Washington State Health Care Authority

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000		x
2.	Equity interests such as stocks, stock options or other ownership interests		x
3.	Status of position as an officer, board member, trustee, owner		x
4.	Loan or intellectual property rights		x
5.	Research funding	x	
6.	Any other relationship		x

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

___Varian Medical Systems_____

___Brainlab_____

_____

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		x

7. If yes, Provide Name and Funding Sources: _____

_____

_____

_____

	Potential Conflict Type	Yes	No
8.	Travel: if an organization or company has financially paid your travel accommodations (e.g. airfare, hotel, meals, private vehicle mileage, etc).		x

8. If yes, Provide Name of Organization / Company and Disclose Travel Accommodations:

_____Varian Medical Systems_____

_____

_____

Washington State Health Care Authority

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may ***attach additional sheets*** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X [redacted] 9/6/12 Martin Fuss

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,
PO Box 42712, Olympia, WA 98504-2712

Last update: March 2012

CURRICULUM VITAE

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DOB: 10/03/1963 in Mannheim, Germany

Current address: 7179 SW Arranmore Way
Portland, OR 97223

Education:
1970-1974 Friedrich-Ebert-Schule, Eppelheim
1974-1983 Kurfürst-Friedrich-Gymnasium, Heidelberg
1983 Matura
1983-1985 Armed Forces (Bundeswehr), Degree: Lieutenant
1985-1986 University of Heidelberg, Study of German Language and History
1986-1994 University of Heidelberg, Medical School
1992-1993 Final year in the Departments of Radiation Oncology and Medical Oncology, Internal Medicine, and Surgery

Magna cum laude Ph.D. thesis: Blood volume changes in normal brain tissue and low-grade astrocytoma following radiation therapy.
Accepted by the Senate of the University of Heidelberg in June 1998

Affiliations

7/94-6/00 Residency: Dept. of Radiation Oncology and Medical Oncology, Univ. of Heidelberg and Dept. of Radiological Diagnostic and Therapy, German Cancer Research Center (dkfz), Heidelberg

8/98-7/99 Research Fellow: Loma Linda University Medical Center, Proton Radiation Therapy, Loma Linda, CA

7/00-6/01 Research Fellow: Dept. of Radiation Oncology, The University of Texas Health Science Center at San Antonio, San Antonio, Texas

7/01-11/03	Assistant Professor, Dept. of Radiation Oncology, University of Texas Health Science Center at San Antonio, San Antonio, Texas
10/01-7/06	Member of the Graduate Faculty, Division of Radiological Sciences, University of Texas Health Science Center at San Antonio, San Antonio, Texas
10/03-7/06	Head of Radiation Techniques Research, Cancer Therapy & Research Center, San Antonio, Texas
12/03-7/06	Associate Professor, Dept. of Radiation Oncology, University of Texas Health Science Center at San Antonio, San Antonio, Texas
8/06-	Professor (adjunct), Director Program in Image-guided Radiation Therapy, Dept. of Radiation Medicine, Oregon Health & Science University, Portland, Oregon
8/06-	Joint Professor, Dept. of Computer Science & Electrical Engineering, Oregon Graduate Institute (OGI) School of Science & Engineering, Portland, OR
7/07	Professor, Dept. of Radiation Medicine, Oregon Health & Science University, Portland, Oregon
8/08	Professor, Dept. of Nuclear Engineering and Radiation Health Physics, Oregon State University, Corvallis, OR
10/08	Vice Chair, Dept. of Radiation Medicine, Oregon Health & Science University, Portland, Oregon
10/10	Graduate Faculty, School of Medicine, Oregon Health & Science University, Portland, Oregon

Member

DEGRO (German Society of Radiation Oncology)
ASTRO (American Society for Therapeutic Radiation Oncology)
ESTRO (European Society for Therapeutic Radiation Oncology)
ISRS (International Stereotactic Radiosurgery Society)
PROS (Pediatric Radiation Oncology Society)

Committee participation

Member of the MD/PhD committee at OHSU, 3 year terms (July 2008 – 2011 and 2012-)
OHSU Knight Cancer Institute Clinical Research Review Committee (2011-)
Member of the Agency for Healthcare Research and Quality (AHRQ) Oregon Evidence-based Practice Center (EPC) Technical Expert Group: Comparative Effectiveness Review (CER) on Intensity-modulated Radiation Therapy, since 2007

Protocol Review and Monitoring System Committee, San Antonio Cancer Institute (SACI, NCI designated Comprehensive Cancer Center), 2 year term (2001-2003)
Institutional Review Board (IRB 3), The University of Texas Health Science Center at San Antonio (UTHSCSA), San Antonio, Texas, 3 year term (2003-2006)
Radiation Safety Committee, The University of Texas Health Science Center at San Antonio (UTHSCSA), San Antonio, TX, 2001-2006
Membership committee, American Society for Therapeutic Radiation Oncology (ASTRO), since 2003. Committee vice-chair 2007.
Search committee for the Director of Medical Physics, Cancer Therapy & Research Center, San Antonio, TX, 2005
Search committee for the Associate Director for Business Development, Knight Cancer Institute, OHSU, 2011

Reviewer

International Journal of Radiation Oncology Biology Physics
Radiology
Radiotherapy & Oncology
Cancer
British Journal of Cancer
Acta Oncologica
Future Oncology
Pancreatology
Cancer Therapy
Technology in Cancer Research and Therapy
Journal of Applied Clinical Medical Physics
Physics in Medicine and Biology
Southern Medical Journal
Expert Opinion on Drug Delivery
European Commission, 6th Framework Program (FP6)
2010 and 2011 Collaborative Health Research Projects competition, Natural Sciences and Engineering Research Council (NSERC) and the Canadian Institutes of Health Research (CIHR)

Awards:

Varian poster prize: Pitfalls in inverse treatment planning: sometimes the physician is the problem. DEGRO annual meeting June 2002, Berlin, Germany

Publications:

1. Tanyi JA, Kato CM, Chen Y, Chen Z, Fuss M. Impact of the high-definition multileaf collimator on linear accelerator-based intracranial stereotactic radiosurgery. Br J Radiol. 2011 Jul;84(1003):629-38
2. Fuss M. Strategies of assessing and quantifying radiation treatment metabolic tumor response using F18 FDG Positron Emission Tomography (PET). Acta Oncol. 2010 Oct;49(7):948-55.
3. Tanyi JA, He T, Summers PA, Mburu RG, Kato CM, Rhodes SM, Hung AY, Fuss M. Assessment of Planning Target Volume Margins for Intensity-Modulated Radiotherapy of the Prostate Gland: Role of Daily Inter- and Intrafraction Motion. Int J Radiat Oncol Biol Phys. 2010 Dec 1;78(5):1579-85
4. Achanta P, Fuss M, Martinez JL Jr. Ionizing radiation impairs the formation of trace fear memories and reduces hippocampal neurogenesis. Behav Neurosci 2009 Oct 123(5):1036-45.
5. Tanyi JA, Summers PA, McCracken CL, Chen Y, Ku LC, Fuss M. Implications of a high-definition multileaf collimator (HD-MLC) on treatment planning techniques for stereotactic body radiation therapy (SBRT): a planning study. Radiat Oncol. 2009 Jul 10;4:22.
6. Lin L, Shi C, Eng T, Swanson G, Fuss M, Papanikolaou N. Evaluation of inter-fractional setup shifts for site-specific helical tomotherapy treatments. Technol Cancer Res Treat. 2009 Apr;8(2):115-22.Fuller CD, Dang ND, Wang SJ, Desai P, Choi M, Thomas CR Jr, Fuss M. Image-guided intensity-modulated radiotherapy (IG-IMRT) for biliary adenocarcinomas: Initial clinical results. Radiother Oncol. 2009 Aug;92(2):249-54.
7. Salter BJ, Fuss M, Sarkar V, Wang B, Rassiah-Szegedi P, Papanikolaou N, Hollingshaus S, Shrieve DC. Optimization of isocenter location for intensity modulated stereotactic treatment of small intracranial targets.Int J Radiat Oncol Biol Phys. 2009 Feb 1;73(2):546-55.
8. Salter BJ, Wang B, Szegedi MW, Rassiah-Szegedi P, Shrieve DC, Cheng R, Fuss M. Evaluation of alignment error due to a speed artifact in stereotactic ultrasound image guidance. Phys Med Biol. 2008 Dec 7;53(23):N437-45.
9. Choi M, Fuller CD, Wang SJ, Siddiqi A, Wong A, Thomas CR Jr, Fuss M. Effect of body mass index on shifts in ultrasound-based image-guided intensity-modulated radiation therapy for abdominal malignancies. Radiother Oncol. 2009 Apr;91(1):114-9.
10. Tanyi JA, Fuss M. Volumetric image-guidance: Does routine usage prompt adaptive re-planning? An institutional review. Acta Oncol. 2008 Jul 25:1-10.
11. Siddiqui F, Shi C, Papanikolaou N, Fuss M. Image-guidance protocol comparison: Supine and prone set-up accuracy for pelvic radiation therapy. Acta Oncol. 2008 Jul 29:1-7.

12. Fuller CD, Schillerstrom JE, Jones WE 3rd, Boersma M, Royall DR, Fuss M. Prospective Evaluation of Pretreatment Executive Cognitive Impairment and Depression in Patients Referred for Radiotherapy. Int J Radiat Oncol Biol Phys. 2008 Oct 1;72(2):529-3.
13. Zhang J, Xu G, Shi C, Fuss M. Development of a geometry-based respiratory motion–simulating patient model for radiation treatment dosimetry. J Appl Clin Med Phys. 2008;9:16-28.
14. Tanyi JA, Krafft SP, Hagio T, Fuss M, Salter BJ. MOSFET sensitivity dependence on integrated dose from high-energy photon beams. Med Phys. 2008 Jan;35(1):39-47.
15. Boda-Heggemann J, Köhler FM, De Meerleer G, De Neve W, Fuss M, Lohr F, Wenz F. Image-guided radiation therapy: many roads lead to Rome? Int J Radiat Oncol Biol Phys. 2008 Feb 1;70(2):646-7 (letter to the editor)
16. Rassiah-Szegedi P, Fuss M, Sheikh-Bagheri D, Szegedi M, Stathakis S, Lancaster J, Papanikolaou N, Salter B. Dosimetric evaluation of a Monte Carlo IMRT treatment planning system incorporating the MIMiC. Phys. Med. Biol. 2007;52:6931-41
17. Fuller CD, Forthuber B, Choi M, Rajagiriyil, Slater BJ, Fuss M. Standard fractionation intensity-modulated radiation therapy (IMRT) for primary and recurrent glioblastoma multiforme. Radiation Oncology 2007;2(26):1-7.
18. Wang SJ, Choi M, Fuller CD, Salter BJ, Fuss M. Intensity-Modulated Radiosurgery for Patients with Brain Metastases: A Mature Outcomes Analysis. TCRT 2007;6:161-168.
19. Fuss M, Salter BJ. Intensity-modulated radiosurgery: improving dose gradients and maximum dose using post inverse-optimization interactive dose shaping. TCRT 2007;6:197-204.
20. Fuss M, Boda-Heggemann J, Papanikolaou N, Salter BJ. Image-guidance for Stereotactic Body Radiation Therapy. Medical Dosimetry 2007;32(2):102-10.
21. Achanta P, Thompson KJ, Fuss M, Martinez JL. Gene Expression Changes in the Rodent Hippocampus Following Whole Brain Irradiation. Neuroscience Letters 2007;418(2):143-7.
22. Tanyi JA, Fuss M, Varchena V, Lancaster JL, and Salter BJ. Phantom investigation of three-dimensional motion-dependent volume aliasing during computed tomography simulation for radiation therapy planning. Radiation Oncology 2007;2:1-15.
23. Fuss M, Wong A, Fuller CD, Salter BJ, Fuss C, Herman TS, Thomas CR Jr. Image-guided intensity-modulated radiation therapy for pancreatic carcinoma. Gastrointestinal Cancer Research 2007;1(1):2-11.
24. Fuller CD, Thomas CR, Wong A, Voeltz L, Salter BJ, Fuss M. Thermo-luminescent dosimeter evaluation of extra-target dose in intensity modulated sequential tomotherapy for pancreatic cancer. J Radiotherapy in Practice 2006;5, 173-176.

25. Fuss M, Shi, C, Papanikolaou N. Tomotherapeutic Stereotactic Body Radiation Therapy: Techniques and Comparison between Modalities. Acta Oncologica 2006;45(7);953-960.
26. Joyner M, Salter BJ, Fuss M. Stereotactic Body Radiation Therapy for Centrally located Lung Lesions. Acta Oncologica 2006;45(7);802-807.
27. Rassiah P. Salter BJ, Fuller D, Blough M, Papanikolaou N, Fuss M. Monte Carlo Characterization of Target Doses in Stereotactic Body Radiation Therapy (SBRT). Acta Oncologica 2006;45(7);989-994.
28. Fuller CD, Thomas CR Jr., Salter BJ, Herman TS, Fuss M. Preliminary endpoint analysis of daily ultrasound-based image-guided IMRT in the treatment of cancers of the gallbladder. Radiotherapy Oncology 2006;81:65-72.
29. Yang G, Wagner T, Fuss M, Thomas CR Jr. Multimodality Approaches for Pancreatic Cancer. CA A Cancer Journal for Clinicians 2005;55(6):352-367.
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31. Fuss M, Salter BJ, Caron JL, Vollmer DG, Herman TS. Intensity-modulated radiosurgery for childhood arteriovenous malformations. Acta Neurochirurgica 2005;147(11):1141-1150.
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33. Salter BJ, Fuss M. The Song, Kavanagh, Benedict, et al. article reviewed. Oncology 2004;18(11):1435-1436.
34. Fuss M, Salter BJ, Herman TS, Thomas CR Jr. External beam radiation therapy for hepatocellular carcinoma: Potential of intensity-modulated and image-guided radiation therapy. Gastroenterology 2004;127(5 Suppl 2):S206-17.
35. Fuss M, Salter BJ, Cavanaugh SX, Fuss C, Sadeghi A, Fuller CD, Ameduri A, Hevezi JM, Herman TS, Thomas CR Jr. Daily ultrasound-based image-guided targeting for radiotherapy of upper abdominal malignancies. Int J Radiat Oncol Biol Phys 2004;59(4):1245-1256.
36. Cavanaugh SX, Kupelian PA, Reddy C, Bradshaw P, Pollock BH, Fuss M. Early PSA kinetics following prostate cancer radiotherapy: prognostic value of a Time and PSA threshold model. Cancer 2004;101:96-105.
37. Fuss M, Salter BJ, Cheek D, Sadeghi A, Hevezi JM, Herman TS. Repositioning accuracy of a commercially available thermoplastic mask system. Radiother Oncol 2004;71(3):339-345.

38. Fuss M, Thomas CR Jr. Stereotactic body radiation therapy: an ablative treatment option for primary and secondary liver tumors. Ann Surg Oncol 2004;11(2):130-138.
39. Fuss M, Salter BJ, Rassiah P, Cheek D, Cavanaugh SX, Herman TS. Repositioning accuracy of a commercially available double-vacuum whole body immobilization system. Technol Cancer Res Treat 2004;3(1):59-68.
40. Lohr F, Fuss M, Tiefenbacher U, Siegsmund M, Mai S, Kunnappallil JM, Dobler B, Alken P, Wenz F. Optimierter Einsatz der Strahlentherapie durch IMRT und Präzisionslokalisationsverfahren bei der Behandlung des fortgeschrittenen Prostatakarzinoms. Urologe A 2004;43(1):43-51.
41. Kraus-Tiefenbacher U, Lohr F, Fuss M, Wenz F. Strahlentherapie beim Pankreaskarzinom. Journal Oncologie 2003;5:16-19.
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44. Fuss M, Cavanaugh SX, Fuss C, Cheek DA, Salter BJ. Daily stereotactic ultrasound prostate targeting: inter user-variability. Technol Cancer Res Treat 2003;2(2):161-170.
45. Steinvorth S, Wenz F, Wildermuth S, Essig M, Fuss M, Lohr F, Debus J, Wannenmacher M, Hacke W. Cognitive functions in patients with cerebral arteriovenous malformations after radiosurgery: prospective long-term follow-up. Int J Radiat Oncol Biol Phys 2002;54:1430-7.
46. Fuss M, Salter BJ, Sadeghi A, Vollmer DG, Hevezi JM, Herman TS. Fractionated stereotactic intensity-modulated radiotherapy (FS-IMRT) for small acoustic neuromas. Med Dosim 2002;27(2):147-154.
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48. Re: Letter to the editor. Regarding The TALON relocatable headframe for stereotactic radiotherapy: Measurement of the repositioning accuracy. Int J Radiat Oncol Biol Phys 2002;53(1):254.
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50. Fuss M, Wenz F, Essig M, Debus J, Herman T, Wannenmacher M. Tumor angiogenesis of low-grade astrocytomas measured by dynamic susceptibility contrast enhanced MRI

(DSC-MRI) is predictive of local tumor control following radiation therapy. Int J Radiat Oncol Biol Phys, 2001;51(2):478-82.

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55. Fuss M. Re: Analysis of dose distribution in multiple-target gamma knife radiosurgery. Letter to the editor. Int J Radiat Oncol Biol Phys. 2001;49(3):901.
56. Fuss M, Poljanc K, Miller DW Archambeau JO, Slater JM, Slater JD, Hug EB. Normal tissue complication probability (NTCP) calculations as a means to compare proton and photon plans and evaluation of clinical appropriateness of calculated values. Int J Cancer 2000;90(6):351-358.
57. Fuss M, Salter B, Herman TS. Computer-based techniques have changed radiation therapy. IMRS, FS-IMRT and other breakthrough developments position the field for even greater success. Advance 2000;10(12):50-51.
58. Fuss M, Poljanc K, Hug EB. Full Scale IQ (FSIQ) changes in children treated with whole and partial brain irradiation: A review and analysis. Strahlenther Onkol. 2000;176(12):573-81.
59. Fuss M, Debus J, Lohr F, Huber P, Rhein B, Engenhart-Cabillic R, Wannenmacher M. Conventionally fractionated stereotactic radiotherapy (FSRT) for acoustic neuromas. Int J Radiat Oncol Biol Phys. 2000;48(5):1381-7.
60. Fuss M, Wenz F, Scholdei R, Essig M, Debus J, Knopp MV, Wannenmacher M. Radiation induced regional cerebral blood volume (rCBV) changes in normal brain and low grade astrocytomas: quantification and time and dose dependent occurrence. Int J Radiat Oncol Biol Phys 2000;48(1):53-8.
61. Wenz F, Steinvorth S, Fuss M, Lohr F, Wildermuth S, Debus J, Wannenmacher M. Akute Strahlenfolgen am ZNS. Wehrmed Monatsschr 2000;44:101-105.

62. Bellmann C, Fuss M, Holz FG, Debus J, Rohrschneider K, Voelcker HE, Wannenmacher M. Stereotatic radiation therapy (SRT) for malignant choroidal tumors: preliminary short term results. Ophthalmology. 2000;107(2):358-65.
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65. Scholdei R, Wenz F, Essig M, Fuss M, Knopp MV. The simultaneous determination of the arterial input function for dynamic susceptibility-weighted magnetic resonance tomography of the A. carotis interna and the A. cerebri media. Rofo Fortschr Geb Rontgenstr Neuen Bildgeb Verfahr 1999;171:38-43.
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68. Essig M, Hawighorst H, Schoenberg SO, Engenhart-Cabillic R, Fuss M, Debus J, Zuna I, Knopp MV, van Kaick G. Fast fluid-attenuated inversion-recovery (FLAIR) MRI in the assessment of intraaxial brain tumors. J Magn Reson Imaging 1998;8:789-98.
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Publications accepted (in press):

Publications submitted for peer review:

Contribution to critical summaries of published research

Mike Martin. How Do You Track Lung Tumor Motion? A Critical Question with Competing Answers. JNCI 2009 101(20):1372-74.

Book chapters

1. Fuss M, Salter BJ. Case study in liver SBRT: Dose optimization via inverse treatment planning. In: Stereotactic Body Radiation Therapy. Ed. Kavanagh/Timmerman. Lippincott Williams & Wilkins 2005.
2. Herfarth K, Fuss M. SBRT for liver tumors. Ed. Solberg/Slotman. Stereotactic body radiation therapy textbook. Taylor and Francis Books 2006.
3. Salter BJ, Fuss M. Serial Tomotherapeutic Approaches to Stereotactic Body Radiation Therapy. Ed. Solberg/Slotman. Stereotactic body radiation therapy textbook. Taylor and Francis Books 2006.
4. Dawson L, Fuss M. Image-Guided Radiation Therapy and Stereotactic Body Radiation Therapy. Biliary Tract & Gallbladder Cancer: A Multidisciplinary Approach. Demos Medical Publishing 2008.
5. Boda-Heggemann J, Lohr F, Fuss M. Ultrasound-based Image-guided Radiation Therapy. Image-Guided Radiation Therapy: A Clinical Perspective (Mundt AJ, Roeske JC, editors). People's Medical Publishing House - USA 2011.

Presentations (invited talks, CME accredited lectures, grand rounds, session chair)

1. Martin Schneider Memorial Lecture, UTMB, Galveston, TX, March 21, 2012
2. Moderator: "Showdown at La Costa: Early stage liver" debate. SRS/SBRT meeting 2012, La Costa, CA, February 24, 2012

3. Martin Schneider Memorial Visiting Professor, UTMB Galveston, TX, September 20-23, 2011.
4. Faculty and lecturer: SBRT for primary liver tumors and interactive case discussion. VU Medical Center Symposium on Stereotactic Body Radiation Therapy (SBRT). Amsterdam, The Netherlands, January 29, 2011.
5. Program Director, panelist (sessions on SBRT lung, SBRT liver, and SBRT spine), and speaker (SBRT for Primary Liver Tumors – Target Volume Delineation and Image-Guidance Considerations). 5th Novalis Circle Meeting. Munich, Germany June 17-19, 2010.
6. Strategies of assessing and quantifying post-treatment metabolic tumor response. BiGART 2010, Aarhus, Denmark, May 28, 2010
7. Radiation Therapy for primary liver tumors - HCC. 2010 Portland Conference. Progress in the Multidisciplinary Management of Hepatobiliary and Pancreatic Cancer. Portland, OR, April 30, 2010.
8. Radiation Therapy for primary liver tumors – Cholangiocarcinoma. 2010 Portland Conference. Progress in the Multidisciplinary Management of Hepatobiliary and Pancreatic Cancer. Portland, OR, April 30, 2010.
9. Optimizing image-guidance for SBRT. AAPM NW chapter Spring Meeting 2010. Portland, OR, April 30, 2010.
10. SBRT for early stage NSCLC – an update. Roseburg Community Cancer Center Grand Rounds. April 20, 2010.
11. SBRT and motion management for treatment of primary liver tumors SBRT. New Technologies and Applications in SRS/SBRT. April 14, 2010. New York, NY
12. Advances in Stereotactic Body Radiation Therapy (SBRT) planning and delivery. AOCR 2010, Taipei, Taiwan, March 21, 2010.
13. Radiation Therapy for Pituitary Tumors Concepts - Techniques and Outcomes. OHSU Endocrinology Grand Rounds. February 1, 2010.
14. SBRT for early stage NSCLC. OHSU Cardiothoracic Surgery Grand Rounds. January 11, 2010.
15. SBRT using the BrainLAB Novalis Tx. BrainLAB users meeting at ASTRO. Chicago, IL, October 31, 2009.
16. SBRT – new curative treatment options for lung and liver cancer. Oregon Cancer Registrars Association (OCRA) Annual Meeting. Portland, OR, October 16, 2009.
17. Spinal SBRT. OHSU Neurosurgery Grand Rounds. June 15, 2009.
18. SBRT for primary liver tumors. OHSU Gastroenterology Grand Rounds. January 16, 2009.
19. Prostate Cancer Update 2008. Lewis River Rotary Club lecture. November 18, 2008.

20. PET in Radiation Oncology. 33rd Western Region Society of Nuclear Medicine Meeting. Portland, OR, October 16, 2008.
21. Radiation Oncology Grand Rounds. SBRT for primary liver tumors Rationale, technique, and preliminary clinical results. University of Maryland, Baltimore, MD, June 26, 2008.
22. SNM continuing education: Nuclear Medicine in Radiation Therapy Planning – Challenges and Opportunities. Goals and Principles of Image Guided Radiation Therapy. Society of Nuclear Medicine, 55th annual meeting, New Orleans, LA, June 16, 2008.
23. SNM categorical seminar: Molecular Imaging Guided Cancer Therapy: Towards Personalized Treatment – Moving away from 'One Size Fits All' Concept? Personalizing Radiation Therapy – Clinical opportunities and challenges. Society of Nuclear Medicine, 55th annual meeting, New Orleans, LA, June 14, 2008.
24. Session chair. Clinical studies: H&N and brain. Acta Oncologica Symposium, Image-guided and adaptive radiotherapy, Aarhus, Denmark June 7, 2008.
25. Multi-modality imaging in Radiation Oncology. Philips Oncology Symposium. Los Angeles, CA, May 15, 2008.
26. Marquam Hill Lecture Series. Image-Guided Radiation Therapy, Portland, OR, April 17, 2008.
27. Image-guided Radiation Therapy. Oregon Radiation Oncology Society, Portland, OR, November 10, 2007.
28. Panelist, The utility of FDG-PET in Head & Neck Cancer. Oregon Academy of Otolaryngology. Portland, OR, November 9, 2007.
29. Panelist, Rare Neoplasms. Hepatocellular carcinoma. ASTRO 2007, Los Angeles, CA October 28, 2007.
30. Discussant. SBRT for lung tumors. ASTRO 2007, Los Angeles, CA, October 31, 2007.
31. Pancreatic cancer: Is radiotherapy still part of the primary treatment? ICRO/OEGRO 8. Salzburg, Austria, May 2007.
32. Photons or Protons: Prostate cancer. ICRO/OEGRO 8. Salzburg, Austria, May 2007.
33. IMRT and IGRT for H&N Tumors. ENT grand rounds. Oregon Health & Science University, Portland, OR, March 19, 2007.
34. Radiation Therapy for CNS Tumors: GBM and brain metastases. Neurooncology grand rounds. Oregon Health & Science University, Portland, OR, February 26, 2007.
35. Image-guided Radiation Therapy: A look behind the curtain. Marquam Hill Steering Committee. Portland, OR, February 15, 2007.
36. Respiratory Gating Summit at ASTRO, November 6, 2006. Philadelphia, PA.
37. Stereotactic body radiation therapy for early stage lung cancer. Cardiothoracic surgery grand rounds, Oregon Health & Science University, October 16, 2006.

38. An introduction to intensity-modulated radiation therapy (IMRT). Medical Oncology Grand Rounds, Oregon Health & Science University, October 20, 2006
39. Tomotherapeutic Stereotactic Body Radiation Therapy. SBRT2006, Copenhagen, Denmark, June 16, 2006.
40. Stereotactic Body Radiation Therapy (SBRT) for early stage lung cancer. Updates in Lung Cancer Treatment. San Antonio, TX, April 21, 2006.
41. Pre-clinical and Clinical Studies of Radiation-induced CNS Injury. 12th annual Blood Brain Barrier Disruption Consortium Meeting. Sunriver, OR. March 23-25, 2006
42. Intensity-modulated radiation therapy (IMRT) Clinical implications and applications. Northwest AAMD/AAPM meeting. Skamania Lodge, WA. February 24-25, 2006.
43. Image-guided radiation therapy (IGRT) Clinical implications and applications. Northwest AAMD/AAPM meeting. Skamania Lodge, WA. February 24-25, 2006.
44. Radiation therapy for CNS tumors. Department of Rehabilitation Medicine Grand Rounds, UTHSCSA. February, 14, 2006.
45. Stereotactic radiation therapy for spinal and paraspinal tumors. Neurooncology Grand Rounds, Oregon Health & Science University (OHSU), Portland, OR. January 20, 2006.
46. Organ motion and its management. 7th Curso de Education Continua de la Sociedad de Fisica Medica de Nueva Leon. Monterrey, Mexico, December 13, 2005.
47. Stereotactic body radiation therapy. 7th Curso de Education Continua de la Sociedad de Fisica Medica de Nueva Leon. Monterrey, Mexico, December 13, 2005.
48. CNS – review of ASTRO presentations. 5th annual ASTRO review. San Antonio, TX. November 19, 2005.
49. New Technical Developments in external beam radiation oncology. 5th annual ASTRO review. San Antonio, TX. November 19, 2005.
50. Radiation therapy for pituitary adenoma. Endocrinology Grand Rounds. UTHSCSA, San Antonio, TX September 22, 2005.
51. Image-guided intensity-modulated radiation therapy for pancreatic cancer, gallbladder cancer and hepatocellular carcinoma. International Society for Gastrointestinal Oncology. Arlington, VA July 14, 2005.
52. SBRT localization of lung and liver tumors. Stereotactic Body Radiation Therapy: State of the science – Dallas 2005. Dallas, TX May 28, 2005.
53. Patient immobilization – implications for precision radiation therapy. TomoTherapy Users Meeting. Shreveport, LA April 16, 2005.
54. Stereotactic Body Radiation Therapy – the UTHSCSA experience. Tumor Board. UTHSCSA, San Antonio, TX March 31, 2005.
55. Protons, Tomotherapy, Cyberknife for EBRT of prostate cancer. Society of Urologic Oncology/NIH annual meeting. NIH, Bethesda, MD December 3, 2004.

56. Prostate target visualization: EPID is better than ultrasound techniques for target check and visualization for IMRT. Presentation and debate: pro ultrasound. 8th Annual International Conference and Workshop: New and future developments in radiotherapy. San Diego, CA, December 14, 2004.
57. IMRT for prostate cancer: Clinical aspects and treatment planning strategies. 8th Annual International Conference and Workshop: New and future developments in radiotherapy. San Diego, CA, December 14, 2004.
58. Debate: HDR is better than LDR seed and IMRT for treatment of early prostate cancer. Pro IMRT. 8th Annual International Conference and Workshop: New and future developments in radiotherapy. San Diego, CA, December 14, 2004.
59. CNS - Highlights of the 46th ASTRO meeting. 4th ASTRO review. San Antonio, TX, November 12, 2004.
60. Intensity-modulated radiosurgery. Lunch Symposium. ESTRO 2004. Amsterdam, Netherlands October 27, 2004.
61. Imaging for target volume delineation: Chair: M. Fuss/P. Lukas. ESTRO teaching course: Imaging for Radiotherapy: Established and Novel Technologies. Amsterdam, Netherlands October 24, 2004.
62. The use of ultrasound, CT and MRI for planning of prostate treatment. ESTRO teaching course: Imaging for Radiotherapy: Established and Novel Technologies. Amsterdam, Netherlands October 24, 2004.
63. The use of ultrasound for treatment verification. ESTRO teaching course: Imaging for Radiotherapy: Established and Novel Technologies. Amsterdam, Netherlands October 24, 2004.
64. Stereotactic Body Radiation Therapy for liver lesions as a bridge to transplant. Transplant Surgery Grand Rounds. UTHSCSA September 24, 2004.
65. RT-Treatment Planning for Lung Cancer. International Masters Program in Medical Physics. Workshop New Approaches in Radiotherapy of Lung Tumors. Mannheim, Germany September 18, 2004.
66. Stereotactic Body Radiation Therapy. Surgery Grand Rounds. UTHSCSA September 13, 2004.
67. Ultrasound-guided Target Volume Positioning for Prostate: Theoretical Background. Symposium Ultrasound-guided Target Volume Positioning. Innsbruck, Austria September 4, 2004.
68. Organ motion and its management. ABRO/BVRO Residential Seminar 2004. Oudenburg, Belgium. May 14-15, 2004.
69. Daily setup for prostate cancer with echography. ABRO/BVRO Residential Seminar 2004. Oudenburg, Belgium. May 14-15, 2004.

70. Stereotactic Body Radiation Therapy (SBRT). MDACC Orlando. Orlando, FL. May 7th, 2004.
71. IMRT and image-guided targeting. Hepatocellular carcinoma: Screening, diagnosis and management. NIDDK/NIH/NIBIB. Bethesda, MD. April 1-3, 2004.
72. Intensity-modulated hypofractionated extracranial radioablation: Preliminary clinical experience. Radiation Oncology Annual Educational Meeting of the Indiana Radiation Oncology Academy. Indianapolis, IN November, 8, 2003.
73. CNS and SBRT. Highlights of ASTRO. 3rd ASTRO review. San Antonio, TX, November 12, 2004.
74. Extracranial intensity-modulated radioablation - preliminary clinical experience. Extracranial Stereotactic Radioablation: Future Directions. Halifax, NS, Canada June 8-10, 2003.
75. Stereotactic targeting for upper abdominal and pancreatic cancer. Texas Radiological Society 2003 Annual Meeting. April 4th 2003, The Woodlands, TX.
76. Extracranial radioablation for Liver Cancer – UTHSCSA experience. First International Symposium on Extracranial Radiosurgery. March 28-29, 2003. Dearborn, Michigan.
77. Extracranial radioablation for liver metastases. Didactic conference. UTHSCSA, Dept. of Medicine, Division of Gastroenterology and Nutrition. February 6, 2003.
78. Fuss M. Cerebral blood volume changes and cognitive changes following cranial radiation. The effects of radiotherapy on brain and behavior trough the lifespan. Rio Grande, Puerto Rico, December 2002.
79. Radiosurgery, concept and clinical indications. Drug development lecture series. Institute for Drug Development, CTRC/SACI, San Antonio, TX, November, 2002.
80. CNS highlights at ASTRO. 2nd annual ASTRO review. San Antonio, TX, November 1, 2002.
81. Image-guided targeting: current controversies. 2nd annual ASTRO review. San Antonio, TX, November 1, 2002.
82. IMRT for Prostate cancer. Clinical aspects. 6th Annual International Conference and Workshop: New and future developments in radiotherapy. Las Vegas, NV, August 2002.
83. IMRT for Breast cancer. Clinical aspects. 6th Annual International Conference and Workshop: New and future developments in radiotherapy. Las Vegas, NV, August 2002.
84. Extracranial radioablation using a tomotherapeutic IMRT technique. Extracranial Stereotactic Radioablation: Future Directions. Niagara Falls, Ontario, May 10-12, 2002.
85. Stereotactic ultrasound target localization – potential impact on liver target radioablation. Extracranial Stereotactic Radioablation: Future Directions. Niagara Falls, Ontario May 10-12, 2002.

86. Fuss M. BAT. Ultrasound Positioning for Upper Abdominal Target Volumes Undergoing Radiotherapy. SWOG Spring Meeting 2002. Dallas, TX April 19, 2002,
87. Radiation induced intellectual deficits in children. Texas Radiological Society 2002 Annual Meeting. Austin, TX April 12, 2002,
88. Radiosurgery, concept and clinical indications. Drug development lecture series. Institute for Drug Development, CTRC/SACI, San Antonio, TX. January 30, 2002.
89. CNS/Functional Imaging/PET – a summary of ASTRO presenations and discussions. 1st annual ASTRO review, San Antonio, TX November 16-17, 2001.
90. Technical innovations in treatment planning and delivery – an ASTRO summary. 1st annual ASTRO review, San Antonio, TX November 16-17, 2001.
91. Brachytherapy is preferable over IMRT for favorable risk prostate cancer - debate. Fuss M, Orton C, Beyer D, Curren B, Alecu R. Fifth Annual International Conference and Workshop: New and future developments in radiotherapy. Rancho Viecho, TX, October 5-7, 2001.
92. Fuss M. IMRT [for prostate cancer] – Clinical aspects. Fifth Annual International Conference and Workshop: New and future developments in radiotherapy. Rancho Viecho, TX, October 5-7, 2001.

Grants:

Forschungsfoerderungs Kommission der Universitaet Heidelberg. Development of novel external beam stereotactic radiation techniques for uveal melanoma. DM 187,000 for two years (July 1997-June 1999). Closed

Forschungsfoerderungs Kommission der Universitaet Heidelberg. Assessment of cognitive functions after prophylactic and therapeutic whole brain irradiation using neuropsychological testing. DM 234,000 for two years (July 2000-June 2002). Closed

CCRC 02-173, Start-up support for the development of a non-invasive PET imaging assessment of radiation-induced brain tissue damage in rats. Children's Cancer Research Center, San Antonio, TX, $160,000 (April 2002-March 2004). Closed

RSNA (Radiological Society of North America) Medical Student Departmental Grant #MSD0205, Executive Control Function as a Measure of Cognitive Function in Patients Receiving Cranial Irradiation. $ 15,000 over five years (October 2002–September 2006). Closed

RSNA Leonard B. Holman Resident Research Grant. ^{11}C acetate PET staging in newly diagnosed high-risk prostate cancer patients. Holman Resident and PI: Sean X. Cavanaugh, MD, PhDc. Scientific mentor: Martin Fuss, MD. $30,000 (July 2003-June 2005). Closed

CCC (Cancer Center Council San Antonio at CTRC, San Antonio, TX), Prospective clinical study to assess tumor response of childhood brain tumors following cranial irradiation using positron emission tomography (PET). $20,000 for one year (June 2003-May 2004). Closed

GCRC Bartter Scholars Program. ^{11}C acetate PET staging in newly diagnosed high-risk prostate cancer patients. Medical student: Clifton D. Fuller. Scientific mentor: Martin Fuss, MD. $2,000 (August - September 2003). Closed

SALSI (San Antonio Life Sciences Institute), Radiation-induced changes in hippocampal functioning. $167,000 for one year (June 2004-June 2006). PI's Fuss M (UTHSCSA) and Martinez J (UTSA). Closed

CCC (Cancer Center Counsil San Antonio at CTRC, San Antonio, TX), 11C-acetate PET for prostate cancer. $18,000 for one year (June 2004-May 2005). Closed

Nomos Corp. (Cranberry Township, PA). Unrestricted educational grant. $15,000 for one year (May 2004-April 2005). Closed

Equipment grant from Nomos, Cranberry Township, PA: Corvus inverse treatment planning stations for education and research. PI Fuss M. (2005/2006). Closed

San Antonio Neuroscience Alliance (SANA). Radiation-induced changes in hippocampal functioning. Awardee Pragathi Achanta. UTSA mentor J. Martinez, UTHSCSA mentor M. Fuss. Stipend support (June 2006 to June 2007). Closed

1R01LM009362-01. 4D Visible Human Modeling for Radiation Dosimetry, PI Xu George, Dept. of Mechanical, Aerospace & Nuclear Engineering, Rensselaer, Troy, NY, Fuss M – effort 10%. 4/2007 – 3/2011. Active

Equipment grant from GE Medical System, Milwaukee, WI: 4-dimensional CT imaging for radiation therapy planning and daily image-guidance. PI Fuss M. (2007). Closed

Equipment grant from Imaging3, Burbank, CA: Clinical evaluation of a mobile cone-beam CT unit for radiation therapy image-guidance. PI Fuss M. (2007). Active

Varian Research Grant. Assessment of Stereotactic Body Radiation Therapy (SBRT) induced Lung Ventilation Changes. PI Fuss M (2009-2011). Active

Varian Research Grant. Quality Assurance for Error Analysis of RapidArc Treatment Delivery abnd Investigation of their Significne. PI Wolfram Laub, PhD; Fuss M Co-investigator (2010-2012). Active

Washington State Health Care Authority
Health Technology Assessment

Intensity Modulated Radiation Therapy
Scheduled Presentations

	Name / Representing	Notes
1	**Huong Pham, MD** Section Head, Radiation Oncology Virginia Mason Medical Center	Letter
2	**John Rieke, MD** American Society of Radiation Oncology Medical Director MultiCare Regional Cancer Center	No presentation materials
3 • **George Laramore, MD** • **Kenneth Russell, MD** • **Jason Rockhill, MD** **Ralph Ermoian, MD** **Edward Kim, MD** University of Washington Medical Center Seattle Cancer Care Alliance		No presentation materials Slide presentation Slide presentation
4	**Joseph Hartman, MD** RadiantCare Radiation Oncology LLC	No presentation materials

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.		
2.	Equity interests such as stocks, stock options or other ownership interests.		X
3.	Status or position as an officer, board member, trustee, owner.		X
4.	Loan or intellectual property rights.		X
5.	Research funding.		X
6.	Any other relationship, including travel arrangements.	X	

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

I'm a radiation oncologist at Virginia Mason and use the service under review, IMRT.

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		X

If yes to #7, provide name and funding Sources: _____

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have pr[redacted], complete, and correct as of this date.

X [redacted] 8/31/12 Huong Pham

Signature *Date* *Print Name*

For questions contact: Christine Masters
Health Technology Assessment
PO Box 42712
Olympia, WA 98504-2712
360-725-5126

Dear Members of the Health Technology Clinical Committee:

I would like to thank the Washington State Healthcare Authority for performing a technology assessment on intensity modulated radiation therapy (IMRT). This assessment provides an excellent review of the studies published on IMRT. After reviewing this report, I have come to several conclusions regarding IMRT which I would like to share with the committee. I thank you for the opportunity to submit my comments in writing since I will be out of town on the day of the public meeting on September 21, 2012.

1. IMRT is clearly a superior technology when compared to 3D-conformal radiation therapy (3-DCRT) or standard external beam radiation therapy (EBRT) at delivering the appropriate dose to a target area while minimizing dose to surrounding normal tissues. Almost all the studies listed demonstrate that IMRT has less chance of causing acute and/or late toxicities than 3DCRT or EBRT. With regards to efficacy, IMRT is either as effective or in some cases better than 3DCRT/EBRT.

2. When the studies are grouped according to disease sites, there is substantial data to conclude that IMRT is better than 3DCRT for reducing late toxicities in prostate cancer (GI/GU toxicity) and head/neck cancers (xerostomia). In prostate and head and neck cancers, the total doses are relatively high (70-80 Gy), the cancers are more common, and therefore the benefit from IMRT can be more easily demonstrated. I think we are also starting to see a benefit for IMRT in cervical cancer which also requires a relatively high dose (60-70 Gy). Breast cancer is a very common cancer and therefore, there is more data in this disease site to suggest a lower risk of skin toxicity with IMRT.

   However, in many of the other sites, there is a lack of data to make any conclusions regarding efficacy or toxicity. However, it should be noted that in many of the other sites, the limited data does suggest a potential benefit to IMRT, especially with regards to reducing toxicity. For these other sites, the treating radiation oncologist is really the only one who can determine for that specific patient, under the specific anatomical considerations whether that patient would benefit from IMRT over 3dCRT/IMRT. I think this is especially important when treating a target surrounded by sensitive structures which have well defined dose tolerances such as small bowel, lung, or optic nerves/or chiasm. Damage to these structures can have devastating and irreversible consequences such as bowel obstruction, perforation, or malapbsorption as in the case of small bowel. Radiation lung damage causes radiation pneumonitis or lung fibrosis resulting in death or chronic oxygen dependency. Damage to the optic apparatus can cause blindness. These toxicities are not only much more expensive and difficult to treat (if treatable at all) but can devastate a patient's quality of life. In contrast, although IMRT for breast cancer has been shown in some studies to reduce skin toxicities which is certainly important but these skin toxicities certainly do not have the same impact to a patient's life as the three I mentioned above.

3. IMRT requires more staff time and effort to plan, perform the QA, and deliver the treatment and is more costly than 3DCRT/EBRT. With rising costs of healthcare, I understand the importance of limiting costs but the costs of managing significant late toxicities are very high (i.e. surgery, hyperbaric oxygen therapy, argon plasma coagulation, medications). An example of how IMRT actually reduced the cost of care is in the treatment of head/neck cancers. In the past, a very expensive drug, amifostine, had to be given intravenously daily with radiation therapy to help reduce the risk of permanent xerostomia in head/neck cancer patients. Many patients experienced significant nausea with amifostine so antiemetics had to be used in conjunction with the drug. Now, with the standard use of IMRT, amifostine use is almost inexistent in treatment of head/neck cancer patients.

I know it will be very difficult to decide what to do regarding insurance coverage policies for IMRT. I know that private insurance companies are struggling with this also. I am a firm believer in practicing evidence based medicine and I urge you to consider my comments. IMRT is a very important technology that has great potential in radiation oncology to give better results than 3DCRT/EBRT for many disease sites. For the reasons stated above, I believe it is one of the greatest advances in radiation oncology during my lifetime, and therefore, while data supporting the use of IMRT may not be conclusive for some applications; cumulative experience will help to define its role. For this reason, I believe that providers should be given some discretion in its use where evidence may not be conclusive as the experience will ultimately lead to better and more cost efficient care. Limiting its use would be impeding progress. I think there are many more studies and clinical trials with IMRT to conduct and I hope the state will help support these studies (by covering its use on study). If cost is an issue, I think limiting the reimbursement amounts as opposed to denying coverage would be a better solution so that it allows the treating physician to decide what is best for the patient. Over time, as radiation centers become more familiar with the technology, they will become more efficient and be able to reduce the expenses associated with it.

Sincerely,

Huong Pham, MD
Section Head, Radiation Oncology
Virginia Mason Medical Center

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.		X
2.	Equity interests such as stocks, stock options or other ownership interests.		X
3.	Status or position as an officer, board member, trustee, owner.		X
4.	Loan or intellectual property rights.		X
5.	Research funding.		X
6.	Any other relationship, including travel arrangements.		X

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).	X	

If yes to #7, provide name and funding Sources:

I AM THE CHAIR OF THE DEPARTMENT OF RADIATION ONCOLOGY AT THE UNIVERSITY OF WASHINGTON AND MEDICAL DIRECTOR OF THE SEATTLE CANCER CARE ALLIANCE PROTON THERAPY CENTER

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X [redacted] 8/24/2012 GEORGE E LARAMORE PHD, MD

Signature *Date* *Print Name*

For questions contact: Christine Masters
Health Technology Assessment
PO Box 42712
Olympia, WA 98504-2712
360-725-5126

Washington State Health Care Authority
Health Technology Assessment

Health Technology Assessment – HTA

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.	X	
2.	Equity interests such as stocks, stock options or other ownership interests.		X
3.	Status or position as an officer, board member, trustee, owner.	X	
4.	Loan or intellectual property rights.		X
5.	Research funding.		X
6.	Any other relationship, including travel arrangements.	X	

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

I SERVE ONE DAY A WEEK AS Medical Director of CALYPSO MEDICAL TECHNOLOGY DIVISION OF VARIAN CORP - WITH HIS KNOWLEDGE & Approval. CALYPSO TECHNOLOGY IS NOT THE TOPIC/Item of the DAY'S Agenda

	Potential Conflict Type	Yes	No
7.	Representation: If representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).	X (KR)	X (KR)

If yes to #7, provide name and funding Sources: REPRESENTING UNIVERSITY OF WASHINGTON MEDICAL CENTER AND SEATTLE CANCER CARE ALLIANCE, FOR WHOM I HAVE BEEN AN EMPLOYEE / FACULTY MEMBER SINCE 1985

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X [redacted] 8/24/12 Date — Ken Russell Print Name

For questions contact: Christine Masters
Health Technology Assessment
PO Box 42712
Olympia, WA 98504-2712
360-725-5126

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.		X
2.	Equity interests such as stocks, stock options or other ownership interests.		X
3.	Status or position as an officer, board member, trustee, owner.		X
4.	Loan or intellectual property rights.		X
5.	Research funding.		X
6.	Any other relationship, including travel arrangements.		X

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		X

If yes to #7, provide name and funding Sources: I am representing my employer Univ of WA.

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X [redacted] 8/24/12 Ralph Ermoian

Signature *Date* *Print Name*

For questions contact: Christine Masters
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PO Box 42712
Olympia, WA 98504-2712
360-725-5126

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.		X
2.	Equity interests such as stocks, stock options or other ownership interests.		X
3.	Status or position as an officer, board member, trustee, owner.		X
4.	Loan or intellectual property rights.		X
5.	Research funding.		X
6.	Any other relationship, including travel arrangements.		X

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

_____

_____

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	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		

If yes to #7, provide name and funding Sources: _____

_____

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If you believe that you do not have a conflict but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X [redacted] 8/24/12

Signature *Date* *Print Name*

For questions contact: Christine Masters
Health Technology Assessment
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Olympia, WA 98504-2712
360-725-5126

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.		✓
2.	Equity interests such as stocks, stock options or other ownership interests.		✓
3.	Status or position as an officer, board member, trustee, owner.		✓
4.	Loan or intellectual property rights.		✓
5.	Research funding.		✓
6.	Any other relationship, including travel arrangements.		✓

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		✓

If yes to #7, provide name and funding Sources: University of Washington – my employer

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X [redacted] 8/24/12 EDWARD KIM

Signature *Date* *Print Name*

For questions contact: Christine Masters
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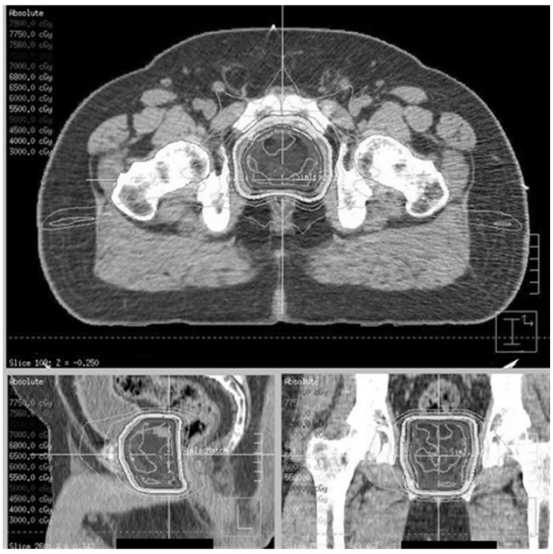
PO Box 42712
Olympia, WA 98504-2712
360-725-5126

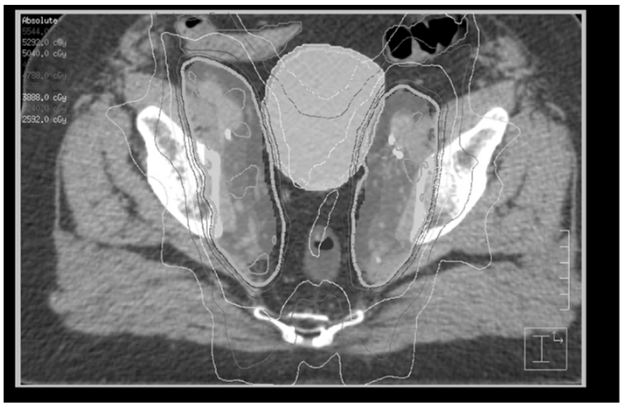
IMRT and Prostate Cancer – A 27 Year Perspective on Treating Men with Prostate Cancer

Kenneth Russell MD
Professor, Vice Chairman
Radiation Oncology
University of Washington
Seattle Cancer Care Alliance

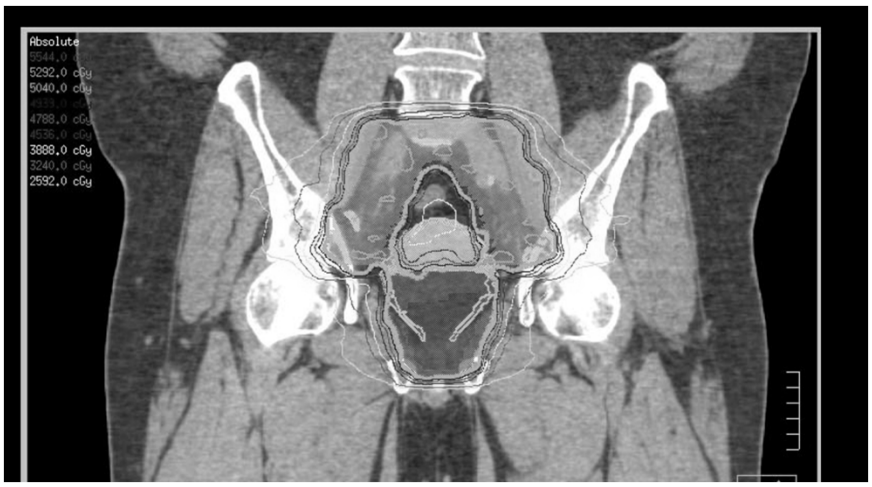
IMRT - "Shrink Wrapping" the Prostate



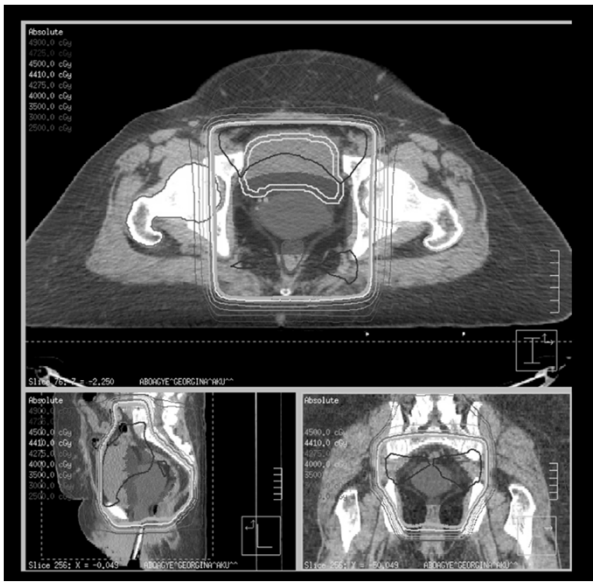
IMRT "Shrink Wrapping" The Pelvic Lymph Glands



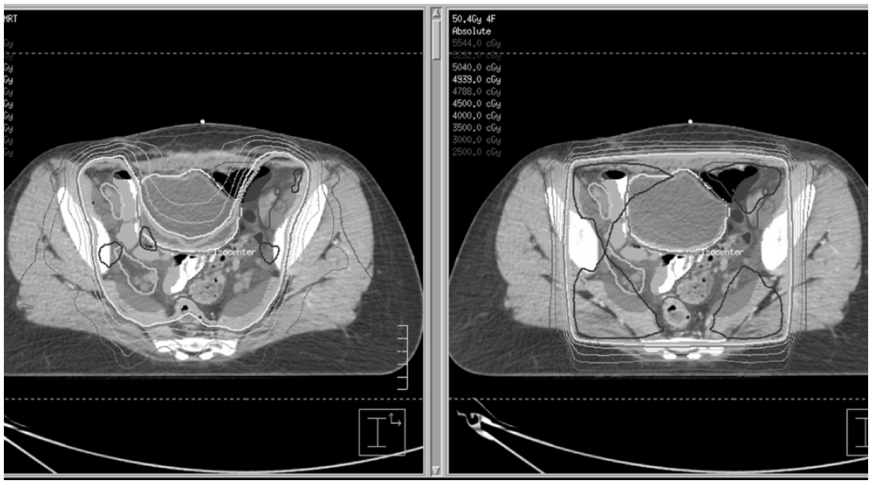
IMRT : "Shrink-Wrapping" the Pelvic Lymph Glands



No IMRT = Whole Pelvic Contents Treated



IMRT vs non IMRT– Pelvic LN



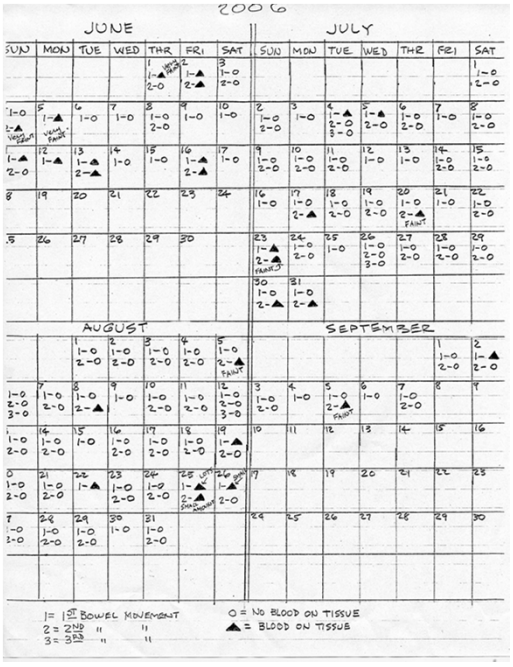
Why IMRT and Prostate Cancer?

- Increase cures
- Diminish side effects
  - Prostate treatment, whether surgery or radiation can cause sexual dysfunction, incontinence, damage to bowel and bladder function
- <u>Side effects have a significant negative impact on patient QOL ….even if they sometimes do not "cost" the healthcare system</u>.

"Grade 2" Rectal Side Effects - per NCI criteria

"Grade 100" - per Patient criteria (7-10 bloody BM/month)

Medical Cost= 0 $
Patient "Cost"= ??



Progress in Prostate Radiation – Last 20 yrs

- Higher dose = more effective
- Higher dose = more side effects
- Higher dose without more side effects =IMRT (better avoidance of normal organs)
- Better aiming (IGRT = Image guided radiation therapy) – even better than IMRT
- (Few large doses may be better than more small doses - Hypofractionation/SBRT)

Dose Matters

PSA Era Randomized Dose Escalation Trials

Author(yr)	n	Dose(Gy)	FFBF	p-value
Kuban(2007)*	151	78	73%(10yr)	0.004
	150	70	50%(10yr)	
Zietman(2010)	195	79.2	83%(10 yr)	<0.001
	197	70.2	68%(10 yr)	
Mamgani(2008)*	333	78	56%(7 yr)	0.03
	331	68	45%(7 yr)	
Dearnaley(2007)❖	422	74	71%(5 yr)	0.0007
	421	64	60%(5 yr)	

*Nadir+2 FFBF; ❖ Neoadjuvant AD 3-6 mo.

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Higher doses (no IMRT used) = Higher GI (Rectal) Complications MDAH Randomized Dose Escal Trial

Table 5. Crude incidence of complications by grade

	Complication grade			
Group	0	1	2	3
GI complications				
70-Gy arm	77	55	15	2
78-Gy arm	71	42	28	10
GU complications				
70-Gy arm	100	35	7	7
78-Gy arm	114	21	11	5

Int. J. Radiation Oncology Biol. Phys., Vol. 70, No. 1, pp. 67–74, 2008

Technique Matters – GI Complications IMRT vs " 3D Conformal". High dose with IMRT fewer complications than lower doses with 3D.

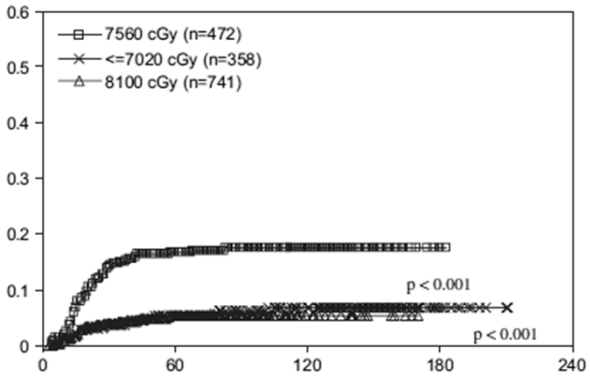


Fig. 1. The incidence of late Grade ≥2 rectal toxicities by prescription dose.

Zelefsky Int J Radiat Oncol Biol Physics 70: 1124-1129, 2008

Acute Side Effects Often Mean Long-Term Side-Effects

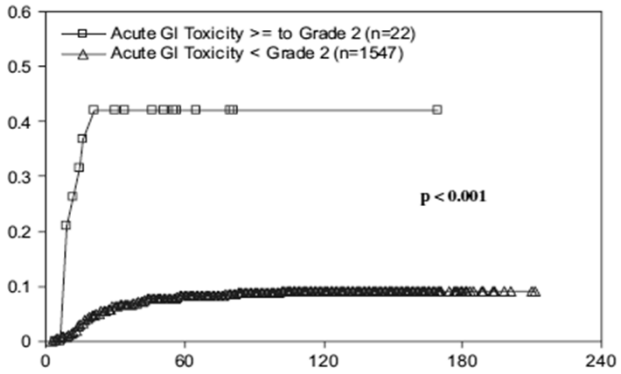
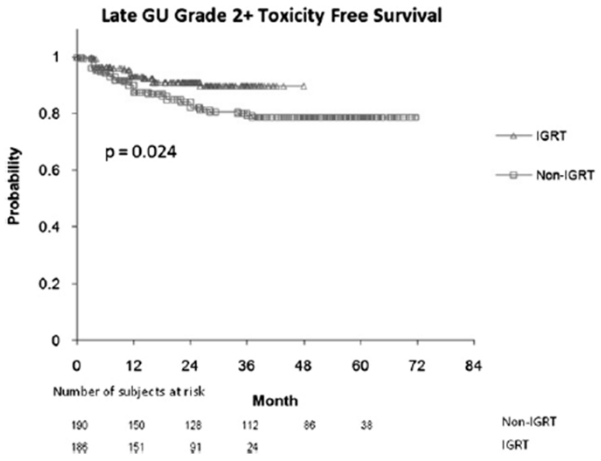


Fig. 2. The incidence of late rectal toxicities (Grade ≥2) correlated by the presence of an acute symptom (Grade ≥2). GI = gastrointestinal.

Zelefsky Int J Radiat Oncol Biol Physics 70: 1124-1129, 2008

Better Aiming (IGRT) yet another step in reducing side-effects

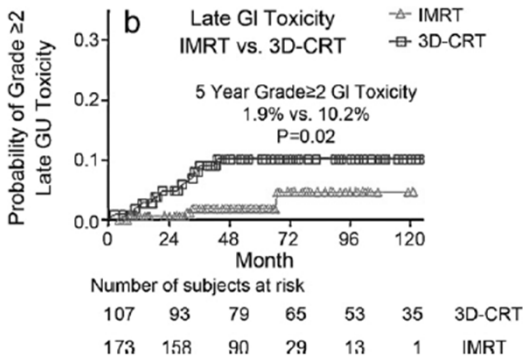


Zelefsky et al 2012 Int J Radiat Oncol Biol Phys

Improved Toxicity Profile Following High-Dose Postprostatectomy Salvage Radiation Therapy With Intensity-Modulated Radiation Therapy

Anuj Goenka[a], Juan Martin Magsanoc[a], Xin Pei[a], Michael Schechter[a], Marisa Kollmeier[a], Brett Cox[a], Peter T. Scardino[b], James A. Eastham[b], Michael J. Zelefsky[a,]*

[a] Department of Radiation Oncology, Memorial Sloan-Kettering Cancer Center, New York, NY, USA; [b] Urology Service, Department of Surgery, Memorial Sloan-Kettering Cancer Center, New York, NY, USA



Reflections

- Prostate cancer patients live a long time – Differences in survival outcomes take a long time (> 10 years).
- Late side effects accumulate. It is best not to cause them in the first place.
- Evidence based outcomes research wants "definitive" randomized trial data.
- Some trials are not do-able.

Ultimate Question

- Given the documented differences in side-effects between IMRT and non-IMRT technologies
- If you had prostate cancer best treated with radiation - would you sign up for an IMRT vs non-IMRT randomized trial?
- If the answer is, “no way”, then please continue to support IMRT for primary and salvage radiation for prostate cancer.

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.	✓	
2.	Equity interests such as stocks, stock options or other ownership interests.	✓	
3.	Status or position as an officer, board member, trustee, owner.	✓	
4.	Loan or intellectual property rights.		✓
5.	Research funding.		✓
6.	Any other relationship, including travel arrangements.		✓

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

I AM AN EQUITY OWNER/PRACTICING PHYSICIAN (RADIATION ONCOLOGIST) WHO USES LINEAR ACCELATOR/IMRT TECHNOLOGY TO TREAT PATIENTS WITH CANCER. I AM PAID FOR MY SERVICE TO PATIENTS USING THIS TECHNOLOGY

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		✓

If yes to #7, provide name and funding Sources: _____

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X _____ 8/23/12 JOSEPH R. HARTMAN

Signature *Date* *Print Name*

For questions contact: Christine Masters
Health Technology Assessment
PO Box 42712
Olympia, WA 98504-2712
360-725-5126

Washington State Health Care Authority

Intensity Modulated Radiation Therapy (IMRT)

State Agency Utilization & Outcomes

Jeff Thompson, Chief Medical Director
Health Care Authority
September 21, 2012

Intensity Modulated Radiation Therapy (IMRT)

Background

- Does the evidence support the widespread use of IMRT?
  - Increased use from 29% in 2002 to 82% in 2005 for prostate cancer treatment and 1% to 11% for breast cancer treatment
- Does IMRT improve the targeting of radiation to the tumor to minimize damage to normal tissue, and increase the dose of radiation delivered to the tumor?
- Does the evidence support modulated radiation therapy (IMRT) in effectiveness, efficacy, safety and costs?

Intensity Modulated Radiation Therapy (IMRT)

Agency Medical Director Perspective

Primary Criteria Ranking

- **Safety = High** Due to higher doses of RT
- **Efficacy = Medium** Questions of efficacy over EBRT
- **Cost = High**

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Washington State Health Care Authority

Intensity Modulated Radiation Therapy (IMRT)

Current State Policy

Medicaid
- LCD, Hayes, NCCN

PEB
- **Anal, prostate, head & neck** = When medically necessary
- **Breast, lung, abdomen, pelvis** = When prior history of RT, critical structure in field, targeted organ with impaired function or limited capacity

Labor and Industries
- Prostate policy for firefighters diagnosed at < 50 years of age

Department of Corrections
- NCCN

Washington State Health Care Authority

Intensity Modulated Radiation Therapy (IMRT)

Medicare Policies

No National Coverage Decision

Three CMS Local Coverage Decisions

- Similar to commercial policies
- Cancers with history of prior radiation, consideration for adjacent critical structures

Washington State Health Care Authority

Intensity Modulated Radiation Therapy (IMRT)

Agency Key Questions

Safety = High Concern

- What are the potential harms of IMRT compared to EBRT? What is the incidence of these harms?
- What is the appropriate duration and frequency of treatment?
- What are subpopulation considerations?
- For some cancers IMRT may be safer
  - Stomatitis for head and neck cancers
  - Cosmesis for breast cancers

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Washington State Health Care Authority

Intensity Modulated Radiation Therapy (IMRT)

Agency Key Questions

Efficacy = Medium Concern

- What is the evidence of efficacy and effectiveness for IMRT compared to EBRT for patients with cancer by site and type of cancer?
- What are subpopulation considerations?

Washington State Health Care Authority

Intensity Modulated Radiation Therapy (IMRT)

Agency Key Questions

Cost = High Concern

- What is the evidence of cost and cost-effectiveness of IMRT compared to EBRT?

Washington State Health Care Authority

IMRT
Agency Utilization
Example of Client IMRT Claims (ICD 9 141.9)

Date of Service	CPT	Description	Billed Amount
2/2	77014	CT scan guidance for placement of radiation therapy fields	$1,329
	77290	Therapeutic radiology simulation-aided field setting; complex	$2,246
2/8	77301	IMRT plan, including dose-volume histograms	$4,585
	77338	Continuing medical physics consultation	$2,302
2/16	77280	Therapeutic radiology simulation-aided field setting; simple	$1,018
	77300	Basic radiation dosimetry calculation, central axis depth dose calculation	$808
	77301	IMRT plan	$8,889
	77334	Treatment devices, design and construction; complex	$1,451
2/23 - 4/15	77418	IMRT delivery (25)	$89,775
2/23 - 4/15	77421	Stereoscopic X Ray guidance (25)	$17,275
3/8	77336	Continuing medical physics consultation	$691

Intensity Modulated Radiation Therapy (IMRT)
Agency Utilization

Agency	2008	2009	2010	2011	4-Year Total	% Change
PEB						
Agency Population	204,804	210,501	213,487	212,596		1.3%
Patients	174	224	219	295	800	*19.0%
Amount Paid	$3.56M	$4.52M	$3.90M	$5.48M	$17.47M	*16.6%
Average Paid / Patient	$20,810	$22,079	$17,528	$19,117	$23,199	-2.9%
Procedures (Patient Average)	4,407 (25.3)	5,401 (24.1)	5,218 (23.8)	7,471 (25.3)	22,497 (28.1)	*19.4%
Average Paid / Treatment	$808	$838	$748	$734	$777	3.0%
Medicaid						
Agency Population	392,808	416,871	424,230	435,187		3.5%
Patients	232	288	452	537	1357	*29.0%
Amount Paid	$3.56M	$4.05M	$4.50M	$6.03M	$18.15M	*15.6%
Average Paid / Patient	$15,364	$14,058	$9,987	$11,223	$13,378	*-8.4%
Procedures (Patient Average)	5,039 (21.7)	5,428 (18.8)	7,472 (16.5)	10,771 (20.1)	28,710 (21.2)	*25.8%
Average Paid / Treatment	$707.37	$745.91	$604.13	$559.54	$632.33	-7.0%
***Adjusted for population growth**						

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Intensity Modulated Radiation Therapy (IMRT)

Agency Utilization

Average Charges Per Course of Treatment				
	PEB Primary (w/o Medicare)	Medicaid	L&I	PEB (w/ Medicare)
Breakdown 1				
Professional Services	$23,484	$5,011	N/A	$13,126
Facility	$18,275	$9,880	N/A	$50,351
Breakdown 2				
Planning Charges	$11,275	$3,248	N/A	$21,571
Navigation/Imaging	$2,905	$649	N/A	$5,204
Delivery and Other	$27,579	$10,993	N/A	$36,703
Average Allowed Per Treatment Course	**$41,759**	**$14,890**	N/A	**$63,478**

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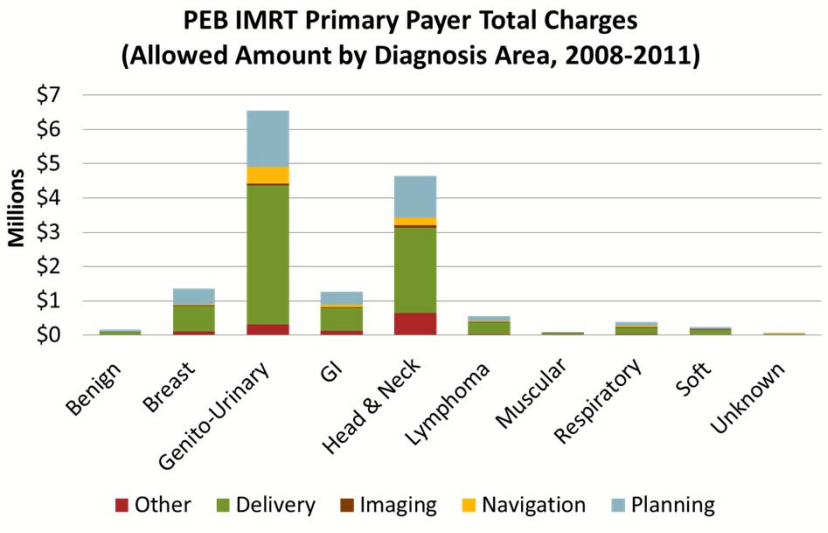
IMRT

Agency Utilization



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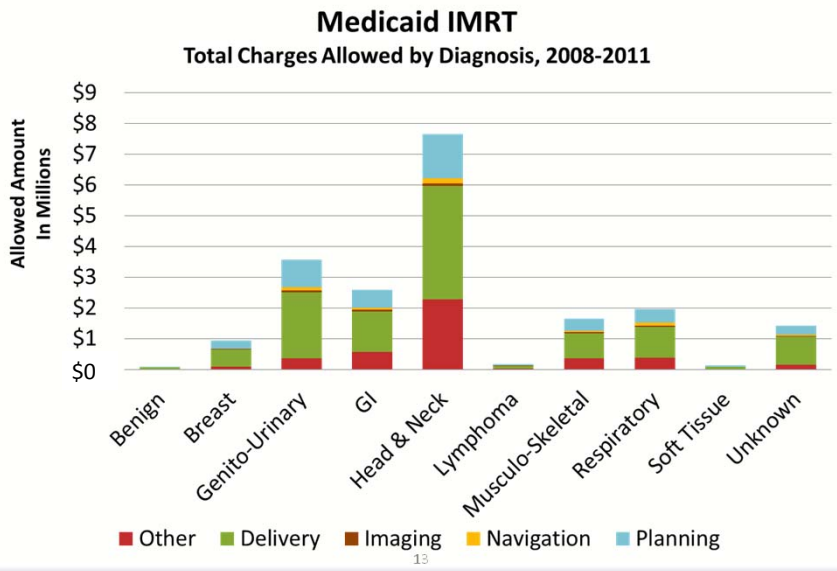
Intensity Modulated Radiation Therapy (IMRT)

Agency Utilization



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Intensity Modulated Radiation Therapy (IMRT)

Risks & Benefits

- **Benefits**
  - Low levels of evidence in efficacy
    - Small Ns
    - Historical controls may inject bias
    - No controls (case series)
- **Risks**
  - Low levels of evidence in safety
    - Small Ns
    - Historical controls or no controls (case series)
    - Did not control for chemotherapies
    - RCT with blinding seems to reduce reported harms

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Washington State Health Care Authority

Intensity Modulated Radiation Therapy (IMRT)

Agency Summary

- **Overall the evidence supporting IMRT vs. EBRT is low:**
  - Studies are largely case series
  - Controls are lacking or historical
  - RCTs (relatively few) refute lower levels of evidence
  - Grade 1-3 adverse event reporting is mixed
  - Cost analyses is based on hypothetical models

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Washington State Health Care Authority

Intensity Modulated Radiation Therapy (IMRT)

Agency Recommendations

Cover with conditions:

- Head and Neck Cancers
- Prostate Cancer
- All other cancers
  - History of previous radiation therapy to same or immediately adjacent area
  - Spare adjacent critical structures
  - Undergoing treatment in context of clinical trial

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Washington State Health Care Authority

Questions?

More Information:
http://www.hta.hca.wa.gov/intensity_radiation.html

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Code	Non-specific codes used in IMRT	Process
77014	Computed tomography guidance for placement of radiation therapy fields	Navigation
77261/2/3	Radiation Therapy Planning: Simple, intermediate, complex	Planning
77280/85 77290/95	Set radiation therapy field, simple, intermediate, complex (0) or 3-dimensional (5)	Planning
77300	Radiation therapy dose plan	Planning
77321	Special telex port plan	Planning
77332/3/4	Radiation treatment aids (simple, intermediate, complex)	Planning
77336	Continuing medical physics consultation	Planning
77370	Special medical radiation physics consultation	Planning
77417	Radiology Port Films (not seen w/ SRS/SBRT)	Planning
77421	Stereoscopic X-Ray guidance (not for use w/ SRS/SBRT)	Navigation
77427/31/99	Radiation treatment management, 5 treatments (not seen w/ SRS/SBRT)	Planning
77470	Special radiation treatment management	Planning

Washington State Health Care Authority

Code	Radiology codes used in IMRT	Process
70010 - 70559	Diagnostic Radiology Head and Neck	Planning
71010 - 71555	Diagnostic Radiology Head and Neck	Planning
72010 - 72295	Diagnostic Radiology Spine and Pelvic	Planning
74000 - 74190	Diagnostic Radiology Abdomen	Planning
74210 - 74363	Diagnostic Radiology Gastrointestinal Tract	Planning
74400 - 74485	Diagnostic Radiology Urinary Tract	Planning
74710-74775	Diagnostic Radiology Gynecological and Obstetrical	Planning
75557-75564	Diagnostic Radiology Spine and Pelvic	Planning

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Washington State Health Care Authority

Intensity Modulated Radiation Therapy (IMRT)

Agency Experience & Utilization

PEB Average Costs by Diagnosis Type, Primary Payers Only, 2008-20110

Diagnosis	No.	Avg Treatments (95% Range)	Avg Treatment Cost	% Delivery Cost	% Planning Cost	Avg Treatment Course Cost (95% range)
Genito-Urinary	146	30.3 (4 - 50)	$1,483.24	62.0%	25.3%	$44,914 ($519 - $89,308)
Head& Neck	98	26.7 (3 - 48)	$1,772.96	53.3%	26.2%	$47,327 ($0 - $95,675)
Breast	44	19.7 (0 - 33)	$1,561.84	55.6%	33.7%	$30,775 ($0 - $63,456)
Gastro-Intestinal	33	24 (6 - 40)	$1,583.91	53.7%	29.8%	$38,062 ($266 - $75,858)
Lymphoma	18	21.2 (4 - 36)	$1,448.70	61.7%	27.2%	$30,745 ($3,801 - $57,689)
Respiratory	12	17.3 (0 - 39)	$1,856.65	51.1%	31.0%	$32,027 ($0 - $56,351)
Benign	5	23.2 (0 - 33)	$1,333.91	62.5%	28.7%	$30,947 ($6,079 - $42,206)
Soft Tissue	5	26.8 (13 - 34)	$1,796.96	66.5%	27.6%	$48,158 ($4863 - $84,553)
Musculo-Skeletal	3	15 (0 - 23)	$1,934.04	40.3%	27.6%	$29,011 ($4,558 - $41,045)
Unknown	2	24 (0 - 33)	$1,209.29	58.2%	31.8%	$29,023 ($10,551 - $35,554)
Grand	**366**	**26.3 (1 - 50)**	**$1,587.28**	**57.8%**	**27.0%**	**$41,759 ($0 - $85,654)**

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Intensity Modulated Radiation Therapy (IMRT)

Agency Experience & Utilization

PEB IMRT Average Costs by Diagnosis Type, Medicare Only, 2008-2011

Diagnosis	No.	Avg Treatments (95% Range)	Avg Treatment Cost	% Delivery Cost	% Planning Cost	Avg Treatment Course Cost (95% range)
Genito-Urinary	255	34.1 (7 - 61)	$2,0624	45.1%	32.1%	$70,244 ($0 - $230,125)
Head& Neck	73	26.5 (3 - 50.2)	$2,693	43.6%	37.8%	$71,493 ($0 - $220,613)
Respiratory	32	18.8 (0 - 41)	$1,776	29.9%	33.4%	$33,294 ($0 - $105,089)
Gastro-Intestinal	26	21.2 (0 - 47.3)	$2,102	52.4%	33.7%	$44,550 ($0 - $155,401)
Breast	22	21.9 (0 - 48.6)	$2,111	44.4%	36.0%	$46,259 ($0 - $152,211)
Lymphoma	7	22 (0 - 39)	$3,252	36.9%	55.7%	$54,575 ($0 - $196,636)
Soft Tissue	6	25 (5 - 33)	$1,612	56.1%	39.0%	$40,303 ($0 - $164,163)
Musculo-Skeletal	4	14.3 (6 - 19)	$896	55.3%	37.8%	$12,774 ($3,639 - $17,710)
Unknown	3	25.7 (11 - 30)	$2,177	42.8%	40.7%	$55,865 ($0 - $159,044)
Benign	1	N/A	$1,000	60.4%	26.5%	N/A
Total	**431**	**29.7 (1 - 58.3)**	**$2,141**	**44.5%**	**34.0%**	**$63,478 ($0 - $211,309)**

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Intensity Modulated Radiation Therapy (IMRT)

Agency Utilization

Charges selected for inclusion in IMRT treatment per patient are:

- Specific IMRT codes (77301, 77338, 77418)
- Non-specific planning and navigation codes within the treatment span of the first and last IMRT code (treatment span)
- Charges matching the diagnosis code of the IMRT treatment within seven days of the treatment span, excluding alternate treatment strategies (chemotherapy, other radiation therapy)
- Closely related non-specific planning codes in the 30 days ahead of the treatment span
- Imaging related by diagnosis code within 30 days of the treatment span

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OREGON HEALTH & SCIENCE UNIVERSITY

Intensity Modulated Radiation Therapy

Presented by: Edgar E. Clark, MD, MHA
Date: September 21, 2012

Introduction

- Background
- PICO
- Methods
- Key Questions
- Findings
- MAUDE Database, Guidelines and Policies
- Overall Summary
- Limitations of the Evidence

Background – *Clinical Overview*

- Half of cancer patients receive some form of radiation treatment (RT) – alone, with surgery or with chemotherapy
- Purpose of RT
  - Destroy or control sites of cancer without causing irreparable damage to adjacent normal tissues
- RT uses high energy waves to deliver energy to the tissues

Potential Harms of Radiation Therapy

- Radiation damages normal tissues as well as cancer tissue
  - Potential harms of radiation therapy occur to tissues adjacent to the tumor and will vary by cancer type/location
    - H&N: xerostomia, dysphagia, mucositis, dermatitis, osteonecrosis
    - Breast: dermatitis, cardiomyopathy, pneumonitis
    - Prostate: hip fracture, proctitis, cystitis, erectile dysfunction, GI bleed, GI obstruction

Background – *Technology Overview*

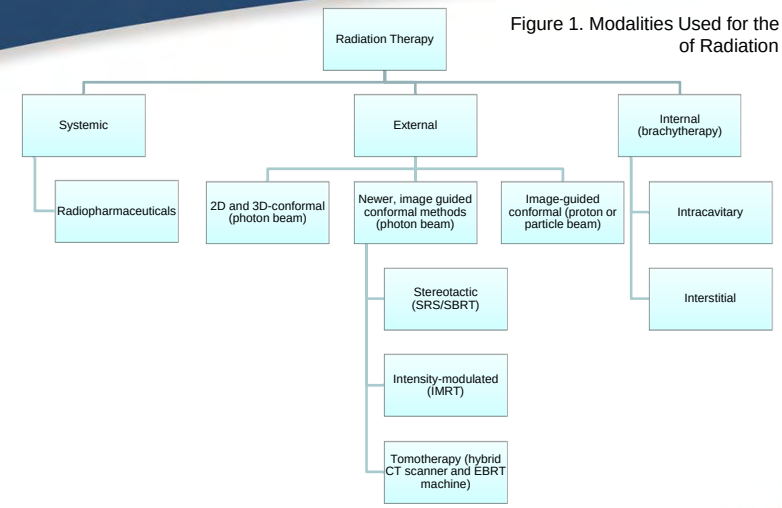

Figure 1. Modalities Used for the Delivery of Radiation Therapy

Center for Evidence-based Policy
Addressing Policy Challenges With Evidence and Collaboration

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Background – *Technology Overview*

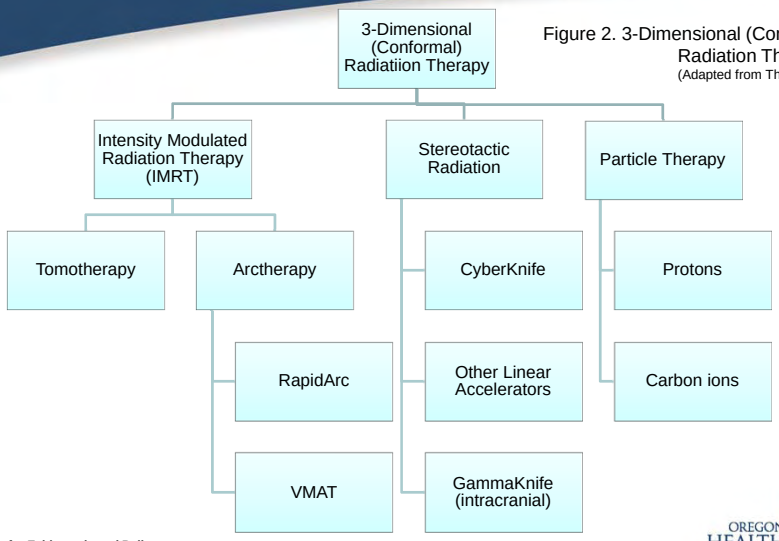

Figure 2. 3-Dimensional (Conformal) Radiation Therapies
(Adapted from Thariat 2011)

Center for Evidence-based Policy
Addressing Policy Challenges With Evidence and Collaboration

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Background – *Clinical Overview*

- IMRT has FDA 510(k) approval for sale
  - No requirement for comparative studies on efficacy or safety for FDA approval
  - This report provides a broader evidence analysis than required for FDA approval
- IMRT use growing in the US
  - Breast cancer
    - IMRT in 1% of cases in 2001; 11% in 2005 (SEER data)
  - Prostate cancer
    - IMRT in 29% of cases in 2002; 98% in 2008 (SEER data)

Background – *Clinical Overview*

- IMRT commonly used for brain, head and neck, breast, lung and prostate cancer
- Cancer incidence in US (cases/100,000/year)
  - Brain = 6.5 H&N = 10.6 Lung = 62
  - Breast = 124 Prostate = 156
- Number of IMRT cases (*not incidence*) for WA PEB and Medicaid (2008 – 2011)
  - Brain = 0 H&N = 519 Lung = 171
  - Breast = 96 GU (prostate) = 507

Background – *Technology Overview*

- Modern external beam radiation treatment is "conformal"
  - Through pre-treatment planning, the radiation beam is collimated or shaped and the direction of the beam is chosen to give the best solution for radiation to the tumor and the surrounding normal tissues to maximize dose to the tumor and minimize dose to the surrounding tissues
  - 2D CRT vs. 3D CRT
    - 2D uses x-rays
    - 3D uses CT or MRI in pre-treatment planning

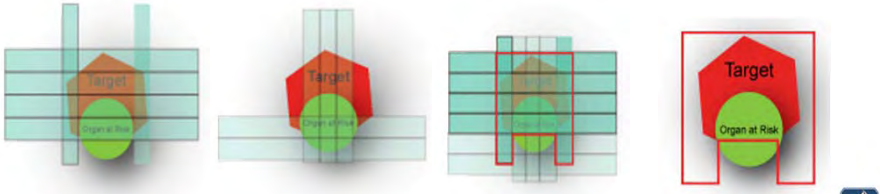
Background – *Technology Overview*

- IMRT increases conformality over 2D CRT and 3D CRT
  - Hundreds of collimators to shape the beam and change its intensity (instead of a fixed port)
  - Increased numbers of beam angles to deliver the radiation (instead of two at right angles)
- IMRT requires increased pre-treatment planning and increased time during each treatment session which increases the cost of IMRT

Background – *Technology Overview*

Figure 3. CRT

Figure 4. IMRT



PICO

Population: Adults and children with malignancies where treatment by radiation therapy is appropriate

Intervention: IMRT

Comparator: Conventional (conformal) external beam therapy (EBRT or CRT)

Outcomes: Survival rate, recurrence, metastases, quality of life, harms including radiation exposure and complications, cost, cost-effectiveness

Methods

- 'Best evidence' systematic review (SR) methodology by malignancy
  - Recent, good quality SRs/technology assessments
  - MEDLINE search for subsequently published individual studies
  - 10 year MEDLINE search for individual studies if no SR/TA identified

Inclusion criteria

- Clinical outcomes (dosage, dose ranging, and dosimetry studies were excluded)
- KQ 1, 3, 4
  - H&N, breast, prostate
    - n ≥ 50
    - Comparative studies only
  - Other cancers
    - n ≥ 20
    - Comparative and non-comparative studies
- KQ 2 (harms)
  - All cancers
    - n ≥ 50 patients
    - Exceptions (n ≥ 20 patients)
      - Serious harms
      - Pediatric populations
    - Comparative and non-comparative studies

Methods: Quality Assessment

- Methodological quality of SRs, guidelines and individual studies assessed: Good, Fair, Poor
- GRADE system used to rate overall strength of evidence (SOE)
  - High – further research is unlikely to change the confidence in the estimate of effect
  - Moderate – further research will likely have an important impact on the confidence in the estimate of effect
  - Low – further research very likely to have an important impact on the confidence in the estimate of effect
  - Very low – any estimate of effect is very uncertain

Key Questions

Key Questions: all compare IMRT to EBRT

- KQ 1 – Clinical efficacy and effectiveness
- KQ 2 – Harms including primarily radiation side effects (often referred to as “toxicities”)
- KQ 3 – Subpopulations
- KQ 4 – Costs and cost-effectiveness

Results

- 2,122 citations reviewed
  - 146 met inclusion criteria
    - 16 SRs and 130 individual studies
    - Most studies were small case series
- 12 citations were submitted during public comment period for draft report
  - 5 met inclusion criteria and incorporated into report
- Two peer reviewers of the report

Findings - *Overview*

- KQ 1 & 2 Findings are grouped by cancer and strength of evidence (SOE)
- KQ 3 & 4 presented in aggregate
- Overall Findings
  - No High SOE
  - Few Moderate SOE

Presentation follows Summary of Findings Table (App. E)

Findings - *Overview*

- Weaknesses in evidence
  - Case series
  - No comparators
  - Historical comparators
  - Increasing radiation dosages during study
  - Mixed tumor stages at initiation of treatment
  - Different chemotherapy regimens

Table of Symbols and Abbreviations

Abbreviations	Symbols (IMRT Compared to EBRT)
OS = overall survival	↑ = increased
PFS = progression free survival	↓ = decreased
DFS = disease free survival	↕ = conflicting results
DSS = disease specific survival	↔ = no significant difference
bDFS = biological disease free survival (PSA free survival for prostate)	
QoL = Quality of Life	
H&N = head and neck	
NSCLC = non-small cell lung cancer	

Findings – Head and Neck

- Key Question 1: Clinical Effectiveness

Strength of Evidence	Findings
Moderate	↑ Xerostomia related QoL with IMRT
Low	↔ Other QoL measures with IMRT
Low	↔ OS, local control, local PFS, 5-year nodal RFS, 5-year DFS with IMRT

Findings – Head and Neck

- Key Question 2: Harms

Strength of Evidence	Findings
Moderate	↓ Grade ≥2 xerostomia • xerostomia ranges in 9 studies 7-79% • IMRT reduced xerostomia by 43-62% (stat. sig. in 8 of 9 studies)
Very Low	↔ Trismus, sensorineural hearing loss, osteonecrosis

Findings – Prostate

- Key Question 1: Clinical Effectiveness

Strength of evidence	Findings
Low	↓ Local recurrence with IMRT • Additional treatment required at 3 yrs – IMRT = 2.5/100 person years (p <0.001) – EBRT = 3.1/100 persons years (p <0.001)
Low	↑ bDFS* at 60 months with IMRT • IMRT = 74%; EBRT = 60% (p<0.001)
Low	↔ bDFS at 30 months, tumor control with IMRT
Low	↕ QoL with IMRT

* bDFS = a PSA which has not risen over 2 ng/ml above the nadir

Findings – Prostate

- Key Question 2: Harms

Strength of Evidence	Findings
Moderate	↓ GI toxicity with IMRT
Low	↓ Hip fractures with IMRT • Rate of hip fractures – IMRT = 0.8% – EBRT = 1.0% (HR 0.65 – 0.93)
Low	↓ GU toxicity with IMRT
Low	↔ Chronic GI toxicity with IMRT
Low	↔ Erectile dysfunction

Findings – Lung

- Key Question 1: Clinical effectiveness

Strength of Evidence	Findings
Low	NSCLC: ↑ OS
Low	NSCLC: ↔ Local PFS, met FS
Very Low (no comparator)	NSCLC: 2- & 3-year survival
Very Low (no comparator)	Mesothelioma: DFS, DSS, local recurrence
Very Low (no comparator)	SCLC: actuarial OS, RFS

Findings – Lung

- Key Question 2: Harms

Strength of Evidence	Findings
Low	NSCLC: ↓ Grade ≥ 3 pneumonitis
Very Low (no comparator)	NSCLC: Grade ≥ 3 pulmonary fibrosis, esophagitis, dysphagia, skin toxicity, radiation pneumonitis
Very Low (no comparator)	Mesothelioma: pneumonitis, esophagitis, nausea, vomiting, fatigue, pericarditis, liver toxicity
Very Low (no comparator)	SCLC: acute pneumonitis, esophagitis

Findings – Breast

- Key Question 1: Clinical effectiveness

Strength of Evidence	Findings
Moderate	↔ QoL with IMRT
Low	↕ OS and DSS with IMRT
Low	↔ Tumor recurrence, distant metastases with IMRT
Very Low (no comparator)	Loco-regional recurrence

Findings – Breast

- Key Question 2: Harms

Strength of Evidence	Findings
Moderate	↓ Telangiectasia with IMRT
Moderate	↔ Acute ≥ Grade 2 toxicities
Moderate	↔ Grade ≥ 3 skin toxicities
Moderate	↓ Moist desquamation with IMRT
Low	↔ Breast cosmesis, chronic Grade ≥ 2 toxicities
Very Low (no comparator)	Breast edema, pain, erythema, fibrosis, chest wall tenderness

Findings – Brain

- Key Question 1: Clinical effectiveness

Strength of Evidence	Findings
Very low	Astrocytoma: ↑ 1- and 2-year OS and PFS
Very Low (no comparator)	Brain metastases: OS, QoL, global health functioning
Very Low (no comparator)	Glioblastoma: 1- and 2-year OS, PFS
Very Low (no comparator)	Medulloblastoma: 5-year PFS and OS (Pediatric population)
Very Low (no comparator)	Meningioma: 3- and 5-year RFS, actuarial survival

Findings – Brain

- Key Question 2: Harms

Strength of Evidence	Findings
Very low	Astrocytoma: ↓ acute Grade 1 neurotoxicities with IMRT
Very low	Astrocytoma: ↑ acute Grade 2-3 neurotoxicities
Very low	Medulloblastoma: ↓ ototoxicity with IMRT (pediatric population)
Very low	Medulloblastoma: ↑ Grade 1-2 toxicity with IMRT (Pediatric population)
Very low	Medulloblastoma: ↔ Neurocognitive functioning

Findings – Abdomen

- Key Question 1: Clinical effectiveness

Strength of Evidence	Findings
Very low	Anus: ↑ 3-year OS, PFS, local control
Very low	Stomach: ↕ 2-year OS, DFS
Very low	Stomach: ↔ Loco-regional control
Very Low (no comparator)	Esophagus: OS, local contol
Very Low (no comparator)	Liver: OS, PFS
Very Low (no comparator)	Pancreas: OS
Very Low (no comparator)	Rectum: OS, PFS

Findings – Abdomen

- Key Question 2: Harms

Strength of Evidence	Findings
Very low	Anus: ↓ diarrhea, skin toxicity, mucosal toxicity, skin and mucosal eruptions on female genitalia, nonhematologic toxicity
Very Low (no comparator)	Esophageal: Acute and chronic ≥ Grade 3 complications
Very Low (no comparator)	Liver: Grade 0-2 hepatic toxicity, esophagitis, N, V, pancreatitis, hepatitis
Very Low (no comparator)	Pancreas: Anorexia, N, V, dehydration, ≥ Grade 3 acute and chronic GI toxicity
Very Low (no comparator)	Rectum: Grade 3 diarrhea, dermatitis, neutropenia

Findings – Other cancers (Thyroid, Sarcoma, Skin, Spinal metastases)

- Key Questions 1 and 2

Strength of Evidence	Findings
Low	Thyroid: ↔ all survival measures
Very low	Thyroid: ↓ late morbidity (esophageal stricture, laryngeal stenosis, chronic dysphagia)
Very Low (no comparator)	Thyroid: Acute mucositis, pharyngitis, xerostomia, laryngeal toxicity, dysphagia
Very Low (no comparator)	Sarcoma: Local recurrence; nausea, fatigue, dry mouth, pharyngitis, pain Grade 4 skin toxicity
Very Low (no comparator)	Skin: Erythema; disease recurrence
Very Low (no comparator)	Spinal metastases: OS, QoL, tumor recurrence; spinal fractures, esophagitis, myelitis, skin reactions

Findings – KQ 3 & 4

- Key Question 3: Sub-populations
  - There is no evidence on sub-populations for **any** cancer
- Key Question 4: Costs and cost-effectiveness
  - Cost only for breast and H&N
  - Cost and cost-effectiveness for prostate
  - *Low SOE for all cost and cost-effectiveness evidence*

Findings – KQ 4: Costs only

- Breast
  - SEER (Medicare database)
    - Mean costs: EBRT = $7,179; IMRT = $ 15,230
  - Suh cost comparison (modeling) analysis
    - Direct costs: EBRT range $6,100 - $10,900; IMRT = $19,300
- Head and Neck
  - Bonastre (France) calculated direct costs for IMRT at €14,192 for centers just beginning IMRT and €6,332 for experienced centers

Findings – KQ 4: Costs and cost-effectiveness

- Prostate
  - Konski (UK) and Pearson (USA) both calculated cost effectiveness using different assumptions for survival and QALYs for toxicities (reported in Hummel TA [2010])
    - Konski
      - Costs for EBRT = $21,500; costs for IMRT $33,873 (2005), $47,931 (2006)
      - Incremental cost effectiveness ratio (ICER) = $16,182/QALY in 2005 and $40,101/QALY in 2006
    - Pearson
      - Costs for EBRT = $10,900; IMRT = $42,450 (2005)
      - ICER = $706,000/QALY

Findings – KQ 4: Costs and cost-effectiveness

- Hummel (2010)
  - Konski assumptions
    - 14% difference in survival IMRT > EBRT
    - Large increase in utility from differences in GI and GU toxicity IMRT > EBRT
  - Pearson assumptions
    - No difference in survival
    - Only increase in utility for IMRT is decrease in rectal toxicity
- Hummel conclusions
  - Konski assumptions do not agree with the evidence

MAUDE Database

- Manufacturers and Users Device Experience at FDA (MAUDE Database)
- Two reports of serious adverse events identified
  - One patient with severe skin reactions from radiotherapy admitted to the ICU
  - One patient admitted to hospital for Grade 3 hematochezia secondary to rectal ulceration and Grade 3 anemia

Guidelines

- 17 guidelines identified
  - 15 NCCN guidelines
  - 2 professional society guidelines on general IMRT procedure and practice
  - *All guidelines rated as poor quality*
    - NCCN – several attempts via phone and email to identify methods
- 11 ACR Appropriateness Criteria® identified
  - *All Appropriateness Criteria® rated as fair quality*
- Recommendations varied by malignancy

Guidelines

Table 1. NCCN and ACR Recommendations

Usually Not Appropriate / Not Recommended	May be Appropriate	Usually Appropriate/Recommended
Colon Cancer (NCCN)	Anal Cancer (ACR) Anal/Rectal Carcinoma (NCCN)	Breast Cancer (NCCN)
Rectal Cancer (NCCN) Resectable Rectal Cancer (ACR)	Esophageal and Esophagogastric Junction Cancers (NCCN)	Cervical Cancer (adjuvant therapy in the mgmt of early stage) (ACR)
Cervical Cancer (ACR)	Gastric Cancers (NCCN)	Resectable Oropharyngeal Cancer (ACR)
Non-Spine Bone Metastases (ACR)	CNS Cancers (NCCN)	Non-Small Cell Lung Cancer (nonsurgical treatment, induction and adjuvant therapy for N2) (ACR)
Testicular Cancer (NCCN)	Cervical Cancer (NCCN)	Prostate Cancer (ACR & NCCN)
	Head and Neck Cancers (NCCN)	
	Malignant Pleural Mesothelioma (NCCN)	
	Non-Small Cell Lung Cancer (NCCN) (postoperative adjuvant therapy) (ACR)	
	Small Cell Lung Cancer (NCCN)	
	Thymomas and Thymic Cancers (NCCN)	

Policies

- No national coverage decisions (NCD) from CMS
- Two regional LCDs (L24318 & L31415)
  - Both LCDs cover IMRT for brain tumors, brain metastasis, prostate cancer, lung cancer, pancreas cancer, and other upper abdominal sites, spinal cord tumors, head and neck cancer, adrenal tumors, and pituitary tumors
- Additional LCD (L30316) for 40 states
  - Indicates IMRT is standard treatment for CNS tumors, head and neck cancers, prostate cancers, selected cases of thoracic and abdominal malignancies, selected cases of breast cancers (with close proximity to critical structures), and pelvic and retroperitoneal tumors

Policies

- Aetna
  - Requires critical structures located near tumors that cannot be adequately protected with EBRT
- Group Health
  - No medical necessity review required for use of IMRT in head and neck and prostate cancers
- Regence BCBS
  - Anal and H&N cancer: IMRT medically necessary
  - Prostate cancer: IMRT may be used as RT after surgery
  - Breast, lung and other abdominal or pelvic tumors: IMRT may be used if previous RT or critical structures in field

Overall Summary

- Key Question 1 – Moderate SOE
  - Local recurrence, distant recurrence, survival
    - **No evidence for any cancer**
  - Quality of Life
    - H&N
      - Xerostomia related QoL is improved with IMRT vs EBRT
    - Breast
      - QoL is comparable for IMRT vs EBRT

Overall Summary

- Key Question 2 – Moderate SOE
  - Breast
    - ↓ Grade 1-3 telangectasia for IMRT vs. EBRT
    - ↓ moist desquamation
    - ↔ for other toxicities
  - H&N
    - ↓ Grade ≥ 2 xerostomia for IMRT vs. EBRT
  - Prostate
    - ↓ GI cases of acute toxicities for IMRT vs. EBRT

Overall Summary

- Key Question 3
  - No evidence on sub-populations
- Key Question 4 – Low SOE
  - Breast, H&N, prostate
    - IMRT costs more than EBRT
  - Prostate
    - ICER – Range $16K/QALY to $706K/QALY

Overall Summary

- Guidelines
  - *Usually appropriate*
    - Breast and prostate cancers
    - Some cervical cancer, H&N, NSCLC cancers
  - *May be appropriate*
    - Anal, anal/rectal carcinoma, selected esophageal, selected gastric, low grade astrocytoma and oligodendroglioma, SCLC, thymomas cancers
    - Some cervical, H&N, mesotheliomas, NSCLC cancers

Limitations of the Evidence

- Limited number of TAs or SRs
  - TAs for breast, H&N, prostate, glioblastoma multiforme only
- Many of the studies lacked a comparator
- Many studies did not adjust for confounding variables
  - Radiation dose, radiation treatment plan, chemotherapy, age, tumor stage, change in standards of care over time, etc.
- Case series
- Small sample sizes

Questions or comments?

HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on these questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are Evidence based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards[2]:

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms[3]:

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

[1] Based on Legislative mandate: See RCW 70.14.100(2).

[2] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

[3] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

Using Evidence as the basis for a Coverage Decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of Evidence:

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the Evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- The amount of evidence (sparse to many number of evidence or events or individuals studied);
- Consistency of evidence (results vary or largely similar);
- Recency (timeliness of information);
- Directness of evidence (link between technology and outcome);
- Relevance of evidence (applicability to agency program and clients);
- Bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

3. Factors for Consideration - Importance

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

Medicare Coverage and Guidelines

Malignancy	Guideline (Year) Quality	Usually Not Appropriate / Not Recommended	May be Appropriate	Usually Appropriate / Recommended
Abdomen				
Anal/Rectal carcinoma	NCCN (2012a) Poor		IMRT may be used in place of 3D conformal RT. Requires expertise and careful target design.	
Anal cancer	Poggi [ACR] (2010) Fair		ACR 6 "cautiously recommends" the use of IMRT if performed outside of a protocol setting.	
Colon cancer	NCCN (2012e) Poor	IMRT reserved only for unique clinical situations including re-irradiation of previously treated patients with recurrent disease.		
Esophageal and esophagogastric junction cancers	NCCN (2012g) Poor		In selected cases to reduce dose to normal structures.	
Gastric cancers	NCCN (2012g) Poor		In selected cases to reduce dose to normal structures.	
Rectal cancer	NCCN (2012m) Poor	IMRT should only be used in clinical trial setting or in unique clinical situations including re-irradiation of recurrent disease after previous radiotherapy).		
Resectable rectal cancer	Suh [ACR] (2007) Fair	ACR 1 (investigational use only)		
Brain				
Central nervous system	NCCN (2012c) Poor		For low-grade astrocytoma and oligodendroglioma. 3D planning or IMRT.	
Breast				
Breast cancer	NCCN (2012b) Poor			Recommended following CT-based treatment planning
Female Pelvis				

Malignancy	Guideline (Year) Quality	Usually Not Appropriate / Not Recommended	May be Appropriate	Usually Appropriate / Recommended
Cervical cancer	Gaffney [ACR] (2010) Fair	"not indicated for routine treatment of cervical cancer" ACR (3-8)		
Cervical cancer	NCCN (2012d) Poor		May be helpful. Not to be used as routine alternative to brachytherapy. Very close attention to detail and reproducibility needed.	
Cervical cancer (role of adjuvant therapy in the management of early stage)	Wolfson [ACR] (2011) Fair			ACR 7 (great care required in delineation of CTV)
Head and Neck				
Head and neck cancers	NCCN (2012h) Poor		Either 3D conformal RT or IMRT. IMRT may be used at the discretion of treating physicians.	
Head and neck cancers (mucosal melanoma)	NCCN (2012j) Poor		IMRT, 3D and 2D conformal techniques may be used as appropriate. IMRT may be used at the discretion of treating physicians.	
Resectable oropharyngeal squamous cell carcinoma	Quon [ACR] (2010) Fair			Dependent on patient characteristics, ACR 8-9
Lung				
Malignant pleural mesothelioma	NCCN (2012i) Poor		IMRT should only be used in experienced centers or on protocol. NCI/ASTRO IMRT guidelines should be strictly followed.	
NSCLC (postoperative adjuvant therapy)	Decker [ACR] (2011) Fair		Dependent on patient characteristics and tumor stage, ACR 6	
NSCLC (nonsurgical treatment)	Gewanter [ACR] (2010) Fair			ACR 8 (with tumor motion strategy required in addition to strict dosimetric criteria)

Malignancy	Guideline (Year) Quality	Usually Not Appropriate / Not Recommended	May be Appropriate	Usually Appropriate / Recommended
NSCLC (induction and adjuvant therapy for N2)	Gopal [ACR] (2010) Fair			ACR 8 (with tumor motion strategy required in addition to strict dosimetric criteria)
NSCLC	NCCN (2012k) Poor		Use of IMRT appropriate when need to deliver adequate tumor doses while respecting normal tissue dose constraints.	
SCLC	NCCN (2012n) Poor		In selected pts, IMRT may be considered.	
Prostate				
Prostate cancer (T1 and T2)	Morgan [ACR] (2011) Fair			Dependent on patient characteristics, ACR 8
Prostate cancer	NCCN (2012l) Poor			3D conformal or IMRT (no preference given)
Postradical prostatectomy irradiation in prostate cancer	Rossi [ACR] (2010) Fair	Dependent on patient characteristics, ACR 2-8		Dependent on patient characteristics, ACR 2-8
Other Cancers				
Non-spine bone metastases	Lutz [ACR] (2011) Fair	Dependent on patient characteristics, ACR 2		
Testicular cancer	NCCN (2012o) Poor	IMRT not recommended		
Thymomas and thymic carcinomas	NCCN (2012p) Poor		IMRT may further improve dose distribution and decrease dose to the normal tissues as indicated. Strictly follow NCI/ASTRO IMRT guidelines.	

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

Discussion Document: What are the key factors and health outcomes and what evidence is there?

Safety Outcomes	**Safety Evidence**
Xerostomia	
Dysphagia	
Mucositis	
Dermatitis	
Osteonecrosis	
Cardiomyopathy	
Pneumonitis	
Fracture	
Proctitis	
Cystitis	
Gastrointestinal problems	
Erectile dysfunction	
Trismus	
Hearing loss	
Nausea or vomiting	
Efficacy – Effectiveness Outcomes	**Efficacy / Effectiveness Evidence**
Overall Survival	
Symptom free remission	
Recurrence	

Metastases	
Quality of life	
Biomarkers	
Special Population / Considerations Outcomes	**Special Population Evidence**
Cost	**Cost Evidence**
Cost effectiveness	
Direct cost	

Clinical Committee Evidence Votes

First Voting Question
The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Is there sufficient evidence under some or all situations that the technology is:

	Unproven (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective				
Safe				
Cost-effective				

Discussion
Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote
Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_____Not Covered _____ Covered Unconditionally _____ Covered Under Certain Conditions

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Clinical Committee Findings and Decisions

Next Step: Cover or No Cover
If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions
If covered with conditions, the Committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence state
   - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Efficacy Considerations:

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
    - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
    - Adverse effect on health that can result in lasting harm or can be life-threatening.
- Other morbidity concerns
- Short term or direct complication versus long term complications
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?