Medical Events Subcommittee Report

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Advisory Committee on the Medical Uses of Isotopes

October 4, 2021

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Subcommittee Members

- Ronald D. Ennis, M.D. (Chair)
- Richard Green
- Darlene Metter, M.D.
- Zoubir Ouhib, M.S.
- Michael O'Hara, Ph.D.
- Michael Sheetz
- Harvey Wolkov, M.D.

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Summary

- Two overarching themes remain
  - Performance of a time out/use of a checklist immediately prior to administration of radioactive byproduct material, as is done in surgery and other settings, could have prevented some MEs
  - Lack of recent or frequent performance of the specific administration or inattention during performance of the procedure/treatment appear to be contributing factor(s) in a number of cases
  - NRC issued an Information Notice alerting the users to this issue in 2019. https://www.nrc.gov/docs/ML1924/ML19240A450.pdf

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Summary

- Specific issues
  - Increase complexity of unsealed source administrations of newer agents may lead to more equipment related MEs in future
  - MEs involving Y90 administration continue to be the most common MEs. We propose the creation of a subcommittee to evaluate this issue in more depth and, in conjunction with the vendors, propose solutions to decrease the frequency of MEs

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35.200 Use of Unsealed Byproduct Material for Imaging and Localization

Medical Events Summary

	2017	2018	2019	2020	Total
Cause					
Wrong drug	0	0	0	0	0
Wrong dosage	2	0	0	0	2
Wrong patient	1	0	0	0	1
Extravasation	1	0	0	0	1
Human error	0	0	1 (8 patients)	0	1 (8 patients)
Total	4	0	1	0	5

3/5 possibly preventable by time out

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35.300 Use of Unsealed Byproduct Material, Written Directive Required

Medical Event Summary

	2017	2018	2019	2020	Total
WD not done or incorrectly	2	1	2	0	5
Error in delivery (#capsules)	1	0	1	0	2
Wrong dose	0	0	0	0	0
Equipment	0	1	4	0	5
Human Error	0	0	1	2	3
Wrong patient	1	0	1	0	2
Total	4	2	9	2	17

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35.400 Manual Brachytherapy

Medical Event Summary

	2017	2018	2019	2020	Total
Applicator issue (e.g. jam, eye plaque dislodged)	0	0	0	2	2
Wrong site implanted (e.g. penile bulb, bladder)	1	1	1	2	5
Activity/prescription error (e.g. air kerma vs mCi, enter wrong activity in planning software)	1	0	1	0	2
Prostate Dose	5	11	3	0	19
New device	0	1	0	0	1
Wrong source	0	0	0	1	1
Patient health (?patient intervention)	0	0	0	1	1

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35.400 Manual Brachytherapy

Medical Event Summary

	2017	2018	2019	2020	Total
Total ME	7	13	5	6	45
"Time out" may have prevented	1	0	1	1	3
Lack of experience/inattention may have played a role	1	1	1	1	4

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35.400 Manual Brachytherapy

Many MEs in this category are no longer categorized as MEs due to change from dose to activity-based definition, although even in 2019 this definition continued to be used for some MEs.

Lack of experience or inattention possibly plays a role in the true MEs of this type, but hard to assess to what degree in each case.

In approximately 15% of cases, a “time out/checklist”, enhanced retraining prior to performance of an uncommon procedure or increase attention during the procedure might have prevented the ME.

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35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic unit

	2017	2018	2019	2020	Total
Wrong position	2	3	4	7	16
Wrong reference length	2	1	4	2	9
Wrong plan	0	2	0	0	2
Wrong dose/source strength	0	1	0	0	1
Machin/applicator malfunction	2	3	1	1	7
Software/hardware failure	2 (9 pts)	0	1	1	4
Treatment planning	0	0	0	2	2
Total	8 (14 pts)	10	10	13	41

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35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic unit

Medical Event Summary

	2017	2018	2019	2020
Location				
Breast	0	1	0	1
Gynecological	7 (14 pts)	7	8	10
Skin/neck	0	1	0	2
Bronchus	0	0	0	0
Prostate	0	0	0	0
Brain	1	1	2	0
Total	8 (14 pts)	10	10	13

GYN tumors most common site of ME

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MEs that may have been prevented by "timeout" (wrong plan or dose)

- 2017 0/8 events
- 2018 3/10 events
- 2019 3/10 events
- 2020 10/13 events

Total 16/41 (39%)

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35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic unit

MEs caused by "infrequent user/inattention"

This is difficult to determine based on information in NMED. For this assessment, assumed wrong position is a surrogate for "infrequent" user/inattention

- 2017 2/8 events
- 2018 1/10 events
- 2019 1/10 events
- 2020 9/13 events

Total 13/41 (32%)

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35.1000 Radioactive Seed Localization

Medical Events Summary

	2018	2019	2020	2021
Total Medical Events	0	1	0	1
Cause:				
Delayed seed removal (patient intervention)	0	1	0	0
Lost seed	0	0	0	0
Wrong implant site	0	0	0	0
Seed migration	0	0	0	1

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35.1000 Intravenous Cardiac Brachytherapy

- **Medical Events Summary**

	2017	2018	2019	2020	Total
Did not follow proper procedure	0	0	1	0	1
Tortuous vessel anatomy	0	1	1*	0	2
Catheter issue	0	1	0	1	2
Total	0	2	2	1	5

*AU felt this is “patient intervention”
No time out issues
Difficult to assess the unfamiliarity issue, but possibly played a role in some

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35.1000 Gamma Knife® Perfexion™ and Icon™

Medical Events Summary

	2017	2018	2019	2020
Total Medical Events	0	1	2	2
Cause:	0	0	0	0
Back-up battery power source failure	0	1	0	0
Patient setup error	0	0	0	1
Patient movement	0	0	2	0
Wrong site (treatment plan)	0	0	0	0
Pt motion management system failure	0	0	0	1

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35.1000 Y-90 Theraspheres

Medical Events Summary

	2017	2018	2019	2020	Total
Total Medical Events	15	14	15	15	59
Cause:					
> 20% residual activity remaining in delivery device	7	11	9	12	39
Delivery device setup error	2	2	1	1	6
Wrong dose (treatment plan calculation error)	4	0	1	0	5
Wrong site (catheter placement error)	2	0	0	2	4
Wrong dose vial selected	0	1	4	0	5

For 2020: Time out 3/15 (20%),
Infrequent/inattention 12/15 (80%)

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35.1000 Y-90 SirSpheres

Medical Events Summary

	2017	2018	2019	2020	Total
Total Medical Events	8	7	11	8	34
Cause:					
> 20% residual activity remaining in delivery device not due to stasis	7	2	8	8	25
Wrong dose (treatment plan calculation error)	0	2	0	0	2
Wrong site (catheter placement error)	1	2	2	0	5
Wrong site (WD error)	0	1	1	0	2

2020: Time out: 0
Infrequent/inattention: 8/8 (100%)

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Actions to Prevent 35.1000 Y-90 Microsphere Medical Events

- Review mechanics of Y-90 microsphere delivery device and setup procedures
- Confirm all data and calculations in treatment plan
- Perform “Time Out” to assure all elements of treatment are in accordance with Written Directive

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Possible Elements of a "Time Out"

- Identity of patient via two identifiers (e.g. name and DOB)
- Procedure to be performed
- Isotope
- Activity
- Dosage –second check of dosage calculation and that the WD and dosage to be delivered are identical
- Others as applicable
  - units of activity (LDR prostate)
  - anatomic location
  - patient name on treatment plan
  - treatment plan independent second check has been performed
  - reference length (HDR)
  - Implant site location (RSL)

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Acronyms

- 10 CFR – Title 10 of the *Code of Federal Regulations*
- AUs – authorized users
- FY – Fiscal Year
- gyn – gynecological
- HDR – high dose-rate
- LDR – low dose rate
- mCi – milliCurie
- ME – Medical Event
- RSL – radioactive seed localization
- Y – Yttrium