BARDA Thermal Burn Medical Countermeasures Program

Julio Barrera-Oro, PhD
Project Officer, Thermal Burn MCMs Program
October 29, 2018
Medical Consequences: Nuclear Detonation

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

- Decorporation
- Biodosimetry

Cutaneous Radiation Injuries
Exposure to Radioactive fallout

Radiation Injuries

Burn Injuries

- Flash Burns
- Secondary Fires

Concomitant Burn & Radiation injury

Mechanical Trauma Injuries

Combined Burn & Mechanical Trauma

Treatment Goals: MCMs for Thermal Burns

Timeline Post-Detonation

0 h
Up to ~ 72 h

Initial Care
- Administer Fluids & Electrolytes
- Secure Airways
- Manage Pain
- Initial Wound Care
  - Identify & Triage Injury Severity
  - Prevent Infection / Detoxify
- Enable Patient Tracking Aids
- Initiate Nutritional Support

72 h

Definitive Care
- Comprehensive Burn Wound Care
  - Prevent Conversion (deep partial to full thickness)
  - Debridement / excision / temporize
  - Wound Coverage (temporary & permanent)
  - Ancillary tools (imaging / aid autograft sparing)
- Aid Functional Recovery
- Donor Site care and Pain Management

144 h
After ~ 72 h

MCMs in
Burn Blast Kit
Strategic National Stockpile (SNS)

MCMs under development via
Broad Agency Announcement (BAA) and
Project BioShield (PBS) Awards
Addressing Initial 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
Treatment Goals: MCMs for Thermal Burns

Timeline Post-Detonation

0 h

Up to ~ 72 h

Initial Care
- Administer Fluids & Electrolytes
- Secure Airways
- Manage Pain
- Initial Wound Care
  - Identify & Triage Injury Severity
  - Prevent Infection / Detoxify
- Enable Patient Tracking Aids
- Initiate Nutritional Support

72 h

Definitive Care
- Comprehensive Burn Wound Care
  - Prevent Conversion (deep partial to full thickness)
  - Debridement / excision / temporize
  - Wound Coverage (temporary & permanent)
  - Ancillary tools (imaging / aid autograft sparing)
- Aid Functional Recovery
- Donor Site care and Pain Management

144 h

After ~ 72 h

MCMs in
Burn Blast Kit Strategic National Stockpile (SNS)

MCMs under development via
Broad Agency Announcement (BAA) and Project BioShield (PBS) Awards
Realities of U.S. Definitive Burn Care

Burn care is specialized care....relatively small market
Estimated burn surgeons in North America

Burn care is limited
Our nation’s burn treatment capacity is limited

127 burn centers nationwide with a total of
1,800 burn beds
200 - 400 burn beds available daily

- 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 & CHALLENGES IN U.S.
- Burn Surgeons & Expertise
- Infrastructure & Communication
- Transfer Policies

BARDA’S SOLUTION
- Reduce Resource Burden
- Reduce Length of Stay - Patients Morbidity
- Reduce Need for Surgery
- Ease of Use

Solutions: Definitive Care

LIMITATIONS & CHALLENGES IN U.S.

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

BARDA’S SOLUTION

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

THERMAL BURN DEFINITIVE CARE CONTINUUM

DAYS
- Limit Burn Conversion
  - Arterioocyte (BioBandage) – Platelet-Rich Plasma
  - Polynovo (ETM) – Biodegradable Matrix
  - Spectral MD (DeepView) – Imaging System

WEEKS
- Temporize Burns
  - MediWound (NexoBrid) – Non-Surgical Debridement
- Aid Debridement/Excision
  - Spectral MD (DeepView) – Imaging System
- Adjuncts to Accelerate Healing/Aids to Spare Autografts
  - Avita (ReCell) – Autograft Sparing
  - Cytori (Celution) – ADRCs Adjunct for STSG
- Skin Substitute/Spare Donor Site Morbidity & Autograft
  - Spectral MD (DeepView) – Imaging System

MONTHS
- Improve Clinical Outcome
  - Avita (ReCell) – Autograft Sparing

Comprehensive – Adoptable – Sustainable

Broad Agency Announcement (BAA) Award
Project BioShield (PBS) Award

Increasing Preparedness by Improving **Routine** Burn Care

**Current Standard of Care**

- **NEXOBRID™** (MediWound Inc)
  - Minimize surgical debridement – Enzymatic at bedside

- **RECELL®** (Avita Medical)
  - Use less donor tissue – Autograft sparing

- **STRATAGRAFT®** (Stratatech/MKDT)
  - Avoid need for donor tissue – Use skin substitute

**Improved Standard of Care**

- **FDA-APPROVAL** Sept 20, 2018
Definitive Care Products: Unmet Needs – New Priorities*

THERMAL BURN DEFINITIVE CARE CONTINUUM

DAYS
- Limit Burn Conversion
- Non-autologous Products to Prevent or Limit Burn Conversion

WEEKS
- Temporize Burns
- Aid Debridement/Excision
- Skin Substitute/Spare Donor Site Morbidity & Autograft

MONTHS
- Adjuncts to Accelerate Healing/Aids to Spare Autografts
- Improve Clinical Outcome
- Products that Reduce the Need for Surgery

*BARDA Broad Agency Announcement (BAA-18-100-SOL-0003) Area of Interest #6
Definitive Care Products: Unmet Needs – Limiting Burn Conversion

**Key Desirable Attributes**

- Easy to manufacture; off-the-shelf (e.g. non-autologous)
- Proof-of-Concept studies showing prevention of burn progression to full-thickness injury
- Topical / Easy to administer even in large area burns
- Applicable to full and partial thickness burns
- Reduce patient morbidity / pain
- Has a mechanism of action rationale that can be substantiated
- Sustainable in market with other clinical indications (e.g. chronic wounds)
Definitive Care Products: Unmet Needs – Smart Imaging / Machine Learning Applications

Key Desirable Attributes

- Non-invasive; Easy to use in early triage assessments; Can be integrated 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 – Reduce the Need for Surgery

Key Desirable Attributes

- Non-autologous products that are Safe, off-the-shelf; without the need for additional procedures
- Can substantiate rationale for mechanism of action to accelerate wound closure
- Easy to integrate in current standard of care
- Commercially sustainable with other indications for use (wounds)
Treatment Goals: MCMs for Initial Care

Timeline Post-Detonation

Initial Care
- Administer Fluids & Electrolytes
- Secure Airways
- Manage Pain
- Initial Wound Care
  - Identify & Triage Injury Severity
  - Prevent Infection / Detoxify
- Enable Patient Tracking Aids
- Initiate Nutritional Support

Definitive Care
- Comprehensive Burn Wound Care
  - Prevent Conversion (deep partial to full thickness)
  - Debridement / excision / temporize
  - Wound Coverage (temporary & permanent)
  - Ancillary tools (imaging / aid autograft sparing)
- Aid Functional Recovery
- Donor Site care and Pain Management

MCMs in
- Burn Blast Kit
- Strategic National Stockpile (SNS)

MCMs under development via
- Broad Agency Announcement (BAA) and Project BioShield (PBS) Awards

Expanding New Area of Focus in FY19

Burn MCMs - Overarching Programmatic Goals

Develop Products which are:

- **Comprehensive** – provide solutions from initial care to definitive care.
- **Adaptable** – with end user needs in mind, designed in partnership with American Burn Association, ASPR/EMMO*, and first responders to ensure use in initial care settings and/or burn centers.
- **Sustainable** – bring value in routine care and expand treatment capacity and reduce resource burden in mass casualty.

*ASPR’s Office of Emergency Management & Medical Operations*
Partners in Transforming Burn Care and Building Preparedness

Government Partners

Non-Profits/Societies

Industry Partners

Advanced R&D; Project BioShield

Spectral MD

Cytori

PolyNovo Limited

Avita Medical

Argentum Medical

Stratatech

MediWound Ltd.
Reach out to the Burn MCM Branch for more information:

• Email:
  - Narayan Iyer (Narayan.Iyer@hhs.gov); Cell 202-510-6609
  - Julio Barrera-Oro (Julio.Barrera-Oro@hhs.gov); Cell 202-260-0393

• We are here - Reach out Burn MCM Branch members at BID: Aaron Bandremer, Danielle Turley, David Simon, Janelle Hurwitz, Hoda Elgendy

• Acknowledgement to Program Contract Officers: Christopher Scott, James Bowers, Jonathan Gonzales, Juan Wooten, Wendell Conyers, George Keane, Mathew Rose, Ethan Mueller, RoShawn Simpson, Phil Hastings
How to contact BARDA

Medical Countermeasures.gov
Portal to BARDA: Register to request a TechWatch meeting!

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

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

www.drive.hhs.gov
DRIVE questions

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