

LUTATHERA[®] EXTRAVASATION

KENDALL BERRY, MSPH, CMLSO, RSO

JESSICA KENDRICK, MS, SENIOR HP

FOX CHASE CANCER CENTER



TOPICS TO BE COVERED

SETTING SCENE

WHAT IS AN EXTRAVASATION ANYWAY?

LUTATHERA EXTRAVASATION

MEDICAL EVENT? YES/NO/MAYBE

GOING FORWARD

CONCLUSION & MY TWO CENTS



PETITION FOR RULEMAKING: REPORTING NUCLEAR MEDICINE INJECTION EXTRAVASATIONS AS MEDICAL EVENTS

- DOCKET NUMBER: NRC-2020-0141
- SEPTEMBER 15, 2020
- PUBLIC MEETING 12/8/2020 (ML21005A436)
- 21 PARAGRAPHS DETAILING STRONG PRACTICE AND SCIENTIFIC BASED OPPOSITION FROM THE REGULATED COMMUNITY
- 3 PARAGRAPHS OF EMOTIONAL, NOT SCIENTIFIC, ARGUMENTS IN FAVOR OR THE PETITION



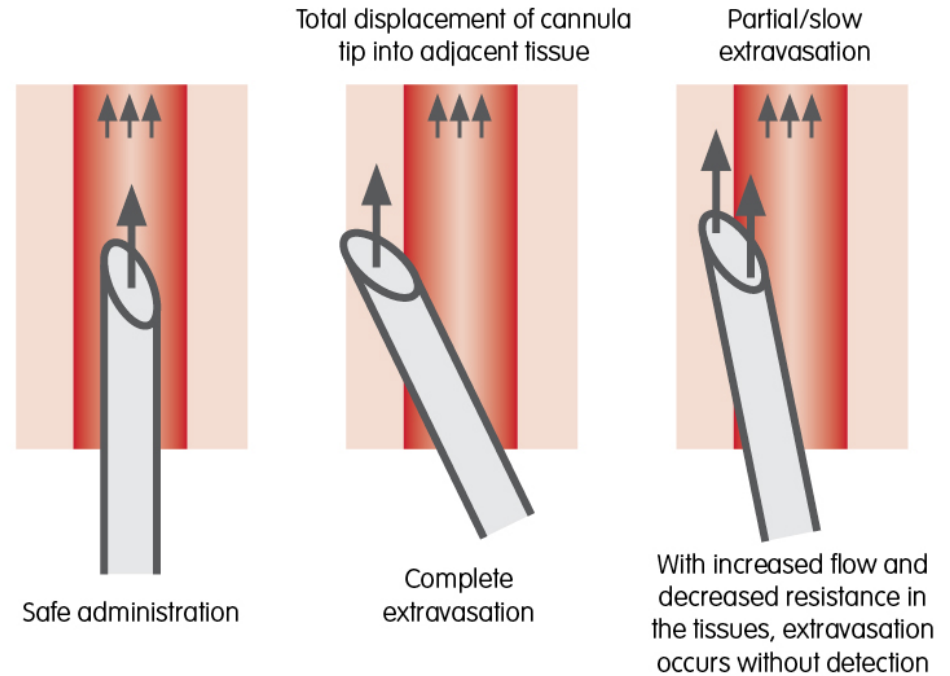
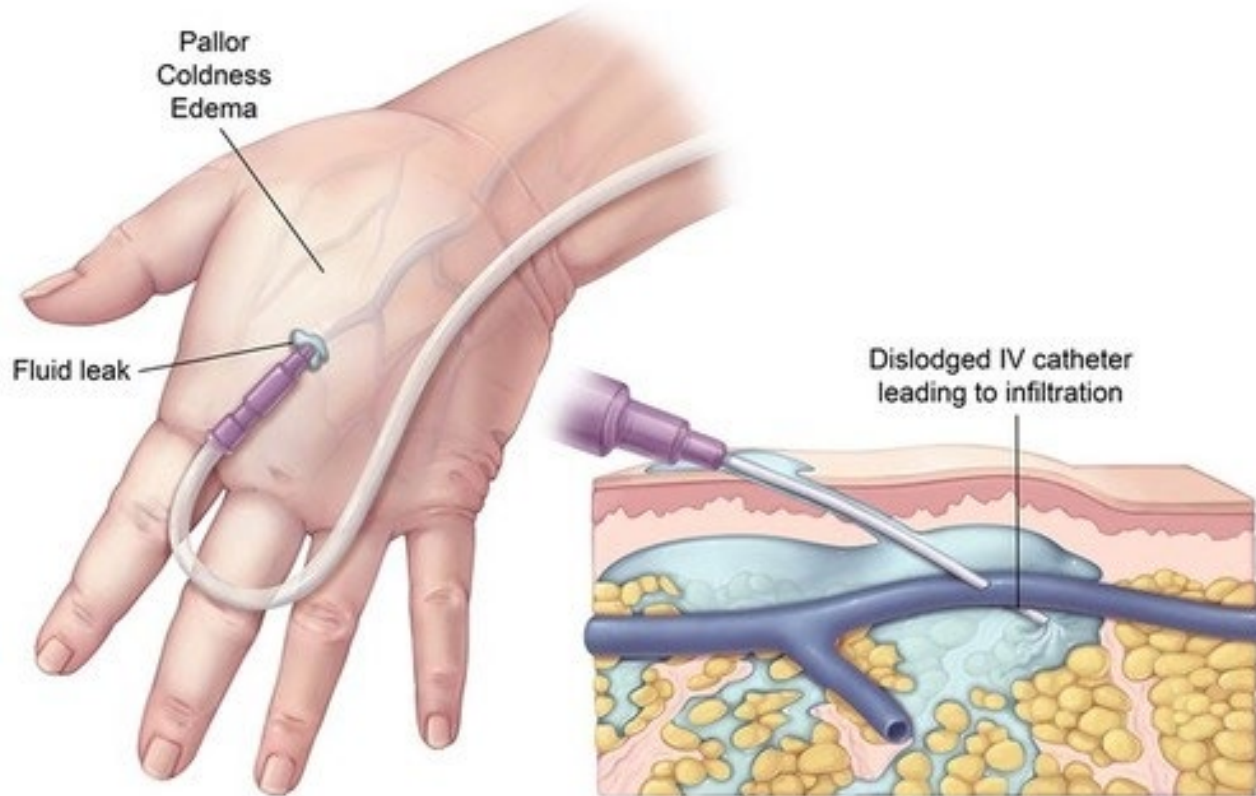
WIDESPREAD OPPOSITION TO THE PETITION

- ASTRO – AMERICAN SOCIETY FOR RADIATION ONCOLOGY
- HPS – HEALTH PHYSICS SOCIETY
- SNMMI - THE SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING
- ASNC - AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY
- ACNM - AMERICAN COLLEGE OF NUCLEAR MEDICINE
- NORTH CAROLINA RADIATION PROTECTION COMMISSION



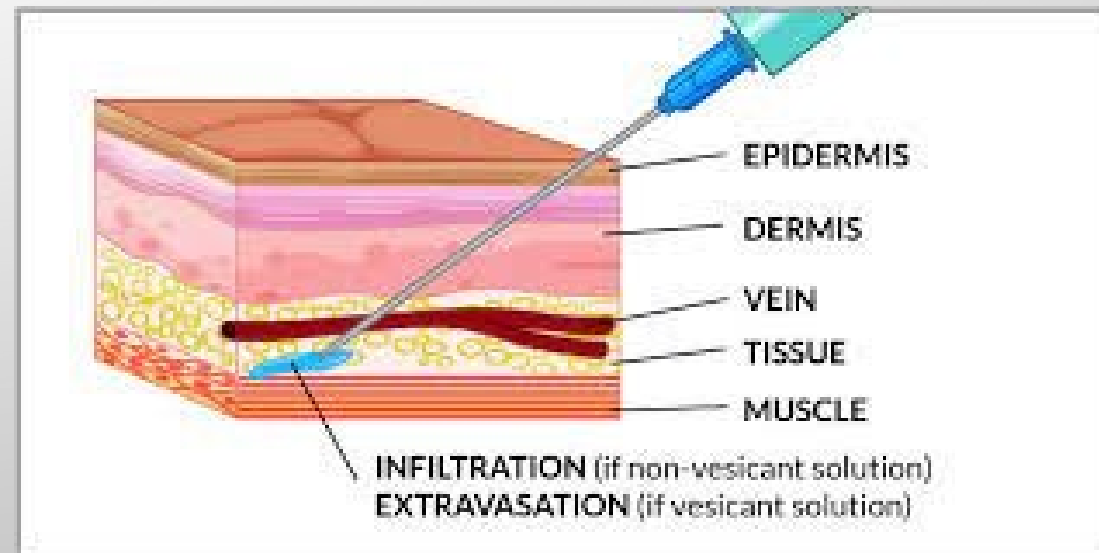
WHAT IS AN EXTRAVASATION?

Intravenous site infiltration



EXTRAVASATION OR INFILTRATION?

- INFILTRATION IS THE ACCIDENTAL LEAKAGE OF NON-VESICANT SOLUTIONS OUT OF THE VEIN INTO THE SURROUNDING TISSUE.
- WHEN THE LEAKED SOLUTION FROM AN INFILTRATION IS A VESICANT DRUG—ONE THAT CAUSES TISSUE INJURY BLISTERS OR SEVERE TISSUE DAMAGE—IT IS REFERRED TO AS AN EXTRAVASATION.



NOVEMBER 12, 2020

- PETITION FOR RULE RESULTING IN LIVELY DISCUSSIONS IN MEDICAL CIRCLES
- NRC'S PUBLIC HEARING IN 18 DAYS
- SHORT STAFFED
- LUTATHERA NURSE CALLS
- LUTATHERA THERAPY EVERY 8 WEEKS
 - LU-177, 7.4 GBq (200 mCi)
 - 6.7 DAY HALF-LIFE
 - 490 keV BETA
 - 113 keV (3%) & 210 keV (11%) GAMMA
 - 30 MINUTE INFUSION OF LUTATHERA AND CONCURRENT 4 HOUR INFUSION OF AMINO ACIDS



FIRST THINGS FIRST - WHAT DO WE KNOW?

- PAIN AND SWELLING
- BUMP AT IV SITE
- 30 MINUTES AFTER THE LU-177 INFUSION FINISHED
- 2.5 HOURS OF AMINO ACID INFUSION LEFT
- 7.66 GBq (206.7 mCi)
- DIFFICULT VEINS



IMMEDIATE ACTIONS

- WITHIN 1.5 HOURS OF THE CONCLUSION OF THE Lu-177 INFUSION:

- COMPRESSION
- ELEVATED
- WARM COMPRESS



- CHEMOTHERAPY EXTRAVASATION RATE:

- "RANGES FROM 0.1% TO 6% WORLDWIDE"¹
- FCCC LUTATHERA EXTRAVASATION RATE: 0.6%



DATA COLLECTION

- EXPOSURE RATE MEASUREMENTS
 - LEFT ARM: CONTACT AT IV SITE AND 30 cm AWAY
 - RIGHT ARM: CONTACT AND 30 cm AWAY
 - MEASURED AT ~2, 3.5, 23, AND 120 HOURS
 - RESIDUAL LUTATHERA VIAL READINGS
 - 451 P IONIZATION CHAMBER
 - GAMMA CAMERA IMAGING
- OBSERVED A 47% EXPOSURE RATE DROP BETWEEN MEASUREMENTS TAKEN AT 2 HOURS AND 3.5 HOURS.



ACTIVITY PRESENT

- $0.12 \text{ GBq} = 0.134 \text{ mSv/hr}$
($3.3 \text{ mCi Lu-177} = 13.4 \text{ mR/hr}$)

Date	Time	Activity (MBq)	Activity (mCi)	Decrease in Activity Present
11/12	12:25	7.65	206.7	
11/12	14:20	1.39	37.7	82%
11/12	16:00	0.75	20.1	47%
11/13	11:08	0.17	4.4	78%
11/17	12:30	0.04	1.0	77%

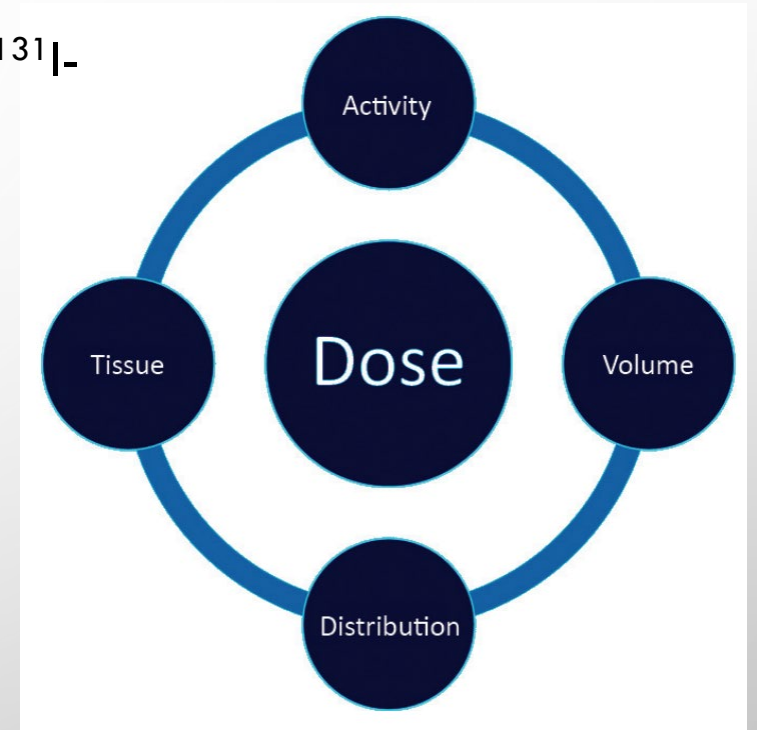


DOSE?

- SNM ARTICLE: “EXTRAVASATION OF A THERAPEUTIC DOSE OF ^{131}I -METAiodobenzylguanidine”²

$$\text{Dose} = \frac{1}{2} \times \frac{E_{av} \times A}{\rho \times V}$$

- E_{AV} IS THE AVERAGE B-ENERGY PER DECAY, 163 keV
- A IS FOR ACTIVITY, 7.66 GBq (207 mCi)
- V IS THE VOLUME DISTRIBUTION, 150 cm³
- ρ IS THE BASAL LAYER'S MASS DENSITY, ASSUMED TO BE 1 g/cm³



DOSE

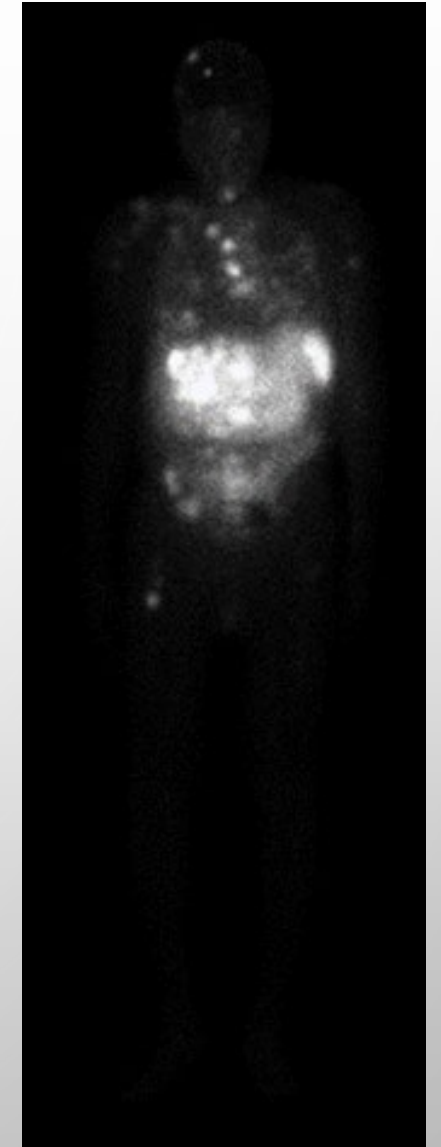
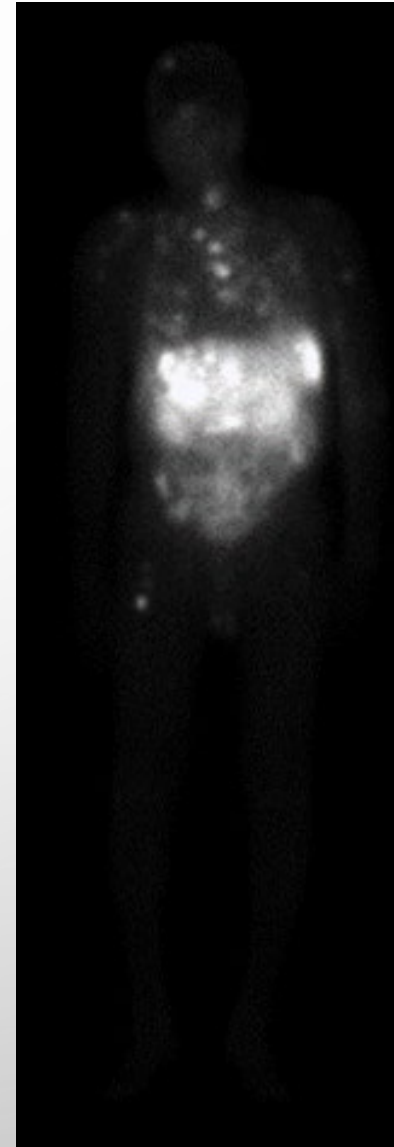
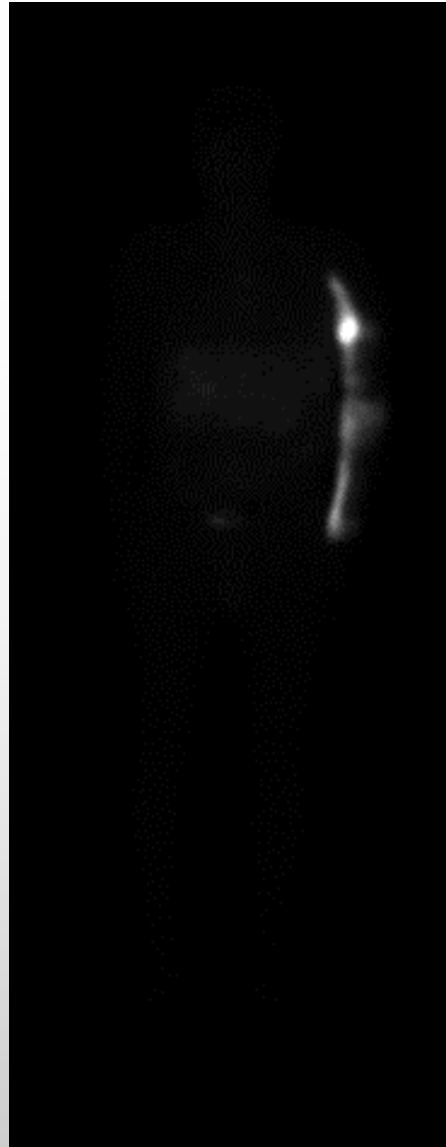
Date	Time	Hours Elapsed	Activity (MBq)	Activity (mCi)	Dose (Gy)
11/12	12:25	1.92	7.65	206.70	4.62
11/12	14:20	1.67	1.39	37.70	0.73
11/12	16:00	19.1	0.74	20.10	4.47
11/13	11:08	97.4	0.16	4.40	4.96
11/17	12:30	96	0.04	1.00	1.07
	Projected	96	0.03	0.70	0.82
	Projected	96	0.01	0.20	0.19
	Projected	96	0.00	0.04	0.04
	Projected	96	0.00	0.01	0.01

TOTAL DOSE = 17 Gy



WHAT DID WE SEE?

- IMAGES WERE OBTAINED AT APPROXIMATELY 4 HOURS, 24 HOURS AND 120 HOURS POST INFUSION.
- AU EXAMINED THE IV SITE PRIOR TO IMAGING.



WATCHFUL WAITING

- IV SITE EXAMINATIONS
- SELF REPORTING EFFECTS
- PICC LINES
 - PERIPHERALLY INSERTED CENTRAL CATHETER
- PATIENT EXPIRED



MEDICAL EVENT?

- EXTRAVASATION SPECIFICALLY EXCLUDED
- WRONG ROUTE & DOSE?
- VARSKIN >>> 50 rem
- 24 HOUR REPORTING WINDOW
- POSSIBLE MEDICAL EVENT



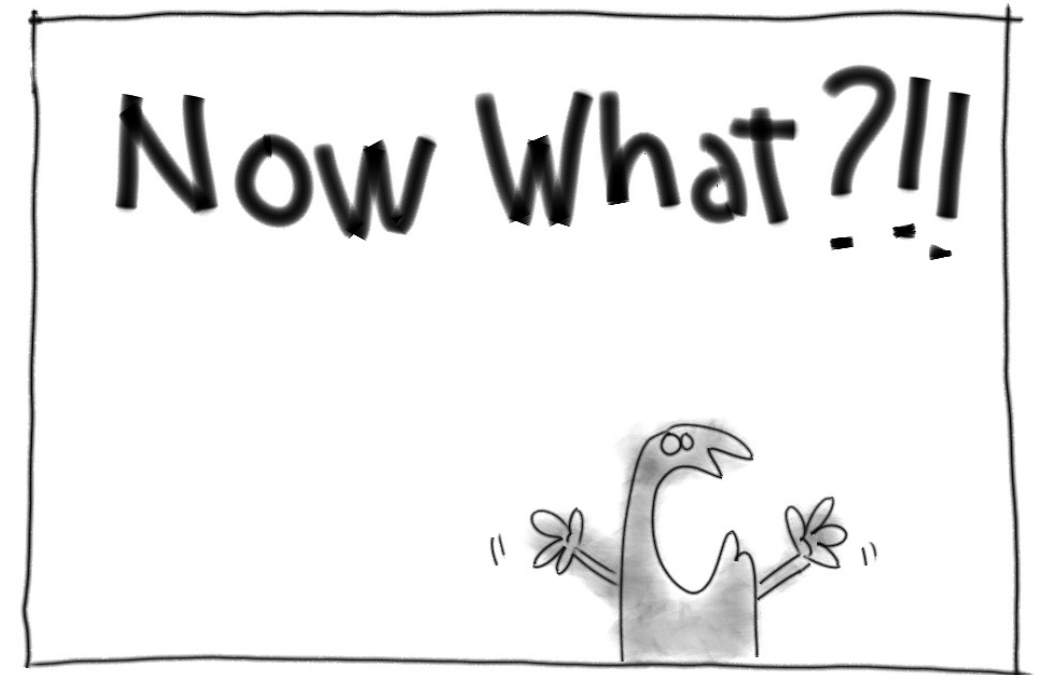
MEDICAL EVENT RETRACTION

- IMMEDIATE ACTIONS TAKEN
- FUTURE ACTIONS PLANNED
- RETRACTION WAS ACCEPTED



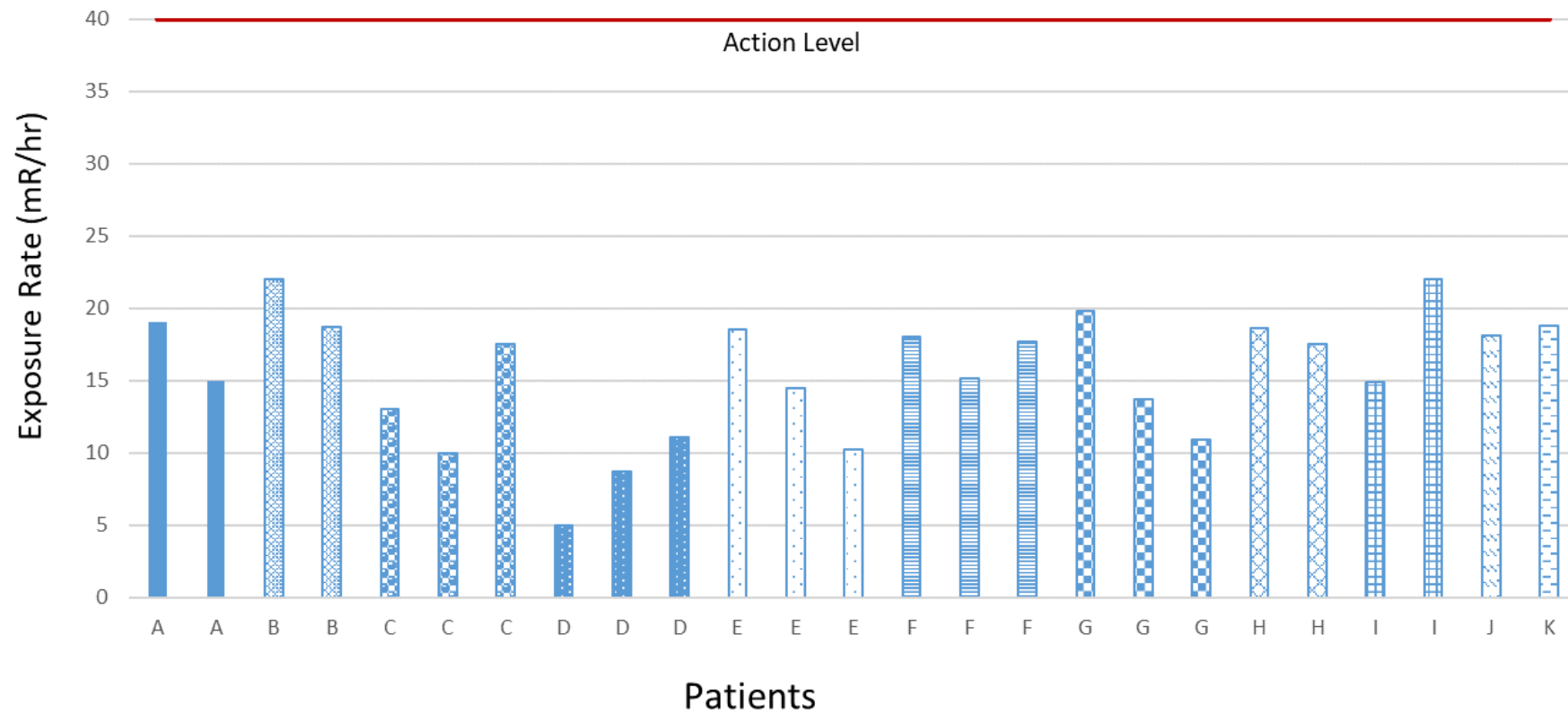
WHAT NOW?

- STRICTLY CANCER PATIENT POPULATION
- EARLIER DETECTION?
 - IV SITE EXPOSURE RATE
 - 5 min POST LU-177 INFUSION
- ACTION LEVEL >> 40 mR/hr
 - NOTIFICATIONS
 - ELEVATE ARM
 - APPLY COMPRESSION AND HEAT



ACTION LEVEL

IV Site Contact Exposure Rates (mR/hr) per Patient per Infusion



CONCLUSION

- ANTICIPATED EVENTS
- READILY IDENTIFIABLE
- QUICK RESPONSE KEY
 - ELEVATION, COMPRESSION & HEAT
- GAMMA CAMERA IMAGING
- CONTINUOUS SKIN MONITORING
- DERMATOLOGY CONSULT IF NEEDED



REFERENCES

1. KREIDIEH FY, MOUKADEM HA, EL SAGHIR NS. OVERVIEW, PREVENTION AND MANAGEMENT OF CHEMOTHERAPY EXTRAVASATION. *WORLD J CLIN ONCOL*. 2016;7(1):87-97.
DOI:10.5306/WJCO.V7.I1.87
2. DACIAN V. BONTA, RAGHUVeer K. HALKAR, NAOMI ALAZRAKI. EXTRAVASATION OF A THERAPEUTIC DOSE OF ¹³¹I-METAiodoBENZYLguanidine: PREVENTION, DOSIMETRY, AND MITIGATION. *JOURNAL OF NUCLEAR MEDICINE*. SEP 2011, 52 (9):1418-1422; DOI: 10.2967/JNUMED.110.083725

THANK YOU

KENDALL.BERRY@FCCC.EDU

JESSICA.KENDRICK@FCCC.EDU

215-728-3021

