

August 5, 2019

Dr. Christopher Palestro

Chairman of the Advisory Committee on the Medical Use of Isotopes

Dear Dr. Palestro,

I recently read an article, *Quality Improvement Initiatives to Assess and Improve Positron Emission Tomography/Computed Tomography Injection Infiltration Rates on Multiple Centers*. I am writing to express my concerns as this topic has significant implications for the care of the cancer patients.

As an oncologist I rely on the accuracy of the PET image at 3 critical points: 1) accurate staging of newly diagnosed cancer patient 2) response to therapy (radiation, chemotherapy or combined) and 3) continued surveillance for recurrence, post therapy. An infiltrated dose of radiopharmaceutical decreases the sensitivity of the nuclear medicine image. Significant infiltration at **any** time could negatively impact the total care and prognosis of the cancer patient. i.e. patients deemed stage I, could be more advanced stage; patients thought to be responding when they are not, because they have recurrent disease and would continue with ineffective therapy and finally “early” recurrent disease would be missed and the cycle of inaccuracies would continue.

I am aware that nuclear medicine infiltrations are currently not monitored primarily because the injection site is out of the field of view in a significant number of patients. For the reasons stated above, it is critical that every injection should be evaluated for significant infiltration and reported to the referring physician in order to increase the certainty that appropriate interpretation and measures are taken in the care of the cancer patient.

I urge the NRC and Advisory Committee on the Medical Use of Isotopes (ACMUI) to modify the 1980 policy that exempts the reporting of infiltration. This would address the concerns I have stated above. Doing so will ensure that all therapeutic decisions could be made with more confidence, knowing that the PET scan injections were done correctly and with utmost certainty. And, if a significant infiltration has occurred the oncologist and or nuclear medicine physician can be given the choice to repeat the scan.

Sincerely,

Mark Yoffe, MD

Mark Yoffe MD

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