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ACMUI's Review and Analysis of Reported Medical Events from Fiscal Years 2021-2023

Richard P. Harvey, DrPH
Advisory Committee on the Medical Uses of Isotopes
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Subcommittee Members

- Richard Harvey, DrPH (Chair)
- Michael Folkert, M.D.
- Richard Green, B.S.
- Darlene Metter, M.D.
- Zoubir Ouhib, M.S.
- Harvey Wolkov, M.D.

- Consultant: John Angle, M.D.
- NRC Staff Resource: Daniel DiMarco, M.S.

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Subcommittee Charge

- Review Medical Events (MEs) to advise the Advisory Committee on the Medical Use of Isotopes (ACMUI) and United States Nuclear Regulatory Commission (NRC) about emerging trends that may need regulatory attention.

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Background

- The NRC and ACMUI review MEs that occur throughout the country.
- MEs occur when radioactive material use in healthcare results in unexpected radiation dose to patients. (Please refer to 10 CFR 35 Subpart M – Reports and more specifically 10 CFR 35.3045 – Report and Notification of a Medical Event for more information.)
- The Medical Events Subcommittee of the ACMUI reviews the data to analyze the nature of medical events, identify emerging trends and provide recommendations to the ACMUI and NRC.

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Medical Event Review

- FY21 – October 1, 2020 to September 30, 2021
- FY22 – October 1, 2021 to September 30, 2022
- FY23 – October 1, 2022 to September 30, 2023

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Summary

- Two overarching themes remain
  - Human Error
    - Communication/feedback
    - Failure to work in teams
  - Inexperience
    - Rapidly evolving use of radiopharmaceuticals
    - Dissemination of use to smaller institutions with lower frequency of procedures performed

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Specific Issues

- Increasing MEs: new and increasing use of current therapeutic radiopharmaceuticals
- ^{90}Y microsphere procedures remain the most common MEs.
    - ACMUI Action: Added 2 specialty-specific subcommittee members
    - ACMUI recommendation: AU adhere to manufacturer recommendations (i.e. avoid aggregation: use recommended catheter size and needle gauge)

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35.200 Use of Unsealed Byproduct Material for Imaging and Localization

Medical Events Summary

	2017	2018	2019	2020	2021	2022	2023	Total
Cause								
Wrong Drug	0	0	0	0	1	0	1	2
Wrong Dosage	2	0	0	0	1	0	0	3
Wrong Patient	1	0	0	0	2	0	0	3
Extravasation*	1	0	0	0	0	0	0	1
Human Error	0	0	1 (8 patients)	0	0	0	0	1 (8 patients)
Total	4	0	1	0	4	0	1	10

5/5 (100%) possibly preventable by time out in 2021 & 2023 (Wrong Drug, Wrong Dosage & Wrong Patient)

*NRC does not have reporting requirement for extravasations

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35.300 Use of Unsealed Byproduct Material, Written Directive Required

Medical Event Summary

	2017	2018	2019	2020	2021	2022	2023	Total
WD not done or incorrectly	2	1	2	0	0	1	1	7
Error in delivery (# capsules)	1	0	1	0	0	1	0	3
Wrong Dose	0	0	0	0	4	3	8	15
Equipment	0	1	4	0	2	1	0	8
Human Error	0	0	1	2	3	4	0	10
Wrong Patient	1	0	1	0	0	0	0	2
Wrong Drug	0	0	0	0	1	0	2	3
Total	4	2	9	2	10	10	11	48

Time out: 2021-5/10 (50%), 2022-3/10 (30%), 2023-10/11 (91%)
(Wrong Drug, Wrong Dosage & Wrong Patient)

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35.400 Manual Brachytherapy

Medical Event Summary

	2017	2018	2019	2020	2021	2022	2023	Total
Applicator issue (e.g. jam, eye plaque dislodged)	0	0	0	2	0	1	1	4
Wrong site implanted (e.g. penile bulb, bladder)	1	1	1	2	2	0	0	7
Activity/prescription error (e.g. air kerma vs mCi, enter wrong activity in planning software)	1	0	1	0	1	0	0	3
Wrong Dose	5	11	3	0	0	0	2	21
New Device	0	1	0	0	0	0	0	1

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35.400 Manual Brachytherapy

Medical Event Summary

	2017	2018	2019	2020	2021	2022	2023	Total
Wrong Source	0	0	0	1	0	0	0	1
Patient Health (?patient intervention)	0	0	0	1	0	0	0	1
Wrong Patient	0	0	0	0	1	0	0	1
Total	7	13	5	6	4	1	3	39
"Time Out" may have prevented	1	0	5	1	2	0	0	9

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35.400 Manual Brachytherapy

Potentially ~23% (9/39) of ME from 2017 to 2023 may have been prevented with the use of a "Time Out" (wrong site, wrong source and wrong patient):

- "Time Out" or checklist for 2021 may have prevented: ¾ (75%)
- No benefit in 2022 or 2023

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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	2021	2022	2023	Total
Wrong position	2	3	4	7	0	1	3	20
Wrong reference length	2	1	4	2	2	2	0	13
Wrong plan	0	2	0	0	0	0	0	4
Wrong dose/source strength	0	1	0	0	0	0	2	1
Machine/applicator malfunction	2	3	1	1	1	2	2	12
Software/hardware failure	2 (9 patients)	0	1	1	0	0	0	4
Treatment planning	0	0	0	2	1	2	0	5
Human Error	0	0	0	0	1	4	1	6
Total	8	10	10	13	5	11	8	65

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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	2021	2022	2023	Total
Location								
Breast	0	1	0	1	0	0	0	2
Gynecological	7	7	8	10	4	2	5	43
Skin/neck	0	1	0	2	1	5	1	10
Bronchus	0	0	0	0	0	0	0	0
Prostate	0	0	0	0	0	0	1	1
Brain	1	1	2	0	0	0	0	4
Unknown	0	0	0	0	0	4	1	5
Total	8	10	10	13	5	11	8	65

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 0/10 events
- 2020 0/13 events
- 2021 0/5 events
- 2022 0/11 events
- 2023 2/8 events

Total 5/65 (8%)

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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 – improved training may be beneficial

- 2017 2/8 events
- 2018 3/10 events
- 2019 4/10 events
- 2020 7/13 events
- 2021 0/5 events
- 2022 1/11 events
- 2023 3/8 events

Total 20/65 (31%)

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35.1000 Radioactive Seed Localization

Medical Events Summary

	2018	2019	2020	2021	2022	2023
Total Medical Events	0	1	0	1	0	1
Cause:						
Delayed seed removal (patient intervention)	0	1	0	0	0	1
Lost seed	0	0	0	0	0	0
Wrong implant site	0	0	0	0	0	0
Seed migration	0	0	0	1	0	0

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35.1000 Intravenous Cardiac Brachytherapy

Medical Events Summary

	2017	2018	2019	2020	2021	2022	2023	Total
Did not follow proper procedure	0	0	1	0	0	0	0	1
Tortuous vessel anatomy	0	1	1*	0	0	0	0	2
Catheter issue	0	1	0	1	0	0	0	2
Wrong Site	0	0	0	0	0	0	1	1
Total	0	2	2	1	0	0	1	6

*AU felt this is “patient intervention”
No time out issues

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35.1000 Gamma Knife® Perfexion™, Icon™ and Esprit™

Medical Events Summary

	2017	2018	2019	2020	2021	2022	2023	Total
Total Medical Events	0	1	2	2	0	2	1	8
Cause:								
Back-up battery power source failure	0	1	0	0	0	0	0	1
Patient set-up error	0	0	0	1	0	0	0	1
Patient movement	0	0	2	0	0	0	0	2
Wrong site (treatment plan)	0	0	0	0	0	0	0	0
Wrong site (human error-shifting of co-registration images)	0	0	0	1	0	1	0	2
Patient motion management system failure	0	0	0	0	0	1	0	1
Device Malfunction	0	0	0	0	0	0	1	1

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35.1000 ^{90}Y Theraspheres

Medical Events Summary

	2017	2018	2019	2020	2021	2022	2023	Total
Total Medical Events	15	14	15	15	23	23	22	127
Cause:								
> 20% residual activity remaining in delivery device/leakage	7	11	9	12	10	2	11	62
Delivery device set-up error	2	2	1	1	1	0	2	9
Wrong dose (treatment plan calculation error)	4	0	1	0	0	3	1	9
Wrong site (catheter placement error & size)	2	0	0	2	1	7	3	15
Wrong dose vial selected*	0	1	4	0	1	1	1	8
Wrong dose (calibration error)*	0	0	0	0	3	1	0	4
Aggregation of microspheres	0	0	0	0	7	9	4	20

For 2021 - 2023: Time out 4/23 (17%), 2/23 (9%), 1/22 (5%) – Wrong Dose*
Infrequent/inattention 10/23 (43%), 2/23 (9%), 11/22 (50%) – > 20% Residual

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35.1000 ^{90}Y SirSpheres

Medical Events Summary

	2017	2018	2019	2020	2021	2022	2023	Total
Total Medical Events	8	7	11	8	18	9	9	70
Cause:								
> 20% residual activity remaining in delivery device/leakage	7	2	8	8	2	1	6	34
Wrong dose (treatment plan calculation error)	0	2	0	0	2	1	0	5
Wrong site (catheter placement error & defective catheter)	1	2	2	0	4	0	1	10
Wrong site (WD error)	0	1	1	0	1	1	2	6
Aggregation of microspheres	0	0	0	0	9	6	0	15

2021 - 2023: Time out: 1/18(6%), 1/9(11%), 2/9(22%) - Wrong Site (WD)
Infrequent/inattention: 2/18(11%), 1/9(11%), 6/9(67%) - >20% Residual

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Actions to Prevent 35.1000 ^{90}Y Microsphere Medical Events

- Ensure familiarity with the mechanics of ^{90}Y 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
- Radiopharmaceutical
- 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
- WD – written directive
- Y – Yttrium