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RADIOPHARMACEUTICAL RADIATION EXPOSURE REDUCTION IN NUCLEAR MEDICINE CLINICAL TRIALS

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To maximize the likelihood of a radiopharmaceutical trial's success, designers usually select administered doses yielding the maximum radiation exposure accepted by regulatory agencies and the public. This becomes the accepted dose carried into regulatory labeling and general use. Unless this dose is necessary to meet trial endpoints, the consequences are considerable. Larger than necessary injected doses yield higher than necessary radiation exposures to study subjects, patients and staff. Larger doses yield fewer doses per batch increasing per dose manufacturing costs. Larger doses can cause greater radiolysis, increasing both manufacturing and development costs. These reduce the value of cyclotrons, hot cells and synthesis boxes and the radiopharmaceutical itself. It can even result in the radiopharmaceutical not being commercially viable. Many strategies have been proposed for reducing doses. Most rely on visual or image-based standards rather than quantitative endpoint-based criteria. We have developed methods to identify the lowest dose allowing a nuclear imaging trial objective to be met using a series of images of the same subject and field of increasing duration to model a range of doses. An ROI analysis determines the change in random variations as a function of modeled dose. The tolerable random variation is based on a predetermined threshold in the performance of each image in the study analysis. This method was used in the development of flurpiridaz F-18. The resulting dosing was successful in two efficacy trials while maintaining radiation doses well below accepted limits. We believe methods of this type may be readily extended to other radiopharmaceuticals and adapted to more general models of the relationship between random noise, dose and acquisition time. Applying these methods to existing radiopharmaceuticals as well as to those in development has the potential to make nuclear medicine both less costly in terms of resources and radiation exposure and more widely available.

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