The NIAID/RNCP Biodosimetry Program: The Need for Predictive Biodosimetry

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Established in 2004, the Radiation and Nuclear Countermeasures Program (RNCP), NIAID/NIH, supports a thriving medical countermeasures (MCM) program and robust biodosimetry portfolio. The mission of RNCP-funded research is to advance MCM products to mitigate/treat radiation injuries and explore biomarkers and technologies to triage potentially irradiated individuals and guide medical management of patients experiencing acute radiation syndrome (ARS), and/or the delayed effects of acute radiation exposure (DEARE) in the event of a radiation public health emergency.

The RNCP biodosimetry mission includes research and development in several key areas. These include: 1) Point-of-care (POC) tests for triage that are qualitative assays, which can be deployed for field triage or at the patient's bedside, primarily to distinguish between exposed and non-exposed populations; 2) High-throughput (HT) devices to measure definitive dose, intended to quantify absorbed radiation in an exposed individual; and 3) Predictive biodosimetry tests to inform the medical consequences of exposure to radiation, for example, indicating clinically significant injury to major organs and potential sequelae. Examples of predictive biodosimetry are the use of biomarkers to predict neutropenia and survival after acute exposure, or markers that indicate an increased risk of late lung complications post-irradiation.

The path for advanced development of POC and definitive HT devices is reasonably well defined[1,2]; however, the third focus area (biodosimetry for prediction of acute or delayed effects) has historically not been as highly prioritized. Given the inherent difference in radiation sensitivity of an individual based on age, sex, nutritional and health status, as well as the inhomogeneity of accidental exposures, there is a great need to understand these variations in predicting any resulting injury. By relying on injury, rather than dose measurement alone, preparedness plans to mitigate the adverse effects of radiation exposure will be more successful and efficient if biodosimetry tests rely on predictive outcomes to inform treatment strategies. The goal is reliable biodosimetry tools, improved preparedness, and saving lives.

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[1] Satyamitra., et al. (2021). "Challenges and Strategies in the Development of Radiation Biodosimetry Tests for Patient Management." Radiation Research **196**(5): 455-467.

[2] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radiation-biodosimetry-medical-countermeasure-devices