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February 12, 2020

Michael Layton, Director
Division of Materials, Safety, Security, State and Tribal Programs
Office of Nuclear Material Safety and Safeguards
Nuclear Regulatory Commission

Dear Michael,

On January 28, I listened to the NRC public meeting on medical uses of radioactive materials. I was pleased to hear that your team is performing an independent evaluation of the 1980 NRC internal policy that exempts all infiltrations that exceed Subpart M reporting thresholds from reporting. I am providing you some additional evidence that your team should consider in their review.

Yesterday, an article - "Assessing and Reducing PET/CT Radiotracer Infiltrations: Lessons in Quality Improvement and Sustainability" - was published online in the American Society of Clinical Oncology *JCO Oncology Practice* journal. Here is a link: https://ascopubs.org/doi/pdf/10.1200/JOP.19.00302 A hard copy of the full-text is attached for your review.

This article is important to your independent evaluation; it demonstrates that the assumption underlying the NRC 1980 exemption policy is incorrect - extravasations can be almost completely avoided. In this paper, five technologists at a single center followed standard quality improvement processes and reduced their four-month Measure phase infiltration rate from 13.3% to 2.9%—a statistically significant decrease of 78% (P< .001). Additionally, the center was able to sustain their improvement during the next 12 months (Control phase) with an infiltration rate of 3.1%, even though seven new technologists joined the original team of five. During this Control phase, the original five technologists reduced their infiltration rate from 2.9% to 2.1%, while the new technologists infiltrated at a rate of 6.1%. This paper demonstrates that quality improvement efforts can significantly and quickly improve infiltration rates, that these improvements can be sustained, and that infiltrations are not “virtually impossible to avoid.”

Since the submission of this manuscript, this center has repeated the quality improvement process for all the technologists. As a result, the two technologists with the highest infiltration rates have now dropped their rate to 2.1%—further evidence that the injection process can be significantly improved. While we often describe infiltrations by rates and statistical significance, the affected patients should not be forgotten. As a result of the effort of these technologists, we estimate that from the beginning of the Improve phase until today (~32 months), **336 patients avoided infiltration as a result of the center’s quality improvement effort.** This dramatic improvement in care will continue to positively affect patients year after year.

Based on ACMUI recommendations, your team may be under the impression that the nuclear medicine and radiology communities think infiltrations are not an issue. While the communities may be currently unaware that infiltrations can result in doses that exceed NRC reporting limits, nuclear medicine leaders already recognize that infiltrations compromise nuclear medicine procedures. For PET/CT studies for example, nuclear medicine clinicians should be following the SNMMI 2006 Procedure Guideline for Tumor Imaging with 18F-FDG PET/CT 1.0 and/or the EANM 2014 FDG PET/CT: EANM procedure guidelines for tumour imaging: version 2.0. Links to these guidelines can be accessed here:

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http://s3.amazonaws.com/rdcms-snmmi/files/production/public/docs/jnm30551_online.pdf
https://www.eanm.org/publications/guidelines/2015_GL_PET_CT_TumorImaging_V2.pdf

These guidelines state:

- Standardize Uptake Values can be negatively affected by injection extravasations.
- The goal of proper patient preparation is to maximize neoplastic uptake and minimize uptake in normal tissue.
- When nuclear medicine clinicians report their findings, they need to describe the quality of the study, describe the location, extent, and intensity of abnormal radiopharmaceutical uptake, and describe limitations that can limit the sensitivity and specificity of the examination. Extravasation of the tracer at the injection site is specifically addressed.
- Report any problems with FDG administration and image the injection area if extravasation is suspected.

Additionally, the Radiological Society of North America organized the Quantitative Imaging Biomarker Alliance (QIBA) to unite researchers, healthcare professionals, and industry to advance quantitative imaging and the use of imagine biomarkers in clinical trials and clinical practice. Many of the leaders of the nuclear medicine community, including the Vice President-Elect of SNMMI, are leaders of QIBA. To demonstrate additional acceptance by the community of the importance of imaging the injection site and evaluating the amount of radiopharmaceutical left in the tissue, the QIBA FDG PET-CT protocol states the following regarding the administration of radiotracer:

> 3.1.3.1.3 Radiotracer Administration Route: FDG should be administered intravenously through a large bore (24 gauge or larger) indwelling catheter placed anatomically remote (e.g., contralateral extremity to site of disease if at all possible) to any site(s) of suspected pathology, preferably in an antecubital vein. Intravenous ports should not be used, unless no other venous access is available. If a port is used, an additional flush volume should be used. As reproducible and correct administration of FDG is required for quantification purposes, extravasation or paravenous administration should be avoided. If an infiltration or extraneous leakage is suspected, the event and expected quantity should be recorded and the infiltration site should be imaged. The approximate amount of infiltration should be estimated from the images where possible. If the infiltration is greater than 5% of the administered activity and the quantitative result from the FDG-PET/CT study is a primary or secondary endpoint, the data point might be censored from review or the subject might not be included in the study. The anatomical location of the injection site should be documented on the appropriate case report form or in the Common Data Format Mechanism (Appendix E).

The published guidelines and QIBA protocol are important to note, since they state that extravasations are a negative issue regarding the quality and quantification of the images. More importantly, they guide clinicians to image the injection site when extravasations are suspected. This imaging, a necessary step to determine the presence and degree of an extravasation, is already part of nuclear medicine guidelines. Therefore, a change to the 1980 exemption that would lead to reporting extravasations that exceed Subpart M reporting thresholds would not be adding an additional burden to the practice of nuclear medicine. Centers should be performing this step already.

To provide further evidence that diagnostic radiopharmaceutical extravasations can result in high doses to the patient's injection site tissue, I have attached three additional patient examples for your team's consideration. Two of the three cases significantly exceed the Subpart M reporting threshold and one just meets the threshold. Regarding the dosimetry used to reach these estimates, I was

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disappointed that no one from NRC was present during the SNMMI Mid-Winter meeting to see Josh Knowland present his new dosimetry method. He has also described the method in an article that will be submitted early next week to a major imaging journal along with a companion article authored by physicians at two nuclear medicine centers regarding the effects of diagnostic radiopharmaceutical extravasations on patients. While we cannot share the manuscripts with you at this point, we are happy to discuss the findings with you or your team in person or over the phone at your convenience. Once these articles have been accepted, we will notify you immediately.

Finally, I was in the D.C. area in early February for meetings with patient advocates, Congress, and Commissioner staff. On my next trip, I would appreciate the opportunity to introduce myself and speak with you in person about our clinical findings.

Sincerely,

DocuSigned by:
Ron Lattanze
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Ron Lattanze
Chief Executive Officer

Enclosures
1. Assessing and Reducing Positron Emission Tomography/Computed Tomography Radiotracer Infiltrations: Lessons in Quality Improvement and Sustainability
2. Three additional dosimetric cases

cc:
Chris Einberg
Lisa Dimmick
Said Daibes
Kellee Jamerson
Donna-Beth Howe

quality in action

Assessing and Reducing Positron Emission Tomography/Computed Tomography Radiotracer Infiltrations: Lessons in Quality Improvement and Sustainability

Jackson W. Kiser, MD[1]; Thad Benefield, MS[2]; Ronald K. Lattanze, MBA[3]; Kelley A. Ryan, BA, MC[3]; and James Crowley, MHA, CNMT[1]

abstract

PURPOSE Accurate administration of radiotracer dose is essential to positron emission tomography (PET) image quality and quantification. Misadministration (infiltration) of the dose can affect PET/computed tomography results and lead to unnecessary or inappropriate treatments and procedures. Quality control efforts ensure accuracy of the administered dose; however, they fail to ensure complete delivery of the dose into the patient's circulation. We used new technology to assess and improve infiltration rates and evaluate sustainability.

METHODS Injection quality was measured, improved, and sustained during our participation in a multicenter quality improvement project using Define, Measure, Analyze, Improve, Control methodology. Five technologists monitored injection quality in the Measure and Improve phases. After seven new technologists joined the team in the Control phase, infiltration rates were recalculated, controlling for technologist- and patient-level correlations, and comparisons were made between these two groups of technologists.

RESULTS In the Measure phase, five technologists monitored 263 injections (13.3% infiltration rate). Nonantecubital fossa injections had a higher probability of infiltration than antecubital fossa injections. After implementing a quality improvement plan (QIP), the same technologists monitored 278 injections in the Improve phase (2.9% infiltration rate). The 78% decrease in infiltration rate was significant ($P < .001$) as was the decrease in nonantecubital fossa infiltrations ($P = .0025$). In the Control phase, 12 technologists monitored 1,240 injections (3.1% infiltration rate). The seven new technologists had significantly higher rates of infiltration ($P = .017$).

CONCLUSION A QIP can significantly improve and sustain injection quality; however, ongoing monitoring is needed as new technologists join the team.

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INTRODUCTION

Accurate and complete administration of the radiotracer dose as a bolus is essential to positron emission tomography (PET) image quality and quantification.[1] An infiltration is the inadvertent paravenous administration of the radiotracer into the soft tissue surrounding the vein. ^{18}F-labeled fluorodeoxyglucose (^{18}F-FDG) dose infiltrations are not uncommon and can negatively affect image quality and quantification. They may adversely affect patient management, including incorrect staging and treatment decisions.[2]

There is no routine quality control to ensure complete delivery of the ^{18}F-FDG dose into the patient's circulation. Infiltrations may be seen on the static images (approximately 60-70 minutes postinjection) but may be underestimated because they can resolve over the course of the uptake period.[3] In addition to the resolving nature of infiltrations, injection sites are often outside the imaging field of view.[4] A literature review identified six studies (2006-2017) from three centers with a total of 2,804 patients and 425 infiltrations (15.2%).[4-9] These centers used routine static images to identify infiltrations that may have underestimated the true infiltration rate. The impact of infiltrations on PET/computed tomography (CT) images, including underestimation of the standardized uptake value, has been previously described in the literature.[4]

Carilion Clinic participated in a multicenter quality improvement project using new technology (Lara System; Lucerno Dynamics, Cary, NC) to help to assess and improve infiltration rates. Rates of infiltration from the seven participating PET/CT centers ranged from 2% to 16%, and individual technologist's rates ranged from 0% to 24%.[10,11] Specific aims of this project were to monitor injection quality, use analysis of factors that contribute to infiltrations to guide improvements, remeasure rates in a similar number of patients, and evaluate sustainability of the intervention.

Author affiliations and support information (if applicable) appear at the end of this article.

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METHODS

Our institutional review board determined that the project was not research as defined by the US Department of Health and Human Services Protection of Human Subjects[12] and that it qualified as a quality assurance/quality improvement activity. Define, Measure, Analyze, Improve, and Control (DMAIC) methodology was followed to assess infiltration rates, measure improvement, and evaluate sustainability.

Define

After a review of the literature on radiotracer infiltrations, an opportunity was identified to evaluate and improve radiotracer injection quality at PET/CT centers, and a quality improvement project was designed. Five certified nuclear medicine technologists at our center with experience ranging from 13 to 28 years (mean, 18.4 years) were trained on the project and the use of the Lara System, a class 1 exempt medical device that uses scintillating crystal technology to identify presence of radiotracer at the injection site.

Measure

Injection quality was evaluated on adult and pediatric patients (n = 263) undergoing routine PET/CT. After gaining venous access and before the ^{18}F-FDG injection, the technologist attached Lara sensors to the patient's skin using atraumatic adhesive pads. One sensor was placed approximately 7 cm proximal to the injection site, and the other, which functioned as a reference, was placed in the mirrored location on the contralateral arm (Fig 1). Utilization of the system was tracked on a weekly basis.

Data were recorded by the system during the radiolabeled tracer uptake period (approximately 45-60 minutes). After removal of the sensors, patient- and procedure-specific variables were uploaded to the system's web application, which then produced time-activity curves (TACs). These curves were used to help to determine injection quality and overall infiltration rate. Our center was initially blinded to the TACs to encourage technologists to perform injections per their usual practice.

Analyze

After 263 injections were monitored, statistical analyses were performed and included by constructing binary decision trees using 20-fold cross validation with inverse prior weights as the assessment measure (SAS Enterprise Miner 14.1; SAS Institute, Cary, NC). Logistic regression using the Bayesian information criterion as the selection criterion was also used (SAS 9.4). Both methods were used in tandem to identify contributing factors. Rates presented are unadjusted unless otherwise stated. Results of the analyses were shared with the Carilion team.

Improve

A quality improvement plan (QIP) was created on the basis of the analysis of contributing factors and discussion with our technologists, managers, and nuclear medicine physician. The QIP included three components: addition of an auto-injector (Medrad Intego PET Infusion System; Bayer HealthCare, Whippany, NJ) to provide consistent infusion and flush parameters across injections, adjustment of uptake room setup to allow for improved access to both sides of the patient, and refresher training for venous access and injection technique. After implementing the QIP, a similar number of injections were monitored (n = 278). TACs were visible to the technologists during this phase. QIP adherence was assessed, and weekly utilization continued to be tracked to ensure consistent use of the system.

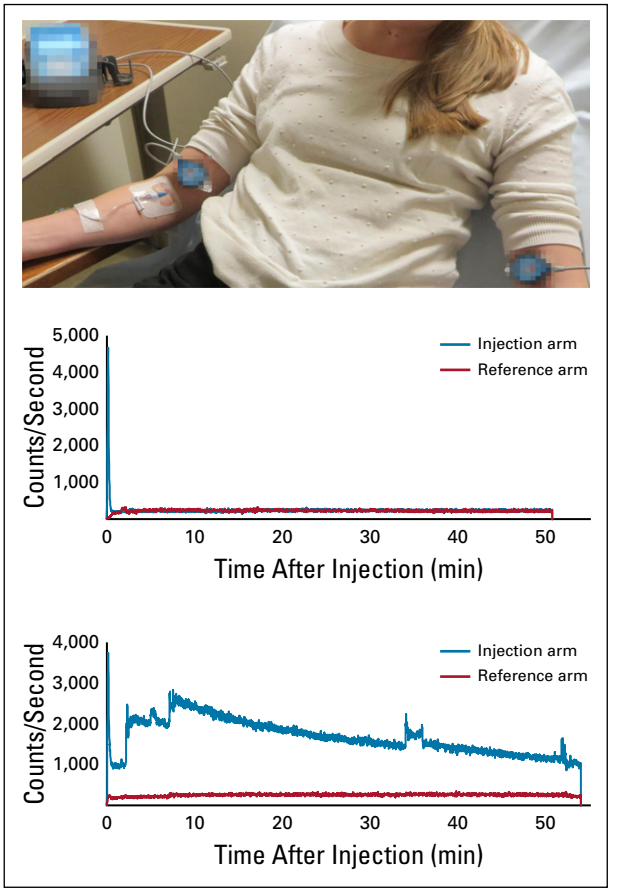

FIG 1. The Lara System (Lucerno Dynamics, Cary, NC) consists of 2 scintillation sensors, 2 pads, a reader, and a docking station. Sensors are placed on the injection arm and the contralateral arm. Time-activity curve (TAC) is provided after data are uploaded. The first TAC represents an ideal injection, and the second TAC shows significant presence of radiotracer at the injection site.

Control

Injection quality monitoring continued for approximately 1 year to assess sustainability of the intervention. During this time, seven new technologists joined the team. These new technologists received our standard onboarding training but were not present for the refresher training done in the earlier Improve phase; however, both the new and the

original technologists experienced the same auto-injector and uptake room conditions during this phase. Infiltration rates were re-assessed. Comparisons were then made between the results from the five technologists who participated in the Measure/Improve phases and the results from the seven new technologists.

RESULTS

Measure and Improve Phases

In the Measure phase, 263 injections were monitored over 13 weeks with a 93% average utilization and an overall infiltration rate of 13.3%. Nonantecubital fossa injections (hands, wrists, forearms) were associated with increased probability of infiltration. Infiltration rates for nonantecubital fossa (n = 63) and antecubital fossa injections (n = 200) were 28.6% and 8.5%, respectively. QIP adherence was estimated to be high; the auto-injector was used 65% of the time, uptake chairs were repositioned, and refresher training was conducted. In the Improve phase, 278 injections were monitored over 12 weeks with an average utilization of 85% and an overall infiltration rate of 2.9%. The 78% decrease in overall infiltration rate was significant ($P < .001$; Fig 2).

The infiltration rate for nonantecubital fossa injections (n = 71) decreased from 28.6% to 7.0%, demonstrating a significant reduction ($P = .0026$). In antecubital fossa injections (n = 207), infiltration rates also had a significant ($P = .0039$) reduction from 8.5% to 1.5%. Use of the auto-injector resulted in 1 infiltration out of 180 injections (0.6%), while 98 manual injections resulted in 7 infiltrations (7.1%).

Control Phase

Monitoring continued for approximately 1 year (n = 1,240 injections), with a resulting infiltration rate of 3.1% (Fig 2). Utilization of the system remained consistent with prior rates on the basis of reported weekly patient volume. Model-based analysis revealed a higher and significantly different ($P = .017$) adjusted infiltration rate for the seven new technologists compared with the original five technologists (Table 1). Larger needles (< 22 gauge) and not using an auto-injector were significantly associated with higher predicted probability of infiltrations for injections administered by the seven new technologists.

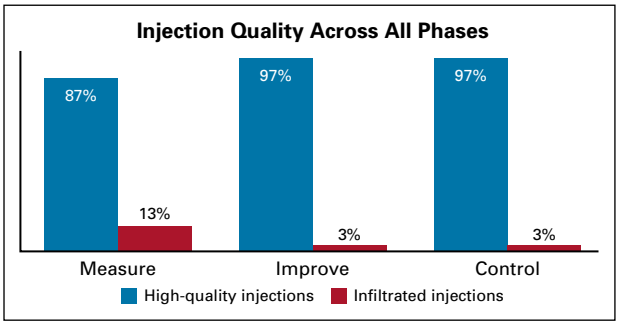

FIG 2. The 78% decrease in infiltration rate in the Improve phase was significant ($P < .001$) and was maintained in the Control phase.

DISCUSSION

We were able to create a tailored QIP specifically for our center that led to improved overall injection quality. In addition to the overall benefit of improved injection quality, we were able to enhance our clinical practice. Before this quality improvement project, our facility scanned all patients' arms to assess the injection site for infiltrations. We also repeated PET/CT studies if large infiltrations were observed on static images. Use of injection monitoring technology allows us to image patients with arms over their head as needed and provides additional insight into the quality of the injection during the uptake period, which aids in our clinical assessment of whether to repeat PET/CT studies. We intend to assess the effect of future interventions by evaluating the overall rate of repeat PET/CT studies.

While the overall improvement project was successful, we experienced several challenges. A facility relocation negatively affected utilization early in the Improve phase. Utilization was 68% over 12 scanning days, with an infiltration rate of 4.8%, as technologists adjusted to a new patient flow and room setup. Utilization during the remaining 10 weeks was 91% (Measure phase, 93%) with an infiltration rate of 2.5%, indicating that the lower utilization early in the Improve phase did not favorably bias the results. In addition, a key component of the QIP, the auto-injector, was not available 100% of the time. Finally, we observed during the Control phase that additional training would be needed for the technologists who did not participate in the retraining in between the Measure and Improve phases.

New monitoring technology to drive radiotracer injection quality improvement was easily incorporated into our routine clinical practice and allowed us to significantly reduce infiltration rates and sustain improvement. Ongoing monitoring allows us to repeat DMAIC cycles to ensure that new and existing technologists achieve and maintain high injection quality. One of our satellite facilities with a mobile unit PET/CT also used the technology as part of the multicenter quality improvement project. This facility experienced similar results, which suggests successful implementation beyond our own center. The mobile team created a customized QIP (which did not include an

TABLE 1. Original Five Technologists Versus Seven New Technologists (Control Phase)

Technologists	Infiltration Rate, %	SE (95% CI)
Original five	2.1	0.0055 (0.83 to 3.26)
Seven new	6.1	1.31 (3.19 to 8.97)

auto-injector), reduced infiltration rates, and sustained improvements. We anticipate inclusion of appropriate DMAIC learnings in our onboarding process and dissemination of the technology and quality initiative to our general nuclear medicine practice, where we expect similar results. Through quality improvement processes, infiltration rates can be reduced. However, ongoing monitoring is needed to ensure that injection quality remains high and that factors that contribute to infiltrations are continually evaluated and addressed.

AFFILIATIONS

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST AND DATA AVAILABILITY STATEMENT

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AUTHOR CONTRIBUTIONS

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Administrative support: Kelley A. Ryan
Collection and assembly of data: Jackson W. Kiser, James Crowley
Data analysis and interpretation: Jackson W. Kiser, Thad Benefield, Ronald K. Lattanze, Kelley A. Ryan
Manuscript writing: All authors
Final approval of manuscript: All authors
Accountable for all aspects of the work: All authors

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Assessing and Reducing Positron Emission Tomography/Computed Tomography Radiotracer Infiltrations: Lessons in Quality Improvement and Sustainability

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Ronald K. Lattanze
Employment: Lucerno Dynamics
Leadership: Lucerno Dynamics
Stock and Other Ownership Interests: Lucerno Dynamics
Patents, Royalties, Other Intellectual Property: Inventor on a patent held by Lucerno Dynamics
Travel, Accommodations, Expenses: Lucerno Dynamics

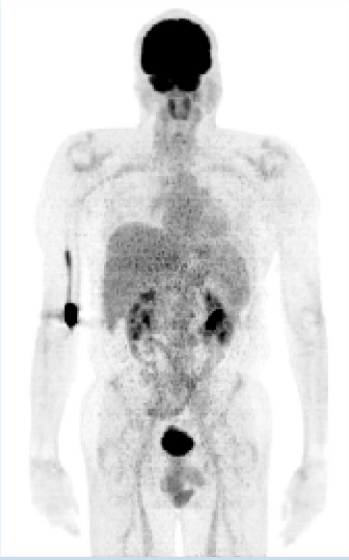
Kelley A. Ryan
Employment: Lucerno Dynamics

James Crowley
Honoraria: Advanced Accelerator Applications, Lucerno Dynamics
Consulting or Advisory Role: Siemens, Progenics
Speakers' Bureau: Cardinal Health, Advanced Accelerator Applications
Patents, Royalties, Other Intellectual Property: Patent submitted 4/15/2019 for a new method for delivering radioactive material (Inst), submitted patent for a new dose monitoring device (Inst)

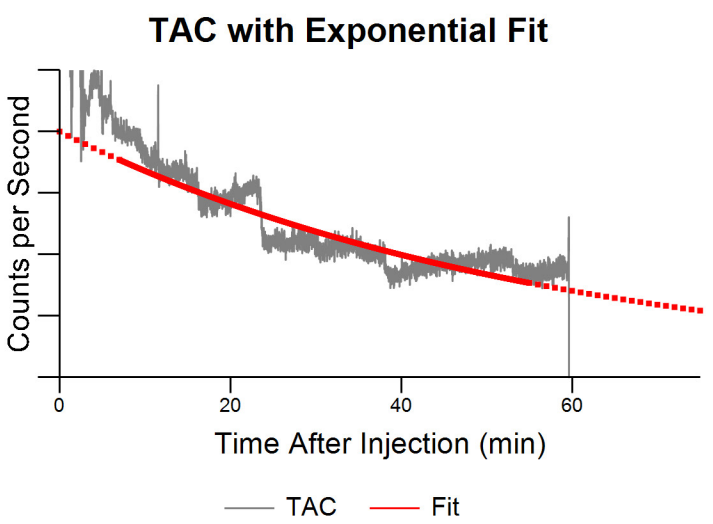
No other potential conflicts of interest were reported.

Scan #1070

Equivalent Dose: 0.2 to 0.5 Sv

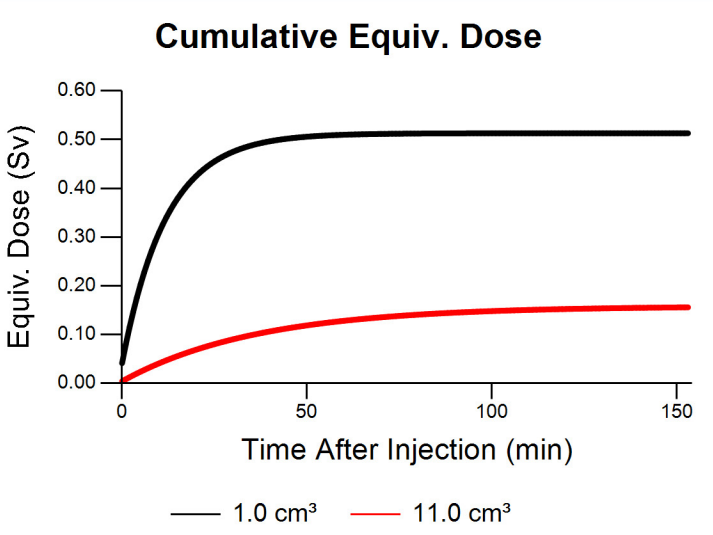


Isotope	F-18
Injection Method	Manual
Injection Location	R Antecubital
Injected Activity	16.87 mCi
Radiotracer Volume	1.50 mL
Saline Flush Volume	10.0 mL
Imaging Time	67.0 min
% Extravasation	3 %
Initial Activity	0.49 mCi
Imaging Time Activity	0.10 mCi
Reabsorption Rate	39.8 min
Dose Calculation Volume	1.00 to 11.00 cm^3
Dose Rate	84.4 to 8.7 mSv/mCi-min
Total Equivalent Dose	0.5 to 0.2 Sv



This patient underwent PET/CT imaging using 18F-FDG. The injection was performed in the right antecubital through an IV with no saline flush. We estimate that 0.49 mCi, or 3%, of the injected activity was extravasated into the arm tissue. At imaging time, only 0.1 mCi remained at the injection site.

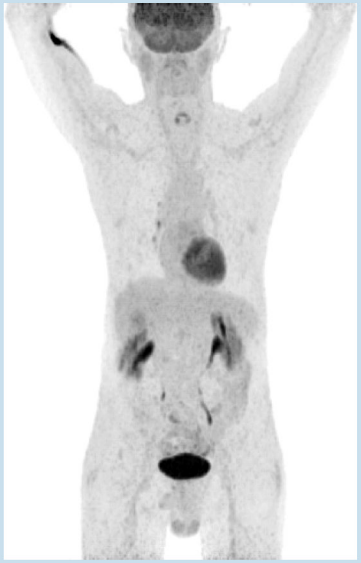
The estimated equivalent dose to the arm tissue is between 0.2 and 0.5 Sv.



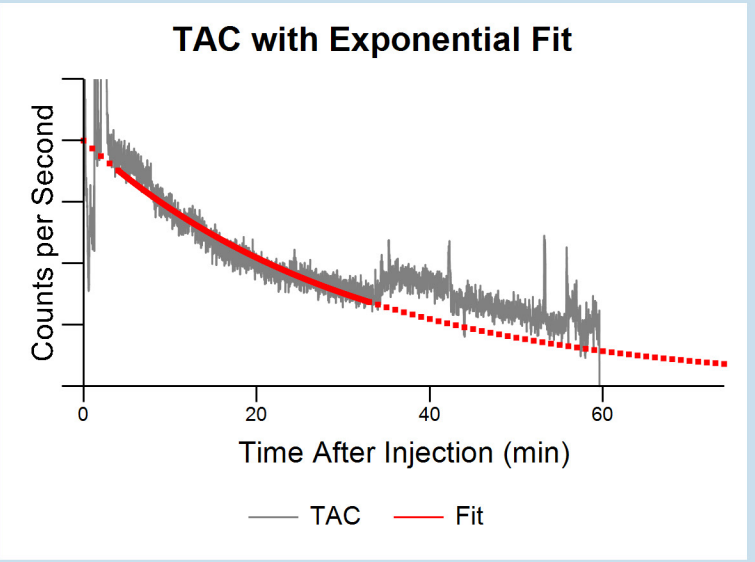
- Dose calculation volume is twice the extravasated radiotracer volume or the total flush volume plus the extravasated radiotracer volume with a minimum volume Of 1 cm^3.
- Initial extravasation amount and reabsorption rate estimates are based on PET measurements and injection site monitoring data from Lara® sensors.
- Volumetric expansion is modeled As a mono-exponential function using initial volumes and PET measurements of volume.
- Dose rates are based on nuclear decay data from ICRP Publication 107 using the IDAC-dose 2.1 software's sphere module.

Scan #17889

Equivalent Dose: 0.5 to 2.8 Sv



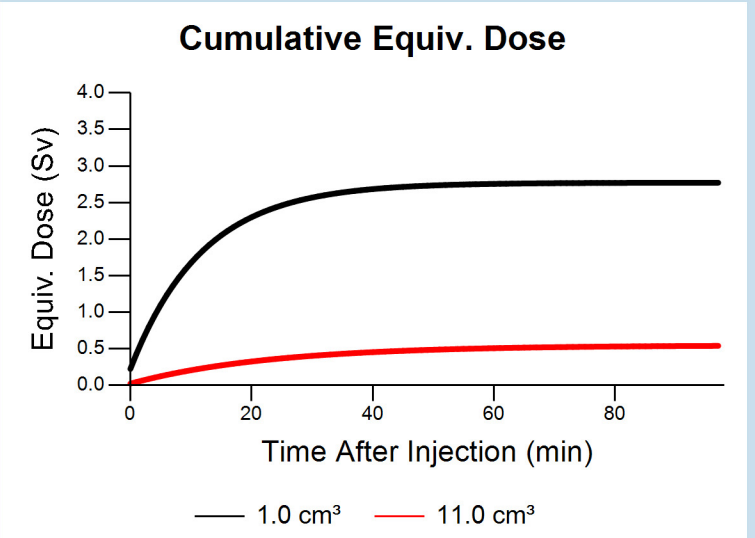
Isotope	F-18
Injection Method	Manual
Injection Location	R Antecubital
Injected Activity	9.80 mCi
Radiotracer Volume	1.00 mL
Saline Flush Volume	10.0 mL
Imaging Time	71.0 min
% Extravasation	27 %
Initial Activity	2.65 mCi
Imaging Time Activity	0.17 mCi
Reabsorption Rate	21.4 min
Dose Calculation Volume	1.00 to 11.00 cm^3
Dose Rate	84.4 to 8.7 mSv/mCi-min
Total Equivalent Dose	2.8 to 0.5 Sv



An 80 year old male presented with a history of bladder carcinoma that had metastasized to the liver. Initial follow-up imaging was determined to be relatively non-diagnostic in quality due to a significant extravasation observed on imaging and external injection monitoring.

The extravasated injection consisted of 9.8 mCi of 18F-FDG in the right antecubital using an IV. The equivalent dose to the injection site tissue was estimated to be 0.55 to 2.77 Sv.

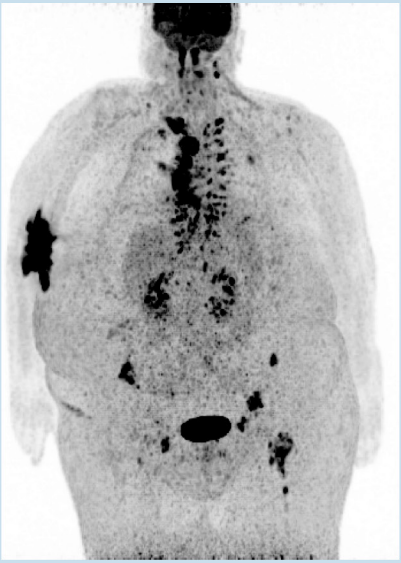
PET/CT scanning was repeated the following day. The repeat imaging confirmed disease progression and identified additional uptake not seen in the prior extravasated scan- including an upper liver lesion, increased hilar node activity, and prostate uptake. Quantitative results showed an average increase in SUVmax of approximately 25%.



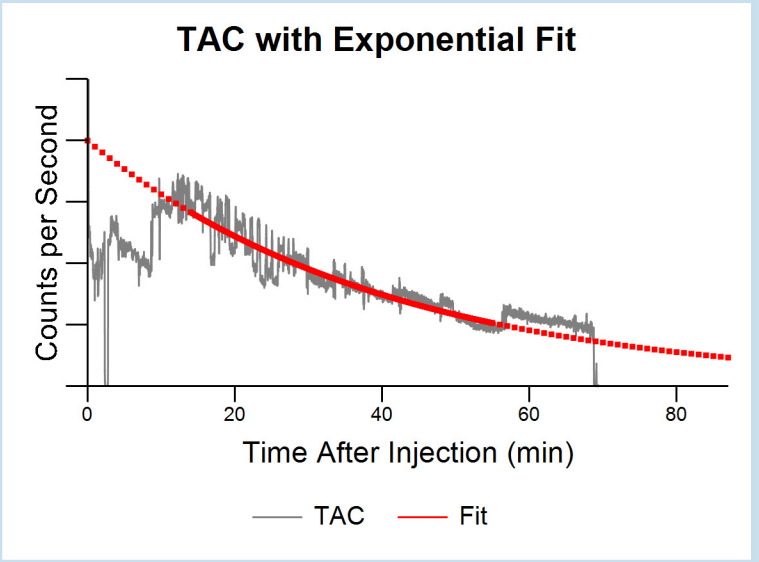
- Dose calculation volume is twice the extravasated radiotracer volume or the total flush volume plus the extravasated radiotracer volume with a minimum volume Of 1 cm^3.
- Initial extravasation amount and reabsorption rate estimates are based on PET measurements and injection site monitoring data from Lara® sensors.
- Volumetric expansion is modeled As a mono-exponential function using initial volumes and PET measurements of volume.
- Dose rates are based on nuclear decay data from ICRP Publication 107 using the IDAC-dose 2.1 software's sphere module.

Scan #17967

Equivalent Dose: 2.0 to 6.5 Sv



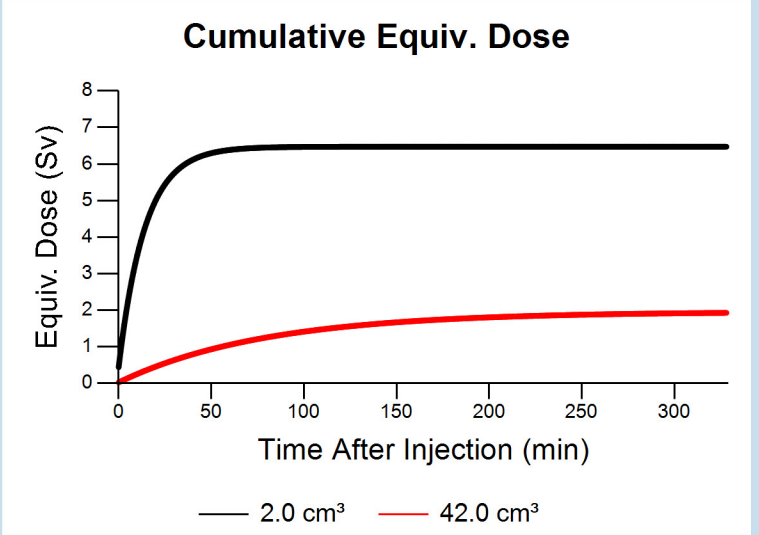
Isotope	F-18
Injection Method	Manual
Injection Location	R Antecubital
Injected Activity	10.10 mCi
Radiotracer Volume	1.00 mL
Saline Flush Volume	40.0 mL
Imaging Time	76.0 min
% Extravasation	100 %
Initial Activity	10.10 mCi
Imaging Time Activity	3.75 mCi
Reabsorption Rate	28.1 min
Dose Calculation Volume	2.00 to 42.00 cm^3
Dose Rate	43.7 to 2.4 mSv/mCi-min
Total Equivalent Dose	6.5 to 2.0 Sv



A 61 year old female presented with a history of breast cancer and malignant right pleural effusion. Follow up imaging identified possible bone involvement and additional PET/CT imaging was ordered. The restaging PET/CT injection was deemed non-diagnostic due to identification of a significant infiltration based on Lara TACs and a large area of activity observed in the arm of the patient.

From the extravasated 18F-FDG injection, arm tissue was estimated to have recieved between 1.96 and 6.47 Sv of equivalent dose.

Repeat PET/CT imaging was ordered and the patient was imaged five days later. Follow up imaging showed diffuse metastatic disease with bone involvement and confirmed further disease progression.



- Dose calculation volume is twice the extravasated radiotracer volume or the total flush volume plus the extravasated radiotracer volume with a minimum volume Of 1 cm^3.
- Initial extravasation amount and reabsorption rate estimates are based on PET measurements and injection site monitoring data from Lara® sensors.
- Volumetric expansion is modeled As a mono-exponential function using initial volumes and PET measurements of volume.
- Dose rates are based on nuclear decay data from ICRP Publication 107 using the IDAC-dose 2.1 software's sphere module.