

Forum on Traumatic Brain Injury

Innovation Trends in Technologies for the Prevention, Treatment, and Management of Traumatic Brain Injury: A Workshop

April 15th, 2024 | 9:00am - 5:00pm EST | Hybrid

MEETING BOOK



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Innovation Trends in Technologies for the Prevention, Treatment, and Management of Traumatic Brain Injury: A Workshop

15 April 2024| 9:00 am - 5:00 pm ET

Keck Center, Room 100 500 Fifth Street, NW, Washington, DC 20001

Presentations and discussions aim to consider significant needs driving TBI innovation, areas of recent research and technical progress, potential near- and mid- term opportunities, and challenges for development and implementation. Selected examples used during the workshop are intended to help illustrate these concepts and do not represent endorsement of any company, technology, or product by the National Academies of Sciences, Engineering, and Medicine or the Forum on Traumatic Brain Injury.

SESSION 1: INTRODUCTION TO THE WORKSHOP

9:00-9:05AM (ET) Welcome and Introductory Remarks

CHRISTINA MASTER, Children's Hospital of Philadelphia, University of Pennsylvania, Workshop Chair

SESSION 2: IMPLEMENTATION

Objectives:

- Provide concrete examples of how patient-centric approaches are critical to the success of research implementation and clinical practice.
- Highlighting the role of patients as leaders, advisors, and partners across all stages of clinical research to ensure the success of its implementation.
- Offer considerations, based on community feedback, to improve the uptake of FDA-cleared diagnostic devices as it relates to issues in reimbursement, portability, and adequacy of the devices for military environments.

9:05-9:10AM Session Introduction

CYNTHIA GROSSMAN, Subject Matter Expert, Science of Patient Engagement and Real-World-Evidence, Moderator

9:10-9:25AM Blood-based Biomarkers for TBI - Conceptualization to Implementation, **Barriers to Widespread Adoption**

LINDA PAPA, Orlando Health

9:25-9:40AM Patient-Centered Research Design for Healthcare Innovation

SUZANNE SCHRANDT. ExPPect

9:40-9:55AM Considerations Regarding Why FDA Cleared Diagnostic Devices for TBI

are Underutilized in Military Environments

KATHY LEE, Warfighter Brain Health Initiative, U.S. Department of Defense

9:55-10:15AM Discussion between Presenters and Invited Panelists:

SHARI LING, U.S. Centers for Medicare & Medicaid Services (virtual)

LESLIE WISE, EvidenceMatters

10:15-10:45AM Discussion/Q&A with Audience

- What are potential approaches to expand the utilization of innovative tools and devices for the diagnosis, monitoring, and treatment of TBI?
- How can patients be better integrated along the entire process of innovation?

SESSION 3: PREVENTION

Objectives:

- Review prevention strategies across the leading causes of TBI (e.g., sports, motor vehicle collisions, and falls in the elderly).
- Identify leading innovations in low tech and high tech approaches to TBI prevention in different contexts.
- Discuss future opportunities for personalized approaches that mitigate injury.

10:45-10:50AM Session Introduction

KRISTY ARBOGAST, Children's Hospital of Philadelphia, Moderator

10:50-11:00AM A Lived Experience Perspective

WESLEY ILANA SCHNAPP, TBI Survivor, University of Arizona

11:00-11:15AM TBI Prevention Strategies in Professional American Football

JENNIFER LANGTON, National Football League

11:15-11:30AM How Automation and Customization will Affect Traumatic Brain Injury

Trends in Motor Vehicle Crashes

RICHARD KENT, University of Virginia

11:30-11:45AM Innovative Approaches to Fall Prevention

THURMON LOCKHART, Arizona State University

11:45-12:15PM Moderated Discussion Among Session Speakers and Audience Q&A

- What are some emerging scientific and technological innovations with the potential to transform TBI protection that you will be watching in the next few years?
- What are some best practices to spur cross-sectoral collaborations in the TBI prevention space that might enhance the transfer of research advances into industry and clinical practice?
- What are some of the main challenges you have faced in your work on TBI prevention and how are you navigating them?

12:15-1:20PM **LUNCH**

1:20-1:30PM HALFTIME TOUCHPOINT

CHRISTINA MASTER, Children's Hospital of Philadelphia, University of Pennsylvania, *Workshop Chair*

SESSION 4: CLINICAL DECISION SUPPORT, FROM DATA TO IMPACT

Objectives:

- Consider emerging approaches to leveraging large and complex datasets from the EHR, advanced imaging, and other digital sources of health data to inform clinical care.
- Explore trends in multimodal TBI classification to describe clinical phenotype and inform a treatment approach.

routhon approach.	
1:30-1:35PM	Session Introduction MICHELLE LAPLACA, Georgia Institute of Technology and Emory University, Moderator
1:35-1:45PM	A Lived Experience Perspective on TBI PATRICIA ADELL, Real Estate Solutions Group, TBI survivor
1:45-2:00PM	Statistical and Machine Learning Approaches to Prediction ADAM FERGUSON, University of California, San Francisco
2:00-2:15PM	Ultra-High Performance 3T MR in TBI KEVIN DEMARCO, Walter Reed National Military Medical Center
2:15-2:30PM	Multimodal Electrophysiological Biomarkers LESLIES PRICHEP BrainScope

- LESLIE S. PRICHEP, BrainScope
- 2:30-2:45PM Concussion Diagnostics with Eye-Tracking UZMA SAMADANI, Oculogica

2:45-3:25PM Moderated Discussion Among Session Speakers and Audience Q&A

- What are or will be key promoters or barriers to obtaining FDA clearance via the individual pathways for your innovation (neuroimaging, electrophysiology, de novo device pathway)?
- What are the potential applications of these innovations (singly and in conjunction with other data) in terms of diagnosis, prognosis, treatment?
- What is the pathway for reimbursement for these innovations?
- 3:25-3:45PM **BREAK**

SESSION 5: TREATMENT

Objectives:

- Describe recent advances in clinical trial designs that are enhancing the efficiency to evaluate therapeutics for heterogeneous medical conditions, such as TBI.
- Present evolving existent evidence base for pharmacological and non-pharmacological (e.g., neuromodulation) therapies in TBI, including ongoing clinical research, and future directions.

 Highlight challenges in translating academic research to therapeutic interventions, including regulatory and industry barriers.

3:45-3:50PM Session Introductions

RAMON DIAZ-ARRASTIA, University of Pennsylvania, *Moderator*

3:50-4:00 PM A Lived Experience Perspective on TBI

WES E. ELY, Caregiver to a family member with TBI, Vanderbilt School of

Medicine (virtual)

4:00-4:15PM Advances in Clinical Trial Design for TBI Interventions

ROGER LEWIS, University of California Los Angeles

4:15-4:30PM Panel: Pharmacological and Non-Pharmacological Treatment

Approaches

DANIEL LASKOWITZ, Duke University

MICHEL BAUDRY, Neuraegis

MAHEEN MAUSOOF ADAMSON, Stanford School of Medicine

JERRY STERN, Ischemix LLC (virtual)

WILLIAM HASKINS, Owl Therapeutics (virtual)

4:30-4:50PM Moderated Discussion Among Session Speakers and Audience Q&A

What are the most pressing challenges you have faced in your own work developing therapeutics for TBI and related disorders?

- How can regulatory guidelines by the FDA best support the development of efficacious new therapies for TBI?
- What are some opportunities for collaboration among therapeutic developers at academic research centers and pharmaceutical companies to advance their research and successful market entry?
- What are some of the promising emerging therapeutic approaches that you are excited about and will be paying attention to in the near future?

SESSION 6: LOOKING TO THE FUTURE

4:50-5:00PM Reflections and Adjournment

CHRISTINA MASTER, Children's Hospital of Philadelphia, University of

Pennsylvania; Workshop Chair

5:00-7:00PM INFORMAL RECEPTION

Keck Center Atrium (Take elevators to third floor)

Workshop Statement of Task

A planning committee of the National Academies of Sciences, Engineering, and Medicine will organize and conduct a one-day public workshop to explore the innovation pipeline for new technologies addressing traumatic brain injury (TBI) prevention, treatment, and management. Invited presentations and discussions may be designed to:

- Discuss how major unmet needs in TBI prevention, treatment, and management may be addressable through technological innovation, with consideration to patient, family, and provider priorities,
- Consider how ongoing scientific and technical advances are leading to promising innovation opportunities for some aspects of TBI prevention, treatment, and management, while others remain underdeveloped,
- Consider how implementation needs should be incorporated into the research and development process, and
- Identify critical knowledge gaps where technology is needed to transform care, particularly with regard to assessing whether, when, and how prevention, treatment, and management approaches improve outcomes over time, and for which patients.

The planning committee will organize the workshop, develop the agenda, select and invite speakers and discussants, and moderate or identify moderators for the discussions. A factual proceedings of the presentations and discussions at the workshop will be prepared by a designated rapporteur in accordance with institutional guidelines.

Planning Committee Roster

Note: The planning committee's role is limited to organizing the event. A proceedings based on the event will be prepared by an independent rapporteur.

Christina Master, MD (Chair)

Professor of Clinical Pediatrics, Children's Hospital of Philadelphia and University of Pennsylvania

Kristy Arbogast, PhD

Scientific Director, Center for Injury Research and Prevention, R. Anderson Pew Distinguished Chair, Department of Pediatrics, Children's Hospital of Philadelphia and University of Pennsylvania

Ramon Diaz-Arrastia, MD, PhD

Director of Clinical TBI Research, University of Pennsylvania Perelman School of Medicine

Adam Ferguson, PhD

Director of Data Science; Professor, Department of Neurological Surgery University of California San Francisco, Zuckerberg San Francisco General Hospital, and San Francisco VA Health Care System

Cynthia Grossman, PhD

Subject matter expert in health data, digital health, behavioral science, patient centricity, and real-world evidence

Frederick Korley, MD, PhD

Associate Professor of Emergency Medicine, University of Michigan Medical School

Michelle LaPlaca, PhD

Director, Neurotrauma and Translational Bioengineering Laboratory, Professor of Biomedical Engineering, Georgia Institute of Technology and Emory University

Christopher Loftus, MD

Chief Medical Officer,
Division of Neurological and
Physical Medicine Devices
U.S. Food and Drug
Administration

Geoffrey Shiu Fei Ling, MD

Professor of Neurology and Attending Physician in Neurocritical Care Johns Hopkins Medical Institution

Luca Marinelli, PhD

Senior Principal Scientist, Biology and Applied Physics GE Healthcare, Technology and Innovation Center

Leslie Prichep, PhD

Chief Scientific Officer BrainScope Company, Inc

Capt. Travis Polk, MD

Director, Combat Casualty Care Research Program U.S. Department of Defense

Biosketches of Speakers



Maheen Mausoof Adamson

Maheen Mausoof Adamson, PhD, is a Clinical Professor of Neurosurgery (Affiliated) at Stanford School of Medicine, Director of Research for Women's Operational Military Exposure Network Center of Excellence (WOMENCOE), and Senior Scientist for Rehabilitation Services at VA Palo Alto Healthcare System. Dr. Adamson's expertise and interests span employing translational neuroscience methodologies for diagnostic and neuromodulation treatments (such as repetitive Transcranial Magnetic Stimulation (rTMS)) for frequent health problems in patients with Traumatic Brain Injury (TBI), psychiatric problems, and Alzheimer's disease. Adamson completed her undergraduate degrees in neurobiology and women's studies at the University of California, Irvine. She completed her Ph.D. in neuroscience from the University of Southern California and a postdoctoral fellowship in Psychiatry and Behavioral Sciences at Stanford School of Medicine. She also has a Masters in Healthcare Leadership from the School of Public Health from Brown University and is a faculty fellow for Stanford Byers Biodesign Program.



Patricia Adell

Patricia Adell (Patty) is Managing Partner at Real Estate Solutions Group, a company that provides real estate and finance advisory services to developers, non-profits and the public sector. Patty has recovered from multiple traumatic brain injuries resulting from a trip and fall on a sidewalk caused by multi-tasking while walking. She received care services to support her recovery at a local hospital initially and then at Children's Hospital in Philadelphia with Dr. Master. The interventions included physical therapy. These experiences equip her with firsthand insights into the landscape of TBI care, and motivate her advocacy for integrated and patient-centered healthcare solutions. She is particularly passionate the importance of physical therapy and not the traditional approach advised by her primary doctor to "sit in the dark and wait for it to get better" when it comes to developing innovations for people living with and recovering from TBI.



Jeffrey Bazarian

Jeffrey Bazarian, PhD, is a tenured Professor of Emergency Medicine and Neurology at the University of Rochester. His research uses advanced brain imaging, helmet sensors and blood sampling to investigate the effects of concussion and repetitive head hits on the brain. Dr. Bazarian was the lead author on the 2018 Lancet Neurology publication detailing the results of the multi-national study that was used to support FDA approval for the first blood-based biomarkers of traumatic brain injury in the US. He currently sees concussion patients at the University of Rochester Medical Center's Child Neurology Clinic. He is a graduate of Brown University and the University of Rochester School of Medicine and Dentistry.



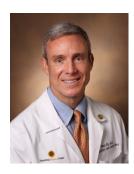
Michel Baudry

Michel Baudry, PhD, is a Professor of Biomedical Sciences and the Dean of Graduate in the Graduate College of Biomedical Sciences at Western University of Health Sciences in Pomona, CA. His Previously, he was a Professor of Biological Sciences, Neurology and Biomedical Engineering at the University of Southern California, Dr. Baudry has also been involved in several biopharmaceutical start-up companies. In 1986 he was one of the co-founders of Synaptics, Inc, the Human Interface company. In 1991, he co-founded Eukarion, Inc., and more recently participated in the transformation of Eukarion into MindSet, Rx. In 2007, he also cofounded Rhenovia Pharma, a drug discovery & development company located in Mulhouse, France. In February 2016, in collaboration with several faculty members at WesternU and entrepreneurs, he started NeurAegis, a neuroscience company directed at developing neuroprotective drugs for the treatment of a variety of neurodegenerative diseases. For achievements in neuroscience, Dr. Baudry was inducted as a Fellow of the American Association of the Advancement of Science (AAAS) in 2021. His research interests include elucidating the neuropathological processes accompanying brain injury.



J. Kevin DeMarco

J. Kevin DeMarco, MD, is a neuroradiologist with the Walter Reed National Military Medical Center. He received his medical degree from Saint Louis University School of Medicine and has been in practice for more than 20 years. He has also served in the Armed Forces, first as a General Medical Officer aboard the USS Kansas City and later, as director of MR at the Navy's flagship west coast hospital in San Diego. In San Diego, Dr. DeMarco published the first article demonstrating excellent correlation of MRA and DSA in depicting carotid stenosis using improved post processing techniques. Since moving to Walter Reed, he continues a 20+ year collaboration with GE towards exciting new developments in ultra-high performance neuroimaging.



Wes E. Ely

Wesley Ely, MD, MPH, is an internist, pulmonologist, and critical care physician. Dr. Ely earned his MD at Tulane University School of Medicine, in conjunction with a Masters in Public Health. He serves as the Grant W. Liddle endowed chair in medicine and is a physician-scientist and tenured professor at Vanderbilt University Medical Center. He is also the associate director of aging research for the Tennessee Valley Veteran's Affairs Geriatric Research Education Clinical Center (GRECC). He is the founder and codirector of the Critical Illness, Brain Dysfunction, and Survivorship (CIBS) Center, and a pioneer in the investigation of delirium and long-term cognitive outcomes, including dementia, in survivors of critical illness. Dr. Ely has had numerous studies published in The New England Journal, JAMA, and The Lancet, and his writing has appeared in The Wall Street Journal, The Washington Post, USA TODAY, State News, The Daily Beast, and numerous other publications. Dr. Ely is the author of Every Deep-Drawn Breath, from which he's donating 100% net proceeds to help COVID survivors and family members rebuild their lives. He can be found @WesElyMD.



William Haskins

William Haskins, PhD, is CEO and Co-founder of Owl Therapeutics. He previously led teams for R&D of gene therapies, therapeutic antibody, and antibody-drug conjugates from Research through Phase I/II/III clinical trials for small and large biotechnology companies, including Genentech. Dr. Haskins is well-respected for developing and applying out-of-the-box solutions to challenging problems. He is highly experienced with analytical and bioanalytical chemistry, proteomics, bioinformatics, CNS biomarkers, and large molecule drug development (OCREVUS®, KADCYLA®, POLIVY®, etc.). He has authored or co-authored more than 73 peer-reviewed publications and numerous patents, and he is the Principal Investigator for several federal grant awards. Lastly, Dr. Haskins completed postdoctoral fellowships at the McKnight Brain Institute and Lawrence Livermore National Laboratories after earning his PhD in Bioanalytical Chemistry from the University of Florida in 2003.



Richard Kent

Richard Kent, PhD, is the Frederick Tracy Morse Professor of Mechanical and Aerospace Engineering, Biomedical Engineering, and Orthopaedic Surgery at the University of Virginia and the chair of the Mechanical and Aerospace Engineering department at UVA. Dr. Kent co-founded the UVA Center for Applied Biomechanics, a joint venture of the UVA Schools of Engineering and Medicine, which conducts injury biomechanics research to support traffic safety policies and the design of vehicle safety systems. A Fellow of the Society of Automotive Engineers and the Association for the Advancement of Automotive Medicine, Dr. Kent has written over 200 articles on topics related to injury prevention, including the reduction of traumatic brain injury risk in automobile crashes.



Jennifer Langton

Jennifer Langton serves as Senior Vice President of Player Health and Innovation for the National Football League, managing the NFL's Innovation and Engineering portfolio. Harnessing technology, analytics, and insights, she and her team are creating breakthroughs that support the health and safety of NFL players and the game, with the goal of ultimately delivering impact well beyond sports. These efforts involve data-driven initiatives, that are harnessing Al and other emerging technologies, to help the NFL to better predict and prevent injuries, reduce head impacts, improve protective equipment, and more. Before joining the NFL, Langton served as the Chief Financial Officer, North America, of Atari, the interactive entertainment company.



Daniel Laskowitz

Daniel Laskowitz, PhD, is Professor of Neurology, Assistant Dean for Scholarly Education, Director of the Clinical Research Institute, and Vice Chair for Academic Affairs in the Department of Neurology at Duke University. His research interests include developing new therapies that address unmet clinical need in acute brain injuries (such as traumatic brain injury, stroke, and intracranial hemorrhage) as well as chronic neurodegenerative diseases such as Alzheimer's and Parkinson's disease. The motivation for this research efforts stems from my more than 25 years of personal experience caring for patients with stroke, trauma, intracranial hemorrhage, and neurological disease. The laboratory uses molecular biology, cell culture, and animal modeling techniques to examine the CNS response to acute injury.



Kathy Lee

Kathy Lee, MS, CRNP, ANP-BC, CNRN, currently serves as the Director of Casualty Management Policy & Programs and is the lead for the US DoD Warfighter Brain Health program supporting the Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight. She brings considerable clinical, educational and research experience in the field of neuroscience and neurotrauma to include more than 200 regional, national and international presentations and more than 30 peerreviewed publications. Ms. Lee has served in a variety of leadership, advisory and operational roles in the US Department of the Army and US Department of Defense for over 15 years; including the Assistant Chief of the Defense and Veterans Brain Injury Center (DVBIC). Deputy Director for the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury; Deputy Director for the Clinical and Educational Affairs Office for DVBIC and the manager of the Office of Clinical Standards at DVBIC. Prior to working in Washington DC, Ms Lee worked in 2 academic/level I trauma centers as a nurse practitioner/clinical care coordinator at the University of Louisville Hospital; and clinical research coordinator in the Division of Neurosurgery at the Medical College of Virginia Hospitals/Virginia Commonwealth University. Ms. Lee holds both Bachelor's and Master's degrees in nursing from Virginia Commonwealth University, as well as a Bachelor of Science in family and child development from Virginia Tech University.



Roger Lewis

Roger Lewis, MD, is a Senior Physician in the Los Angeles County Department of Health Services, Professor of Emergency Medicine at the David Geffen School of Medicine at UCLA, and a Senior Medical Scientist at Berry Consultants, LLC, a group that specializes in innovative clinical trial design. Dr. Lewis is also the senior statistical editor for JAMA and editor of the JAMA series entitled "JAMA Guides to Statistics and Methods." His expertise centers on adaptive and Bayesian clinical trials, including platform trials; general clinical research methodology; data and safety monitoring boards, and the oversight of clinical trials. Dr. Lewis was elected to membership in the National Academy of Medicine in 2009. He is a fellow of the American College of Emergency Physicians, the American Statistical Association, and the Society for Clinical Trials. Dr. Lewis received his PhD in Biophysics and his MD from Stanford University.



Shari Ling

Shari M. Ling, MD, is the Centers for Medicare and Medicaid Services (CMS), Deputy Chief Medical Officer serving in the Center for Clinical Standards and Quality (CCSQ), responsible for assisting the CMS Chief Medical Officer in the Agency's pursuit of higher quality health care, healthier populations, and lower cost through quality improvement. Dr. Ling's long-standing focus is on the achievement of meaningful health outcomes through delivery of high quality beneficiary-centered care across all care settings, with a special interest in the care of persons with multiple chronic conditions and functional limitations, and reducing health disparities.Dr. Ling has served as the lead coordinator and facilitator of the CCSQ Measures Forum. Dr. Ling represents CMS on the Health and Human Services (HHS) Multiple Chronic Conditions workgroup, and the National Quality Forum Measures Application Partnership Post-acute Care/Long-term Care workgroup, and chairs the Measures and Data sources sub-workgroup for the HHS Action Plan for Healthcare Associated Infection (HAI) Prevention in Long-term Care facilities. Dr. Ling also serves as the clinical sub-group lead for the HHS National Alzheimer's Project Act. Dr. Ling is a Geriatrician and Rheumatologist who received her medical training at Georgetown University School of Medicine where she graduated as a member of the Alpha Omega Alpha Honor Society. Dr. Ling received her clinical training in Internal Medicine and Rheumatology at Georgetown University Medical Center, and completing Geriatric Medicine studies at Johns Hopkins University.



Thurmon Lockhart

Thurmon Lockhart, PhD. is the Inaugural MORE Foundation Professor of Life in Motion Professor in the Biomedical Engineering program in the School of Biological Health and Systems Engineering at Arizona State University. Dr. Lockhart's research interests include the identification of injury mechanisms and quantification of sensorimotor deficits and movement disorders associated with aging and neurological disorders on fall accidents. As PI or co-Investigator on several NIH, NSF and DOD grants, Dr. Lockhart led groundbreaking work towards developing effective measures of instability, frailty, stress and fatigue associated with aging, obesity, osteoporosis, and Parkinson's Disease using wearable sensors and computational nonlinear dynamics. Current research directions include - collection of real-time physiological data about an individual's health behaviors (e.g., fall risk, fatigue, frailty etc.) and performances (e.g. wearable systems -heart rate variability using PPG and gait stability using Graphene sensors as well as EMG, FMG, and ECG etc.). For recognition of excellence in research, Lockhart and co-workers were awarded the Alexander C. Williams, Jr., Design Award from the Human Factors and Ergonomics Society in 2008.



Linda Papa

Linda Papa, MD, MSc. is an Emergency Medicine Physician and Director of Academic Clinical Research for the Orlando Health Orlando Regional Medical Center level one trauma center. She is a Professor of Emergency Medicine at the University of Central Florida, an Associated Professor of Medicine at Florida State University, an Adjunct Professor of Emergency Medicine at the University of Florida, as well as an Adjunct Professor of Neurology and Neurosurgery at McGill University. Dr. Papa holds a Masters' Degree in Clinical Epidemiology and Community Medicine and has worked closely with various groups and agencies across the country to improve outcomes and advocate for patients with trauma and traumatic brain injury. She was part of a task force in Florida that helped to pass Florida's Youth Athlete Concussion bill (HB-291) that provides concussion guidelines to ensure young athletes are adequately evaluated during sports. She is the recipient of several National Institutes of Health and Department of Defense grants to improve the care of patients with traumatic brain iniury. Most notable, was her involvement in the discovery and validation of the very first FDA-approved blood test for traumatic brain injury (GFAP and UCH-L1), a journey which began over 20 years ago with a pilot study she designed and conducted in the emergency department on a shoestring budget. This study led to the first publication demonstrating the accuracy of GFAP in detecting intracranial lesions after a mild traumatic brain injury in 2008. As traumatic brain injury biomarker point-of-care devices are entering the market for clinical use, Dr. Papa is actively involved in evaluating their impact on clinical practice, further defining their journey from bench to bedside.



Uzma Samadani

Uzma Samadani, MD, PhD, FACS, FAANS is a neurosurgeon and neurotrauma researcher in Minneapolis, MN. She is an Adjunct Associate Professor in the Department of Bioinformatics and Computational Biology at the University of Minnesota with a graduate faculty appointment in Neuroscience. She is also an attending neurosurgeon at the Minneapolis Veterans Administration Medical Center and founder of the neurodiagnostic start-up Oculogica Inc, which has developed the first baseline free concussion diagnostic cleared for marketing approval by the FDA. She is on the Executive Committee of the American Association of Neurological Surgeons/Congress of Neurological Surgeons Joint Section on Neurotrauma and Critical Care and served as Scientific Program Chair for their meeting in conjunction with the National Neurotrauma Society from 2014-7. She has received more than six million dollars in research grants from national and international competitive funding agencies to study diagnostics, risks, outcomes and treatments for brain and spinal cord injury. She is a fellow of the American College of Surgeons and American Association of Neurological Surgeons. She has published more than 80 peer-reviewed scientific papers and an additional 30 reviews and chapters including in the Journal of Neurotrauma, JAMA Neurology, Journal of Neurosurgery and the New England Journal of Medicine. Dr. Samadani also served as an unaffiliated neurotrauma consultant to the National Football League from 2015 to 2018.



Wesley Ilana Schnapp

Wesley Schnapp is a Christine Mirzayan Science & Technology Policy Fellow at the National Academies, working with the Forum on Neuroscience and Nervous System Disorders. Wesley's journey into neuroscience was catalyzed by a transformative experience during her high school years—a severe traumatic brain injury (TBI) from an alpine ski racing accident. Emerging from a coma and facing a long, challenging path to full recovery. Wesley's personal encounter ignited a deep-seated passion for understanding the complexities of the brain. This drive led her to pursue a Neurobiology degree with a Psychology minor at Cornell University. She is now finishing up her PhD in the University of Arizona's Neuroscience Graduate Interdisciplinary Program, researching how neural circuits in the amygdala regulate eating behavior and energy balance and, more specifically, their role in development of the eating disorder, anorexia nervosa. Alongside her academic pursuits, Wesley is committed to bridging the gap between scientific inquiry, societal impact, and public engagement through science communication and outreach. Recently, she has been working with a local non-profit in AZ to develop and utilize a curriculum for primary through high school students that introduces neuroscience to foster an understanding of brain function, emotional behavior, and social interactions while promoting brain health awareness. Wesley is also passionate about being active and spending time outdoors. In her leisure moments, she finds joy in mountain biking, trail running, skiing, caring for her houseplants, culinary exploration, and sharing homemade treats with friends.



Suzanne Schrandt

Suzanne Schrandt, JD, is a patient advocate and patient engagement expert with a health and disability policy background. She is the Founder and CEO of ExPPect, a patient engagement initiative focused on improving healthcare and research through the expertise and partnership of skilled patient partners. Ms. Schrandt previously served as Director of Patient Engagement at the Arthritis Foundation, and as Deputy Director of Patient Engagement for PCORI. Her career spans work in health reform, bioethics, genetic discrimination, and chronic disease self-management, as well as a long history in patient-led health professions education. Schrandt is one of nine voting members on the FDA's inaugural Patient Engagement Advisory Committee, the Chairperson for the International Society of Pharmacoeconomics and Outcomes Research Global Patient Council, and has been an invited speaker at numerous US and international conferences.Ms. Schrandt received her law degree from the University of Kansas and has co-authored multiple peer-reviewed articles on health policy and the value of patient engagement.

Jerry Stern

Jerry O. Stern, MD, joined Ischemix on January 1, 2022 as Chief Medical Officer. Previously, he served as Corporate Vice President and Global Therapeutic Area (TA) Head Medicine at Boehringer Ingelheim Pharmaceuticals for more than 15 years. As a TA Head, he was responsible for the development strategy and implementation of all clinical development projects within the therapeutic area. He has a strong track record of success leading international teams from early concepts through preclinical and clinical phases (1-4) of development which culminated in numerous INDs, NDAs and MAA's. He received his M.D. from the Albert Einstein College of Medicine in New York

where he spent an additional 4 years in laboratory research in pharmacology and biochemistry. He received his medical training and board certifications at New York University Medical Center/Bellevue Hospital, NY, NY where he was a member of the academic faculty for more than twenty years before joining the Pharmaceutical R&D sector.



Leslie Wise

Leslie Wise, JD, is CEO of EvidenceMatters, a Global Market Access consulting firm. Before starting EvidenceMatters, Leslie worked for Bristol Myers-Squib, Sanofi, Biomet Orthopedics and AngioDynamics, where she her reimbursement, value evidence generation, clinical research strategy and frontline regulatory and payer experience substantially added to the bottom-line. The experience gained working in the Pharma, MedTech and Payers verticals honed her into a strategic and sought after gamechanger in the healthcare commercialization space. With more than 20 years of experience across multiple verticals, Leslie uses this knowledge and global experience to support market access efforts for both early stage and established medical technology companies. Leslie advises her clients on defining their market access strategy which includes development of their value platform, evidence planning, publishing strategy, product launch planning, communication tools, payer management and the integration of regulatory and reimbursement strategy.

Biosketches of Moderators and Planning Committee Members

Christina Master, MDPlanning Committee Chair



Christina Master, MD, is a Professor of Clinical Pediatrics at the University of Pennsylvania Perelman School of Medicine. Dr. Master is also a pediatric and adolescent primary care sports medicine specialist and an academic general pediatrician at the Children's Hospital of Philadelphia (CHOP). Additionally, she is the co-founding director of the Minds Matter Concussion Program, a CHOP Frontier Program which provides comprehensive cutting-edge and multidisciplinary clinical care and rehabilitation for concussion, community advocacy and outreach. The Minds Matter Concussion Program also advances the field of concussion and mild traumatic brain injury in children, youth and young adults through translational clinical research. Her research focuses on visual deficits following concussion, its role in persistent post-concussive symptoms, its potential as a target for active intervention and treatment, and its usefulness as

an objective physiological measure serving as a quantitative biomarker of injury and recovery. She is board-certified in Pediatrics, Sports Medicine, and Brain Injury Medicine, and is also an elected fellow of the American College of Sports Medicine. She treats over 800 children, youth and young adults with concussion annually in her clinical sports medicine practice while also continuing in her 28th year of general academic pediatric practice. She completed her undergraduate studies at Princeton University with an A.B. in Molecular Biology and graduated summa cum laude from the University at Buffalo School of Medicine and Biomedical Sciences. She completed pediatric residency training with an additional year as chief resident at CHOP. Subsequently, she completed a Sports Medicine fellowship at the Hospital of the University of Pennsylvania and went on to serve for 14 years as the Associate and Vice Program Director for the Pediatric Residency Program.

Kristy Arbogast, PhD



Kristy Arbogast, PhD, is the scientific director for the Center for Injury Research and Prevention and the R. Anderson Pew Distinguished Chair of Pediatrics at Children's Hospital of Philadelphia. She is also a professor of Pediatrics at the University of Pennsylvania. Dr. Arbogast's research interests are pediatric injury biomechanics, injury causation and the effectiveness of safety products for children with a concentration in pediatric concussion and brain health, as well as the safety of children and youth in motor vehicle crashes. Dr. Arbogast served on the Institute of Medicine Committee on Sports Concussion in Youth and co-leads Children's Hospital's clinical research effort in concussions with a focus on the use of head impact sensors to understand the biomechanics, utilizing bioengineering technology for objective measures of concussion diagnosis and leveraging the electronic health record to define the

natural history of concussions in children. She also co-leads an initiative for the National Football League and NFL Players Association to design and implement head impact sensors to understand the loading conditions in professional football with the goal of enhancing head protection through improvements in protective equipment. Dr. Arbogast earned their doctorate in Bioengineering at the University of Pennsylvania in 1997.

Ramon Diaz-Arrastia, MD, PhD



Ramon Diaz-Arrastia, MD, PhD, is a Professor of Neurology at the University of Pennsylvania, where he leads the TBI Clinical Research Initiative. His research interests are focused on understanding the molecular, cellular, and tissue- level mechanisms of neuronal injury and neuroregeneration, with the goal of developing neuroprotective and neuroregenerative therapies. Prior to coming to UPenn, he served as faculty at the University of Texas Southwestern, the Uniformed Services University of the Health Sciences, and the National Institute of Neurologic Disorders and Stroke (NINDS). Dr. Diaz-Arrastia has published over 250

primary research papers, as well as over 40 invited reviews and book chapters. He serves as a scientific advisory board member or scientific advisor for various health technology companies, including BrainBox Solutions, NovaSignal, NeurAegis, MesoScale Discoveries, and Ischemix, Inc. He has also served on several national committees related to traumatic brain injury, epilepsy, and dementia, convened by the National Institutes of Health, the Department of Defense, the Veterans Administration, and the National Academy of Medicine. Dr. Diaz-Arrastia received his MD and PhD from Baylor College of Medicine and completed post-graduate training at Harvard and Columbia.

Adam Ferguson, PhD



Adam Ferguson, MS, PhD, is a Professor of Neurosurgery at the University of California San Francisco, Director of Data Science in the Brain and Spinal Injury Center (BASIC) at the Zuckerberg San Francisco General Hospital, and Principal Investigator in the San Francisco VA Healthcare System. Their research interests are mechanistic neuroscience in model organisms to large-scale clinical data science and precision medicine research for TBI and SCI. Dr. Ferguson directs a diverse team of researchers performing a hybrid of bench neuroscience in the laboratory and translational data science, supported by grants from the NIH, VA, DARPA, and nonprofits. He has published over 200+ peer-reviewed scientific papers focusing on neuroscience and the role of big-data analytics for accelerating scientific

discovery and healthcare decision-support. Dr. Ferguson serves as the President of the National Neurotrauma Society. Dr. Ferguson has also served as the founding Principal Investigator and co-director of the International Open Data Commons for Spinal Cord Injury and traumatic brain injury. Dr. Ferguson earned their doctorate degree in Psychology (Behavioral and Cellular Neuroscience) at Texas A&M University and completed a post-doctoral fellowship in Cellular and Molecular Neuroscience at the Ohio State University College of Medicine.

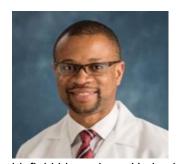
Cynthia Grossman, PhD



Cynthia (Cyndi) Grossman, PhD, is the former Head of Real-world Research Networks at Biogen Digital Health. Dr. Grossman has spent her career applying her social and behavioral science expertise transforming research programs to better address unmet health needs of patients and communities. She is an experienced leader across industry, government, non-profit and academia and is passionate about advancing better health outcomes for all through data and bringing the lived experience of patients into decision-making. Prior to Biogen, Dr. Grossman was Director Science of Patient Input at with the Milken Institute's FasterCures initiative. Earlier in her career, she directed funding for HIV-related research programs at the

National Institutes of Health (NIH). Dr. Grossman has received multiple grants and awards, including Phi Beta Kappa, and grants from NIH and Patient-Centered Outcomes Research Institute A(PCORI). She received her doctoral degree in clinical psychology from the University of Vermont, and completed a postdoctoral fellowship in pediatric clinical psychology at the Warren Alpert Medical School of Brown University.

Frederick Korley, MD, PhD



Frederick Korley, MD, PhD, is a Professor of Emergency Medicine and the Associate Chair for Research at the University of Michigan Emergency Department. He is the Scientific Director of Massey TBI Grand Challenge at the Weill Institute, University of Michigan. His research work is focused on the development of diagnostics and therapeutics for traumatic brain injury (TBI). He is a co-investigator of the largest observational study of TBI in the US (the Transforming Research and Clinical Knowledge in TBI, TRACK-TBI). In collaboration with colleagues in engineering, Dr. Korley is developing a credit card-sized microfluidic device for point-of-care measurement of TBI

biofluid biomarkers. He is also a national principal investigator of two federally funded multi-center studies run by the Strategies to Innovate Emergency Clinical Care Trials (SIREN) network, that are investigating the use of biofluid-based biomarkers for subject selection in clinical trials and monitoring individual patient response to neuroprotective agents. With regards to the development of novel diagnostics, Dr. Korley has two patents for biofluid-based biomarkers for brain injury detection and outcome prognostication. In collaboration with colleagues in engineering, Dr. Korley is developing a credit card-sized microfluidic device for point-of-care measurement of TBI biofluid biomarkers.? He received his medical and emergency medicine education at Northwestern University School of Medicine (2003), and doctoral training in clinical investigation at the Johns Hopkins University School of Public Health with election to Phi Beta Kappa (2013).

Michelle LaPlaca, PhD



Neurosurgery.

Michelle LaPlaca, PhD, is the Director of the Neurotrauma and Translational Bioengineering Laboratory at the Georgia Institute of Technology. She is also a Professor at the Wallce H. Coulter Department of Biomedical Engineering at the Georgia Institute of Technology and Emory University. Dr. LaPlaca's research interests are in neurotrauma, injury biomechanics, and neuro-engineering as they relate to TBI. Her lab works to better understand acute injury mechanisms in order to develop strategies for neuroprotection, neural repair, and more sensitive diagnostics. Dr. LaPlaca and colleagues have developed and patented an abbreviated, objective clinical neuropsychological tool (Display Enhanced Testing for Cognitive Impairment and Traumatic Brain Injury, DETECT) to assess cognitive impairment associated with concussion and mild cognitive impairment. Dr. LaPlaca earned her PhD in Bioengineering from the University of Pennsylvania, followed by a postdoctoral fellowship at UPenn's Department of

Geoffrey Shiu Fei Ling, MD



Geoffrey S. F. Ling, MD, PhD, is a medical doctor, TBI specialist, and retired United States Army colonel. He is a Professor of Neurology at the Uniformed Services University of the Health Sciences, where he serves as the founding director of the Neuro Trauma Laboratory. Here, his research team models and characterizes clinical phenotypes of explosive blast TBI and penetrating ballistic TBI to better characterize, mitigate, and treat these conditions. He is also a Professor of Neurology and Attending Physician in Neuro Critical Care at the Johns Hopkins Hospital. He also serves as the deputy director of the Defense Sciences Office. Previously, he served as the founding director of the Defense Advanced Research Projects Agency (DARPA) Biological Technologies Office.. As it relates to TBI, his research interests include the prevention of violent, explosive neurologic trauma. Dr. Ling is a recipient of

the Humanitarian Award from the Brain Mapping Foundation. Dr. Ling earned his doctorate in pharmacology from Cornell University School of Medicine and an MD from Georgetown University School of Medicine He completed postdoctoral training in neuropharmacology at the Sloan-Kettering Memorial Cancer Center. Ling earned. Both his neurology internship and later residency were completed at Walter Reed Army Medical Center. Ling also completed a Neurosciences Critical Care Unit (NCCU) fellowship at Johns Hopkins University.

Christopher Loftus, MD



Christopher Loftus, MD, is the Chief Medical Officer in the Division of Neurological and Physical Medicine Devices at the U.S. Food and Drug Administration. Dr. Loftus, who is board-certified in neurosurgery, is also the Professor of Neurosurgery at Temple University Lewis Katz School of Medicine. Dr. Loftus serves as the Vice President of the World Federation of Neurosurgical Societies. His research interests are instrument and device design, hemostasis and anticoagulation, and regulatory matters at the FDA level. Dr. Loftus earned their medical degree from SUNY-Downstate Medical Center, and then did their Residency in Neurosurgery at the Neurological Institute of New York, Columbia-Presbyterian Medical Center in New York, NY.

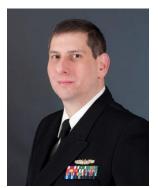
Luca Marinelli, PhD



Luca Marinelli, PhD, is Senior Principal Scientist at the GE HealthCare, Technology & Innovation Center. During his time at GE HealthCare, Dr. Marinelli has led the clinical research study part of the GE/NFL Head Health Initiative, a partnership between GE and National Football League on Traumatic Brain Injury. He is currently co-PI on the GE-MIT performing team for DARPA Measuring Biological Aptitude, a study focused on biological drivers of human performance. His research interests are quantitative MRI, fast MRI imaging, and advanced algorithms for accelerated image acquisition and reconstruction, including the development of early compressed sensing applications to MRI, and diffusion imaging in the brain. Dr. Marinelli is a co-

author on over100 journal publications, book chapters, and conference proceedings. Dr. Marinelli also serves on the scientific advisory board of the ALS Finding a Cure Foundation. Dr. Marinelli completed a PhD in Physics at Harvard University, after which he completed a postdoctoral fellowship in Information Theory and Wireless Telecommunications at Bell-Laboratories-Lucent Technologies.

Capt. Travis Polk, MD



Captain Travis Polk, MD, has served as the Director of the Combat Casualty Care Research Program since July 2020. As Director of the Combat Casualty Care Research Program and Chair of the Joint Program Committee-6, CAPT Polk is responsible for the strategic planning and management of the DoD science and technology investment that supports the development of knowledge and material solutions for combat-related trauma on the current and future battlefield. In this role, he exercises primary planning, programming, budgeting and execution of the integrated Combat Casualty Care research portfolio for the Defense Health Program and US Army (approximately \$150 million in FY21), including programs in Neurotrauma, Prolonged Care, Severe Burns, En Route Care, Battlefield Resuscitation of Combat Casualties, Medical

Photonics, Medical Simulation, and Medical Assist Support Technologies. CAPT Polk received his Bachelor of Science in Nursing from Norwich University in 1997 and his Doctor of Medicine from the Uniformed Services University in 2001. He completed his general surgery training at Naval Medical Center Portsmouth in 2008 and a fellowship in traumatology, surgical critical care and emergency surgery at the University of Pennsylvania in 2012. He is an Assistant Professor of Surgery at the Uniformed

Services University and is board certified in general surgery with an added qualification in surgical critical care. CAPT Polk's awards include the Meritorious Service Medal (five awards), the Navy Commendation Medal (two awards), and Surface Warfare Medical Department Officer qualification device.

Leslie Prichep, PhD



Leslie Prichep, PhD, is the Chief Scientific Officer of BrainScope, a medical device neurotechnology company. Here, she directs research and algorithm development efforts that use machine learning to identify scientifically-validated biomarkers of traumatic brain injury and concussion. Dr. Prichep's research interests are in quantitative electrophysiology, clinically applied translational research, source localization, and multivariate classification methodology. Throughout her career, her focus on quantitative electrophysiology and translational research has been applied to several brain-related disease states including traumatic brain injury, dementia, addiction, depression, pain, and schizophrenia. Dr. Prichep has

successfully led programs integrating objective measures of brain function into commercially available medical devices, from concept through FDA clearance, for several applications. Dr. Prichep has led the BrainScope team to eight FDA clearances, and eight Department of Defense research contracts for product development, substantially adding to the company's patent portfolio. Previously, Dr. Prichep was the Director of the Brain Research Laboratories (BRL) and a Professor of Psychiatry at the New York University School of Medicine, where she remains a professor in retirement. At BRL, Dr. Prichep and her colleagues were the first to publish normative equations demonstrating that features of the EEG could be were lawful as a function of age.?She has published in over 130 peer-reviewed journals, with another 55 book chapters, books, published proceedings and monographs to her name. In 2019, she was elected as a Fellow to the National Academy of Inventors.



Forum on Traumatic Brain Injury

Traumatic Brain Injury (TBI) is a significant and complex health problem in both civilian and military populations, affecting all ages and communities. According to CDC and DoD data, over 2.8 million people in the U.S. receive medical attention for TBI annually—including over 800,000 children—while over 430,000 service members have been diagnosed with TBI in the past 20 years. TBI can result from sports injuries, falls, vehicle crashes, domestic violence, military service, or from other causes. Lifetime costs for TBI sustained each year are estimated to reach billions of dollars.

In 2022, the National Academies' released <u>Traumatic Brain Injury: A Roadmap for</u>

<u>Accelerating Progress</u>, which examines the landscape of basic, translational, and clinical TBI research and identifies gaps and opportunities to accelerate research progress and improve care with a focus on the biological, psychological, sociological, and ecological impacts. This report calls not merely for improvement, but for a transformation of attitudes, understanding, investments, and care systems for TBI.

A Forum to Move this Key Area Forward

As a next step in addressing TBI, the National Academies established the Forum on TBI, bringing together public and private sectors to make progress on issues of shared interest and concern. The Forum provides an ongoing mechanism and neutral setting for the spectrum of public and private sector experts and stakeholders to explore opportunities for collective action and address emerging issues important to short- and long-term planning for advancing TBI research and care. This includes current research gaps, the complexity of the systems involved in TBI treatment and recovery, the challenge of system coordination, and the wide range of related needs and

challenges facing the full breadth of stakeholders in this field.

Forum membership includes the spectrum of parties interested in fostering action and improving prevention, treatment, and care for people with TBI. This includes leaders in federal, state, and local governments; military and veterans' health organizations; the private sector; organized sports; academia; patient advocates; the clinical community; philanthropic organizations; TBI researchers; and others in related fields.

The Forum on TBI:

- Fosters multi-disciplinary relationships and cross-sector collaboration across the diverse TBI stakeholder community.
- Spurs continued progress and innovation in the scientific and clinical understanding of TBI and its prevention, diagnosis, prognosis, and treatment.
- Inspires action to improve TBI research and care systems along the full continuum from prevention through acute care, rehabilitation, and return.
- Informs policy dialogues and priority setting to advance TBI research and care.

How Forums Operate and What They Do

National Academies' forums convene leaders in government, industry, academia, advocacy organizations, foundations, and other interested parties to discuss complex issues of mutual interest in a neutral setting. Members meet several times per year to share ideas and information, sponsor public workshops, and produce workshop proceedings, commissioned papers, and other products.

The National Academies of Sciences, Engineering, and Medicine are private, nonprofit institutions that provide independent, objective analysis and advice to solve complex problems and inform public policy decisions related to science, technology, and medicine. The National Academies operate under an 1863 congressional charter to the National Academy of Sciences, signed by President Lincoln. <u>Visit the Forum online</u>.

MEMBERS

Donald Berwick, Institute for Healthcare Improvement, *Co-chair*

Corinne Peek-Asa, University of California, San Diego, Co-chair

Joe Bonner, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

Joe Brennan, Avalon Action Alliance

Javier Cardenas, American Academy of Neurology

Nancy Chockley, National Institute for Health Care Management Foundation

John Corrigan, Brain Injury Association of America

Ramon Diaz-Arrastia, University of Pennsylvania Perelman School of Medicine

Jill Daugherty, Centers for Disease Control and Prevention

E. Wesley Ely, Critical Illness, Brain Dysfunction, and Survivorship Center

Bruce Evans, National Association of Emergency Medical Technicians

Jonathan Fisher, American College of Emergency Physicians

Steven Flanagan, American Academy of Physical Medicine and Rehabilitation

Brian Hainline, National Collegiate Athletic Association

Odette Harris, Stanford University School of Medicine

Stuart Hoffman, Department of Veterans Affairs

Richard Hodes, National Institute on Aging

James Kelly, Marcus Institute for Brain Health

Frederick Korley, University of Michigan

Walter Koroshetz, National Institute of Neurological Disorders and Stroke

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Forum on Traumatic Brain Injury

Action Collaborative on Traumatic Brain Injury Care

The lack of mechanisms for multidisciplinary follow-up care after traumatic brain injury (TBI) is a key gap identified in *Traumatic Brain Injury: A Roadmap for Accelerating Progress* (NASEM, 2022). This Action Collaborative was established under the auspices of the <u>Forum on Traumatic Brain Injury</u> to make progress toward addressing this need by compiling and disseminating best practices and resources on symptom management, care models, patient, family, and provider educational materials, and other information aimed at enhancing recovery in the period after TBI.

Defining the Challenge

Traumatic brain injury is often a persisting condition, not a one-time event. Across all demographic and socio-economic strata, it remains a leading cause of disability and death worldwide. The global burden of this condition has profound implications for patients, as well as their families and communities. The severity of TBI ranges from concussion to coma, however most presentations of brain injury are poorly understood, under-treated, or left untreated. While public health campaigns and increased media coverage have begun to raise awareness of TBI in recent years, it has also highlighted the limitations of what we know. There is an urgent need to better understand TBI as a complex, multisystem condition requiring a coordinated effort to improve diagnosis, treatment, and follow-up care.

The impact of this is underscored by a remarkable statistic: each year, 4.8 million patients in the United States seek emergency department care for a community-acquired head injury. And yet many are told to, "go home and rest," with or without a proper diagnosis and treatment plan. Over half of those patients receive no education about their TBI or follow-up care, despite many suffering from ongoing symptoms. There are currently no widely implemented best practices or clinical models of post-acute care for community-acquired TBI.

These needs animate the goals of this Action Collaborative to further clear and informed treatment protocols for clinicians, expand and enhance educational resources for patients and their families, and identify a framework for creating learning health care systems to advance models of post-acute care that improve TBI outcomes.

The Action Collaboratives is an ad hoc activity convened under the auspices of the Forum on Traumatic Brain Injury at the National Academies of Sciences, Engineering, and Medicine. The work the collaborative produces does not necessarily represent the views of any one organization, the TBI Forum, or the National Academies and is not subjected to the review procedures of, nor is it a report or product of, the National Academies.

Current Activities

Members of the Action Collaborative seek to advance learning systems of care for individuals with TBI by developing a toolkit of resources to inform the development of TBI follow-up care clinics that can help assess the impacts of such programs on recovery outcomes.

Current activities focus on marshaling and disseminating the evidence base on best practices and clinical care models during the follow-up period after acute care for adults with community-acquired TBI at the milder end of the severity spectrum. Collaborative participants have formed working groups taking these efforts forward:

- Action Collaborative Lead: Geoffrey Manley, University of California San Francisco
- Working Group on Follow Up Care: Members are developing a framework that translates
 the 2022 report recommendations into multidimensional goals relevant to TBI follow-up
 care (led by Michael, McCrea, Medical College of Wisconsin and Flora Hammond, Indiana
 University School of Medicine).
- Working Group on Clinical Components: Members are identifying and describing core elements that form part of a multidisciplinary follow-up care clinic for TBI (led by Javier Cardenas, West Virginia University Health System and Christina Master, Childrens' Hospital of Philadelphia).
- Working Group on Clinical Practice Guidelines: Members are analyzing available clinical
 practice guidelines to inform evidence-based management for optimizing recovery and
 wellness for people with TBI (led by Noah Silverberg, University of British Columbia and
 Kathy Lee, Department of Defense).
- Working Group on TBI Educational Materials and Discharge Instructions: Members are
 providing input on adult TBI discharge instructions, symptom-based recovery tips, and
 return to work information (led by Kelly Sarmiento, Centers for Disease Control and
 Prevention and Odette Harris, Stanford University).
- Lived Experience Perspectives: Adults who have experienced traumatic brain injuries have shared their insights through several focus groups. A white paper is available on the Forum website summarizing perspectives and themes, authored by Scott W. Hamilton and Alan Hamilton.

Article I. Preventing Discrimination, Harassment, and Bullying Expectations for Participants in NASEM Activities

The National Academies of Sciences, Engineering, and Medicine (NASEM) are committed to the principles of diversity, integrity, civility, and respect in all of our activities. We look to you to be a partner in this commitment by helping us to maintain a professional and cordial environment. All forms of discrimination, harassment, and bullying are prohibited in any NASEM activity. This commitment applies to all participants in all settings and locations in which NASEM work and activities are conducted, including committee meetings, workshops, conferences, and other work and social functions where employees, volunteers, sponsors, vendors, or guests are present.

Discrimination is prejudicial treatment of individuals or groups of people based on their race, ethnicity, color, national origin, sex, sexual orientation, gender identity, age, religion, disability, veteran status, or any other characteristic protected by applicable laws.

Sexual harassment is unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature that creates an intimidating, hostile, or offensive environment.

Other types of harassment include any verbal or physical conduct directed at individuals or groups of people because of their race, ethnicity, color, national origin, sex, sexual orientation, gender identity, age, religion, disability, veteran status, or any other characteristic protected by applicable laws, that creates an intimidating, hostile, or offensive environment.

Bullying is unwelcome, aggressive behavior involving the use of influence, threat, intimidation, or coercion to dominate others in the professional environment.

Section 1.01 REPORTING AND RESOLUTION

Any violation of this policy should be reported. If you experience or witness discrimination, harassment, or bullying, you are encouraged to make your unease or disapproval known to the individual, if you are comfortable doing so. You are also urged to report any incident by:

- Filing a complaint with the Office of Human Resources at 202-334-3400, or
- Reporting the incident to an employee involved in the activity in which the member or volunteer is participating, who will then file a complaint with the Office of Human Resources.

Complaints should be filed as soon as possible after an incident. To ensure the prompt and thorough investigation of the complaint, the complainant should provide as much information as is possible, such as names, dates, locations, and steps taken. The Office of Human Resources will investigate the alleged violation in consultation with the Office of the General Counsel.

If an investigation results in a finding that an individual has committed a violation, NASEM will take the actions necessary to protect those involved in its activities from any future discrimination, harassment, or bullying, including in appropriate circumstances the removal of an individual from current NASEM activities and a ban on participation in future activities.

Section 1.02 CONFIDENTIALITY

Information contained in a complaint is kept confidential, and information is revealed only on a need-to-know basis. NASEM will not retaliate or tolerate retaliation against anyone who makes a good faith report of discrimination, harassment, or bullying.

Article V. Diversity, Equity, and Inclusion Statement and Guiding Principles

We, the National Academies of Sciences, Engineering, and Medicine (the National Academies), value diversity among our staff, members, volunteers, partners, vendors, and audiences. We recognize that talent is broadly distributed in society and that many perspectives enhance the quality of our work and drive innovation and impact.

We pledge to cultivate a workplace culture and climate that promotes inclusion, belonging, accessibility, and anti-racism; upholds equity; and values the participation of all who are engaged in advancing our mission.[1] By embracing the values of diversity, equity, and inclusion in our programs, institutional policies and practices, and products, we will be able to better advise the nation on the most complex issues facing society and the world.

Guiding Principles:

The following diversity, equity, and inclusion principles guide our work at the National Academies:

- 1. Integrate diverse perspectives and experiences into our programs, institutional policies and practices, and products.
- 2. Foster a culture of inclusion where all staff, members, and volunteers have full access to participation and feel welcomed, respected, valued, and a sense of belonging.
- 3. Approach scientific endeavors with a consideration of diversity, equity, and inclusion frameworks.
- 4. Cultivate mutually beneficial diverse partnerships and collaborations with a variety of communities, including, but not limited to, marginalized and underrepresented communities.

Our institutional strategy for putting these values and principles into practice are outlined in the National Academies DEI Action Plan, a comprehensive five-year plan that charts a path toward achieving our diversity, equity, and inclusion goals. The DEI Action Plan is one of many ways that we commit to systems of accountability and transparency to uphold these principles and allow for continuous learning and improvement.

Updated June 7, 2018