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Re-envisioning the North American Biodosimetry Assessment Networking Group

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Abstract

The RNCP/NIAID recommends the creation of a North American Biodosimetry Assessment Networking Group (BANG) by developing a blueprint for integrating the relevant national capabilities to provide emergency biodosimetry assistance in civilian populations following a radiological or nuclear incident. The goals of BANG are to: 1) establish a collaborative network (public/private partnership) and engage its membership to address emergency preparedness, response, and recovery, 2) promote strategic relationships between network members to encourage resource sharing, 3) engage with stakeholders to utilize recommended tools and support training exercises, and 4) advance bioinformatics and machine learning approaches to integrate and utilize the network data for managing emergency situations.

To be adequately prepared for large-scale radiological or nuclear incidents, a coordinated network among well-trained, commercial, hospital, and/or academic laboratories is a critical factor for providing rapid exposure assessments. Interactive and productive collaborations between North American laboratories will improve the capabilities of the network by offering a wider range of complementary biological and physical techniques. BANG would connect community service providers with various biodosimetry capabilities, and enable members to discuss best practices, common goals, emergency planning/ training, and sharing of resources, to increase the nation's resiliency before, during, and after a radiological public health emergency.

In early 2006, a Biodosimetry Task Force within the US Department of Health and Human Services composed of subject matter experts from several US Government agencies prepared a draft report on Precise and Accurate Dosimetry On-Time. The group, calling themselves the Biodosimetry Integration Group: Biodosimetry Expert Network, or "BIG BEN," set as their objectives to coordinate nationally and internationally expertise, techniques, protocols, and analyses to accurately and rapidly assess potentially exposed individuals for treatment following a radiation public health emergency. To achieve this, the group proposed establishing a network of laboratories with the ability to carry out cytogenetic testing of samples, as well as radiation bioassays (to detect internal contamination). This coordination would be achieved through sharing of standardized procedures and data across the participating institutions, with frequent drills and assessments to ensure a robust national capability. Initially, 9 sub-groups were proposed, which included focus areas such as establishment of current assets, assay methods, standards, protocols, patient databases, populations monitoring, and needs. Also considered were development of a business plan, coordination via an oversight group, and exploration of international collaborations.

Several issues were initially identified that would need to be addressed to appropriately plan and implement the network. These topics included: 1) modeling the number of individuals that would be affected by a radiological or nuclear incident and would require assessment; 2) assessing the strength and limitations of existing techniques to determine radiation dose received, and constructing tools to accurately assess individuals who would most benefit from medical attention; 3) defining what assay(s) and protocols would be the most appropriate; and 4) harmonizing methods to minimize variations between laboratories. At the time of the working group meetings, there were difficulties in establishing the necessary budget commitments that would be required to make the program successful. These resources were needed to identify, train, and equip core laboratories, establish standard operating procedures, conduct tabletop and inter-laboratory comparisons on blinded samples, and expand international collaborations.

In 2019, concepts of operations (CONOPS) were proposed for a US individual dosimetry and biodosimetry network that included laboratories at Yale University School of Medicine, the Radiation Emergency Assistance Center/Training Site (REAC/TS), the Naval Dosimetry Center, and the Uniformed Services University of the Health Sciences (USUHS)/Armed Forces Radiobiology Research Institute (AFRRI).[1] Now, in 2024, grassroots efforts by key players in the US Government and Canada to revive this crucial program have led to a re-envisioning of BIG-BEN into the North American Biodosimetry Assessment Networking Group (BANG). Resources have been many and have included concepts that have been implemented successfully in other countries. In addition, in 2024 the NIAID Radiation and Nuclear Countermeasure Program (RNCP) established a Biodosimetry Blue Ribbon Panel (BBRP) composed of subject matter experts in biodosimetry to review the evolving components of biodosimetry areas to reassess their strategic plan. As part of this charge, the BANG concept was one that this group of experienced researchers and public policy professionals were asked to evaluate. Building on the early work of BIG-BEN, with incorporation of the BBRP assessments and the formation of a writing team of internationally known biodosimetry specialists, this manuscript endeavors to make recommendations for the formation of this new network and will provide an outline and initial proposals as to how to best approach this important North American, trans-governmental need.

Overview of Biodosimetry Networks

In the case of large-scale radiological or nuclear incidents involving several hundreds and thousands of exposed individuals, effective medical management and resource allocation will hinge largely on the severity of the radiation exposures. In a hypothetical scenario of a 10kT nuclear bomb detonation in a North American metropolitan city with a population of 2 million, it is estimated that ~200 000 individuals that survive the initial blast and thermal pulse will likely receive medically-significant radiation doses.[2] The acute radiation syndrome (ARS) and delayed effects of acute radiation exposure (DEARE) follow a deterministic path in most cases, with distinct dose-dependent clinical outcomes: hematologic effects at doses of ~2 to ~6 Gy, prominent gastrointestinal effects at doses >6 Gy and a rapid progression of other effects at higher doses.[3] The $LD_{50/60}$, the lethal dose for 50% mortality of the exposed human population in 60 days, is thought to be ~4 Gy. Lessons learned from Chernobyl victims and atomic bomb survivors indicate that medical management of radiation-exposed victims is critical for mitigating most of the immediate and many of the delayed health risks caused by irradiation. For example, during the Chernobyl disaster (1986), there were 600 workers on site, and 28 of 134 workers who suffered from ARS died within a few weeks. Subsequently, there were 3940 deaths from radiation-induced cancers and leukemias among the ~200 000 emergency workers.[4,5] More than 100 radiological or nuclear accidents/incidents have been reported as of 2014, with 57 of those occurring since Chernobyl.

To minimize mortality and to improve health outcomes, rapid assessment of exposure dose, particularly in excess of 2 Gy, is critical for effective utilization of available medical resources to save the lives of acutely exposed individuals.[6] Performing absorbed-dose estimation for numerous individuals in the aftermath of mass casualty incidents will pose a great challenge. Any single laboratory at a local, state, or regional level may not be able to deal with the biodosimetry needs of such an incident, owing to the lack of both manpower and other resources. It has been estimated that, in a hypothetical event involving a population of ~1 million, triaging 15 individuals per hour by the dicentric chromosome assay (DCA) will provide dose estimations only for ~1810 individuals on day 10 from the date of incident and would require increasing the triage rate to 15 000 per hour to complete the dose estimation in the same time frame for all the individuals.[7] The only way to enhance the biodosimetry capabilities at the national and global levels is to integrate the concerted activities of multiple laboratories working together through an organized network.

Realizing the importance of biodosimetry networks for radiological/nuclear emergencies, different regions/countries/continents established biological and physical dosimetry networks. European Radiation Dosimetry (EURADOS) was the first to be initiated in 1982, followed by the Canadian Network in 2002, and the Latin American Biological Dosimetry Network (LBDNet), and the WHO Biodosimetry Network (BioDoseNet) in 2007. Later, the European Network of Biological and Retrospective Physical Dosimetry (RENEB) and Asian Radiation Dosimetry Group (ARADOS) were stood up in 2012 and 2015, respectively. Additionally, countries in Asia (India, Bangladesh, Malaysia, Singapore, Indonesia, Bangladesh, China, Republic of Korea, Philippines, Saudi Arabia, Sri Lanka, Thailand, Vietnam, and Japan), Africa (Ghana), Europe (Romania, Turkey, Czech Republic, Greece, France, Hungary, Germany, Spain, Italy, Ukraine, Russian Federation, and the UK), Eurasia (Kazakhstan), South America (Argentina, Bolivia, Chile, Brazil, Ecuador, Peru, Paraguay, and Uruguay), India, and North America (Canada and the US) have developed their own networks of laboratories that collaborate with global networks through participation in inter-laboratory comparison (ILC) exercises. Some distinct advantages of these networks are achieved through: 1) leveraging laboratory resources within and across nations; 2) utilization of medical resources for facilitating triage; 3) cross-validation of various dosimetry tools for specificity and sensitivity; 4) improving operational infrastructure within national and international networks to adequately respond to large-scale events; and 5) developing novel biodosimetry tools for predicting short- and long-term health risks. Among the networks, WHO BioDoseNet is a critical component of global efforts to protect public health in the face of radiological threats, ensuring that countries are better equipped to respond to radiation emergencies. The BioDoseNet was initially built on the premise of WHO Radiation Emergency Medical Preparedness and Assistance Network (REMPAN). A recent review by Wilkins et al.[8] summarizes the survey results of WHO BioDoseNet on the biodosimetry capabilities of the participating laboratories. WHO BioDoseNet currently has 90 participating laboratories around the globe, and the average number of samples that can be processed by the BioDoseNet participating laboratories has been steadily increasing over the years (e.g., 170 samples/group in 2009, 200 samples/group in 2015, and 346 samples/group in 2021).[8]

North America has been working towards a binational network involving Canada and the US. This network was conceived in Canada in 2002, after developing the National Biological Dosimetry Response Plan (NBDRP). This initial plan brought together 4 reference testing facilities, along with several hospital laboratories to assist with scoring when the reference laboratories were overwhelmed.[9] The 4 reference laboratories (Consumer and Clinical Radiation Protection Bureau, Health Canada (HC, Ottawa), Defense Research and Development Canada (DRDC, Ottawa), Atomic Energy of Canada Limited (now the Canadian Nuclear Laboratories (CNL), Chalk River), and the McMaster Institute of Applied Radiation Sciences (McIARS, Hamilton) were selected for their experience in biodosimetry, having well-developed methodologies, existing radiation dose calibrations curves, and/or sufficient expertise in biodosimetry. To date, US groups from AFRRI, Oak Ridge Institute for Science and Education (ORISE), Nebraska Medical Center, Yale New Haven Hospital, and ASELL, LLC have participated in at least 1 ILC. Although informal, this effort has been the beginning of the North American network. To date, 13 interlaboratory comparisons have been conducted, with some also including laboratories outside of North America (e.g., the Korean Institute of Radiological and Medical Sciences, Taiwan Institute of Nuclear Energy Research, Argentina Nuclear Regulatory Authority, Defense Science Organization, Singapore, and National University of Singapore). The main goal for conducting ILC exercises within and across network laboratories is to achieve the following: 1) harmonization of multiparametric assays across the laboratories; 2) improvements in the dose prediction accuracy of the dosimetry tools; 3) development of appropriate point of care tools for triage; and 4) identification of potential gaps in our knowledge and solutions for achieving an effective medical triage. Being the first of its kind, EURADOS has several working groups, with each one dedicated to different disciplines, such as harmonization of individual monitoring, environmental dosimetry, computational dosimetry, internal dosimetry, dosimetry in radiotherapy, retrospective dosimetry, dosimetry in high energy radiation fields, and dosimetry in medical imaging. A detailed review on the scientific achievements of the EURADOS working groups was recently published.[10] A multi-biodose approach was undertaken in 1 of the EURADOS exercises, where 3 of the biodosimetry assays (DCA, cytokinesis-block micronucleus (CBMN) assay, and gamma-H2AX foci assay) were compared and evaluated for the purpose of triage categorization.[11] The RENEB active network, which originally had 23 laboratories from 16 countries, has joined EURADOS to conduct several ILC exercises and integrate new biological and physical dosimetry methods into European Union (EU) emergency response plans.[12] A recent exercise involved DCA, gene expression, Raman spectroscopy of blood cells, and thermoluminescence of the gorilla glass of cell phones, and had 17 participating laboratories. Several other retrospective dosimetry exercises were also carried out by RENEB and EURADOS working group 10.[13–15]

In July 2021, RENEB conducted the biggest international ILC exercise involving 8 assays (DCA, CBMN, fluorescence in situ hybridization (FISH)-based translocation, premature chromosome condensation (PCC), gamma H2AX foci, gene expression, electron paramagnetic resonance (EPR), and optically stimulated luminescence (OSL)). This exercise included 86 dosimetry expert teams from 46 organizations in 27 countries, including the North American Network.[16] The North American Network intercomparisons have generally comprised the irradiation, blinding, and shipping of 10 blood samples from Health Canada to each of the participating facilities, with each laboratory providing scoring and dose estimate data back to Health Canada for analysis. Typically, DCA or CBMN assays were performed.[17] Many of the participating laboratories are also involved in research into new methods for biodosimetry, and as they become established, they have been included in the ILC efforts. For example, both HC and CNL have developed an imaging flow cytometry (IFC) CBMN[18] method and ASELL has developed the CytoRADx™ method,[19,20] both of which have been tested in recent ILCs. In addition to the Canadian-led ILC exercises, laboratories from the North American network have participated in other ILCs, one of the earliest being led by AFRRI and including HC and REAC/TS, along with Bundesamt fuer Strahlenschutz (BfS), Oberschleissheim, Germany, and the Research Center for Radiation Emergency Medicine, the National Institute of Radiological Sciences in Chiba, Japan.[21] By participating in these ILC exercises, confidence has been gained in the capabilities of the North American laboratories in confirming that selected biodosimetry methods provide accurate and timely dose estimates, with good agreement between the laboratories. This outcome is critical for a successful network, as it allows blood samples to be shared between laboratories when the capacity of a single facility is overwhelmed.

North American Biodosimetry Assessment Networking Group Conops

The current envisioning of the North America Biodosimetry Assessment Network of commercial/hospital laboratories and Cytogenetic Biodosimetry Laboratories (CBLs) located at multiple sites could be developed to meet the expectations of US and Canadian government agencies and health-care professionals to provide estimates of individual radiation dose for a mass casualty radiological or nuclear incident. A premium should be placed on alignment, with the common goal of providing timely, yet accurate, biodosimetry estimates. This objective would need to include agility for immediate access to a hosted server with rapid stand-up; and consistency with utilization of the same equipment, supplies, standard operating procedures, cross-training of technicians in all CBLs on a rotating schedule, and identical calibration curves for each radiation quality and scoring criteria for dicentrics. Stakeholders in this activity should include both US and Canadian health care providers in the civilian sector and military, who require knowledge of individual biodose to inform radiation triage and medical management, as well as for monitoring after exposure for potential development of radiation-related diseases such as dysfunction of lung, kidney, cardiac, central nervous system, and cancer.

Purpose of the North American BANG – Scope of Activity

The RNCP/NIAID envisions the formation of BANG, with the goal of creating a framework for the US and Canada to build relevant national capacities for providing emergency diagnostic assistance to the exposed population in the event of a radiological/nuclear emergency. Collaboration between laboratories across the continent will improve the capabilities of a network, by offering a wider range of complementary biological and physical techniques. These early ventures will facilitate the selection of the best possible approaches for various emergency situations. A tiered approach is also conceivable, starting with fast screening of the potential victims in tier I followed by precise analysis of radiation biomarkers for an individual dose estimation in tier II in those persons with positive initial screening results in tier I. Besides the increase in capability, an enhanced dose prediction capability can be achieved by networking laboratories through training involving interlaboratory exchange of irradiated samples for comparison of dose estimates between institutions. The goal of this network would be provision of support in case of a large radiological or nuclear emergency, where the number of persons requiring biological dosimetry would outweigh the country's current capacity (Figure 1). There exist both near- and long-terms goals that have been suggested by the NIAID-convened BBRP. They include the following:

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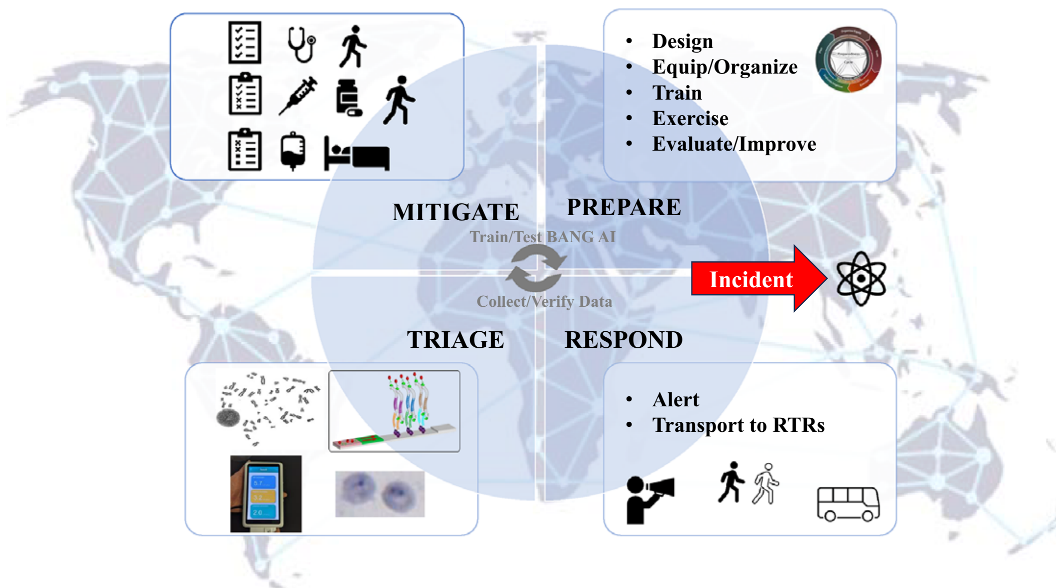

Figure 1. The North American Biodosimetry Assessment Networking Group.
RTR= Radiation triage, treatment, and transport sites.

Immediate goals

- Establish a networking group composed of US and Canadian government employees and outside stakeholders to consider emergency preparedness, response, and recovery in relation to biodosimetry techniques;
- Promote strategic relationships between members of the network to encourage collaboration and resource sharing;
- Coordinate with other countries that have established networks for biodosimetry assessment;
- Engage with government partners, academia, and corporate entities to utilize recommended tools and training;
- Explore bioinformatics, artificial intelligence, and machine learning approaches to integrate large volumes of data for emergency crisis management.

Long-term goals

- Develop a US and Canadian public/private network that can respond rapidly to any future public health emergency involving radiation exposure;
- Establish dedicated funding source(s) to establish, train, and maintain a biodosimetry network capable of rapidly responding in case of a radiological or nuclear incident.

NIH hopes to assist in the pursuit of these goals primarily through partnership with academia, private industry, and US and non-NIH government partners. To be successful, it will be necessary to carry out market research to learn from previous attempts and to identify existing laboratories across all North American nations (e.g., laboratories conducting cytogenetic, proteomic, genomic, transcriptomic, and metabolomic assays, as well as radio-bioassays and EPR). These initially identified facilities will serve as reference laboratories to train, equip, and establish numerous laboratories capable of running multiple biodosimetry assays as mentioned above. Both core (reference laboratories) and satellite centers will be needed to respond to surge requirements, and exercises must be regularly scheduled to continually assess accuracy, capability, logistics, besides identifying gaps. In addition to participation between the US and Canada, continued international exercises will also be necessary to ensure accuracy, capability and logistics across the international networks. Finally, with the advent of cutting-edge computing techniques, inclusion of artificial intelligence (AI)/machine learning (ML) in the development and implementation of disaster management strategies will be critical. The ultimate mission of BANG should be to align human and laboratory resources in North America to:

1. Provide secure tracking of biological samples;
2. Generate biodosimetry results (e.g., cytogenetics, multi-omics, radio-bioassays and EPR);
3. Analyze results;
4. Determine radiation doses and outcome of exposure;
5. Host a central database of Health Insurance Portability and Accountability Act (HIPAA)-protected results;
6. Provide access of individual results to health care providers, and aggregated data to US and Canadian Government agencies;
7. Drive innovation in individualized/personalized biodosimetry through technological advances for developing field deployable, easily performed, rapid assays to increase throughput and provide estimates of biodose.

This Network should also serve as a North American resource for technology innovation, and a “think tank” for exploring and developing novel biodosimetry technologies that work with and serve the needs of multiple government agencies, allowing them to apply tools for both rapid and retrospective biodosimetry in small or large volume incidents. Additional benefits that could be realized from implementation of BANG include technological advances (using a wide scope of techniques, cytogenetics and molecular tools, radio-bioassays for internal contamination assessment, and EPR); and centrally-managed computer hosting with on-demand availability and lower costs than multiple individual private servers. Expectations for BANG participation are many, but at a minimum should include a demonstrated capability to mobilize the radiation laboratory, ideally within 4 hours after the incident; willingness to respond 24/7/365; laboratory capacity to perform approved biodosimetry techniques; experienced leadership proficient in the related

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biodosimetry technology; an openness to developing and implementing new technologies in a collaborative group setting; and a desire to access systems for e-learning and hosted services for analysis and biodose estimation. Whenever possible, high-throughput technologies should be applied, using commercial platforms that have been already developed.

ML and AI – Big Data at All Levels of the BANG Network

The core objectives first proposed by BIG BEN will now be the task of BANG to accomplish. Multiple means of communication currently available now make it possible to integrate information such as biodosimetry readouts and subject matter expertise into a computational framework usable in real-time. However, an efficient, fool-proof, standardized platform that encompasses all the requirements involved in rapidly sharing accurate data that is private yet easily accessible to scientific and medical responders will require a colossal effort. This task will rely on computational methods capable of combining massive amounts of information from multiple data sources to generate or predict outcomes – information that could potentially be used to facilitate triage and guide medical treatment strategies during a public health emergency.

Artificial Intelligence (AI) is trainable with increasing ability to learn and autonomously locate properties within any data type and perform complex tasks. With these characteristics, AI is poised to revolutionize predictive modeling for radiation exposures in multiple ways: 1) analysis of available biological data for the discovery of organismic or organ-specific biomarkers; 2) time series (kinetic) analysis for progression of radiation effects/injuries, specifically in the case of Acute Radiation Syndrome (ARS); 3) integration of multi-omics data in predictive modeling for early and delayed effects/risks in various organ systems; 4) image-based analysis of cellular damage to detect changes that are presumably precursors to delayed effects; and 5) dose-response modeling for personalized medicine for radiation injuries.

AI has been employed to perform intricate functions and has already made its mark in radiation research. Techniques in machine learning (ML), a subset of AI, have been applied in the hunt for potential drug targets for radiation injuries. ML has been used to identify radiation-relevant miRNA signatures that could serve as biomarkers of radiation injury, with the potential to develop novel, targeted medical countermeasures.[22] Approaches in computational dosimetry also utilize ML for predictive modeling using *in silico* phantoms and radionuclide biokinetics that could help mitigate risk of injury in a variety of circumstances, such as radiological emergencies, space travel, military, and occupational hazards in nuclear medicine and nuclear power plants.[23] In a study at Columbia University, ML methods were used to perform quantitative biodosimetry with the purpose of distinguishing between partial- and total-body irradiation (PBI and TBI) exposures in male and female mice. Knowing the extent of radiation exposure is a critical piece of information in a post-incident scenario where triage decisions are being made. This study showed that a combination of radiation-specific biomarkers and B and T cell counts are suitable to complement existing methods for biodosimetry of PBI and TBI exposures.[3]

The potential use of ML for real-time dosimetry after a radiological incident could be central to the North American BANG. Much can be learned from emergency departments in the US and around the world, where in some cases, ML is already in use to support patient stratification procedures.[24] The requirements of a BANG-specific system must have the capability of expanding and accelerating triage and treatment decisions that may possibly involve thousands of citizens in need of immediate attention (Figure 1).

Biodosimetry is just one piece of the information required to build an AI system that could be used in a emergency response. Metrics on drug availability, space in treatment centers, locations of these resources, and accessible routes to these resources are just a glimpse of the extraordinary level of information that will need to be available, coordinated, and made easily accessible. The volume of data and its accuracy are key. Large data sets including animal studies and the extensive historical data from incidents involving humans such as Chernobyl could be integrated to develop a reliable BANG AI model. While the development of a fully autonomous AI system for use in a radiological/nuclear incident may be years away, the possibility of developing AI tools to support responders is indeed currently feasible.

Conclusion

Combining the expertise and experience in the biodosimetry community within North America and around the world can greatly enhance our ability to provide timely and accurate dosimetry results after a large-scale radiological or nuclear incident. Increasing the collective capacity of North American network members can be achieved through activities such as training, knowledge sharing, ILC exercises, and research into novel, high-throughput methodologies. With the addition of AI/ML tools for event management and data analysis, a robust North American Network could be realized in the form of the Biodosimetry Assessment Network Group.

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