

RECOMMENDATIONS

Health and Medicine Division

JUNE 2016 • A NATIONAL TRAUMA CARE SYSTEM

RECOMMENDATION 1

The White House should set a national aim of achieving zero preventable deaths after injury and minimizing trauma-related disability.

RECOMMENDATION 2

The White House should lead the integration of military and civilian trauma care to establish a national trauma care system. This initiative would include assigning a locus of accountability and responsibility that would ensure the development of common best practices, data standards, research, and workflow across the continuum of trauma care.

To achieve the national aim (Recommendation 1), the White House should take responsibility for

- creating a national trauma system comprising all characteristics of a learning organization as described by the Institute of Medicine;
- convening federal agencies (including HHS, DOT, VA, DHS, and

DoD) and other governmental, academic, and private-sector stakeholders to agree on the aims, design, and governance of a national trauma care system capable of continuous learning and improvement;

- establishing accountability for the system;
- ensuring appropriate funding to develop and support the system;
- ensuring the development of a data-driven research agenda and its execution;
- ensuring the reduction of regulatory and legal barriers to system implementation and success;
- ensuring that the system is capable of responding domestically to any (intentional or unintentional) mass casualty incident; and
- strategically communicating the value of a national trauma care system.

RECOMMENDATION 3

The Secretary of Defense should ensure combatant commanders and the Defense Health Agency (DHA) Director are responsible and held accountable for the integrity and quality of the execution of the trauma care system in support of the aim of zero preventable deaths after injury and minimizing disability. To this end

- **The Secretary of Defense also should ensure the DHA Director has the responsibility and authority and is held accountable for defining the capabilities necessary to meet the requirements specified by the combatant commanders with regard to expert combat casualty care personnel and system support infrastructure.**
- **The Secretary of Defense should hold the Secretaries of the military departments accountable for fully supporting DHA in that mission.**
- **The Secretary of Defense should direct the DHA Director to expand and stabilize long-term support for the Joint Trauma System so its functionality can be improved and utilized across all combatant commands, giving actors in the system access to timely evidence, data, educational opportunities, research, and performance improvement activities.**

To meet the needs of the combatant commanders, the accountable DHA leader should sustain and fund elements of a learning trauma care system that are performing well within DoD, and better align efforts that today are fragmented or insufficiently supported. Steps to take to these ends include

- developing policies to support and foster effective engagement in the national learning trauma care system;
- integrating existing elements of a learning system into a national trauma care system;
- maintaining and monitoring trauma care readiness for combat and, when needed, for domestic response to mass casualty incidents;
- continuously surveying, adopting, improving and, as needed, creating novel best trauma care practices, and ensuring their consistent implementation across combatant commands;
- supporting systems-based and patient-centered trauma care research;
- ensuring integration across DoD and, where appropriate, with the VA, for joint approaches to trauma care and development of a unified learning trauma care system;
- arranging for the development of performance metrics for trauma care, including metrics for variation in care, patient engagement/satisfaction, preventable deaths, morbidity, and mortality; and
- demonstrating the effectiveness of the learning trauma care system by each year diffusing across the entire system one or two deeply evidence-based interventions (such as tourniquets) known to improve the quality of trauma care.

RECOMMENDATION 4

The Secretary of Health and Human Services (HHS) should designate and fully support a locus of responsibility and authority within HHS for leading a sustained effort to achieve the national aim of zero preventable deaths after injury and minimizing disability. This leadership role should include coordination with governmental (federal, state, and local), academic, and private-sector partners and should address care from the point of injury to rehabilitation and post-acute care.

The designated locus of responsibility and authority within HHS should be empowered and held accountable for

- convening a consortium of federal (including HHS, DOT, VA, DHS, and DoD) and other governmental, academic, and private-sector stakeholders, including trauma patient representatives (survivors and family members), to jointly define a framework for the recommended national trauma care system, including the designation of stakeholder roles and responsibilities, authorities, and accountabilities;
- developing a national approach to improving care for trauma patients, to include standards of care and competencies for pre-hospital and hospital-based care;

- ensuring that trauma care is included in health care delivery reform efforts;
- developing policies and incentives, defining and addressing gaps, resourcing solutions, and creating regulatory and information technology frameworks as necessary to support a national trauma care system of systems committed to continuous learning and improvement;
- developing and implementing guidelines for establishment of the appropriate number, level, and location of trauma care centers within a region based on the needs of the population;
- improving and maintaining trauma care readiness for any (intentional or unintentional) mass casualty incident, using associated readiness metrics;
- ensuring appropriate levels of systems-based and patient-centered trauma care research;
- developing trauma care outcome metrics, including metrics for variation in care, patient engagement/satisfaction, preventable deaths, morbidity, and mortality; and
- demonstrating the effectiveness of the learning trauma care system by each year diffusing across the entire system one or two deeply evidence-based interventions (such as tourniquets) known to improve the quality of trauma care.

RECOMMENDATION 5

The Secretary of Health and Human Services and the Secretary of Defense, together with their governmental, private, and academic partners, should work jointly to ensure that military and civilian trauma systems collect and share common data spanning the entire continuum of care. Within that integrated data network, measures related to prevention, mortality, disability, mental health, patient experience, and other intermediate and final clinical and cost outcomes should be made readily accessible and useful to all relevant providers and agencies.

To implement this recommendation, the following specific actions should be taken:

- Congress and the White House should hold DoD and the VA accountable for enabling the linking of patient data stored in their respective systems, providing a full longitudinal view of trauma care delivery and related outcomes for each patient.
- The Office of the National Coordinator for Health Information Technology should work to improve the integration of prehospital and in-hospital trauma care data into electronic health records for

all patient populations, including children.

- The American College of Surgeons, the National Highway Traffic Safety Administration, and the National Association of State EMS Officials should work jointly to enable patient-level linkages across the National EMS Information System project's National EMS Database and the National Trauma Data Bank.
- Existing trauma registries should develop mechanisms for incorporating long-term outcomes (e.g., patient-centered functional outcomes, mortality data at 1 year, cost data).
- Efforts should be made to link existing rehabilitation data maintained by such systems as the Uniform Data System for Medical Rehabilitation to trauma registry data.
- HHS, DoD, and their professional society partners should jointly engage the National Quality Forum in the development of measures of the overall quality of trauma care. These measures should include those that reflect process, structure, outcomes, access, and patient experience across the continuum of trauma care, from the point of injury, to emergency and in-patient care, to rehabilitation. These measures should be used in trauma quality improvement programs, including the American College of Surgeons Trauma Quality Improvement Program (TQIP).

RECOMMENDATION 6

To support the development, continuous refinement, and dissemination of best practices, the designated leaders of the recommended national trauma care system should establish processes for real-time access to patient-level data from across the continuum of care and just-in-time access to high-quality knowledge for trauma care teams and those who support them.

The following specific actions should be taken to implement this recommendation:

- DoD and HHS should prioritize the development and support of programs that provide health service support and trauma care teams with ready access to practical, expert knowledge (i.e., tacit knowledge) on best trauma care practices, benchmarking effective programs from within and outside of the medical field and applying multiple educational approaches and technologies (e.g., telemedicine).
- Military and civilian trauma management information systems should be designed, first and foremost, for the purpose of improving the real-time front-line delivery of care. These systems should follow the principles of bottom-up design, built around

key clinical processes and supporting actors at all levels through clinical transparency, performance tracking, and systematic improvement within a learning trauma care system. Therefore, the greater trauma community, with representation from all clinical and allied disciplines, as well as electronic medical record and trauma registry vendors, should, through a consensus process, lead the development of a bottom-up data system design around focused processes for trauma care.

- HHS and DoD should work jointly to ensure the development, review, curation, maintenance, and validation of evidence-based guidelines for prehospital, hospital, and rehabilitation trauma care through existing processes and professional organizations.
- Military and civilian trauma system leaders should employ a multipronged approach to ensure the adoption of guidelines and best practices by trauma care providers. This approach should encompass clinical decision support tools, performance improvement programs, mandatory pre-deployment training, and continuing education. Information from guidelines should be included in national certification testing at all levels (e.g., administrators, physicians, nurses, physician assistants, technicians, emergency medical services).

RECOMMENDATION 7

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 requiring a resourced, coordinated, joint approach to trauma care research across the U.S. Department of Defense, the U.S. Department of Health and Human Services (National Institutes of Health, Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, U.S. Food and Drug Administration, Patient-Centered Outcomes Research Institute), the U.S. Department of Transportation, the U.S. Department of Veterans Affairs, and others (academic institutions, professional societies, foundations).

This National Trauma Research Action Plan should build upon experience with the successful model of the NRAP and should

- direct the performance of a gap analysis in the military and civilian sectors that builds on previous analyses, looking at both treatment (clinical outcome studies) and systems research to identify gaps across the full continuum of care (prehospital and hospital-based care and rehabilitation) and considering needs specific to mass casualty incidents (e.g., natural disasters, terrorist attacks) and special patient populations (e.g., pediatric and geriatric patient populations);
- develop the appropriate requirements-driven and patient-centered research strategy and priorities for addressing the gaps with input from armed forces service members and civilian trauma patients;
- specify an integrated military–civilian strategy with short, intermediate and long-term steps for ensuring that appropriate military and civilian resources are directed toward efforts to fill the identified gaps (particularly during interwar periods), designating federal and industry stakeholder responsibilities and milestones for implementing this strategy; and
- promote military–civilian research partnerships to ensure that knowledge is transferred to and from the military and that lessons learned from combat can be refined during interwar periods.

RECOMMENDATION 8

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 (i.e., guidance documents).

In the process of implementing this recommendation, the following issues are points to consider:

- Prior national committees and legislative efforts have recommended that Congress, in instances of minimal-risk research where requiring informed consent would make the research impracticable, amend the U.S. Food and Drug Administration’s (FDA’s) authority so as to allow the FDA to develop criteria for waiver or modification of the requirement of informed consent for minimal-risk research. The present committee supports these recommendations, which would address current impediments to the conduct of certain types of minimal risk research in the trauma setting (e.g., diagnostic device results that would not be used to affect patient care).
- For nonexempt human subjects research that fall under either HHS or FDA human subjects protections as applicable, DoD should consider eliminating the need to also apply 10 U.S.C. 980, “Limitation on Use of Humans As Experimental Subjects” to the research.
- HHS’s Office for Civil Rights should consider providing guidance on the scope and applicability of the Health Insurance Portability and Accountability Act (HIPAA) with respect to trauma care and trauma research such that barriers to the use and disclosure (sharing) of protected health information across the spectrum of care (from the prehospital or field setting, to trauma centers and hospitals, to rehabilitation centers and long-term care facilities) will be minimized.
- The FDA, in consultation with DoD, should consider establishing an internal Military Use Panel, including clinicians with deployment experience and a patient representative(s) (i.e., one or more injured soldiers), that can serve as an interagency communication and collaboration mechanism to facilitate more timely fielding of urgently needed medical therapeutic and diagnostic products for trauma care.
- In trauma settings in which there are unproven or inadequate therapeutic alternatives for life-threatening injuries, the FDA should explore the appropriate scientific and ethical balance between premarket and postmarket data collection such that potentially life-saving products are made available more quickly (after sufficient testing). At the same time, the FDA should consider developing innovative methods for addressing data gaps in the postmarket setting that adhere to regulatory and statutory constraints.
- Consistent with its approach to applications for rare diseases, the FDA should consider exercising flexibility in evidentiary standards for effectiveness within the constraints of applicable law when a large body of clinical evidence (albeit uncontrolled) supports a new indication for an FDA-approved product for the diagnosis or treatment of traumatic injury, and pragmatic, scientific or ethical issues constrain the conduct of a randomized controlled trial (e.g., on the battlefield or in the prehospital setting).
- A learning trauma care system involves continuous learning through pragmatic methods (e.g., focused empiricism) and activities that have elements of both quality improvement and research. HHS, when considering revisions to the Common Rule, should consider whether the distinction it makes between quality improvement and research permits active use of these pragmatic methods within a continuous learning process. Whatever distinction is ultimately made by HHS, the committee believes that it needs to support a learning health system. Additionally, HHS, working with DoD, should consider providing detailed guidance for stakeholders on the distinctions between quality improvement and research, including discussion of appropriate governance and oversight specific to trauma care (e.g., the continuum of combat casualty care, and prehospital and mass casualty settings).

RECOMMENDATION 9

All military and civilian trauma systems should participate in a structured trauma quality improvement process.

The following steps should be taken to enable learning and improvement in trauma care within and across systems:

- The Secretary of HHS, the Secretary of Defense, and the Secretary of the VA, along with their private-sector and professional society partners, should apply appropriate incentives to ensure that all military and civilian trauma centers and VA hospitals participate

RECOMMENDATION 10

Congress, in consultation with the U.S. Department of Health and Human Services, should identify, evaluate, and implement mechanisms that ensure the inclusion of prehospital care (e.g., emergency medical services) as a seamless component of health care delivery rather than merely a transport mechanism.

Possible mechanisms that might be considered in this process include, but are not limited to:

- Amendment of the Social Security Act such that emergency medical services is identified as a provider type, enabling the establishment of conditions of participation and health and safety standards.

RECOMMENDATION 11

To ensure readiness and to save lives through the delivery of optimal combat casualty care, the Secretary of Defense should direct the development of career paths for trauma care (e.g., foster leadership development, create joint clinical and senior leadership positions, remove any relevant career barriers, and attract and retain a cadre of military trauma experts with financial incentives for trauma-relevant specialties). Furthermore, the Secretary of Defense should direct the Military Health System to pursue the development of integrated, permanent joint civilian and military trauma system training platforms to create and sustain an expert trauma workforce.

Specifically, within 1 year, the Secretary of Defense should direct the following actions:

- Ensure the verification of a subset of military treatment facilities (MTFs) by the American College of Surgeons as Level I, II, or III trauma centers where permanently assigned military medical personnel deliver trauma care and accumulate relevant administrative experience every day, achieving expert-level performance. The results of a needs assessment should inform the selection of these military treatment facilities, and these new centers should participate fully in the existing civilian trauma system and in the American College of Surgeons' TQIP and National Trauma Data Bank.
- Establish and direct permanent manpower allocations for the assignment of military trauma teams representing the full spectrum

in a risk-adjusted, evidence-based quality improvement program (e.g., ACS TQIP, Vizient).

- To address the full continuum of trauma care, the American College of Surgeons should expand TQIP to encompass measures from point-of-injury/prehospital care through long-term outcomes, for its adult as well as pediatric programs.
- The Center for Medicare & Medicaid Innovation should pilot, fund, and evaluate regional, system-level models of trauma care delivery from point of injury through rehabilitation.

- Modification of CMS's ambulance fee schedule to better link the quality of prehospital care to reimbursement and health care delivery reform efforts.
- Establishing responsibility, authority, and resources within HHS to ensure that prehospital care is an integral component of health care delivery, not merely a provider of patient transport. The existing Emergency Care Coordination Center could be leveraged as a locus of responsibility and authority (see Recommendation 4) but would need to be appropriately resourced and better positioned within an operational division of HHS to ensure alignment of trauma and emergency care with health delivery improvement and reform efforts.
- Supporting and appropriately resourcing an EMS needs assessment to determine the necessary EMS workforce size, location, competencies, training, and equipping needed for optimal prehospital medical care.

of providers of prehospital, hospital, and rehabilitation-based care to civilian trauma centers. Provision should be made for these teams to obtain experience in prehospital care, burn care, pediatric trauma, emergency general surgery, and other aspects of trauma care across the system.

- Identify the optimum placement of these teams based on criteria determined by the DHA including but not limited to volume, severity, diversity, and quality of care outcomes of trauma patients at the civilian trauma centers, as well as the required number of teams as determined by a comprehensive DoD assessment.
- Develop and sustain a research portfolio focused on optimizing mechanisms by which all (active duty, Reserve, and National Guard) military medical personnel acquire and sustain expert-level performance in combat casualty care, to include research on evolving training modalities and technologies (e.g., simulation, telemedicine).
- Hold the DHA accountable for standardizing the curricula, skill sets, and competencies for all physicians, nurses, and allied health professionals (e.g., medics, technicians, administrators). The development of these curricula, skill sets, and competencies should be informed by data from the DoD Trauma Registry and DoD-developed clinical practice guidelines (including tactical combat casualty care and JTS guidelines); best civilian trauma care practices, outcomes, and data; and professional organizations representing the full spectrum of the military trauma care workforce. The JTS should validate these curricula, skill sets, and competencies.

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