BARDA Thermal Burn Medical Countermeasures Program

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BARDA Industry Day
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BARDA’s Burn Medical Countermeasures (MCMs) Development Priorities

- Primary Goals
- Challenges & Strategy
- Burn MCMs Under Development & Acquisition
- Unmet Needs- Highlighting New Priorities

Engaging with BARDA

- At BARDA Industry Day
- Other opportunities
Medical Consequences: Improvised Nuclear Device (IND) Detonation

- Acute Radiation Sub-syndromes
  - Hematopoietic: cytopenias
  - Gastrointestinal & Pulmonary Injury

- Decorporation
- Biodosimetry

Cutaneous Radiation Injuries
Exposure to Radioactive fallout

- Flash Burns
- Secondary Fires

Concomitant Burn & Radiation injury

Radiation Injuries

Burn Injuries

Mechanical Trauma Injuries

Combined Burn & Mechanical Trauma
Treatment Goals: MCMs for Thermal Burns

Timeline Post-Detonation

0 h

Up to ~ 72 h

Field Care
- Administer Fluids & Electrolytes
- Secure Airways
- Manage Pain
- Initial Wound Care
  - Prevent Infection / Detoxify
  - Prevent Conversion (deep partial to full thickness)
- Enable Patient Tracking Aids
- Initiate Nutritional Support

72 h

After ~ 72 h

Definitive Care
- Comprehensive Burn Wound Care
  - Debridement / excision / temporize
  - Wound Coverage (temporary & permanent)
  - Ancillary tools (imaging / aid Autograft sparing)
- Aid Functional Recovery
- Donor Site care and Pain Management
- Ongoing Nutritional Support

144 h

Addressed via
Burn Blast Kit MCMs in the Strategy National Stockpile

Addressed via
Broad Agency Announcement (BAA) and Project BioShield (PBS) Awards
Addressing Field Care: MCMs to control infection

Silverlon™ by Argentum Medical
Interagency Agreement with Defense Logistics Agency

Previous Approach
Silvadene Cream
- Painful
- Need to sedate patients
- Need for multiple/daily applications

2015 BARDA Acquisition to the Strategy National Stockpile

Current Approach
Silverlon - Burn Dressing
- Easy to use
- Applied once for up to 7 days
- Field tested by warfighters
- Multiple threat potential
Realities of U.S. Definitive Burn Care

Burn care is Specialized Care..., relatively small market
Estimated burn surgeons in North America

350

Our nation's burn treatment capacity is limited
127 burn centers nationwide

1,800 burn beds
200 - 400 burn beds available daily

Burn care is labor and resource intensive
- Requires specific medical expertise excision, grafting, etc
- Long hospital stays
1 to 1.5 days per % Total Body Surface Area (TBSA)
- Higher medical resource utilization
1 nurse per 1 patient
Solutions: Definitive Care

Limitations and Challenges in US

BARDA’s Solution

- Reduce Resource Burden
- Reduce Length of Stay
- Reduce Need for Surgery
- Ease of Use
Solutions: Definitive Care

Limitations and Challenges in US

- Procedures with “bottlenecks”
- Limited Products with Ability to “Temporize”
- Need for Smart Products

BARDA’s Solution

- Limit Conversion to FT burns
- Temporizing Strategies
- Minimize Autografting
- Expand Throughput
Definitive Care Products Under Development at BARDA

Thermal Burn Definitive Care Continuum

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- Spectral MD (DeepView)- Imaging System
- Arteriocyte (BioBandage) – Platelet-Rich Plasma
- PolyNovo (BTM) - Biodegradable Matrix
- MediWound (NexoBrid)- Non-Surgical Debridement
- Avita (ReCell)- Autograft Sparing
- Cytori (Celution) - ADRCs Adjunct for STSG
- Stratatech (Stratagraft) – Skin Substitute
Increasing Preparedness by Improving Burn Care

**NEXOBRID™**
Minimize Surgical Debridement – Enzymatic @bedside

**RECELL®**
Use less Donor Tissue – Autograft Sparing

**STRATAGRAFT®**
Avoid need for donor tissue – Use Skin substitute
Definitive Care Products: Unmet Needs – New Priorities

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1- Allogenic Products or Small Molecules to Prevent or Limit Burn Conversion

2- Easy to Use- ‘Smart’ Imaging Systems

3- New Products to serve as adjuncts to Accelerate Healing
Definitive Care Products: Unmet Needs – New Priorities

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### Key Desirable Attributes
- Proof-of-Concept studies showing prevention of burn progression to full-thickness injury
- Topical / Easy to administer even in large area burns
- Safe on full thickness burns.
- Reduce patient morbidity/ pain.
- Has a mechanism of action rationale that can be substantiated
- Easy to produce; Off-the-shelf; (e.g. non-autologous)
- Sustainable in market with other clinical indications (wounds)

1- Allogenic Products or Small Molecules to Prevent or Limit Burn Conversion
Definitive Care Products: Unmet Needs – New Priorities

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Key Desirable Attributes

- Non-invasive; Easy to use in early triage assessments; Integrate into current care practices (e.g. hand-held, portable / bedside).
- Provide rapid, reliable guidance on burn depth- healing potential & need for surgery (may not be a diagnostic). Sustainable-other clinical uses.
- Aid burn surgeons in multiple stages of burn care (e.g. assessment of viability of wound bed).
- Multiplex capabilities to assess wound trauma.
Definitive Care Products: Unmet Needs – New Priorities

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### Key Desired Attributes
- Can substantiate rationale for mechanism of action to accelerate wound closure.
- Easy to integrate in current standard of care
- Safe, off-the-shelf; without the need for additional procedures (e.g. allogenic products).
- Commercially sustainable with other indications for use (wounds).

3- New products to serve as adjuncts to Accelerate Healing
4. **Products for treatment of inhalational injuries**
   - Preliminary efficacy data
   - Can demonstrate rationale for mechanism of action to lower morbidity
   - Open to various product types (imaging, precision ventilation, etc.)

5. **Countermeasures for Cutaneous Radiation Injuries (CRI)**
   - Novel products with preliminary efficacy data in related human clinical condition (e.g. radiation dermatitis)
   - Data demonstrating lowered morbidity, prevention of wound progression, or acceleration of resolution
   - Potential to treat CRI Grades I, II, III
BARDA is building burn care preparedness by solutions which are Comprehensive – Adoptable – Sustainable.

- Meet Technical Level Readiness Requirements
- Have a Regulatory Strategy to FDA approval

Seeking New MCMs to address unmet need areas:
1. Limiting Burn Conversion
2. Smart Imaging
3. Adjuncts to Accelerate Healing
4. Products for Treatment of Inhalation Injuries
5. Countermeasures for CRI
Partners in Changing Burn Care: Building Preparedness

Concerted Effort of Governmental Agencies – Companies - Non-Profits
Engaging the BARDA Team

• At Industry Day: Learn more at ..

• Email: Narayan Iyer [narayan.iyer@hhs.gov]
• Call: Julio Barrera-Oro [202-260-0393]
• Reach Out: David Simon; Danielle Turley; Oxana Selivanova; Janelle Hurwitz
Online Resources

https://www.medicalcountermeasures.gov/home.aspx
  • Portal to BARDA: Register to request a TechWatch meeting

https://www.fbo.gov/ ("FedBizOpps")
  • Official announcements and info for all government contract solicitations

https://www.usajobs.gov/
  • Join the team!

https://www.phe.gov/about/BARDA/Pages/default.aspx
  • Program description, information, news, announcements
THANK YOU