Bridging the Gap

A Cloud-based Collaboration with LMICs

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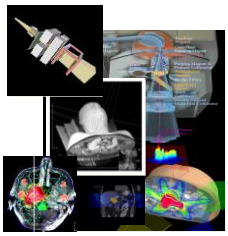
We made great progress in optimizing the planning and delivery of radiotherapy (Circa 2016)



Virtual simulation, 3D computation & optimization, IMRT, IGRT, MC Computation, PT, IMPT, etc.

Radiation Oncology Challenges in the LMICs

- **Safe practice of advanced radiotherapy procedures require complex and intricate information flow and handoffs.**

Challenges are:

- poor hardware/software integration,
- inadequate QA, inadequate training of healthcare professionals,
- poorly-defined clinical workflow,
- non-adherence to established clinical practice standards, and
- ambiguities in decision making process.

Radiation Oncology Challenges in the LMICs

- **Paucity of the state-of-the art equipment and trained staff**
  - Economic/Socio pressure to treatment as many patients as possible with advanced techniques in a given day creates stressful environment, which is potentially prone to errors.
- **Peer Pressure**
  - Complex treatment techniques have become the standard of care for the treatment of a wide variety of disease sites without systematic collection of high-quality evidence of improved outcomes and effectiveness under local conditions.

Need Assessment in the LMICs

- **The quality of radiotherapy in facilities in the developing world is highly variable, ranging from outstanding to needs improvement**
  - Challenge is to identify and improve substandard practices, as well as move the average towards higher quality and improved patient care.
- **Radiation Oncology is a technology driven medical specialty**
  - Challenge is to continue to deploy cutting-edge, effective, and safe technologies that adhere to consensus clinical practice guidelines.
    - **Guidelines must recognize local environment**
- **Radiation Oncology is a team-orientated medical specialty**
  - Challenge is to have well-educated, trained, disciplined and attentive healthcare team members.

Need Assessment in the LMICs

- **Development of a radiation treatment plan requires acquisition and synthesis of patient data from disparate sources and the stepwise generation of new data from patient intake to plan development to treatment.**
  - Challenge is to develop clinical/technical processes to improve quality of RT and reduce harm to patients.
- **Complex and expensive RT imaging and treatment techniques are sold in LMICs without much consideration to physical infrastructure.**
  - Challenge is to deter such practices.

Safety Lapses in Radiotherapy

Human factors are responsible for more than 80% of the safety lapses

- Develop a culture of safety
- Empower team members
- Define roles and responsibilities of all team members
- Understand technique specific process of care

IAEA Data

➢**Rigorous practice standards, accreditation, training, and education can improve the quality and safety of modern day radiotherapy but they will not prevent catastrophic errors.**

- ➢Standards of practice will likely need to be quite stringent to make a real difference

➢**Rigorous policies and procedures, reminders, checklists can minimize the frequency and consequences of errors but cannot eliminate them**

- ➢ASTRO/ACR/AAPM Consortium has developed "white papers", which provide a comprehensive review of all issues relevant to safe patient treatment (topics: IMRT, IGRT, SBRT, HDR, Peer Review)

➢**Better equipment design**

- ➢Forcing functions and constraints (e.g. interlocks, barriers, computerized order entry with feedback) and automation and computerization (e.g. barcodes, automated monitoring and verification, etc.)

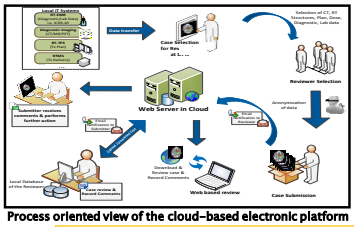
How Can HICs Help LMICs?

- Provide training and education in the safe implementation of advanced radiotherapy techniques
  - Customized to the local environment
- Work with the manufacturers in the development of radiotherapy equipment that is appropriate for LMICS
- Leverage electronic infrastructure to provide remote peer review of radiation oncology services in LMICs.

Cloud-based Collaboration for Global Radiotherapy Clinical Trials, Research and Training (Palta: PI)*

Specific Aim 1: Develop and deploy advanced facility for Cloud-based global peer review, QA, and sharing of anonymized radiotherapy data.

Specific Aim 2 : Provide radiation oncologists at the Massey Cancer Center and Tata Memorial Centre a CEP to plan advanced technology radiotherapy trials and facilitate collaborative research and training.



Process oriented view of the cloud-based electronic platform

Collaborators: Tata Memorial Center, Mumbai, India

NIH Funding: HHSN261200800001E; Administered by Leidos Biomedical Research Inc.

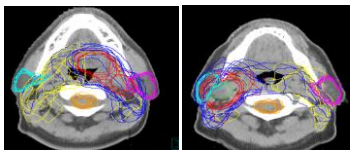
***Publications:** (1) Palta et. al., "Web-based submission, archive, and review of radiotherapy data for clinical quality assurance: A new paradigm", Int. J. Rad. Biol. Phys., 2003,57, 1427:1436, 2003
(2) Bekelman et. al. "Redesigning radiotherapy quality assurance: opportunities to develop an efficient, evidence-based system to support clinical trials-report of the national cancer institute work group on radiotherapy quality assurance, Int J Radiat Oncol Biol Phys. 2012, 83:782-90.

Quality Care in Radiation Oncology

(Peer Review)

What is needed:

- Consistency in clinical target and normal structure delineation



Concordance among GTV drawn by 'experts' ranged from 82% to 0%. Average was 53%".

Chao KS et al. IJROBP (2007)

The Peer-Review System (PRS)

Concept

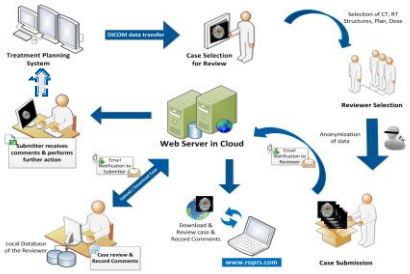
Develop a web-based IT Infrastructure for remote peer review of radiotherapy treatment planning data.

- *Interactive peer review*
- *Teaching Case examples*

Rationale

- Web-based technology can provide word-wide access to RT Data for peer review
- These resources allow the requester of peer review to collate RT Data and securely transmit for peer review without using any 3rd party software.

Typical PRS Workflow



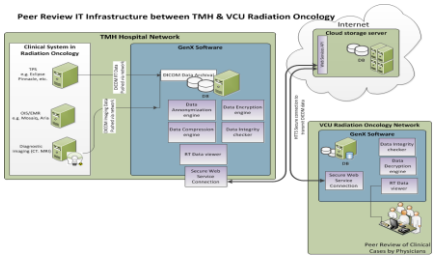
The GenXViewer Components

Web-based Secure Archiving System in the Cloud
- *Web-based secure DICOM-RT PACS*

Local Secure Archiving System
- *Local secure DICOM-RT PACS*

GenXViewer Uploading / reviewing station
- *Auto-anonymizing / uploading / case review tool*

GenXViewer Architecture



GenXViewer Components

1. Web-based Secure Archiving System in the Cloud: Web-based RT PACS

- Secure archiving system in the cloud that stores DICOM / non-DICOM anonymized data.
- Communicates with local secure archiving system for transfer of data.
- Database
  - *A collection of database tables*
  - *Database scheme, which is designed as a combination of DICOM object hierarchy and the requirements of the data collection and review process for protocol based data submission system.*
  - *A collection of stored procedures*
  - *An access application client designed for database management*
- Support for 12 bit gray scale clinical images
- Support for the storage of complimentary data to facilitate peer-review (for e.g. PDF, word, JPEG files).

GenXViewer Components

2. Local Secure Archiving system- Web-based RT PACS

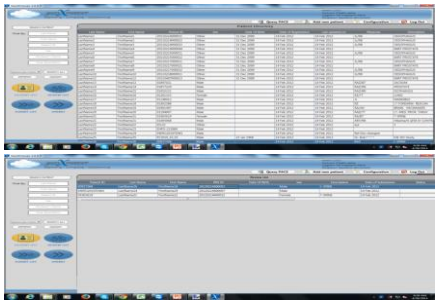
- Database is similar to the cloud based secure archiving system.
- Provides functionality of auto upload and download of data from the cloud based secure archiving system.
- Facilitates user account management.
- Network installation and interface facilities.
- Provide secure communication with Treatment Planning systems for transfer of DICOM data.
- Support for 12 bit gray scale clinical images
- Support for the storage of complimentary data to facilitate peer-review (for e.g. PDF, word, JPEG files).

GenXViewer Components

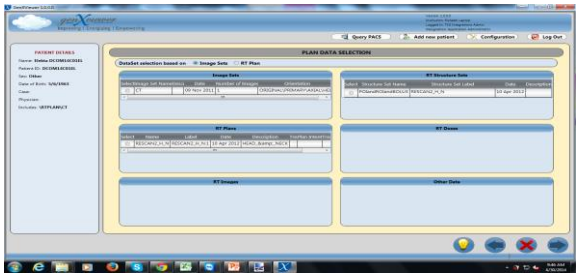
3. PRS Uploading / Reviewing station

Software functionalities

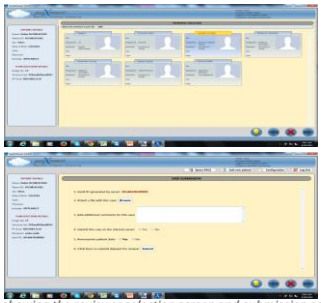
- DICOM Q / R service to query and retrieve DICOM RT data from PACS
- DICOM Push service to receive RT data from RT-TPS
- Auto-Anonymization of patient information before submitting to PRS web-server.
- Support for 12 bit gray scale clinical images
- Facility to select peer-reviewers
- Facility to attach additional supporting documents with the case submitted.
- Generate a unique GenX Case ID for each case submitted for peer review.
- Automatic notification to peer reviewers via email.
- Local case review capabilities.
- Automatic notification of status of submitted cases.



Screenshots of Patient directory & Review worklist on the local review station

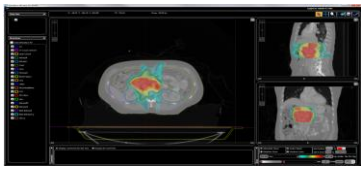


Screenshots of the DICOM RT data selection window.



Screenshots showing the reviewer selection screen and submission screen. Patient data anonymization is performed before the case is submitted for review.

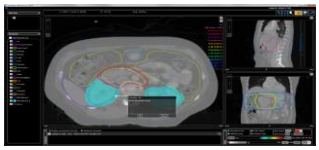
PRS Upload/Reviewing station – Review Process



Visualize the case

- Transverse, coronal and sagittal views of images
- CT images (in future MR / PET images will be presented)
- Scrolling, zooming and panning of images
- Dose display on images – color wash, isodose levels, absolute / relative dose.
- Point dose display
- Display of structures
- DVH computed and displayed
- Demographics (real or anonymized)

PRS Upload/Review Station – Review Process



Record Comments

- Comments can be recorded
  - For a plan.
  - for a transverse, coronal or sagittal section.
  - via annotating a point or free-hand drawing.
- Comment text can be of any length
- Record any number of comments for a case
- Comments are stacked serially and displayed
- Reviewer can modify/delete/add comments
- On submission of comments by the reviewer an email is generated and sent to the submitter giving the status of the case.
- Comments are automatically transferred to the submitter's local database.
- Submitter displays the review comments and takes appropriate further action

Clinical Collaboration with a LMIC: India

Opportunities:

- Large, genetically diverse patient population (over one billion) which greatly facilitates patient recruitment
- Significantly reduced cost of conducting clinical research (60% less than in the HIC) are major contributing factors.
- The emergence of common Western cancers in the Indian population
- The availability of advanced RT technologies (comparable to HIC)
- Qualified and skilled clinical investigators
- English-speaking hospital personnel

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Clinical Collaboration with a LMIC : India

Challenges:

- All clinical trial applications including RT are submitted to the Drugs Controller General of India (DCGI) for approval
- Additional approval from other agencies such as the Indian Council of Medical Research (ICMR) and the Department of Biotechnology (DBT) is necessary and time consuming
- India's Ethical Guidelines for Biomedical Research on Human Subjects include patient compensation for participation
  - This requirement introduces unspecified and unpredictable financial burden on the sponsor.

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Clinical Collaboration with a LMIC : India

What is needed?

- Regulatory overhaul (leadership and enforcement of regulations, resolution of ambiguity in regulations, staffing, training, guidelines, and ethical principles [e.g., compensation]).
- Education and training of research professionals, clinicians, and regulators.
- Awareness programs for patients, the public, and the media providing information about clinical research and empowering and encouraging participation (principles of autonomy, societal consent, community relevance, and shared responsibility).
- Never perform a study in LMIC that would not be approved in in the United States or Europe.

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Clinical Collaboration with a LMIC : India

Future:

- Indian government is seriously committed to improving the regulatory environment
  - Adoption of ICH-GCP (International Council for Harmonization- Good Clinical Practice) guidelines
- FDA plans to strengthen regulatory relationship with its counterpart; India Government's Central Drug Standards Control Organization (CDSCO)

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Summary

- Safe implementation of advanced radiotherapy technologies in LMICS requires special consideration of the local environment
  - Resources, physical and personnel infrastructure, training and education, etc.
- Electronic infrastructure (cloud-based) can facilitate rapid interaction, peer review, and clinical collaboration amongst HICs and LMICs