

The Downstream Effect of Mo-99 Supply Chain Issues

Mo-99 Topical Meeting

Knoxville, TN.

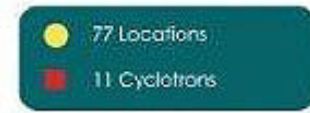
September, 2018



Overview UPPI LLC.

- UPPI is an alliance of small business and university owned radiopharmacies.
- Formed in 1998, it has 77 low energy and 11 high energy radiopharmacies.
- UPPI represents 8,000 of the approximately 50,000 unit doses dispensed every day in the U.S.

United Pharmacy Partners



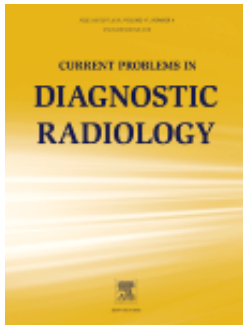
UPPI LEU Member Pharmacies



Supply Chain Challenges: Radiology/Nuclear Medicine

Current Problems in Diagnostic Radiology

Available online 12 June 2018



The Financial Burden of Missed Appointments: Uncaptured Revenue Due to Outpatient **No-Shows** in Radiology

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<https://doi.org/10.1067/j.cpradiol.2018.06.001>

Supply Chain Challenges: Radiology/Nuclear Medicine

Radiology departments lose \$1M a year due to no-shows

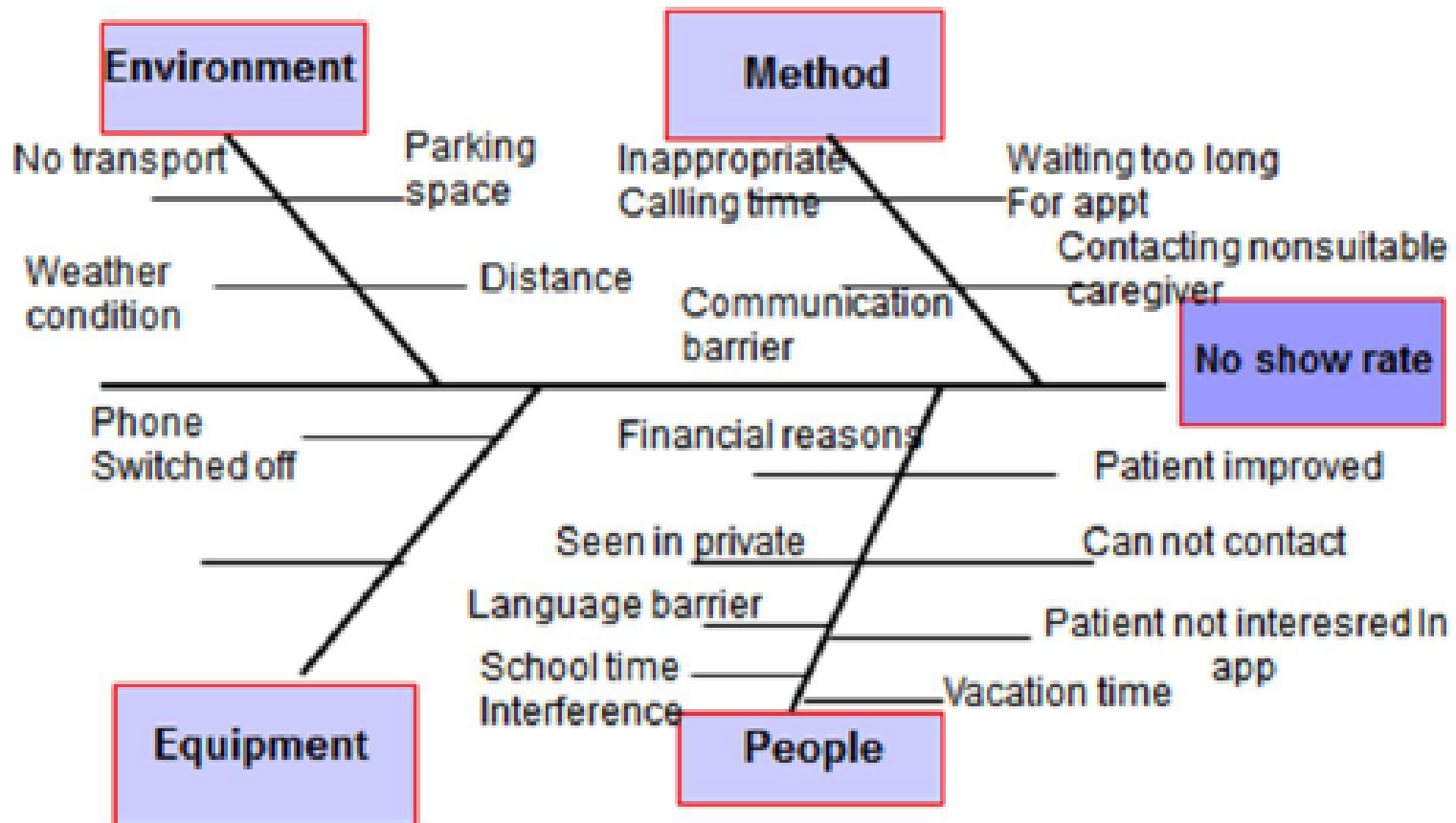
June 19, 2018 | [Melissa Rohman](#) | [Healthcare Economics & Policy](#)



Outpatient no-shows for scheduled imaging exams can cost a radiology department at a standard U.S. academic medical center as much as \$1 million in lost revenue per year, according to a [study](#) published June 12 in *Academic Radiology*.

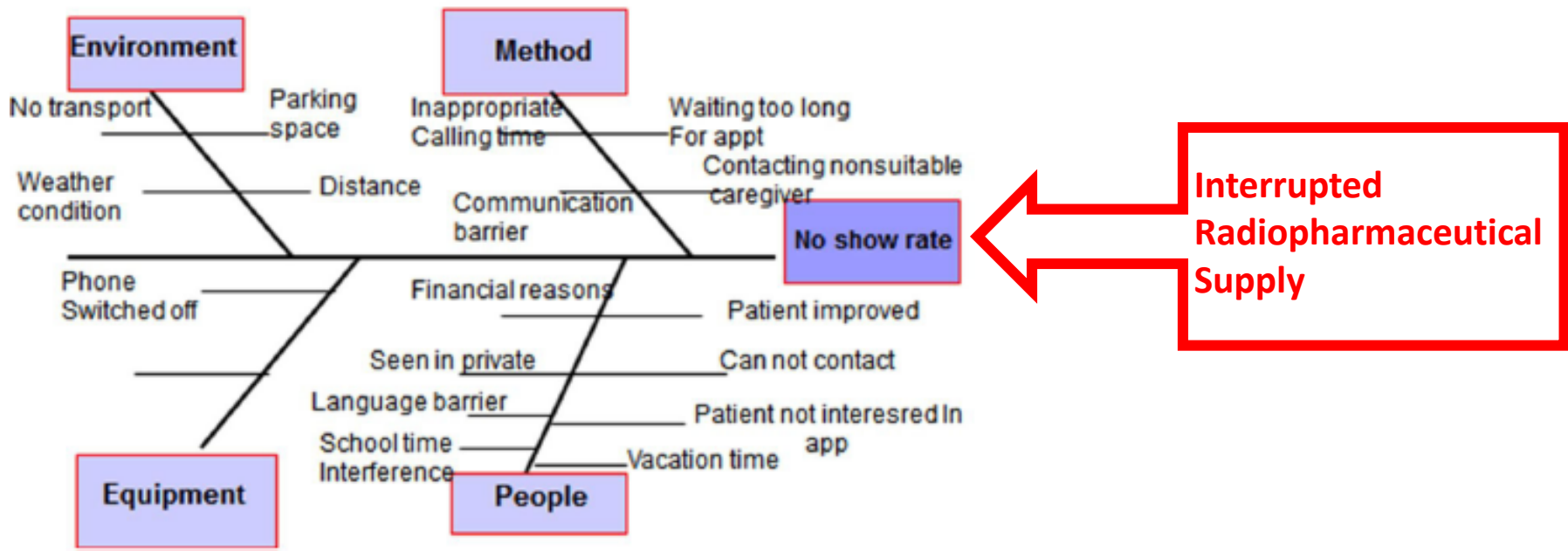
Supply Chain Challenges: Radiology/Nuclear Medicine

Cause and Effect Diagram



Supply Chain Challenges: Radiology/Nuclear Medicine

Cause and Effect Diagram



All efforts to engage the patient to show up are lost when the radiopharmaceutical dose is not available on short notice due to supply chain disruption.

Interrupted Radiopharmaceutical Supply: Effect on Patient

- In emergency need:
 - **Tc99m dose for GI bleed** –time lapsed imaging to determine active bleeding site with radiolabeled red blood cells.
 - Lack of dose can cause a patient to wait for surgery.
 - Could result in a radiographic study that gives a higher radiation exposure to the patient.
 - **Tc99m doses for Pulmonary emboli imaging** –ventilation and perfusion studies to locate blood clot.
 - Lack of dose can cause a patient to undergo spiral CT that gives a higher radiation exposure.
 - Patient receive anti-coagulants as a preventive treatment without image confirmation of emboli.
 - **Tc99m dose for gall bladder obstruction** –time lapsed imaging to determine location of obstruction: gall bladder, cystic duct, common bile duct.
 - Lack of dose for functional imaging could affect the definitive diagnosis for obstruction.

Tc99m Supply

Impact of Disruptions in the Tc-99m Supply Chain on Cardiac Testing

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FRANKEL CARDIOVASCULAR
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UNIVERSITY OF MICHIGAN HEALTH SYSTEM

https://mo99.ne.anl.gov/2016/pdfs/presentations/S2P2_Presentation_Murthy.pdf

Mo99 Supply Chain Issue Effect on UPPI

- UPPI members are impacted by Mo99 supply chain issues without prejudice to the Mo99 generator manufacturer.
- UPPI spectrum of purchases by members range from 100% of the Mo99 supplied, with one manufacturer or the other, through a course of 50-50% split or other variant.
- Even at 50-50% utilization there is an impact on delivered doses when a Mo99 generator is not received, or received with a smaller yield.
- In many instances of short notice, it is not possible to call another vendor for the lost curies of Mo99. Supply response is not robust

Mo99 Supply Chain Issue Effect on UPPI

- In a Mo99 shortage, bulk Tc99m product for on-site vial preparation disappears first:
 - After-hours coverage is effected, ICU, Coronary Intensive Care and ER patients have to queue for individualized Tc99m doses and time for results/ treatment is sacrificed.
- In a Mo99 shortage, reduced sized Tc99m unit doses is the next step:
 - Amended total activity of dose equated to increased imaging time to acquire the same detail as the prescribed dose, even with enhanced acquisition methods.
 - A sub-optimal image could require a repeat study and a greater patient dose.
- Thallium 201 to replace a rest/stress Tc99 cardiac study is a third step:
 - Longer imaging times, poor photon density, disrupted imaging schedules to the routine Tc99m stress/rest protocols.

Mo99 Supply Chain Issue Effect on UPPI: Lost Procedures

Weekly January thru June Sestamibi/TL201 Doses 2017-2018

Doses Jan-June																										
Weeks	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
Sestamibi 2017	2194	3284	3505	3250	3226	3282	3322	3495	3344	3385	3240	3198	3282	3243	3062	3188	3268	2752	3255	3145	2845	2357	3028	2999	2780	2834
Sestamibi 2018	1889	3223	3370	2214	2879	3255	3318	3161	3179	3168	3110	3101	2863	3147	3116	3135	3074	3125	3136	3129	3108	2421	3149	2195	2910	3063
Difference	-305	-61	-135	-1036	-347	-27	-4	-334	-165	-217	-130	-97	-419	-96	54	-53	-194	373	-119	-16	263	64	121	-804	130	229
Thallium 201 2017	29	44	42	51	67	64	71	62	50	65	61	63	47	62	64	50	61	58	66	66	53	232	64	51	52	54
Thallium 201 2018	91	36	38	596	341	74	43	24	97	31	28	27	25	30	26	21	16	21	18	15	18	19	18	457	99	25
Difference	62	-8	-4	545	274	10	-28	-38	47	-34	-33	-36	-22	-32	-38	-29	-45	-37	-48	-51	-35	-213	-46	406	47	-29

Most lost Tc99m cardiac studies are not recovered in Thallium 201 doses and literally there is no Rebound in studies the following days. The cardiac imaging studies are lost to other modalities or forms of medical management.

Supply Chain Disruption



- Loyola University Chicago
- Sister Jean Bobblehead
- 25 years chaplain men's basketball
- Out of Stock
- Sports memorabilia collector waits
- Order filled and accepted later than originally scheduled

Mo99 Supply Chain Issue Effect on UPPI: Lost Procedures

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Difference	62	-8	-4	545	274	10	-28	-38	47	-34	-33	-36	-22	-32	-38	-29	-45	-37	-48	-51

- Nuclear cardiology patients do not wait for a return to stock
- There was not a doubling of studies following the shortage gap (green circle)
- Thallium 201 imaging compensated for a portion of demand, may not be immediate supply uptick

Mo99 Supply Chain Issue Effect on the Nuclear Pharmacy

- Pressure to provide the client with Tc99m dose, the size of the dose, the delivery time and how often is pushed onto the nuclear pharmacy when the disruption is:
 - Prolonged
 - Recurrent
 - Short notification of the supply issue
 - Under-sized Curies for the Mo99
- Each nuclear pharmacy call to physician/clinic/imaging center is a magnitude larger than the manufacturer's calls to the nuclear pharmacy on a supply disruption issue.
- Each physician/clinic/imaging center needs their unit doses today – now.
- Physician/clinic/imaging center might not be able to reach the patient arriving for the procedure that causes a patient to be upset when the procedure is delayed or cancelled.

Mo99 Supply Chain Issue Effect on the Nuclear Pharmacy

- Nuclear pharmacies do not elute Mo99 generators once per day.
- Shortage and under-sized Mo99 generators effects when and how many times generators are eluted –based on Mo99 build-up curves.
- Yields have the downstream effect on total dose utilization – do some small use kits forego preparation to conserve milliCuries?

Mo99 Supply Chain Issue Effect on the Nuclear Pharmacy

- Stress on determining the changes in delivery logistics which results in shifting destinations and timing of delivery or creating repetitive ad hoc routing.
- Prioritizing patient burden becomes a problem for the nuclear pharmacy in long duration or sudden Mo99 Curie shortfalls.
- Short beyond use dating for Tc99m prepared products and the number of kits to be prepared when not enough activity is eluted from the Mo99 generator.
- Longer work hours for nuclear pharmacist and the delivery staff

There are no one to fill in for the nuclear pharmacist Authorized User or the specially trained and certified delivery staff... airline flight crews time out and replacements take over –not so in nuclear pharmacies.

Mo99 Supply Chain Issue Effect on Nuclear Imaging

- What happens if a new patient load for Tc99m labeled doses enters the diagnostic imaging system?
 - For example, Tc99m labeled PSMA for prostate cancer imaging
- Supply chain disruptions will exasperate the issue.
- The molecular imaging market remains a “just-in-time” delivery challenge critically reliant on a steady Mo99 supply chain.

Mo99 Supply Chain Issue Effect on the Insurance Carriers

FDG-PET in Place of ^{99m}Tc Skeletal Scintigraphy:

There is no longer a temporary shortage of technetium 99-m (^{99m}Tc), which is used in nuclear medicine for skeletal scintigraphy (bone scans). Therefore, Aetna will no longer consider FDG-PET an acceptable alternative to bone scans for detecting skeletal abnormalities for medically necessary indications.

http://www.aetna.com/cpb/medical/data/1_99/0071.html#dummyLink1

UPPI LEU Walk Update



Mo-99 Transition Fireside Chat



Discussion of vision and next steps

UPPI Focus Group Mo-99 Domestic Production

Vision and mission of the transition to non-HEU domestic Mo-99 solutions



Representing Mo-99 supply chain from Manufacturer to Hospital Purchasing

CMS Update: UPPI Activities

- Continuation and increase in non-HEU Tc99m reimbursement Q9969
 - Response to 2018 OPPS rules –December 2017
 - Meeting with Division of Outpatient Care –April 2018
 - Additional meeting with Division of Outpatient Care –July 2018
 - CMS response meeting MWWPR –August 2018
 - Comments submitted to 2019 OPPS proposed rules
 - Meeting with Medicare Part D -TBD

CMS Update: UPPI Ask

- Make the Q9969 a basic service -opportunity to encourage other Medicare programs.
- Make the payment available to other than OPPS, such as Free-standing Imaging Center –Part B setting and IDTF or Independent Diagnostic Testing Facility.
- Educate the Medicare Administrative Contractor (MACS) with an article on how the reimbursement for Tc99m doses at greater than 95% LEU/non-HEU Tc99m works.
- Create a MedLearn article with references to the final rule that can be used with facilities concerned with improper billing.
- Increase the current Q9969 code from \$10.00 to \$30.00 reimbursement.

CMS Update

A coalition of support in comments to CMS in support of the added reimbursement

- Thank you!
 - Non-proliferation support
 - American Hospital Association
 - Vizient
 - Mo-99 manufacturers and processors
 - Mo-99 generator manufacturers
 - Senator Ed Markey's office

How Will SPECT Stand: the Future Issues

- Implementation of Full Cost Recovery, Outage Reserve Capacity and Uranium Lease and Take Back costs to the per mCi acquisition cost of LEU/non-HEU Tc99m.
- Drive success in the development of domestic Mo99 production sources to stabilize the supply chain.
- Remodel the reimbursement structure for radiopharmaceuticals to keep the nuclear medicine imaging department whole on acquisition cost.
- Expand added-on reimbursement to other promote other non-HEU medical isotopes: Xe-133, I-131, Y-90

Thank You

