ASPR
ADMINISTRATION FOR STRATEGIC PREPAREDNESS AND RESPONSE

BARDA

Improving Medical Countermeasure Deployment Using End User Feedback

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The BARDA Model

BARDA develops and makes available medical countermeasures (MCMs) by forming unique public-private partnerships to drive innovation off the bench to the patient to save lives.

- Flexible, nimble authorities
- Multi-year funding
- Cutting edge expertise
- Facilitate partnerships
- Promote innovation

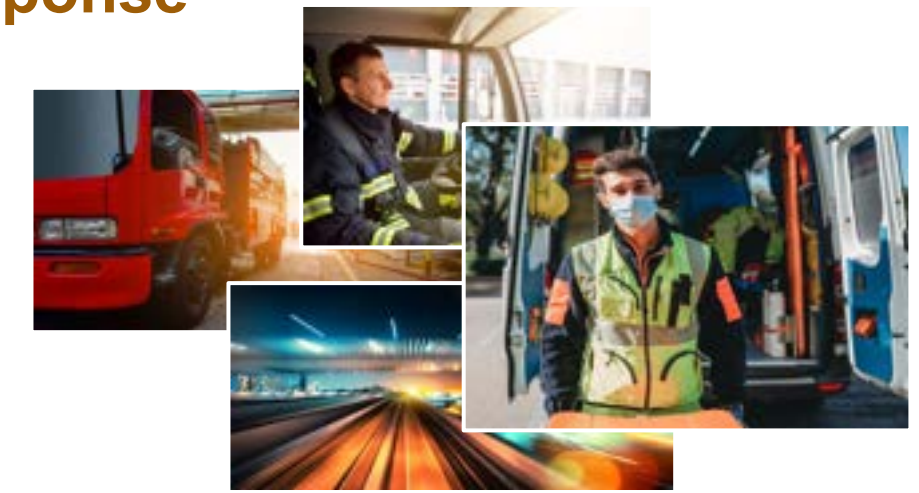
Why are we here?

- Discuss BARDA's End User engagements to improve treatments and technologies for CBRN threats
- Hear directly from end users about emergency medical preparedness and response gaps
- Explore how BARDA can help enhance capabilities through stakeholder-informed development of resources

Time is of the Essence!

Challenges for CBRN Mass-Casualty Incident Response

- Injury happens QUICKLY
- **Treatment must occur** RAPIDLY
- Treatments positioned ideally with end-user
- Information limited during an emergency
- **Treat the injury, not the threat**



Rapid treatment saves lives!

Emergency responders need resources to facilitate treatment of CBRN injury

Challenges for CBRN Response through the Continuum of Care

Prehospital	Hospital	Outpatient
• Treatments not positioned far-forward enough • Ambient temperatures. No/limited cold chain – expiry dates • Limited (re)supply • Lack of specialized training for CBRN incidents • Patients may outnumber available resources	• Limited resource environment • Patients outnumber available beds and treatments • Patients may be contaminated or contagious • Lack of specialized training for CBRN incidents • *Unfamiliarity with CBRN threats or product(s) may delay treatment*	• Compliance with self-administered treatments • Treatments must be easy to administer • Oral formulations are preferred in outpatient settings

Making MCMs More Accessible to the End User

Medical Countermeasures (MCMs) are products (drugs, biologics, devices, diagnostics) intended to **enable response to public health emergencies** caused by CBRN threats, pandemic influenza, and emerging infectious diseases.

CBRN Operational Environment – Key Program Priorities

- **Repurpose** common drugs for CBRN indications
- Develop **threat-agnostic** countermeasures – treat the injury, not the threat
- Develop **sustainable**, adoptable solutions – including leveraging **commercially available** products
- **Improve end user engagement**

Chemical

Radiological/ Nuclear

Burn & Blast




BARDA Addressing Challenges across the Continuum of Care

Create Response Tools

Decision-aid Tools & Guidance for Emergency Response

Increase Availability of Treatments

Medical treatments where they're needed, when they're needed

Improve Usability

Leverage modern technology to deliver new Emergency Response treatments, diagnostics, and tools

CHEMICAL PROGRAM

Addressing Challenges Across the Continuum of Care

Ensure that medical countermeasures for chemical injury are readily available for the end-user

Create Emergency Response Tools

Decision-aid tools & Guidance for Emergency Response

- Human Decontamination Guidance – PRISM
- Digital Resources – CHEMM
- Decision Aids – ASPIRE and CHEMM-IST

Increase Availability of Treatments

Medical treatments where they're needed, when they're needed

- Therapies that "*Treat the injury, not the agent*":
  - Midazolam (Seizalam) for seizures, including those caused by nerve agents
  - Silverlon for all burns, including those caused by chemicals.
- Use available drugs for chemical indications (atropine eyedrops for nerve agents)

Improve Usability

Leverage modern technology to deliver emergency care

- Novel drug delivery technologies – Needle-free autoinjectors
- Use of Artificial Intelligence (AI) to develop better drugs

RADIOLOGICAL AND NUCLEAR PROGRAM

Addressing Challenges Across the Continuum of Care

Improve health outcomes for all survivors of nuclear detonations and radiation exposure

Create Emergency Response Tools

Decision-aid tools & Guidance for Emergency Response

- Point of Care – Endotype Signature Identification
- Digital Resources – REMM
- Prehospital Transfusion Working Group – training and education

REMM

Increase Availability of Treatments

Medical treatments where they're needed, when they're needed

- Prehospital Transfusion Working Group – Expanding Scope of Practice and Reimbursement
- Enabling use and availability of blood products; whole blood, dried plasma

Improve Usability

Leverage modern technology to deliver Emergency Care

- Novel drug delivery technologies – Tranexamic Acid (TXA) autoinjectors; dried plasma
- Self-administration kits

Improving End User Engagement

Establishing Relationships with the Emergency Response Community

Goals

- To understand emergency medical responders' operational challenges and gaps to ensure BARDA develops products that fully meet end users' needs.
- To establish and foster mutually beneficial relationships between BARDA, State officials, and the end user community.

MCM End User Outreach

BARDA has been engaging with MCM end users, including first responders, first receivers, and State EMS & Medical Directors by organizing and attending:

- **Individual & group meetings**: Targeted meetings with key members of the end user community,
- **Focus groups**: Engagements with specific end users to request their input on new BARDA products,
- **Conferences**: NAEMSP, NASEMSO, FDIC/JEMS, EMS World, NHCPC, among others.

What We Learned From You / What We Are Doing About It (1 of 2)

Feedback	Challenge	BARDA Actions
Developing "nationwide" standards for emergency response is difficult	• Diverse regulations and scope of practice among jurisdictions. • Different jurisdictions →Different rules	• Engaging with state emergency medical response community to ensure BARDA products meet their needs
Increase availability of Emergency MCMs in prefilled devices	• In some states, EMTs not allowed to draw and administer treatment unless premeasured (e.g. autoinjectors). • Autoinjectors are $$$ → single use/cost prohibitive for most EMS Departments	• Exploring potential alternatives to pricey autoinjectors • Market Research to develop Universal Autoinjector that is reusable and adaptable to existing standard vials
Responders lack awareness of USG resources available for their use	• Lack of awareness of USG products available for responders' use during emergencies (e.g.,CHEMPACK and Burn Kits)	• Direct outreach to responders to increase awareness USG resources • Potential symposium for end users to obtain their feedback on how current and upcoming products can best meet their needs

What We Learned From You / What We Are Doing About It (2 of 2)

Feedback	Challenge	BARDA Actions
Diverse Opinions on existing and upcoming MCMs	• Blood Products have short shelf-life and need cold-chain. • In some states, paramedics are not allowed to perform pre-hospital blood transfusions solo. • EMS provider perception of Nalmefene varies widely.	• Engaging with Depart. of Transportation for prehospital blood access. • Engaging with Pre-hospital Coalition for practice, reimbursement, and end user adoption. • Clarifying messaging about Nalmefene through direct end user engagement and messaging in EMS journals.
Responders need more frequent training and exercises for CBRN threats	• CBRN events are infrequent → Training is sporadic. • Challenging for EMS to maintain CBRN-related skills.	• BARDA conducting a landscape analysis of existing relevant exercises to identify gaps and redundancies. • A Mass-casualty **decontamination course** for responders based on PRISM **to be piloted at NHCPC on Wednesday @ 3:00PM!**

Remaining Challenges

Key obstacles to uptake

1) Future access to products is unclear (e.g., due to costs).
2) Training requirements are a concern (e.g., integrating training modules for new devices).

Next steps

1) Ensure the right products are being developed.
2) Identify and address gaps in end user training.
3) Gain a deeper understanding of what a responder needs to enter a CBRN incident zone and successfully deliver care.

Questions and Answers

Do you know how to gain access to federally provided assets?

Decision-aid tools & Web-based resources:

- Are you aware of **CHEMM**? **REMM**?
- **How/when** would your agency use these types of digital resources during a response? **Who** would use them?

CHEMM

REMM

Would these types of tools help during a response?

- **CHEMM-IST**: Digital tool for identifying the chemical family (toxidrome) a patient was exposed to based entirely on symptoms

- **Product administration Instructional Video (Nplate Reconstitution)**

Thank you for your participation!

BARDA is working to be responsive to your needs.

Contact Us

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