Gynecologic Cancer InterGroup
Cervix Cancer Research Network

GYNECOLOGIC CANCER INTERGROUP
An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

Global Cervical Cancer Clinical Trials

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National Institutes of Health
United States of America

Cervix Cancer Education Symposium, January 2017, Mexico

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Trials across cancer continuum

Prevention

Screening

Treatment of pre-cancer

Treatment of invasive cancer

Symptom management

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Prevention

Safety and efficacy of prophylactic HPV vaccines

Gardasil & Cervarix

Reduced dosing of prophylactic HPV vaccines

Two doses vs three doses

Two doses vs one dose

<u>Screening trials</u>

Visual inspection with acetic acid (VIA)

HPV diagnostics

See-and-treat algorithms

Interventions to ensure adherence to recommendations for follow-up

- Patient navigation
- M-health, E-health, mobile phones

Treatment of precancer

Novel technology for ablation

- Novel cryotherapy technology
- Novel thermocoagulation technology

Adjuvant immunotherapy

Treatment of invasive cancer: I

Fertility-sparing approaches

- Conservative surgery vs more radical surgery
- Neoadjuvant chemotherapy-> conization

Neo-adjuvant chemotherapy

Dosing & schedule of platinum-based chemoradiation

Novel chemoradiation

Adjuvant chemotherapy

Immunotherapy

Treatment of advanced and metastatic disease

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Treatment of invasive cancer: I

Novel chemoradiation

Image-guided therapy

Resource-sparing approaches

Adjuvant chemotherapy

Immunotherapy

Treatment of advanced and metastatic disease

Symptom management and survivorship

Intimacy

Preservation of sexual, bladder, and rectal function

Fatigue

Facilitating return to normal family life and work

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Clinical Research Initiative for Global Health

Founded January 2017

Builds on Organization for Economic Cooperation and Development (OECD) Global Science Forum recommendations to strengthen international collaboration in non-commercial clinical trials (2011 & 2013)

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Clinical Research Initiative for Global Health

- Infrastructure and funding
- Global core competencies
- Research ethics
- Patient involvement
- Comparative effectiveness research
- Regulatory awareness

National Cancer Institute

CENTER FOR GLOBAL HEALTH

Affordable Cancer Technologies (NCI ACTs) Initiative

Cervical Cancer Portfolio

PRRR Side Meeting

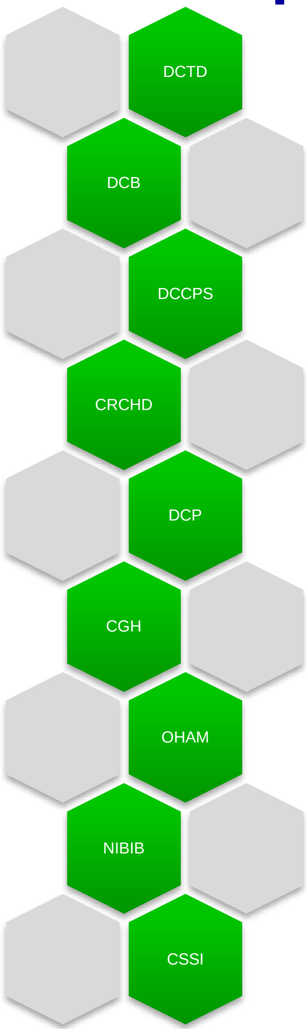
Paul Pearlman, PhD

NCI Center for Global Health

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Trans-NCI and NIBIB Effort



Result of collaboration by PDs across the the DOCs to identify priority areas and manage grants.

<u>Critical Elements</u>

- Two-phase cooperative agreement.
- Three Rounds: Awards run until 2022.
- **Phase I (UH2) - two years:**
  - Demonstrate clinical potential in a global health setting
- **Phase II (UH3) - three years:**
  - Validate device in global health setting
- **Progression from UH2 to UH3:**
  - Grantee must meet specified milestones
  - Milestones reviewed by NCI program staff.

NIBIB

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CA202665-01: The Radiation Planning Assistant for Radiation Planning in Low- and Middle-Income Countries

- Software to improve quality of RT treatment plans & increase productivity.
- Automates several routine, but critical tasks performed by physicists.
- UH2 Phase: Finalize development of tool at MD Anderson & initial testing in the Philippines and South Africa
- UH3 Phase: Deployment & evaluation.

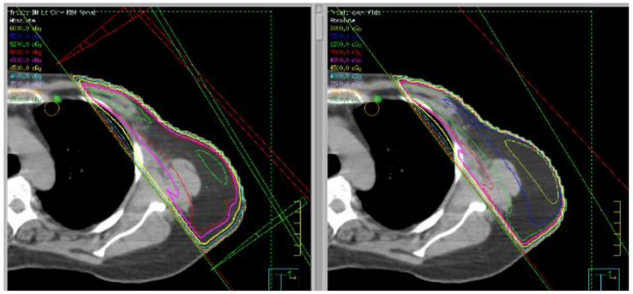

Figure 2. Comparison of the dose distribution for a chest wall treatment with optimized wedges (left) and with open fields (right). The non-optimized plan has a large region of soft tissue receiving 60Gy (6000cGy), compared with 52Gy (5200cGy) in the optimized plan.

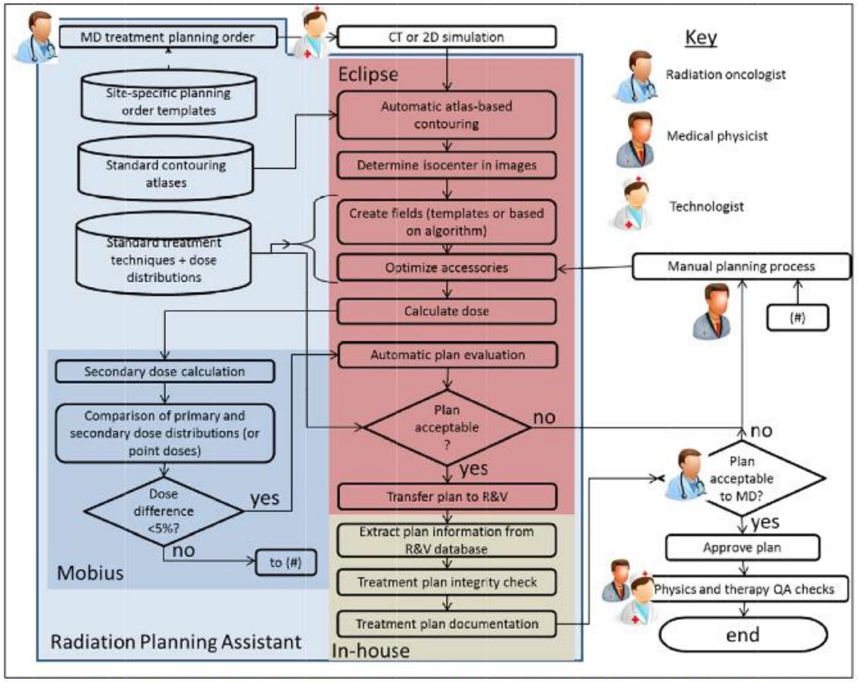

Figure 3. Radiation Planning Assistant process flow. The goal is that once the CT or 2D simulation images are passed to the Radiation Planning Assistant system, no more user interactions are performed until the plan is ready. Some data transfer (e.g., to the record-and-verify [R&V] system) likely requires some user input, although we will work to minimize this. Most of the steps shown here also have parallel steps in which the same processes are carried out independently. These parallel steps are used as QA checks.

A cost-effective radiation treatment delivery system for low- and middle-income countries

- Goal: Develop cost-effective system for delivering RF that will provide IMRT at low cost.
  - Achieved using physical compensator adaptable to Cobalt-60 devices and linear accelerators.
  - Solution is both innovative and practical.
  - Has potential to improve the delivery of quality radiation in LMIC settings.
  - Investigators team are widely-respected medical physicists, physicians and engineers with experience in RT in the global setting.

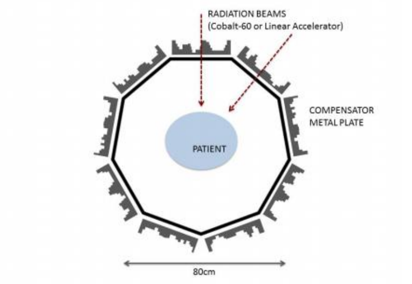

Figure 3: Proposed design to enable high-efficiency Intensity Modulated Radiation Therapy (IMRT). Physical compensators (plates filled with reusable tungsten pellets) are arranged in a compensator ring around the patient. Because staff do not need to enter the radiation vault between beams this system provides for extremely efficient treatment delivery.

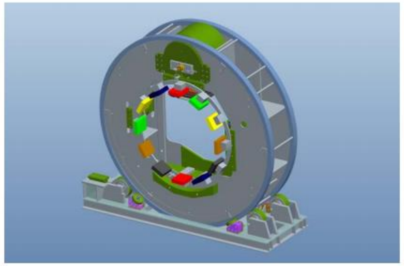

Figure 5: Prototype ring modulator system developed by the commercial partners, Panacea Medical Technologies Pvt. Ltd. (Bangalore, India). The treatment head and compensator exchange system is shown at the top (green).

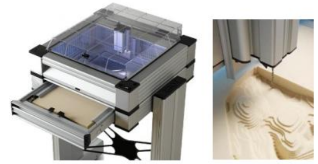

Figure 8: Desktop milling device for use in making physical compensator molds. The resolution is controlled by the size of the material subtraction bit (right panel).

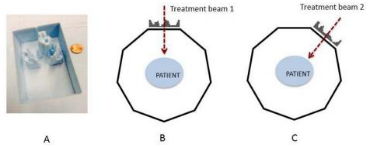

Figure 9: Schema for the use of compensators. **A:** compensator molds of foam or plastic are cut. Shown here is a prototype mold made on the machine shown in Figure 8. **B:** At the time of treatment a mold filled, with tungsten beads, is moved into position and the beam is treated. **C:** The device rotates to the next treatment angle. The next compensator is loaded and the next beam is treated. The process continues until all beams are treated.

Questions?

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