



NIH Music and Health



Laying the

Foundation:

Defining the Building Blocks of
Music-Based Interventions

SOUND HEALTH



Wednesday
March 31, 2021

1:00-5:00 p.m. ET

U.S. Department of Health & Human Services
National Institutes of Health

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Foreword from Dr. Francis Collins

My passion for music began as a boy growing up on a Virginia farm. One of my pleasures throughout my career has been performing with colleagues and meeting other amazing artists. But my personal delight in music and my scientific endeavors have generally occupied different times and spaces. That all changed when I met Renée Fleming at a dinner event a handful of years ago. We quickly discovered a shared interest in the power of music and its role in health and healing, and how that might connect with the rapid progress being made in neuroscience.

In her role as the best-known operatic soprano of our current era, and mine as the Director of the National Institutes of Health (NIH), we had both heard anecdotes about the effects of music on learning, the mind, recovery from illness, reduction of stress, language skills, etc. But the time seemed right to explore the connections between music and the mind more deeply, and in a more coordinated fashion. The outgrowth of those fortuitous conversations with Ms. Fleming, who is now a friend and sometimes co-performer, was the founding of the Sound Health Initiative, a collaborative effort of NIH and the Kennedy Center for the Performing Arts, along with our colleagues at the National Endowment for the Arts. This initiative has led to many wonderful things, including scientific workshops, community activities, performances with a focus on sharing the science of music, the development of NIH funding opportunities, the awarding of numerous research grants exploring the effects of music, and the formation of the Sound Health Network. For our part at NIH, we have formed the Trans-NIH Music and Health Working Group, which brings together scientific leaders from across NIH to discuss and advance research into music and health.

Today's meeting, *Laying the Foundation: Defining the Building Blocks of Music-Based Interventions*, the first in a series of three, marks the start of a new activity for the Trans-NIH Music and Health Working Group. In partnership with the Renée Fleming Foundation and the Foundation for the NIH, the working group hopes ultimately to create and share a toolkit for research on music and health across the lifespan, including a consolidated set of common data elements for music-based intervention protocols. In this series of meetings, the team will begin by focusing first on music-based interventions for brain disorders of aging, including Alzheimer's disease and Parkinson's disease, as this area of music research provides some of the most compelling evidence for health benefit. Zeroing in on this piece of the lifespan first will focus our efforts and help create a model for future work.

I want to thank the many panelists who have gathered today to share their expertise in neuroscience, music therapy and music medicine, behavioral intervention development, clinical trial methodology, and patient advocacy and arts-based organization leadership. A special thanks to Mr. Alan Weil, editor of *Health Affairs*, for serving as our facilitator for this important dialogue. Many thanks to all of you for joining us and sharing your questions as we begin this process. I wish this team success in their discussions, and look forward to seeing this toolkit take shape as a means of advancing the field of music and health research.

Francis Collins, M.D., Ph.D.
Director, National Institutes of Health

Foreword from Renée Fleming

On some level, I have always been aware of strong connections between health and the arts. Building technique for classical singing is a physical process requiring years of practice, coaxing involuntary muscles to cooperate in the creation of a highly cultivated sound. For stage performers, anxiety can abound, and singing live before thousands of people (and critics) made me intensely cognizant of the mind-body connection. I have observed firsthand the powerful effect that music can have on listeners' emotions.

But I really became fascinated by this area when I noticed coverage in the press of the use of music by neuroscientists to explore brain function. It was extraordinarily compelling to me to discover this neurological connection.

To my extreme good fortune, at about that time I found myself in company with one of the great scientists of our time, Dr. Francis Collins. I was delighted to discover that he was also a musician; and before long, our shared interest in music and health led to the launch of the NIH Sound Health collaboration with the Kennedy Center (where I am an artistic advisor), with the participation of the National Endowment for the Arts.

It was a steep learning curve for me, once I found myself at a conference table with Dr. Collins at NIH, listening to presentations by researchers and music therapists. That's when I learned how much there was still to accomplish, and the very granular research needed in this field. Since then, I have become increasingly active in my advocacy. On my concert tours across North America and around the world, it has been both a privilege and a thrill to offer presentations at local health care institutions, universities, and performing arts centers, inviting scientists, physicians, and practitioners to share their research and experience with the general public and each other.

In my discussions at NIH and on my travels, I encountered a recurring theme, an issue that was mentioned both by institutional leaders and individual researchers. A common stumbling block in the practical advancement of this work is the variable quality of research. There is a pressing need for enhanced data collection, with guidelines for scientifically rigorous studies—essentially, a “toolkit” for investigators. Research that is acceptable to NIH is crucial in order to develop evidence-based clinical trials of music and arts therapy interventions. Stringent standards of inquiry can also help dispel an outdated misconception that this area is “soft science.”

So, I am honored and excited that the Renée Fleming Foundation can contribute to this effort, supporting the initiative, “Developing Evidence-Based Music Therapies for Brain Disorders of Aging.” I am profoundly grateful to Dr. Collins and the many brilliant researchers and administrators at NIH for finding common purpose. And I send thanks in advance to all the panelists and observers for this convening and others in the months ahead. Your dedication to this work is inspiring.

Renée Fleming, Renowned Soprano, Arts and Health Advocate

Agenda

Wednesday, March 31, 2021: 1:00–5:00 p.m. ET

1:00–1:10 p.m. Introduction
Francis S. Collins, M.D., Ph.D., Director, National Institutes of Health
Renée Fleming, Renowned Soprano, Arts and Health Advocate

1:10–1:20 p.m. Welcome
Sponsoring Institute and Center Directors:
– Helene Langevin, M.D., Director, National Center for Complementary and Integrative Health
– Richard J. Hodes, M.D., Director, National Institute on Aging
– Nina F. Schor, M.D., Ph.D., Deputy Director, National Institute of Neurological Disorders and Stroke

1:20–1:50 p.m. Orchestrating Rigorous Research
Shai Silberberg, Ph.D., Director of Research Quality, National Institute of Neurological Disorders and Stroke
Presentation (20 minutes)
Question and Answer Session (10 minutes)—moderated by Robert Finkelstein, Ph.D., Director, Division of Extramural Activities, National Institute of Neurological Disorders and Stroke

1:50–2:00 p.m. Charge to Panelists and Thematic Group Discussion Setup
Emmeline Edwards, Ph.D., Director, Division of Extramural Research, National Center for Complementary and Integrative Health
Alan Weil, J.D., M.P.P., Editor-in-Chief, Health Affairs

2:00–2:25 p.m. Theme 1: What is the importance of conceptual frameworks for music-based interventions?
– Hypothesis
– Supporting data: rationale, extant literature, rigor of existing data, and knowledge from practice

2:25–2:45 p.m. Theme 2: Who should be included on the investigative team?
– Interdisciplinary team with expertise in music therapy/music medicine, neuroscience, clinical trials methodology, behavioral

interventions, and patient engagement

- Considerations for bringing this team together: strategies to identify and assemble the best team as guided by the research question, workforce development, partnership, and collaborations
-

2:45–3:25 p.m.

Theme 3: What building blocks are needed to develop rigorous and reproducible music-based interventions?

- Intervention characteristics: type, intensity, dose, frequency, duration, and followup
 - Intervention strategies and protocol: delivery, feasibility, optimization, fidelity, and adherence
 - Choice of population, disease condition, and lifespan
 - Study design considerations: sample size, control group/comparator, blinding, and randomization
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3:25–3:30 p.m.

Break

3:30–3:55 p.m.

Theme 4: What are the best metrics to track mechanistic and clinical outcomes?

- Mechanistic outcomes: neural, psychological, physiological, and behavioral
 - Clinical outcomes: health status, quality of life, and function
-

3:55–4:20 p.m.

Theme 5: Are there additional methodological research and trial design issues to be considered?

- Subject burden
 - Acceptability
 - Use of technology and telemedicine
 - Caregiver participation
-

4:20–4:50 p.m.

Broad Question and Answer Session

Videocast audience and Zoom meeting participants

4:50–5:00 p.m.

Wrap-Up and Next Steps

Coryse St. Hillaire-Clarke, Ph.D., Program Director, Sensory and Motor Disorders of Aging Program, Division of Neuroscience, National Institute on Aging

Robert Finkelstein, Ph.D., Director, Division of Extramural Activities, National Institute of Neurological Disorders and Stroke

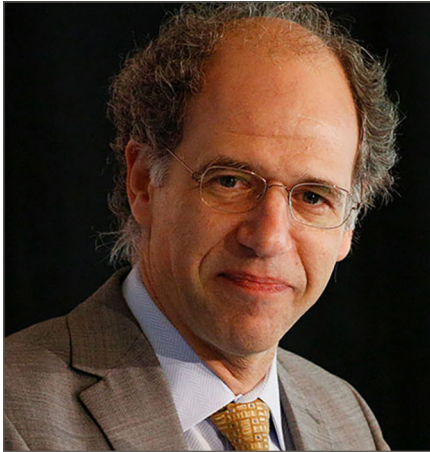
Abstract for Dr. Shai Silberberg's Presentation

Orchestrating Rigorous Research

This introductory talk addresses key measures that can be implemented to ensure high-quality studies. First and foremost, it is important to recognize that all humans, including scientists, have subconscious biases, and actions need to be taken to minimize the risk of bias when planning, conducting, analyzing, and interpreting experiments. In well-designed experiments, attempts should be made to ensure equal conditions and handling for the comparison groups throughout the experiment, except for the parameters being tested. To achieve this equality, subjects should be appropriately randomized to comparison groups, and, whenever possible, the scientists should be blinded. Blinding minimizes the potential risk of bias and, ideally, would be applied at all stages of the experiment, including during subject allocation, data collection, and data analysis. In addition, comparison groups should include sufficient samples to reduce the possibility of chance observations, and all elements of the experiments should be reported in publications transparently. Because of the tendency toward bias, critical assessment of results and publications is important. Researchers must rigorously plan experiments to disprove hypotheses; design, execute, and analyze experiments; and favor larger effects. Adhering to these principles will help accelerate the development of rigorous music-based interventions for brain disorders of aging.

Facilitator and Panelist Biographies

Facilitator



Alan Weil, J.D., M.P.P., *Health Affairs*

Alan Weil, J.D., M.P.P., became the editor-in-chief of *Health Affairs* in 2014. For the previous decade he was the executive director of the National Academy for State Health Policy, an independent, nonpartisan, nonprofit research and policy organization. Previously, he directed the Urban Institute's Assessing the New Federalism project, one of the largest privately funded social policy research projects ever undertaken in the United States; held a cabinet position as executive director of the Colorado Department of Health Care Policy and Financing; and was assistant general counsel in the Massachusetts Department of Medical

Security. Mr. Weil is a frequent speaker on national and state health policy, Medicaid, federalism, and implementation of the Affordable Care Act. He is the coeditor of two books, publishes regularly in peer-reviewed journals, has testified before Congress more than half-a-dozen times, and is called upon by major media outlets for his knowledge and analysis. He earned his bachelor's degree from the University of California, Berkeley, a master's degree from Harvard's Kennedy School of Government, and a J.D. from Harvard Law School.

Behavioral and Social Science Intervention Development



Donald Edmondson, Ph.D., M.P.H., Columbia University Medical Center

Donald Edmondson, Ph.D., M.P.H., is a tenured associate professor of behavioral medicine at Columbia University Irving Medical Center (CUIMC) and director of the Center for Behavioral Cardiovascular Health at the CUIMC. He has led a number of large, NIH-funded observational studies among patients with cardiovascular disease (CVD). These studies have documented the psychological and emotional consequences of cardiovascular events and how psychological and emotional reactions to CVD may

influence behavioral and physiological mechanisms that increase secondary CVD risk in acute coronary syndrome and in people who have had a stroke. Dr. Edmondson is also the principal investigator of the Resource and Coordinating Center for the NIH Science of Behavior Change program, which works to bring basic, translational, and clinical scientists together to apply the experimental medicine approach to uncover and reliably influence

mechanisms of human behavior change. He is also a cofounder of the Columbia Roybal Center for Fearless Behavior Change (led by Ian M. Kronish, M.D.), which supports early-phase development and testing of interventions that target fear-based mechanisms of behavioral CVD risk using the Science of Behavior Change approach. Dr. Edmondson has authored more than 100 peer-reviewed scientific articles since 2007. He received the 2018 American Psychological Association Award for Distinguished Scientific Early Career Contributions to Psychology for his theoretical and empirical contributions to health psychology, and he received the 2014 Neal Miller Young Investigator Award from the Academy of Behavioral Medicine Research for his contributions to behavioral medicine.



Eric L. Garland, Ph.D., L.C.S.W., University of Utah

Eric L. Garland, Ph.D., L.C.S.W., is the distinguished endowed chair in research, an associate dean for research, and a professor at the University of Utah College of Social Work. He is also the director of the Center on Mindfulness and Integrative Health Intervention Development and the associate director of integrative medicine for the Supportive Oncology and Survivorship Center at the Huntsman Cancer Institute. Dr. Garland is the developer of an innovative, multimodal, mindfulness-based intervention founded on insights derived from cognitive, affective, and

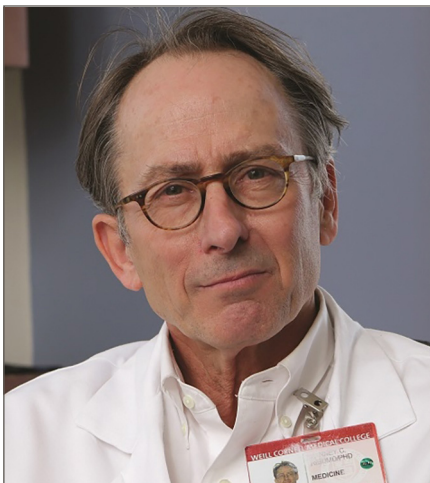
neurobiological science called Mindfulness-Oriented Recovery Enhancement (MORE). As a principal or coprincipal investigator, he has received nearly \$50 million in research grants from a variety of prestigious entities, including NIH, the U.S. Department of Defense, and the Patient-Centered Outcomes Research Institute. He conducts translational research on biopsychosocial mechanisms implicated in stress and health, including randomized controlled trials of MORE as a treatment for prescription opioid misuse and chronic pain conditions. In recognition of his national expertise in mindfulness research, in 2019, Dr. Garland was appointed by NIH Director Francis Collins, M.D., Ph.D., to the multidisciplinary working group of NIH HEAL (Helping To End Addiction Long-termSM) Initiative. Dr. Garland served as past chair of the research working group of the national Academic Consortium for Integrative Medicine and Health. Dr. Garland has had more than 160 scientific articles and book chapters published in respected, peer-reviewed outlets, and he currently serves as associate editor for the journal *Mindfulness*. To complement his expertise in clinical research, Dr. Garland is a licensed psychotherapist with more than a decade of clinical experience working with persons suffering from addictive behaviors, mood disorders, traumatic stress, chronic pain, and psychosomatic conditions. He has provided mindfulness-based therapy, cognitive behavioral therapy, and clinical hypnosis for these patients across a wide range of integrative medicine and mental health settings.



Allison G. Harvey, Ph.D., University of California, Berkeley

Allison G. Harvey, Ph.D., is a professor and licensed clinical psychologist in the Department of Psychology, University of California, Berkeley. Her clinical training and Ph.D. were completed in Sydney, Australia. Dr. Harvey moved to the University of Oxford as a postdoctoral fellow in the Department of Psychiatry and then joined the Department of Experimental Psychology as faculty with a fellowship at St. Anne's College. In 2004, she moved to the University of California, Berkeley. Dr. Harvey is a treatment development researcher who conducts experimental and intervention

studies focused on understanding and treating sleep and circadian problems, severe mental illness, and behavior change processes. More recently, she has expanded her focus to the science of dissemination and implementation. Dr. Harvey has had the honor of participating in the Training Institute for Dissemination and Implementation Research in Health hosted by the National Cancer Institute. She has published more than 250 peer-reviewed papers and chapters and authored 3 books. Her team's research is funded by the National Institute of Mental Health and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development. Dr. Harvey is a recipient of numerous awards, including awards from the Association for Behavioral and Cognitive Therapies and the Brain and Behavior Research Foundation. Dr. Harvey has also been awarded an honorary doctorate from Örebro University, Sweden, and she is a fellow of the Association for Psychological Science. This year she will receive a distinguished scientist award by the Sleep Research Society.



Cary Reid, M.D., Ph.D., NewYork-Presbyterian/Weill Cornell Medical Center

Cary Reid, M.D., Ph.D., has practiced geriatric medicine at NewYork-Presbyterian/Weill Cornell Medical Center since 2003. Dr. Reid completed his residency in medicine at Dartmouth-Hitchcock Medical Center and completed fellowships in both clinical epidemiology and geriatric medicine at Yale University. He has received many research awards over the years, including a Robert Wood Johnson Foundation Generalist Physician Faculty Scholars award and a Paul Beeson Physician Faculty Scholars in Aging Research award. Dr. Reid's work in New York City at the

Translational Research Institute on Pain in Later Life, which is an Edward R. Roybal Center that focuses on chronic pain and is funded by the National Institute on Aging, supports translational research on pain and aging.



Gloria Y. Yeh, M.D., M.P.H., Harvard Medical School and Beth Israel Deaconess Medical Center

Gloria Y. Yeh, M.D., M.P.H., is an associate professor of medicine at Harvard Medical School and a clinician-investigator in the Division of General Medicine at Beth Israel Deaconess Medical Center. She is the director of clinical research at the Osher Center for Integrative Medicine at Harvard Medical School and Brigham and Women's Hospital and director of the Harvard Medical School Research Fellowship in Integrative Medicine. Dr. Yeh's research expertise is on clinical trials of mind and body exercise for chronic disease, including cardiovascular and pulmonary conditions.

Clinical Trials Methodology



Karl Kieburtz, M.D., M.P.H., Clintrex LLC

Karl Kieburtz, M.D., M.P.H., is a neurologist and clinical researcher. After an undergraduate degree in neuroscience at Amherst College, he completed medical school and a neurology residency at the University of Rochester and obtained an M.P.H. degree from the same institution. He was the initial Robert J. Joynt Professor in the Department of Neurology and is currently professor of neurology (part time) at the University of Rochester. He was the founding director of the Center of Health + Technology and served as the director of the Clinical and Translational Science Institute and senior associate dean for clinical research at the University of

Rochester. He was director of the clinical coordinating center for the Parkinson's Progression Markers Initiative program sponsored by the Michael J. Fox Foundation and a scientific advisor to the foundation. He is a project director in the National Institute of Neurological Disorders and Stroke-funded Udall Center for Parkinson Disease at Rochester. Dr. Kieburtz was the past chair of the U.S. Food and Drug Administration Peripheral and Central Nervous System Advisory Committee and of the Department of Veterans Affairs Cooperative Studies Scientific Evaluation Committee. He also chaired the Parkinson Study Group Executive Committee and was a member of the Huntington Study Group Executive Committee. He served as vice president of the American Neurological Association, was a member of the International Executive Committee of the Movement Disorder Society, served on the board of directors of the American Society for Experimental Neurotherapeutics, and was associate editor of the journals *Neurology* and *Movement Disorders*. He has been global principal investigator for more than 50 multicenter and multinational NIH-, industry-, and foundation-sponsored clinical trials, including the large, multicenter NIH Exploratory Trials in Parkinson's Disease study. He was elected a fellow of the American Association for the Advancement of Science in 2014. He cofounded Clintrex in 2008, providing scientific and regulatory advisory

services to companies developing central nervous system therapies, and continues to serve as president. He serves on the scientific advisory boards of large pharmaceutical companies as well as for emerging therapeutics and data technology companies.



Eric J. Lenze, M.D., Washington University School of Medicine in St. Louis

Eric J. Lenze, M.D., is a professor of psychiatry at Washington University School of Medicine in St. Louis. He is a geriatric psychiatrist and clinical trialist with more than 20 years of experience studying pharmacologic and behavioral treatments in randomized controlled trials. He has embraced clinical trial innovations, including fully remote trials that use e-consent and incorporate mHealth techniques such as high-density measurement of patients via smartphones. Dr. Lenze has used this technique to repurpose the drug fluvoxamine for early treatment of COVID-19, and he is currently leading a confirmatory trial that is recruiting throughout the United States and Canada. Dr. Lenze has successfully led several trials that have generated an evidence base in two areas of geriatric psychiatry. The first area is pharmacologic management of treatment-resistant depression. Dr. Lenze directs the large clinical trial “Optimizing Outcomes of Treatment-Resistant Depression in Older Adults.” The second area is pharmacologic and psychological management of anxiety disorders. Other areas of Dr. Lenze’s clinical trial research include testing treatments to improve age-related cognitive decline, cognitive training with vortioxetine versus placebo, and improving functional outcomes among older adults undergoing postacute rehabilitation. Dr. Lenze has published approximately 280 articles and book chapters, including more than 200 peer-reviewed papers. As a principal or coprincipal investigator, he has received approximately \$51 million in funding from the Federal Government and the Patient-Centered Outcomes Research Institute. He has mentored 40 individuals, ranging from college undergraduates to junior and midcareer faculty.



Inbal Nahum-Shani, Ph.D., University of Michigan

Inbal Nahum-Shani, Ph.D., is a research associate professor at the Institute for Social Research and a founding member of the Data-Science for Dynamic Decision Making Lab (D3 Lab) at the University of Michigan. Her research focuses on conceptual and methodological issues pertaining to the construction of effective adaptive interventions, a treatment design in which ongoing information from the person is used to individualize the type, dose, and modality of support or treatment, and to just-in-time adaptive interventions, a special form of adaptive intervention in which mobile devices are used to provide support in a timely and ecological manner. Dr. Nahum-Shani collaborates with multiple scientific teams on the development of technology-based interventions that deliver support in real time, including interventions for engaging individuals

in self-monitoring behaviors, emotion-regulation exercises, and mental health treatments. Dr. Nahum-Shani provides leadership for three federally funded research projects to inform the development of adaptive interventions and just-in-time adaptive interventions targeting substance use (funded by the National Institute on Drug Abuse), obesity (funded by the National Institute of Diabetes and Digestive and Kidney Diseases), and smoking (funded by the National Cancer Institute).



Sheri L. Robb, Ph.D., M.T.-B.C., Indiana University

Sheri L. Robb, Ph.D., M.T.-B.C., is a professor at the Indiana University (IU) School of Nursing with international recognition for her expertise in pediatric music therapy and behavioral intervention research. She is a member of the IU Simon Comprehensive Cancer Center and director for the Indiana Clinical and Translational Sciences Institute (CTSI) KL2 Young Investigator Program, and she serves on the Sound Health Network leadership team. Dr. Robb is a board-certified music therapist with degrees in music therapy and early childhood special education. She completed an R25 postdoctoral fellowship in behavioral oncology and

cancer control at IU, followed by a KL2 training award in clinical and translational research from the Indiana CTSI. Dr. Robb's research program focuses on development and testing of music interventions to manage distress and improve positive health outcomes in children and adolescents with cancer and their caregivers. Most recently, her team has begun incorporation of biomarkers to understand more fully how active music interventions work to mitigate cancer-related stress and their potential to improve immune function. Dr. Robb is an established investigator with 15 years of continuous funding from NIH, including the National Institute of Nursing Research, National Cancer Institute, and Children's Oncology Group. She also led publication of Reporting Guidelines for Music-Based Interventions to address calls for more transparent and accurate reporting in music intervention research.



Jeff D. Williamson, M.D., Wake Forest School of Medicine

Jeff D. Williamson, M.D., is professor of internal medicine and epidemiology, and chief, Section on Gerontology and Geriatric Medicine, at Wake Forest School of Medicine. He is an internationally known geriatrician and clinical trialist. He also serves as director of the Center for Healthcare Innovation. He is coleader of the Alzheimer's Disease Research Center and clinical core leader for the Wake Forest Claude Pepper Older Americans Independence Center. Dr. Williamson received his medical degree from the Medical College of Georgia and a master's degree in epidemiology from the Johns Hopkins University School

of Hygiene and Public Health. He completed a fellowship in geriatric medicine at Johns Hopkins. Dr. Williamson's primary research interests are in understanding relationships

between chronic diseases such as hypertension and diabetes and maintaining brain health and physical function in aging adults, preventing aging-related loss of independence, and developing research methods for including elderly persons in clinical trials.

Music Therapy/Music Medicine



Melita Belgrave, Ph.D., M.M., Arizona State University

Melita Belgrave, Ph.D., M.M., received her bachelor's degree in music therapy from Michigan State University. She also earned her master's degree in music therapy, a certification in aging studies, and a doctorate in music education with an emphasis in music therapy at Florida State University. Dr. Belgrave has worked as a music therapist in special education, mental health, rehabilitation, hospice, geriatric, and intergenerational settings throughout Texas, Florida, Kansas, and Missouri. Her research interests are music therapy with older adults and intergenerational programming.

She has presented at regional, national, and international conferences, and her research has been published in national and international journals including the *Journal of Music Therapy*, *Music Therapy Perspectives*, *Frontiers in Medicine*, and *Journal of Music Teacher Education*. She coauthored the text *Music Therapy and Geriatric Populations: A Handbook for Practicing Music Therapists*. Her current service includes working as the chair of the Diversity, Equity, and Inclusion Committee for the American Music Therapy Association.

Additionally, Dr. Belgrave serves as a member of the editorial board for *Music Therapy Perspectives* and was the 2016–2018 chair of the International Seminar of the Commission on Special Music Education and Music Therapy. Prior to her appointment at Arizona State University (ASU), Dr. Belgrave taught in the music therapy program at the University of Missouri–Kansas City as an assistant and associate professor. At ASU, she teaches undergraduate and graduate music therapy courses, serves as the advisor for the music therapy student organization, and has been appointed as the administrator of the Arizona State University Music Therapy Clinic. Dr. Belgrave has also been appointed as a research affiliate at the Mayo Clinic in Arizona and conducts creative aging music groups in the community. In 2018, she was recognized by the Black Music Therapy Network with the annual service award in recognition for her exemplary commitment to advanced knowledge and practice in the field of music therapy. Additionally, Dr. Belgrave has authored a chapter in and coedited the text for *Music Therapy in a Multicultural Context: A Handbook for Music Therapy Students and Professionals*.



Joke Bradt, Ph.D., M.T.-B.C., Drexel University

Joke Bradt, Ph.D., M.T.-B.C., is professor and program director of the Ph.D. in Creative Arts Therapies program at Drexel University and a board-certified music therapist. Her federally funded research is focused on the use of music therapy for chronic pain and symptom management. She currently is conducting two NIH-funded clinical trials: a multisite trial on music therapy for chronic pain management in people with advanced cancer and a study examining the impact of music therapy on opioid tapering in cancer survivors with chronic pain. As a research team member

of Creative Forces: National Endowment for the Arts Military Healing Arts Network, she has investigated the impact of music therapy on clinical outcomes in service members with post-traumatic stress, traumatic brain injury, and other psychological health concerns. She is the lead author of several Cochrane systematic reviews on music interventions with medical patients, and she is editor-in-chief of the *Nordic Journal of Music Therapy*.



Elizabeth L. Stegemöller, Ph.D., M.T.-B.C., Iowa State University

Elizabeth L. Stegemöller, Ph.D., M.T.-B.C., is an associate professor in the Department of Kinesiology at Iowa State University. She is also the director of the interdepartmental Neuroscience Graduate Program. As a music therapist, Dr. Stegemöller has witnessed several intriguing experiences in which patients with neurological disorders have overcome debilitating conditions through music. These experiences have motivated her research goals. Dr. Stegemöller earned her bachelor's degrees in music therapy and biology with a

minor in chemistry from the University of Missouri–Kansas City in 2001. After receiving her degrees, she worked as a clinical music therapist before returning to graduate school, earning her doctorate in neuroscience at Northwestern University in 2010. Dr. Stegemöller completed a postdoctoral fellowship in the Department of Neurology and the Department of Applied Physiology and Kinesiology at the University of Florida. She joined Iowa State University in 2013. Dr. Stegemöller's main research focus is to determine how music and music therapy facilitate movement and modulate associated brain activity in persons with Parkinson's disease. She currently has multiple projects examining the effects of music or singing on swallowing, stress and inflammation, repetitive movements, and associated neurophysiology in persons with Parkinson's disease. Dr. Stegemöller also has contributed to more than 40 publications in her early career. Along with her research, Dr. Stegemöller offers several outreach programs for persons with Parkinson's disease, including weekly singing, dance, yoga, and boxing groups, as well as yearly events, such as the Parkinson's Disease Singing Festival and a Dancing With the Students spring show. Dr. Stegemöller is very passionate about her work and hopes that through her research and outreach efforts, she can contribute

to the development of new and innovative therapies that demonstrate the effectiveness of music therapy in the treatment and care of persons with Parkinson's disease.



Michael H. Thaut, Ph.D., University of Toronto

Michael H. Thaut, Ph.D., is currently a professor of music at the Rehabilitation Sciences Institute, University of Toronto. He also has cross-appointments in rehabilitation science and neuroscience. He also holds appointments as collaborator scientist at the Centre for Addiction and Mental Health Hospital Neuroimaging Division and the Li Ka Shing Knowledge Institute at St. Michael's Hospital, Toronto. He is director of the university's Music and Health Science Research Center and Music and Health Sciences graduate programs. His appointment is endowed by a Canada

Research Chair Tier 1 award from the federal government of Canada. Dr. Thaut received his master's degree and Ph.D. in music from Michigan State University, with a cognate minor in movement science. He holds a special diploma in music from the Mozarteum University in Salzburg, Austria and a German Diplom in Psychology/Education from the University of Muenster. Prior to his appointment at the University of Toronto, he was a professor of music and professor of neuroscience as well as director of the School of the Arts at Colorado State University. He has held many visiting positions internationally including at the University of Michigan Department of Movement Science, Düsseldorf University Medical School, National Institute for Neuroscience Research IRCCS Santa Lucia/Rome, Heidelberg University of Applied Sciences, and Kurashiki Sakuyo Music University in Japan. Dr. Thaut is an international leader in the basic and clinical neuroscience of music and has internationally recognized research in relation to the applications of auditory neuroscience, specifically for music and rhythm, to brain rehabilitation. He has more than 250 scientific publications and is the coeditor of the *Oxford Handbook of Music Psychology* and senior editor of the *Oxford Handbook of Music and Brain* and the *Oxford Handbook of Neurologic Music Therapy*, which was second in the annual British Medical Association book award in the category "Best New Book in Neurology 2015." He is president emeritus of the International Society for Clinical Neuromusicology, vice president of the International Society for Music and Medicine, vice chair for Special Study Sections at the World Federation for NeuroRehabilitation, and an Overseas Fellow of the Royal Society of Medicine, United Kingdom. His research team, in collaboration with medical science and clinician groups worldwide, developed the field of neurological music therapy, an evidence-based system of music-based interventions applied to neurorehabilitation practiced by certified clinicians in more than 50 countries and endorsed by the World Federation for NeuroRehabilitation. As a former professional violinist in the classical and folk genres, Dr. Thaut has recorded several albums and has toured throughout Europe extensively.

Neuroscience



Mounya Elhilali, Ph.D., Johns Hopkins University

Mounya Elhilali, Ph.D., is a professor of electrical and computer engineering at the Johns Hopkins University with a joint appointment in the Department of Psychology and Brain Sciences. She received her Ph.D. in electrical and computer engineering from the University of Maryland, College Park in 2004. She directs the Laboratory for Computational Audio Perception and is affiliated with the Center for Speech and Language Processing and the Center for Hearing and Balance. Her research examines sound processing by humans and machines in noisy soundscapes

and investigates reverse engineering intelligent processing of sounds by brain networks with applications to speech and audio technologies and medical systems. She was named the Charles Renn Faculty Scholar in 2015, received a Johns Hopkins University Catalyst Award in 2017, and was recognized as an outstanding woman innovator in 2020. Dr. Elhilali is a recipient of a National Science Foundation CAREER award and the Office of Naval Research Young Investigator award.



John R. Iversen, Ph.D., University of California, San Diego

John R. Iversen, Ph.D., is a cognitive neuroscientist at the University of California, San Diego who studies the interactions between music and the brain. He directs the Studying the Influence Music Practice Has on Neurodevelopment in Youth (SIMPHONY) project and codirects the Early Academic Readiness and Learning Intervention (EARLI) project, part of a National Endowment for the Arts Research Laboratory. SIMPHONY and EARLI are longitudinal studies of the impact of music training on children's brain and cognitive development. They place the

impact of music into a broader neurodevelopmental framework, in which researchers are charting the "growth curves" of the developing brain to understand how brain development shapes the emerging skills of each child. Dr. Iversen also studies fundamental brain mechanisms underlying human perception and production of sound and rhythm, mapping what they tell us about how the motor system may influence what we hear, as well as studies of biomarkers and brain mechanisms of navigation and complex skill learning. After undergraduate studies in physics at Harvard University, Dr. Iversen received graduate degrees in philosophy of science and in speech at the University of Cambridge and received a Ph.D. in speech and hearing science from the Massachusetts Institute of Technology. He is currently an associate research scientist in the Institute for Neural Computation and an associate director of the Swartz Center for Computational Neuroscience at the University of California, San Diego.



Daniel J. Levitin, Ph.D., McGill University

Daniel J. Levitin, Ph.D., is a professor in the Department of Psychology at McGill University. He earned his B.A. in cognitive science from Stanford University and his M.Sc. and Ph.D. in cognitive psychology with a minor in music technology from the University of Oregon. He completed his postdoctoral training in neuroimaging and perception at the Stanford University School of Medicine and the University of California. He taught at Stanford University in the Departments of Computer Science, Psychology, History of Science, and Music and has been a visiting

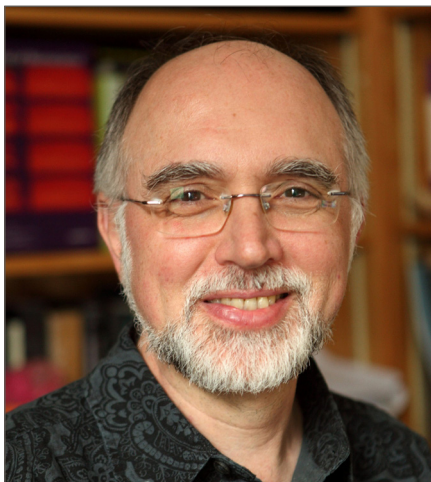
professor at Dartmouth College and the University of California, Berkeley. He is currently the founding dean of arts and humanities at the Minerva Schools at Keck Graduate Institute, San Francisco, California, and the James McGill Professor Emeritus of psychology, neuroscience, and music at McGill University. Dr. Levitin is an award-winning neuroscientist, musician, and best-selling author. His research encompasses music, the brain, health, productivity, and creativity. Dr. Levitin has published more than 300 articles in periodicals such as *Science*, *Nature*, *Proceedings of the National Academy of Sciences*, *The New Yorker*, *The Atlantic*, and *The Wall Street Journal*. His research has been featured more than 1,800 times in the popular press, including 17 articles in *The New York Times* and in *The Times*, *Scientific American*, and *Rolling Stone*. He is a frequent guest on National Public Radio and on CBC/Radio-Canada and has appeared on *Good Morning America*, *Today*, *CBS This Morning*, and *CNN*. His TED Talk is among the most popular of all time. He is the author of four *New York Times* bestselling books: *This Is Your Brain on Music*, *The World in Six Songs*, *The Organized Mind*, and *Successful Aging*, as well as the international bestseller *A Field Guide to Lies*. Dr. Levitin is a popular public speaker and has given presentations to parliament in London, the U.S. Congress, Microsoft, Google, and Amazon. He has consulted for a number of companies and organizations, including Apple, Booz Allen Hamilton, Microsoft, the U.S. Navy, Sonos, Philips, Sony, Fender, and AT&T. As a musician (tenor saxophone, guitar, vocals, and bass), he has performed with Mel Tormé, David Byrne, Rosanne Cash, Sting, Bobby McFerrin, Victor Wooten, and Tom Scott. Dr. Levitin has produced and consulted on albums by artists such as Stevie Wonder, Steely Dan, and Joni Mitchell, he has consulted on the films *Good Will Hunting* and *Pulp Fiction*, and he has been awarded 17 gold and platinum records.



Eric J. Nestler, M.D., Ph.D., Icahn School of Medicine at Mount Sinai

Eric J. Nestler, M.D., Ph.D., is the Nash Family Professor of Neuroscience at the Icahn School of Medicine at Mount Sinai in New York, where he serves as dean for Academic and Scientific Affairs and director of the Friedman Brain Institute. He received his B.A., Ph.D., M.D., and psychiatry residency training from Yale University. He served on the Yale faculty as the Elizabeth Mears and House Jameson Professor of Psychiatry and Neurobiology and as the director of the Division of Molecular Psychiatry from 1987

to 2000. He moved to Dallas in 2000 and was the Lou and Ellen McGinley Distinguished Professor and Chair in Psychiatry at the University of Texas Southwestern Medical Center until moving to New York in 2008. Dr. Nestler is a member of the National Academy of Medicine (1998) and a fellow of the American Academy of Arts and Sciences (2005). He is a past president of the American College of Neuropsychopharmacology (2011) and the Society for Neuroscience (2017). He is a founder and the chair of the scientific advisory board for PsychoGenics, and he is a member of the board of directors for Berg, a biotechnology company. Dr. Nestler also chairs the scientific advisory boards for One Mind, the Hope for Depression Research Foundation, and the Rainwater Charitable Foundation's Tau Consortium. The author of approximately 700 publications and 5 books, Dr. Nestler studies the molecular basis of drug addiction and depression.



Robert J. Zatorre, Ph.D., McGill University

Robert J. Zatorre, Ph.D., is a cognitive neuroscientist at the Montreal Neurological Institute of McGill University. He was born and raised in Buenos Aires, Argentina, and carried out his doctoral studies at Brown University with the late Peter Eimas, followed by postdoctoral work with Brenda Milner. He currently holds a Canada research chair at the Montreal Neurological Institute of McGill University. In 2006 he became the founding codirector, with Isabelle Peretz, of the international laboratory for Brain, Music, and Sound Research. His work has been recognized with several awards, including the Ipsen Foundation prize in neuronal

plasticity in 2011, the Knowles prize in hearing research from Northwestern University in 2013, election to the Royal Society of Canada in 2017, and the de Carvalho-Heineken prize in cognitive science from the Netherlands Academy of Arts and Sciences in 2020. He is also a fellow of the Canadian Institute for Advanced Research. Dr. Zatorre's lab studies the neural substrates of auditory cognition, with special emphasis on two complex and characteristically human abilities: speech and music. With his collaborators and students, Dr. Zatorre has published more than 300 scientific papers on topics including pitch and melody perception, auditory imagery, music production, brain plasticity in musicians, and the role of the dopaminergic reward circuitry in mediating musical pleasure. His research spans all

aspects of human auditory processing, from the functional and anatomical properties of auditory cortex and its connectivity to how these properties differ between the hemispheres, and how they change with training or sensory loss. Examples of recent research projects include: using graph theory models to understand anatomical connectivity of the auditory cortex from magnetic resonance diffusion data; using magnetoencephalopathy to track the cortical and subcortical responses to periodicity; applying machine learning algorithms to functional magnetic resonance imaging (fMRI) to investigate reward-related brain activity to music; demonstrating hemispheric asymmetries in fMRI activity to speech and melody in relation to spectrotemporal modulations; and application of brain stimulation paradigms to enhance auditory working memory and to modify hedonic responses to music. Dr. Zatorre's activities are funded by the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, the Canada First Research Excellence Fund, and the Canadian Institute for Advanced Research.

Patient Advocacy and Arts Organizations



Jamie Eberling, Ph.D., Michael J. Fox Foundation for Parkinson's Research

Jamie Eberling, Ph.D., is a neuroscientist with background in neuroimaging, Alzheimer's and Parkinson's diseases, gene therapy, and translational research. Dr. Eberling received her B.S. and Ph.D. in biological psychology from the University of California, Berkeley. She oversees the imaging portfolio with a particular emphasis on positron emission tomography (PET) tracer development. She is responsible for building and advancing the alpha-synuclein tracer development program, one of the highest research

priorities for the Michael J. Fox Foundation (MJFF). Prior to joining MJFF, Dr. Eberling was a research scientist at the Lawrence Berkeley National Laboratory, where she used PET imaging to evaluate the efficacy of gene therapy approaches for Parkinson's disease.



Barbara A. Else, M.P.A., M.T.-B.C., American Music Therapy Association

Barbara A. Else, M.P.A., M.T.-B.C., is a senior research and policy advisor with the American Music Therapy Association (AMTA). She coordinates AMTA's research initiatives and is the business manager for the AMTA's two peer-reviewed journals, the *Journal of Music Therapy* and *Music Therapy Perspectives*. She also serves as managing editor for the *Journal of Music Therapy*. Ms. Else practiced as a hospital-based music therapist and has been active as a researcher in health policy and economics. She maintains a part-time

music therapy practice in community mental health. She provides training and presentations on the use of music therapy to mitigate the effects of trauma. Ms. Else was the recipient of

a postgraduate fellowship and later served as a project officer with the U.S. Public Health Service at the Agency for Health Care Policy and Research (later renamed the Agency for Healthcare Research and Quality) for medical effectiveness research, policy analysis, and grants management. Her publication credits focus on health policy, research methods, trauma and music therapy, and health economics. Ms. Else volunteers with the American Red Cross in disaster services/mental health and training. She serves in an advisory role for disaster response for the AMTA and the World Federation of Music Therapy. As a musician, Ms. Else is active (in nonpandemic times) in the jazz scene and is a studio recording artist specializing in concert and ethnic flutes.



Ramona Hicks, Ph.D., One Mind

Ramona Hicks, Ph.D., is the director of science and technology at One Mind, a nonprofit organization dedicated to the acceleration and implementation of research to promote brain health, and an affiliate professor in the Department of Neurological Surgery at the University of Washington. In addition to managing the One Mind science and research portfolio, she participates in numerous projects to advance open science, digital health, learning health care, and early detection and intervention for youth mental health. Prior to joining One Mind, she held faculty appointments at the University of Kentucky

and the University of Washington, where she studied the effects of pharmacologic and nonpharmacologic interventions on hippocampal function and recovery following traumatic brain injury (TBI). Dr. Hicks also served as a program director at the National Institute of Neurological Disorders and Stroke, where she managed the TBI research portfolio and led numerous interagency and international research initiatives.



Sunil Iyengar, National Endowment for the Arts

Sunil Iyengar is director of the Office of Research & Analysis at the National Endowment for the Arts (NEA). Under his leadership, the office has produced dozens of research reports, hosted periodic research events and webinars, led strategic plan development for the agency, and established research and data partnerships with the U.S. Census Bureau and the Bureau of Economic Analysis. His office also conducts program evaluations and performance measurement for the Arts Endowment. Working with his team, Mr. Iyengar has created and pursued a long-

term research agenda (based partly on an arts “system map” his office helped to design), founded a national data repository for the arts, and launched two awards programs for arts researchers, including the NEA Research Labs initiative. He chairs a Federal Interagency Task Force on the Arts and Human Development. For nearly a decade, he has contributed a monthly research post (“Taking Note”) to the agency’s official blog. Mr. Iyengar and his

team have collaborated with organizations such as the Brookings Institution, the National Academy of Sciences, the Robert Wood Johnson Foundation, the Association of American Medical Colleges, and NIH to explore the arts in relation to such topics as health and well-being, economic development, and STEM (science, technology, engineering, and mathematics) and medicine. His office provides research consultative support to Creative Forces: NEA Military Healing Arts Network. Most recently, he has led a research funding partnership with NIH as part of Sound Health. His office supports the Sound Health Network. Prior to joining the agency, Mr. Iyengar worked as a reporter, managing editor, and senior editor for news publications covering the biomedical research, medical device, and pharmaceutical industries. He writes poems, book reviews, and literary essays. Mr. Iyengar has a B.A. in English from the University of Michigan.



Anne Leonard, M.P.H., B.S.N., R.N., American Stroke Association/American Heart Association

Anne Leonard, M.P.H., B.S.N., R.N., is a senior science and medicine advisor for the American Stroke Association (ASA) division of the American Heart Association (AHA). She is the lead for the Stroke Council, Council on Hypertension, and Council on Clinical Cardiology and staffs several science subcommittees within those councils. She has worked in stroke science since 1987, when she worked for the Department of Neurology at the University of Texas Health Science Center at San Antonio on the Stroke Prevention in Atrial Fibrillation study, which was funded by

the National Institute of Neurological Disorders and Stroke. During her 20-year tenure with this department, she also coordinated other studies on acute stroke treatment, primary/secondary prevention of stroke, and novel early-phase neuroprotective agents. Her work on these research studies included the roles of study coordinator and subinvestigator. She also was involved in quality improvement projects at affiliated hospitals. She worked 5 years of her career with the Department of Neurosurgery, coordinating and executing clinical research trials on intracerebral hemorrhage, including two surgical intervention studies (the Minimally Invasive Surgery and rtPA for Intracerebral Hemorrhage Evacuation study and the Clinical Trial on Treatment of Intraventricular Hemorrhage), as well as an epidemiology study (Ethnic/Racial Variations of Intracerebral Hemorrhage). She served as the interim stroke coordinator in the five-hospital system for a year and consulted with this system thereafter. During those years, she taught residents, medical students, nurses, paramedics, and allied health professionals about stroke. Before leaving the university, she consulted with the AHA/ASA about its stroke portfolio. She rejoined the AHA/ASA in 2013.



Susan Magsamen, M.A.S., Johns Hopkins University

Susan Magsamen, M.A.S., received a bachelor's degree in communications studies from Towson University in 1982 and a master's degree in advanced study from Johns Hopkins University in 1986. She is the founder and executive director of the International Arts + Mind (IAM) Lab, a pioneering neuroaesthetics initiative from the Pedersen Brain Science Institute at Johns Hopkins University School of Medicine. Her body of work lies at the intersection of brain sciences and the arts — and how our unique response to aesthetic experiences can amplify human potential.

Ms. Magsamen is the author of the Impact Thinking model, an evidence-based research approach to accelerate how we use the arts to solve problems in health, well-being, and learning. In addition to her role at the IAM Lab, she also serves as codirector of the NeuroArts Blueprint initiative in partnership with the Aspen Institute. Prior to founding the IAM Lab, Ms. Magsamen worked in both the private and public sectors, developing social impact programs and products addressing all stages of life — from early childhood to aging adulthood. She created Curiosityville, an online personalized learning world, acquired by Houghton Mifflin Harcourt in 2014, and Curiosity Kits, a hands-on multisensory company, acquired by Torstar in 1995. Ms. Magsamen, an award-winning author for children and families, has published seven books, including *The Classic Treasury of Childhood Wonder*, *The 10 Best of Everything Families*, and *Family Stories*, a five-part interactive series that included *Nighty Night*, *Tooth Fairy Times*, *My Two Homes*, *Family Night*, and *Making Spirits Bright*. She is a fellow at the Royal Society of the Arts and a strategic advisor to several innovative organizations and initiatives, including the Academy of Neuroscience for Architecture, the American Psychological Association, the National Association for the Education of Young Children, Brain Futures, Learning Landscapes, and Creating Healthy Communities: Arts + Public Health in America.



Heather M. Snyder, Ph.D., Alzheimer's Association

Heather M. Snyder, Ph.D., is the vice president of medical and scientific relations at the Alzheimer's Association. In this role, she oversees association initiatives that accelerate innovative Alzheimer's research and provide opportunities for the global dementia community to connect and collaborate. Dr. Snyder is responsible for the progress the association has made in Alzheimer's disease and dementia research funding. She leads the association's International Research Grant Program, the vehicle through which the association funds promising investigations that advance understanding of Alzheimer's disease and moves the field

toward solutions for the global Alzheimer's disease crisis. As the world's largest nonprofit funder of Alzheimer's disease research, the association is currently investing \$167 million in more than 500 active, best-of-field projects in 27 countries. As part of this effort, Dr. Snyder

is instrumental in advancing grant programs that explore sex- and gender-based disease vulnerability. These grant programs contributed to the Women's Alzheimer's Research Initiative, one of the only focused funding programs in this area. The programs also fund studies to uncover how biological and genetic factors shape disease development and progression in women as compared to men, a factor that may influence diagnostic and treatment options as research moves closer to precision medicine. To increase knowledge about prevention and risk reduction, Dr. Snyder serves on the executive team for the U.S. Study To Protect Brain Health Through Lifestyle Intervention To Reduce Risk. In addition, she oversees the development and management of the Alzheimer's Association's leading clinical neurology journal, *Alzheimer's and Dementia*, and its companion open-access journals, which help bridge the knowledge gaps across a wide range of dementia research disciplines. Dr. Snyder sits on the programmatic review committee for the U.S. Department of Defense Congressionally Directed Medical Research Programs for Alzheimer's disease. She has been a peer reviewer for NIH, the Polish government, the Centers for Disease Control and Prevention, and California's Alzheimer's disease funding program. An expert in the field, Dr. Snyder has been featured in numerous television interviews, including the *Dr. Oz Show*, and in news articles in *The New York Times*, *The Washington Post*, *Crain's Chicago Business* "40 Under 40," and *The Wall Street Journal*. She holds a Ph.D. in molecular biology from Loyola University Chicago Stritch School of Medicine and a bachelor's degree in biology and religious studies from the University of Virginia.

Group Abstracts

Behavioral and Social Science Intervention Development

Lessons learned from behavioral science and mind-body therapies specifically that are likely to be beneficial for rigorous science on music's therapeutic value/design of music therapies include the following:

1. Systematic review of basic and neuroscientific findings should inform theoretical models to study 1) the components of music/music therapies that are likely to 2) influence cognitive/emotional/physiological mechanisms that, in turn, 3) result in change in the outcome of interest (cognitive/emotional/functional).
2. The National Institutes of Health (NIH) Stage Model offers a clear and rigorous roadmap for intervention development, as well as suggested research designs at each stage of intervention development.
3. The NIH Science of Behavior Change (SOBC) program illustrates the experimental medicine approach to identifying and testing hypothesized mechanisms of action of therapies at each stage of intervention development. It also offers a bridge between basic, translational, and clinical trials researchers, all of whom may contribute uniquely to identifying, measuring, influencing, and/or determining the magnitude of the mediated effect of an intervention through a given mechanism.
4. Example of behavioral research expertise applied to music intervention development at the intervention development level:
 - a. The initial (preintervention) literature review should include components of the music itself, such as frequency, tempo, and melody; the volume at which the music is played; and other intervention components, such as imagery, that would be used along with the music and that are important/shown to engage hypothesized mechanisms or desired outcomes, which are thought to be necessary/sufficient.
 - b. If building an intervention from basic science components, experiments may need to be done on the individual components of an intervention before designing a multicomponent experiment. If trying to understand a seemingly efficacious intervention, experimental designs can determine which of the components are driving the effect. Pragmatic studies can focus on the impact of an intervention as a whole, but follow-up studies could dismantle the active ingredients. A mechanistic perspective from the outset can guide these decisions.
 - c. From mind-body intervention experts (e.g., yoga, mindfulness-based stress reduction): Specifying domains and mechanisms that are expected to be relevant, such as the emotional, cognitive, and physical domains, is crucial. A hindrance early on for research in mind-body therapies was that authority, dogma, and history rather than mechanisms drove research design and hypotheses. It would be preferable to

build interventions based on what is known about mechanisms from basic science and mechanisms-focused theory.

Clinical Trials Methodology

The Clinical Trials Methodology subgroup will be more helpful once they have **more information on the state of the science on music-based interventions**. However, preliminary conversations were robust and resulted in the following observations/recommendations, with key points organized across four key areas: overarching considerations, design issues, investigative teams, and approach.

Overarching Considerations

Participants were in full agreement that the **methods used should serve the scientific question** and not the other way around. The top priority at this stage is to understand the research questions critical to the field; the methodology can then be matched to the research question. Having a fundamental understanding of the biologic effects of sound in general and music specifically would provide a good platform for optimization studies. Beyond this, though, sound and music affect functional outcomes, such as cognitive and physical function, in older people without affecting disease (or biological) outcomes.

Design Issues

National Institutes of Health (NIH) representatives indicated that the initial studies would be in two phases, with a didactic phase followed by pilot work. Large-scale trials would come at a later time. The early-stage nature of the trials suggests that studies would be testing mechanisms, making adaptations, and determining the best way to optimize interventions.

Several frameworks exist for such early-stage research; one is the Multiphase Optimization Strategy (MOST). MOST includes a preparation stage (formative work), pilot testing, and then a small factorial or other randomized controlled trial design that informs how to put together the optimized intervention. These stages precede formal effectiveness (or efficacy) testing. Example: <https://pubmed.ncbi.nlm.nih.gov/33253787/>.

Another framework is stakeholder-driven adaptation, which is often a recursive or iterative design. The implementation science field has used a Collaborative Planning Approach to formalize this (for example: <https://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-6-80>). The advantage of this approach is that it treats implementation as critical at the outset of intervention development (rather than only after the intervention has been developed and tested). Another point is that early-stage piloting need not involve randomization. Relatedly, conducting well-designed interviews (qualitative analysis) with participants is an essential feature of studies that seek to understand the mechanisms and outcomes of an intervention.

A third point is that, more perhaps than other behavioral interventions, music interventions would likely need to be tailored to the individual. Tailoring should be done in a standardized way, with clear, theory-based boundaries placed on the clinical decision-making process.

One recent framework, the Precision Clinical Trial framework, summarizes approaches for individual tailoring within clinical trials <https://pubmed.ncbi.nlm.nih.gov/33206039/>.

Finally, it was noted that it is possible to overemphasize mechanisms. If there is preliminary evidence of benefit, this might be sufficient to move to larger trials.

Investigative Teams

Clinical trialist expertise is essential, preferably for one of the principal investigators. The group also recommends including people not only with expertise in biological/disease outcomes but also with expertise in functional, nondisease outcomes including quality-of-life outcomes. Depending on the scientific questions, include research experts in music perception and/or applied music intervention research. Finally, include clinicians, staff, and family who are engaged in treatment delivery/receipt in the study design phase.

Approach

The group discussed six topics related to scientific approach.

- **Control group** consideration will be critical for randomized trials. See <https://pubmed.ncbi.nlm.nih.gov/30826377/>, which provides a framework for how to think about and justify a specific control group. One noted strategy to manage expectancy, recruitment, and engagement is to present conditions as equal.
- **Blinding** participants, in most cases, will not be possible. Measuring and accounting for expectancy and credibility will be important. See <https://pubmed.ncbi.nlm.nih.gov/32017250/> for a discussion of and recommendations on this issue. It will be important to blind outcome assessors.
- **Measurement strategies.** Both outcome and process (mechanistic) measures will need excellent validity characteristics, including high test-retest reliability. It will be important to consider in-the-moment measures, as well as postintervention and more longitudinal measures. Also, behavioral coding (observation) is a method that can provide a different piece of information (beyond self-report/patient-reported outcomes [PROs] or biologic/neurologic measures).
- **Rigorous fidelity strategies** are needed (that take into account all five areas of fidelity; NIH Behavior Change Consortium Recommendations). See <https://pubmed.ncbi.nlm.nih.gov/15367063/>. This includes ongoing monitoring of intervention delivery to prevent drift and cross contamination.
- **Enrichment trial design.** Studies should consider enrichment in trial design, that is, recruiting study participants who seem likely to be particularly responsive to an intervention because of demographic or clinical features (or due to initial response or engagement with an acute bout of the therapy).
- Finally, studies should consider **patient engagement** as a type of mechanism itself. This could and probably should be measured in trials.

Music Therapy/Music Medicine

The group spent a significant amount of time discussing the question about conceptual models for music-based interventions. They agreed that the choice of model depends on the targeted outcome and/or research question. There are many valuable neuromechanistic and behavioral models that can be employed in music-based intervention research. Identifying a conceptual model is essential in developing hypotheses and determining outcome measures or biomarkers. There was some disagreement in the group as to whether the conceptual model must be explicitly music based. One view was that any conceptual model used in music-based intervention research needs to be music-based. Another view was that there are many non-music specific behavioral models that can be valuable in the development and testing of music-based interventions. However, it is essential that researchers postulate how the proposed music interventions target specific components of the model. Some National Institutes of Health (NIH)-funded music therapy studies with pediatric cancer patients were used as an example, as this research is guided by a resilience model that was not developed specifically for music interventions. It was also noted that models can be based on preexisting scientific theories (e.g., a neuromechanistic model) or built on clinical practice (e.g., through careful testing of what works and what doesn't).

Next, the group discussed the role of supporting data for proposed hypotheses. The group agreed that studies need to be built on prior research/extant literature. All too often in music-based intervention research, similar studies with small sample sizes are conducted (e.g., music listening for anxiety reduction in people with cancer) rather than moving research forward by carefully building studies on past research and refining the intervention.

The group suggested that the question about content of the intervention should be divided into two questions—one about the actual content of the intervention and the other about the structure (i.e., intensity, dose, duration). Intervention content should be based on the conceptual model, clinical practice, and prior research (e.g., refinement of the intervention). A challenge in determining intervention content is that people's responses to music and music-based interventions can widely vary. However, the use of flexible treatment protocols may help address this. The group agreed that well-developed treatment protocols and treatment fidelity testing are important components of rigorous research. Decisions around structure should be informed by a systematic building of research studies that address dosage/frequency questions. The structure of the interventions should furthermore be informed by factors such as uptake potential and insurance coverage. A strong recommendation was to involve participant perspective/input early in the research process, as participants are a rich source of information on what is and is not working for them and can offer valuable input regarding effective and/or desirable treatment delivery methods. Including stakeholders' perspectives early in a research program can significantly shorten the timeframe of the intervention research pipeline from development to implementation.

Finally, the group recommended that the following people should be included in the investigative team:

1. People with expertise in the intervention, health problem/population, and target outcomes (e.g., biomarkers)

2. Methodological expert(s)
3. Statistician
4. Competent clinician(s) to deliver the intervention
5. Stakeholders (e.g., patients, caregivers)
6. Skilled study coordinator to supervise recruitment, data collection, adherence to study protocol by all team members, data management, etc.
7. Person with experience managing NIH-funded grants

In addition, it is important that there is evidence of prior collaborations among key personnel.

Neuroscience

The group discussed several important principles, while also acknowledging there is no one-size-fits-all prescription for research on the benefits of music-based interventions on the diverse trajectories associated with aging, and specific choices for experimental designs, interventions, and measurements depend on the disorder considered. Fundamental themes do emerge: The group emphasized the **importance of fundamental research to complement clinical applications** as well as **urging that neuroscientific and mechanistic conceptions be present even in research that is not overtly neuroscientific**, opening the way for ever-finer control of interventions and understanding of which individuals may or may not benefit. The group identified a number of principles that permeated their specific responses to the themes:

- **Observation 1: Music is multifaceted.** Music consists of many diverse elements that can be exploited to address specific aspects of cognition, function, or wellness: melody, harmony, rhythm, text, expression, communication, interaction, coordination, creativity, genre, familiarity, and execution, to name some. This very diversity is what may give music a great deal of power in its application to a variety of disorders, but it also poses a challenge to the design of appropriate research and/or applied protocols because it may not be clear which component(s) of music may have been responsible for any given effect.

Proposals: Interventions should be clearly specified in terms of an ontology of which components of music are thought to be the most critical to its efficacy, and thus arrange to experimentally modify those components while carefully controlling for others to test this. The group will present specific recommendations during the discussion. Important considerations about delivery method (live vs. recorded), intensity, accessibility, and practicality are equally important, as a key challenge is to establish objectively the intensity of intervention needed to observe clinical improvements. Finally, it is critically important to have appropriate proximal outcomes relevant to the musical intervention to complement more distal and clinical outcomes, in order to build a chain of evidence from intervention through proposed mechanisms to outcome.

- **Observation 2: *Music engages many neural systems.*** The research literature indicates that music engages many neural systems, including perception, sensory-motor, memory, attention, and emotion/reward.

Proposals: Applications of music to specific disorders should take into consideration the match between neural subsystems involved both in the disorder and in the intervention. To address a particular disorder, a researcher ought first to identify the networks that might be targeted by a musical intervention and then design the protocol accordingly. For example, in the case of gait abnormalities, it would be the motor system that would be engaged by the treatment. Or in the case of motivational problems or anhedonia, music's ability to recruit the reward system could be exploited. There are many existing measures of brain structure and function that should likewise be matched to the mechanistic hypothesis and will be discussed. This is not to suggest that every study become a neuroscientific study but that all studies provide mechanistic conceptual grounding that builds connections between clinical and fundamental research.

- **Observation 3: *Testing music-based interventions requires broad expertise and access to appropriate clinical populations.*** Expertise on mechanisms, music, medicine, and brain measurement and access to clinical populations are not always available at any one institution or research group, and is often difficult in practice due to disciplinary silos, reward structures, and funding.

Proposals: High-quality research thus requires interdisciplinary collaboration, and this can be supported by funding agencies through explicit funding for collaborative research, funding for preliminary explorations, and support for matchmaking and ultimately multisite studies. Looking outside the field to how other domains have made transitions from anecdote to clinical trial is useful. Building bridges takes time and is an essential, valuable activity in its own right.

- **Observation 4: *Basic, mechanistic, and clinical outcome research are mutually beneficial.*** Taken as axiomatic.
- **Observation 5: *Many principles for effective study design can be articulated.***

Proposals: In addition to proposals above, the choice of target population (e.g., relating to subtypes or severity of disorders), the control group, and the importance of studying time courses longitudinally (including longer-term followups) were emphasized. Providing analyzed "reference experiments" may be useful to illustrate these principles.

Patient Advocacy and Arts Organizations

The development of conceptual frameworks for music-based interventions (MBIs) is beset with the following challenges:

- The fact that MBIs may affect multiple domains of outcomes
- The need to include knowledge from a variety of disciplines and fields of practice

- Different components of music (e.g., rhythm and pitch), personal or cultural preferences (e.g., for musical genres), and modes of engagement (e.g., whether listening to or creating or performing music)

In addition, clinical evidence supporting conceptual models for MBIs remains limited and inconsistent in quality.

For music therapists, a “triangle” model involving coping, communication (verbal or nonverbal), and attachment or relationship building has been identified (note: this model has not yet been published). Group participants suggested that neurobiological and other elements could be integrated with this model for broader applicability across MBIs.

Interdisciplinary collaborations will prove necessary for pursuing MBI research in general. As an analogous field of practice that might yield comparable lessons for MBI, physical therapy was mentioned. In this case, cross-sector learning from areas such as exercise science and athletic training advanced the field to the extent that large clinical trials ultimately were adopted. (Traumatic brain injury was named as another field that led to standardized research approaches invoking multiple disciplines.)

Group participants agreed that an MBI investigative team should include consumers and caregivers but also, depending on the intervention or study, neuroscientists, members of the nursing profession, biostatisticians and bioinformatics experts, vascular neurologists, and psychiatrists and/or psychologists. Both clinical and mechanistic outcomes will be important to track, but so will studies of cost-benefit comparisons and quality-of-life outcomes. Pain, stress, and trauma were singled out as outcome areas worthy of study. Adaptive trial designs and ancillary studies of MBIs within larger clinical trials were championed, as was greater use of systematic reviews.

Panelists' Questions

Behavioral and Social Science Intervention Development Group

- What are the characteristics of an effective hypothesis?
- Based upon existing basic science, what are the potential active/required/essential components/ingredients for the music-based intervention?
- What are the primary domains (emotion, cognition, sensory, motor, etc.) to be included and what else should be captured?
- What should be considered to ensure fidelity of intervention delivery and outcome measures?
- Are there additional methodological research and trial design issues to be considered?
- What intervention strategies should be considered (delivery method: live vs. recorded, individual vs. group, in person vs. virtual, single vs. multimodal; optimization, adherence, fidelity)?

Clinical Trials Methodology Group

- What needs to be considered, scientifically, before a music-based intervention is adapted for a specific population and/or disease condition?
- What research questions require what types of specific comparator or control groups, and why?
- What are the key challenges related to blinding and/or randomization?
- What research designs and metrics are best for tracking mechanistic and clinical outcomes in response to music-based interventions?
- What are other study design considerations (recruitment and retention strategies, cross sectional vs. longitudinal, data collection, management and analysis, manual of operations)?
- Who should be included on the investigative team (interdisciplinary team with expertise in music therapy/music medicine, neuroscience, clinical trials methodology, behavioral interventions, and patient engagement)?

Music Therapy/Music Medicine Group

- What is the importance of conceptual frameworks for music-based interventions?

- What are supporting data for the proposed hypothesis (rationale, extant literature, rigor of existing data, knowledge from practice)?
- How to decide on the characteristics of the proposed intervention (type, intensity, dose, frequency and duration, population)?
- What are critical intervention strategies (delivery method: live vs. recorded, individual vs. group, in-person vs. virtual, single vs. multimodal; optimization, adherence, fidelity) to consider?
- Who should be included in the investigative team (interdisciplinary team with expertise in music therapy/music medicine, neuroscience, clinical trials methodology, behavioral interventions, and patient engagement)?

Neuroscience Group

- What are the characteristics of an effective hypothesis?
- What are supporting data for the proposed hypothesis (rationale, extant literature, rigor of existing data, knowledge from practice)?
- Based upon existing basic science, what are the potential active/required/essential components/ingredients for the music-based intervention?
- How can change processes be studied, at the behavioral, affective, and neurobiological levels, in studies determining the effect of music interventions on diseases of aging?
- What are metrics to track mechanistic outcomes—neural, physiological, behavioral; and clinical outcomes—health status, quality of life, function?

Patient Advocacy and Arts Organization Group

- What is the importance of conceptual frameworks for music-based interventions?
- What are supporting data for the proposed hypothesis (rationale, extant literature, rigor of existing data, knowledge from practice)?
- What are the most critical outcome measures (metrics to track mechanistic outcomes—neural, physiological, behavioral; and clinical outcomes—health status, quality of life, function)?
- Who should be included on the investigative team (interdisciplinary team with expertise in music therapy/music medicine, neuroscience, clinical trials methodology, behavioral interventions, and patient engagement)?
- Are there additional methodological research and trial design issues to be considered?

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