SBRT: QA and Safety Considerations

SESSION: Therapy 4:
Current Advantages and Safety Considerations in SBRT"

Presented at the AAPM Spring Clinical Meeting
Dallas, Texas
18 March 2012

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DISCLOSURES

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References

- Potters L, Kavanagh B, Galvin JM, et al. **American Society for Therapeutic Radiology and Oncology (ASTRO) and American College of Radiology (ACR) practice guideline for the performance of stereotactic body radiation therapy.** *Int J Radiat Oncol Biol Phys*. 2010;76:326–332
- Benedict SH, Yenice KM, Followill D, et al., "**Stereotactic Body Radiation Therapy: The Report of AAPM Task Group 101"** *Med Phys*. 2010;37:4078–4101
- Cunningham J, Coffey M, Knöös T, Holmberg O. **Radiation Oncology Safety Information System (ROSIS)–profiles of participants and the first 1074 incident reports.** *Radiother Oncol*. 2010;97:601–607
- Timothy D. Solberg PhD, James M. Balter PhD, Stanley H. Benedict PhD ,Benedick A. Fraass PhD, Brian Kavanagh MD, Curtis Miyamoto MD , Todd Pawlicki PhD, Louis Potters MD, Yoshiya Yamada MD , "**Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy**" Practical Radiation Oncology (2011)
- E. Klein, J. Hanley, J. Bayouth, et al" **Task Group 142 report: Quality assurance of medical accelerators"** , *Med Phys*. 36(9):4197-4212, 2009

What is SBRT?

•A single fraction treatment?

•A treatment with "n" fractions (n is your choice)?

•Whenever you are treating a "small" target?

•Any treatment that uses image guidance?

•Any treatment that uses a stereotactic frame?

•Any treatment on a machine claiming "stereotactic" capability?

Conventional RT vs. SBRT (I)

Characteristic	Conventional RT	SBRT
Dose / Fraction	1.8 – 3 Gy	6 – 30 Gy
No. of Fractions	10 – 30	1-5
Target definition	CTV / PTV gross disease + clinical extension: tumor may not have a sharp boundary.	GTV / CTV / ITV/ PTV well-defined tumors: GTV=CTV
Margin	Centimeters	Millimeters
Physics / dosimetry monitoring	Indirect	Direct
Required setup accuracy	TG40, TG142	TG40, TG142
Primary imaging modality used for tx plannning	CT	Multi-modality: CT/MR/PET-CT

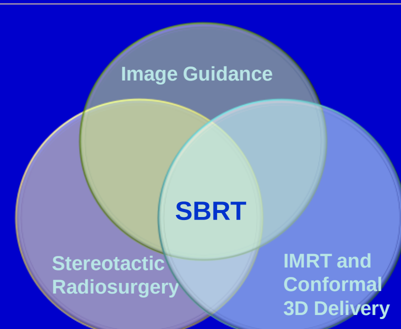
Conventional RT vs. SBRT (II)

Characteristic	Conventional RT	SBRT
Redundancy in geometric verification	No	Yes
Maintenance of high spatial targeting accuracy for the entire treatment	Moderately enforced (moderate patient position control and monitoring)	Strictly enforced (sufficient immobilization and high frequency position monitoring through integrated image guidance)
Need for respiratory motion management	Moderate – Must be at least considered	Highest

Conventional RT vs. SBRT (III)

Characteristic	Conventional RT	SBRT
Staff Training	Highest	Highest + special SBRT Training
Technology implementation	Highest	Highest
Radiobiological understanding	Moderately well understood	Poorly understood
Interaction with systemic therapies	YES	YES

So…What is SBRT?



An Introduction to the Recommendations for Physicists and Physicians from the AAPM Task Group No. 101….. Benedict, et al***Medical Physics* 37(8): 4078-4101, Au**

Stereotactic body radiation therapy: The report of AAPM Task Group 101

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Major Topics Covered in TG101:

1. History and Rationale for SBRT
2. Current status of SBRT patient selection criteria
3. Simulation Imaging and Treatment Planning
4. Patient Positioning, Immobilization, Target localization, and Delivery
5. Special Dosimetry Considerations
6. Clinical Implemetation of SBRT
7. Future Directions

A few brief TG101 topics in this talk ..

1. Participation in SBRT clinical trials
2. Normal Tissue Tolerances
3. Normalized Tumor Doses
4. Patient Immobilization

SBRT Participation In Trials

Recommendation: The most effective way to further the radiation oncology community's SBRT knowledge base is through participation in formal group trials

- •Single- or multi- institution
- •Ideally NCI-sponsored or NCI-cooperative groups (e.g. RTOG)
- •If no formal trial, look to publications
- •If no publications, structure as internal clinical trial

What is the most effective way to further the radiation oncology community's SBRT knowledge base?

0%	1. Industry research to improve the technology and delivery
0%	2. Attendance at national and regional meetings
0%	3. Participation in SBRT clinical trials, ideally NCI sponsored or NCI cooperative groups
0%	4. Using the internet to promote the sophisticated features and capabilities.
0%	5. Developing theoretical and computer based radiobiological models

10

Answer: 3

- Participation by clinicians in SBRT clinical trials, ideally NCI sponsored or NCI cooperative groups (ie, RTOG), but also single or multi-institutional protocols.

- Although industry research making improvement to our equipment, attendance at meetings by clinicians, and research into radiobiological modeling will advance our knowledge base – the most effective way to truly further our SBRT ***clinical*** knowledge base is by participation in clinical trials and communicating the analysis of the data to our clinicians. There is no evidence that promoting the features of medical equipment on the internet furthers our knowledge base of SBRT at all

- **Reference**:
- Potters L, Kavanagh B, Galvin JM, et al. **American Society for Therapeutic Radiology and Oncology (ASTRO) and American College of Radiology (ACR) practice guideline for the performance of stereotactic body radiation therapy.** *Int J Radiat Oncol Biol Phys*. 2010;76:326–332
- Benedict SH, Yenice KM, Followill D, et al., "**Stereotactic Body Radiation Therapy: The Report of AAPM Task Group 101"** *Med Phys*. 2010;37:4078–4101

Normal Tissue Tolerances

Recommendation: Normal tissue dose tolerances in the context of SBRT are still evolving. So…. CAUTION!

•If part of an IRB-approved phase 1 protocol, proceed carefully

•Otherwise, the evolving peer-reviewed literature must be respected!

Table of Normal Tissue Tolerances

TG 101: Table 3

SOME CAVEATS!

Serial tissue	Max critical volume above threshold	One fraction: Threshold dose (Gy)	One fraction: Max point dose (Gy)[a]	Three fractions: Threshold dose (Gy)	Three fractions: Max point dose (Gy)[a]	Five fractions: Threshold dose (Gy)	Five fractions: Max point dose (Gy)[a]	End point (≥Grade 3)
Optic pathway	<0.2 cc	8	10	15.3 (5.1 Gy/fx)	17.4 (5.8 Gy/fx)	23 (4.6 Gy/fx)	25 (5 Gy/fx)	Neuritis
Cochlea			9		[illegible]		25 (5 Gy/fx)	Hearing loss
Brainstem (not medulla)	<0.5 cc	10	15	18 (6 Gy/fx)	[illegible] (7.7 Gy/fx)	23 (4.6 Gy/fx)	31 (6.2 Gy/fx)	Cranial neuropathy
Spinal cord and medulla	<0.35 cc	10	14	[illegible]	[illegible] (7.3 Gy/fx)	23 (4.6 Gy/fx)	30 (6 Gy/fx)	Myelitis
	<1.2 cc	7		[illegible]		14.5 (2.9 Gy/fx)		
Spinal cord subvolume (5–6 mm above and below level treated per Ryu)	<10% of subvolume	10	[illegible]	18 (6 Gy/fx)	21.9 (7.3 Gy/fx)	23 (4.6 Gy/fx)	30 (6 Gy/fx)	Myelitis
Cauda equina	<5 cc	14	16	21.9 (7.3 Gy/fx)	24 (8 Gy/fx)	30 (6 Gy/fx)	32 (6.4 Gy/fx)	Neuritis
Sacral plexus	<5 cc	[illegible]	16	22.5 (7.5 Gy/fx)	24 (8 Gy/fx)	30 (6 Gy/fx)	32 (6.4 Gy/fx)	Neuropathy
Esophagus[b]	<5 cc	[illegible]	15.4	17.7 (5.9 Gy/fx)	25.2 (8.4 Gy/fx)	19.5 (3.9 Gy/fx)	35 (7 Gy/fx)	Stenosis/fistula
Brachial plexus	<3 cc	[illegible]	17.5	20.4 (6.8 Gy/fx)	24 (8 Gy/fx)	27 (5.4 Gy/fx)	30.5 (6.1 Gy/fx)	Neuropathy
Heart/pericardium	<15 cc	[illegible]	22	24 (8 Gy/fx)	30 (10 Gy/fx)	32 (6.4 Gy/fx)	38 (7.6 Gy/fx)	Pericarditis
Great vessels	<10 cc	31	37	39 (13 Gy/fx)	45 (15 Gy/fx)	47 (9.4 Gy/fx)	53 (10.6 Gy/fx)	Aneurysm
Trachea and large bronchus[b]	<4 cc	10.5	20.2	15 (5 Gy/fx)	30 (10 Gy/fx)	16.5 (3.3 Gy/fx)	40 (8 Gy/fx)	Stenosis/fistula
Bronchus-smaller airways	<0.5 cc	12.4	13.3	18.9 (6.3 Gy/fx)	23.1 (7.7 Gy/fx)	21 (4.2 Gy/fx)	33 (6.6 Gy/fx)	Stenosis with atelectasis
Rib	<1 cc	22	30	28.8 (9.6 Gy/fx)	36.9 (12.3 Gy/fx)	35 (7 Gy/fx)	43 (8.6 Gy/fx)	Pain or fracture
	<30 cc			30.0 (10.0 Gy/fx)				
Skin	<10 cc	23	26	30 (10 Gy/fx)	33 (11 Gy/fx)	36.5 (7.3 Gy/fx)	39.5 (7.9 Gy/fx)	Ulceration

Table of Normal Tissue Tolerances

- There is sparse long-term follow-up for SBRT.
- Data in table 3 should be treated as a first approximation!
- Doses are mostly unvalidated, but doses are based mostly on observation and theory.
- There is some measure of educated guessing!

R. Timmerman, 10/26/09, pers. comm.

Normal Tissue Tolerances – Serial Tissue

	One Fraction			Five Fractions		
Serial Tissue	**Max critical volume above threshold**	**Threshold dose (Gy)**	**Max point dose (Gy)****	**Threshold dose (Gy)**	**Max point dose (Gy)****	**Endpoint (≥Grade 3)**
Optic Pathway	<0.2 cc	8 Gy	10 Gy	23 Gy (4.6 Gy/fx)	25 Gy (5 Gy/fx)	neuritis
Heart/ Pericardium	<15 cc	16 Gy	22 Gy	32 Gy (6.4 Gy/fx)	38 Gy (7.6 Gy/fx)	percarditis
Brainstem (not medulla)	<0.5 cc	10 Gy	15 Gy	23 Gy (4.6 Gy/fx)	31 Gy (6.2 Gy/fx)	cranial neuropathy
Spinal Cord and medulla	<0.35 cc <1.2 cc	10 Gy 7 Gy	14 Gy	23 Gy (4.6 Gy/fx) 14.5 Gy (2.9 Gy/fx)	30 Gy (6 Gy/fx)	myelitis
Rectum	<20 cc	14.3 Gy	18.4 Gy	25 Gy (5 Gy/fx)	38 Gy (7.6 Gy/fx)	proctitis/fistula

Normal Tissue Tolerances (Parallel)

	One Fraction			Five Fractions		
Parallel Tissue	**Minimum critical volume below threshold**	**Threshold dose (Gy)**	**Max point dose (Gy)****	**Threshold dose (Gy)**	**Max point dose (Gy)****	**Endpoint (≥Grade 3)**
Lung (Right & Left)	1000 cc	7.4 Gy	NA – Parallel tissue	13.5 Gy (2.7 Gy/fx)	NA - Parallel tissue	Pneumonitis
Liver	700 cc	9.1 Gy	NA – Parallel tissue	21 Gy (4.2 Gy/fx)	NA - Parallel tissue	Basic Liver Function
Renal cortex (Right & Left)	200 cc	8.4 Gy	NA - Parallel tissue	17.5 Gy (3.5 Gy/fx)	NA - Parallel tissue	Basic renal function

R. D. Timmerman, "An overview of hypofractionation and introduction to this issue of seminars in radiation oncology," Semin Radiat Oncol **18**, 215-222 (2008).

N. E. Dunlap, J. Cai, G. B. Biedermann, W. Yang, S. H. Benedict, K. Sheng, T. E. Schefter, B. D. Kavanagh and J. M. Larner, "Chest Wall Volume Receiving >30 Gy Predicts Risk of Severe Pain and/or Rib Fracture After Lung Stereotactic Body Radiotherapy," Int J Radiat Oncol Biol Phys (2009).

Biological Effects

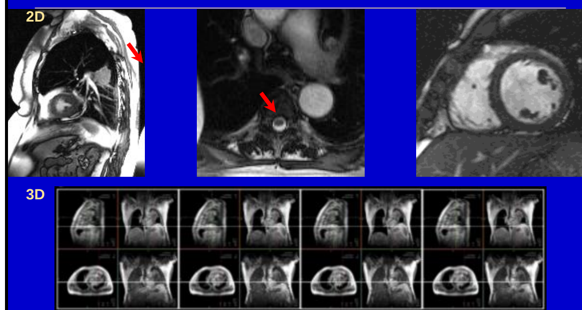
- NOT the same as traditional radiation therapy!!!!
- Cannot extrapolate from the linear quadratic model!!!!

Biological Dose Equivalents

Total Physical Dose (Gy)	NTD_{10} (Gy)	Log_{10} Cell Kill	Estimated 30 mo local progression-free survival	NTD_3 (Gy)
30 x 2 = 60* (in 6 weeks)	65	9.9	17.7 % (w. repopulation)	60
35 x 2 = 70* (in 7 weeks)	72	10.9	28.4 % (w. repopulation)	70
4 x 12 = 48	83	12.6	78.9 % (no repopulation)	144
3 x 15 = 45	94	14.2	90.8 % (no repopulation)	162
5 x 12 = 60	110	16.7	97.1% (no repopulation)	180
3 x 20 = 60	150	22.7	>99% (no repopulation)	276
3 x 22 = 66	176	26.7	>99% (no repopulation)	330

* NTD = Normalized Tissue Doses estimated using an α/β of 10 (late) an 3 Gy (early)

Managing Tumor Motion



Dinkel et al, 2009, 3D time-resolved echo shared gradient echo technique combining parallel imaging with view sharing (TREAT) sequence; ~ 1 frame/sec; voxel size ~ 3 mm.

Simulation with Motion or Imaging Artifacts

Recommendation: If target and/or critical structures cannot be localized accurately due to motion or metal artifacts……

STOP!

Do NOT pursue SBRT as a treatment option!

When target and/or critical structures cannot be localized accurately due to motion or metal artifacts which of the following applies…

0% 1. Utilize the deformable image registration features of the treatment planning system to develop a treatment plan

0% 2. Contour the target and critical structures as best you can and increase the margins on the target to a level that is necessary to account for the motion

0% 3. Reduce the dose and/or fractionation from the standard protocol to account for the errors in localization

0% 4. Use orthogonal (AP and lateral) kV planar imaging to develop a 2D plan for treatment and set-up.

0% 5. Do not pursue SBRT as a treatment option.

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Answer: 5

- If one is unable to localize the target and adjacent critical structures due to motion or metal artifacts SBRT should not be a treatment option.
- Deformation registration and other imaging tools may be instructive for targeting, but if the target and/or adjacent critical structures are not localizable than SBRT is not an appropriate delivery.
- **Reference**:
- Benedict SH, Yenice KM, Followill D, et al., "**Stereotactic Body Radiation Therapy: The Report of AAPM Task Group 101"** *Med Phys*. 2010;37:4078–4101

Patient Positioning, Immobilization, Target Localization, and Delivery

Recommendation: For SBRT, image-guided localization techniques **shall** be used to guarantee the spatial accuracy of the derived dose distribution.

•Body frames and fiducial systems are OK for immobilization and coarse localization

•They shall NOT be used as a sole localization technique!

For thoracic and abdominal targets, a patient-specific tumor motion assessment is recommended for planning and delivery of SBRT. Which of the following is a suitable approach?

0% 1. Adoption of a body frame will allow the planning, localization, and delivery for all thoracic and abdominal targets.

0% 2. The use of external markers or fiducials will allow accurate assessment of tumor position and re-localization.

0% 3. Employing abdominal compression has been shown to eliminate the need for tumor motion assessment

0% 4. Developing a standard protocol for all target margins in the treatment planning process will eliminate the need for a patient specific tumor motion assessment.

0% 5. The use of fiducials and body frames may be helpful for patient positioning in SBRT, but they are no substitute for employing IGRT technology, such as CBCT. SBRT requires IGRT.

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Answer: 5

- For SBRT, image-guided localization techniques **shall** be used to guarantee the spatial accuracy of the derived dose distribution. Other techniques, such as body frames, fiducuals, and abdominal compression may be employed but they are no substitute for IGRT technology.
- **Reference**:
- Benedict SH, Yenice KM, Followill D, et al., "**Stereotactic Body Radiation Therapy: The Report of AAPM Task Group 101"** *Med Phys*. 2010;37:4078–4101

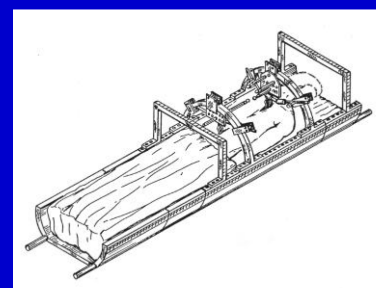
Patient Positioning, Immobilization, Target Localization, and Delivery

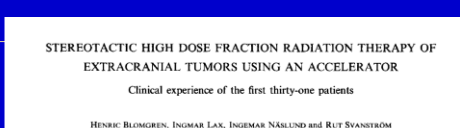
•It is **crucial** to maintain spatial accuracy **throughout** treatment delivery!

- •Integrated image-based monitoring
- •Aggressive immobilization

Development of Body Frames

Challenge: Creating a rigid external frame that will provide a repeatable reference for sites in the body.





STEREOTACTIC HIGH DOSE FRACTION RADIATION THERAPY OF EXTRACRANIAL TUMORS USING AN ACCELERATOR

Clinical experience of the first thirty-one patients

HENRIC BLOMGREN, INGMAR LAX, INGEMAR NÄSLUND and RUT SVANSTRÖM

-Blomgren et al, Acta Oncol 1995

What is frameless?

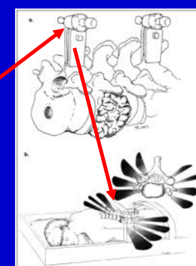
- Non-invasive frames provide repeatable (relocatable) immobilization.
- Designed for single or multiple treatments: Stereotactic radio<u>therapy</u>
- Can be used for cranial and body sites

Relocatable 'Frameless' Frames



Frame-based spinal SRS

- University of Arizona experience
  - 45 Gy external radiation previous XRT
  - 8-10 Gy for recurrent tumor in single fraction
- Setup aided by surgically implanted device that docked into external frame
- 5 patients followed median 6 months
  - Good local control and palliation described

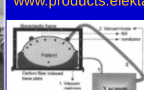


Hamilton et al, Neurosurgery. 36(2):311-319, February 1995

'Frameless' Immobilization Systems

Lax, Blomgren SBF (Elekta)



BodyFIX (Elekta) www.products.elekta.com

Pro-lok (www.civco.com)

Respiratory Motion Management

Recommendation: For thoracic and abdominal targets, a patient-specific tumor motion assessment is recommended.

•Quantifies motion expected over respiratory cycle

•Determines if techniques such as respiratory gating would be beneficial

•Helps in defining margins for treatment planning

•Allows compensation for temporal phase shifts between tumor motion and respiratory cycle

Simulation with motion or **Imaging Artifacts**

- **Recommendation:** If target and radiosensitive critical structures cannot be localized on a sectional imaging modality with sufficient accuracy because of motion and/or metal artifacts, SBRT should not be pursued as a treatment option.

SBRT Target Margins

Recommendation: At the current time, it remains difficult to base target margins directly on clinical results. The adequacy of ICRU definitions depend on:

•Understanding of how high absolute doses and sharp dose falloffs affect accuracy

•Limitations on in-house localization uncertainty

•Guidance from current peer-reviewed literature

Make an effort to gather and analyze your own clinical results to improve margin design!

Physicist Presence

Single-Fraction SRS	Physicist present for entire procedure
Multiple-Fraction SRS	Physicist present for 1st fraction and at setup of remaining fractions
SBRT	Physicist present for 1st fraction, and setup for every fraction to verify imaging, registration, gating, immobilization

SRS Event in the News…

Making a Complex Machine Even More Complex

Bogdanich W, Rebelo K. The radiation boom: A pinpoint beam strays invisibly, harming instead of healing. *The New York Times* (New York Edition). December 28, 2010; section A:1

ASTRO has committed to a six-point patient protection plan that will improve safety and quality and reduce the chances of medical errors.

1) Working with the Conference of Radiation Control Program Directors (CRCPD) and other stakeholders to create a database for the reporting of linear accelerator- and computed tomography-based medical errors.

2) Launching a significantly enhanced practice accreditation program, and beginning the development of additional accreditation modules specifically **addressing new, advanced technologies such as IMRT, SBRT and brachytherapy.**

3) Expanding our educational training programs to include specific courses on **quality assurance and safety**, and adding additional content to other educational programs

ASTRO commits to six-point patient protection plan

4) Working with patient support organizations to develop tools for cancer patients and caregivers for use in their discussions with their radiation oncologist to help them understand the quality and safety programs at the centers where they are being treated. These tools will include questions to ask their treatment team, such as, **"Do you have daily safety checks?" and "What kinds of safeguards do you have to make sure I'm given the right treatment?"**

5) Further developing our Integrating the Healthcare Enterprise – Radiation Oncology (IHE-RO) connectivity compliance program to ensure that medical technologies from different manufacturers can safely transfer information to reduce the chance of a medical error.

6) Providing our members' expertise to policymakers and advocating for new and expanded federal initiatives to help protect patients, including support for immediate passage of the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy (CARE) Act to require national standards for radiation therapy treatment team members; additional resources for the National Institute of Health's Radiological Physics Center to evaluate the safety of treatments; and funding for a national reporting database.

ASTRO has committed to a six-point patient protection plan that will improve safety and quality and reduce the chances of medical errors… which of the following is not part of the plan?

0%	1.	Working with the Conference of Radiation Control Program Directors (CRCPD) and other stakeholders to create a database for the reporting Therapists
0%	2.	Developing new accreditation modules specifically addressing new technologies, such as SBRT
0%	3.	Expanding our educational training programs to include specific courses on quality assurance and safety.
0%	4.	Working with patient support organizations to develop tools for cancer patients and caregivers for use in their discussions with their radiation oncologist to help them understand the quality and safety programs
0%	5.	Committing to a single manufacturer for each specialized treatment delivery and thereby eliminating problems associated with combining different technologies transferring erroneous information between systems

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Answer: 2

- The majority of reported incidents were detected by the radiation therapists at the treatment unit and were found during a treatment appointment. Detection by the QC process was the next most common method of detection. Although QC checklists and checks by dosimetry and physicists are important, they are no substitute for vigilance at the machine, particularly on the first day of treatment.

- **Reference**:

- Cunningham J, Coffey M, Knöös T, Holmberg O. **Radiation Oncology Safety Information System (ROSIS)–profiles of participants and the first 1074 incident reports.** *Radiother Oncol*. 2010;97:601–607

ASTRO, AAPM, ACR and other organizations have developed guidance documents aimed at understanding radiation risks

- Several guidance documents aimed at understanding radiotherapy risks and mitigating radiotherapy errors have been forthcoming recently from national and international organizations; these include: the World Health Organization (WHO), the International Commission on Radiological Protection (ICRP), the National Health Service (NHS) of the United Kingdom and the Alberta Heritage Foundation for Medical Research.
- A list of some of the common factors contributing to radiotherapy incidents has been summarized from these documents and they include…….

Solberg & Medin: *Jour. of Radiosurgery and SBRT*, Vol. 1, pp. 13-19, 2011

Common factors contributing to radiotherapy incidents

- Lack of training, competence or experience
- Inadequate staffing and/or skills levels
- Fatigue and stress, staffing and skills levels
- Poor design and documentation of procedures
- Complexity and sophistication of new technologies
- Over-reliance on automated procedures
- Poor communication and lack of team work
- Inadequate infrastructure and work environment
- Changes in processes

Solberg & Medin: *Jour. of Radiosurgery and SBRT*, Vol. 1, pp. 13-19, 2011

The WHO has suggested a number of general preventative measures aimed at reducing radiotherapy errors:

- A thorough quality assurance program to reduce the risks of systematic equipment and procedural related errors;
- A peer review audit program to improve decision making throughout the treatment process;
- Extensive use of procedural checklists;
- Independent verification through all stages of the process;
- Specific competency certification for all personnel;
- Routine use of in-vivo dosimetry.

Solberg & Medin: *Jour. of Radiosurgery and SBRT*, Vol. 1, pp. 13-19, 2011

SRS Events Reported to the NRC

Table 1. List of radiosurgery events reported to the NRC during the period 2005-2010

Event Description	Treatment Implication
Patient orientation entered incorrectly at MR Scanner	Wrong location treated
Fiducial box not seated properly during CT imaging	Wrong location treated
Malfunction of automatic positioning mechanism following re-initialization	Wrong location treated
Right trigeminal nerve targeted instead of left	Wrong location treated
Facial nerve targeted instead of trigeminal nerve	Wrong location treated
Mistake in setting isocenter coordinates	Wrong location treated
Head not secured to stereotactic device (2 events)	Wrong location treated
Selected collimators did not match planned	Wrong dose/distribution delivered
Physician mistakenly typed 28 Gy instead of 18 Gy into planning system	Wrong dose delivered
Physicist calculated prescription to 50% isodose instead of 40%	Wrong dose delivered
Microphone dislodged, causing stereotactic device to break	Treatment halted after 2 of 5 fractions
Couch moved during treatment	None; personnel interrupted treatment

Journal of Radiosurgery and SBRT Vol. 1 2011 15

Solberg & Medin: *Jour. of Radiosurgery and SBRT*, Vol. 1, pp. 13-19, 2011

Radiation Oncology Safety Information System (ROSIS) – Profiles of participants and the first 1074 incident reports

Radiotherapy and Oncology 97 (2010) 601–607

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journal homepage: www.thegreenjournal.com

Radiation safety

Radiation Oncology Safety Information System (ROSIS) – Profiles of participants and the first 1074 incident reports

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Radiation Oncology Safety Information System (ROSIS) – Profiles of participants and the first 1074 incident reports

- Established in 2001, The aim of ROSIS is to collate and share information on incidents and near-incidents in radiotherapy, and to learn from these incidents in the context of departmental infrastructure and procedures
- A voluntary web-based cross-organizational and international reporting and learning system was developed
- ROSIS departments represent about 150,000 patients, 343 megavoltage (MV) units, and 114 brachytherapy units

Discipline who detected the incident

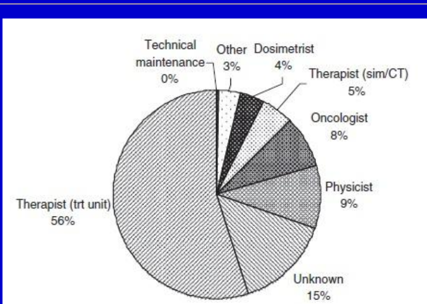

Fig. 1. Discipline who detected the incident.

J. Cunningham et al. / Radiotherapy and Oncology 97 (2010) 601–607

QA Incident Detection

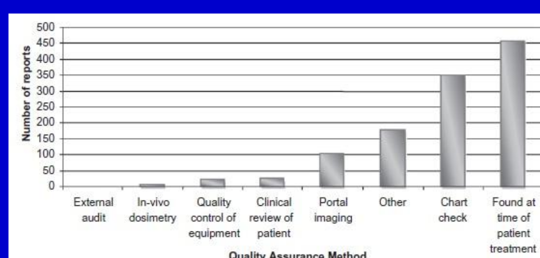

Fig. 2. Quality assurance method by which the incident was detected.

J. Cunningham et al. / Radiotherapy and Oncology 97 (2010) 601–607

A recent report by Cunningham et al on 1074 radiation oncology incident reports determined which discipline was most likely to detect an incident?

0%	1. Radiation Oncologists
0%	2. Therapists
0%	3. Physicists
0%	4. Dosimetrists
0%	5. Unknown, it has not been determined

10

Answer: 2

- The majority of reported incidents were detected by the radiation therapists at the treatment unit and were found during a treatment appointment. Detection by the QC process was the next most common method of detection. Although QC checklists and checks by dosimetry and physicists are important, they are no substitute for vigilance at the machine, particularly on the first day of treatment.

- **Reference**:
- Cunningham J, Coffey M, Knöös T, Holmberg O. **Radiation Oncology Safety Information System (ROSIS)–profiles of participants and the first 1074 incident reports.** *Radiother Oncol*. 2010;97:601–607

QA and Safety in SRS/SBRT
(Executive Summary and Supplemental Material)

SUPPLEMENTAL MATERIAL

Practical Radiation Oncology (2011)

pro

Quality and Safety Considerations in Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy

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This document was prepared by the SBRT experts invited by the Multidisciplinary Quality Assurance Subcommittee of the Clinical Affairs and Quality Committee of the American Society for Radiation Oncology (ASTRO) as a part of ASTRO's Target Safety Campaign.

Serious SRS Events Reported

- A calibration error on a radiosurgery linac that affected 77 patients in Florida in 2004-2005
- Similar errors in measurement of output factors affecting 145 patients in Toulouse, France in 2006-2007, and152 patients in Springfield, MO from 2004 to 2009
- An error in a cranial localization accessory that affected 7 centers in the U.S. and Europe
- Errors in failure to properly set backup jaws for treatments using small circular collimators affecting a single arteriovenous malformation patient at an institution in France, 3 patients at an institution in Evanston, IL.38

Planning Aspects for New SBRT Program

Table 1. Essential planning aspects for developing a new SBRT program and/or considering new disease sites.

Recommendation	Duration or Frequency	Reference
Establish clinical program goals, specify disease sites, identify program specialists, develop guidelines for treatment, follow-up and assessment.	Initially	33-34, 36
Identify required resources: expertise, personnel, technology, time.	Initially, and for each new technology and/or disease site	32-33
Perform technology assessment commensurate with clinical goals, identify equipment and processes for simulation, immobilization, image guidance, management of organ motion, treatment delivery.	Initially, and for each new technology and/or disease site	32-33
Perform assessment of staffing levels, develop processes for initial and ongoing training of all program staff.	Initially, and for each new technology and/or disease site	32-35
Develop and use checklists for all aspects of SRS/SBRT processes.	Initially, and for each new technology and/or disease site	34-36
Provide documentation for a culture and environment fostering clear and open communication.	Ongoing	32
Develop quality assurance processes that encompass all clinical and technical SBRT program aspects, clearly following available guidance, with regard to procedures and tolerances.	Initially, and for each new technology and/or disease site	32-36, 43
Conduct clinical SBRT patient conferences for pre-treatment planning and post-treatment review.	Ongoing	
Develop processes for documentation and reporting, peer review, regular review of processes and procedures, updating clinical guidelines and recommendations, ongoing needs assessment, and continuous quality improvement.	Ongoing	32-35

"Quality and Safety Considerations in SRS and SBRT", Solberg et al, *Practical Rad Onc*, 2011

Personnel Qualifications for an SRT Program

Table 2. Personnel qualifications of a stereotactic program

Recommendation	Duration or Frequency	Reference
All personnel must demonstrate initial attainment of knowledge and competence in their respective discipline through graduation from an approved educational program, board certification and licensure as appropriate.	Initially	32-33
All personnel must receive vendor provided equipment -specific training prior to involvement in an SBRT program.	16 hours per staff member	32, 34
All personnel must receive disease-site-specific training prior to involvement in a stereotactic program.	16 hours per staff member	32, 34
All personnel must maintain their skills by lifelong learning through continuing professional development. For physicians and physicists this is the ABR Maintenance of Certification process.	Ongoing	32, 34-35
There must be adequate resources in place to meet the demands of the stereotactic program with sufficient staff. Staff must have sufficient time to carry out the necessary tasks without undue pressure.	Ongoing	32-33, 37, 39
Job description and list of responsibilities should be clearly delineated in writing for all stereotactic program individuals.	Initially	32-33
Non-radiation oncology specialists can sometimes lend expertise in the area of target delineation for SBRT, given a deep fund of knowledge in the anatomy of various body sites. Examples of such specialists include neurosurgeons, pulmonologists, hepatologists, and oncologic surgeons.		

"Quality and Safety Considerations in SRS and SBRT", Solberg et al, Practical Rad Onc, 2011

Commissioning of a SRS Program

Table 3. Essential commissioning elements of a stereotactic program.

Recommendation	Duration	Reference
Appropriate resources, specialized equipment, personnel, time, must be evaluated and available prior to initiation of acceptance and commissioning processes and procedures.	8-16 weeks	32-33
Independent assessment of measured beam data should be performed prior to initiating a clinical SBRT program.	1 week	
Independent verification of absolute calibration should be performed prior to initiating a clinical stereotactic program.	<1 week	
Comprehensive treatment planning system commissioning incorporating a full range of stereotactic delivery parameters and techniques, and specifically addressing use of inhomogeneity corrections with specific dose algorithm(s), must be performed prior to initiating a clinical stereotactic program.	4-8 weeks	33
Independent verification of system commissioning, utilizing appropriate specialized phantoms such as those from the Radiological Physics Center, should be performed prior to initiating a clinical stereotactic program and prior to initiating new clinical sites and/or treatment techniques.	2-4 weeks	
Thorough commissioning of simulation devices and processes, including 4D CT if used, must be performed prior to initiating a clinical stereotactic program.	2-4 weeks	33
Management of respiratory motion is an essential element of SBRT simulation, planning and delivery. Measures must be developed to ensure effective and safe operation of these technologies.	2-4 weeks	33-34, 40
Evaluation of individual and end-to-end localization capabilities of the image guidance system must be performed prior to initiating a clinical stereotactic program and prior to initiating new clinical sites and/or treatment techniques.	2 weeks	33-34
End-to-end commissioning procedures, incorporating simulation, treatment planning and dosimetry, image guidance, management of motion, and treatment management systems, must be performed prior to initiating a clinical stereotactic program and prior to initiating new clinical sites and/or treatment techniques. In addition, users may find it useful to deliberately introduce known errors, and evaluate the capabilities of the system and processes in detecting such errors.	2 weeks	33

"Quality and Safety Considerations in SRS and SBRT", Solberg et al, Practical Rad Onc, 2011

Appendix 1 – Recommendations to Guard Against Catastrophic Failures in SRS and SBRT

Procedure and Tests	Principal	Primary Review	Secondary Review
1. Commissioning Treatment Devices and Planning Systems			
Machine output calibrations and factors in accordance with relevant guidelines (TG-51, TG-101, TG-142).	Physicist	2nd physicist	Independent assessment (RPC, etc.)
Treatment planning system commissioning should include test cases similar to those encountered in SBRT (TG-53).	Physicist	2nd Physicist	Physicists and Dosimetrists
2. Patient Selection			
Patient selection should be in accordance with an approved clinical protocol.	Physician	Physicians and Physici	ALL
3. Patient Simulation			
Patient simulated in accordance with approved protocol (immobilization and respiratory management) and supervised by physician.	Simulation Therapist	Physician	Physicists and Dosimetrists
4. Patient Treatment Planning			
Verify the patient information, treatment site, and prescription.	Dosimetrist	Physician	All
Verify correct positioning of the high dose and intermediate regions of isodose plan relative to targets.	Dosimetrist	Physician	Physicist
Verify the reference images and any shift information - physician determines IGRT technique.	Dosimetrist	Physicist	ALL
5. Pre-Treatment Quality Assurance			
Verify that the correct version of the patient's treatment plan is approved, sent to treatment management system, and used for patient-specific QA.	Dosimetrist	Physicist	ALL
Perform a thorough chart review.	Therapist	Physicist	ALL
Perform a complete chart check including review of information in treatment management system, field apertures in treatment management system, and check of dose to verify TPS calculation.	Dosimetrist	Physicist	ALL
Before the first treatment or for any change in treatment, perform patient-specific QA to guarantee that data transfer between systems is correct before patient treatment begins.	Physicist	Physicist	ALL
6. Treatment Delivery			
Halt a procedure if the operator is unclear about what is being done.	ALL	ALL	ALL
Perform a check of treatment parameters before start of each treatment against a fixed version of the treatment plan.	Therapist	2nd Therapist	ALL
Perform a time out prior to treatment delivery.	Therapist	2nd Therapist	ALL
Assess patient clinically during course of SBRT to identify any acute effects.	Physician, Therapist, and Nurse	Physician, Therapist, and Nurse	
7. Quality Performance and Improvement			
Perform end-to-end testing to guarantee transfer of data among all systems involved in imaging, planning and dose delivery (annually and after any software or hardware changes).	Physicist	2nd Physicist	Physicists and Dosimetrists

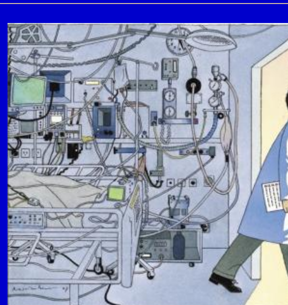
Recommendations to guard against catastrophic failures:

- Principals
- Primary Reviews
- 2nd Reviews

"Quality and Safety Considerations in SRS and SBRT", Solberg et al, *Practical Rad Onc*, 2011

Develop checklists for your program.

THE NEW YORKER
ANNALS OF MEDICINE
THE CHECKLIST
If something so simple can transform intensive care, what else can it do?
BY ATUL GAWANDE
DECEMBER 10, 2007



Appendix: Example checklists from 3 Institutions for SBRT

- Frame-based SRS Checklist
- Frameless SRS Checklist
- SBRT Spine Worklist
- SBRT Lung Worklist
- SRS Checklist
- Trigeminal neuralgia SRS checklist
- SBRT Checklist
- SBRT – Elekta SBRT Frame
- Beam Configuration
- Planning

"Quality and Safety Considerations in SRS and SBRT", Solberg et al, *Practical Rad Onc*, 2011

Sample Checklist for SRS Program: Lung


Appendix 2 – Institution 1: Lung SBRT worklist example

SBRT Lung Worklist:

Patient Name:
MRN:
Date of Implant:
Target Area:
Rad Oncologist:

"Quality and Safety Considerations in SRS and SBRT", Solberg et al, *Practical Rad Onc*, 2011

Many tasks are repeated a number of times over the course of an SBRT treat-ment and the use of procedural checklists for all aspects of the process can be particularly effective at ensuring compliance and minimizing error. Which of the following best describes the use of checklists for treatments

0%	1. Checklists are helpful for the initial stages of an SBRT program, but they may be removed from service once the staff have adequate experience
0%	2. The adoption of site specific checklists from other institutions with well established programs will usually suffice for another program initiating the same service
0%	3. Checklists are exclusively for the therapists to review and ensure that the patient has been set-up correctly and in accordance with the treatment plan.
0%	4. Check-lists to be used prior to daily treatment must be custom-ized to the particular treatment planning and delivery systems available at the institution.
0%	5. Site specific and machine specific checklists should not be used since they will add much confusion to the therapists activities.

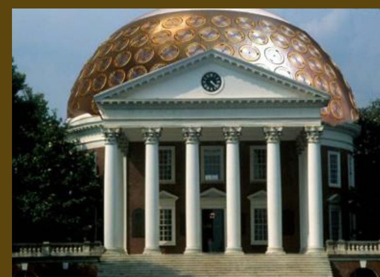
10

Answer: 4

- Checklists should be used, and they should be customized to match the technology and treatment site. These checklists should also be updated regularly to reflect any changes in procedures or technological updates in the SBRT program.

- **Reference**:
- Timothy D. Solberg PhD, James M. Balter PhD, Stanley H. Benedict PhD ,Benedick A. Fraass PhD, Brian Kavanagh MD, Curtis Miyamoto MD , Todd Pawlicki PhD, Louis Potters MD, Yoshiya Yamada MD , “Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy” Practical Radiation Oncology (2011)

Acknowledgements



The University of Virginia Rotunda

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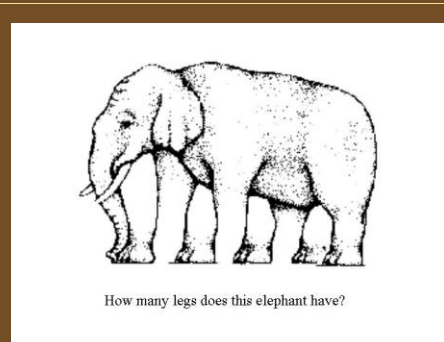
- James Larner, M.D.,
- and the Faculty and Staff at the University of Virginia

Is <u>all</u> image guidance helpful…..



Be Efficient – Be Safe

Thank You!