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Improve Threat Responses and Casualty Outcomes Using Pharmacomedical Telemanagement

The United States, NATO and others have awakened to the chemical, biological, radiological, nuclear, explosives (CBRNE), threats, threats from weapons of mass destruction (WMDs) to both civilian and military personnel. The threats come from governments and non-state actors and their surrogates, and from lone-wolf attacks. Recent discoveries paint an alarming picture of the potential access of violent extremists to WMDs. While actions to defend against WMD threats are sometimes controversial and always difficult, there is agreement that improved pharmacomedical responses to WMDs are essential.

Mass casualty incidents can overwhelm emergency medical resources. Untreated single casualties can require even more long-term resources. Having effective delivery devices and systems for pharmacomedical telemanagement* are as important as having effective treatment modalities. Without connectivity, there is little assurance of informed intervention, or of accurate data on resource storage and use.

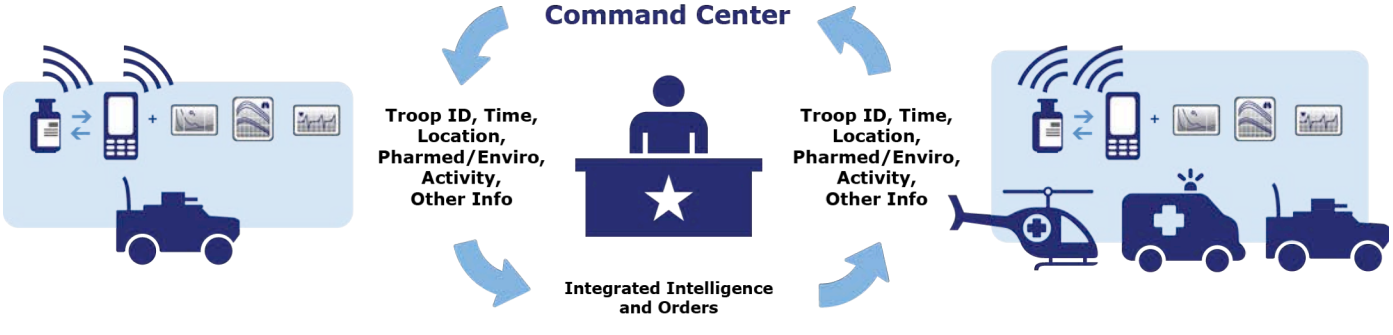
Because the military serves highly mobile, mission-critical populations, often in remote and hazardous locations, the U.S. Department of Defense has historically led in telemedicine. Pharmacomedical telemanagement enablers are already largely in place. It is essential that the U.S. fund and field improved medical responses now.

**Pharmacomedical telemanagement combines information on the patient, the environment and pharmaceutical products to enable medical professionals and other stakeholders to manage casualties and manage pharmaceutical and medical-resource logistics deployed in remote locations.*

BENEFITS:

Response plans that include real-time pharmacomedical telemanagement can improve casualty care and outcomes, while lowering risks and reducing costs:

- Monitoring of drug location, operability, storage, use, misuse and non-use; specifics about each use and expiration info based on cumulative temperature exposure; automatic replacement of used or expired product
- Assistance and instruction, and informed intervention that avoids unnecessary, disabling treatments
- Better pharmaceutical resource management. (Many emergency pharma treatments are injectables, which often require environmental control. Some are subject to diversion and abuse.)
- Better management of human factors, REMS and CAPA, as well as better clinical study management and faster regulatory approvals
- Pharma data collection for integration with other healthcare-related information, entry into electronic medical records and population health analyses
- Improved communications and relationships between and among stakeholders, as well as improved real-time and perceived readiness, reducing stress and improving quality of life and performance



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Planning and Partnering for CBRNE Protection and Preparedness

Responsibility for U.S. Department of Defense and Department of Homeland Security CBRNE response has been made into a unified command, and there is an expressed need for immediate information at the individual troop level. Telemedicine, including pharmacomedical telemanagement, are critical additions to protective capabilities. The CBRNE command and their partners have the ability to lead in the development of pharmacomedical telemanagement systems. Here are a few partnering examples:

- The Joint Program Manager for Medical Countermeasures Systems (JPM-MCS) has established the Medical CBRN Defense Consortium, MCDC. There is strong industry and academic participation in MCDC as it accelerates product development for medical countermeasures to prevent, detect, and treat CBRN casualties. The MCDC utilizes the newly named Applied Technology Institute (ATI) as the management arm of the consortium and contracts are awarded under an Other Transaction Agreement. The ATI follows a model developed by NASA. Openness to novel approaches can bring needed acceleration to the fielding of such improved medical countermeasures as pharmacomedical telemanagement systems.
- Many companies have developed technologies to support the requirements of the Drug Supply Chain Security Act and Unique Device Identifier Regulations. Using automated identifier and data capture systems enables serialization for tracking and tracing prescription drugs and medical devices through the lifecycle. The FDA and CMS will demand serialization for high-risk healthcare products, enhancing logistic functions, populating EMRs and pharmacomedical telemanagement.
- University of Pittsburgh Center for Military Medicine Research and other universities, along with for-profit entities, adapt, develop and commercialize connected emergency response systems.
- University of Cincinnati Enmont: wearable nanoparticle monitoring devices. Mutualink: seamless emergency communications across platforms.

Other factors to consider:

- The Project BioShield Act of 2004 and continuing funding related to medical countermeasures have advanced research. Current RFPs; BAAs; preclinical and clinical work; approved and pending NDAs; and NDAs, PMAs and 510(k)s for new pharmacomedical therapies and telemanagement await implementation.
- Technological advances in and public acceptance of many related consumer and industrial products have brought lower costs for electronics and prototyping. Big-data capabilities; miniaturized, ruggedized, low-energy sensor systems; improved batteries; secure communications capabilities.
- Standards and FDA draft guidances are providing regulatory clarity.
- Military emergency providers have unique advantages. Commercial emergency providers have grown larger, enabling investment in technology. Emphasis on EMRs and reducing ER visits/readmissions encourages telemedicine.
- The success of telestroke networks, TBI treatment and similar programs.
- Technology is becoming widely available; e.g., Aterica's telemanagement device Veta is in development for EpiPen.

- Granted and pending patents have broad claims and disclosures on devices, systems and technology that enable civilian and military telemedicine programs; e.g., the mMed portfolio, related to pharmaceutical dispensers, such as autoinjectors and emergency response systems. Some granted claims cover pharma delivery systems that identify products and patients; and signal storage conditions, damage, use, and location at time of use. Integrated pharma, patient and environmental data enables informed decisions. Patent protection can help ensure U. S. leadership.

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