE-RO profile
- Analysis and group discussion of each RT plan parameter and their associated errors
- An "event" is an error or a near-miss (events from a multi-institutional ILS)
- The FMEA values demonstrate that the implementation of QAPV could reduce the Risk Priority Number values in 15 of 22 (68%) of evaluated parameters, with an overall average reduction in RPN of 68 (range, 0-216)

Physics Contribution

Quality Assurance With Plan Veto: Reincarnation of a Record and Verify System and Its Potential Value

Camille E. Noel, PhD,* VeeraRajesh Gutti, PhD,† Walter Bosch, DSc,* Sasa Mutic, PhD,* Eric Ford, PhD,† Stephanie Terezakis, MD,§ and Lakshmi Santanam, PhD*

IJROP, 88(5), 2014

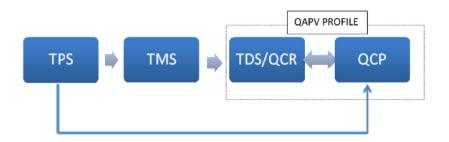


Table 2 Occurrence (O), severity (S), detectability (D), and risk priority numbers (RPNs) assigned after FMEA of the DICOM RT plan parameters

	0	s	D		RPN	
DICOM RT plan parameter			Without QAPV	With QAPV	Without QAPV	With QAPV
Patient Identification information*†	6	9	2	1	108	54
Plan Identification information*:	8	5	7	4	280	160
Number of Fractions Planned	8	9	4	4	288	288
Number of Beams	2	6	6	4	72	48
Beam Dose Specification Point	1	2	9	9	18	18
Beam Meterset [‡]	6	9	6	2	324	108
Institution Name	3	7	9	9	189	189
Treatment Machine Name	6	8	6	2	288	96
Beam Type	1	8	2	2	16	16
Radiation Type	1	9	3	2	27	18
High-Dose Technique Type	4	9	4	4	144	144
Treatment Delivery Type	2	4	4	4	32	32
Wedges*‡	4	9	7	2	252	72
Number of Control Points	1	5	4	1	20	5
Nominal Beam Energy	5	7	5	1	175	35
RT Beam Limiting Device Type [‡]	5	8	5	1	200	40
Leaf/Jaw Positions	3	8	7	3	168	72
Gantry Angle	1	7	5	1	35	7
Beam Limiting Device Angle	3	6	5	1	90	18
Patient Support Angle	3	5	3	3	45	45
Isocenter Position [‡]	6	9	4	2	216	108
Cumulative Meterset Weight	2	5	9	1	90	10

Abbreviations as in Table 1.

- * Parameter that was grouped with several related parameters.
- Moderate-risk RPN scores with the implementation of QAPV.
- [‡] Highest RPN scores without QAPV.

QAPV - work in progress

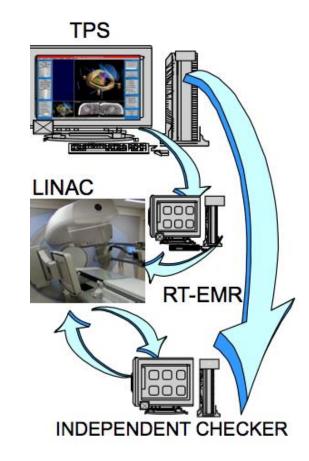
- The analyzed data show that QAPV theoretically has the potential to improve the safety of RT operations
- It is unclear how complicated it would be to support such a system and how often a clinic would encounter false-positive or false-negative alerts
- Low specificity could lead to unintended consequences, such as unnecessary delays in treatment or wasted time/personnel investigating false positives
- It is doubtful that such a system would become mandatory, and it is unclear at this time to what extent it would become

Physics Contribution

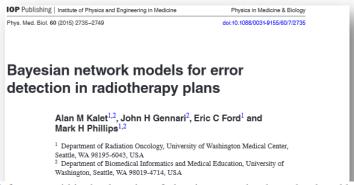
Quality Assurance With Plan Veto: Reincarnation of a Record and Verify System and Its Potential Value

Camille E. Noel, PhD,* VeeraRajesh Gutti, PhD,† Walter Bosch, DSc,*
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Lakshmi Santanam, PhD*

IJROP, 88(5), 2014



"Plan-review": new methods



difficult. Software to aid in the detection of planning errors has been developed by a number of groups (Azmandian *et al* 2007, Ebert *et al* 2008, Siochi *et al* 2009) by means of rule-based systems. One limitation of such an approach is the system's inability to alert the user to errors of judgment. That is, many plans may and do meet all rule based criteria for acceptability, yet still contain errors or suboptimal treatment choices. Rules and checklists can verify the existence of hard constraint violations such as monitor unit matching of electronic plan transfer from radiation treatment planning (RTP) system to radiation delivery device, but they cannot reliably capture error classes such as a misinterpretation of prescription or inappropriate planning technique for a given tumor type/location.

In addition, an expert plan review must account for the complexity of the medical decision making process. The relationships between many variables and the magnitudes of the variables cannot be encapsulated easily into rules since they depend on details of the disease, its location, and prior treatments, none of which are apparent in the treatment plan itself. In addition, physician preference can be a contributing factor, for example, in the decision to use a certain fractionation scheme. All of these factors lead to the conclusion that in many cases probabilistic relationships are the most appropriate way of characterizing plan variables. Furhang *et al* have explored the performance of an automated initial chart checking processes that employs case-based reasoning to measure similarity between the current plan parameters and historic plan parameters in a probabilistic way (Furhang *et al* 2009), however, the probability parameters of these models are independent of each other and static. One way to encapsulate more dynamic probability distributions which represent interdependency between variables is to employ probabilistic networks such as Bayesian networks.

THE CHART CHECKER: APPLYING DATA MINING TECHNIQUES TO DETECT MAJOR ERRORS IN RADIOTHERAPY TREATMENT CHARTS

A Thesis Presented

IOP PUBLISHING PHYSICS IN MEDICINE AND BIOLOGY
Phys. Med. Biol. 52 (2007) 6511–6524 doi:10.1088/0031-9155/52/21/012

Towards the development of an error checker for radiotherapy treatment plans: a preliminary study

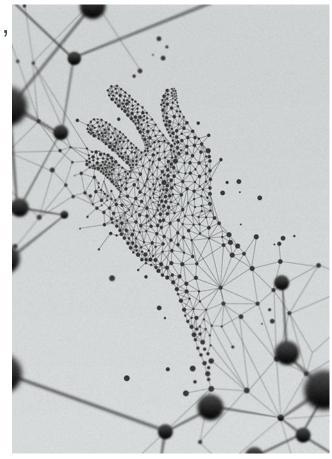
Fatemeh Azmandian¹, David Kaeli¹, Jennifer G Dy¹, Elizabeth Hutchinson², Marek Ancukiewicz², Andrzej Niemierko² and Steve B Jiang^{2,3}

The basic idea of the proposed computer-clustering-based treatment plan error checker is to first cluster the treatment parameters for a large number of patients having been treated previously. Then, when checking a new treatment plan, the parameters of the plan will be tested to see whether or not they belong to the established clusters. If not, they will be considered as 'outliers' and therefore highlighted to catch the attention of the human experts. Clustering is a data-mining and machine-learning technique that is used to extract valuable information from a set of unlabeled data (Fayyad 1996, Jain *et al* 1999). It is one of the most important data-mining methods applied to discover patterns and relations in complex medical datasets (Greene *et al* 2004). The goal of clustering is to separate data into groups, called clusters, such that objects in the same cluster are similar to each other and dissimilar to objects in other clusters.

QA in R&V and OIS - summary

Check of the information (quality of data),
 not only check integrity of data and
 logical consistency

- Automation of QA (Plan Checker)
- Quality = Safety → workflow



Arrivederci



"2001: a space odissey", S Kubrick, 1968