



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response

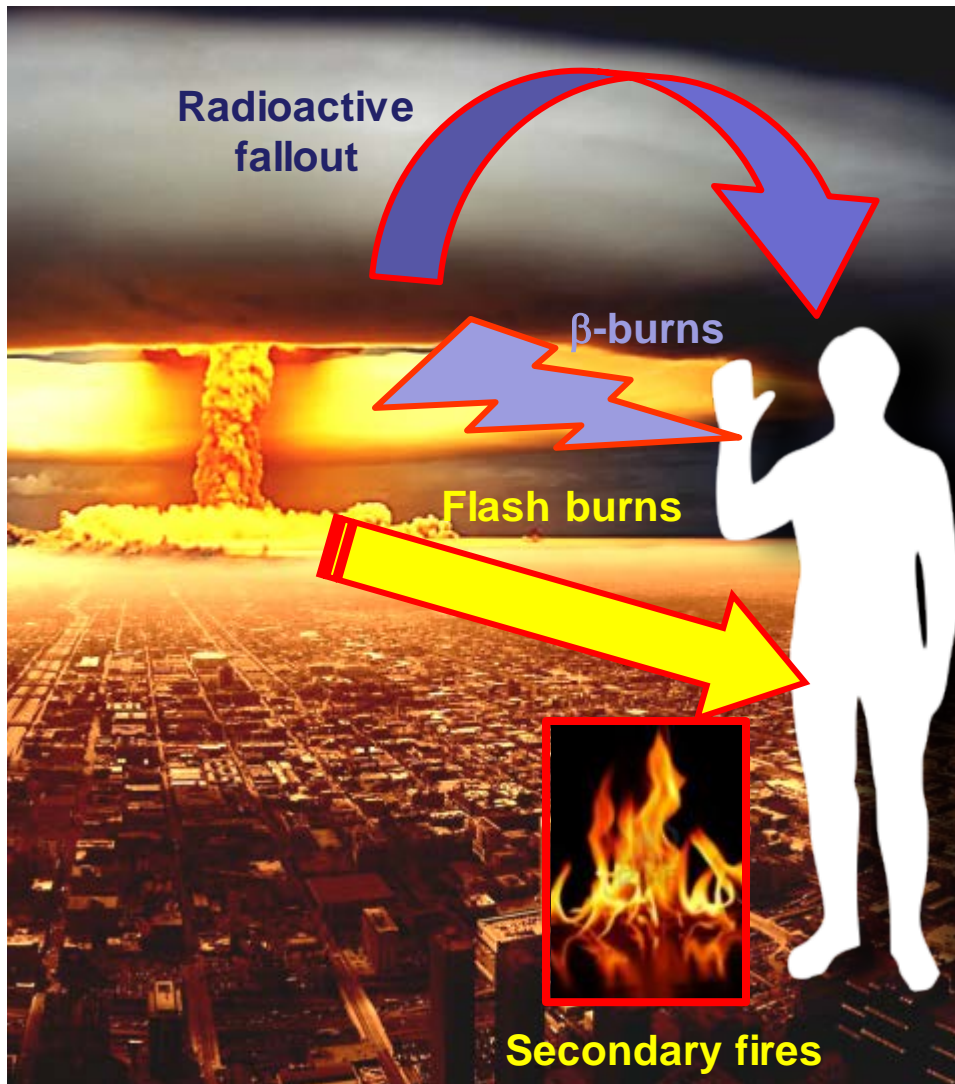


Medical Countermeasures for Thermal & Radiation Burn Injuries FY14 Advanced R&D Priorities

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IND Detonation & Mass Casualty

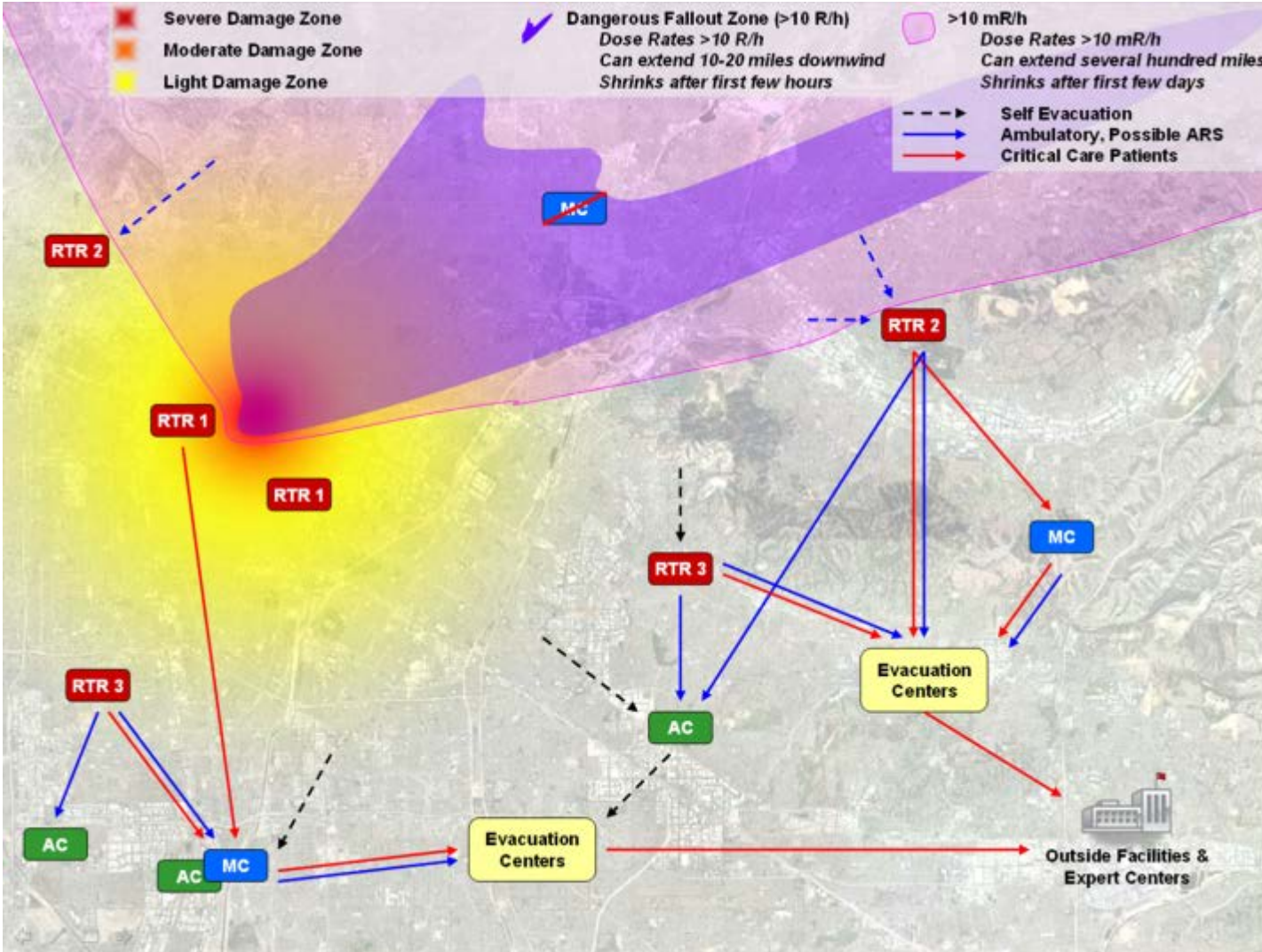
Thermal Burn Injury

- Line-of-site to detonation (flash burns)
- Secondary fires (conventional burns)

Cutaneous Radiation Injury

- Exposure to radioactive fallout
- Direct exposure to beta-radiation (“beta burns”)

Concept of Operations (CONOPs)



Primary Triage
(RTR1, RTR2, RTR3)



Assembly Centers
(AC)



Medical Centers
(MC)



Evacuation Centers

Timeline Post-Detonation

0 hrs 24 hrs 48 hrs 72 hrs 96 hrs 120 hrs 144 hrs

Goals: first 72 hrs

Thermal Burns:

- Prevent infection
- Prevent conversion of deep partial thickness to full-thickness

Cutaneous radiation injury

- Prevent infection
- Mitigate latent damage

Goals: after 72 hours

Thermal Burns

- Debridement / excision
- Temporary grafting, if necessary
- Conclusive wound care

Cutaneous radiation injury

- Debridement / excision
- Conclusive wound care

Current Focus

Field Care Products

Compatible w/ Triage Sites

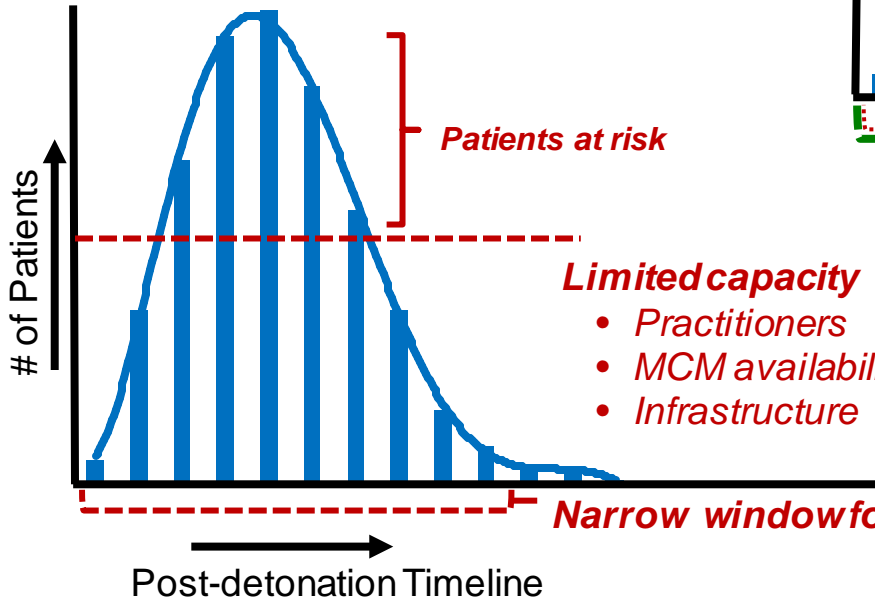
- **Ease of administration**
Topical creams, bandages, etc.
- **High therapeutic index required**
Poor diagnostics, worried well patients
- **Robust storage, easy deployment**
Controlled room temperature, etc.

Definitive Care Products

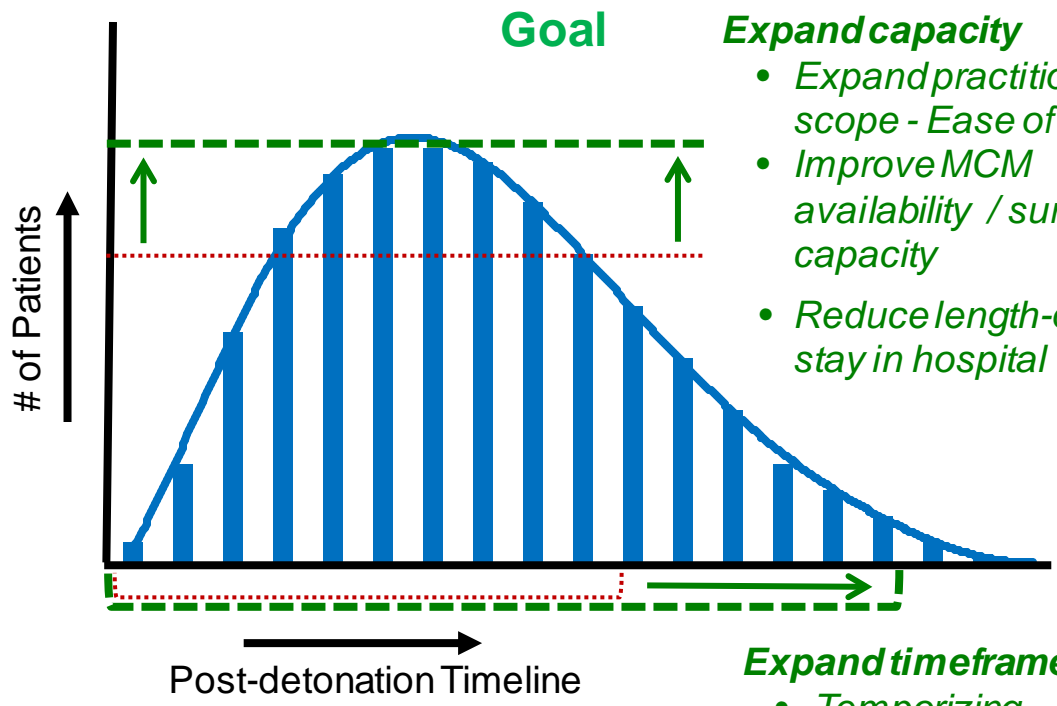
Compatible w/ Hospital Care

- **Expertise required to administer**
Surgical grafting, intravenous, etc.
- **Low therapeutic index acceptable**
Better diagnostics and patient monitoring
- **Low storage requirements**
Frozen, cryopreservation, etc.

Current Situation



- Limited capacity**
- Practitioners
 - MCM availability
 - Infrastructure



Goal

- Expand capacity**
- Expand practitioner scope - Ease of Use
 - Improve MCM availability / surge capacity
 - Reduce length-of-stay in hospital

- Expand timeframe**
- Temporizing strategies
 - Efficacy even with delayed treatment



Burn MCMs: Target Characteristics



- **Expedite first treatment / temporize wound**
 - Increase early throughput, expand treatment window
- **Reduce hospitalization / labor burden**
 - Minimize hospitalization and burden-of-care
- **Ease-of-Use**
 - Expand end-user scope to non-burn surgeons & other practitioners
- **Delayed efficacy**
 - Still effective when treatment is delayed beyond standard-of-care timeframe
- **Commercially sustainable**
 - Sufficient day-to-day clinical use to sustain market presence
 - Additional / broad indications (soft tissue wounds, diabetic ulcers, etc.)
 - Cost-competitive AND lower cost of burn care
- **Surge capacity**
 - Production can be surged based on warm-base manufacturing
- **Robust storage / shelf-life**
 - Facilitate availability (managed inventory), commercial sustainability



Burn MCMs

Advanced Development Pointers



Key Considerations

- **Address characteristics that expand use timeframe & capacity**
 - ☑ Ease of Use
 - ☑ Ability to 'Temporize'
 - ☑ Reduce Burden
- **Create sustainable (& *de facto*) preparedness via managed inventory**
 - ☑ Commercial Viability
 - ☑ Multiple Indications
 - ☑ Amenable to UMI or VMI
- **Recognize CONOPS: Focus on Definitive Care**
 - ☑ Debridement / excision
 - ☑ Deter DPT/ FT Progression
 - ☑ Reduce Demand for Autograft
 - ☑ Conclusive Wound Care
 - ☑ Lower Overall Cost of Burn Care

Learn More

- **Refer to previous special instructions:** BARDA-CBRN-BAA-12-100
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- www.fedbizopps.gov
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