



Simulated Clinical Environments and Virtual System-of-Systems Engineering for Health Care

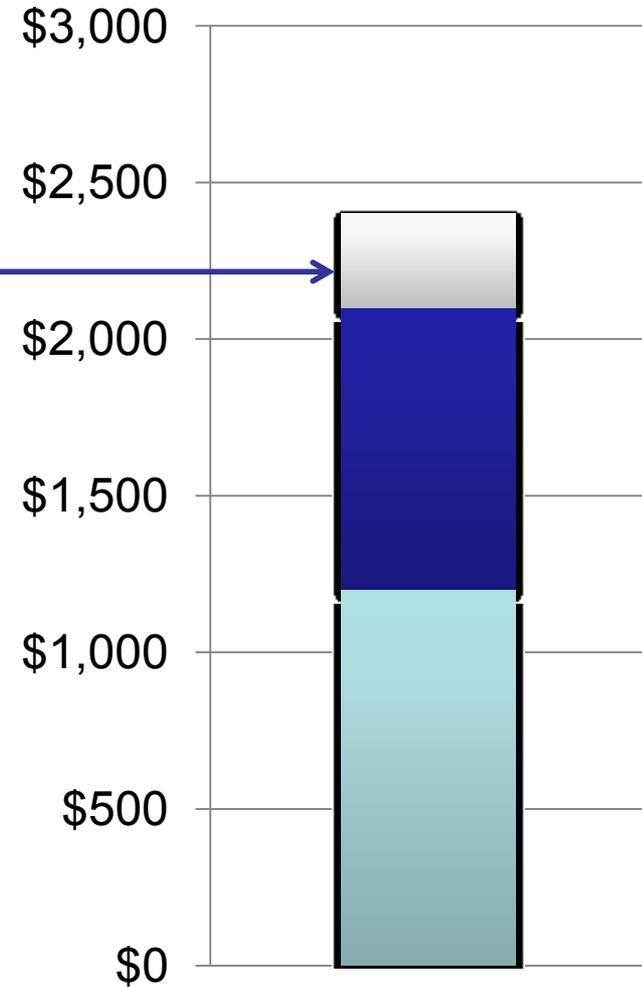
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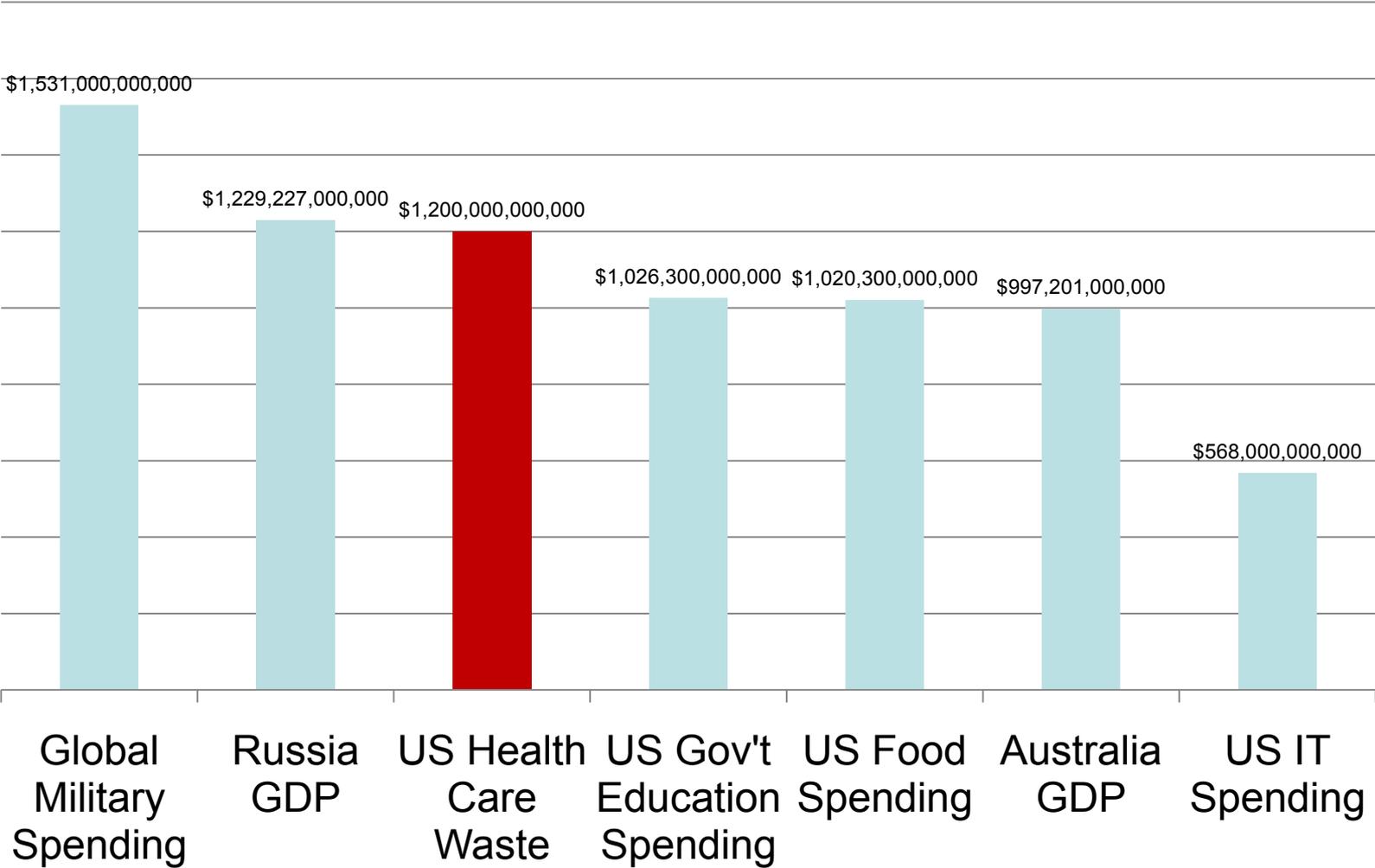
Health Care Consumes a Growing Share of the US Economy



- Health care is a \$2.4 trillion industry in the US
- \$1.2 trillion of this is preventable waste
- \$300 billion of this waste is in areas amenable to engineering-based improvement
 - *Medical mistakes*
 - *Defensive medicine*



US Health Care Waste in Context

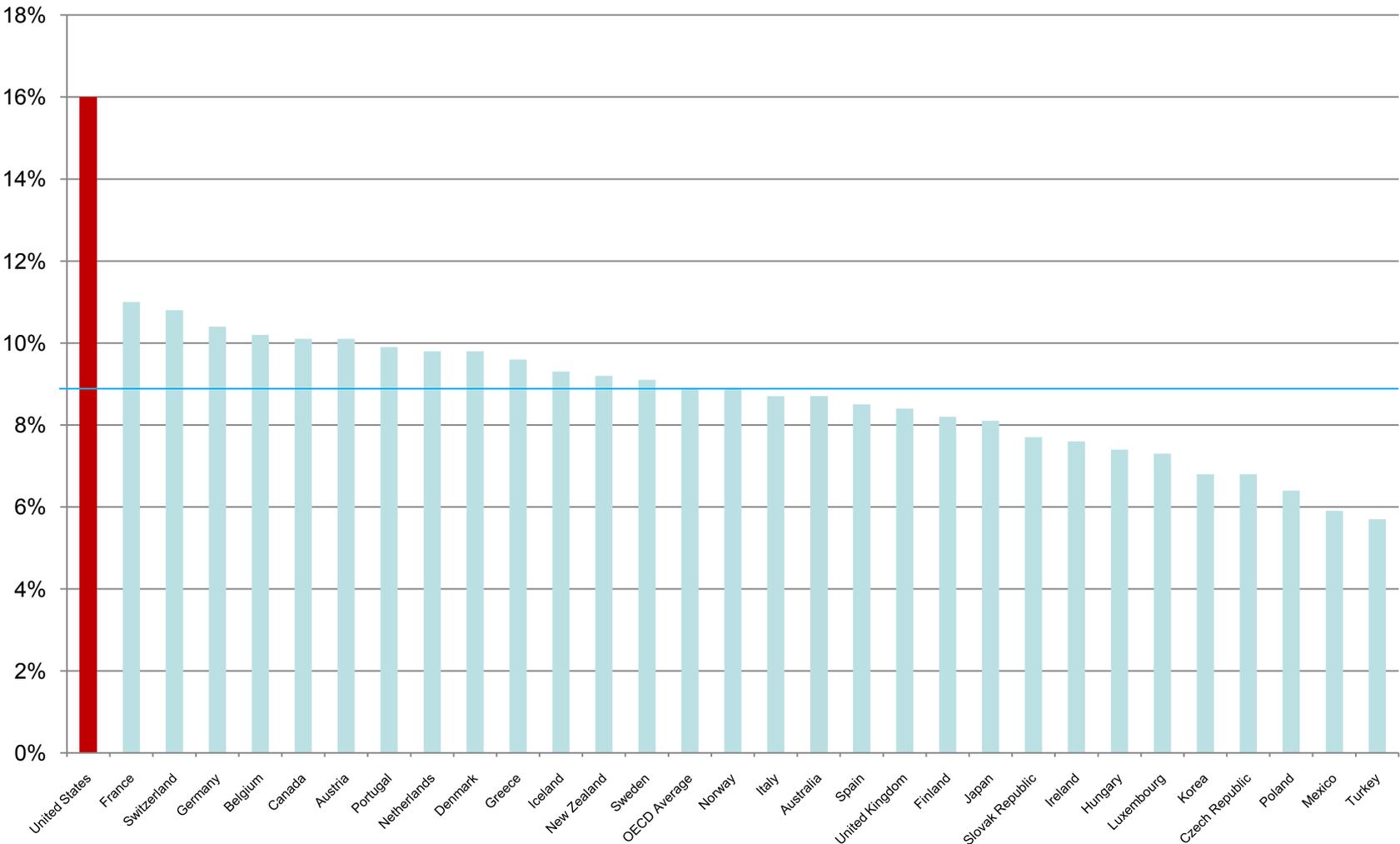


Sources: SIPRI, PricewaterhouseCoopers, USGovernmentSpending.com, USDA, IMF, Forrester Research

Health Care is an Economic Security Issue



Health Care Expenditures as a Share of GDP, 2007

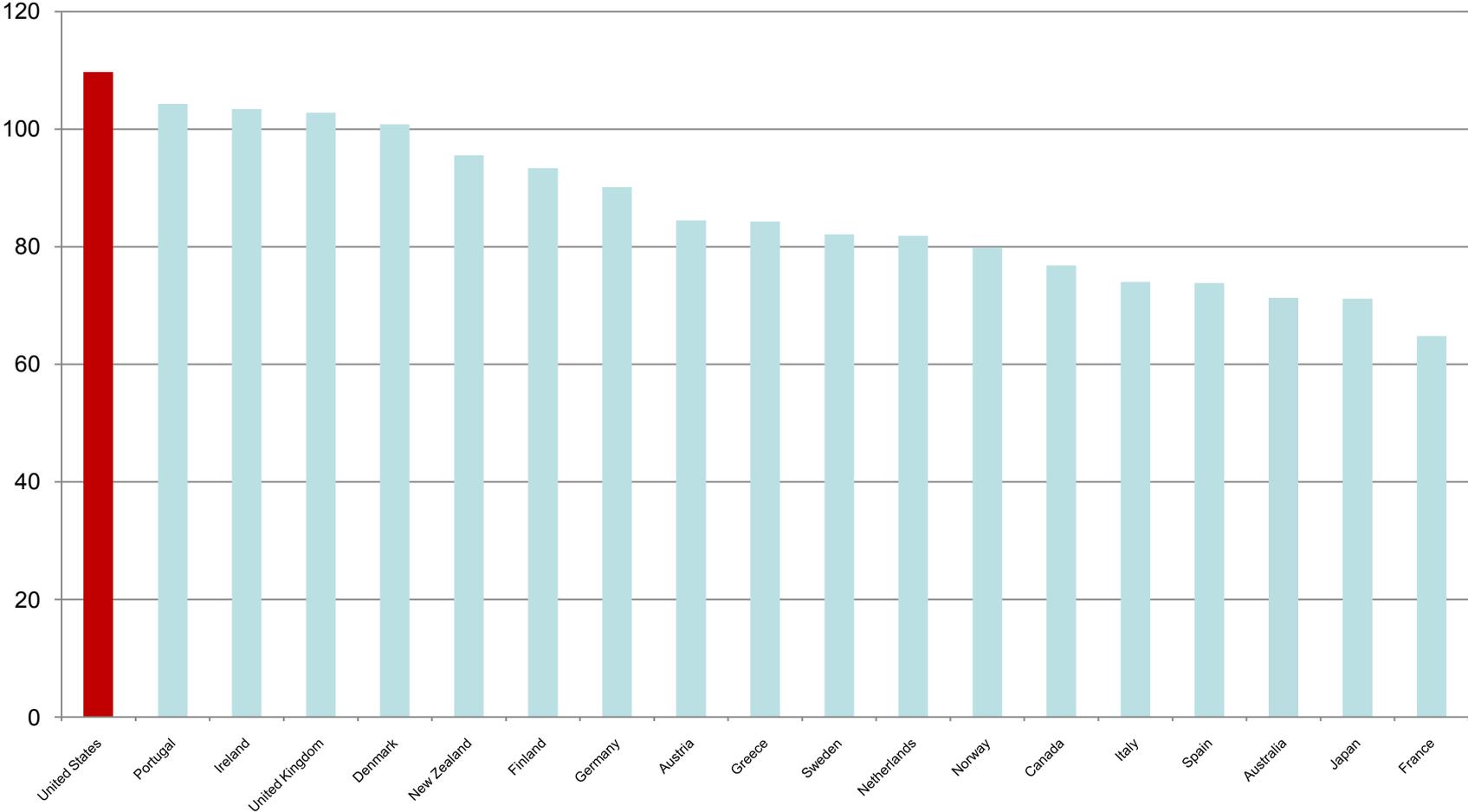


Source: OECD

Health Care is an Economic Security Issue



Mortality Amenable to Health Care, 2002-2003



Source: Nolty & McKee, "Measuring the Health of Nations," *Health Affairs*

Medical Mistakes Represent a Serious Problem



- Medical mistakes cause 40,000-200,000 deaths/year in the US
- If broken out separately, medical mistakes would be between the third and tenth leading cause of death

Cause	Deaths
Heart disease	631,636
Cancer	559,888
Medical mistakes (high estimate)	200,000
Stroke (cerebrovascular disease)	137,119
Chronic lower respiratory diseases	124,583
Accidents (unintentional injuries)	121,599
Diabetes	72,449
Alzheimer's disease	72,432
Influenza and Pneumonia	56,326
Nephritis, nephrotic syndrome, and nephrosis	45,344
Medical mistakes (low estimate)	44,000

Health Care Professionals Report Similar Core Issues



- How can health care organizations and clinicians...
- ...improve the safety of clinical care...
- ...and its efficiency...
- ...in an environment of rapidly growing demand...
- ...and relentless pressure to reduce costs?

- Health care reform in the US presents a new set of challenges to the system



Health Care Organizations Must Prevent “Never Events”



- **Never events are the 28+ inexcusable outcomes in health care**
- **Never events are non-reimbursable by insurers and government agencies**
- **Never events lead to:**
 - *Apologies*
 - *Event reporting*
 - *Root cause analyses*

1. Artificial insemination with the wrong donor sperm or donor egg
2. Unintended retention of a foreign object in a patient after surgery or other procedure
3. Patient death or serious disability associated with patient elopement (disappearance)
4. Patient death or serious disability associated with a medication error
5. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products
6. Patient death or serious disability associated with an electric shock or elective cardioversion while being cared for in a healthcare facility
7. Patient death or serious disability associated with a fall while being cared for in a healthcare facility
8. Surgery performed on the wrong body part
9. Surgery performed on the wrong patient
10. Wrong surgical procedure performed on a patient
11. Intraoperative or immediately post-operative death in an ASA Class I patient
12. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility
13. Patient death or serious disability associated with the use or function of a device in patient care, in which the device is used or functions other than as intended
14. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility
15. Infant discharged to the wrong person
16. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility
17. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility
18. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility
19. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates
20. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
21. Patient death or serious disability due to spinal manipulative therapy
22. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
23. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility
24. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility
25. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
26. Abduction of a patient of any age
27. Sexual assault on a patient within or on the grounds of the healthcare facility
28. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the healthcare facility

Certification and Non-Deterministic Systems



- **Regulatory and standard-setting agencies are increasingly concerned about the testing and certification of medical devices in non-deterministic systems**
- **These are systems-of-systems in which...**
- **...the complexity of individual devices...**
- **...multiplied by the complexity of their interconnections...**
- **...results in an environment in which the behavior of specific devices can no longer be reliably predicted**

Clinical Care Has Grown Incredibly Complex



- Modern hospitals are filled with complex, lifesaving technology
- Clinical care—especially critical care—is beyond the comprehension of any single clinician or clinical engineer
- This complexity continues to grow at a pace that is unsustainable in terms of clinical process management



SoS Engineering and Integration Is Atypical in Health Care

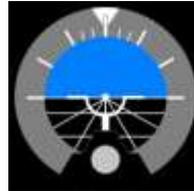


- **A system-of-systems (SoS) is:**
 - *“A collection of task-oriented or dedicated systems that pool their resources and capabilities together to obtain a new, more complex ‘meta-system’ that offers more functionality and performance than simply the sum of the constituent systems”*
- **SoS-based engineering and integration is atypical in health care**
- **Clinical systems are improved not via revolutionary approaches but rather via accretive processes**
- **This provides gradual improvement and a perceived incrementalist form of safety, but misses out on the significant gains available through clean-sheet redesign**

SoS Engineering and Integration Is Atypical in Health Care



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Health Care is Far Behind Aviation in the Use of Simulation



- Health care is as much as 40 years behind aviation in the use of simulation for:
 - *Design*
 - *Prototyping*
 - *Training*
 - *Analysis*
- There are two primary reason for this lag:
 - *Technological—simulating health care is vastly more difficult than simulating flight*
 - *Cultural—many clinicians are only now beginning to see continuous process improvement as an integral part of their jobs*

Medical Device Interoperability is Progressing but Still Early



- Efforts are underway to increase the interoperability of clinical systems
 - *Healthcare Enterprise International (IHE)*
 - *Integrated Clinical Environment (ICE)*
 - *Medical Device Free Interoperability Requirements for the Enterprise (MD FIRE)*
 - *Medical Device Plug-and-Play Interoperability Program (MD PnP)*
 - *Patient Care Device Domain (PCD)*
- However, these are still in their early stages and will take time to come to fruition



Simulations vs Simulators



- When health care professionals use the word *simulation*, they usually mean mannequins and related *simulator* equipment
- Software-based simulations of complex clinical processes are much less common
- There is no common platform for medical simulation that enables the rapid development of complex, realistic, clinical scenarios



Efficiency, Cost Reduction, and System-of-System Engineering



- How to reduce cost / improve efficiency in health care?
 - *Prevention efforts can be effective but typically take many years to bear results*
 - *Increased rationing has quicker results but is unacceptable to many stakeholders*

	Faster impact	Delayed impact
More desirable	Efficiency	Prevention
Less desirable	Rationing	Irrelevancy

- Experience in aviation and other fields demonstrates that system-of-system (SoS) engineering and integration can dramatically improve the efficiency and effectiveness of complex systems, including:
 - *Improvements to existing systems*
 - *New systems designed from scratch*

Simulation as a Way Forward



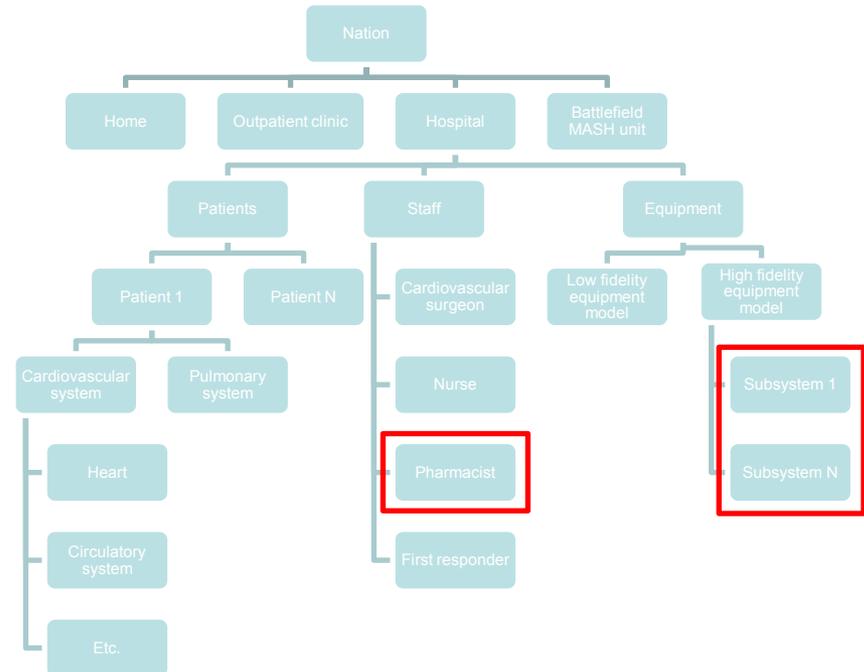
- Simulation offers a mechanism by which complex clinical environments can be modeled and experiments run within them
- Clinical environments include a variety of entities:
 - *Devices*
 - *Processes*
 - *Patients*
 - *Clinicians*
 - *Settings*



Simulating Clinical Care Requires Multiscale Models



- **Multiscale model-based design enables the creation of context-specific models at varying levels of fidelity**
- **Each model can be modified or replaced by another model**
 - *Improves the fidelity of the overall system*
- **Where possible, each model can be replaced by a real system**
 - *Refines and validates the simulation model*



Conclusions



- **Simulation-based system-of-systems (SoS) engineering and integration is a path forward to improving health care efficiency**
- **As with aviation, our goal for simulation-based tools for health care is to make analysis and training:**
 - *Fast*
 - *Safe*
 - *Measureable*
 - *Reproducible*
- **This will represent a significant step forward, given the lag in the adoption of software simulations for health care**
- **This holistic approach will pave the way for the next generation of health care tools:**
 - *Decision support*
 - *Medical devices*
 - *Training systems*