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Statistical and radiobiological anomalies discovered in novel experiments used in setting standards for cancer treatment: importance of preserving original data

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Abstract:

Original data from experiments performed by a single individual over a 4 year period were examined in an attempt to understand why these results could not be replicated. Statistical studies of original data in the form of cell counts using a Coulter ZM counter and colony counts show that the deviation from the null hypothesis for random or uniform of both is highly significant. Similarly generated data from 8 other individuals in the same laboratory are consistent with the null hypothesis. Efforts by 2 other investigators in this laboratory failed to replicate the two key questioned experiments on 22 occasions. Radiation survival results by the questioned individual deviate markedly from reports in the literature of similar experiments under similar conditions. Results from the questioned experiments have been published in 8 articles in 4 peer-reviewed journals and were used in support of 2 approved and funded RO1 grant applications from the National Cancer Institute. At last count, the articles have been cited more than 260 times in the literature. The non-reproducibility of the results has never been reported. The experiments based on these questioned results were designed to improve doses used in nuclear medicine for both cancer diagnosis and therapy. Erroneous adjustments of doses could lead to over exposure and potential harm in diagnosis and therapy and/or to less or ineffective therapy. It is fortunate that the protocols and results for all of these experiments were preserved; otherwise, it would not have been possible to perform the recorded analyses.

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