Agenda

- 9:00 AM: Welcome by Project Officer (Dr. Deye)
- 9:15 AM: ATC P.I. Report (Dr. Purdy)
  - Overview of ATC activities
  - Review of ATC Steering Committee March 2003 input/response
- 10:15 AM: Advanced Technology Credentialing: IMRT Phantoms & prostate brachy (RPC: Francisco Aguirre & Andrea Nelson Molineu)
- 10:30 AM: IMRT Benchmark and ATC Method 2 use by COG (Drs. FitzGerald and Urie)
- 10:45 AM: RTOG dosimetry QA review and protocol development (Ms. Martin)
- 11:00 AM: Demonstration of ATC web-based tools (Drs. Bosch and Frouhar)
- 11:20: Discussion of meeting presentations (All participants)
- 12:00 PM: Lunch (ATC Steering Committee Executive Session) (ATC Members separate room)
- 1:00 PM: Questions/Discussion (All participants)
- 3:00 PM: Adjourn

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Providing support in quality assurance and data management for radiation therapy clinical trials

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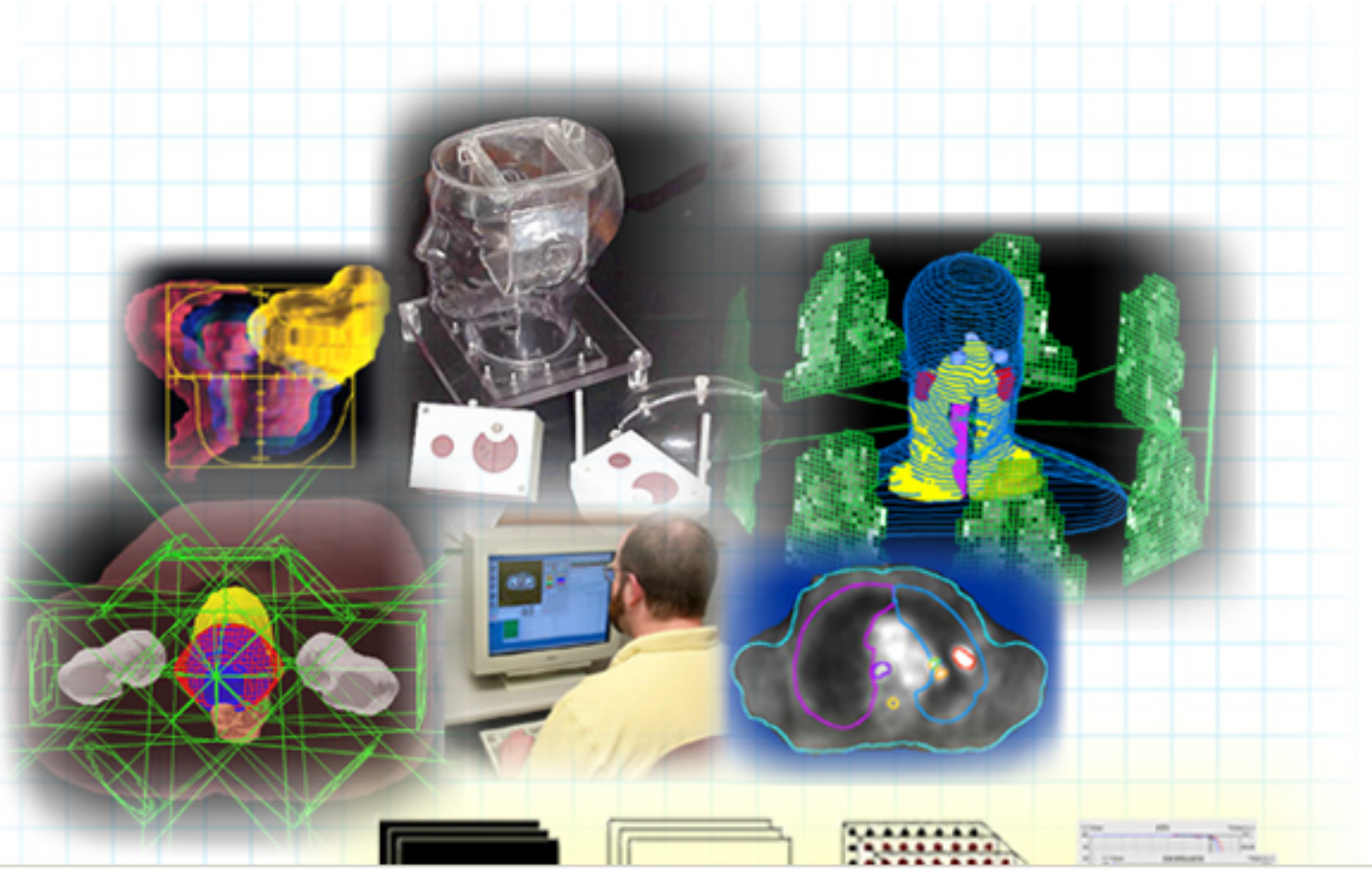
ATC DICOM Workshop
Apr 14, 2004

- ATC Members
  - Image-Guided Therapy Center (ITC)
  - Quality Assurance Review Center (QARC)
  - Radiation Therapy Oncology Group (RTOG)
  - Radiological Physics Center (RPC)
  - Resource Center for Emerging Technologies (RCET)



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The Nation's Investment in

Cancer Research

A Plan and Budget Proposal for Fiscal Year 2005

Prepared by the Director National Cancer Institute

Radiation oncologists are providing care for increasing numbers of cancer patients at some point during the course of their disease. Radiation is used both alone and in combination with other modes of therapy. For example:

Proton radiation therapy is used to treat melanoma cancer of the choroidea, the middle layer of the vertebrate eye, between the retina and sclera.

- Radiation oncology is at the forefront of image-guided therapy. Beam-shaping techniques such as 3D-conformal therapy and intensity-modulated radiation therapy (IMRT) allow health care providers to administer higher doses of radiation to the tumor while exposing normal tissue to reduced amounts.
- Technological advances in brachytherapy permit radiation sources to be placed within certain tumors.
- Proton particle beam therapy allows more precise administration of radiation to cancerous tissue.
- Radioimmunotherapy involves the use of radioactive molecules attached to monoclonal antibodies to attack cancer cells throughout the body.
- Combination radiation and chemotherapy permits organ-sparing curative treatment and has increased patient survival rates for a number of diseases, compared to using either type of therapy alone.
- New molecularly targeted anti-cancer drugs are often more effective when administered in combination with radiation therapy. Basic and clinical researchers are studying cancer-related molecular pathways to design improved chemo-radiation approaches.

NCI places a high priority on crosscutting research into new radiation technologies.

NCI's intramural researchers collaborate with universities and industry, linking studies in molecular imaging, molecular biology, and molecularly targeted therapy. This multidisciplinary research is helping oncologists to understand molecular processes affected by radiation, improve tumor control, and lessen injury of normal tissue. Research in normal tissue radiation toxicity will also help the Nation to prevent and/or treat possible injury from radiological or nuclear terrorism.

Beyond intervention development, NCI has been a leader in radiation oncology quality assurance, pioneering the Patterns of Care studies over three decades ago to investigate adoption of recommended treatments for the most common cancers. (See page 52.) NCI is now implementing shared quality assurance programs that will improve the technological sophistication of radiation oncology, worldwide, and create data sharing abilities via telemedicine. This improvement in technological resources is the

Due to the increasing complexity of radiation therapy methods, such as IMRT, and the rapid commercialization of computation and optimization algorithms that have not been fully tested clinically, there is a growing concern that the implementation of these algorithms may compromise clinical trials employing radiation therapy.

To address the cross-disciplinary modeling and computational challenges inherent in IMRT treatment planning,the National Cancer Institute (NCI) and National Science Foundation (NSF) jointly sponsored a workshop on Operations Research Applied to Radiation Therapy (ORART), held in Herndon, VA, Feb. 7–9 2002. Thirty invitees were divided nearly equally among radiation oncologists, radiation physicists, and members of the operations research (OR) community. As a result of the workshop, the ORART CollaborativeWorking Group (CWG) was formed,consisting of a multidisciplinary team of researchers. The initial goal of the CWG involves developing standards for web-based tools that will enhance the development and validation of dose computation and optimization algorithms in the delivery of radiation treatments.

July 17, 2002

Henry Keys, M.D.
Chair, GOG Radiation Oncology Committee
Department of Radiation Oncology
Albany Medical College A-137
47 New Scottland Avenue
Albany, NY 12208-3479

Dear Dr. Keys:

The NCI Cancer Therapy Evaluation Program has received numerous requests to permit utilization of IMRT techniques as a routine option into clinical trials protocols that utilize radiation therapy. This document is to serve as a template for development of protocols that wish to incorporate IMRT as a routine radiation therapy treatment technique.

Radiation therapy treatment planning and delivery are in the process of changing dramatically. This change is being driven in large part by continuing advances in computer technology that has led to the development of sophisticated three-dimensional radiation treatment planning (3DRTP) systems and computer-controlled radiation therapy treatment delivery systems. Such planning and delivery systems have made practical the implementation of three-dimensional conformal radiation therapy (3DCRT). The goal of 3DCRT is to conform the spatial distribution of the prescribed dose to the

Protocol Requirements

1. Protocols permitting IMRT treatment delivery must be written using the nomenclature ---

3. The protocol must provide a clear definition of the prescription dose and dose heterogenei IMRT treated patients.

4. The protocol must require that a volumetric treatment planning CT study be used to define

5. The protocol must clearly define the organs-at-risk that are required for each study and pr organ-at-risk in the irradiated volume must be defined. This should include a reasonable definit protocol specified limits.

6. The GTV, CTV, PTV, PRV(s), and skin contours must be depicted on all planning CT slic

7. The protocol must require that specific procedures be in place to insure correct, reproducil orthogonal portal images (film or electronic) are to be required.

8. Copies of all images required by the protocol in defining the GTV must be submitted to th the coronal, axial, and sagittal planes must be submitted for QA review. Isodose lines superimp prescription dose must be clearly indicated, as well as "cold spots" within the PTV. DVHs for t must be completed within the first week of treatment or before the treatment is 15% completed.

9. A DVH will be submitted for a category of tissue called "unspecified tissue" that is define other structure. This will help insure that the IMRT plan does not result in increased doses in no of treatment or before the treatment is 15% completed.

10. The treatment machine monitor units generated using the IMRT planning system must be i for a check as long as the plan's fluence distributions can be recomputed for a phantom geometr

11. IMRT for lung cancer, esophageal tumors, or other areas with significant heterogeneities, o

Skeleton QA Outline
NSABP/RTOG Phase III Partial Breast
1-18-04 – following discussions at RTOG Meeting New Orleans

RPC, Jeff Ibbott, explained their role in credentialing institutions for participation. They will begin development of process. Two questionnaire will be developed. First to assess equipment, expertise available and the second a bench mark exercise for each treatment technique to establish knowledge of methodology and accuracy of treatment plan development/delivery. They are targeting to have these questionnaires available for review in one month.

ATC, Jim Purdy, explained their role of creating and managing the digital QA submission and review process. We discussed need for rapid review – although at that meeting were uncertain as to extent of need. ATC uncertai of ability therefore will push RTOG 0319 and test rapid review ability. Dr Vicini commented that process in place for RTOG 0319 is working well and is user friendly.

CANCER RESEARCH: Von Eschenbach Revises the NCI Agenda

Jocelyn Kaiser

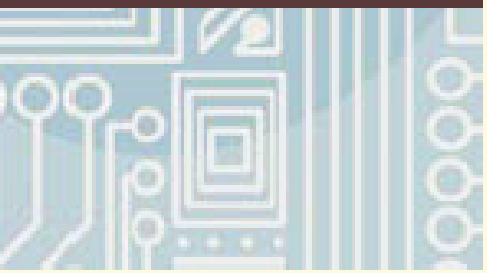
Science, Vol 303, Issue 5666, 1952
Friday, 26 March 2004

Reacting to a tightening budget, the National Cancer Institute (NCI) **plans to promote the sharing of clinical data** and boost the field of systems biology, among other priorities, by trimming $75 million partly from intramural research. The swap is part of a wave of decisions by NCI Director Andrew von Eschenbach that includes adding more deputies.

"He's getting a much better grasp of the situation," says oncologist Richard Schilsky of the University of Chicago, who was briefed on the changes last week at a Board of Scientific Advisors meeting. Earlier this year, von Eschenbach said he was slicing 5% from NCI's 2004 operating budget to fund new initiatives.Last week he announced where the money will go.

Topping the list is $15 million to ramp up the Cancer Biomedical Informatics Grid for sharing clinical data across cancer centers.

caBIG Will Expedite Access to Bioinformatics Resources



NCI plans to deploy a biomedical informatics infrastructure called the cancer Biomedical Informatics Grid or caBIG. As part of this effort, NCI, in partnership with others in the cancer research community, is creating a common, extensible informatics platform that integrates diverse data types and supports interoperable analytic tools. This platform will allow research groups to tap into the rich collection of emerging cancer research data while supporting their individual investigations.

Because Cancer Centers provide the institutional framework around which much of NCI-supported research is conducted, NCI is working with a representative sample of these Centers in the pilot phase of the project. Center resources will be joined into a common web of communications, data, and applications.

The caBIG pilot includes:

- "Co-developers" that contribute mature infrastructure and applications
- "Adapters/adopters" that take contributed infrastructure and applications and implement or adapt them for local needs
- "Users" that utilize the applications and infrastructure provided, contribute data sets and study populations, and assist in establishing the needed functionality of the caBIG effort

NCI is soliciting ongoing feedback from the Cancer Centers through working groups engaged in specific development areas, workshops to review models and system development, and a project Website (caBIG.nci.nih.gov) and mailing list. The workshops and Website are available to the entire cancer research community. As consensus is achieved, projects are executed and implemented, initially at the funded pilot centers and then more broadly across the Cancer Centers, Specialized Programs of Research Excellence, new NCI research initiatives, and intramural research programs.

The caBIG pilot effort strives to:

- Maintain the current momentum of the informatics efforts at NCI.
- Create tools and systems that are adaptable to different institutional settings, meet Food and Drug Administration compliance requirements, and can retrieve common information important to biomedical research from existing biomedical information systems.
- Involve all Cancer Centers through updates of progress and solicitation of comments and feedback, while working directly with a few Centers for pilot development.

We envision that QARC will continue its major mission of supporting the QA of radiation oncology for the cooperative groups. QARC should continue do develop and maintain flexible systems and software that will permit it to accomplish its mission to provide quality assurance for radiation therapy to the NCI funded cooperative groups and consortiums that come under its purview. A variety of systems at various levels of sophistication is expected. **Interactions with ATC should be improved realizing that the ATC's mission is to create mechanisms and software tools to facilitate QA reviews of treatment planning and verification data submitted by institutions participating in cooperative group clinical trials that utilize advanced technologies. After "production-level" quality systems are validated by the ATC,** with the help of QARC, the expectation is that data necessary for QARC to fulfill its mission will be come directly to a QARC controlled data server via these systems.