Summary: Medical Event Reporting Issues

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Chair, ACMUI Medical Event Subcommittee

Subcommittee Charge

- Evaluate 20% Threshold in ME rule
- How best to communicate risk
- Permanent interstitial brachytherapy

Medical Event Subcommittee (MESC) activities

- Membership
- Two closed conference calls; two noticed public calls Consultant: Louis Potters, MD
- Recommendations: April 2005

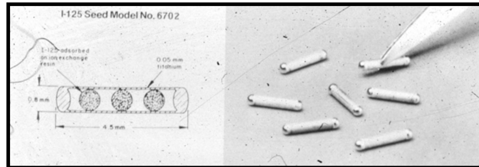
Outline

- **Review ME issues in prostate permanent seed brachytherapy**
- **Review MESC consensus achieved to date**
- **Review issues still under discussion**

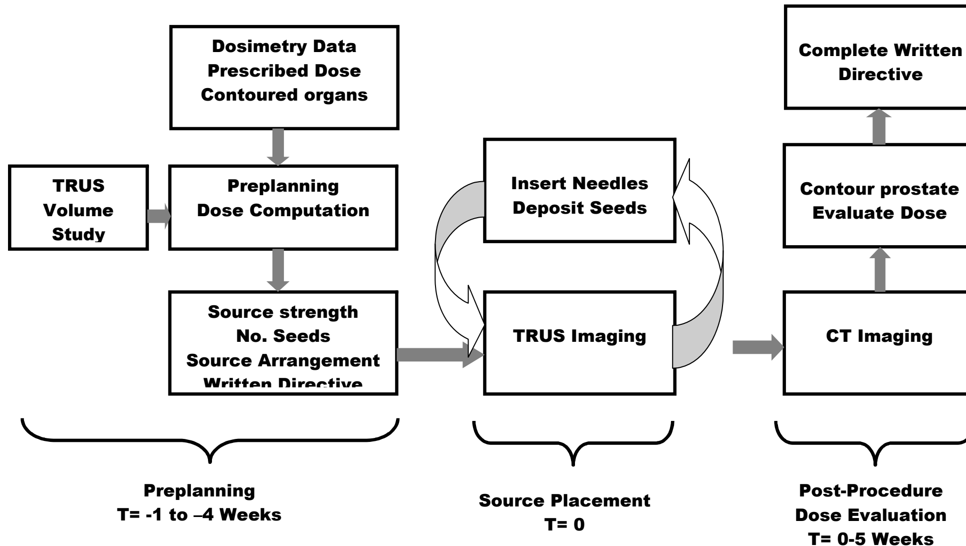
Image-Guided Source Insertion Procedure

- 18 gauge (1.3 mm diameter) needle for seed placement
- Ultrasound probe in rectum for needle guidance
- TRUS = Trans-rectal ultrasound imaging

TRUS Image Guidance

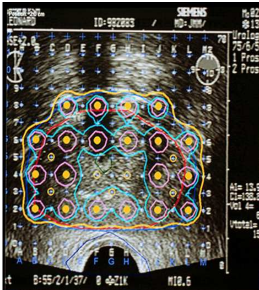


Prostate Brachytherapy Procedure Flow



Preplanning

- **TRUS imaging 2 wks before implant**
- **Dose calculations to find needle loadings & seed strengths that deliver desired dose to clinical target volume (CTV)**



Needle Loading Report

MMS-TherpacPLUS B3DTUI 6.7 (Build 812) · Seattle Prostate Institute · 479 · 1 · 2/23/00 4:21:13 PM

Study: PREPLAN I-125 / PRIMARY
Variation: Default
Scans: 9
Template: B & K Standard
Shift: X = 0.00cm Y = 0.50cm

Isotope: I-125 (6711) 1999nist
Seeds: 124
Target Dose: 145.000
Anisotropic Correction: 0.930

U/mCi: 1.270
U/Seed: 0.377
mCi/Seed: 0.297

Needle Number	Retraction (cm)	Hole Location	Number Seeds
1	0.00	c6.0	5
2	0.00	d6.0	5
3	0.50	C5.5	4
4	0.50	E5.5	4
5	0.00	b5.0	5
6	0.00	c5.0	5
7	0.00	d5.0	5
8	0.00	e5.0	5
9	0.50	B4.5	4
10	0.50	F4.5	4
11	1.00	a4.0	2
12	0.00	b4.0	5
13	0.00	c4.0 *	2
14	0.00	d4.0 *	2
15	0.00	e4.0	5
16	1.00	f4.0	2
17	0.50	B3.5	4
18	0.50	F3.5	4
19	1.00	a3.0	2
20	0.00	b3.0	5
21	0.00	c3.0	5
22	0.00	d3.0	5
23	0.00	e3.0	5
24	1.00	f3.0	2
25	0.50	B2.5	4
26	0.50	F2.5	4
27	0.00	b2.0	5
28	0.00	c2.0	5
29	0.00	d2.0	5
30	0.00	e2.0	5

● * Indicates special loading

* loose; free load

Retraction Legend

Plane 0	Plane 1	Plane 2	Plane 3	Plane 4	Special
0.00 cm	0.50 cm	1.00 cm	1.50 cm	2.00 cm	other

Number of Needles	Seeds per needle
6	2
8	4
16	5

Plan Summary	
Total Activity [U]	46.75
Total Activity [mCi]	36.81
Total Needles	30
Total Seeds	124
Extra Seeds	10
Total Seeds to Order	134

MD: 3/1/00 Planned By: Dnaidoo
Physicist: mp Date Planned: 2/23/00
Loaded By: ______ Implant Date: 4/14/00

Seed Insertion Procedure

- **Patient anatomy may differ from preplan**

- **AU must be free to adapt preplan to anatomy imaged during procedure**

Post-Procedure Dose Evaluation

- CT imaging: 0-30 days later
- Contour CTV and organs at risk & calculate doses
- Post-implant doses, e.g., D_{90}, most definitive estimate of delivered dose

Current ME Definition

10 CFR 35.3045

- **ME = byproduct material administration, in which**
  - **|Delivered - Prescribed|> 50 Rem AND > 20% OR**
  - **Dose to extra-target site > expected (planned) dose by 50 Rem AND 50%**

Is 20% Level Justifiable?

MESC consensus

- For temporary implants, 20% is a reasonable regulatory action level
- Permanent Implants: No

Rationale: Prostate

- Variability in Post-Implant CT vs. written directive dose comparisons
  - CT vs. US CTV: 50% differences
  - Large CT contouring variations
  - Long/variable interval from Implant to dose calculation
  - legitimate preplan modifications

Other Permanent Implant Issues

- **WD: 35.40(b)(6)(ii) allows AU to specify No. sources and dose at any time post-Implant**
- **Wrong site ME: unenforceable**

MESC Proposal

- **Define ME in terms of where sources are implanted rather than dose delivered**
- **Recommendation 1**

MESC Proposal

- **Recommendation 2:** Replace wrong site and target volume ME definitions

MESC Proposal

- **Recommendation 3:** For permanent implants amend 35.40(c) and (b)(6)(iii) to require completion and any revision of WD within 1 working day of source insertion

Rationale: Recommendations 1-3

- Determining fraction of seeds
- Determine seed fraction intraoperatively
- Limiting WD revisions

Risk Communication

MESC proposals under discussion

- **Recommendation 4:** Treat ME strictly as QA performance surrogate divorced from patient harm

Rationale Rec 4:

- **ME reporting perception**

- **AU reporting dilemma**

Rationale Rec 4:

- **Industry practice**
  - **Errors alone not grounds for punishment**
  - **Error reports used to improve overall process**
  - **QA deliberations not discoverable**

Unresolved Issues

- Dose calculation errors
- Williamson: Add dose-calculation error ME pathway limited to preplanning
  - ME = any calculation ⇒ error in source strength WD > 20%

Other ME issues

- **Is current wrong-site ME criterion workable and justifiable for other types of brachytherapy and external beam treatments?**