Database Sharing Model for Research and Decision Support in Radiation Therapy

The Oncospace Experience
Disclosures

This work has been partially funded with collaborations from:

Philips Radiation Oncology Systems
Elekta Oncology Systems
Toshiba Medical Systems

as well as

Commonwealth Foundation
Maritz Foundation
Objectives

1. Strategies for prospective collection and management of clinical data

2. Data-driven solutions to improve quality and efficiency in radiotherapy

3. Requirements for successful data sharing in multi-institutional efforts
Objectives

1. Strategies for prospective collection and management of clinical data
   a. What is “Oncospace”? 
   b. How is data collected, and what do we collect? 
   c. Patient privacy and IRB considerations
What is “Oncospace”? 

1. A solution for individualized patient care in radiation oncology 
   - Learning from prior patients 
   - Improving care for future patients 

2. A platform for data-driven insight discovery 
   - Prospective collection of clinical data 
   - Storage of 2D and 3D treatment planning data 
   - Support for multi-institutional data sharing
What is “Oncospace”? 

- Integration of data collection with clinical workflow 

Clinical Assessment  

Quality of life  

Disease Status
What is “Oncospace”?

- Integration of data collection with clinical workflow
- Database design, security, and distributed web-access
What is “Oncospace”? 

How to best to treat individual patient? 

Prediction of complications for early intervention? 

- Pathology 
- Diagnosis 
- Performance Status 
- Comorbidities 

TREATMENT 

- Surgery 
- Radiotherapy 
- Chemotherapy 

CONSULT 

FOLLOW-UP 

- Patient History 
- Survival 
- Quality of Life 
- Lab Values 
- Toxicities 
- Disease Status 

How to best to treat individual patient? 

Prediction of complications for early intervention? 

- Clinical assessments 
- Lab Values 
- Toxicities 
- Disease Status 

Follow-up
What is “Oncospace”?

- **Family History**
- **Social History**
- **Medical History**
- **Medications (chemo)**
- **Surgical Procedures**
- **Test Results (Labs)**
- **Assessments (Toxicities)**
- **Clinical Events**

**Patient**

**Private Health Info (access restricted)**

- **Tumors**
- **Radiation Summary**
- **Organ Dose Summaries**
- **Patient Representations (CT based geometries)**
- **Image Transform**

- **Image Feature**
- **Pathology Feature**
- **Organ DVH Data**
- **Organ DVH Feature**
- **Radiotherapy Sessions**
- **ROI Dose Summary**
- **ROI DVH Data**
- **ROI DVH Features**
- **Regions of Interest**
- **Shape Descriptor**
- **Shape Relationship**

1 : N multiple instances
1 : 1 single instance
m : n relates m to n
What is “Oncospace”?

• Tools for query, analysis, navigation and decision support

Browser Tools

Python Tools

MATLAB Tools

SAS, Java, and more
What do we collect?


Knowledge Base

Registry

Quality Reporting

Decision Support

Research

N↑  $/pt ↑
What do we collect?

Who am I about to see?

How are they doing?

Summarize in text?
What do we collect?

ROIs, DVH Curves, 3D Dose

Shape relationships
- Parotids
- PTV
How is data collected?

Electronic data capture directly into Mosaiq

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<td>Y</td>
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</tbody>
</table>
How is data collected?

Patient reported outcomes
How is data collected?

- Web interface
- SQL Queries
- Labs, Toxicities, Assessments

- Python scripts
- From TPS or DICOM
- ROIs, OVH, DVH, 3D dose

MOSAIQ

Pinnacle TPS & DICOM RT PACS

Oncospace
How is data collected?

• **Rule #1**: All patient data should be part of the official patient record
  – Discourage use of separate spreadsheets

• **Rule #2**: All patient data should be collected prospectively
  – Reduce the likelihood of bias in retrospective chart review
  – Improve data integrity and treatment quality
Changing landscape: it is unethical to \textit{not} learn from data we collect on our patients.
Patient privacy and IRB

• For data collected as standard of care:
  – No IRB necessary for collection into our oncology information system (OIS)
  – Expedited IRB usually sufficient for anonymized, retrospective “chart review”
Patient privacy and IRB

• For data collected as standard of care:
  – No IRB necessary for collection into our oncology information system (OIS)
  – Expedited IRB usually sufficient for anonymized, retrospective “chart review”

• **IRB approval is essential when practice extends beyond standard of care**
Objectives

1. Strategies for prospective collection and management of clinical data

2. Data-driven solutions to improve quality and efficiency in radiotherapy

3. Requirements for successful data sharing in multicenter efforts
Objectives

2. Data-driven solutions to improve quality and efficiency in radiotherapy
   a. Generating patient-specific DVH objectives
   b. Impact of treatment paradigm shifts
   c. Toxicity trends and prevalence
   d. Prediction of treatment-related complications
   e. Learning health system and decision support
2a. Automatic generation of patient-specific DVH objectives

- More efficient plan optimization (10 fold)
- Normal tissue doses reduced (5-10%)
- Clinically released for Pancreatic Cancer

Decisions:
- Plan quality assessment
- Automated planning
- Expected toxicities
- Dosimetric trade-offs

Courtesy of B. Wu
2a. Automatic generation of patient-specific DVH objectives

<table>
<thead>
<tr>
<th></th>
<th>Brain (Gy) (max)</th>
<th>Brainstem (Gy) (max)</th>
<th>Cord4mm (Gy) (max)</th>
<th>L inner ear (Gy)(mean)</th>
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<tbody>
<tr>
<td>original</td>
<td>61.25</td>
<td>54.58</td>
<td>41.75</td>
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<td>re-plan</td>
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<td>61%</td>
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<tr>
<td>original</td>
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<tr>
<td>re-plan</td>
<td>38.38</td>
<td>63.78</td>
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</table>
2b. Assessing the impact of treatment paradigm shifts

- **Group 1: Traditional Practice (2007-2011)**
  - Routine use of narcotics reactive to pain

- **Group 2: Gaba (2011-2013)**
  - Prophylactic gabapentin with narcotics as needed

- **Group 3: Gaba+Oxy (2013-2014)**
  - Prophylactic gabapentin with prophylactic low-dose narcotics titrated to effect

Courtesy of W. Yang, Z. Cheng
2b. Assessing the impact of treatment paradigm shifts

<table>
<thead>
<tr>
<th></th>
<th>Traditional (n=305)</th>
<th>Gaba (n=171)</th>
<th>Gaba+Oxy (n=45)</th>
<th>p-value</th>
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<td>Male, %</td>
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<td>76</td>
<td>71</td>
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<td>Caucasian, %</td>
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<td>54</td>
<td>60</td>
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<td>6897</td>
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<td>35</td>
<td>35</td>
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<td>Pharynx, %</td>
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<td>49</td>
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<td>0.0433</td>
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<td>Chemotherapy, %</td>
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<td>72</td>
<td>62</td>
<td>&lt;.0001</td>
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<td>N Stage ≥2, %</td>
<td>63</td>
<td>55</td>
<td>67</td>
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<td>T Stage ≥3, %</td>
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<td>43</td>
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</table>

Courtesy of W. Yang, Z. Cheng
2b. Assessing the impact of treatment paradigm shifts

<table>
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<th></th>
<th>Traditional</th>
<th>Gaba</th>
<th>Gaba+oxy</th>
<th>p-value</th>
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<td>1</td>
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<tr>
<td>Tx Duration, day</td>
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<td>&lt;.0001</td>
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<td>Weight Loss</td>
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<td>Kg,</td>
<td>7</td>
<td>6</td>
<td>5</td>
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<td>%</td>
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<td>8</td>
<td>7</td>
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</tbody>
</table>

Courtesy of W. Yang, Z. Cheng
2c. Toxicity trends and prevalence

**Dysphagia**
Swallowing

- Worsens after Tx for many patients then improves long term

**Mucositis**
Inflammation

- Heals after Tx for most patients

**Xerostomia**
Dry Mouth

- Tends to be permanent
2c. Toxicity trends and prevalence

- Dysphagia < 1
- Xerostomia < 2
- Mucositis < 2
- Taste (Dysgeusia) < 1
- Weight Loss < 1

4 yrs

Courtesy of P. Lakshminarayanan
2d. Predicting treatment-related complications
2d. Predicting treatment-related complications

TOXICITIES / OUTCOMES

MODELLED RISK

10%/Gy

5%/Gy
2d. Predicting treatment-related complications

Grades 0-1 xerostomia
Grades 2-3 xerostomia
DrA (mean 1.32)
DrB (mean 1.13)
DrC (mean 1.59)

Acute Xerostomia Scores

Acute Xerostomia
2e. Learning health system and decision support

Knowledge Database

Predictive Modeling

Decisions

Presentation of Predictions

Data Feedback (Facts, Outcomes)

Facts

Controls

Outcomes

time

Decision Point
2e. Learning health system and decision support

Post-Treatment Weight Loss Prediction
Endpoint: > 5kg loss at 3 months post RT

At planning

- Diagnostic ICD-9
  - Larynx
  - Salivary glands
  - Nasal cavity
- Superior Constrictor Muscle D100 < 40Gy
- Masticatory Muscle D90 < 14Gy

At end of RT

- Larynx D78 < 24Gy
- Parotid D96 < 7Gy
- Skin Acute < 3
- N stage < 2
- Pain Intensity < 5
- Distance: PTV to Larynx >= -1.3cm
- Parotid D96 < 7Gy

Able to eat foods I like >= 3

Courtesy of N. Minoru, Z. Cheng
2e. Learning health system and decision support

Pancreas Resectability Prediction

<table>
<thead>
<tr>
<th>Variable, mean</th>
<th>LA (n=76)</th>
<th>BR (n=20)</th>
<th>P-value</th>
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<td>PTV volume</td>
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<td>66.7585</td>
<td>0.0065*</td>
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</table>

Courtesy of N. Minoru, Z. Cheng
Objectives

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3. Requirements for successful data sharing in multicenter efforts
Objectives

3. Requirements for successful data sharing in multicenter efforts
   a. Syntactic vs semantic interoperability
   b. The Oncospace consortium: data governance model
   c. Pragmatic controlled trials: every patient on trial
Syntactic vs semantic interoperability

- Syntactic: **format** of data is consistent between systems
  - Example: two pain scales with four choices:

- Semantic: **meaning** of data is consistent between systems
The Oncospace consortium: data governance model

Johns Hopkins

- Pancreas 150+ pts
- Panc SBRT
- Head & Neck 700+ pts
- Thoracic
- Prostate 400+ pts

Institution 1-N (UW)

- Head & Neck
- Panc SBRT
- Prostate

Limited access

Shared
The Oncospace consortium: data governance model

- Institutions own their data
- Institutions enter into agreements on exactly what *anonymized* data may be shared
- Shared data may be raw, filtered, or processed
The Oncospace consortium: data governance model

• Data sharing is not perceived to be a technical problem

• Anticipated challenges:
  – Whose data dictionary to use?
  – Who gets credit for the data collected?
  – How should findings, recommendations be disseminated?
Pragmatic controlled trials: every patient on trial

• How can we learn from every patient we treat?

• How can we assess the efficacy of current treatment paradigms?

• How do we identify areas in need of the greatest improvement?
Pragmatic controlled trials: every patient on trial

• Separation of responsibilities
  – **Physicians** drive a culture of data collection
  – **Residents, nurses**, other staff generally collect the data
  – **Medical physicists** promote data integrity
  – **Computer programmers, IT personnel** support data flow, security
    • DICOM destinations
    • Web access, user permissions
Pragmatic controlled trials: every patient on trial

• Collect what matters
  – Time and resources often limited
  – Can’t document everything

• Adopt a standard (RTOG, CTCAE, etc.)
  – Sometimes possible to map between standards, as in ROI naming conventions

• Collect data electronically

• Encourage data reuse
Pragmatic controlled trials: every patient on trial
Pragmatic controlled trials: every patient on trial

• Viability and Value
  – Predictive factors must be accessible for new patients
  – Predictions must be clinically valuable and EXTEND the knowledge of the clinician
Pragmatic controlled trials: every patient on trial

- *Deeper data leads to deeper insight!*
Pragmatic controlled trials: every patient on trial

- Correlation is not causation!
The future of Oncospace at Johns Hopkins

• Continued integration of data sources

• Higher data resolution and objectivity

• Continuous monitoring of patient quality of life outside of hospital walls
The future of Oncospace at Johns Hopkins

• Decision support
  – **SAFETY**: alerts when patient treatment information deviates from normal
  – **QUALITY**: predicting *and* achieving high treatment plan efficacy
  – **PERSONALIZATION**: continuous learning from current patients to benefit future patients
Acknowledgments
Program Director: Dr. Todd McNutt

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  - Theodore DeWeese MD
  - Michael Bowers
  - GI Team
    - Joseph Herman MD
    - Amy Hacker-Prietz PA
  - H&N Team
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    - Giuseppe Sanguineti MD
    - Heather Starmer MD
    - Jeremy Richmond MD
    - Anna Keiss MD

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    - Patrick Kwok

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