BURN MEDICAL COUNTERMEASURES
CBRN / BARDA

Narayan Iyer, Ph.D., Chief, Burn MCM, CBRN, BARDA
Julio Barrera-Oro, Ph.D.,
Danielle Turley, Ph.D.
David Simon, Ph.D.
Oxana Selivanova, Ph.D.

Gary Disbrow, Ph. D., Director, CBRN, BARDA

October 18-20, 2016
BARDA INDUSTRY DAY

Resilient People. Healthy Communities. A Nation Prepared.
Outline

BARDA’s Burn MCM Development Priorities

- Primary Goals
- Challenges & Strategy
- Burn MCMs Under Development & Acquisition
- Unmet Needs- Seeking New MCM Candidates

Engaging with BARDA

- At BARDA Industry Day
- Other Portals
Threat: Improvised Nuclear Device (IND)

- **Severe damage** (collapsed buildings): local
- **Moderate damage** (structural damage): within 1 mile
- **Light damage** (broken windows): within 3 miles
- **Dangerous fallout**: dependent on weather

**Effects:**

- **Blast**: overpressure + shockwave  ➔ *Trauma*
- **Thermal**: thermal pulse + ignited fires  ➔ *Burns*
- **Radiation**: prompt+ fallout  ➔ *Acute radiation syndrome, cutaneous radiation injury*
Medical Consequences: IND Detonation

**Radiation Injuries**
- Acute Radiation Sub-syndromes
  - Hematopoietic: cytopenias
  - Gastrointestinal & Pulmonary Injury
- Decorporation
- Biodosimetry

**Burn Injuries**
- Flash Burns
- Secondary Fires

**Mechanical Trauma Injuries**

**Concomitant Burn & Radiation injury**

**Cutaneous Radiation Injuries (CRI)**
Exposure to Radioactive fallout & beta-radiation

Distribution Size is Notional
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 (DPT to FT)
- 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
Challenges of Definitive Care (>72 hr to weeks)

- **Burn care is Specialized Care....relatively small market**
  - Estimated 350 burn surgeons in North America
  - <10,000 surgeries a year

- **National burn treatment capacity is limited**
  - 127 burn centers nationwide: ~1800 burn beds total
  - Average daily availability: ~400-200 burn beds

- **Burn care is labor and resource intensive**
  - Requires specific medical expertise - *excision, grafting, etc.*
  - Long hospital stays – 1 to 1.5 day per %TBSA
  - Higher medical resource utilization - 1 nurse per 1 patient
Limitations in US for Definitive Burn Care

1. Treatment Capacity
   - Burn surgeons & Expertise
   - Infrastructure & Communication
   - Transfer Policies

2. Efficient Throughput (in mass casualty)
   - Procedures with ‘bottlenecks’
   - Products with ability to ‘temporize’
   - Need for ‘Smart’ products
BARDA’s Solution

Addressing Definitive Care (>72 hr to weeks)

I. Expand Capacity for Definitive Care
   - Ease of Use
   - Reduce Resource Burden
   - Reduce Demand for Autograft

II. Expand Timeframe / Increase Throughput
   - Limit Conversion to FT burns
   - Temporizing strategies
   - Efficacy even with delayed treatment

- Shorten hospital stay
- Reduce need for surgery
- Reduce patient morbidity
- Leverage trauma surgeons
- Enable smaller autograft or Skin substitutes

Comprehensive – Adoptable – Sustainable
Definitive Care MCM Products
Under Development at BARDA

Thermal Burn Definitive Care Continuum

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- Arteriocyte- PRP
- BioBandage
- PolyNovo- BTM Biodegradable Matrix
- Spectral MD- DeepView Imaging System
- Spectral MD- DeepView Imaging System
- MediWound- Non-Surgical Debridement
- Cytori- ADRCs Adjunct for STSG
- Avita (ReCell)- Autograft Sparing
- Stratatech- Stratagraft Skin Substitute

Comprehensive – Adoptable – Sustainable

PBS $  ARD $
Addressing Treatment Bottlenecks in Skin Graft during Definitive Care

- Minimize Surgical Debridement
- Enzymatic @bedside (NexoBrid)
- Avoid need for donor tissue
- Use Skin substitute (StrataGraft)
- Use less Donor Tissue
- Autograft Sparing (ReCell)
- Direct use of Skin substitute (StrataGraft)
- Accelerate healing with cells (ReCell)
Definitive Care MCM Products

Under Procurement

- Most Advanced Products in the Portfolio
  - NexoBrid – enzymatic debridement product
  - Recell – autograft-sparing product
  - Stratagraft – cell-based skin substitute

- Under Vendor-Managed Inventory
  - Enabled by continuous demand for routine use
  - Products may have market presence for chronic wounds
  - Increased demand = increased feasibility for larger VMIs

- Geared for Integration into Routine Care
  - Products would improve patient care
  - Products could lower overall cost of definitive care
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Definitive Care MCM Products

Unmet Needs- Seeking New Candidates

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1. New Products to Prevent or Limit Burn Conversion

2. Easy to Use - ‘Smart’ Imaging Systems

3. New Allogenic / Biologicals or small molecules serve as adjuncts to Accelerate Healing
# Definitive Care MCM Products

## Unmet Needs - Seeking New Candidates

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### Key Desirable Attributes

- Topical / Easy to administer even in large TBSA
- Safe on full thickness burns.
- Reduce patient morbidity / pain.
- Has an MOA rationale that can be substantiated
- Easy to mfr; Off-the-shelf; sustainable in market with other clinical indications for use.
### Definitive Care MCM Products

#### Unmet Needs - Seeking New Candidates

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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).
Definitive Care MCM Products

Unmet Needs - Seeking New Candidates

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**Key Desired Attributes**

- Easy to integrate in current SOC.
- Safe, off-the-shelf; without the need for additional procedures (e.g. allogenic products).
- Can substantiate rationale for MOA to accelerate healing.
- Commercially sustainable with other indications for use.

3- New Allogenic / Biologicals or small molecules serve as adjuncts to Accelerate Healing.
BARDA is building burn care preparedness by solutions which are Comprehensive – Adoptable – Sustainable

Seeking New MCMs to address unmet need in three areas:
1. Limiting Burn Conversion
2. Smart Imaging
3. Adjuncts to Accelerate Healing
Engaging BARDA Burn Team

- At Industry Day: Learn more at:
  - Narayan Iyer [narayan.iyer@hhs.gov or 202-510-6609]
  - Julio Barrera-Oro, David Simon; Danielle Turley; Oxana Selivanova

- Near-Term:
  - Visit www.medicalcountermeasures.gov
    - Learn more & Register & Request a Meeting (TechWatch)
  - Visit ASPR-TRACIE (Stands for Technical Resources-Assistance Center – Information Exchange)
    - ASPRtracie.hhs.gov
    - 1-844-5-TRACIE
    - askasprtracie@hhs.gov
Partners in Changing Burn Care Paradigm
Building Burn Care Preparedness

Concerted Effort of Governmental Agencies – Companies - Non-Profits
Thank You