National Institutes of Health (NIH)

Research Plan on Rehabilitation

National Institutes of Health
Turning Discovery Into Health

NIH Pub. No. 21-HD-8171
October 2021

National Institutes of Health (NIH) Research Plan on Rehabilitation

2021

U.S. Department of Health and Human Services (HHS)

Developed by the National Center for Medical Rehabilitation Research,
in consultation with the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, NIH, the NIH Medical Rehabilitation Coordinating Committee, and the National Advisory Board for Medical Rehabilitation Research

Table of Contents

Executive Summary

Rehabilitation seeks to improve the function and participation of the millions of Americans living with disabilities. In concept, rehabilitation addresses the whole person—from basic biological processes and functional impairments, to multisystem body responses and structural changes, to assistive supports and mobility aids and community and family integration—as well as environmental and societal supports or barriers. The goal of rehabilitation is to help all people achieve and maintain their full potential.

The National Center for Medical Rehabilitation Research (NCMRR) within the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, part of the National Institutes of Health (NIH), coordinates federal medical rehabilitation research. NCMRR leads the effort to update and publish this research plan on rehabilitation in collaboration with the NIH Medical Rehabilitation Coordinating Committee, which includes other NIH Institutes, Centers, and Offices that support and conduct rehabilitation research.

The 2021 NIH Research Plan on Rehabilitation reports on the agency's progress since the 2016 research plan by examining the investments and activities in six theme areas identified as priorities in the 2016 plan: A: Rehabilitation Across the Lifespan, B: Community and Family, C: Technology Use and Development, D: Research Design and Methodology (includes Clinical Trials), E: Translational Research, and F: Building Research Capacity and Infrastructure.

This plan also outlines the changes in NIH's rehabilitation research investment, which was $847 million in Fiscal Year 2020, a significant increase from the $514 million in Fiscal Year 2015, prior to the publishing of the 2016 plan. The 2021 plan also includes revised research objectives within the six themes established in 2016 and describes collaborations with other agencies.

Changes to this plan were informed by input from the research and consumer communities. In April 2019, NCMRR sought public comment on progress since the 2016 plan through a Request for Information. Working with the National Advisory Board for Medical Rehabilitation Research, NCMRR also solicited individual feedback from researchers at three public meetings in December 2019, August 2020, and December 2020.

The NIH-hosted virtual conference, *Rehabilitation 2020: Envisioning a Functional Future*, in October 2020 included individual input from targeted breakout sessions on each research theme. Finally, the revised research objectives were made available for public comment in September 2020.

The 2021 NIH Research Plan on Rehabilitation will guide the rehabilitation research community in continued efforts to improve the health and lives of people across a wide range of ability levels.

Foreword on COVID-19 and Health Disparities

Shortly after work on this document commenced in the fall of 2019, the world changed in an unprecedented manner, as the greatest public health emergency in a century occurred. Although some research has shown the extent of the COVID-19 pandemic's impact on the lives of people with disabilities and on the field of rehabilitation research, these challenges are still unfolding and have yet to be fully determined.

The authors of this plan reflected on how to address current events without changing the whole focus to address COVID-19 illness and recovery or the impact of COVID-19 mitigation strategies on people with disabilities. Rehabilitation research needs existed before the pandemic and will continue after it is remediated. However, we recognize that events of 2020 will influence biomedical research in the future, and how the needs of people with disabilities are addressed.

The COVID-19 pandemic has created an environment in which virtual work, school, recreation, worship, and healthcare experiences are more common, almost expected. This dramatic shift may have large repercussions on accessibility and inclusion of people with disabilities in their communities and schools. Despite the immense potential of these expanded opportunities, accessibility and access to virtual environments are not guaranteed. Moreover, this new virtual era only heightens the need to overcome barriers to inclusion and accessibility not only in society and medicine, but also in research and community services.

Although certain aspects of the plan's research objectives were adapted to address needs raised or exacerbated by the pandemic, the authors intentionally did not create a research objective focused on COVID-19 to ensure a consistent focus on rehabilitation. Those interested in pandemic-specific research activities should consult the National Institutes of Health (NIH) Strategic Plan for COVID-19 Research (PDF 3.5 MB).

Finally, we would be neglectful if we did not address the need for more research on health disparities that has been made apparent by the COVID-19 pandemic. We recognize that the disability rights movement of the 1970s, which led to the Rehabilitation Act of 1973, the Americans with Disabilities Act, and the establishment of the National Center for Medical Rehabilitation Research in 1990, emerged from the Civil Rights movement.

We cannot fully address rehabilitation needs without also addressing health disparities and health inequities for individuals with disabilities. Even though there is a specific research objective on health disparities in this plan, the other research objectives are only achievable with inclusion and diversity. The NIH rehabilitation research community actively participates in the broader efforts of NIH to address health disparities and increase the overall diversity of the scientific workforce.

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Eunice Kennedy Shriver National Institute of Child Health and Human Development
On behalf of the NIH Medical Rehabilitation Coordinating Committee

Introduction

The Need for Rehabilitation Research

About 26% of Americans—1 in 4 adults—have at least one disability of some kind[1,2]. Self-care tasks, like dressing or bathing, and skills necessary for independent living are difficult for 34 million Americans. About 44 million Americans have a disability that impairs mobility, causing serious difficultly walking or climbing stairs. Cognitive disability is also common, with 35 million Americans estimated to have difficulty concentrating, remembering, or making decisions. Disabilities associated with sensory abilities are also widespread; about 19 million American adults report having serious hearing difficulties or deafness, and about 16 million Americans having serious visual impairments or blindness.

When setting national health priorities as part of the Healthy People 2020 initiative, the Department of Health and Human Services documented[3] that individuals with disabilities are more likely to experience health disparities than those without disabilities. People with disabilities are more likely to experience delays or difficulties in accessing health care, have fewer preventive tests or procedures (e.g., Pap tests or mammograms), spend less time on fitness activities, and have higher rates of tobacco use and obesity than the general population. Furthermore, the Agency for Healthcare Research and Quality (AHRQ) noted[4] that patient-centered care, which is supported by good provider-patient communication, can be impaired by the effects of disabilities on patients' healthcare experiences.

Disability affects not only those who experience these challenges firsthand but also those who support or care for them. Based on data[5] from the Bureau of Labor Statistics, the Pew Research Center estimates that one in seven U.S. adults provides unpaid care of some kind to another adult. Even though caregiving is often viewed[6] as meaningful, people who provide care can experience emotional stress, poor health, decreased opportunity to work, financial strain, and decreased ability to participate in social or community roles.

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[1] Okoro, C.A., et al. (2018). Prevalence of Disabilities and Health Care Access by Disability Status and Type Among Adults - United States, 2016. *MMWR Morb Mortal Wkly Rep, 67*(32): 882-887.
[2] Centers for Disease Control and Prevention, HHS. (2019). Disability and Health Data System (DHDS). https://www.cdc.gov/ncbddd/disabilityandhealth/dhds/index.html
[3] Peacock, G., et al. (2015). Health Care for Americans with Disabilities--25 Years after the ADA. *N Engl J Med, 373*(10): 892-893.
[4] 2018 National Healthcare Quality and Disparities Report. Rockville, MD: Agency for Healthcare Research and Quality; September 2019 (last reviewed April 2020). AHRQ Publication No. 19-0070-EF. https://www.ahrq.gov/research/findings/nhqrdr/nhqdr18/index.html.
[5] U.S. Bureau of Labor Statistics, American Time Use Survey: https://www.bls.gov/tus/.
[6] Pew Research Center Analysis of 2012-2017 American Time Use Survey Data, 2018. https://www.pewresearch.org/fact-tank/2018/11/08/adult-caregiving-often-seen-as-very-meaningful-by-those-who-do-it/

The extent of disability in the United States and its widespread public health impact on families and communities require a response aimed at improving function, activity, and participation for people with disabilities. The primary aims of rehabilitation research at the National Institutes of Health (NIH) are to improve rehabilitation and habilitation approaches for individuals with disabilities and to gain knowledge about the underlying diseases that cause disability. The 21st Century Cures Act (P.L. 114-255) defines medical rehabilitation research as "the science of mechanisms and interventions that prevent, improve, restore, or replace lost, underdeveloped, or deteriorating function" for people with disabilities in the context of their environment[7]. Function includes a person's body system performance, ability to complete activities and participate in society, and satisfaction with their quality of life.

Rehabilitation research faces many methodological challenges that have parallels in other areas of medicine. Those who could benefit from this research may have limitations—in transportation, mobility, finances, and access to information—that can interfere with their participation in research studies. These factors, in turn, place significant limitations on researchers' ability to conduct appropriately powered studies. Novel study designs that incorporate real-world measures and community-based interventions provide opportunities to engage people with disabilities outside the laboratory environment. Although NIH has made significant investments in developing and validating the psychometric properties of patient-reported outcomes, many outcome metrics rely on more subjective self-report and individual clinician measurements, which can vary over time. Despite the urgent need for evidence-based therapies, conducting a tightly controlled study can be difficult. Finding a well-matched comparison group also poses significant challenges. Masking the treatment and control conditions, which is useful to ensure an impartial analysis of the results, can be problematic in rehabilitation research.

Despite incredible progress over the past 30 years, new directions and challenges are apparent and underlie the need for revised priorities to advance rehabilitation science.

NIH's Commitment to Rehabilitation Research

The Americans with Disabilities Act and the subsequent NIH Amendments of 1990 (P.L. 101-613) provided for the establishment of the National Center for Medical Rehabilitation Research (NCMRR) within the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), one of NIH's 27 Institutes and Centers (ICs). NCMRR's mission[8] is to reduce disability by conducting and supporting research and research training and career development in medical rehabilitation. The establishing legislation requires NIH to develop a comprehensive research plan for rehabilitation that encompasses: 1) current medical rehabilitation research activities conducted or supported by the federal government; 2) opportunities and needs for additional research, and priorities for such research; 3) recommendations for the

[7] 42 USC 285g-4(h) (Sec. 452): https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section285g-4&num=0&edition=prelim
[8] 42 USC 285g-4 (Sec. 452): https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section285g-4&num=0&edition=prelim

coordination of such research conducted or supported by NIH and other federal government agencies; and 4) goals and objectives for conducting, supporting, and coordinating medical rehabilitation research, consistent with the purpose of NCMRR.

NCMRR's authorizing language was further amended in 2016 as part of the 21st Century Cures Act to clarify NCMRR's role as coordinator of rehabilitation research at NIH, in conjunction with the trans-NIH Medical Rehabilitation Coordinating Committee (MRCC), and to direct NCMRR to revise the research plan no less than every five years. This document fulfills the latter requirement.

The nearly 30 years since the establishment of the NCMRR have featured several noteworthy efforts:

- In 1993, NCMRR published its first research plan for rehabilitation, including a conceptual model of disability that incorporated scientific principles and social values.
- In 1995, NCMRR established rehabilitation training programs in multiple rehabilitation-focused disciplines to increase the number of people entering the field.
- In 2004, NCMRR created a research infrastructure network to provide consultation, training, education, and small pilot-grant opportunities in diverse fields including simulation research, neuromodulation, commercialization, analysis of publicly available data, genomics, and other individual markers of rehabilitation intervention and outcome.
- In 2012, the Director of NIH convened a Blue Ribbon Panel on Medical Rehabilitation Research to assess the state of rehabilitation research at NIH and determine how NCMRR and NIH could catalyze and support rehabilitation research across the agency.
- In 2016, NCMRR, the NIH MRCC, and the National Advisory Board on Medical Rehabilitation Research (NABMRR) published an updated NIH Research Plan on Rehabilitation: *Moving the Field Forward* (PDF 443 KB).
- In 2017, President Obama signed the 21st Century Cures Act, which included language to improve medical rehabilitation research at the NIH. This law called for a revised research plan not less than every five years. It also defined medical rehabilitation research[9] as "the science of mechanisms and interventions that prevent, improve, restore, or replace lost, underdeveloped, or deteriorating function."
- In 2020, NIH hosted the *Rehabilitation Research 2020: Envisioning a Functional Future* conference.

This research plan takes roughly the same form as the 2016 plan and demonstrates the progress and investments by NIH in the six thematic areas defined in that plan. This

[9] 42 USC 285g-4(h) (Sec. 452): https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section285g-4&num=0&edition=prelim

plan also represents an integrated and comprehensive vision from stakeholders across NIH and includes revised research objectives that were informed by input from the MRCC and NABMRR, individual input from public meetings (December 2019, August 2020, and December 2020) and the virtual scientific conference held in 2020, as well as from the larger rehabilitation research community through Requests for Information (NOT HD-19-006 and NOT HD-20-033) and a crowdsourcing platform called IdeaScale.

This plan will guide NIH's support for rehabilitation programs and projects until 2026 and advance the science of rehabilitation medicine across the conditions, diseases, and syndromes that challenge individuals with disabilities. These efforts aim to optimize individuals' functional abilities, address physical and environmental barriers, and ensure that individual, family, and community voices are heard and included in the rehabilitation interventions.

NIH Rehabilitation Research Activities (2016 to 2020)

Rehabilitation research is a dynamic field that benefits from extensive investments by NIH to understand basic biological mechanisms; improve access to data related to rehabilitation care and outcomes; and develop new tools and technological applications in medical diagnostics, imaging, bioinformatics, regenerative medicine, and assistive technology and mobility devices. Rehabilitation research has always included a wide range of medical and allied disciplines, but today requires even more expertise, demanding an integrative view of disability, fostering collaborations, and expanding opportunities to enhance abilities, increase participation, and improve human health.

NIH's rehabilitation research portfolio is broad and reflects the agency mission "to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability," as well as the specific missions of the various Institutes, Centers, and Offices (ICOs) involved with this research. The portfolio encompasses the full range of biomedical, behavioral, and social sciences research, from basic to applied, across most ICs that fund extramural research. In addition, the NIH Common Fund, within the NIH Office of the Director, funds cross-cutting, trans-NIH scientific programs that are high-impact, transformative, and designed to achieve specific, high-impact goals and milestones within a 5- to 10-year timeframe. The Common Fund supports several programs that align with rehabilitation research goals and allows for a strategic and nimble approach to addressing key roadblocks in biomedical research and capitalizing on emerging opportunities.

The last five years have also seen the creation of several large Common Fund and trans-NIH programs that incorporate rehabilitation research, including the NIH Health Care Systems Research Collaboratory and the Stimulating Peripheral Activity to Relieve Conditions program in the Common Fund, and the Brain Research through Advancing

Innovative Neurotechnologies® (BRAIN) and NIH Helping to End Addiction Long-term℠ (HEAL) Initiatives.

The following analysis illustrates NIH's funding efforts within the six themes established in the 2016 plan and continued in the 2021 Research Plan on Rehabilitation. Since 2015, rehabilitation projects were awarded by 24 of the 27 NIH ICs and the NIH Office of the Director.

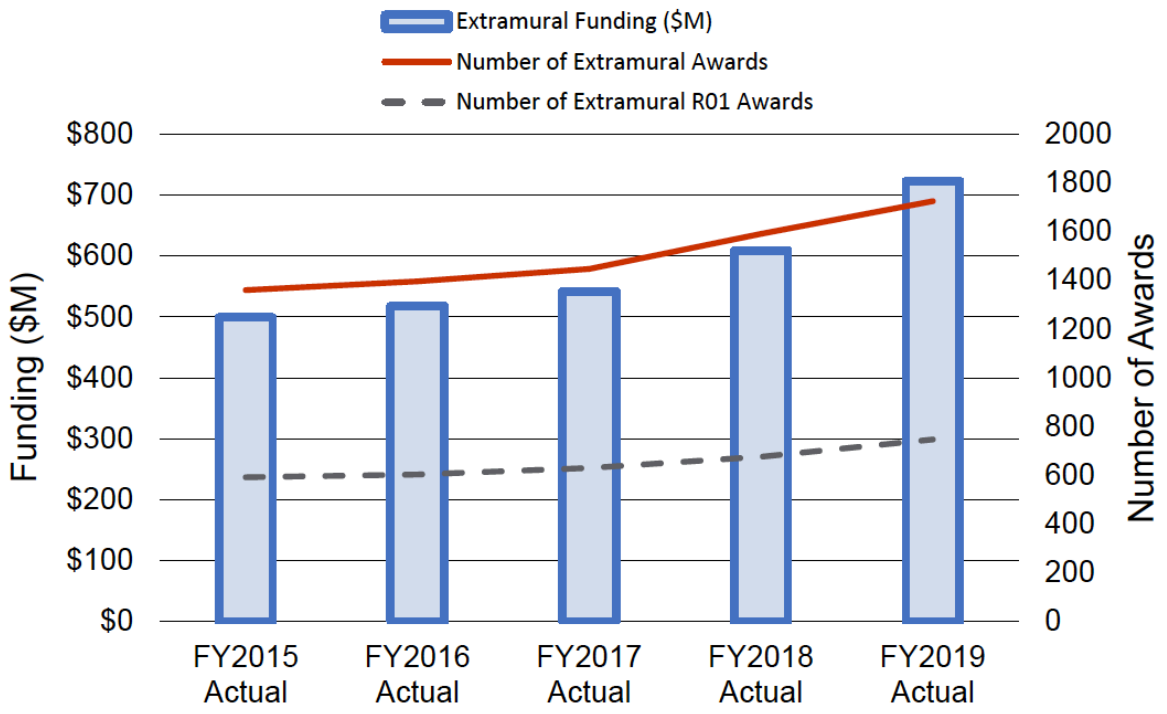

Figure 1: NIH rehabilitation extramural funding in millions of dollars (bars), number of all extramural awards (solid line), and number of R01 awards (dashed line)

Further analysis of the "rehabilitation" category in the NIH's Research, Condition, and Disease Categorization (RCDC) system, a computerized process NIH uses to organize and consistently report funding levels for more than 280 RCDC categories, showed the following trends for the years 2015 through 2020:

- The number of, and total funding for, NIH extramural rehabilitation awards increased each year in the timeframe (Figure 1). Specifically, there was a:
    - 49-percent increase in overall funding
    - 32-percent increase in number of awards
- The number of R01 awards steadily increased from 592 in 2015 to 747 in 2019, or about 43 percent of the total funded rehabilitation awards each year, and 51 percent to 55 percent of the total funding. R01s reflect independence and

promotions at academic institutions and help to build the workforce and research pipelines.

- Training grants accounted for 15 percent to 17 percent of the total extramural awards and about 5 percent of extramural funding each year (Figure 2). Training and career development grants help researchers gain experience to progress through the funding pipeline.
    - The funding investment for F and T awards was steady across years, but the funding for K awards generally increased across years.
    - Similarly, there were small fluctuations in the number of F and T awards and a general increase in the number of K awards.

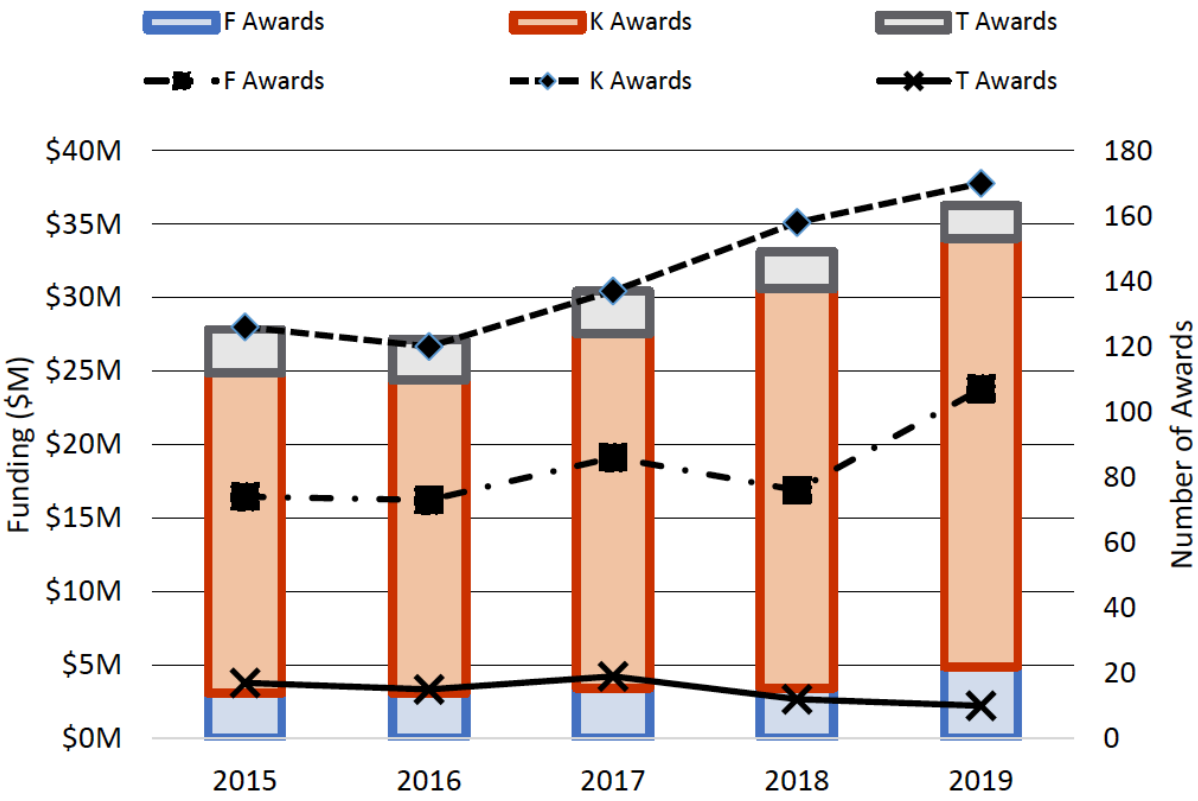

Figure 2: NIH funding for rehabilitation research training in millions of dollars (bars), total and by award type, and numbers of rehabilitation training awards by award type (lines)

Table 1: NIH rehabilitation portfolio: Scientific influence and translational science metrics, for Fiscal Years 2015 to 2019

Year	2015	2016	2017	2018	2019
Total Publications	36,287	39,135	34,039	32,263	44,748
Publications/Year	885.0	931.8	830.2	768.2	1065.4
Max Relative Citation Ratio (RCR)	220.00	208.90	208.90	208.90	209.38
Mean RCR	2.19	2.08	2.06	2.04	2.10
Median RCR	1.26	1.19	1.19	1.19	1.10
Average Approximate Potential to Translate	45.3%	42.5%	41.6%	39.8%	41.8%
Number of Publications Cited by a Clinical Document	11,751	11,676	9,663	8,707	13,742

Table 1 provides metrics on the scientific influence and translational science data for the NIH rehabilitation research portfolio for 2015 to 2019. These data were pulled from the Research Portfolio Online Reporting Tool Expenditures and Results database on September 21, 2020.

The relative citation ratio (RCR) is a citation-based measure of a paper's scientific influence[10] adjusted for time and field. The citations per year of a paper are normalized to the citations per year by all NIH-funded papers in the same field and year. The median NIH RCR is 1.0 for all fields. An RCR number greater than 2 indicates that, relative to the average NIH-funded paper in this field, papers resulting from awards in the NIH rehabilitation portfolio are being cited more than twice as often per year. In general, publications with high citation rates are viewed as seminal research papers, review articles, or methods papers.

The average approximate potential-to-translate metric is a machine learning-based estimate of the likelihood that a paper will be directly cited by later clinical articles. Many publications are cited by a clinical document (26 percent to 32 percent per year), and this measurement is often used as a "soft" indicator of research being translated into practice.

[10] Hutchins, B.I., et al. (2016). Relative Citation Ratio: A new metric that uses citation rates to measure influence at the article level. *PLoS Biol, 14*(9): e1002541. doi:10.1371/journal.pbio.1002541.

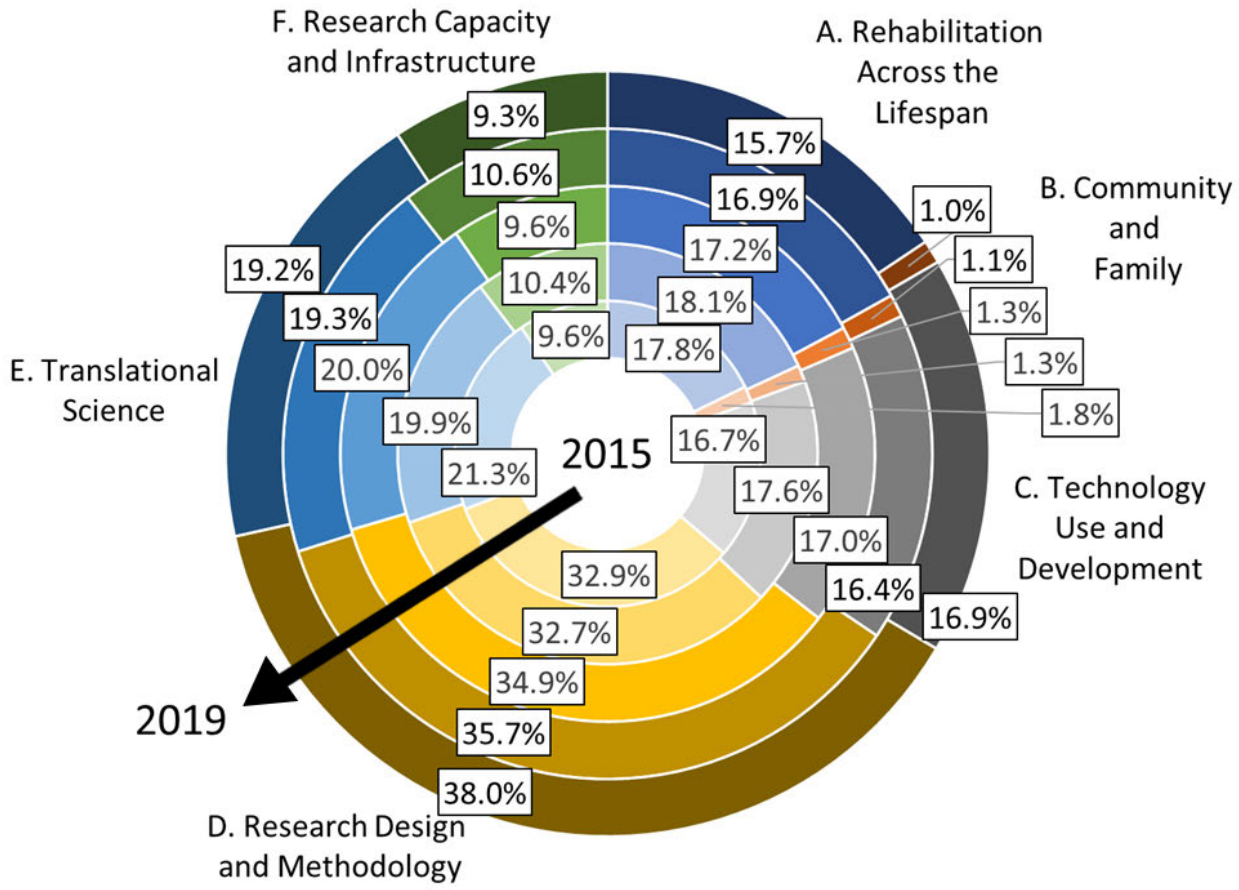

Figure 3: Primary theme classification of grants (in percentages) for the total NIH rehabilitation portfolio, for fiscal years 2015 (inner rings/lightest colors) to 2019 (outer rings/darker colors); original figure published in Jackson & Cernich, 2020[11]

Each grant in the official NIH rehabilitation RCDC category was assigned a primary[11] and a secondary theme, based on those defined in the 2016 plan[12]. These themes include:

- A: Rehabilitation Across the Lifespan
- B: Community and Family
- C: Technology Use and Development
- D: Research Design and Methodology (includes Clinical Trials)
- E: Translational Research

[11] Jackson, J.N. & Cernich, A.N. (2020). NIH Rehabilitation Research Plan: Analysis and Progress. *Arch Phys Med Rehab. 101*(8): 1313-1321. 10.1016/j.apmr.2020.04.005.
[12] NIH Research Plan on Rehabilitation: Moving the Field Forward. (2016). https://www.nichd.nih.gov/sites/default/files/publications/pubs/Documents/NIH_ResearchPlan_Rehabilitation.pdf (PDF 443 KB).

- F: Building Research Capacity and Infrastructure

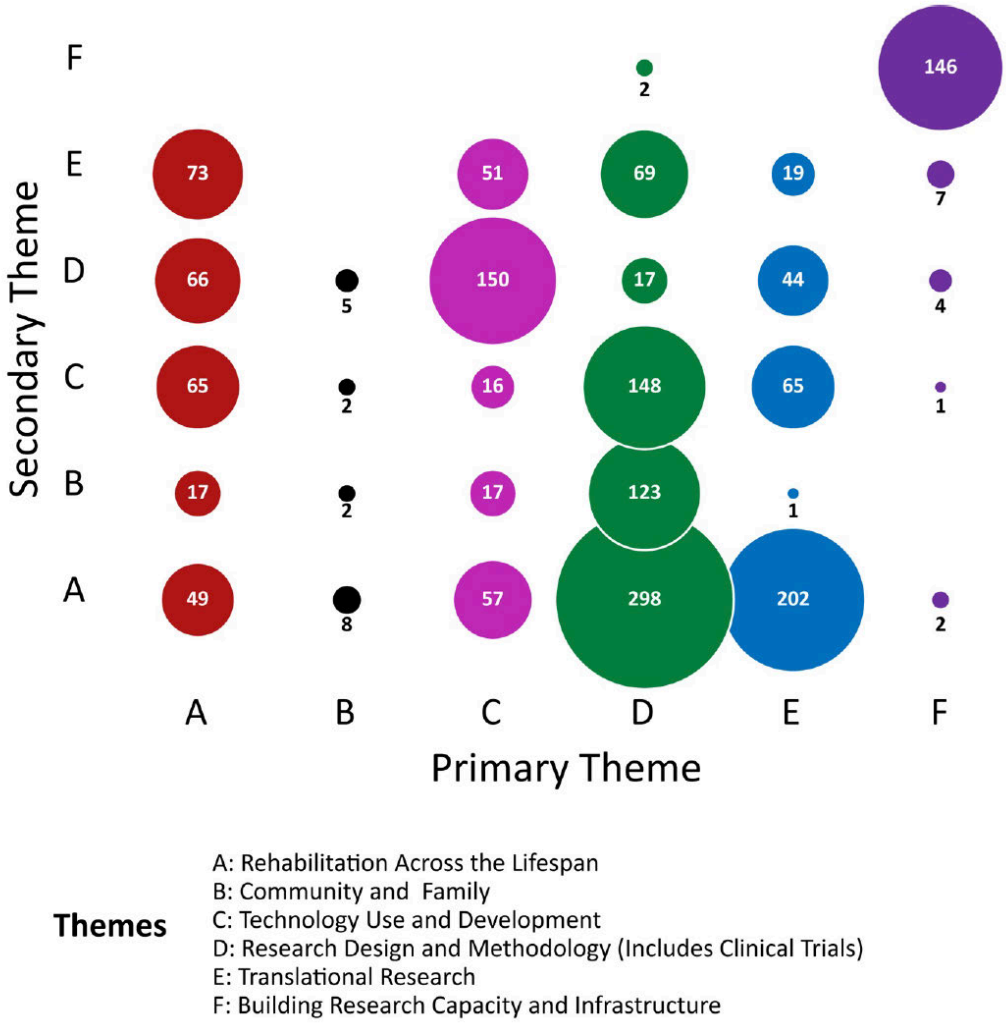

Figure 4: Primary (x-axis) and secondary (y-axis) theme pairings and number of grants for each paring of 2019 rehabilitation data mapped to the 2016 NIH Research Plan on Rehabilitation themes

Some projects only had a primary theme (e.g., A-A, B-B, etc.). A noticeable gap exists for Community and Family (Theme B) research. While Theme B was not typically a primary theme, about 7 percent to 9 percent of projects have a secondary Theme B, usually when paired with the theme D (Figure 4). It may be difficult to determine primary interest in community and family research over time because of coding rules (e.g., clinical trials default to primary Theme D). It is also worth noting that 8 percent to 10 percent of all rehabilitation grants were categorized as Training and Infrastructure (Theme F) only. Of the remaining grants, 16 percent to 18 percent had Theme F as a tertiary category based on the funding activity.

Figure 5: Word cloud representation (i.e., larger type indicates more funding) of RCDC categories for 2019 NIH rehabilitation portfolio

An additional way to examine rehabilitation funding at NIH is to look at the overlapping categorization of rehabilitation grants. Many projects within the rehabilitation category also fall into other RCDC groups. Figure 5 is a representation of NIH's Fiscal Year 2019 spending on rehabilitation awards in RCDCs other than rehabilitation. The size of the word indicates the associated amount of funding (i.e., larger word indicates more funding). Clinical research, neurosciences, and behavioral and social science are the top three overlapping categories; rehabilitation is common to all awards.

Another way to analyze the NIH rehabilitation portfolio is using topic maps. We used machine-learning techniques to assign grants to one or more of 50 topics, based on the frequency of associated key words that appear in grant abstracts for each fiscal year; topics with five or more grants in common were considered "connected." Figure 6

features topics with at least 15 projects for Fiscal Year 2019. The size of the circles indicates the number of grants in that topic, so a larger circle (i.e., sound perception and processing) indicates more grants than a smaller circle, (i.e., stroke rehabilitation). Similarly, the thickness of the connecting lines indicates the number of overlapping grants between topics, with a thicker line (i.e., career development to research centers and cores) indicating more overlapping grants than a thinner line (i.e., interventions to pain management).

The colors indicate the overall grant category clusters for each topic; the five overall topics were originally chosen based on most frequent abstract terms and manual inspection of the grants assigned to that topic in 2015 and maintained across years. Of the 50 topics each year that were used most frequently in terms and the project titles, 17 topics were common across all years.

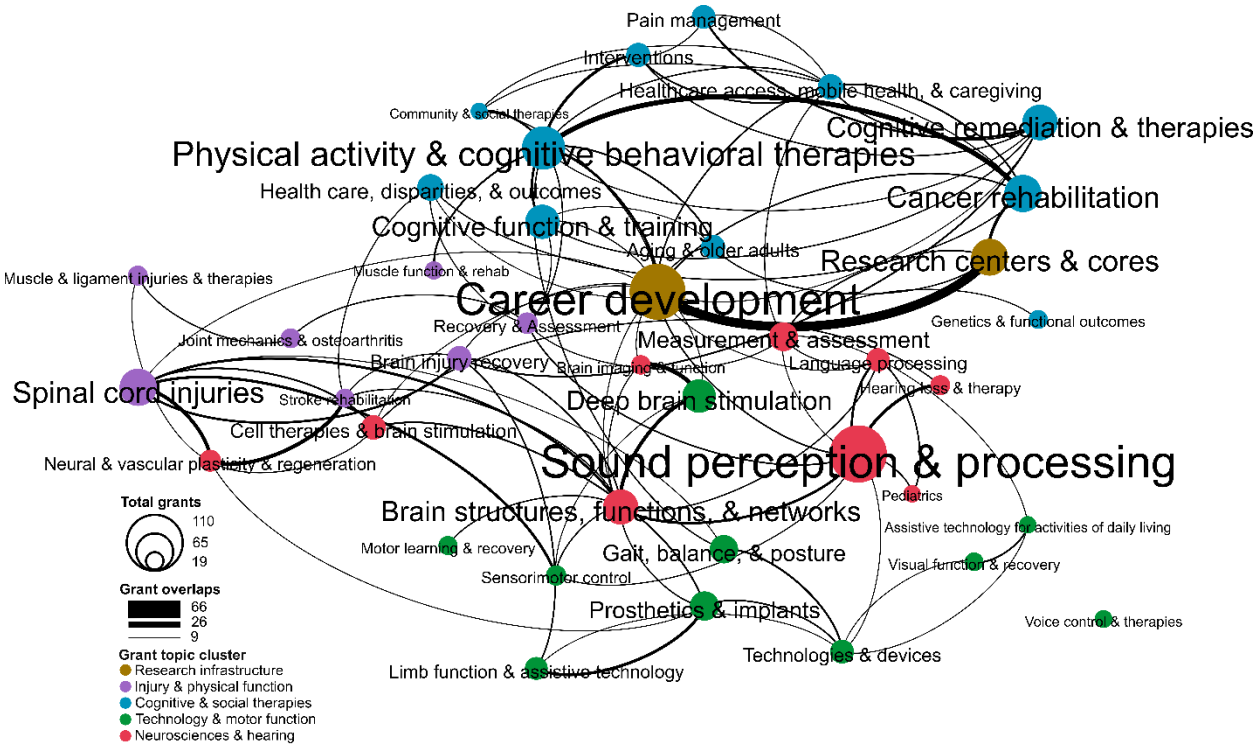

Figure 6: Latent Dirichlet Allocation Topic Map for the 2019 Rehabilitation Portfolio

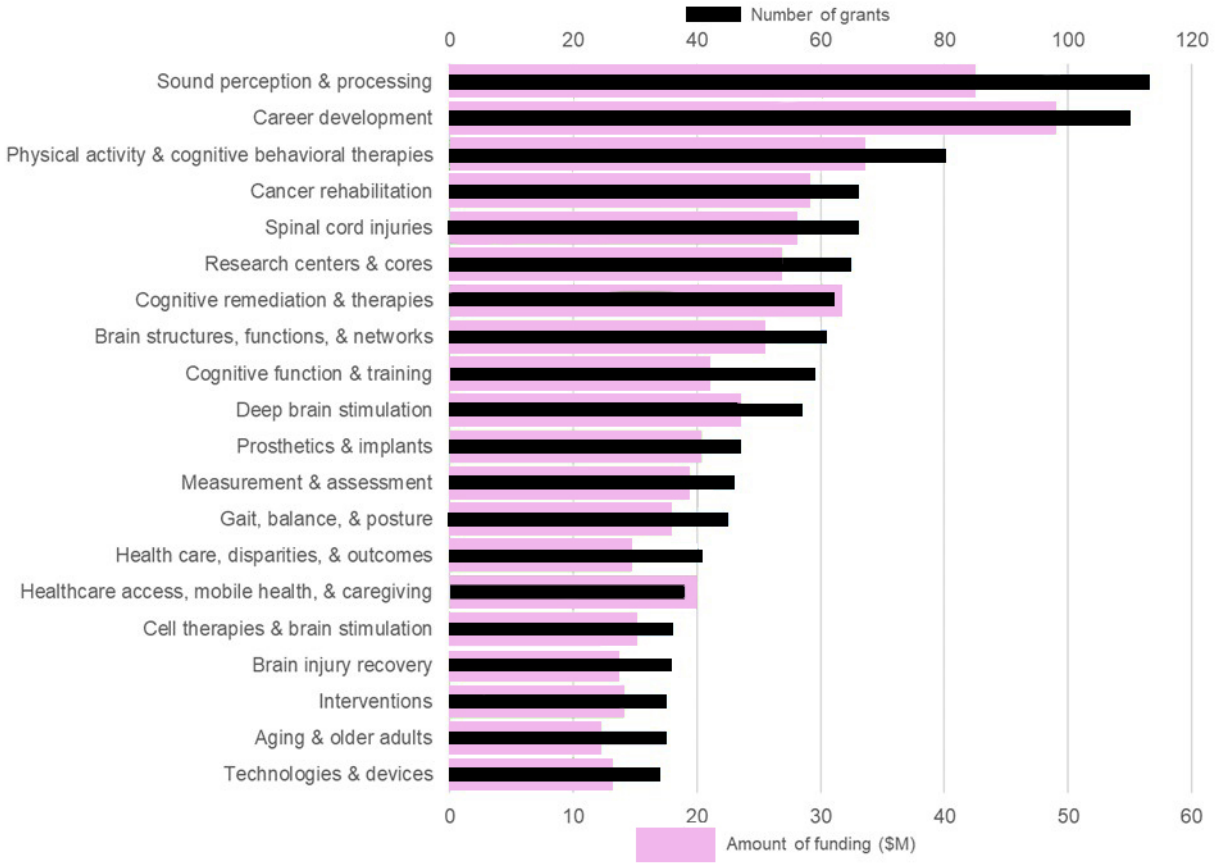

Figure 7: Number of grants and funding per topic in the 2019 rehabilitation portfolio. The top axis is the number of grants (thin bar) and the bottom axis is the amount of funding in millions of dollars (thick bar).

The top 20 topics extracted from the machine-learning analysis are listed in descending order by number of grants in Figure 7. Career development had the most funding and the second highest number of grants, further illustrating NIH's commitment to the rehabilitation research workforce pipeline. Because training grants tend to be less expensive than R01s and other awards, the funding amount is typically less than that of other topics, but more projects were grouped into this category in 2019 than in previous years.

The continual growth of the NIH rehabilitation portfolio each year is encouraging. Using this analytical framework now in place, NIH can continue these analyses into the next phase of the NIH Research Plan on Rehabilitation to track progress, incorporating new metrics and data as they become available.

Progress on the 2016 Research Plan

It is clear from the analyses that not all research themes from the 2016 plan advanced at the same rate. The data suggest that although strong investments were made in Research Design and Methodology and Translational Science (Themes D and E), the response to the Community and Family (Theme B) topic was less robust.

The following section describes specific programmatic efforts by NIH to advance the research themes of the 2016 plan. These lists are not comprehensive—most NIH funding continues to be investigator-initiated—but the descriptions are meant to illustrate ways in which NIH has implemented the 2016 plan.

Progress on Theme A: Rehabilitation Across the Lifespan

In addition to typical lifespan considerations, this theme includes comorbidities and human factors, such as racial and ethnic diversity, socioeconomic status, and gender identity. NIH has taken several concrete steps to address parts of this theme, including:

- In 2017, NIH announced the Inclusion Across the Lifespan Policy to strengthen its stance that research must include children and older adults unless there are scientific or ethical reasons not to include them. Additionally, grantees are required to report data on participant age at enrollment in progress reports.
- The National Institute on Aging (NIA) issued a Request for Applications (RFA) (RFA-AG-18-016) to solicit R01 applications on tailoring cardiac rehabilitation to enhance participation of older adults.
- NCMRR/NICHD published an RFA (RFA-HD-20-005) soliciting R01 applications for pediatric rehabilitation research.
- In 2019, through its StrokeNet program, the National Institute of Neurological Disorders and Stroke (NINDS) launched the I-ACQUIRE study, a Phase III multisite, randomized, controlled trial comparing two dosages of intensive pediatric rehabilitation for infants born with perinatal arterial stroke.
- NICHD and NINDS partnered with the NIH Office of Disease Prevention (ODP) to develop and implement a Pathways to Prevention Program. Convened in 2020, the program assessed and synthesized the evidence base on physical activity interventions for people who use wheeled mobility devices.
- NCMRR is working with the Department of Defense (DoD) to create a limb loss and preservation registry to better understand the surgeries and devices used by civilian and military amputees across the lifespan.
- In 2017, NINDS, NCMRR, the NIH Office of Research in Women's Health (ORWH), and Defense and Veteran's Brain Injury Center hosted the *Understanding Traumatic Brain Injury (TBI) in Women* workshop.
- NCMRR partnered with the Centers for Disease Control and Prevention (CDC) to add disability-related questions to the ongoing Pregnancy Risk Assessment

Monitoring System (PRAMS) to better understand the needs and reproductive health experiences of women with functional limitations.

- As part of the NIH HEAL Initiative[SM], several rehabilitation programs to treat pain were funded and are ongoing:
    - The Back Pain Consortium Research Program is a translational, patient-centered effort to address the need for effective and personalized therapies for chronic low back pain. It will examine biomedical mechanisms within a biopsychosocial context by using interdisciplinary methods and exploring innovative technologies.
    - The Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing project will support multiple pragmatic trials to conduct research embedded in healthcare systems. These include:
        - Determining whether physical therapy plus transcutaneous electrical nerve stimulation in women with fibromyalgia is more effective than physical therapy alone at community physical therapy clinics
        - Employing primary spine practitioners, such as chiropractors and physical therapists, as first-line providers of nondrug care for low back pain

Progress on Theme B: Community and Family

As demonstrated by the data provided in the previous section, this theme continues to be a gap area in the NIH research portfolio. Efforts taken by NIH to support research in this theme include:

- The National Heart, Lung, and Blood Institute issued an RFA (RFA-HL-18-019) soliciting applications to increase the use of cardiovascular and pulmonary rehabilitation in traditional and community care settings.
- In 2018, the National Institute on Nursing Research (NINR) and the NIA issued a joint Program Announcement (PA) (PA-18-376) for R01 applications on self-management for health in chronic conditions.
- Led by the NIH ODP, a trans-NIH Funding Opportunity Announcement (FOA) (PAR-17-306) was published inviting projects that test interventions for health-enhancing physical activity, with specific language for rehabilitation research. After the FOA expired, a new Notice of Special Interest (NOSI) (NOT-OD-21-087) was issued in April 2021. This NOSI encourages highly innovative and promising translational research to improve understanding of ways to increase and maintain health-enhancing physical activity and includes specific language for research focused on individuals with disabilities.
- Following individual input from the 2017 NINR-led Summit, *Science of Caregiving: Bringing Voices Together*, NINR published a PA (PAR-19-023) on addressing caregiver symptoms through technological tools.

- NIH's Basic Behavioral and Social Science Opportunity Network (OPPNET), in conjunction with several NIH institutes, published a pair of FOAs (PAR-19-373, PAR-19-384) for research on biopsychosocial factors of social connectedness and isolation on health, wellbeing, illness, and recovery that included specific language on rehabilitation research.
- NIH made concerted efforts to seek individual input from consumers of rehabilitation services and their caretakers in the planning and conduct of NIH-sponsored meetings related to rehabilitation research, including:
    - Pathways to Prevention Program to assess and synthesize the evidence base on physical activity interventions for people who use wheeled mobility devices
    - The NINDS- and NCMRR-sponsored *SCI 2020: Launching a Decade for Disruption in Spinal Cord Injury (SCI) Research*
    - December 2019 NABMRR meeting session entitled Teaming with Participants to Improve the Validity and Rigor of Rehabilitation Research (PDF 2.2 MB)

Progress on Theme C: Technology Use and Development

NIH has made strong investments in this thematic area, as evidenced by the portfolio analysis earlier in this document. In addition, NIH has targeted several specific areas for additional development:

- NCMRR and the National Science Foundation (NSF) hosted the *Can Technology Make a Difference in Pediatric Rehabilitation?* workshop.
- NCMRR, NINDS, the Department of Veterans Affairs (VA), DoD, and the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) hosted a workshop entitled *Optimizing the Investment in Medical Devices for Rehabilitation*.
- In collaboration with other NIH institutes, the National Institute of Biomedical Imaging and Bioengineering (NIBIB) leads efforts for FOAs on Bioengineering Research Partnerships, with specific rehabilitation language.
- NINR and the National Institute on Deafness and Other Communications Disorders (NIDCD) issued a PA (PA-18-146) for R01 applications on self-management interventions and technologies to sustain health and optimize functional capabilities.
- The NIH Small Business Innovation Research and Small Business Technology Transfer Research programs have been and continue to be major supporters of rehabilitation and assistive technologies activities.
- Fogarty International Center, NIBIB, NICHD, National Institute of Mental Health (NIMH), NINDS, National Cancer Institute (NCI), NIH Office of Behavioral Health and Social Science Research (OBSSR), and ORWH issued a PA (PA-19-376) to

solicit applications on mobile health technology and outcomes in low- and middle-income countries.

- In collaboration with NSF, 21 NIH ICOs participate in the Smart and Connected Health Program (NOT-OD-18-149), which includes specific language for rehabilitation engineering. The announcement was initially published in 2018, and it is notable that 11 additional NIH ICOs joined the reissued announcement.
- NIBIB supports a P41 Biomedical Technology Resource Centers (PAR-18-205) program, with contributions from NCMRR, that includes rehabilitation-specific language.
- As part of the NIH BRAIN Initiative, many ICOs have made large investments in the development and translation of neural interfaces for both the brain and spinal cord. These efforts include early feasibility clinical trials for enhanced prosthetic control and sensation, communication devices, visual restoration, auditory restoration, and treatment of movement disorders, such as tremor and Parkinson's disease.
- NIH hosted the International Society for the Measurement of Physical Behavior annual meeting in 2017.
- The trans-NIH Big Data to Knowledge (BD2K) Program funded several projects on wearable sensors in the rehabilitation space. The BD2K funding included support for the Mobilize Center of Excellence, which conducts mobility research using innovative data science methods, and the Mobile Sensor 2 Knowledge (MD2K) Center of Excellence, which uses big data solutions to reliably quantify physical, biological, behavioral, social, and environmental factors that contribute to health and disease risk.
- Through StrokeNet, NINDS supported a multisite clinical trial of telerehabilitation for upper limb stroke rehabilitation.

Progress on Theme D: Research Design and Methodology

Because it includes clinical trials, this theme receives the largest amount of overall funding. The following highlights research efforts related to specific disease or condition categories.

- NINDS and NCMRR hosted several meetings and workshops to gain individual input to inform research agendas on specific clinical populations:
    - *Translational Stroke Research: Vision and Opportunities Workshop*
    - *Stroke Recovery Workshop: Bridging the Translational Gap in Stroke Recovery and Rehabilitation Research*
    - *Translational Research in Cerebral Palsy*
    - *SCI 2020: Launching a Decade for Disruption in Spinal Cord Injury (SCI) Research*

- NCMRR hosted a workshop on improving clinical trials in rehabilitation entitled *The Future of Medical Rehabilitation Clinical Trials* (PDF 205 KB).
- The NIH OBSSR supported the Training Institute for Dissemination and Implementation Research in Health effort.
- Multiple ICOs participated in a PA (PA-19-274) soliciting R01 applications for Dissemination and Implementation Science research in health, with specific language for rehabilitation research.
- NIH has made large investments in developing and validating Patient-Reported Outcome Measures for clinical trial outcomes, which are available for free through the Patient-Reported Outcome Measurement Information System (PROMIS) at http://www.healthmeasures.net/.
- NINDS and NCMRR commissioned the creation of Common Data Elements (CDEs) for clinical trials research in rehabilitation, to augment the large set of CDEs already developed for neurological conditions by NINDS.
- The Pain Management Collaboratory is a joint NIH, DoD, and VA pragmatic clinical trial network for non-pharmacological approaches to pain management. National Center for Complementary and Integrative Health (NCCIH) and NCMRR co-fund a clinical trial through the Collaboratory to improve pain care among Veterans.
- NCMRR issued an RFA (HD-16-001) to support an R21 on secondary analyses of existing TBI databases to explore outcomes relevant to medical rehabilitation.
- NINDS funds the Study in Parkinson Disease of Exercise (SPARX3) Trial, a multisite Phase III study led by researchers at Northwestern University.
- NINDS published several FOAs that include calls for rehabilitation therapies, including:
    - Comparative Effectiveness Research in Clinical Neurosciences (PAR-19-171)
    - NINDS Efficacy Clinical Trials (PAR-18-422)
    - NINDS Exploratory Clinical Trial (PAR-18-240)
- NCI issued PAR-19-325 to support basic, translational, and clinical research projects that evaluate the mechanisms of cancer treatment-induced adverse sequelae and translate the mechanistic understanding into approaches to prevent or minimize these adverse sequelae, including peripheral neuropathy, cardiovascular complications, radiation-induced fibrosis, and cognitive function problems.

Progress on Theme E: Translational Research

This thematic area includes efforts to advance understanding of the fundamental biological, physiological, and behavioral mechanisms that underlie disease.

- In 2015, NIH launched the Precision Medicine Initiative known as *All of Us*, which will gather data from 1 million or more people living in the United States to accelerate research and improve health. By taking into account individual differences in lifestyles, environment, and biology, researchers will uncover paths toward delivering precision medicine. Outreach to include people with disabilities in the *All of Us* cohort has been a priority, including the creation of a participant-provided information portal on disability.
- NINDS and NCMRR hosted several workshops aimed at advancing translational studies in specific disease areas.
    - *Translational Stroke Research: Vision and Opportunities Workshop*
    - *Stroke Recovery Workshop: Bridging the Translational Gap in Stroke Recovery and Rehabilitation Research*
    - *Translational Research in Cerebral Palsy*
    - *SCI 2020: Launching a Decade for Disruption in Spinal Cord Injury (SCI) Research*
- Several NIH institutes have supported regenerative rehabilitation research activities, including the Symposium on Regenerative Rehabilitation.
- NIH, in conjunction with NSF, VA, and DOD, published a Perspective on Regenerative Medicine and Rehabilitation in *Nature Regenerative Medicine.*
- The NIH HEAL Initiative[SM] includes a Biomarkers for Pain program for discovery of biomarkers, biomarker signatures, and endpoints for pain (RFA-NS-18-041).
- NINDS Division of Translational Research supports research on several rehabilitation device therapies.

Progress on Theme F: Building Research Capacity and Infrastructure

Training and career development in rehabilitation research has long been a priority and is supported by the commitment of funds to training and career development grants at NIH. This theme focuses on fellowships, training, career development, and shared infrastructure investments by NIH.

- NIH continues its commitment to research infrastructure through the Medical Rehabilitation Research Resource Network of sites (RFA-HD-20-004) that provide consultations, didactic opportunities, pilot funds, and sabbaticals in areas of rehabilitation research. The re-competition of this program in 2020 included funding by NCMRR, NINDS, NINR, NIDCD, NIBIB, and NCCIH.
- NIH supports many grant writing and mentoring workshops including NCMRR's Training in Grantsmanship in Rehabilitation Research (TIGRR) and the Rehabilitation Medicine Scientist Training Program (R25). Rehabilitation researchers also attend grant-writing workshops supported by individual ICs, including the National Institute of Arthritis and Musculoskeletal and Skin Diseases, NINR, NIDCD, NINDS, NCCIH, and NIA.
- NIH has supported many institutional training and career development programs in rehabilitation including T32 and K12 programs.
- Beyond the traditional F, T, and K (particularly K01) mechanisms, many institutes have funding opportunities for Early Career Researchers, such as the NIDCD R21 (PAR-18-487) and NCMRR R03 (PAR-20-042) FOAs.
- Program officers participate in early career researcher activities at many national meetings.
- The NIH Diversity Supplement program supports administrative supplements to improve the diversity of the research workforce by recruiting and supporting students, postdoctoral fellows, and eligible investigators from groups that have been shown to be underrepresented in health-related research. This supplement opportunity is also available to research grant Program Directors/Principal Investigators who are or become disabled and need additional support to accommodate their disability in order to continue to work on the research project.

Rehabilitation Research Themes and Objectives

NIH advances scientific knowledge about disabilities and rehabilitation while also providing vital support and focus for the field of medical rehabilitation research. This work is routinely coordinated across NIH, and programs collaborate closely to ensure that NIH supports rehabilitation science in all areas that affect public health. The goals and objectives of the ICOs that support medical rehabilitation were formulated by the MRCC, which includes representatives from the 17 ICs that fund rehabilitation research. These ICs have their own individual strategic plans and research agendas, which are aligned with legislative mandates related to specific diseases or body systems.

The NIH Research Plan on Rehabilitation dovetails with the plans and agendas of the ICOs. The coordination and collaboration among the ICOs enhance NIH's overarching work to promote innovative and integral science in medical rehabilitation. NIH accomplishes this coordination and collaboration not only through the extramural funding awarded to universities, academic health centers, small businesses, and other research institutions to support research and research training, but also through the intramural laboratories and Clinical Center on NIH's main campus in Bethesda, Maryland.

It is outside the scope of this plan to address specific goals for individual conditions or specific challenges of certain populations or individuals. Each participating ICO will support rehabilitation research in their respective mission areas to appropriately address the breadth of the conditions, diseases, and approaches related to rehabilitation.

A: Rehabilitation Across the Lifespan

The NIH rehabilitation research portfolio reflects the essential need for research at all points during the lifespan. Models of rehabilitation may require different approaches, implementation strategies, or considerations given the developmental stage of the individual receiving the services, the extent of disability and comorbidities, and the social contexts and environmental challenges the individual faces. People who benefit from rehabilitation services represent different racial and ethnic populations, socioeconomic levels, gender identities, and reproductive statuses and reside in diverse communities with different levels of access to rehabilitation services. NIH's first research priority addresses this critically understudied issue.

Objectives

- Increase the quality of evidence for rehabilitation interventions in populations across the lifespan (pediatrics through geriatrics), including increased studies of aging with a disability and aging into disability.

- Determine the mechanisms by which lifestyle and wellness interventions for physical activity, nutrition, and sleep can promote overall health and prevent comorbidities to improve health-related quality of life.
- Investigate health disparities and intervene to reduce their impact on the effectiveness, implementation, and uptake of rehabilitation interventions, common medical interventions, and preventive services for people with disabilities.
- Improve transitions through the lifespan (e.g., from infancy and childhood to adolescence, from adolescence to adulthood, from adulthood to late life) to enable the highest level of function from health interventions.
- Capitalize on programs like *All of Us* and other large dataset projects to study the natural history of conditions that cause disability and common secondary conditions associated with disability.

B: Community and Family

Each person with a disability lives within the context of a community that may include a family, social groups, and other supports. Understanding the interplay among individuals and their contexts is a key research priority area for NIH.

In addition, as the population ages, the degree of disability in the community will increase and, with it, the need for rehabilitation services to maintain function, rehabilitate chronic conditions that limit activity, and support caregivers and families who provide formal and informal assistance to individuals with disabilities.

Objectives

- Develop self-management strategies and interventions to promote and maintain independence and participation for people with disabilities in the communities of their choice.
- Evaluate the stressors, challenges, and benefits experienced by care partners of individuals with disabilities; formulate approaches to address the impact of these on the health of both the care partner and the care recipient.
- Examine interventions to reduce the negative impact of social determinants of health on the outcomes of rehabilitation programs, especially those designed to promote participation and community integration.
- Include consumers of rehabilitation services as partners in the research enterprise.
- Identify characteristics and strategies that enable families and communities to provide high quality of life and participation, while reducing barriers, for persons with disability.

C: Technology Use and Development

Technology continues to play a significant role in rehabilitation science research and clinical applications in the form of diagnostics, treatment devices, assistive devices and technology, orthotics, prosthetics, and other rehabilitation support geared toward self-management and treatment delivery. Computational science is also key to rehabilitation science, providing advanced algorithms for device control, increased use of modeling and simulation, and artificial intelligence for analyzing Big Data.

To best harness technology in the laboratory and treatment settings, NIH must promote interdisciplinary collaborations within health disciplines and with colleagues in industry, computer science, math, statistics, and engineering. The end users of the technology must also play a role in its development and evaluation to achieve scalable technologies and democratize access.

Objectives

- Develop systems to facilitate the rapid development of innovative, effective, and affordable user-centric technologies. Such facilitation includes providing a framework for sharing user preferences and feedback on experiences with existing devices, promotion of open-source standards for sharing common rehabilitation technologies, and generation of open-source computational models for designing new rehabilitation technologies and predicting their functional outcomes.
- Increase access to rehabilitation services through telehealth and remote assessment, delivery of care, and adherence monitoring. This effort should explore combining novel sensors and technology with the science of behavior change and motivation research.
- Define new and innovative metrics and measures that link functional outcomes with the physiological and psychosocial processes that drive them; apply these metrics and measures to the use and development of various technologies for rehabilitation.
- Apply augmented intelligence systems to process and interpret data from individuals and populations. This activity may include development of intelligent systems for processing multimodal data available from existing and new sensing systems and applying these data to laboratory and community settings.

D: Research Design and Methodology

Evidence-based approaches are essential for the rehabilitation of individuals with disabilities. The results of recently completed, large, efficacy trials of rehabilitation approaches have also demonstrated the need for new methods, strategies, and approaches to address challenges, such as generating consistent clinical data from heterogeneous situations. Intervention development and refinement, data sharing, and knowledge translation are also essential. Interdisciplinary research must also be encouraged to provide comprehensive approaches to rehabilitation.

Objectives

- Expand the evidence base for new and existing treatment interventions, emphasizing validated protocols associated with improved outcomes and knowledge of underlying mechanisms for treatment effects.
- Conduct clinical trials based on an integrated translational model that considers all stages of rehabilitation science development, from intervention development and refinement, to efficacy and effectiveness, to implementation and dissemination. Incorporate randomized, controlled clinical trials, trials with novel statistical designs such as adaptive and pragmatic approaches, and disease-specific statistical analyses to optimize statistical power when applicable.
- Use innovative health-services research and epidemiological methods on existing databases and clinical registries to evaluate relationships among rehabilitation interventions, technologies, devices, and patient-centered outcomes in real-world contexts.
- Encourage dissemination and implementation research to achieve more efficient and successful translation of evidence-based approaches and best practices.
- Use economic methodologies to measure the impact of rehabilitation interventions, technologies, and devices on health-related behaviors, healthcare utilization, and health outcomes.
- Improve the quality and quantity of data sharing from clinical trials when appropriate, including promotion of CDEs and reporting of adverse events.

E: Translational Research

NIH sponsors multiple programs to advance understanding of the fundamental biological, physiological, and behavioral mechanisms that underlie disease. For the purpose of rehabilitation research, this understanding encompasses genomic and other cell-based, process-level contributions to plasticity and adaptation; body system-level responses to injury; and methods by which people adapt to and accommodate for injury or illness at the cellular, tissue, and system levels. Basic understanding of intervention effects, both in animal models and in humans, is also needed.

Precision medicine also emerges as a possible approach for disease treatment and prevention because it accounts for individual variability in genes, environment, and lifestyle. Although researchers have made some advances in precision medicine, the practice is not in use for most diseases or conditions and has not been widely applied in rehabilitation medicine. Nonetheless, the possibilities for tailored treatments make precision medicine an attractive approach to improving functional and quality-of-life outcomes.

Objectives

- Leverage existing interventions and knowledge to develop rapid solutions that are responsive to the needs of rehabilitation communities.

- Integrate cellular, tissue-, and model organism-based research to identify the principal physiological and behavioral mechanisms and key interventional targets in the adaptive and maladaptive changes associated with disabling conditions.
- Support “bench-to-bedside-to-bench” translation, building on knowledge of the mechanisms of disease and recovery to develop clinical implementation strategies.
- Use staged intervention development and refinement processes to generate mechanism-based clinical rehabilitation strategies that exploit the beneficial biological and physiological adaptations discovered in the laboratory.
- Advance precision medicine approaches for rehabilitation by supporting the development and use of biomarkers associated with specific injuries, illnesses, and disorders that are prognostic or that guide prescription of rehabilitation interventions (e.g., biotypes to identify responders and non-responders), as well as those that help assess target-engagement and other biological and physiological changes expected to predict clinical efficacy.
- Determine the effectiveness of integrative, multimodal interventions that target multiple synergistic mechanisms to enhance and accelerate recovery following injury or disease.

F: Building Research Capacity and Infrastructure

The capacity of the rehabilitation research field is exponentially greater than it was when NCMRR was established in 1991. Throughout this timeframe, NIH has provided steadfast support to the community by creating a research infrastructure network that offers training, consultation, and collaboration; funding training programs targeted at the development of basic scientists, physician scientists, health science professionals, and engineers who focus on biomedical devices or rehabilitation; and providing courses at regional, national, and international conferences.

As noted in the report[13] from the 2005 Rehabilitation Medicine Summit, capacity includes: 1) researchers; 2) research culture, environment, and infrastructure; 3) funding; 4) partnerships; and 5) metrics. NIH is actively involved in all these areas and will continue to find novel and innovative ways to build capacity for rehabilitation science.

Objectives

- Develop training programs that provide diverse researchers and clinician-scientists at all career stages with access to cutting-edge approaches and methodologies and the insight needed to apply these approaches to advance rehabilitation science.

[13] Frontera, W.R., et al. (2005). Rehabilitation Medicine Summit: Building research capacity. *Topics in Stroke Rehab. 12*(4):68-80.

- Support individual training and career development awards from rehabilitation researchers, as well as early career awards and pilot funding though infrastructure grantmaking mechanisms.
- Develop infrastructure to connect rehabilitation researchers across domains of expertise and career stages to create a robust, self-sustaining network.
- Continue to expand collaboration and connection among rehabilitation researchers by promoting rehabilitation and disability research in trans-NIH and Common Fund programs.
- Develop ways to incentivize interdisciplinary collaboration in rehabilitation research, including metrics that evaluate and encourage interdisciplinary science, and that accurately reflect the contributions of scientists who work to advance the field.
- Create and implement a strategy for recruiting individuals with disabilities and underrepresented minority groups into research careers; consider enhanced diversity supplements and partnerships with other federal agencies (e.g., NSF, NIDILRR).

Collaboration with Other Federal Agencies

NIH recognizes that it is not the only federal agency committed to developing and funding research that addresses disability and rehabilitation and training in the field. NIH is active in coordination and collaboration of these activities throughout the federal government:

- NIH has regular interactions with federal partners through the NABMRR, where NIH partners serve as *ex officio* members, and through the Interagency Committee on Disability Research (ICDR), where NIH serves as an executive member.
- NIH program staff serve on scientific and programmatic review panels for other federal agencies, such as DoD, VA, NSF, and NIDILRR.
- NIH staff coordinates joint presentations with other federal funders of rehabilitation research at national meetings and conferences.

These interactions serve not only to help synergize efforts, but also to spur unique collaborations and opportunities for the entire rehabilitation research community. Although the following section describes several departments and agencies that are close partners in rehabilitation research, it does not fully encompass all the federal entities with which NIH collaborates.

Collaborations with Multiple Agencies

In 2017, NINDS and NICHD entered a memorandum of understanding with NIDILRR, as part of their work through ICDR, to create a Government Wide Inventory (GWI) of all federally supported research projects on disability. Launched in 2020 and housed at the NIH Library, this publicly searchable database includes research projects from NIH, VA, NIDILRR, and NSF, starting with awards from fiscal year 2016. The database is being expanded to include other federal agencies, such as CDC and DoD, as well as more data for subsequent fiscal years. The establishment of this GWI benefits the federal research portfolio in disability, independent living, and rehabilitation and allows for better visibility for public and legislative stakeholders as to the focus and progress of federal research in this area.

In 2019, NCMRR convened an interagency panel with members from NIH, VA, DoD, AHRQ, the Center for Medicare & Medicaid Services (CMS), the Administration on Community Living (ACL), and Food and Drug Administration (FDA) to “develop and publicize consensus criteria that will begin to provide the basis for the development of the best evidence possible to demonstrate the potential functional and safety benefits of new and evolving prosthetic technology,” as recommended by the 2016 Lower Limb

Prosthetic Workgroup Consensus Document[14]. A systematic review commissioned by CMS and conducted by the AHRQ Evidence-based Practice Center Program in 2018 informed the panel and consensus statement[15]. In 2020, the group recommended a set of CDEs[15] to standardize the collection of data for amputation, orthotics, and prosthetics research and will adjust those standards based on feedback from the research community.

Department of Defense (DoD)

The Joint Program Committee-8/Clinical and Rehabilitative Medicine Research Program (JPC-8/CRMRP) focuses on definitive and rehabilitative care innovations required to "reset" wounded warriors, in terms of both duty performance and quality of life. The program has multiple initiatives to achieve its goals, which include improving prosthetic function, enhancing self-regenerative capacity, improving limb and organ transplant success, creating full-functioning limbs and organs, repairing damaged eyes, treating visual dysfunction following injury, improving pain management, and enhancing rehabilitative care. JPC-8 representatives have served on the NICHD Advisory Council and the NABMRR as *ex officio* members representing the DoD.

NIH collaborations with DoD also include assisting with Capability-Based Assessments conducted by the Defense Health Agency to guide the DoD's research agenda and priorities; participating in joint program reviews and analysis of the DoD's rehabilitation medicine and TBI portfolios; and working with the U.S. Army Medical Materiel Development Agency on projects to develop and commercialize pharmaceuticals and devices that benefit individuals with disabilities.

In addition, NIH joins VA and DoD in the SCI Research Program vision-setting meeting, which aims to ensure that agencies' respective portfolios are aligned with their missions and to reduce funding overlap. A cooperative agreement between NIH and DoD allows the support of regenerative medicine approaches to limb, craniofacial, burn, scarless wound, and genitourinary repair through the Armed Forces Institute of Regenerative Medicine.

In 2018, NCMRR, in partnership with DoD, established a Limb Loss and Preservation Registry to collect clinical information on civilians, military personnel, and veterans who experience limb loss or preservation at care sites outside the DoD or VA. As leading funders of research on amputation, prosthetic development, and post-amputation rehabilitation, NCMRR and DoD view support of this resource as crucial to the advancement of the limb loss health field.

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[14] Lower Limb Prosthetic Interagency Workgroup, Centers for Medicare & Medicaid Services. (2017). Lower Limb Prosthetic Workgroup Consensus Document, https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/LLP_Consensus_Document.pdf (PDF 773 KB).

[15] Lower Limb Prosthetic Interagency Workgroup, Centers for Medicare & Medicaid Services. (2016). Guidance Document https://www.hhs.gov/guidance/document/lower-limb-prosthetic-workgroup-consensus-document-0

Defense Advanced Research Projects Agency (DARPA)

For 60 years, DARPA has held to a singular and enduring mission: to make pivotal investments in breakthrough technologies for national security. NIH works closely with DARPA's Biological Technologies Office on programs to consider complementary funding opportunities and plan for future initiatives. Over the past five years, these programs have included Revolutionizing Prosthetics, Hand Proprioception and Touch Interfaces, Neural Engineering System Design, Next-Generation Nonsurgical Neurotechnology, Systems-Based Neurotechnology for Emerging Therapies, and Bridging the Gap Plus. These research programs cover multiple disciplines and seek to develop technologies and enhance understanding of biological processes associated with quality of life and human performance, disease, and healing.

Department of Health and Human Services (HHS)

Agency for Healthcare Research and Quality (AHRQ)

AHRQ is a health services research agency within HHS with a mission to generate evidence to make healthcare safer, higher quality, more accessible, more equitable, and more affordable and to work within HHS and with other partners to make sure that the evidence is understood and used. AHRQ also has a congressional mandate to conduct health research and disseminate research findings about and for persons with disabilities, who are a priority population for the agency. AHRQ is a valued NIH partner, especially in the provision of quality data indicators, research reports, and systematic reviews and assessments of available research in particular areas of health and health technology.

From 2017-2021, NIH collaborated with AHRQ on a Pathways to Prevention (P2P) workshop to assess and synthesize evidence about physical activity among wheeled-device users. P2P workshops identify research gaps in a selected scientific area or health issue, define methodological and scientific weaknesses in that scientific area, suggest research needs, and move the field forward through an unbiased, evidence-based assessment. As part of the P2P process, ODP, NINDS, and NCMRR worked with and through the AHRQ Evidence-based Practice Center Program to conduct a systematic review of the literature, which was presented for public comment in late 2020 in conjunction with a three-day NIH workshop.

Centers for Disease Control and Prevention (CDC)

CDC works to protect the United States from health, safety, and security threats, both foreign and domestic, and collaborates with communities and citizens to counter diseases that are chronic or acute, are curable or preventable, and result from human error or deliberate attack. For example, NIH routinely works with CDC to coordinate efforts related to health, disability, and injury prevention, especially efforts related to epidemiology of specific diseases and coordination of CDEs to improve reporting. NIH and CDC partner on initiatives related to TBI, including the development of CDC's pilot national concussion surveillance system, reports to Congress, and initiatives focusing on the standardization of data elements related to TBI.

NIH and CDC also collaborate to achieve the goals, objectives, and priorities related to the Disability and Health area, which aims to maximize inclusion and participation to improve outcomes as part of the Healthy People Initiative. NCMRR staff co-coordinated the latest Healthy People Disability and Health Workgroup, which includes representatives from the NCMRR, NIH, the Office of Disease Prevention and Health Promotion, ACL, and CMS within HHS, the CDC's National Center for Health Statistics and National Center on Birth Defects and Developmental Disabilities, the Department of Education, and the Department of Housing and Urban Development. The workgroup supports objectives that address the health of individuals with disabilities and provides data to track progress toward achieving these objectives throughout the decade. For example, development, implementation, and tracking of the PROMIS initiative resulted from the workgroup's efforts.

In 2018, an interagency agreement between the NCMRR and the CDC led to the development of a survey supplement to assess disabilities among postpartum women using PRAMS, a surveillance project of state health departments and the Division of Reproductive Health in the CDC's National Center for Chronic Disease Prevention and Health Promotion. PRAMS, which currently covers about 83 percent of all U.S. births, collects state-specific, population-based data on maternal attitudes and experiences before, during, and shortly after pregnancy. The data can be used to identify groups of women and infants at high risk for health problems, monitor changes in health status, and measure progress toward goals in improving the health of mothers and infants. Data collected through this survey supplement will provide the research community with valuable information about pregnancy, delivery, and postpartum experiences, care, and outcomes in women with disabilities. In 2020, this work was extended to link PRAMS data to vital statistics data (e.g., birth and death certificates) through funding from the Patient Centered Outcomes Trust Fund. This collaboration with CDC also aligns with *Research Theme 3: Setting the Foundation for Healthy Pregnancies and Lifelong Wellness* in the NICHD Strategic Plan.

Food and Drug Administration (FDA)

The FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. The agency also advances public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health. NIH works in close partnership with the FDA to enable efficient and effective exchanges of information related to drugs, supplements, and devices that apply to rehabilitation research.

The Medical Device Research Interest Group (MDRIG) is an initiative that includes representatives from 16 NIH ICs as well as from the FDA and CMS. It meets quarterly to discuss programs, initiatives, and partnerships that aid the development of medical devices, including rehabilitation devices and assistive technology. The goal of MDRIG is to provide a forum for discussion and collaboration on issues related to research and development and other topics critical to innovation of medical device technologies.

NINDS established a memorandum of understanding and a regularly meeting working group with the FDA Center for Devices and Radiological Health (CDRH). The agreement allows for the exchange of information and discussion of issues of common interest to the CDRH and NINDS missions, including devices that are relevant to paralyzed individuals. This memorandum complements a decades-long agreement and working group between NINDS and the FDA Center for Biologics Evaluation and Research, which focuses on issues in the realm of stem cells, gene therapy, and other biological products.

FDA is also the agency that regulates hearing aids. Despite the association between hearing loss and loneliness, depression, declining physical function, risk for falls, and cognitive decline, most adults with hearing loss do not seek or do not receive hearing healthcare. In 2016, the National Academies of Sciences, Engineering, and Medicine published a landmark consensus study[16] on adult hearing healthcare in the United States. The study, funded by NIDCD in conjunction with other federal and private partners, developed a series of recommendations for federal, professional, and private stakeholders aimed at improving access to and affordability of hearing healthcare for adults. One of the recommendations was for the FDA to create a new category of over-the-counter hearing aids that could be sold directly to consumers with perceived mild-to-moderate hearing loss. NIDCD-funded science informed the recommendation. In August 2017, Public Law 115-52 (PDF 460 KB) passed, requiring the FDA to establish a category of over-the-counter hearing aids through the rulemaking process. Once the FDA issues a final rule to establish this category, over-the-counter hearing aids are anticipated to be a reality in the United States, and they are expected to increase competition in the industry and decrease barriers to care for millions of Americans with hearing loss.

National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)

Newly located within the HHS ACL, NIDILRR is a federal agency that funds grantees to generate new disability and rehabilitation knowledge and promote its use and adoption. NIDILRR encompasses a broad range of investigator-initiated research, centers, model systems, and training programs, including Disability and Rehabilitation Research Projects Program, Rehabilitation Research and Training Centers Program, Rehabilitation Engineering Research Centers Program, Mary E. Switzer Fellowships Program, Field-Initiated Projects Program, SCI Model Systems Program, Advanced Rehabilitation Research Training Program, and Small Business Innovation Research Program.

NIH's coordination with NIDILRR focuses on three primary areas: 1) representation on and work with the ICDR, chaired by NIDILRR; 2) collaboration with NIDILRR's Model Systems Programs to develop and implement CDEs, share data from these systems with NIH researchers, and use the infrastructure sustained by NIDILRR to encourage

[16] National Academies of Sciences, Engineering, and Medicine. 2016. Hearing Health Care for Adults: Priorities for Improving Access and Affordability. Washington, DC: The National Academies Press. https://doi.org/10.17226/23446

intervention and treatment studies; and 3) serving as reviewers for NIDILRR's programmatic review panels.

National Science Foundation (NSF)

NSF is an independent federal agency created by Congress in 1950 to promote the progress of science; advance national health, prosperity, and welfare; and secure national defense. NSF and NIH have enjoyed a fruitful partnership through a variety of collaborative funding opportunities.

NIH's ability to work with a network of researchers with expertise in engineering, computer science, data science, computational neuroscience, and a host of other skills has augmented the strategies that NIH scientists use to address disability and rehabilitation. For example, the National Robotics Initiative (NRI) promotes collaborative robots (known as co-robots) for a variety of applications, including rehabilitation. The NIH component of the NRI is especially interested in promoting assistive medical robotics for home care and long-term personalized care; robotic support for wellness/health promotion and maintenance; robotic behavioral therapy; robotic aids for mobility, manipulation, communication, and cognition and for vision for non-sighted persons; and assistive robotics to eliminate health disparities across populations. NIH also partners with NSF on the Cyber-Physical Systems, the Collaborative Research in Computational Neurosciences, and the Smart and Connected Health Programs.

In 2016, NCMRR and NSF co-hosted the *Can Technology Make a Difference in Pediatric Rehabilitation?* workshop at NIH to discuss how technology may benefit and be tailored for pediatric rehabilitation. In 2020, program staff from NIH and NSF co-hosted a webinar, Navigating the NIH-NSF divide for Rehabilitation Researchers, to help prospective applicants understand the differences between the two agencies.

Department of Veterans Affairs (VA)

The VA Rehabilitation Research & Development Service (RR&D) supports preclinical, clinical, and applied rehabilitation research with a strong focus on clinical translation implications for Veterans. Study areas supported by RR&D include the following: injuries, disorders, and diseases with potential to cause long-term impairment or disability; rehabilitation interventions, techniques, and devices designed to maximize motor, sensory, and psychological recovery; and endpoints that include functional outcomes. Portfolio areas include SCI and neuropathic pain, regenerative medicine, TBI and stroke, musculoskeletal/orthopedic rehabilitation, sensory systems/communication disorders, psychological health and social reintegration, rehabilitation engineering and prosthetics/orthotics, and aging and neurodegenerative disease.

Because the VA RR&D is an intramural program focused on research and its benefits to Veterans, NIH contributes to VA strategic planning, programmatic review, and areas of research of mutual interest through this collaboration. NIH and VA are partnering to develop specific technologies, in parallel, to benefit not only Veterans but also non-Veterans, such as advanced prosthetic devices and control systems; Brain-Computer Interface technologies; tissue regeneration; retinal prosthetics; wheelchairs and mobility

devices; and a variety of specific rehabilitation techniques and approaches for spasticity, contractures, pain, and other conditions. The Director of VA RR&D serves as an *ex-officio* member of both the NICHD Advisory Council and the NABMRR.

The Pain Management Collaboratory, jointly supported by the NIH, DoD, and VA, aims to develop the capacity to implement cost-effective, large-scale, pragmatic clinical research in military and Veteran healthcare delivery organizations, with a focus on non-pharmacological approaches to pain management and comorbid conditions. NCMRR provides co-funding to NCCIH in support of one of the pragmatic trials within the Collaboratory.

NCMRR staff also participates in the Advisory Committee on Prosthetics and Special Disabilities Programs, which advises the Secretary of Veterans Affairs on VA prosthetics programs and the rehabilitation research, development, and evaluation of prosthetics technology. The Committee also assesses VA programs that serve veterans with SCI, blindness or vision impairment, loss of or loss of use of extremities, deafness or hearing impairment, or other serious incapacities.

World Health Organization (WHO)

WHO directs and coordinates international health within the United Nations system, working in areas of health systems, health through the life-course, noncommunicable and communicable diseases, preparedness, surveillance, and response. In a 2020 report[17], the WHO estimated the global number of people who benefit from rehabilitation services at 2.4 billion. This staggering figure supports the importance of NIH's involvement in rehabilitation programs at WHO, which began in 2018. Some of these activities include the following:

- NCMRR contributed to the creation of the priority interventions package and to the WHO Rehabilitation 2030 activities[18].
- NCMRR co-sponsored the meeting to develop global rehabilitation outcome measures and the meeting to set global priorities for a rehabilitation research agenda.
- NCMRR, the Fogarty International Center, and NIDCD are working with WHO on a research plan to complement the implementation of the priority interventions package in low- and middle-income countries, while also working with other high-income country funders to ensure this work moves forward.
- NIDCD has played a significant role in the World Report on Hearing[19], released in March 2021.
- NCMRR staff serve on the WHO Secretary General's Advisory Panel for Rehabilitation.

[17] Cieza, A. et al. (2020). Global estimates of the need for rehabilitation based on the Global Burden of Disease study, 2019: A systematic analysis for the Global Burden of Disease Study 2019. *The Lancet, 396*(10267): 2006-2017. 10.1016/S0140-6736(20)32340-0.

[18] https://www.who.int/iris/handle/10665/339910

[19] World report on hearing. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO. https://www.who.int/publications/i/item/world-report-on-hearing

Appendix A: NIH Medical Rehabilitation Coordinating Committee Institutes, Centers, and Offices

NIH Institutes

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

National Cancer Institute (NCI)

National Eye Institute (NEI)

National Heart, Lung, and Blood Institute (NHLBI)

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

National Institute of Dental and Craniofacial Research (NIDCR)

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

National Institute of Mental Health (NIMH)

National Institute of Neurological Disorders and Stroke (NINDS)

National Institute of Nursing Research (NINR)

National Institute on Aging (NIA)

National Institute on Deafness and Other Communication Disorders (NIDCD)

NIH Centers

Center for Scientific Review (CSR)

Fogarty International Center (FIC)

National Center for Advancing Translational Sciences (NCATS)

National Center for Complementary and Integrative Health (NCCIH)

NIH Clinical Center (CC)

NIH Offices

NIH Office of the Director

Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)

Office of Behavioral and Social Sciences Research (OBSSR)

Office of Dietary Supplements (ODS)

Office of Disease Prevention (ODP)

Office of Research on Women’s Health (ORWH)