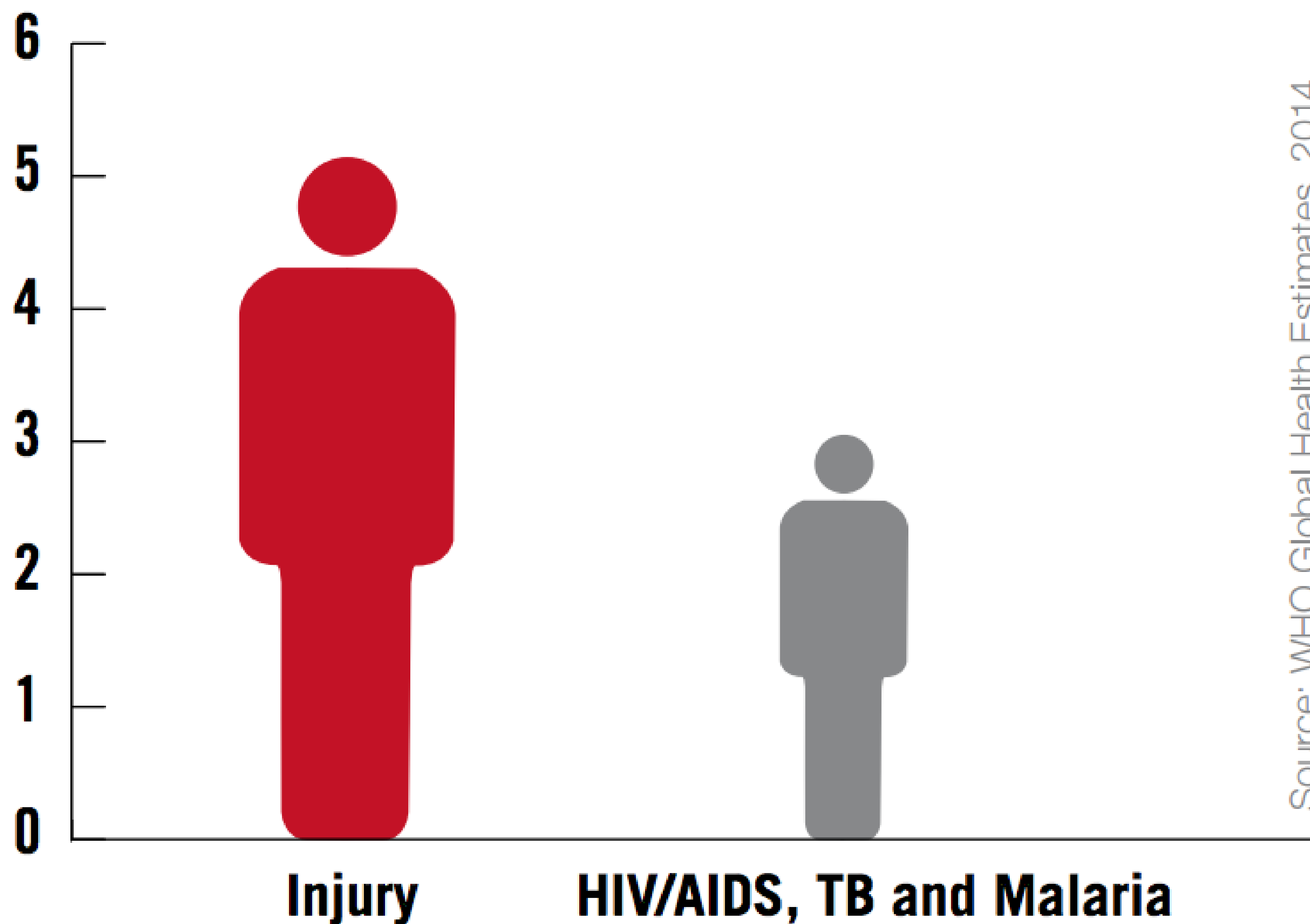
NASEM Strategy conference April 2017

TRAUMA RESEARCH: Funding and Direction

Eileen M. Bulger, MD

AMERICAN COLLEGE OF SURGEONS

Committee on Trauma


Deaths per year (millions)
6
5
4
3
2
1
0
Injury
HIV/AIDS, TB and Malaria
Source: WHO Global Health Estimates, 2014

A Learning Healthcare System

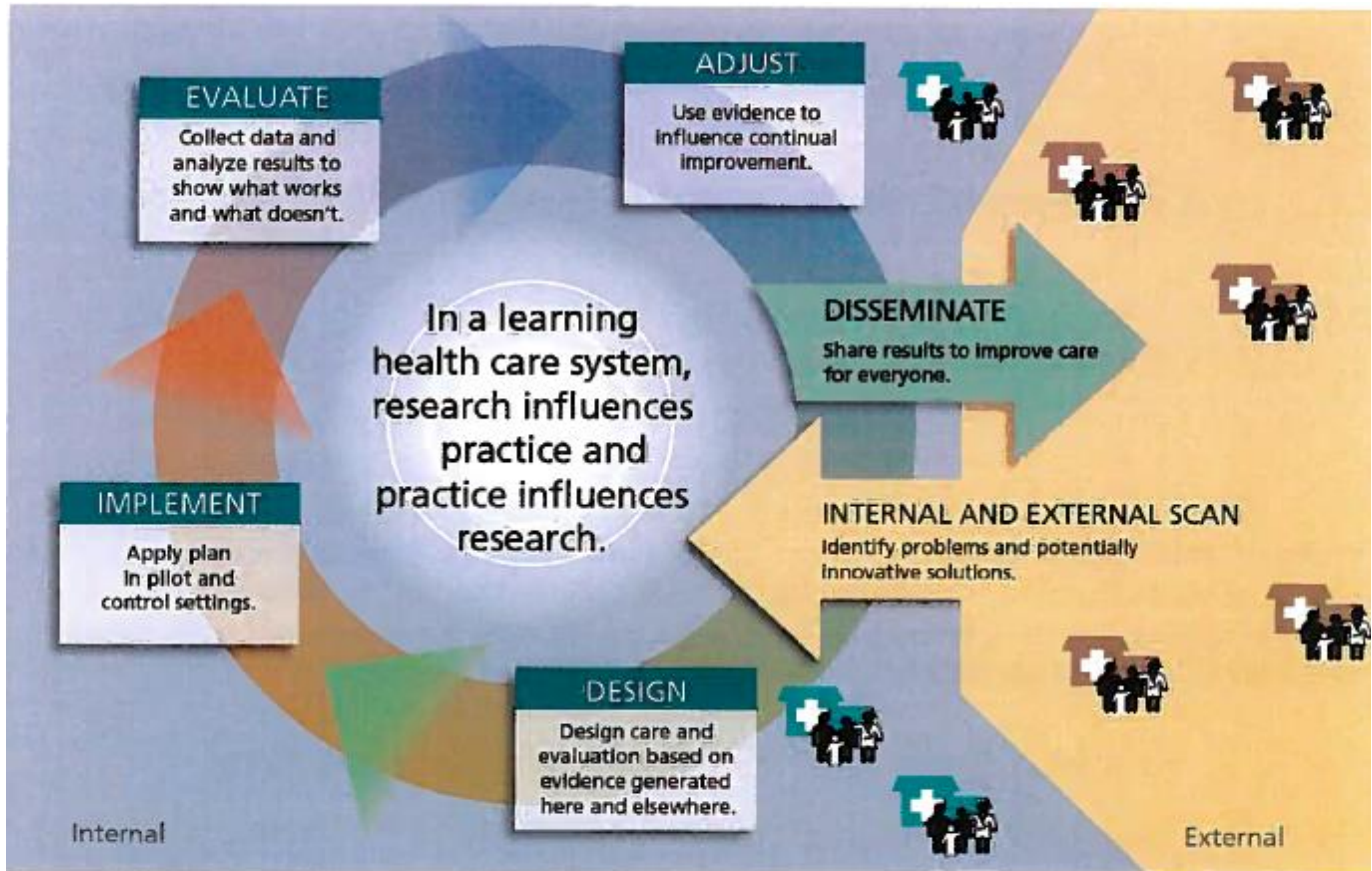


FIGURE 3-1 How a continuously learning health system works.
SOURCE: From Greene et al., 2012. Copyright © 2012 American College of Physicians. All Rights Reserved. Reprinted with the permission of American College of Physicians, Inc.

Research as the Foundation

FIGURE 5-1 The trauma care workforce comprises the clinical team as well as a much larger number of support personnel.

AMERICAN COLLEGE OF SURGEONS

Committee on Trauma

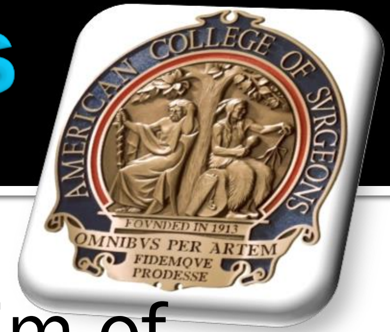
NASEM Recommendations

- "To strengthen trauma research and ensure that the resources available for this research are **commensurate with the importance of injury** and the potential for improvement in patient outcomes, the White House should issue an executive order mandating the establishment of a National Trauma Research Action Plan"

AMERICAN COLLEGE OF SURGEONS

Committee on Trauma

NASEM Recommendations



- To accelerate progress toward the aim of zero preventable deaths after injury and minimizing disability, regulatory agencies should revise research regulations and reduce misinterpretation of the regulations through policy statements

Current Challenges

- Lack of sustainable research funding
  - NIH: percent of funding relative to burden of disease (-11.8%)
  - DOD: funding tied to active conflict, not a top priority for CDRMP funding
  - CDC: focus on injury prevention, not a top priority for the agency
  - AHRQ: Not on the priority list

Injuries Cost the U.S. $671 Billion in 2013

Over two-thirds of these costs were due to nonfatal injuries

Fatal Injury
$214 Billion

32%

Nonfatal Injury
$457 Billion

68%

Lifetime medical and work loss costs of injury, United States, 2013

Florence C, Simon T, Haegerich T, et al. Estimated Lifetime Medical and Work Loss Costs of Fatal Injury, United States 2013. *MMWR* 2015;64(38).
Florence C, Haegerich T, Simon T, et al. Estimated Lifetime Medical and Work Loss Costs of Emergency Department Treated Nonfatal Injuries, United States 2013. *MMWR* 2015;64(38).

CDRMP Funding FY92-16 $10.8 B

- Breast Cancer $3,286.1 million
- Prostate $1,530.0 million
- Ortho (incl trauma) $308.5 million
- TBI/Pysch health $889.7 million
- Neurofibromatosis $302.9 million
- Cancer $199.8 million
- Spinal Cord Injury $187.9 million
- Lung Cancer $101.5 million
- Autism $66.9 million
- Trauma $15 million

American College of Surgeons Inspiring Quality: Highest Standards, Better Outcomes 100+years
The Committee on Trauma
NHTSA
NIH

© American College of Surgeons 2017. All rights reserved Worldwide.

DoD Medical Research and Development

DEFENSE MEDICAL RESEARCH AND DEVELOPMENT

IN THE LAB, ON THE BATTLEFIELD

Military Operational Medicine

- Psychological health and resilience, suicide prevention
- Human performance (sleep, nutrition, fitness), extreme environments

Military Infectious Diseases

- Vaccines, prophylaxis, treatment
- Vector control, diagnostics

Medical Chemical and Biological Defense

- Threat agent vaccines, prophylaxis
- Threat agent diagnostics treatments and medical intelligence

Clinical and Rehabilitative Medicine

- Definitive care, pain management, vision and hearing
- Prosthetics, transplants and regenerative medicine

Combat Casualty Care

- Traumatic brain injury diagnostics and therapeutics
- Hemorrhage, blood products, extremity trauma, en-route care

~20% of the budget

Prone to shifting priorities and not stable platform for trauma research

NASEM Report

- DOD's trauma research agenda and funding level fluctuate during interwar periods. Responding to a fluctuating agenda is difficult while conducting multi-year clinical trials.

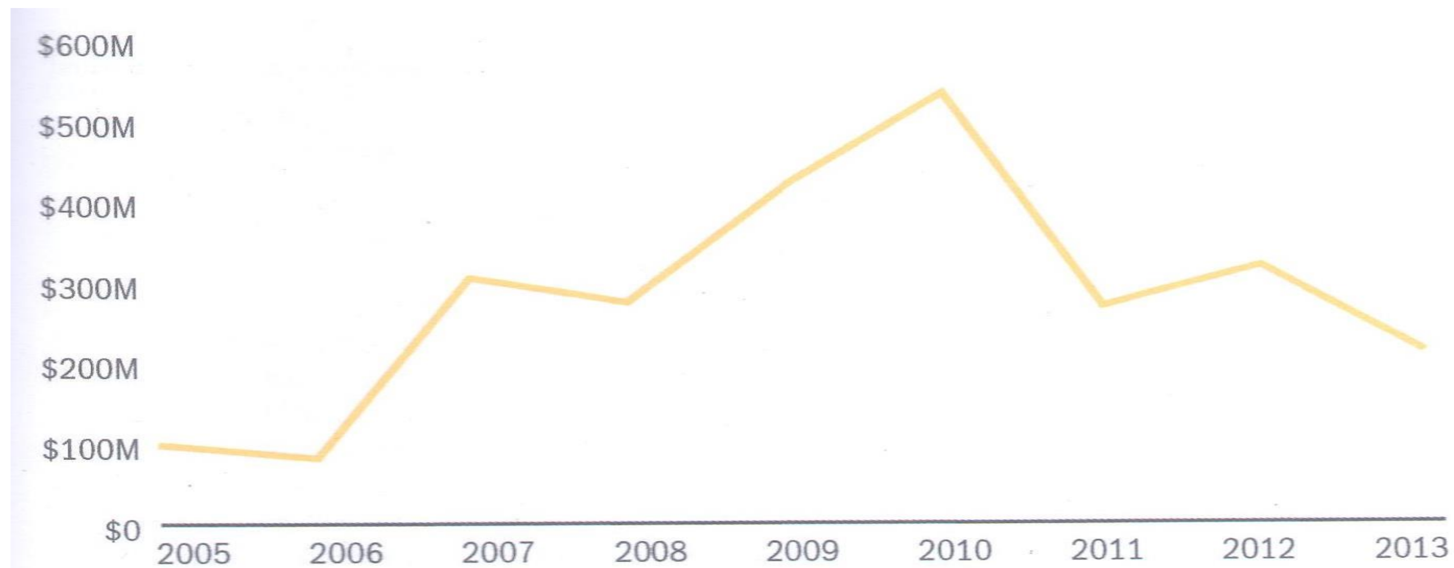


FIGURE 4-6 Military medical research investment in trauma care, 2005-2013.
SOURCE: Adapted from GAO (2013, p. 5).

American College of Surgeons — Inspiring Quality: Highest Standards, Better Outcomes — 100+years
The Committee on Trauma
NHTSA
NIH

© American College of Surgeons 2017. All rights reserved Worldwide.

CDC Priorities, Domestic Grant Programs

- Hospital and Public Health preparedness
- Immunizations and Vaccines for Children
- HIV prevention programs
- Epidemiology for Infectious diseases
- Cancer Preventions and control
- Preventative Health services
- Prevention and control of Diabetes, Heart disease, Obesity
- STD prevention
- Tuberculosis elimination programs

American College of Surgeons
Inspiring Quality: Highest Standards, Better Outcomes
100+years
The Committee on Trauma
NHTSA
NIH

© American College of Surgeons 2017. All rights reserved Worldwide.

More Challenges

- Lack of a uniform, comprehensive research agenda
- Disjointed advocacy efforts
- Difficulty in linking data across platforms
  - Pre-hospital → Hospital → Rehab/SNF
- Lack of patient/family engagement in advocacy efforts
- Significant regulatory burden for trials in the emergency setting

National Trauma Research Action Plan

- Define the scope of trauma research
  - Continuum of care
  - Uniting the community, all subspecialties
- Defining the lead agency, Home for trauma research?
- Advocate for commensurate funding

THE DEBATES

- The DOD should be the primary federal home for trauma research
  - PRO: Dr. Todd Rasmussen
    - Director of US Combat Casualty Care Research programs
  - CON: Dr. William Cioffi
    - Co-Director of the Coalition for National Trauma Research

Coalition for National Trauma Research (CNTR)

- Includes: AAST, COT, EAST, WEST, NTI
- Advocacy efforts (2yrs: $20 million)
- Research agenda
- DOD funding for national study on preventable death (PI: Eastridge)
- Applying for funding to support NASEM implementation

Advantages of the DOD

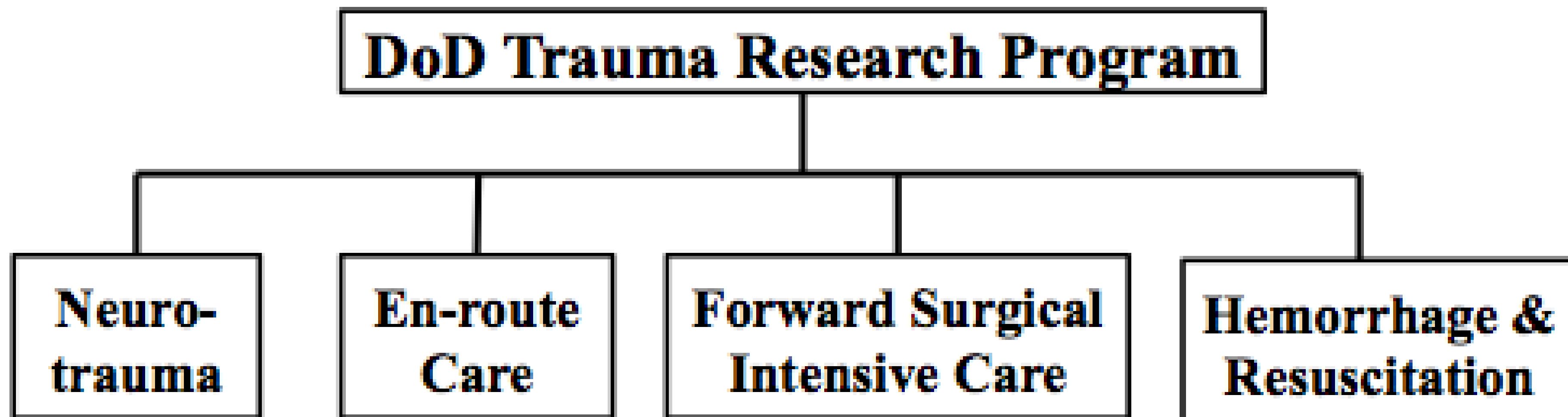
- Established Executive Function
  - Active program management: avoids redundancy, creates leverage among different awardees, minimizes gaps in topics covered
- Scope of Research
  - DOD has defined injury research priorities across the continuum of care

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

© American College of Surgeons 2017. All rights reserved Worldwide.

Scope & Meaning of Trauma Research

- DoD has for the 1st time broadly defined areas of trauma research within a federal program (i.e. domains of topics along the range of care – point of injury, en-route and facility-based)



- Within each "bin" are specific lines or topics of research spanning basic to applied to clinical (i.e. a functional framework for the $)

More Advantages to the DOD

- Mission Focus
  - Delivering solutions, avoids “research for research sake”, product development pathway
- Expediency
  - DOD approach to research is established and recognized

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

© American College of Surgeons 2017. All rights reserved Worldwide.

Disadvantages to the DOD

- Mission Differences between Civilian and Military systems
  - DOD mission does not include: geriatrics, pediatrics, rural populations
  - Trauma systems issues are different between civilian and military systems
  - DOD prehospital research does not address civilian challenges with data linkage and variability in care

American College of Surgeons
Inspiring Quality:
Highest Standards, Better Outcomes
100+*years*

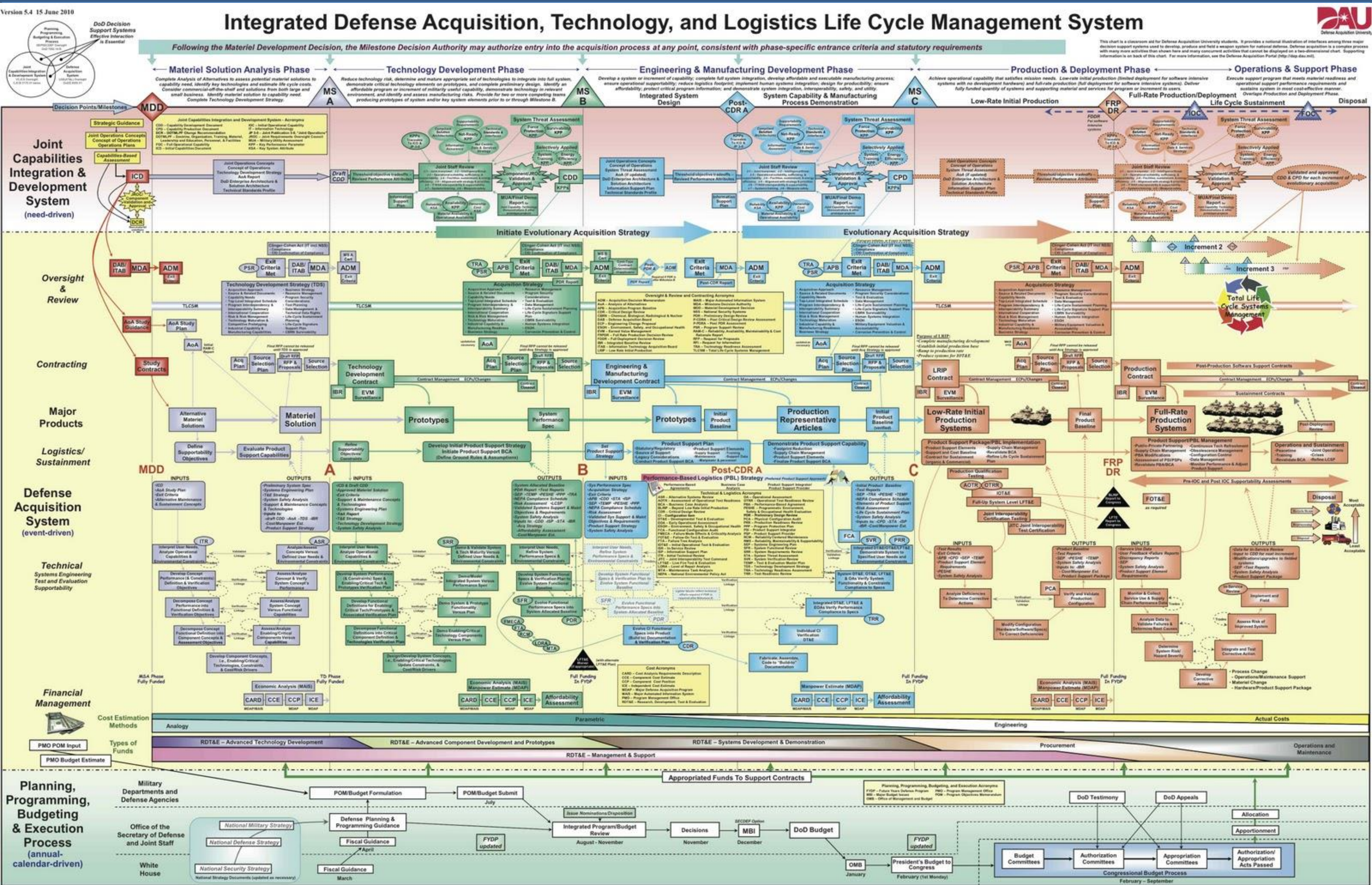
© American College of Surgeons 2017. All rights reserved Worldwide.

More Disadvantages to DOD

- DOD research process is cumbersome
  - Treated as a part of acquisition process (Like buying a tank)
  - Contract not grant, not investigator initiated
  - Concerns about scientific review process, can be over ruled by mission relevance
  - Delays and more delays: award process and regulatory review for clinical trials
- EFIC requires approval from Secretary of the Army

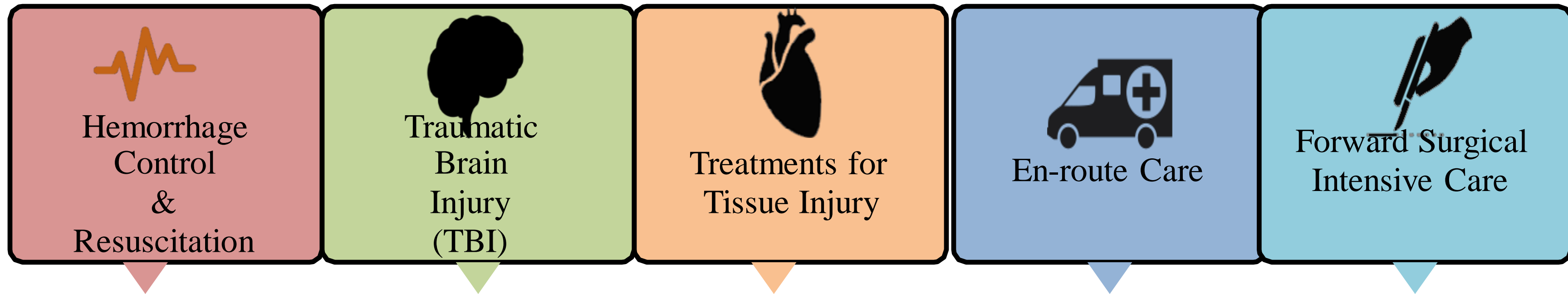
American College of Surgeons
Inspiring Quality:
Highest Standards, Better Outcomes

© American College of Surgeons 2017. All rights reserved Worldwide.



Source: Integrated Life Cycle Chart (https://ilc.dau.mil/)

“The Bins are Empty”



	Hemorrhage Control & Resuscitation	Traumatic Brain Injury (TBI)	Treatments for Tissue Injury	En-route Care	Forward Surgical Intensive Care
DHP	$21M	$31M	$9M	$10M	$18M
Army	$14M	$8M	$8M		$5M
Congressional		$40M	$40M		
Total	$35M	$79M	$57M	$10M	$23M

Conclusions

- DOD program is appreciated and necessary and led to major improvements in outcomes in past decade of conflict.
- The program is underfunded and often duplicative of other agency funding of non-trauma issues. Funding has not kept up with NIH increases.
- The program is complex and hampered by bureaucracy which leads to inordinate delays.
- The “acquisitions” nature not always conducive to research. These are contracts not grants.
- Immediate needs approach does not always lend itself to full spectrum of basic-translational-clinical research.

© American College of Surgeons 2017. All rights reserved Worldwide.

DEBATE #2

- We should advocate for a National Institute of Trauma Research at the NIH
  - PRO: Dr. Jerry Jurkovich
    - Chairman of the Board National Trauma Institute
  - CON: Dr. Timothy Fabian
    - Immediate past Chair of the Board of the National Trauma Institute

National Trauma Institute

- 501c, independent, non-profit organization established in 2006
- Civilian-military collaboration
- Advocacy and management of trauma research funds
- National Trauma Research repository in development
- Managed approx $40million over 10 years

Advantages to a Dedicated NIH Institute

- Establishes Trauma as a public health priority for the civilian community, stable funding
- Will include priority civilian populations: geriatrics, pediatrics
- Investigator initiated, fosters innovation
- Rigorous, respected scientific review, informed an attuned study sections

American College of Surgeons
Inspiring Quality:
Highest Standards, Better Outcomes

© American College of Surgeons 2017. All rights reserved Worldwide.

More Advantages NIH Institute

- Motivate and Train future investigators
- National coordination, centralized IRB, adequate funding for clinical trials
- Transparent funding priorities and allocation process

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

100+*years*

© American College of Surgeons 2017. All rights reserved Worldwide.

Why Not Advocate for NIH Institute?

- Not feasible in current climate
  - NIH funding not a priority for current administration
  - Concerns about NIH funding cut proposals in current budget
  - DOD is the best bet for the near future

American College of Surgeons
Inspiring Quality: Highest Standards, Better Outcomes

© American College of Surgeons 2017. All rights reserved Worldwide.

Next steps?

- National Trauma Research Action Plan
  - Articulate a unified Research Agenda across the continuum of care
  - Define the ASK for financial investment
  - Define a strategy for a federal home for trauma research funding
  - Develop strategies to address regulatory burden
  - Develop a unified approach to advocacy

Next steps?

- ADVOCACY, ADVOCACY, ADVOCACY
- Define Research agenda and priorities to support advocacy efforts
- Advocate for a National Trauma Research Institute?
- Advocate for a National Trauma Research Action Plan
- Bring all organizations interested in trauma research together to advocate with a unified/coordinated approach
  - Eliminate: “bone/blood/burn/brain”
- Engage the public and trauma survivors in advocacy efforts

Discussion

AMERICAN COLLEGE OF SURGEONS

Committee on Trauma