U.S. Military’s Role in a National Trauma Action Plan to Increase Homeland Security & Our Country’s Response To Mass Casualties

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November 15th, 2018

Disclosures
- Viewpoints are those of the presenter and are not official positions of U.S. Government
- Inventor of REBOA & Vascular Shunt technology – patents assigned to the Department of Defense & U.S. Air Force
- No consulting, advisory board, royalty stream, speakers fees, stock equity or other financial conflicts to disclose

Backdrop for the US as it Considers Civilian Trauma & Injury Care

- Wartime experience confirms that force protection and primary preventative measures do not work all the time and there needs to be a trauma care system at the ready to reduce death & disability

Military Role Anchored with ACS Partnership

A Shared Ethos: The Military Health System
Strategic Partnership with the American College of Surgeons

Renewed and - for the first time - formalized Strategic Partnership with American College of Surgeons
- Established lines of effort with which to integrate military surgery into civilian sector (while improving readiness, quality, research)

Integration of Military into Civilian Trauma Care

Tragedies of 2017 showed how military medical partners can help at home

Partnerships in civilian trauma systems and centers (there is now congressionally-mandated increase in this aspect of partnership)
- Military assigned to civilian centers, or military medical centers operating as level I trauma centers increase the surge capacity following shootings, natural disasters & accidents

Three Facets of Military’s Role in National Plan

1. Military caring for injured civilians (3-4 models of this approach)
2. Military research investment results in products for civilian care
3. DoD working with other federal agencies to improve preparedness & readiness (e.g. HHS, DHS, DoJ, etc.)
Military as Federal Source for Trauma Research

The vast majority of research dollars dedicated to topics in trauma & injury care are from the DoD (this fills important gap)

The DoD need to develop new products for the battlefield also compels other federal partners (i.e. HHS, DHS, etc.) to acknowledge and accommodate the topic

Example of Translation of Military Experience

https://www.dhs.gov/stopthebleed

FDA Working to Accommodate New Products

A strategically aligned Food and Drug Administration: New ways to leverage research and deliver safe, effective, and secure devices for trauma care

Strengthen clinical trial enterprise – including accommodating and accepting military-relevant endpoints and those more appropriate for study of severe injury and shock

Balance of pre- & post-market data; e.g., 2016 FDA guidance document on use of real-world evidence (RWE)

FDA Working to Accommodate New Products

Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

Guidance for Industry and Food and Drug Administration Staff

“Greater use of real world evidence can help devices come to market faster and expand the depth and reliability of information we have to inform the safe and effective use of new products” FDA Commissioner Scott Gottlieb, MD

FDA Working to Accommodate New Products

Public Law 115–92

An Act

To amend the Federal Food, Drug, and Cosmetic Act to authorize additional emergency use for medical products to reduce deaths and severity of injuries caused by agents of war, and for other purposes.

Dec 12, 2017

FDA and DoD formalize collaboration to advance medical products in support of American military personnel

Formalized an accommodating approach by the FDA to products being developed by the DoD for wartime illnesses or injuries

Stance also enhances national preparedness (i.e. homeland security)

Conclusion

U.S. military plays multi-faceted role in a National Trauma Action Plan to increase homeland security & response to mass casualties

When it comes to effective military and civilian trauma care in we’ll either succeed together or we’ll fail together…