LDR PROSTATE 2
CONFLICTS OF INTEREST FOR THIS SESSION

- Zhe (Jay) Chen: Reports an NIH research grant
- Zoubir Ouhib: is a member of the Elekta Speakers’ Bureau
- The following speakers have no conflicts to declare relevant to this session.
  - Ron Sloboda
  - Luc Beaulieu
- Specific commercial equipment and materials are cited to fully explain the procedures. Such citation does not imply endorsement by the speaker nor imply that the commercial product is necessary or the best available for the procedure.
- Opinions expressed are solely those of the speaker and are not meant to supersede official societal guidance.
LDR PROSTATE: ADAPTIVE WITH TRUS OR MRI

Ron S. Sloboda, Ph.D., FCCPM
Senior Physicist, Cross Cancer Institute
Professor, University of Alberta
Edmonton, AB, Canada
Learning Objectives

- Identify 3 considerations motivating adaptive planning for LDR prostate brachytherapy
- Distinguish between intraoperative preplanning, interactive planning, and dynamic dose calculation
- Describe the steps involved in seed localization for interactive planning using a monochrome B-mode US imager and biplane TRUS probe
Motivation

- Patient set-up for a pre-implant TRUS study cannot be replicated exactly in the OR
- Prostate shape and size can change between the pre-implant TRUS study and the implant
- Pre-planning does not offer a means to compensate for imprecise seed placement
- Pre-planning does not account for prostate edema associated with needle introduction
Approaches to Adaptive Planning

After initial imaging for TP in the OR, patient and imaging set-ups remain fixed. TG-137 identifies 3 distinct forms of adaptive planning:

▪ Intraoperative preplanning – TP creation followed by immediate execution in the OR

▪ Interactive planning – stepwise refine of a TP using image-based needle position feedback

▪ Dynamic dose calculation – constant TP updating using continuous deposited-seed-position feedback
Intraoperative preplanning

- Aims to address changes in prostate volume with time and replication of the patient set-up in the OR
- Distinctions from conventional preplanning are the planning venue, and the need to maintain a stock of brachytherapy seeds
- Differential fiscal costs and procedural risks vs. conventional preplanning are proportional to the OR time spent in TP
Interactive Planning

- Aims to improve on intraop preplanning by using seed locations inferred from imaged needle positions
- TP adaptations: (1) reposition current needle; (2) modify positions of remaining needles
- Dosimetry updated per physician preference
- Anatomical structure delineations typically not updated (though they can be)
Interactive Planning

(a) TRUS longitudinal image plane identification
(b) Needle & seed locating in the longitudinal plane
## Interactive Planning

<table>
<thead>
<tr>
<th>Consideration</th>
<th>Conventional Preplanning</th>
<th>Interactive Planning</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRUS volume study location</td>
<td>imaging room</td>
<td>operating room</td>
</tr>
<tr>
<td>preplanning location</td>
<td>planning room</td>
<td>operating room</td>
</tr>
<tr>
<td>seed order</td>
<td>based on preplan</td>
<td>estimated or from seed bank</td>
</tr>
<tr>
<td>implant dosimetry basis</td>
<td>pre-implant structure contours,</td>
<td>optionally updated contours,</td>
</tr>
<tr>
<td></td>
<td>preplanned seed positions</td>
<td>real-time needle positions</td>
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<tr>
<td>implant variations guidance</td>
<td>brachytherapist alone</td>
<td>real-time dosimetry, brachytherapist</td>
</tr>
</tbody>
</table>
Dynamic Dose Calculation

- Aims to improve on interactive planning by capturing deposited seed locations in real time, and accounting for prostate motion and size/shape changes during implantation.
- TP adaptations: (1) reposition current needle; (2) modify positions of remaining needles.
- Dosimetry updated automatically.
- Anatomical structure delineations updated as implant progresses.
Dynamic Dose Calculation

(a) fluoroscopy-aided set-up including tracking fiducial; (b) axial TRUS image; (c) x-ray image

From Dehghan et al, in Abdomen and Thoracic Imaging: An Engineering and Clinical Perspective, Springer US, 2014; 587-621, with permission
Dynamic Dose Calculation

Workflow: (a) axial TRUS data; (b) reconstructed TRUS volume; (c) 3-view C-arm data; (d) seed centroid reconstruction; (e) TRUS axial slice overlaid with registered seeds, prostate contour, Rx isodose

From Dehghan et al., in Abdomen and Thoracic Imaging: An Engineering and Clinical Perspective, Springer US, 2014; 587-621, with permission
MODEL-BASED DOSE CALCULATION IN PROSTATE SEED IMPLANTS

Luc Beaulieu, Ph.D., FAAPM

Professor and Director, Université Laval Cancer Research Centre Medical Physicists, Quebec City University Hospital
LEARNING OBJECTIVES

- Understand the limitations of TG43 for LDR seed implants

- Provide an order of magnitude of the effect of heterogeneities
  - Tissue
  - Inter-seed attenuation
  - Calcification

- A radiobiology perspective
KEY REFERENCES


• Brachytherapy physics, 2ed, AAPM monograph #31, 2005.

• This summer school book!
<table>
<thead>
<tr>
<th>anatomic site</th>
<th>photon energy</th>
<th>absorbed dose</th>
<th>attenuation</th>
<th>shielding</th>
<th>scattering</th>
<th>beta/kerma dose</th>
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<td></td>
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</tbody>
</table>

IMPORTANCE OF THE PHYSICS: WATER VS. TISSUES

IMPORTANCE OF THE PHYSICS: ATTENUATION BY METALS

From NIST website
PROSTATE LDR BRACHYTHERAPY

JF Carrier et al., IJROBP 2007

≈ 4% ↓

≈ 3% ↓
Interseed Attenuation

Fig. 7. D90 attenuation in two cases due to complete seed geometry.

JF Carrier et al., Med Phys 2006
Afsharpour et al., Med Phys 2008
CALCIFICATIONS

- Chibani & Williamson, Med. Phys. 2005
CALCIFICATIONS

(g) Significant calcification

(h) Typical patient

CA Collins-Fekete et al., Radiother Oncol 2014
AVERAGE OF 42 SELECTED PATIENTS WITH VISIBLE CALCIFICATIONS

<table>
<thead>
<tr>
<th></th>
<th>D_WATER</th>
<th>D_CALCI</th>
<th>D_FULL_MC</th>
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<tbody>
<tr>
<td>D_{10%}</td>
<td>98.7±0.4</td>
<td>94.8±08.8</td>
<td>92.3±08.4</td>
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<tr>
<td>D_{90%}</td>
<td>98.4±0.4</td>
<td>88.6±12.1</td>
<td>86.8±09.2</td>
</tr>
<tr>
<td>V_{100%}</td>
<td>99.6±1.1</td>
<td>93.5±18.4</td>
<td>93.8±17.7</td>
</tr>
<tr>
<td>V_{150%}</td>
<td>99.1±0.6</td>
<td>92.1±12.0</td>
<td>90.7±10.2</td>
</tr>
<tr>
<td>V_{200%}</td>
<td>97.2±1.1</td>
<td>84.9±13.3</td>
<td>80.8±12.6</td>
</tr>
</tbody>
</table>

**TABLE:** Dosimetric indices differences to TG-43

CA Collins-Fekete et al., Radiother Oncol 2014
CALCIFICATIONS

\[
\begin{align*}
V_{100} & \quad y = (-1.62)x + (-2.45) \\
R^2 &= 0.71
\end{align*}
\]

\[
\begin{align*}
D_{90} & \quad y = (-2.51)x + (-5.68) \\
R^2 &= 0.84
\end{align*}
\]

Miksys et al., IJROBP 97 (2017) 606-615
CALCIFICATIONS

Miksys et al., IJROBP 97 (2017) 606-615
IMPACT ON RADIOBIOLOGICAL DOSE
Summary of results
11 biological doses models (varying complexity) and corresponding TCP estimates

Radiobiological doses – also considered IED = Isoeffective dose [Zaider & Minerbo, PMB 45 (2000); Zaider & Hanin, PMB 52, 6355 (2007)]

Miksys et al, Med Phys 2017 (Online – accepted manuscript)

Slide by Rowan Thomson
CONCLUSION

- TG43 underestimate the actual dose received in prostate seed implants
  - Average -6% on D90
  - Patient dependent

- Strong impact of localized calcifications
  - About 10% of the patients in the cohort studied
  - 0.3 cc adds -4-5% on D90. 1.5 cc leads to -25%
  - Potential cold spots in tumor bearing areas

- Small differences between MC and TG43 in biological dose can lead to large differences in TCP
  - Effect of low dose regions amplified
LDR PROSTATE II - RADIOBIOLOGY

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Professor
Department of Therapeutic Radiology
Yale University School of Medicine
New Haven, Connecticut
LEARNING OBJECTIVES

- Get acquainted with some of the tools used in investigating the biologic effects of LDR prostate brachytherapy

- Become aware of the key radiobiological features of LDR prostate brachytherapy & their potential clinical implications and applications
DOSE-DELIVERY CHARACTERISTICS

- Sources used in current clinical practice:

<table>
<thead>
<tr>
<th>Radio-nuclide</th>
<th>&lt;Energy&gt; (keV)</th>
<th>Half-Life (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$^{125}$I</td>
<td>28.5</td>
<td>59.4</td>
</tr>
<tr>
<td>$^{103}$Pd</td>
<td>21</td>
<td>17.0</td>
</tr>
<tr>
<td>$^{131}$Cs</td>
<td>30.4</td>
<td>9.7</td>
</tr>
</tbody>
</table>

- Each with a unique temporal dose delivery pattern:
**SURROGATES OF BIOLOGIC EFFECT**

- **Linear-quadratic (LQ) cell survival model**

  \[ S = \exp[-(\alpha D + \beta D^2)] \]

  \[ S = \exp[-(\alpha D + \beta G(\mu,T)D^2) + \ln 2(T - T_k) / T_d] \]

  - Dose protraction / DNA repair effect
  - Repopulation effect

- **Biologically effective dose (BED)**

  \[ BED \equiv - \frac{1}{\alpha} \ln S = D(T) \left(1 + \frac{G(\mu,T)D(T)}{\alpha / \beta}\right) - \ln 2 \cdot (T - T_k) / \alpha T_d \]

  - Relative effectiveness
**LQ-BASED BED MODEL: DALE FORMALISM**

\[
BED = D(T)RE(T) - \frac{\ln 2 \cdot (T - T_k)}{\alpha T_d}
\]

\[
RE(T) = 1 + \frac{D(T)}{(\alpha / \beta)} \times \frac{\lambda}{\mu - \lambda} \frac{2}{(1 - e^{-\lambda T})^2} \left\{ \frac{1}{2\lambda} \left(1 - e^{-2\lambda T}\right) - \frac{1}{\lambda + \mu} \left(1 - e^{-(\mu + \lambda)T}\right) \right\}
\]

- It captures the interacting effects of changing dose rate during dose delivery with DNA damage repair (\(\mu\)) and cellular proliferation (\(T_d\))

**Basic assumptions:**

- For uniform dose distribution or dose at a point of interest
- Radiobiological properties by five parameters (\(\alpha, \beta, \mu, \gamma, T_k\))
- Mono-exponential repair kinetics
- Uniform proliferation rate
- BED evaluated at the "effective treatment time", \(T_{eff}\), is adequately representative of biological effects produced by the implant

(Dale RG, *BJR* 62, 241-244, 1989; & 58, 515-528, 1985)
BED MODEL: DALE FORMALISM

Definition of “effective treatment time”, $T_{eff}$

- In absence of cell proliferation:
  \[ \text{BED}_{T=\infty} = D \times \left\{ \frac{\lambda}{\lambda + \mu} \frac{D}{\alpha/\beta} \right\} \]

- In presence of cell proliferation:
  - BED becomes negative at $T = \infty$
  - $T_{eff}$ is defined as the time at which the rate of cell kill equals the rate of cell repopulation

\[ T_{eff} = T_{avg} \ln \left( \alpha D \frac{T_d}{T_{1/2}} \right) \]

($^{125}\text{I}$, $D=145\text{ Gy}$, $t_{1/2}=0.27\text{ h}$, $\alpha=0.15\text{ Gy}^{-1}$, $\alpha/\beta=3\text{Gy}$, $T_k=0$)
Zaider et al. introduced an iso-effective dose (IED) formalism that is mathematically well behaved in the limit of $t \to \infty$

$$IED(t) = -\frac{1}{\alpha} \log \left[ \frac{S_0(t)e^{(b-d)t}}{1 + bS_0(t)e^{(b-d)t}} \int_{0}^{t} \frac{du}{S_0(u)e^{(b-d)u}} \right]$$

- $S_0(t)$: cell survival probability at time $t$, in absence of cell proliferation
- $b$: cell birth rate
- $d$: spontaneous cell death rate
- $b-d = \ln(2)/T_d$

\(^{125}\text{I}, D=145 \text{ Gy}, t_{1/2}=0.27 \text{ hr}, \alpha=0.15 \text{ Gy}^{-1}, \alpha/\beta=3\text{ Gy}, T_d=42 \text{ days}, T_k=0\)
**BED VS. IED**

- Impact on deriving iso-effective prescription dose for new sources:
  - e.g., using $^{125}\text{I}$ implant with 145 Gy as a reference:
    - Prescription dose derived using BED
    - Prescription dose derived using IED
  - BED model produces lower iso-effect prescription dose than IED model
  - The difference becomes greater for faster-growing tumors using source of shorter half-life
    - For $T_d = 42$ days: the difference is 2.7% & 3.5% lower for $^{103}\text{Pd}$ and $^{131}\text{Cs}$, respectively
    - For $T_d = 5$ days: the difference is 8.4% & 13.4% lower for $^{103}\text{Pd}$ and $^{131}\text{Cs}$, respectively

*(Chen Z and Nath R, *IJROBP*, 2012; 84:S755)*
Sources with shorter decay half-lives are biologically more effective than sources with longer decay half-lives when delivering the same dose.
Sources with shorter decay half-lives are less susceptible to the negative effects of cellular proliferation.

Biologic effectiveness reduces rapidly for faster-growing tumors (e.g. $T_d < 20$ days).
- Biologic effect is greater on cells with less efficient damage repair.
- Sources with shorter decay $T_{1/2}$ are more effective against negative effect of DNA damage repair.
Variations in $\alpha/\beta$ have lesser biologic impact in continuous low dose irradiation than in fractionated and hypofractionated dose deliveries.

Sources with shorter decay $T_{1/2}$ are more susceptible to variations in $\alpha/\beta$ ratio.
COMPARISON OF $^{125}$I, $^{103}$Pd, & $^{131}$Cs IMPLANTS

- For monotherapy

<table>
<thead>
<tr>
<th>Radio-nuclide</th>
<th>$&lt;$Energy$&gt;$ (keV)</th>
<th>Half-Life (day)</th>
<th>Total Dose (Gy)</th>
<th>Initial DR (cGy/h)</th>
<th>$T_{\text{eff}}$ (day)</th>
<th>BED (Gy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$^{125}$I</td>
<td>28.5</td>
<td>59.4</td>
<td>145</td>
<td>7</td>
<td>236</td>
<td>111</td>
</tr>
<tr>
<td>$^{103}$Pd</td>
<td>21</td>
<td>17.0</td>
<td>125</td>
<td>21</td>
<td>94</td>
<td>115</td>
</tr>
<tr>
<td>$^{131}$Cs</td>
<td>30.4</td>
<td>9.7</td>
<td>120</td>
<td>36</td>
<td>61</td>
<td>117</td>
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<tr>
<td>$^{131}$Cs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>107</td>
</tr>
</tbody>
</table>

AAPM TG-137 parameter set ($\alpha=0.15$ Gy$^{-1}$, $\alpha/\beta=3$ Gy, $t_{1/2}=0.27$ h, $T_d = 42$ days, $T_k = 0$)
INFLUENCE OF PROCEDURE-INDUCED EDEMA

- Are sources with shorter decay half-life always better in practice?
  - “Yes”, for static implants
  - “?”, when tumor/source position varies during treatment

- Severity & time-to-resolution vary widely from patient to patient
  (magnitude: 30 to 100%; resolution half-life: 4 to 25 days)*

- Edema forces the sources to deviate from their planned locations

- It can have a significant impact on the actual dose delivered to patient**

INFLUENCE OF PROCEDURE-INDUCED EDEMA

- Edema-induced reduction in BED as a function of edema magnitude and resolution half-life for pre-planned prostate implant

⇒ Sources with shorter decay half-life and lower photon energy are more sensitive to edema induced reduction in BED

(Chen Z, et al, PMB, 2011; 56:4895-4912; IJROBP, 2008; 70:303-310)
Many questions related to LDR prostate brachytherapy have been examined using the BED/IEL models, e.g.,

- Effects of dose heterogeneity,
- RBE of different radionuclides,
- Relative effectiveness of LDR and HDR techniques,
- Biologic effects of mixing different radionuclides,
- Impact of tumor shrinkage,
- Effects of prostate edema,
- As an index for treatment response
- Effects of combining LDR BT with external beam RT
- Impact of dose calculation accuracy
- ...

(consult references in the summer school book for further information)
The unique spatial-temporal dose delivery pattern of LDR prostate brachytherapy can have a significant effect on treatment response.

Radiobiological models are useful tools in understanding the potential impact of LDR brachytherapy dose-delivery on treatment response.

Current models are good for relative comparison of different treatment techniques and/or patients with different radiobiological characteristics.

A good understanding of the model and model limitations is key for proper use and interpretation of modeling studies.

CONCLUSION
LDR PROSTATE: POST-IMPLANT EVALUATION

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Learning Objectives

- Give 3 reasons to perform post-implant evaluation
- List 5 primary dose-volume reporting metrics for prostate & organs at risk recommended by TG-137
- Identify recommended post-implant dosimetry times for $^{125}\text{I}$, $^{103}\text{Pd}$ and $^{131}\text{Cs}$ implants
- Compare and contrast CT and MRI as post-implant dosimetry imaging modalities, specifically as regards anatomical structure definition and seed localization
Rationale & Metrics

Rationale:

- Verify Rx dose delivery to the CTV
- Confirm OAR doses are within tolerance
- Identify suboptimal implants for remediation
- Obtain objective, quantitative feedback on implant quality on an ongoing basis
**Rationale & Metrics**

<table>
<thead>
<tr>
<th>Anatomical structure</th>
<th>Dose-volume metric</th>
<th>Units</th>
<th>Desired value</th>
</tr>
</thead>
<tbody>
<tr>
<td>prostate</td>
<td>V100</td>
<td>% SV</td>
<td>&gt; 95%</td>
</tr>
<tr>
<td>prostate</td>
<td>V150</td>
<td>% SV</td>
<td>≤ 50%</td>
</tr>
<tr>
<td>prostatic urethra</td>
<td>D90</td>
<td>% PD</td>
<td>&gt; 90%</td>
</tr>
<tr>
<td>rectum</td>
<td>D10</td>
<td>% PD</td>
<td>&lt; 150%</td>
</tr>
<tr>
<td>rectum</td>
<td>D2cm³</td>
<td>% PD</td>
<td>&lt; 100%</td>
</tr>
</tbody>
</table>

%SV = percentage of the anatomical structure volume  
%PD = percentage of the prescribed dose

Primary D-V metrics recommended by TG-137
Complexities & Timing

Complexities:

- Needle insertion causes tissue swelling, which changes prostate size & inter-seed distances; the edema resolves in about a month.
- The dynamics of edema resolution & radioactive decay alter dosimetry, but edema dynamics are not known for each patient.
- Seeds can move from their implanted locations. Image-based dosimetry obtained on implant day differs from that 1 week or 1 month later.
### Complexities & Timing

<table>
<thead>
<tr>
<th>Radionuclide</th>
<th>Post-implant time</th>
</tr>
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<tbody>
<tr>
<td>$^{125}$I</td>
<td>1 month ± 1 week</td>
</tr>
<tr>
<td>$^{103}$Pd</td>
<td>16 ± 4 days</td>
</tr>
<tr>
<td>$^{131}$Cs</td>
<td>10 ± 2 days</td>
</tr>
</tbody>
</table>

TG-137 post-implant evaluation timing recommendations (scientific)
### Complexities & Timing

<table>
<thead>
<tr>
<th>Timing consideration</th>
<th>Day 0/1</th>
<th>Day 30</th>
</tr>
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<tbody>
<tr>
<td>Implant quality (IQ) assessment without delay</td>
<td>✔️</td>
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</tr>
<tr>
<td>IQ assessment based on dose-response data</td>
<td></td>
<td>✔️</td>
</tr>
<tr>
<td>Patient convenience</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>Edema resolution mostly complete</td>
<td></td>
<td>✔️</td>
</tr>
</tbody>
</table>

Post-implant timing considerations for I-125 implants (scientific & clinical)
CT-Based Evaluation

- Current standard of care
- Provides good source visualization, but only moderate soft tissue contrast
- 2-3 mm (vs. 5 mm) thick contiguous axial slices recommended by TG-137, yield more accurate seed localization
- Anatomical structure contouring guidance available in TG-137, McLaughlin et al. IJROBP 2009; 76:369-78
CT-Based Evaluation

Post-implant CT slice near mid-prostate
CT-Based Evaluation

Seed localization
CT-Based Evaluation

Sector analysis
MRI-CT Fusion-Based Evaluation

- “Ideal” (TG-137)
- CT provides good source visualization, MRI good soft tissue contrast
- CT and MR images should be acquired closely in time, with body position as nearly as possible identical
- 3D registration should be based on a volume immediately surrounding the prostate, and not the entire pelvis
MRI-CT Fusion-Based Evaluation

Corresponding post-implant (a) CT and (b) T2 MRI slices near mid-prostate
MRI-CT Fusion-Based Evaluation

Mid-prostate MRI overlaid with seed centroids (red dots) after rigid CT-MR image registration
Medical Events in Prostate Brachytherapy

Zoubir Ouhib

Department of Radiation Oncology
Learning Objectives

- discuss medical event definition for prostate implant
- discuss medical errors for prostate brachytherapy (HDR & LDR)
- understand impact of medical errors on medical staff
§ 35.3045 Report and notification of medical event
Medical Event Definition: Prostate Cancer

A brachytherapy *radiation dose*:

- involving wrong individual, wrong radionuclide, or wrong treatment site
- involving sealed source that is leaking
- when calculated *administered dose* differs *by >20% from prescribed dose*
- *fractionated dose* delivered differs from prescribed dose (for 1 fraction), by *>50% (HDR case)*
- migrated seeds originally implanted at correct site *is not a medical event*
Medical Events: Prostate Cancer

- **Types**: underdose, overdose, missing target, unintended area, wrong patient, wrong radionuclide, etc
- **Magnitude**: small to significant, mm to cm
- **Impact**: minor, unknown to adverse effects
- **Source of errors**: human, equipment (software/hardware), training, communication, others
- **Types**: LDR, HDR
Medical Events in HDR Prostate BT 2000-2012

<table>
<thead>
<tr>
<th>types</th>
<th># cases</th>
</tr>
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<tbody>
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<td>skin</td>
<td>5</td>
</tr>
<tr>
<td>esophagus</td>
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</tr>
<tr>
<td>prostate</td>
<td>24</td>
</tr>
<tr>
<td>breast</td>
<td>30</td>
</tr>
<tr>
<td>lung</td>
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<tr>
<td>GYN</td>
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</tr>
<tr>
<td>others</td>
<td>43</td>
</tr>
</tbody>
</table>

Total=162
Medical Events in **LDR Prostate BT**

**2000-2012**

<table>
<thead>
<tr>
<th>Years</th>
<th># Cases</th>
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<tbody>
<tr>
<td>2000</td>
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<tr>
<td>2001</td>
<td>7</td>
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<tr>
<td>2002</td>
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<td>2004</td>
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<td>2005</td>
<td>4</td>
</tr>
<tr>
<td>2006</td>
<td>15</td>
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<td>2007</td>
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<td>2008</td>
<td>106</td>
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<td>2009</td>
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<tr>
<td>2011</td>
<td>53</td>
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<tr>
<td>2012</td>
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</tr>
</tbody>
</table>

Total = 338
Medical Events in **LDR Prostate BT 2000-2012**

**Reasons for Medical Events**

<table>
<thead>
<tr>
<th>Reason</th>
<th># Cases</th>
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<tbody>
<tr>
<td>overdose</td>
<td>17</td>
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<tr>
<td>underdose</td>
<td>246</td>
</tr>
<tr>
<td>leaking seeds</td>
<td>16</td>
</tr>
<tr>
<td>wrong locale</td>
<td>26</td>
</tr>
<tr>
<td>wrong patient or source strength</td>
<td>9</td>
</tr>
<tr>
<td>lost sources</td>
<td>23</td>
</tr>
<tr>
<td>cremation</td>
<td>1</td>
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</tbody>
</table>

Total: 338
Background on Medical Events for Permanent LDR Brachytherapy

- April 2012, NRC staff provided the Commission recommendations for changes to ME definition for permanent brachytherapy. They were approved.

- July 2014, NRC published the “Proposed Rule” for public comment. Proposed rule changed ME definition for permanent brachytherapy to source strength (activity) based.

- Proposed Rule included criteria for absorbed dose to normal tissue. Numerous public comments (including from ABS) demonstrated such criteria would be difficult to implement. Absorbed dose criteria were removed.
Current Status of NRC Rules Changes

• Draft Final Rule containing changes to definition for reporting permanent BT ME (along with >30 significant changes) was submitted to Commission for June 2016 vote (not all Commissioners voted).

• No significant changes are anticipated from the Draft Final Rule language.

• Upon approval of new Rules, licensees have 180 days to implement changes.
August 2012, Commission directed NRC staff to develop IEP for those radiation oncologists authorized users wishing to use total source strength as their criteria for reporting ME

- Authorized users switching early will not be sited for violating current rules
- IEP was intended to provide a “bridge” to the new Rule
Impact of Errors on Physicians’ Life Domains by Level of Error Severity

- **Increased Anxiety about Future Errors**: 66% (Serious), 51% (Minor), 56% (Near Miss)
- **Decreased Job Confidence**: 51% (Serious), 36% (Minor), 31% (Near Miss)
- **Decreased Job Satisfaction**: 48% (Serious), 34% (Minor), 34% (Near Miss)
- **Increased Sleeplessness**: 48% (Serious), 33% (Minor), 34% (Near Miss)
- **Harm to Professional Reputation**: 15% (Serious), 9% (Minor), 10% (Near Miss)

Waterman et al., JCAHO 33, 467-476 (2007)
CONCLUSIONS

- Prostate brachytherapy errors, based on dose criteria, made the headlines in the past decade.
- Less number are being reported (less procedures?)
- Proposed rules, if and when approved, will reduce the number of errors.
- Proper training, knowledge, and understanding of the new rules are keys to error reduction.