



# BARDA INDUSTRY DAY

## BARDA Thermal Burn Medical Countermeasures Program

**Julio Barrera-Oro, PhD**  
**Project Officer, Thermal Burn MCMs Program**  
**October 29, 2018**

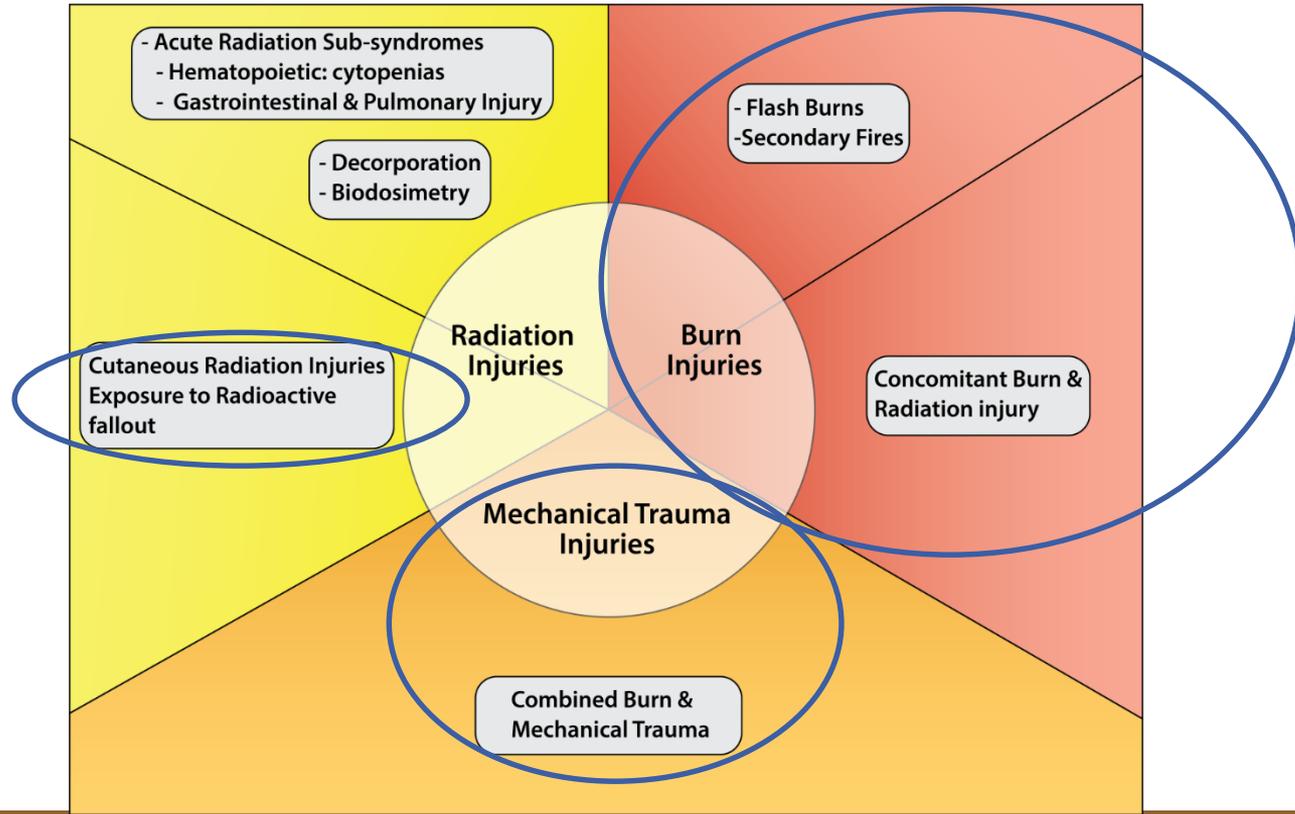
### **Burn MCM Team**

**Branch Chief:**  
Narayan Iyer  
Julio Barrera-Oro  
Danielle Turley  
Janelle Hurwitz  
Aaron Bandremer  
Hoda Elgendy  
David Simon

October 29-30, 2018 | Grand Hyatt • Washington, D.C.



# Medical Consequences: Nuclear Detonation



# Treatment Goals: MCMs for Thermal Burns

## Timeline Post-Detonation



0 h

Up to 72 h

72 h

After ~ 72 h

144 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

### 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



**ASPR**  
ASSISTANT SECRETARY FOR  
PREPAREDNESS AND RESPONSE



Saving Lives. Protecting Americans.

# 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

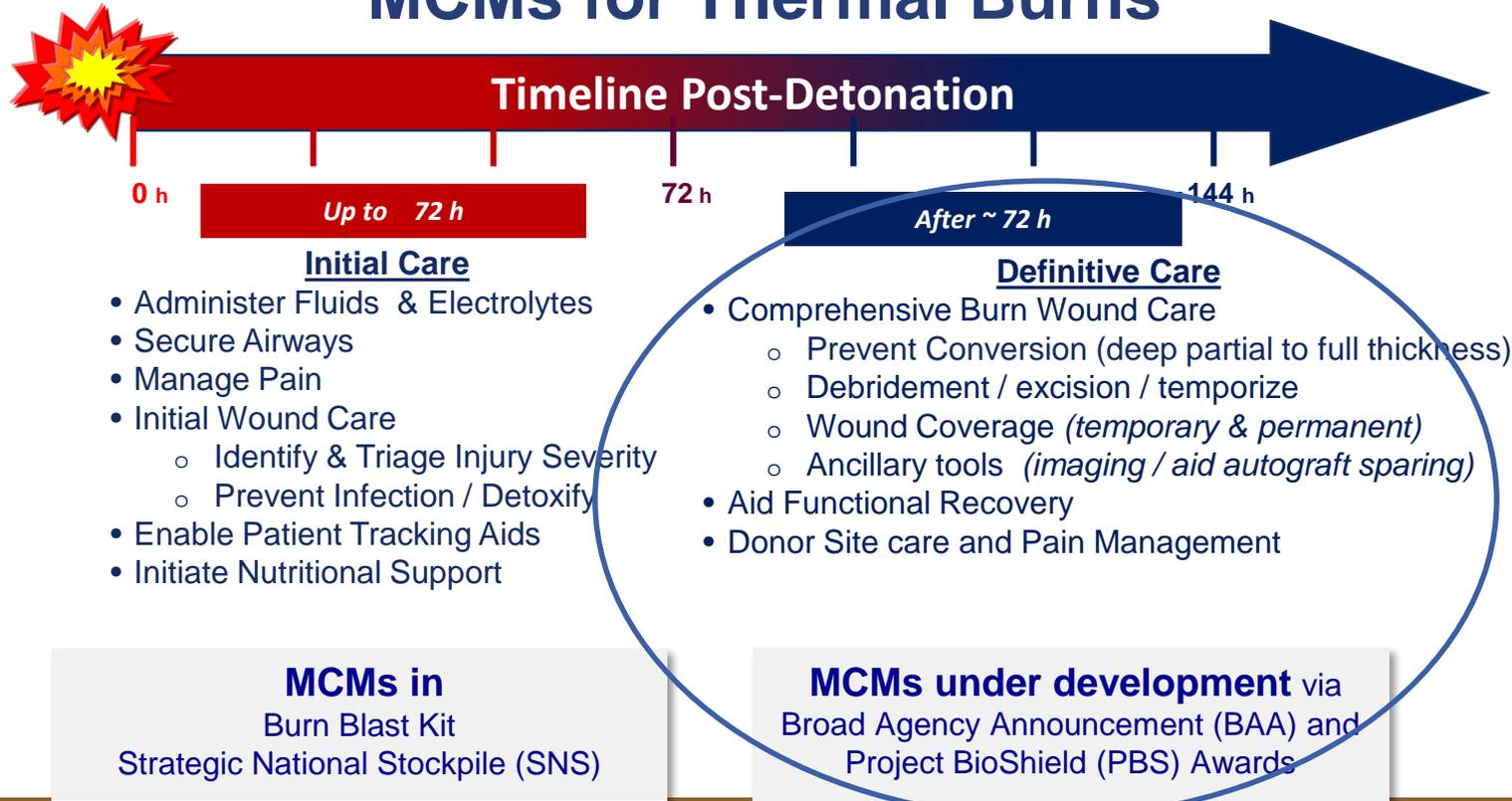


2018  
Funding to  
Develop for  
Cutaneous  
Radiation  
Injury (CRI)



Saving Lives. Protecting Americans.

# Treatment Goals: MCMs for Thermal Burns



# Realities of U.S. Definitive Burn Care



weeks/months

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

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



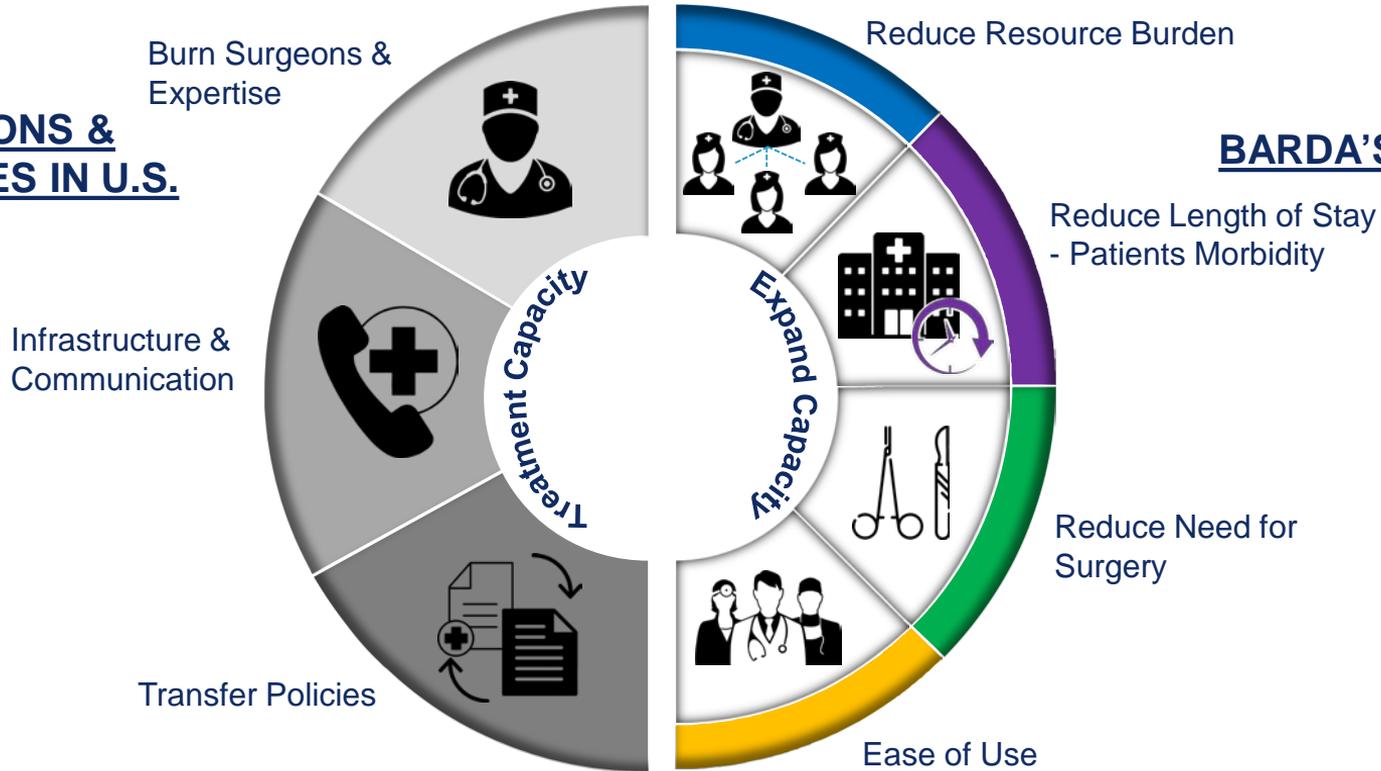
1 nurse per 1 patient

*Burn care is labor and resource intensive*

# Solutions: Definitive Care

## LIMITATIONS & CHALLENGES IN U.S.

## BARDA'S SOLUTION



# Solutions: Definitive Care

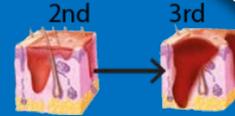
## LIMITATIONS & CHALLENGES IN U.S.

## BARDA'S SOLUTION

Procedures with  
"bottlenecks"



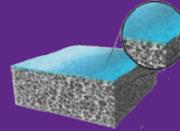
Limit Conversion to  
FT Burns



Limited Products  
with Ability to  
"Temporize"



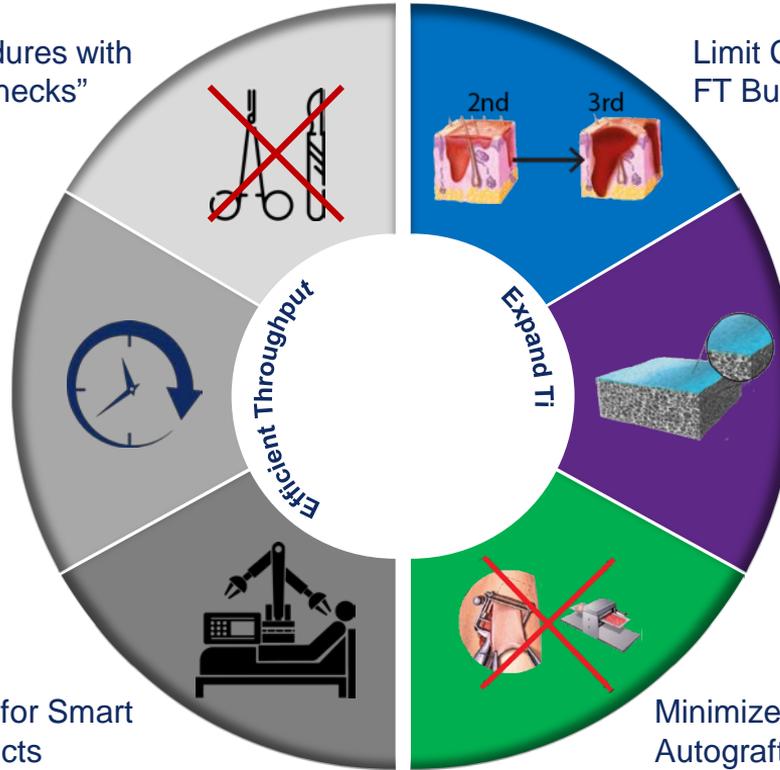
Temporizing  
Strategies



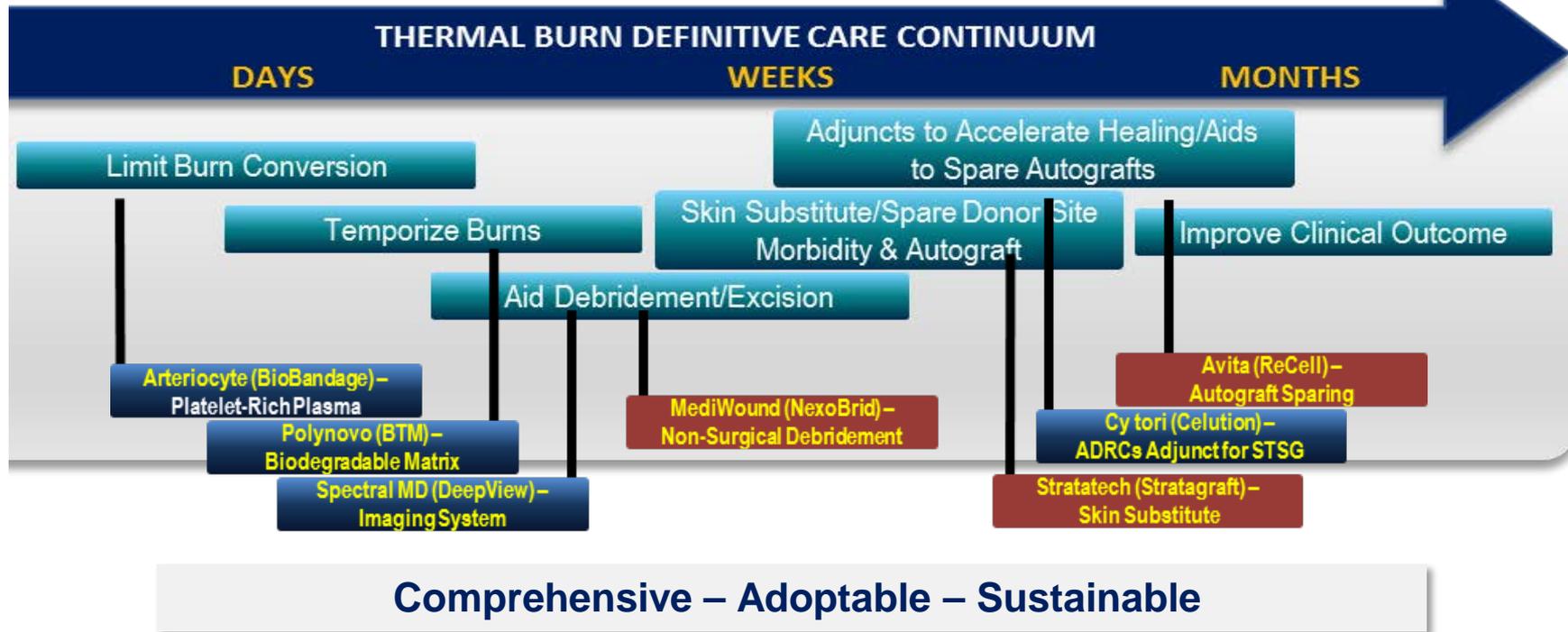
Need for Smart  
Products



Minimize  
Autografting



# Definitive Care Products Under Development at BARDA



Broad Agency Announcement (BAA) Award

Project BioShield (PBS) Award



*Saving Lives. Protecting Americans.*

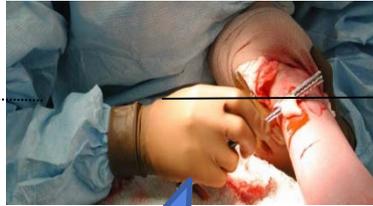
# Increasing Preparedness by Improving Routine Burn Care

Current Standard of Care

Improved Standard of Care

**NEXOBRID™**  
(MediWound Inc)

Minimize surgical  
debridement –  
Enzymatic at bedside

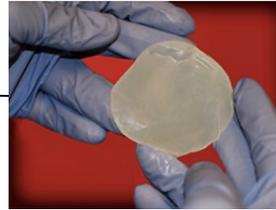
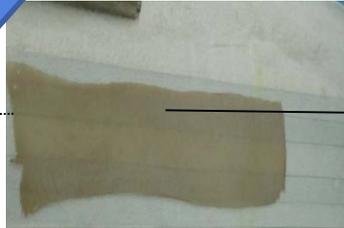


**RECELL®**  
(Avita Medical)  
Use less donor tissue –  
Autograft sparing



**STRATAGRAFT®**  
(Stratatech/MKDT)

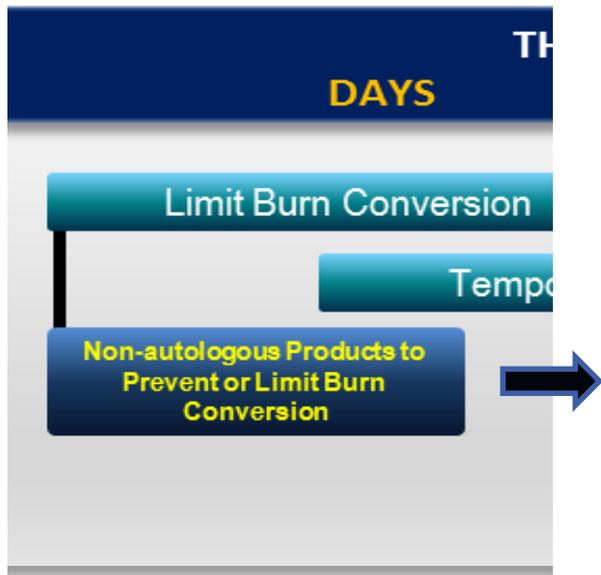
Avoid need for donor  
tissue –  
Use skin substitute



FDA  
APPROVAL  
Sept 20,  
2018



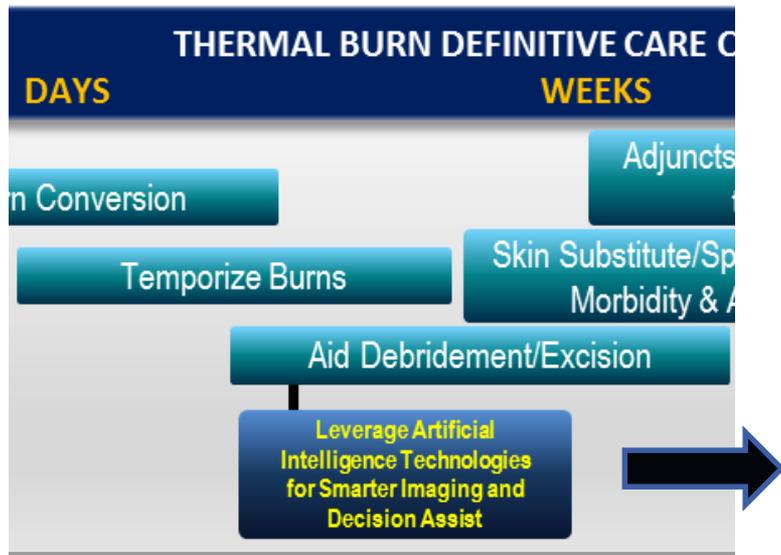
# Definitive Care Products: Unmet Needs – Limiting Burn Conversion



## 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)

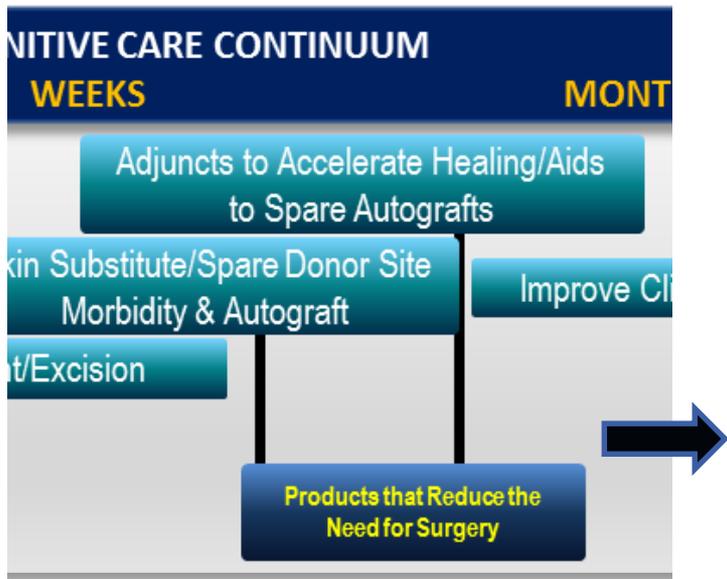
# Definitive Care Products: Unmet Needs – Smart Imaging / Machine Learning Applications



## 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



Expanding  
New Area  
of Focus  
in FY19

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 **After ~ 72 h** 144 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

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

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



# Burn MCMs- Overarching Programmatic Goals

Develop Products which are:

- ✓ **Comprehensive** – *provide solutions from initial care to definitive care.*
- ✓ **Adoptable** – *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



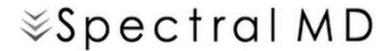
## Non-Profits/Societies



AMERICAN COLLEGE OF SURGEONS  
Inspiring Quality:  
Highest Standards, Better Outcomes



## Industry Partners Advanced R&D; Project BioShield



Saving Lives. Protecting Americans.

# Reach out to the Burn MCM Branch for more information:

- **Email:**
  - Narayan Iyer ([Narayan.Iyer@hhs.gov](mailto:Narayan.Iyer@hhs.gov)); Cell 202-510-6609
  - Julio Barrera-Oro ([Julio.Barrera-Oro@hhs.gov](mailto: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

[medicalcountermeasures.gov/home.aspx](https://www.mediccountermeasures.gov/home.aspx)

Portal to BARDA: **Register to request a TechWatch meeting!**



[www.fbo.gov/](http://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](http://www.drive.hhs.gov)  
*DRIVE questions*

**USAJOBS**  
"WORKING FOR AMERICA"

<https://www.usajobs.gov/>  
*Join the team!*