Impact of Complexity and Computer Control on Errors in Radiation Therapy

Benedick A Fraass PhD, FAAPM, FASTRO, FACR

Vice Chair for Research and Director of Medical Physics
Department of Radiation Oncology
Cedars-Sinai Medical Center, Los Angeles, CA

and

Professor Emeritus, University of Michigan
• H/N patient received 3 x 13 Gy: (open MLC with IMRT MUs)
• Breast patient received 27 Fx, w/o large wedge (3.5x expected dose)
Complexity, Computer Control and Radiotherapy Errors

- Basic Radiotherapy Methods
- Studying Errors in Radiotherapy
- Efforts to Address Radiotherapy Safety
- Conclusions
1. Define the Target Volume(s) and Create an Anatomical Model of the Patient
2. Focus Multiple Beams on the Target
3. Calculate and Evaluate the Dose
3. Calculate and Evaluate the Dose
4. Treat the Patient
Complexity, Computer Control and Radiotherapy Errors

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- Conclusions
1950s-80s: 2-D Radiotherapy
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A dose distribution that **conforms** to the shape of the target volume(s), in 3-D, while **minimizing** dose to critical normal structures.
A dose distribution that conforms to the shape of the target volume(s), in 3-D, while minimizing dose to critical normal structures.

95% Isodose Surface

Bladder

Prostate

Target Volume

Rectum

Beam's Eye View (BEV)
2000s: Conformal Therapy with Intensity Modulated Radiation Therapy (IMRT)

**IMRT:** Rather than uniform intensity beams, optimize the intensities of “beamlets” to allow further improvement of the dose distribution.
2010: Image-Guided Radiotherapy (IGRT)

Cone beam CT at the treatment unit
Now that we can visualize + monitor motion, where/when do we need to take it into account?
In recent years, complexity of radiation treatment delivery has increased due to:

- 3-D treatment planning
- Conformal radiotherapy
- Computer-controlled treatment machines
- Multileaf collimators
- Intensity modulated radiation therapy (IMRT)
- 4-D everything

Does all the complexity lead to more errors?
Radiotherapy Planning/Delivery Process

Prescription

Target + few normal contours

3-D Treatment Planning

MU Calculation

Tx Delivery Prep

Check MUs

Download to Deliv. System

Pat. Setup+

Imaging

Tx: One field at a time, single shape

Portal image Verification +/- R/V
Radiotherapy Planning/Delivery Process

Prescription

IMRT: Plan Directive

RT: 45 Gy to Isocenter, 2 Gy/Fx
RT: 45 Gy to Isocenter, 2 Gy/Fx

Radiotherapy Planning/Delivery Process

Prescription

IMRT: Plan Directive
Radiotherapy Planning/Delivery Process

- Prescription
- Target(s) + normal contours
Radiotherapy Planning/Delivery Process

Prescription

Target(s) + normal contours

Bladder

Rectum

Target

Bladder
Radiotherapy Planning/Delivery Process

**Prescription**

**Target(s) + normal contours**

**IMRT:** Unlike 3DCRT, must carefully define any structure that you want to influence the plan.
Radiotherapy Planning/Delivery Process

Prescription

Target + few normal contours

3-D Treatment Planning
Radiotherapy Planning/Delivery Process

- Prescription
- Target + few normal contours
- Inverse Treatment Planning
- IMRT: Each beam divided into many beamlets
Radiotherapy Planning/Delivery Process

Head/Neck IMRT protocol planning objectives for Inverse Planning

<table>
<thead>
<tr>
<th>Structure</th>
<th>Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTV1</td>
<td>70 Gy (mean +/- 3%, min 93%, max 115%)</td>
</tr>
<tr>
<td>PTV2</td>
<td>60 Gy (mean +/- 3%, min 93%, max 115%)</td>
</tr>
<tr>
<td>Nodal Boost PTV</td>
<td>70 Gy (mean +/- 3%, min 93%, max 115%)</td>
</tr>
<tr>
<td>High Risk Nodal PTV</td>
<td>64 Gy (mean +/- 3%, min 93%, max 115%)</td>
</tr>
<tr>
<td>Low Risk Nodal PTV</td>
<td>57.6 Gy (mean +/- 3%, min 93%, max 115%)</td>
</tr>
<tr>
<td>Spinal Cord</td>
<td>Less than or equal to 45 Gy</td>
</tr>
<tr>
<td>Spinal Cord + 5 mm</td>
<td>Less than or equal to 50 Gy</td>
</tr>
<tr>
<td>Brainstem</td>
<td>Less than or equal to 54 Gy</td>
</tr>
<tr>
<td>Right Parotid</td>
<td>Mean dose less than or equal to 26 Gy</td>
</tr>
<tr>
<td>Left Parotid</td>
<td>Mean dose less than or equal to 26 Gy</td>
</tr>
<tr>
<td>Mandible</td>
<td>Less than or equal to 70 Gy</td>
</tr>
<tr>
<td>Submandibulars</td>
<td>Minimize dose</td>
</tr>
<tr>
<td>Oral Cavity</td>
<td>Less than or equal to 70 Gy</td>
</tr>
</tbody>
</table>
Radiotherapy Planning/Delivery Process

- Prescription
- Target + few normal contours
- Inverse Treatment Planning
Radiotherapy Planning/Delivery Process

MU Calculation

Tx Delivery Prep

\[ \text{MU} = \frac{\text{Dose}}{(\text{Cal} \times \text{TPR} \times \text{Scp} \times \text{ISL} \ldots)} \]
Radiotherapy Planning/Delivery Process

**MU Calculation**

**IMRT: MLC Sequencing algorithm to calc MLC trajectories and intensities**

\[ \text{MU} = \frac{\text{Dose}}{(\text{Cal} \times \text{TPR} \times \text{Scp} \times \text{ISL} \ldots)} \]
Radiotherapy Planning/Delivery Process

- **MU Calculation**
- **Tx Delivery Prep**
- **Check MUs**

Check by hand:
Dose = MU x Cal x TPR x Scp x ISL . . . )
Patient-specific IMRT QA: Measure delivered IMRT distribution in phantom, each field, then composite for plan.
Some Technical Safety Issues for IMRT

- Delineation of targets + normal tissues is crucial
- Good vs bad plan determined indirectly by optimization cost function – not direct clinical input
- Beam shapes, intensities, directions not intuitive
- Monitor Units (MU) not directly related to dose – no back of the envelope checks
- Hand checks of plan, MLCs, MUs not possible
- Plan, beams, MUs not intuitive
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Most of the intuitive checks we used to have, and the ability to confirm “reasonability”, can no longer be done by therapists - or anyone
Complexity, Computer Control and Radiotherapy Errors

• Basic Radiotherapy Methods
• Changes in Radiotherapy: New Technology, New Goals, New Complexity
• Studying Errors in Radiotherapy
• Efforts to Address Radiotherapy Safety
• Conclusions
# Radiotherapy Errors

(detected with independent Record/Verify System)

<table>
<thead>
<tr>
<th>Error Rate</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 % / Session</td>
<td>Kartha, 1977</td>
</tr>
<tr>
<td>1% / Field</td>
<td>Podmaniczky 1985</td>
</tr>
<tr>
<td>0.18% / Field</td>
<td>Macklis, 1998 *</td>
</tr>
</tbody>
</table>

* Some errors caused by R/V
% of Errors “due to” Record/Verify

<table>
<thead>
<tr>
<th>Error Rate</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.3 %</td>
<td>Macklis, 1998</td>
</tr>
<tr>
<td>23.7 %</td>
<td>Patton, 2003</td>
</tr>
<tr>
<td>15.6 %</td>
<td>Huang, 2005</td>
</tr>
</tbody>
</table>
R/V-Related Errors

• Solution: Integrate the R/V system into the planning/delivery system
• However, this removes the independence of the R/V system.
• We are left with an integrated computer-controlled treatment delivery system
UM-CCRS: Computer-controlled Conformal Radiotherapy System

- TxPlan
- Optim.
- Tx Plan Conversion
- CCRS e-chart
- Clinic Sched
- Charge Capture
- Computer-controlled Tx Delivery
- Auto Setup
- Tx Verif.
- EPID Use
- Tx Delivery Planning
- Tx Documentation

1988-2001
Does computer-controlled Tx delivery decrease error rates, in spite of an increase in Tx complexity?

• Had opportunity to compare errors between manual and computer-controlled Tx (UM CCRS)
• All ExtBeam Txs 7/96 thru 9/97 were studied (>34k fractions)
• Tx delivery errors from QA logs, retrospective e-chart analysis, logged by therapists

## Manual vs. Computer-Controlled Radiation Therapy

### Machine:
- **M1**: C6-100
- **M2**: C1800
- **M3**: C2100CD
- **M4**: Microtron

### Computer Control
- **M1**: None
- **M2**: None
- **M3**: Mostly
- **M4**: Full control

### Treatment Delivery Method
- **Manual**: Individual fields set by therapists

### Field Shaping

![Field Shaping Image]

**CCRS**
Increasing Plan Complexity

Machines:

M1 → M4

High Dose Brain Tx:
5 fields/9 segs, CCRS

Few-Field Plans w/ Blks
### Tx Delivery Error Analysis

(34k Tx sessions, 114k segments)

#### Machine Errors (%/Segment)

<table>
<thead>
<tr>
<th>Errors</th>
<th>M1</th>
<th>M2</th>
<th>M3</th>
<th>M4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machine Setup</td>
<td>.03</td>
<td>.13</td>
<td>.02</td>
<td>.003</td>
</tr>
<tr>
<td>Accessories</td>
<td>.09</td>
<td>.09</td>
<td>.02</td>
<td>.003</td>
</tr>
<tr>
<td>Total/Segment (%)</td>
<td>.12</td>
<td>.22</td>
<td>.03</td>
<td>.006</td>
</tr>
</tbody>
</table>

Expect that these errors are under-reported, probably are 1-2 %
Almost no way to find random setup errors for manual setup, except weekly portal images.

### Setup+Prescription Errors (%/session)

<table>
<thead>
<tr>
<th>Errors</th>
<th>M1</th>
<th>M2</th>
<th>M3</th>
<th>M4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient setup</td>
<td>.03</td>
<td>.07</td>
<td>.21</td>
<td>.12</td>
</tr>
<tr>
<td>Patient/Plan choice</td>
<td>0</td>
<td>0</td>
<td>.04</td>
<td>.03</td>
</tr>
<tr>
<td>Prescription/Chart</td>
<td>.01</td>
<td>.10</td>
<td>.04</td>
<td>.03</td>
</tr>
<tr>
<td>Total/session (%)</td>
<td>.05</td>
<td>.17</td>
<td>.28</td>
<td>.18</td>
</tr>
</tbody>
</table>

No way to identify these manual errors

- Automated QA check of daily table coords highlights all setup inconsistencies
- One specific process problem: 90% of these errors

Fraass IJROBP 42 (1998)
Deviation rate as MLC technology was introduced

Technology, by itself, is not the problem

<table>
<thead>
<tr>
<th>Type of Error</th>
<th>Rel. Risk (95% CL)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLC</td>
<td>1.9 (1.3 - 2.9)</td>
<td>0.001</td>
</tr>
<tr>
<td>External Blk</td>
<td>4.4 (3.1 - 6.3)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>External Wdg</td>
<td>1.3 (0.8 – 1.9)</td>
<td>0.28</td>
</tr>
<tr>
<td>Internal Wdg</td>
<td>2.6 (1.4- 4.5)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

- External Block required direct daily actions by RTT, while MLC was set by control system
- External Wdg had direct visual check by RTT, while programmed internal Wdg did not.

Despite Complexity, Errors Can Decrease

<table>
<thead>
<tr>
<th>Type</th>
<th>Non-IMRT</th>
<th>IMRT</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Error</td>
<td>0.21 %</td>
<td>0.03 %</td>
<td>0.0004</td>
</tr>
<tr>
<td>Error and Potential Error</td>
<td>0.40 %</td>
<td>0.14 %</td>
<td></td>
</tr>
</tbody>
</table>

24,775 courses over 3 years.
3 academic and 16 community practices

- Multivariate analysis of higher severity and any error correlated with reduced errors with IMRT.
- No significant difference between academic and community practices.
- No change in error frequency despite 39 changes by centralized Quality Improvement Committee

AC Olson, RE Wegner, C Scicutella, DE Heron, JS Greenberger, S Huq, G Bednarz, JC Flickinger: QA Analysis of a Large Multicenter Practice: Does Increased Complexity of IMRT Lead to Increased Error Frequency? IJROBP 81: S565, 2011
Should We Avoid Complexity?

Is complexity associated with improved overall survival?

1733 NSCLC (IIIB) patients >65 yrs

<table>
<thead>
<tr>
<th>Patients</th>
<th>RT Planning</th>
<th>Hazard Ratio *</th>
</tr>
</thead>
<tbody>
<tr>
<td>148</td>
<td>Simple</td>
<td>-</td>
</tr>
<tr>
<td>1138</td>
<td>Intermediate</td>
<td>0.75 (0.62 – 0.91)</td>
</tr>
<tr>
<td>447</td>
<td>Complex</td>
<td>0.69 (0.55 – 0.86)</td>
</tr>
</tbody>
</table>

* p = 0.0002

## IMRT vs 3D/Conventional

<table>
<thead>
<tr>
<th>Type of Tx</th>
<th>Error Rate (95% CL)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>3D/Conventional</td>
<td>0.07% (0.06 – 0.09%)</td>
<td>0.0008</td>
</tr>
<tr>
<td>IMRT</td>
<td>0.03% (0.02 – 0.05%)</td>
<td></td>
</tr>
</tbody>
</table>

**DN Margalit, YH Chen, PJ Catalano, K Heckman, T vivenzio, K Nissen, LD Woldsberger, RA Cormack, P Mauch, AK Ng: Technological advancements and error rates in RT delivery. IJROBP 81: in press, 2011**
## Errors Detected by Systematic In Vivo Dosimetry

7519 patients, in vivo dosimetry (5 years)

<table>
<thead>
<tr>
<th>Tx Preparation</th>
<th>Tx Execution</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 Prescription</td>
<td>7 Tx Setup</td>
</tr>
<tr>
<td>3 Planning</td>
<td>19 Delivery</td>
</tr>
<tr>
<td>46 Calculation</td>
<td>1 Technical Failure</td>
</tr>
</tbody>
</table>

78 / 79: involved human error

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A Noel, P Aletti, P Bey, L Malissard: Detection of errors in individual patients in radiotherapy by systematic in vivo dosimetry. Radiotherapy and Oncology 34:144-151, 1995
How Big are the Errors?

13,385 patients, 10 years

A big challenge:
The rate of dosimetrically-significant errors (>10%) is << 0.1 %, so we are looking for such errors in 1-2 patients per year in a normal clinic.
Complexity, Computer Control and Radiotherapy Errors

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One note: nearly all the error-related studies discussed earlier were performed and published before these articles.
Good Results of the NY Times Publicity:

Various National Safety-Related Initiatives

- Has led to introspection within many depts, opening windows for analysis + action
- Publicity has led to new involvement in QA + safety issues within ASTRO, AAPM, ACR etc:
  - New analysis and initiatives by FDA
  - AAPM Task Groups – Safety, not just QA
  - Safety White Papers (ASTRO et al)
  - Work toward National Event-Reporting Program
  - Safety Stakeholders Initiative – Vendors + Orgs (ASTRO, AAPM, etc)
Bad Results of the NY Times Publicity?

A few incorrect conclusions “learned” from the NY Times IMRT error:

1. We can fix this with one new QA test . . .
   But almost all errors have many contributing factors

2. High-tech Tx techniques are the problem . . .
   But what about recent stereotactic calibration errors?

3. The vendors and FDA just need to make error-free software and control systems. . . .
   But testing cannot find all errors

4. More rigorous practice standards and/or accreditation, by themselves, will prevent this
   But catastrophic errors happen to good people
Given all the bad things that can happen, we must do much more QA

NO.

• We must evaluate risks, processes, potential failure modes
• We must better prioritize our safety/QA efforts
• We must spend our efforts on the most frequent, severe, and risky problems, not just the problems amenable to QA
Conclusions

• Radiotherapy is immensely more complex than 20 years ago, but complexity in RT is neither bad nor good – it’s just different
• Error rates, especially for clinically significant errors, are very low
• The types of errors which occur now are very different: New QA approaches are required
• Improving radiotherapy safety requires:
  • Comprehensive efforts for each treatment method
  • Process-oriented safety analysis and QA
  • Careful, complete QA programs in each clinic
  • Realistic + sophisticated guidance from regulators and other organizations