NRL BAA Announcement
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MULTIECHELON DIAGNOSTICS (MEDx) TECHNOLOGY DEVELOPMENT AND TIERED EVALUATION

Recent advances in diagnostic technologies are blurring the standard definitions of Echelons of Care *[see Appendix A for definitions]*. As smaller, faster, more sensitive, and easier to perform become superlatives of emerging technologies, those technologies may now be applicable to more than one Echelon of Care. For example, complex genomic analysis for alleles, SNPs, or other unique genomic markers may have started out as an Echelon 4 activity, but can now be performed on a portable thermocycler device that has the operational characteristics to be successfully deployed at Echelons 1 or 2. Therefore, the community has never been more empowered to introduce new technologies across the battlespace, specifically the same technology with multiple concepts of operation.

The Naval Research Laboratory (NRL) is seeking Research & Development partners to advance technology developed for *in vitro* diagnostic devices that are amenable to military hardening and integration with communication capabilities to support the medical diagnostic and epidemiological detection and biosurveillance needs of the US military across multiple Echelons of Care and specifically for field deployment at Echelons 1 or 2.

Desired Design and Performance Capabilities

The Government is interested in proposals offering innovative, high functioning approaches for *in vitro* diagnostic devices that can operate at Echelon 1; however, superlative diagnostic technologies that operate at Echelon 2 will be considered. Offered technologies must be mature enough to enter into the Tiered Evaluation Model described in a later section of this call.

Proposals for both genomic and immuno-analysis technologies are sought. Desired performance capabilities for the two use cases are:

Genomic Analysis Platforms: Devices capable of detecting specific nucleic acid targets and/or examining molecular sequences at clinically relevant concentrations in complex clinical sample matrices, to include whole blood, serum/plasma, urine, and nasal swabs. An integrated or very simple method to nucleic acid sample preparation/purification is needed to operate without any complex external sample manipulation. Specifically DNA and/or RNA pathogen genomic signatures and/or host

response biomarker targets must be measured, to provide positive identification of the causative agent of illness on a hand-held or man portable diagnostics system. Analysis should be multiplexed (minimum of four; preferred more than 5, including internal positive controls. Sample adequacy/processing controls and negative template controls are also encouraged) to provide a syndromic approach to disease identification; including sub-typing for diseases as appropriate (*e.g.,* dengue virus serotypes 1, 2, 3, and 4, phylogenetic differentiation of Ebola strains, et cetera).

High Performance Non-Nucleic Acid Analysis Platforms: Devices capable of identification of affinity ligand binding antigen capture (*e.g.,* immunoassay target platforms that promote identification of the causative agent of illness. Analysis should be multiplexed (minimum of three, preferred more than 4) to provide a syndromic approach to disease identification; including sub-classification for diseases as appropriate. Assays for immunological targets that indicate acute infections are preferred, particularly for deployment in endemic areas.

In either use case, the Device and Assay must have the following characteristics: The device must be a low-complexity diagnostic device usable by personnel following minimal training. A total sample to answer timeframe of one hour or less is preferred. The final technology package should be for use in field forward, often austere environments with limited resources. Important assumptions for these environments include that they have no surgical and limited patient holding capability, are manned by a Physician, Physician Assistant (PA), or Medic, with the mission of providing triage, and treatment to return military personnel to duty, or stabilizing them for evacuation to the next level care facility. The device must have communications ability or can be easily integrated with a communication capability. The base requirement is that the communication of the resulting analytical data is possible via electronic means (*e.g.,* text message, email, image, PDF, et cetera). The device should have battery capability that assures no disruption in assay completion should field conditions change abruptly. Full battery operation with periodic battery charging is preferred. It is not required that the device is handheld, but the physical parameters of weight and footprint will be evaluated.

Devices should demonstrate sufficient analytical sensitivity, specificity and total (positive and negative) predictive value for infectious disease diagnostic applications. The Devices and Assays should be designed to diagnosis diseases whose origin is an infectious agent, pathogen, or toxin (organized as panels by syndromic presentation or pathogen class), and/or biomarkers of exposure to said agents. Analytes of interest include both pathogen and host-related exposure class-differential diagnostic markers. The ability to differentiate between pathogens that cause non-specific febrile systemic disease that needs to be differentially ruled in (and preferably ruled out) such as Malaria (specifically *P. falciparum*), Arboviral diseases (e.g. dengue, chikungunya, etc.), Typhoid, Arenaviral diseases, Rickettsial diseases, Viral hemorrhagic fevers (specifically Lassa fever and Ebola), Plague, Tularemia (*Francisella tularensis*), and melioidosis (*Burkholderia pseudomallei*) is desirable. The government is also highly interested in capabilities for the rapid analysis of Antimicrobial/Multi-drug resistance (AMR/MDR) sensitivity. Detection should be possible out of the appropriate sample

matrix (*e.g.,* whole blood, serum, urine, saliva) with sample collection occurring at similar environmental conditions to the device operation. Sample preparation should be minimal or preferably automated. It is not a requirement that the device technology fulfilling the requirements outlined above be specifically designed for these pathogens/diseases, but the technology must be easily adaptable to such pathogens/diseases. A full use scenario from sample collection, through sample preparation, to answer must be offered with preference given to fully automated and user-friendly solutions.

NRL will work cooperatively with the Offeror to test and verify performance of the devices and to assist in the integration of the diagnostic devices with communication and device hardening for Echelon 1 application. The offeror must demonstrate manufacturing capability, or partnerships for manufacturing, that assure prototype Devices and Assays will be available for field deployment and testing at the end of the performance period.

Any potential International Traffic in Arms Regulations (ITAR) restrictions, including any anticipated restrictions likely to be generated by the proposed work plan, must be listed.

Tiered evaluation model

It is anticipated that the MEDx program will provide up to two years of funding for research and development through competitive prototyping. The timeline will be divided into three Tiers. The first Tier will be no more than 5 months and include time for NRL to independently benchmark the performance of the offerors technology with the current assay that best matches the stated diagnostic needs; note that not every need must be met by the technology at the time of proposal, but a clear path towards meeting those needs within the overall span of the program options must be described. Technologies of sufficient merit will be advanced to an optional second Tier that engages the offeror in research and development of the technology to meet all needs outlined with a performance period up to 12 months. Following the performance period, the developed technology will be again be independently benchmarked by NRL. Finally, an optional third Tier of 3-9 months can be activated for the field deployment of the developed technology. The offeror will need to manufacture enough devices to supply the field study. Exact number of devices will depend on the offered technology, but anticipated requirements are for 500-5000 devices. These three Tiers include device development, testing and demonstration, evaluation, reporting, and selection activities. Selection of device candidates to be advanced into Tier 2 and Tier 3 will be based on specific parameters and metrics being successfully met in demonstration exercises. The government shall provide technical data and support for demonstrations, as well as facilitate interaction with relevant DoD and Interagency stakeholders.

Address White Papers (WP) to medx@nrl.navy.mil . Allow one month before requesting confirmation of receipt of WP, if confirmation is desired. Substantive contact should not take place prior to evaluation of a White Paper by NRL. If necessary, NRL will initiate substantive contact.

Appendix A: Echelons of Care Definitions. Information taken from:

Cubano, M.A,; Lenhart, M.K. *Emergency War Surgery*; US Army, Office of the Surgeon General; eBook; 2014; pp 410; ISBN: 016092197X.

Chapter 2

Levels of Medical Care

Military doctrine supports an integrated health services support system to triage, treat, evacuate, and return soldiers to duty in the most time efficient manner. It begins with the soldier on the battlefield and ends in hospitals located within the continental United States (CONUS). Care begins with first aid (self-aid/buddy aid, and combat lifesaver), rapidly progresses through emergency medical care (EMT) and advanced trauma management (ATM) to stabilizing surgery, and is followed by critical care transport to a level where more sophisticated treatment can be rendered.

There are **five levels of care (also known as "roles")**, previously referred to as echelons by NATO and ABCA (USA, Britain, Canada, Australia) countries. Levels should **not to be confused with American College of Surgeons use of the term in US trauma centers**. Different levels denote differences in capability, rather than the quality of care. Each level has the capability of the level forward of it and expands on that capability. Soldiers with minor injuries can be returned to duty after simple treatments at forward locations, all others are prepared for evacuation with medical care while en route to a higher level.

Level I

- Immediate first aid delivered at the scene.
  - First aid and immediate life-saving measures provided by self-aid, buddy aid, or a **combat lifesaver** (nonmedical team/squad member trained in enhanced first aid).
  - Care by the trauma specialist (91W) (**combat medic**), assigned to the medical platoon, trained as an Emergency Medical Technician-Basic (EMT-B). Some other primary

care providers, with various levels of training, include the Special Forces Medical Sergeant 18D, Special Operations Combat Medic 91W, SEAL Independent Duty Corpsman, Special Boat Corpsman, Pararescueman, and Special Operations Medical Technician.
  - Initial treatment of nuclear, biological, and chemical casualties, treatment of toxic industrial material casualties, primary disease prevention, combat stress control measures, and nonbattle injury prevention.
- Level I medical treatment facility (MTF) (commonly referred to as the Battalion Aid Station [BAS]).
  - Provides triage, treatment, and evacuation.
  - Physician, Physician Assistant (PA), and medics.
  - Return to duty, or stabilize and evacuate to the next level.
  - Can be chem/bio protected.
  - No surgical or patient holding capability.
- US Marine Corps (USMC): Shock Trauma Platoon (STP).
  - Small forward unit supports the Marine Expeditionary Force (MEF).
  - Stabilization and collecting/clearing companies.
  - 2 physicians.
  - No surgical capability.
  - Patient holding time limited to 3 hours.

Level II

- Increased medical capability and limited inpatient bed space.
- Includes basic primary care, optometry, combat operational stress control and mental health, dental, laboratory, surgical (when augmented) and X-ray capability.
- 100% mobile.
- Each service has a slightly different unit at this level.

- **Army.**
  - **Level II MTFs** operated by the treatment platoon of divisional/nondivisional medical companies/troops.
    - Basic/emergency treatment is continued.
    - Packed RBCs (Type 0, Rh positive and negative), limited X-ray, laboratory, and dental.
    - 20–40 cots with 72-hour holding.

- Can be chem/bio protected.
- No surgical capability.

- **Forward Surgical Team (FST).**
  - Continuous operations for up to 72 hours.
  - Life-saving resuscitative surgery, including general, orthopedic, and limited neurosurgical procedures.
  - 20-person team with 1 orthopedic and 3 general surgeons, 2 nurse anesthetists, critical care nurses and technicians.
  - The supporting medical company must provide logistical support and security. (Doctrinally, the FST is collocated with a Medical Company.)
  - ~1,000 sq ft surgical area.
  - Can be chem/bio protected.
  - Operational within 1 hour of arrival at the supported company.
  - May be transported by ground, fixed wing, or helicopter; some fleet surgical teams (FSTs) are airborne deployable.
  - 2 operating tables for a maximum of 10 cases per day and for a total of 30 operations within 72 hours.
  - Post-op intensive care for up to 8 patients for up to 6 hours.
  - X-ray, laboratory, and patient administrative support provided by the supporting medical company.
  - Requires additional electricity, water, and fuel from the supporting medical company.
  - The FST is not designed, staffed, or equipped for stand alone operations or conducting sick-call operations. Augmentation requirements are discussed in FM 4-02.25.

- **Air Force.**
  - **Mobile Field Surgical Team (MFST).**
    - 5-person team (general surgeon, orthopedist, anesthetist, emergency medicine physician, and OR nurse/tech).
    - 10 life/limb saving procedures in 24–48 hours from five backpacks (350 lb total gear).
    - Designed to augment an aid station or flight line clinic.
    - Not stand alone, requires water, shelter of opportunity, communications, among other things.

    - Integral to remainder of Air Force (AF) Theater Hospital System.
  - **Small Portable Expeditionary Aeromedical Rapid Response (SPEARR) team.**
    - 10-person team: 5-person MFST, 3-person CCATT (see Chapter 4, Aeromedical Evacuation) and a 2-person preventive medicine (PM) team (flight surgeon, public health officer).
    - Stand alone capable for 7 days, 600 sq ft tent.
    - 10 life/limb saving procedures in 24–48 hours.
    - Designed to provide surgical support, basic primary care, post-op critical care, and PM for early phase of deployment.
    - Highly mobile unit, with all equipment fitting in a one-pallet–sized trailer.
  - **Expeditionary Medical Support (EMEDS) Basic.**
    - Medical and surgical support for an airbase, providing 24-hour sick call capability, resuscitative surgery, dental care, limited laboratory and X-ray capability.
    - 25 member staff includes SPEARR team.
    - 4 holding beds, 1 OR table, 3 climate controlled tents, and 3 pallets.
    - 10 life/limb saving procedures in 24–48 hours.
    - ~2,000 sq ft.
  - **EMEDS + 10.**
    - Adds 6 beds to EMEDS Basic, for total of 10.
    - No additional surgical capability.
    - 56-person staff.
    - 6 tents, 14 pallets.
    - Can be chemically hardened.

- **Navy.**
  - **Casualty Receiving & Treatment Ships (CRTS)**. CRTSs are part of an Amphibious Ready Group (ARG) and usually comprise one landing helicopter assault or amphibious (LHA) Tarawa-class or landing helicopter deck (LHD) Wasp-class ship, which are Marine amphibious

assault helicopter carriers that function as casualty receiving platforms. An ARG includes up to 6 ships with surgical capability only on the CRTS.

- 47-48 beds, 4-6 ORs, 17 ICU beds.
- 300 additional medical care beds may be available once Marines disembark.
- Fleet Surgical Teams (FSTs): 3-4 physicians, 1 surgeon, 1 CRNA or anesthesiologist and support staff.
- Usually 2 general surgeons and 2 orthopedic surgeons. OMFS (oral maxillofacial surgery) support available through the dental department. Can be substantially augmented.
- Laboratory, X-ray.
- Excellent casualty flow capability (large helicopter flight deck and landing craft units [LCU] well deck).
- Mass casualty (MASCAL) capability with triage area for 50 casualties.
- Doctrinally, holding capability is limited to 3 days.

- **Aircraft Carrier (CVN) Battle Group.**
  - 1 OR, 40–60 beds, 3 ICU beds.
  - 1 surgeon, 5 other medical officers.
  - Up to 9 ships, but usually only the CVN has physicians. Medical assets aboard aircraft carriers are intended for use by the aircraft carrier and its task force. Aircraft carriers are NOT casualty receiving ships and are not figured into medical assets for support to ground forces.
- **USMC.**
  - **Surgical Company**.
    - Provides surgical care for a MEF (Marine Expeditionary Force). Basis of allocation is 1 per infantry regiment.
    - 3 ORs, 60-bed capability.
    - Patient holding time up to 72 hours.
    - Stabilizing surgical procedures.
  - **Forward Resuscitative Surgical System (FRSS)**.
    - Embedded organically as part of the TO&E of the surgical company, if employed reduces the capability of its parent surgical company.

- Rapid assembly, highly mobile.
- Resuscitative surgery for 18 patients within 48 hours without resupply.
- 1 OR, 2 surgeons.
- No holding capability.
- No intrinsic evacuation capability.
- Chem/bio protected.
- Stand alone capable.

Level III

Represents the highest level of medical care available within the combat zone with the bulk of inpatient beds. Most deployable hospitals are modular, allowing the commander to tailor the medical response to expected or actual demand.

- **Army.**
  - Two different Corps-level Combat Support Hospital (CSH) designs.
    - Medical Force 2000 (MF2K) CSH.
    - Medical Reengineering Initiative (MRI) CSH will replace the MF2K.
  - **Combat Support Hospital.**
    - **MF2K CSH.**
      - Resuscitation, initial surgery, post-op care, and either return to duty or stabilize for further evacuation.
      - Up to 296 patients, typically divided into 8 ICUs (96 ICU beds), and 7 Intermediate Care Wards (ICWs) (140 beds), 1 neuropsychiatric (NP) ward (20 beds), and 2 minimal care wards (40 beds).
      - 175 officers, 429 enlisted; specialty attachments may increase numbers.
      - Up to 8 OR tables for a maximum of 144 operating hours per day.
      - General, orthopedic, urologic, neurosurgical, dental and oromaxillofacial surgery.
      - Blood bank, laboratory, X-ray/computer tomography (CT); nutrition, physical therapy and NP capabilities.
      - Dependent on a number of Corps support elements for personnel, finance, mortuary, legal, laundry,

security, and enemy prisoners of war (EPW) management, support.

- ◊ Transportation support required for both incoming and outgoing patient evacuation, and to transport the hospital.
- ◊ Transported via semitrailer, railcar, air cargo, or ship.
- ◊ Fully deployed CSH (including motor pool, billeting, heliport, and other life support activities) covers 30.3 acres.
- ◊ Divided into modules, deployed as a single unit or separately as the mission dictates. The main modules are the Hospital Unit-Base (HUB) and the Hospital Unit-Surgical (HUS).
  - HUB is the infrastructure of the CSH.
    - Up to 236 patients, divided into 36 ICU, 140 intermediate, 40 minimal, and 20 NP beds.
    - Two operating modules with specialty surgical care capability.
    - HQ, administrative, personnel, chaplain, laboratory, pharmacy, X-ray, and blood bank services.
    - Part of the HUB can be chem/bio protected (FM 4-02.7).
  - HUS capabilities.
    - 60 ICU patients, 2 OR modules, X-ray.
    - Dependent on the HUB for all logistical support.
    - Can be deployed forward, separate from the HUB, for brief periods as the mission dictates.

- **MRI CSH (Corps)**.
  - Provides hospitalization and outpatient services for all classes of patients in the theater, either returned to duty or stabilized for further evacuation.
  - Headquarters/headquarters detachment: 15 officers and 44 enlisted.
  - Up to 248 patients, typically divided into an 84-bed hospital company and a 164-bed hospital company, with split base operations capability.

- **84-bed hospital company.**
  - 24 ICU beds.
  - Up to 2 OR tables, maximum of 36 operating hours per day.
  - 3 ICWs (total 60 beds, including NP patients).
  - 56 officers and 112 enlisted personnel.
    - Some patient care areas can be chem/bio protected.
- **164-bed hospital company.**
  - 24 ICU beds.
  - Up to 4 OR tables, maximum of 60 operating hours per day.
  - 7 ICWs (total 140 beds, including NP patients).
  - 84 officers and 169 enlisted personnel.
    - Some patient care areas can be chem/bio protected.
- **Applicable to 84-, 164-, and 248-bed (see CSH [Echelon of Care, EAC] below) hospital companies.**
  - General, orthopedic, urologic, thoracic, OB/GYN, neurosurgical, dental and oromaxillofacial surgery.
  - Blood bank, laboratory, X-ray, nutrition, and physical therapy.
  - Dependent on EAC support elements for personnel, finance, mortuary, legal, laundry services, security and EPW support.
  - Parts can be chem/bio protected.
  - Transportation support required for both incoming and outgoing patient evacuation, and to transport the hospital.
  - Transported by semi-trailer, railcar, air cargo, or ship.
  - Fully deployed, covers 5.7 acres.
  - Minimal care wards are provided by an attached minimum care detachment.

- **Air Force.**
  - **EMEDS +25.**
    - 25-bed version of EMEDS Basic.
    - 84 personnel, 2 OR tables, 9 x 600 sq ft tents, and 20 pallets.
    - 20 operations in 48 hours.
    - Can be chemically hardened.

    - Additional specialty modules can be added, including vascular/cardiothoracic, neurosurgery, OB/GYN, ear, nose and throat (ENT), ophthalmology teams; each comes with own personnel and equipment.
- **Navy.**
  - **Fleet Hospital.**
    - 500-bed hospitals, 80 ICU beds, and 6 ORs.
    - 1,000 personnel.
    - Stand alone; full ancillary services.
    - 8–10 days to be operational.
    - Large footprint — 28 acres, 450 isolation (ISO) shelters.
    - No limit on holding capability.
  - **Hospital Ships (TAH) — USNS Mercy and USNS Comfort.**
    - 1,000 beds, 100-bed ICU capability, and 12 ORs.
    - 1,000 staff, over 50 physicians.
    - Extensive laboratory and X-ray capabilities.
    - Patient holding is doctrinally limited to 5 days.

Level IV

- Definitive medical and surgical care outside the combat zone, yet within the communication zone/EAC of the theater of operations (TO).
- Patients requiring more intensive rehabilitation or special needs.
- Traditionally includes the MF2K Field Hospital (FH) and General Hospital (GH).
- In some situations, the MF2K CSH or a fixed hospital may act as a Level IV facility (eg, Landstuhl Army Regional Medical Center, Germany).
  - **Field Hospital.**
    - Semipermanent hospital that provides primarily convalescent care.
    - At least 2 OR tables for 24 OR hours per day.
    - General, orthopedics, OB/GYN, urologic, oral surgery, and dental services.
    - Up to 504 patients, with 2 ICUs (24 patients), 7 ICWs (140 patients), 1 NP ward (20 patients), 2 minimum care wards (40 patients), and 7 patient support sections (280 patients).

- **General Hospital.**
  - Usually a permanent or semipermanent facility.
  - At least 8 OR tables for 144 OR hours per day.
  - General, orthopedic, gynecologic, urologic, and oral surgery.
  - Dental and optometry services.
  - Outpatient specialty and primary care services.
  - Up to 476 patients, with 8 ICUs (96 patients), 16 ICWs (320 patients), 1 NP ward (20 patients), and 2 minimum care wards (40 patients).

The MRI CSH Echelon Above Corps (EAC) will replace the FH and GH.

- **CSH (EAC).**
  - Headquarters/headquarters detachment: 17 officers and 33 enlisted.
  - Cannot operate in a split-based mode like the CSH (Corps).
  - 248-bed hospital company.
    - 4 ICUs (total 48 ICU beds), and 10 ICWs (total 200 beds, including NP patients). A specialty clinic section that can treat NP patients. Minimal care wards are provided by attached minimum care detachments.
    - 140 officers, 244 enlisted personnel.
    - Up to 6 OR tables for 96 operating hours per day.
    - Fully deployed (including motor pool, troop billeting, heliport, and other life support activities), covers 9.3 acres.
    - See other general characteristics under MRI CSH (Corps).

Level V

This level of care is provided in the CONUS. Hospitals in the CONUS sustaining base will provide the ultimate treatment capability for patients generated within the theater. Department of Defense (DoD) hospitals (military hospitals for the tri-services) and Department of Veterans Affairs (DVA) hospitals will be specifically designated to provide the soldier with maximum return to function through a combination of medical, surgical, rehabilitative, and convalescent care. Under the

National Disaster Medical System, patients overflowing DoD and DVA hospitals will be cared for in designated civilian hospitals.