Career Development: Strategy Primer to Address Young Investigator Skill Set Gaps for Clinical Research

Charles R. Thomas, Jr., MD
Dept. of Radiation Medicine
OHSU Knight Cancer Institute
Portland, Oregon, USA
I did have a latte; don’t own stock
Learning Objectives

- Summarize the gap in clinical investigation.
- Describe the limitations of standard residency training to provide clinical investigation experience.
- Describe opportunities to learn how to design and execute prospective clinical trials.
- Novel ways to utilize residency elective training to fill gaps in your clinical research skill set.
- CTSA (Clinical & Translational Science Award) program opportunities.
- Attendance at RTOG/NRG and regionally convenient cooperative group meetings; working group, steering comm.
- Calendar.
Be Willing to Learn New Skill Sets
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6 Core Competencies (ACGME)

1) patient care, 2) medical knowledge, 3) practice-based learning and improvement, 4) interpersonal and communication skills, 5) professionalism, and 6) system-based practice.

**Patient care (PC)**
Provide patient care through safe, efficient, appropriately utilized, quality-controlled radiation therapy and effectively communicate with the referring physician and/or other appropriate individuals in a timely manner.

**Medical knowledge (MK)**
Engage in continuous learning using up to date evidence and applying appropriate state of the art radiation therapy techniques to meet the needs of patients, referring physicians and the health care system.

**Practice-based learning and improvement (PBLI)**
Participation in the evaluation of one's personal practice utilizing scientific evidence, practice guidelines and standards as metrics, and self-assessment programs in order to optimize patient care through lifelong learning.
6 Core Competencies (ACGME)

**Interpersonal and communication skills (IC)**
Communicate effectively with patients, colleagues, referring physicians and other members of the health care team concerning informed consent, safety issues, and the indications for and the benefits, risks, and side effects of radiation, as well as the integration with other treatment modalities and the proper work-up and follow-up of patients. Communicate effectively with all members of the health care team regarding specific patient management issues.

**Professionalism (P)**
Commit to high standards of professional conduct, demonstrating altruism, compassion, honesty and integrity. Follow principles of ethics and confidentiality and consider religious, ethnic, gender, educational and other differences in interacting with patients and other members of the health care team.

**System-based practice (SBP)**
Understand how the components of the local and national healthcare system function interdependently and how changes to improve the system involve group and individual efforts. Optimize coordination of patient care both within one's own practice and within the healthcare system. Consult with other healthcare professionals, and educate healthcare consumers, regarding the most appropriate utilization of radiation oncology resources.
ACGME Program Requirements for Graduate Medical Education in Radiation Oncology

IV.B. Residents’ Scholarly Activities

IV.B.1. The curriculum must advance residents’ knowledge of the basic principles of research, including how research is conducted, evaluated, explained to patients, and applied to patient care. (Core)

IV.B.2. Residents should participate in scholarly activity. (Core)

IV.B.2.a) Residents must complete an investigative project under faculty member supervision. (Core)

IV.B.2.a).(1) Projects should take the form of biological laboratory research, clinical research, translational research, medical physics research, or other research approved by the program director. (Detail)

IV.B.2.a).(2) The results of such projects should be suitable for publication in peer-reviewed scholarly journals or presentation at scientific meetings. (Detail)
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2011 ASCO/AACR Workshop
Methods in Clinical Cancer Research
July 30-August 5, 2011 • Vail Marriott Mountain Resort • Vail, Colorado

This intensive workshop provides the essentials of effective clinical trial design of therapeutic interventions in the treatment of cancer. Clinical fellows and junior faculty clinical researchers in all oncology subspecialties, including radiation and surgical oncology and radiology, are invited to apply. All accepted applicants receive financial assistance to attend.

Supported by a generous grant from the National Cancer Institute and educational grants from corporate sponsors.

Program Committee
Co-Chairs:
Mary L. (Mimi) Distler, M.D., University of Washington, Seattle, WA
Lee M. Ellis, M.D., University of Texas MD Anderson Cancer Center, Houston, TX

Faculty Members: Miguel A. Villalona-Calero, A. William Blackstock, Vivian Weinberg

Students: Ronald Chen, Tara Gregory, Jenny Kim, Joshua Meyer, Thomas Pugh, Kristin Redmond, Devin Schellenberg, Benjamin Smith

Faculty Members: S. Gail Eckhardt, Charles R. Thomas, Jr.; Richard L. Wahl; Alfred W. Rademaker

Students: Seema Harichand-Herdt, Johnny Kao, Scott Morgan, Alan Nichol, Elexia Outlaw, Julie Schwarz, Joshua Silverman, Aaron Spalding

2014 AACR/ASCO Workshop
Methods in Clinical Cancer Research
July 26-August 1, 2014 • Vail Marriott • Vail, Colorado

An intensive workshop in the essentials of effective clinical trial design of therapeutic interventions in the treatment of cancer for clinical fellows and junior faculty clinical researchers in all oncology subspecialties, including radiation and surgical oncology and radiology.

Supported by a generous grant from the National Cancer Institute and educational grants from corporate sponsors.

For those protocols using agents from a pharmaceutical company listed on the FDA approval for the disease under study, the final application requires a letter of commitment from the collaborating company stating that the drug will be supplied for the proposed trial at no cost of the company or the institution. The letter of commitment must be signed by the appropriate official of the pharmaceutical company. The letter of commitment must be submitted as part of the application package.

Workshop Co-Directors
Neil L. Herskind, M.D.
James L. Vee Towner, M.D., M.B., B.S.

2009 Vail Methods/Workshop Group Photo

2011 Vail Workshop Maryland and Family

2014 AACR/ASCO Workshop Group Photo
Article Info

A systematic methodology review of phase I radiation dose escalation trials

Madelon Pijls-Johannesma a,c, Ghislaine van Mastrigt a,b, Steve M. Hahn a, Dirk De Ruyscher a, Brigitta G. Baumert a, Guido Lammering a, Jeroen Buusens a, Soren M. Bentzen b, Yolande Lievens c, Andrew Kramer c, Philippe Lambin c

a,b Department of Radiation Oncology (MAASTRO), GROW School for Oncology and Developmental Biology, Maastricht University Medical Centre, The Netherlands. c Department of Human Oncology, School of Medicine and Public Health, University of Wisconsin, Madison, WI, USA. d Department of Radiotherapy, Hospital of the University of Pennsylvania, Philadelphia, USA. e Department of Radiation Oncology, Université Libre de Bruxelles, Brussels, Belgium.

Article history:
Received 17 September 2012
Accepted 8 February 2013
Available online 24 March 2013

Abstract

Background and purpose: The purpose of this review is to evaluate the methodology used in published phase I radiotherapy (RT) dose escalation trials. A specific emphasis was placed on the frequency of reporting late complications as an endpoint.

Materials and methods: We performed a systematic literature review using a predefined search strategy to identify all phase I trials reporting on external radiotherapy dose escalation in cancer patients.

Results: Fifty-three trials (phase I: n = 38, phase I-II: n = 17) fulfilled the inclusion criteria. Of these, 30 used a modified Fibonacci design for the RT dose escalation, but 12 did not specify a design. Late toxicity was variably defined as >1 month (n = 43) or >6 month (n = 3) after RT, or not defined (n = 7). In only nine studies the maximum tolerated dose (MTD) was related to late toxicity, while only half the studies reported the maximum follow-up period for dose escalation (n = 25).

Conclusions: In phase I/II trials, late complications are often not taken into account and there is currently no consensus on the methodology used for radiation dose escalation studies. We therefore propose a decision-tree algorithm which depends on the endpoint selected and whether a validated early surrogate endpoint is available. In order to choose the most appropriate study design.

Article Type: Review (Unsolicited)

Keywords: radiotherapy, stereotactic, dose prescription, normal tissue tolerance

Manuscript Draft

Elsevier Editorial System® for The Lancet Oncology

Manuscript Number:

Title: Increasing the therapeutic ratio of stereotactic ablative radiotherapy by individualized isotoxic dose prescription based on normal tissue tolerance levels

Article Type: Review (Unsolicited)

Keywords: radiotherapy, stereotactic, dose prescription, normal tissue tolerance

Corresponding Author: Mr. Jaap Doeke Zindler, MD

Corresponding Author’s Institution: Department of Radiation Oncology (MAASTRO), GROW School for Oncology and Developmental Biology, Maastricht University Medical Centre, Maastricht, The Netherlands

First Author: Jaap Doeke Zindler, MD

Order of Authors: Jaap Doeke Zindler, MD; Charles R Thomas Jr, MD; Stephen M Hahn, MD; Aswin L Hoffmann, MSc, PhD; Esther G Troutt, MD, PhD; Philippe Lambin, MD, PhD

Manuscript Region of Origin: NETHERLANDS
2013 Clinical Trials Methodology Workshop

Learn to develop a protocol for your Imaging Clinical Trial

Location:
Hyatt Regency Scottsdale Resort and Spa at Gainey Ranch in Scottsdale, Arizona

Workshop dates:
January 12-18, 2013

Learning objectives:
Acquire the tools and expertise to develop a protocol and become a funded principal investigator for imaging clinical trials.

Who should apply:
M.D. and Ph.D. investigators who are faculty members or fellows in radiology, radiation oncology or nuclear medicine departments.

Application deadline:
June 4, 2012 Applications are available online at RSNA.org/CT2013. For more information, contact Fiona Miller at 1-630-590-7741 or fmiller@rsna.org.

Note:
Candidate’s department must commit to providing financial support for transportation and hotel (onsite stay required).

The Radiological Society of North America (RSNA) is holding its eighth Clinical Trials Methodology Workshop. Applicants will undergo a competitive selection process for entrance into the 6½ day course. Successful applicants will participate in advance preparation, didactic sessions, one-on-one mentoring, small discussion sessions, self-study and individual protocol development. Participants will learn how to develop protocols for the clinical evaluation of imaging modalities. Familiarity with basic concepts and techniques of statistics and study design is required.

A dynamic and experienced faculty will cover topics including:
- Principles of clinical study design
- Statistical methods for imaging studies
- Practicalities of running a clinical trial
- Sponsorship and economics of imaging trials
- Regulatory processes

This live activity has been approved for AMA PRA Category 1 Credit™.

Apply today at RSNA.org/CT2013
DO'S AND DON'TS IN DRAFTING INFORMED CONSENT FORMS

WHAT MAKES INDUCEMENTS UNDUE?

| LEARNING OBJECTIVES and FINANCIAL DISCLOSURE STATEMENT |
| WORKSHOP AGENDA WITH PRESENTATION HANDBOUTS |
| INSTRUCTIONS FOR THURSDAY EVENING POSTER SESSION |
| STUDENT HANDBOOK |
| 2011 CTMW FACULTY & BIOS |
| 2011 STUDENT CATALOG |

PRE-COURSE REQUIREMENT - CHECKLIST

PRE-COURSE REQUIREMENT - BIBLIOGRAPHY
Clinical trials workshop 2014

14 October 2014

Bookings are no longer being taken online for this event. Please contact the Conference Office or phone 020 7406 5942 to check if places are available.

The event is not available to book.

The Royal College of Radiologists, 63 Lincoln’s Inn Fields, London

This event is free to attend

5 RCR CPD Credits awarded

A joint event by The Royal College of Radiologists and the NCRI Clinical and Translational Radiotherapy Research Working Group

Objectives:

To discuss the components of a good clinical trial proposal

Use specific clinical trial proposals to illustrate and discuss key issues

Understand the roles and responsibilities of the Chief Investigator

09:30 Registration and coffee

Chair: Professor Chris Nutting, Professor of Radiation Oncology, Royal Marsden Hospital

10.00 Welcome

10:05 Introduction – CTRad progress report and clinical trial proposal assessment process

10:10 Getting the question right – Developing the scientific question, CSG and portfolio fit, information required for application and funding streams

Professor Neil Burnet, Professor of Radiation Oncology, Cambridge University

Professor Tim Maughan, Professor of Clinical Oncology & Department Director, Gray Institute for Radiation Oncology and Biology, University of Oxford
2nd Annual Course on Clinical Trials in Radiation Oncology

TO REGISTER:
Please register online at www.penncmeonline.com. Please click on CME Activities, then on Live Events, then on the green box at the bottom. Scroll down to “2nd Annual Course on Clinical Trials in Radiation Oncology”, and click on “register” link on right side.

For content related questions, please contact 215-573-8677 or Chiharu.Sako@uphs.upenn.edu; for registration questions, please call Office of CME at 215-898-8005.

LOCATION:
Arthur H. Rubenstein Auditorium, Smilow Center for Translational Research Building, University of Pennsylvania, 3400 Civic Center Blvd., Philadelphia, PA 19104

If you would like an overnight room, please follow the link on event website by September 19, 2013 to receive the group rate.

COURSE DIRECTORS:
Nehe Vapiwala, MD
Abigail Berman, MD

IN CONJUNCTION WITH:
Perelman School of Medicine at the University of Pennsylvania
Department of Radiation Oncology

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Pacific Northwest Annual Workshop on Methods in Radiation Oncology Clinical Trials

 Attendance will be limited

Place: Collaborative Life Sciences Building

When: April 23-25, 2015

Course Director: Charles R. Thomas, Jr., MD

Course Co-Directors: Mohamed Khan, MD, PhD & Ramesh Rengan, MD, PhD

Further details forthcoming

Bridgett Sparkman, Executive Specialist
Department of Radiation Medicine
sparkman@ohsu.edu | 503-494-1998

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Knight Cancer Institute
Oregon Health & Science University
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Novel ways to utilize residency elective training to fill gaps in your clinical research skill set

- Auditing opportunity for your local IRB during your residency
- Auditing the contract negotiating process for industry clinical trials during your residency
- Audit the capital acquisition & budget process
- Actually look at a funded NIH grant from a faculty

- CTSA (Clinical & Translational Science Award) program opportunities
- Attendance at RTOG/NRG and regionally convenient cooperative group meetings; working group, steering comm.
- Calendar
Capital Project XXX

Dept. of Radiation Medicine, CR Thomas, Presenter

-What is the project? (1 slide)

-Describe how your project supports the pillars of OHSU (or your institution) (1 slide for each): Service, People, Quality, Growth, Finance, Infrastructure

<table>
<thead>
<tr>
<th>Hospital Capital Request FY10</th>
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<tbody>
<tr>
<td>FY11 Capital Spending:</td>
</tr>
<tr>
<td>Deferred (Future Year) Capital Spending:</td>
</tr>
<tr>
<td>FY11 Operating Net Impact:</td>
</tr>
<tr>
<td>10 Year NPV (11.08%):</td>
</tr>
<tr>
<td>Return On Investment :</td>
</tr>
<tr>
<td>Payback (Years)</td>
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Financial Intelligence
A Manager’s Guide to Knowing What the Numbers Really Mean

KAREN BERMAN + JOE KNIGHT I With JOHN CASE
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With support of the National Institutes of Health (NIH), the Clinical and Translational Science Award (CTSA) program was launched in 2008 and has expanded to about 60 academic medical institutions across the country. Each component of the CTSA program is crucial in supporting our mission: Accelerating Discoveries Toward Better Health. Working together, we can help shape the future of healthcare.

The CTSA offers something for everyone.

- **Researchers**: access tools, resources, and collaborative academic partnerships
- **Trainees**: find extensive educational materials and resources
- **Volunteers**: learn about participating in research

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**Clinical and Translational Science Awards (CTSA) program**
The CTSA program aims to strengthen and support the spectrum of translational research by accelerating the process of translating laboratory discoveries into treatments for patients, training a new generation of clinical and translational researchers, and engaging communities in clinical research efforts. **Read More**

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**Contact Us**
Questions, comments or ideas? Reach out to us via phone, email or brief survey.

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**What's Happening**
- **Health Disparities Calculator (HD*Calc)**
  A powerful tool for evaluating and monitoring health disparities.
- **7th Annual Conference on the Science of Dissemination & Implementation**
- **CTSA Accelerated Clinical Trial Agreement Information**
- **2014 CTSA PI Retreat**
  View agenda and individual presentations

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**Toolbox**

**Learn**
Learn about the CTSA Consortium
Learn More

**Find**
Find resources, tools, collaborators, and best practices
Learn More

**Plan**
Plan to leverage CTSA resources for multi-center studies
Learn More

**View**
View the scientific portfolio of the CTSA Consortium
Learn More

**Participate**
Participate in committees, events, training, and collaborations
Learn More

**Submit**
Submit news, science stories, questions, comments, ideas
Learn More
PROGRAM OVERVIEW
The Human Investigations Program offers an integrated clinical and translational research education curriculum.

Does the program offer a degree?
There are three tracks, one of which results in a master's degree of clinical research. HIP also offers a certificate in human investigations and the opportunity to take individual courses. More about the program tracks.

HIP is open to faculty, clinical and post-doctoral fellows and graduate students in the schools of medicine, nursing and dentistry. More about eligibility.

Courses are based on nationally-recognized competencies for clinical and translational research. More about curriculum.

STUDENT RESOURCES
Sokal Electronic Course System
Class Schedules
HIP Tuition and Fees Information
Bursar/Student Billing
Graduate Studies Program
OHSU Registrar
Banner: Student Online Information System (ISIS)
OHSU Library
Acknowledging HIP and OCTRI support in your publications
Resources for mentorship
Career Development for Researchers

UPCOMING EVENTS
9/18/2014  Funding Focus
10/15/2014  Funding Focus
11/19/2014  Funding Focus
12/18/2014  Funding Focus
2/15/2015  Funding Focus
2/19/2015  Funding Focus
See all »

ENHANCING RESEARCH CAREERS

- Enhance your career in clinical and translational research.
- Gain practical skills in conducting successful research studies.
- Connect with faculty who share a commitment to translational research.
- Acquire knowledge that directly supports your research and expands your Collaboration opportunities.

ANNOUNCEMENTS

Interested in Applying?
Watch more about applying to the HIP program.

Information for continuing HIPsters:
If you are continuing on in the certificate program or interested in applying for the MGR, may want to see what is offered this summer term or look ahead to fall.

See announcements for continuing students.

Applying for a career development award or your first R01?
The OCTRI Scholars Program supports early-career faculty in obtaining their first independent research funding. You are eligible for the program if you are applying for or currently have a career-development award.

Learn more about the OCTRI Scholars Program.
CERTIFICATE APPLICATION

APPLICATION INSTRUCTIONS: HIP CERTIFICATE TRACK

All application materials are to be submitted to the HIP program coordinator by July 15th. Applications will be considered on a space available basis after this date. All applications are reviewed at one time and applicants will be notified of admission decisions by mid-August.

Graduate students currently enrolled in a Ph.D. program at OHSU should contact the HIP program office before submitting an online application to learn about additional application materials.

1. Complete online application. Apply Now.

   Once you log into the application, select Human Investigations Program for Fall 2013. When completing the online application, you must choose Certificate Track or planned course of study even if your long-term plans include the Master of Clinical Research. Applications to the MCR track are only accepted after completing the first year curriculum.

Submit the following material by e-mail to hip@ohsu.edu:

2. A current CURRICULUM VITAE, which includes education, residencies and fellowships.

3. A SUPPORTING DOCUMENT answering the following questions (please keep each question to under a page in length).

   A. What are your professional responsibilities for the next 2 years? (Specify clinical administrative and research time.)
   B. What are your career goals for the next 5-10 years and how will this course help you achieve these goals?
   C. Please discuss your research focus for the next two years. Including specific proposals you plan to submit or implement. (If you have a research mentor, please note this.)
   D. List all research proposals or grants you have submitted, including those that have not been funded.
   E. List all publications (if any) in journal format. Do not list abstracts.

Submit the following material by mail or personally deliver to:

Human Investigations Program
Mail Code: BIC
Oregon and Clinical Translational Research Institute
OHSU Health & Science University
3181 SW Sam Jackson Park Rd.
Portland, OR 97239-3096

Located on the 5th floor of the Biomedical Informatics Communication Center (BIC or Library Building), on the OHSU campus, BIC 526F. We're in the first row of cubicles on the east side.

4. COLLEGE TRANSCRIPTS. You must provide an official transcript from the university or college that granted your doctoral degree. The transcripts must arrive in a sealed envelope and should be mailed directly to the HIP program. Alternatively, if you submit the transcripts personally, they must be in a sealed (unopened), original envelope. A notarized copy of your doctoral degree diploma is acceptable if a graduate from a foreign university and you are on faculty or staff of OHSU or the VA.

5. LETTER OF RECOMMENDATION. A letter of recommendation from your Department Chair or Training Director is required. In addition to requesting comments that will assist us in evaluating your application, we will also ask for a commitment of protected time to complete the program.

Please download the Letter of Reference waiver form, and send to the person providing the letter of reference. The letter of recommendation may be sent directly to the program office. If the letters are delivered by the applicant, the recommender should return the completed letter to us in a sealed.
Resident Opportunities

On this page: Resident Research Training Program
- RRTP Ambassadors
- Designing Clinical Research
- Resident Research Symposium
- Clinical and Translational Research Pathway for Residents

Resident Research Training Program (RRTP)

Many graduate medical education programs at UCSF are working to facilitate clinical and translational research opportunities for residents who plan to make research a part of their careers. CTST has established a research elective and other initiatives to help promote residents' career development. The goals are to create opportunities for all residents to gain a foundational understanding of clinical and translational research methods and evidence-based medicine skills, and to inspire and facilitate residents to pursue future opportunities for career development as investigators.

The program is comprised of training, career development, courses, funding opportunities for clinical research, and travel to present findings at scientific meetings, and an annual research symposium.

RRTP Ambassadors

The Resident Research Training Program has appointed ambassadors for each residency program. The ambassadors will provide guidance and information to residents interested in pursuing research training. Please click on a department's name for information on that program:

Department Research Page | Ambassador
--- | ---
Anatomic Pathology | Patrick Treselera
Anesthesia and Perioperative Care | Helen Kim
Clinical Pathology | Enrique Terrazas
Dermatology | Wilson Liao
Emergency Medicine | Robert Rodriguez
Epidemiology and Biostatistics | George W. Ruthford
Family and Community Medicine | Teresa Villena
Internal Medicine | Jeff Kohlwey

Application Materials
- Designing Clinical Research (DCR)
  - August Course
  - October Course
- Resident Research Symposium (RRSy)
  - 2014 Submission Form
  - Deadline is Sunday, April 5, 2014
  - Sample Blank Submission Form (pdf 115KB)
  - 2013 Program Book (pdf 3.8MB)
- CTR Pathway for Residents
  - 2014 Closed. Next Application due February 2015

Questions?
- Contact: Christian Lohasa

Funding Opportunities
- Resident Research Funding (RRF) Program
- Resident Research Travel (RRT) Program

Resources for Residents, Program Directors, and Mentors
- Selecting a Research Project and Mentor
- Introduction to Clinical Research Design

QuickLinks
- Find Consultation Services
- Search UCSF Research Core Facilities & Services
- Use Clinical Research Services
- Find Research Experts with UCSF Profiles
- Talk to a Research Navigator
- Learn How to Work with Industry
- Learn How to Work with Community Members
- Browse Training Opportunities Matrix
- Stay Informed
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- **Attendance & sponsorship at RTOG/NRG and regionally convenient cooperative group meetings; working group, steering committee**

- **Mentoring & Sponsorship, intramural or extramural**

- Calendar
Human–Computer Interaction in Radiotherapy Target Volume Delineation: A Prospective, Multi-institutional Comparison of User Input Devices

Multi-Institutional Target Delineation in Oncology Group

Published online: 27 October 2010
© Society for Imaging Informatics in Medicine 2010

Abstract The purpose of this study was the prospective comparison of objective and subjective effects of target volume region of interest (ROI) delineation using mouse-

Portions of these data were presented at the 2010 Society of Imaging Informatics in Research Annual Meeting, June 3–6, 2010, in Minneapolis, MN. These data were presented as an invited paper at the XVIIth International Conference on the Use of Computers in Radiation Therapy, May 31–June 3, 2010, in Amsterdam, the Netherlands.

The following collaborators contributed to the current report: Coen R.N. Rasch, MD, PhD, Joop C. Dupeyn, Ing., Roel J. Steeman, MD, PhD (Department of Radiation Oncology, Netherlands Cancer Institute-Antoni van Leeuwenhoek Hospital, Amsterdam, NL); Daniel Baseman, MD, Tony Y. Eng, MD, Clifton D. Fuller, MD, Anna M. Harris, MD, William E. Janecz, III, MD, Ying Li, MD, PhD, Elizabeth Maani, MD, Dominic D. Nguyen, MD, MBA, Gregory P. Swanson, MD (Department of Radiation Oncology, The University of Texas Health Science Center at San Antonio, San Antonio, TX, USA); Celine Bicquart, MD, Patrick Gagnon, MD, MS, John Holland, MD, Tasha McDonald, MD, Charles R. Thomas, Jr, MD, Samuel J. Wang, MD, PhD, Martin Fuss, MD, PhD (Department of Radiation Medicine, Oregon Health & Science University, Portland, OR, USA); Hadley J. Sharp, MD, Michelle Ludwig, MD, David I. Rosenthal, MD (Department of Radiation Oncology, The University of Texas M.D. Anderson Cancer Center, Houston, TX, USA); Aidan Z. Diaz, MD (Department of Radiation Oncology, Rush University, Chicago, IL, USA); Carlo G.N. Demandante, MD (Radiation Oncology Flight, Willard Hall Medical Center, Lackland Air Force Base, San Antonio, TX, USA); Ronald Shapiro, MD (Department of Radiation Oncology, Indiana University, Indianapolis, IN, USA).

Electronic supplementary material The online version of this article (doi:10.1007/s10278-010-9341-2) contains supplementary material, which is available to authorized users.

Multi-Institutional Target Delineation in Oncology Group (2010)
PROSPECTIVE RANDOMIZED DOUBLE-BLIND PILOT STUDY OF SITE-SPECIFIC CONSENSUS ATLAS IMPLEMENTATION FOR RECTAL CANCER TARGET VOLUME DELINEATION IN THE COOPERATIVE GROUP SETTING

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Purpose: Variations in target volume delineation represent a significant hurdle in clinical trials involving conformal radiotherapy. We sought to determine the effect of a consensus guideline-based visual atlas on contouring the target volumes.

Methods and Materials: A representative case was contoured (Scan 1) by 14 physician observers and a reference expert with and without target volume delineation instructions derived from a proposed rectal cancer clinical trial involving conformal radiotherapy. The gross tumor volume (GTV), and two clinical target volumes (CTV1, including the internal iliac, presacral, and perirectal nodes, and CTVB, which included the external iliac nodes) were contoured. The observers were randomly assigned to receive (Group A) or non-receive (Group B) of a consensus guideline and atlas for anorectal cancers and then instructed to contour the same case/images (Scan 2). Observer variation was analyzed volumetrically using the conformation number (CN), where CN = 1 equals total agreement.

Results: Of 14 evaluative contour sets (1 expert and 7 Group A and 6 Group B observers), greater agreement was found for the GTV (mean CN, 0.75) than for the CTVs (mean CN, 0.46-0.65). Atlas exposure for Group A led to significantly increased interobserver agreement for CTVB (mean initial CN, 0.68, after atlas use, 0.76, p < 0.05 and increased agreement with the expert reference (initial mean CN, 0.68, after atlas use, 0.69, p = 0.02). For the GTV and CTVB, neither the interobserver nor the expert agreement was altered after atlas exposure.
Consequences of anorectal cancer atlas implementation in the cooperative group setting: Radiobiologic analysis of a prospective randomized in silico target delineation study

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ABSTRACT

Purpose: The aim of this study is to ascertain the subsequent radiobiological impact of using a consensus guideline target volume delineation atlas.

Materials and methods: Using a representative case and target volume delineation instructions derived from a proposed IMRT rectal cancer clinical trial, gross tumor volume (GTV) and clinical/planning target volumes (CTV/PTV) were contoured by 13 physician observers (Phase 1). The observers were then randomly assigned to follow (atlas) or not-follow (control) a consensus guideline/atlas for anorectal cancers, and instructed to re-contour the same case (Phase 2).

Results: The atlas group was found to have increased tumor control probability (TCP) after the atlas intervention for both the CTV (p < 0.0001) and PTV1 (p = 0.0011) with decreasing normal tissue complication probability (NTCP) for small intestine, while the control group did not. Additionally, the atlas group had reduced variance in TCP for all target volumes and reduced variance in NTCP for the bowel. In Phase 2, the atlas group had increased TCP relative to the control for CTV (p = 0.03).

Conclusions: Visual atlas and consensus treatment guideline usage in the development of rectal cancer IMRT treatment plans reduced the inter-observer radiobiological variation, with clinically relevant TCP alteration for CTV and PTV volumes.

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A PHASE II TRIAL OF HIPPOCAMPAL AVOIDANCE DURING WHOLE BRAIN RADIOTHERAPY FOR BRAIN METASTASES

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News Release

Embargoed until 8:30 a.m. ET, Monday, September 23, 2013

Avoiding specific region of brain during whole-brain radiotherapy prevents memory loss

Atlanta, September 23, 2013—Limiting the amount of radiation absorbed in the hippocampal portion of the brain during whole-brain radiotherapy (WBRT) for brain metastases preserves memory function in patients for up to six months after treatment, according to research presented today at the American Society for Radiation Oncology’s (ASTRO’s) 55th Annual Meeting.
Willingness to Define to Pathways for your Prospective Team
Learning Objectives

- Summarize the gap in clinical investigation.
- Describe the limitations of standard residency training to provide clinical investigation experience.
- Describe opportunities to learn how to design and execute prospective clinical trials.
- Novel ways to utilize residency elective training to fill gaps in your clinical research skill set.
- CTSA (Clinical & Translational Science Award) program opportunities.
- Attendance at RTOG/NRG and regionally convenient cooperative group meetings; working group, steering comm.

Calendar
RSNA Clinical Trials Methodology Workshop (Jan. 2016)
Application deadline: Early June, 2015

Application deadline: Feb.-March, 2015

ECCO-AACR-EORTC Methods in Clinical Cancer Research Flims Workshop (June 20-26, 2015):
Application deadline: Feb., 2015

Royal College of Radiologists Clinical Trials Workshop (Fall 2015)
Penn 3rd Annual Course on Clinical Trials in Radiation Oncology

Application deadline: per Drs. Vapiwala & Berman

Pacific Northwest Annual Workshop on Methods in Radiation Oncology Clinical Trials (April 23-25, 2015):

Application deadline: Winter-Spring 2015
Bring a Needed Skill Set to your Prospective Team
Learning Objectives

- Summarize the gap in clinical investigation.
- Describe the limitations of standard residency training to provide clinical investigation experience.
- Describe opportunities to learn how to design and execute prospective clinical trials.
- Novel ways to utilize residency elective training to fill gaps in your clinical research skill set.
  - Auditing opportunity for your local IRB during your residency
  - Auditing the contract negotiating process for industry clinical trials during your residency
  - Audit the capital acquisition & budget process
- CTSA (Clinical & Translational Science Award) program opportunities
- Attendance at RTOG/NRG and regionally convenient cooperative group meetings; working group, steering comm.
- Calendar
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