

Blue Ribbon Panel on Medical Rehabilitation Research at the NIH

Final Report

Revised: December 18, 2012

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Executive Summary

In May 2011, Dr. Alan E. Guttmacher, Director, *Eunice Kennedy Shriver* National Institute of Child Health & Human Development (NICHD), appointed a member of the National Advisory Child Health and Human Development (NACHHD) Council and a member of the National Advisory Board on Medical Rehabilitation Research (NABMRR) to co-chair a Blue Ribbon Panel to review medical rehabilitation at the NIH. Thirteen panel members met between August 2011 and April 2012 to review medical rehabilitation research at the NIH. Legislation established the National Center for Medical Rehabilitation Research (NCMRR) in 1990 (Public Law 101-613). In order to assess the present status of NCMRR, the Panel sought to understand the nature of congressional legislation with focus on identifying elements that are required by law, elements that are desirable, but not required, and elements that are actionable. According to PL 101-613, "The general purpose of the Center is the conduct and support of research and research training,...the dissemination of health information, and other programs with respect to the rehabilitation of individuals with physical disabilities resulting from diseases or disorders of the neurological, musculoskeletal, cardiovascular, pulmonary, or any other physiological system..." In order to assess the scope of medical rehabilitation research across the NIH, total funding levels supporting medical rehabilitation research at each Institute/Center (IC) were presented and reviewed. Institutes with more funding for rehabilitation research than the National Center for Medical Rehabilitation Research (NCMRR), NICHD were invited to present the scope of rehabilitation research and to describe any coordination with NCMRR. Members of the NIH Coordinating Committee for Rehabilitation Research described current methods to contribute to the advancement of rehabilitation research across the NIH. Leadership from several of the Coordinating Bodies within the NIH was interviewed to gather information related to the mission, nature and success of the coordination function, and resource allocations. NICHD staff and leadership met with panel members to compare activities and funding for NCMRR and focused on additional quantitative data comparing NCMRR and other NICHD Centers. The data were reviewed by the Panel and discussed with respect to the 6 specific questions in the charge. Preliminary recommendations were formulated via consensus. A preliminary report of the Blue Ribbon Panel's findings and recommendations were presented to the Advisory Board of the NCMRR on May 3, 2012 and to the Advisory Council of the NICHD on June 7, 2012. The final report was submitted to Dr. Alan Guttmacher, MD, Director of NICHD, on August 31, 2012. The co-chairs of the Panel met one final time with the Advisory Board of the NCMRR on December 3, 2012 to discuss the final report. A minor error was noted in the final report regarding recommendation 1. After consulting with the entire panel and achieving unanimous consensus, a revised final report was submitted to Dr. Alan Guttmacher, MD on December 18, 2012.

The Panel concluded that funding for rehabilitation research across the NIH was flat during 2009-2011 and comprises approximately 1.2% of the NIH budget. The NCMRR of the NICHD funded only approximately 20% of rehabilitation research at the NIH. Although NCMRR developed a Comprehensive Research Plan in 1993, it has not been revised or updated. Compared to other Coordinating Bodies reviewed within NIH that have the staff and budget allocations for trans-NIH coordination, NCMRR has no dedicated personnel and no budget for coordination. Thus, current rehabilitation research activities across the NIH have not been tracked consistently, and opportunities and needs for additional research and priorities have not been identified in a comprehensive and iterative manner. There are significant opportunities for coordination across the NIH in order to maximize efficiency, identify priorities, and co-fund promising applications. NCMRR and NIH rehabilitation research portfolios do not appear to be addressing the scope of disorders equitably or related to prevalence; ~50% of the rehabilitation research conducted at the NIH is predominantly neurological in nature. This emphasis is not congruent with the breadth of diseases and conditions identified in PL 101-613, or with the actual practice of clinical rehabilitation. Although funds allocated to the NCMRR from NICHD for grant support have grown tremendously since its inception, the NCMRR has experienced a steady decline in their grant funding levels and the number of Funding Opportunity Announcements relative to other Centers in the NICHD over the past 4 years.

In summary, based on its analysis over the past year, it is the Panel's judgment that the NCMRR is functioning, but not thriving within the NIH. With the exception of the periodic revision of the Research Plan, the NCMRR is

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satisfying the “letter of the law,” and is providing important services that were recommended by PL-101-613, but not required by law. Given the limited number of staff and resources at its disposal, the NCMRR should be commended for what it has been able to accomplish. Nevertheless, it is the Panel’s view that there are important missed opportunities and significant new initiatives that are needed to help the NCMRR meet the broader performance criteria with respect to the spirit or intent of PL 101-613 – the advancement of rehabilitation science, and the improvement of function and quality of life of Americans with disabilities.

Recommendations

Disability affects 13-14 percent of Americans (IOM, 2007) with a global prevalence of 15% (WHO, 2011). With the ageing population in the US, this prevalence is expected to grow substantially. Yet, the NIH expenditure on rehabilitation research is less than 1.2% of total budget and there is no trans-NIH coordination. Furthermore, the incongruity between prevalence and expenditure must be reconciled. This means that even though basic science and early efficacy trials that focus on discovery, mechanisms of disease and impairments have received more resources than other types of rehabilitation research, there are still substantial opportunities in these types of research that should be pursued. Thus there is a critical need to substantially increase all aspects of rehabilitation research across the continuum of translational research in order to meet the growing rehabilitation needs of Americans. The Panel developed the following recommendations:

1. Functional Requisites

In order to satisfy the broader performance criteria, NCMRR, as an entity, must satisfy the following functions:

- Granting – with independent control
- Coordination – within NIH, across federal agencies
- Budgetary control and stability for granting and coordination function
- Reporting mechanism – opportunity for negotiation for budgetary control and stability
- Capacity building
- Advocacy (persons with disability centered, not “us”)
- Single-entity

NIH investment, with dedicated funding, in strategic, comprehensive, and systematic coordination of rehabilitation research is a priority. It requires strategic collaborations among other institutes and agencies and networking with the rehabilitation research and advocacy communities to more broadly and comprehensively identify rehabilitation research needs and to help these institutes prioritize rehabilitation research with the goal of:

- Co-writing RFAs, RFPs, with or without dedicated funds
- Co-writing funding opportunities for training
- Planning and organizing conferences to identify opportunities with advocacy groups and interested Institutes/Centers (ICs)/Offices
- Avoiding duplication of efforts
- Defining priorities
- Coordinating study groups

The Panel recommends that dedicated funding be allocated for this coordination function; bringing money to the table when working with other NIH entities would ensure better success.

2. Structural Change

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In order to satisfy the functional requisites, the Blue Ribbon Panel recommends a structural change where the NCMRR is transitioned into an independent IC or a new Office in the Office of the Director.

The independent IC should function in a manner similar to the other NIH ICs with the following unique features. A major objective of the new IC is to provide trans-NIH coordination. The new IC develops and implements a trans-NIH strategic plan with input from all ICs and other stakeholders. Rehabilitation research is centrally coordinated by the new IC as a “cross-cutting” element distributed across all NIH ICs. Thus, significant portion of the budget should be dedicated toward this coordination function. Given this strategic importance of coordination, the performance criteria and budget allocation for the new IC should include:

- Number of grants co-funded with other ICs
- Number of “topping off” grants with other ICs
- Growth of rehabilitation research across the entire NIH
- Growth of new investigators in rehabilitation research across the entire NIH

An alternative to an independent IC is a new Office of Rehabilitation Research (ORR) in the Office of the Director. Given the parallels between AIDS and rehabilitation, the Office of AIDS Research serves as the model for the proposed ORR. The ORR develops an annual trans-NIH strategic plan with input from IC program staff and senior leadership, trans-NIH coordinating committees, advisory council, representatives from other federal agencies, outside organizations and advocates, and community stakeholders. Unlike ICs, the ORR does not have grant-making authority, but helps coordinate research across the NIH. Every IC has a designated Rehabilitation Research Coordinator (with access to the IC Director) to liaise with the ORR. Institutes and Centers submit funding proposals to the ORR, and the Office distributes funds to ICs based on scientific priorities as outlined in the strategic plan.

3. Rehabilitation Research Definition

“The study of mechanisms and interventions that prevent, improve, restore or replace lost, underdeveloped or deteriorating function, where “Function” is defined at the level of impairment, activity and participation according to the WHO-ICF Model.

- 4. Develop, implement, and periodically update a NIH Rehabilitation Research Plan that includes a trans-NIH strategic plan to tackle rehabilitation problems that span the life-span across a myriad of conditions in a transdisciplinary manner.**
- 5. Network strategically with (1) staff of other institutes and (2) selected members of the rehabilitation research community to broadly and comprehensively identify rehabilitation research needs and opportunities worth pursuing, and to facilitate prioritizing rehabilitation research within each relevant Institute and Center. This role of joint or coordinated funding would be equivalent to the current NCMRR granting authority role.**
- 6. Increase the clinical and societal relevance of rehabilitation research throughout the NIH by addressing the gaps in the continuum of translational research and the WHO-ICF framework.**
- 7. Substantially increase funding for ALL aspects of rehabilitation research across the continuum of translational research and the WHO-ICF framework, including basic science and early phase clinical trials.**
- 8. Continue to build research capacity.**
- 9. Increase participation of persons with disability and public advocates in the development and implementation of the Research Plan.**

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10. Change name of the Center to National Center for Rehabilitation Research.

The Panel agreed to recommend replacing the medical aspect of the label “medical rehabilitation” or “rehabilitation medicine” because this implied profession and was perceived as very narrow in the field. We recognize the history of the term “rehab” implying drug and psychiatric rehabilitation. Given the maturation of the field and the growing body of knowledge, the Panel agreed that rehabilitation was strong enough to stand on its own.

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I. Introduction

A. Background and Charge

Alan E. Guttmacher, MD, appointed Director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH) in July 2010, began to develop a 10-year vision for the Institute soon after his arrival. Celebrating the 20th year of the National Center for Medical Rehabilitation (NCMRR), NICHD, in 2011 provided an additional opportunity to reflect on the NICHD vision *vis a vis* rehabilitation research.

A Blue Ribbon Panel was convened as a result of discussions among the medical rehabilitation research community, NIH Director Francis Collins, MD, PhD, and Alan E. Guttmacher, MD. Within the NIH, the NICHD's NCMRR supports research needed to enhance the health, productivity, independence, and quality-of-life of people with disabilities. Other NIH Institutes and Centers (ICs) also support and conduct research relevant to medical rehabilitation in carrying out their respective missions.

In May 2011, Dr. Alan E. Guttmacher appointed co-chairs to a Blue Ribbon Panel on Rehabilitation Research at the NIH. The Panel was co-chaired by a member of the National Advisory Child Health and Human Development (NACHHD) Council and by a member of the National Advisory Board on Medical Rehabilitation Research (NABMRR). In August 2011, 13 scientists were appointed to a Blue Ribbon Panel to review medical rehabilitation research at the NIH. During the initial meeting with the 13-member panel in October 2011, Dr. Guttmacher encouraged the panel to focus on NCMRR, the organization over which he has most influence as well as on rehabilitation research at the NIH. This panel was asked to consider both function and structure, although function was viewed as more important by Dr. Guttmacher. The Panel was given the charge to address the following questions:

- How do we define rehabilitation research?
- What is the scope of rehabilitation research within NIH?
- Is NCMRR doing what it is supposed to be doing?
- Can or should there be coordination of all rehabilitation research within NIH?
- What are the scientific opportunities?
- What barriers prevent rehabilitation science to progress?

The Panel was asked to formulate specific recommendations with respect to these questions.

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**B. Roster of the Blue Ribbon Panel on Medical Rehabilitation Research at the NIH
(August, 2011 to September, 2012)**

John Chae, M.D. (Co-chair)

Professor and Vice Chair
Department of Physical Medicine and
Rehabilitation
Professor of Biomedical Engineering
MetroHealth Medical Center
Case Western Reserve University

Rebecca Craik, Ph.D., PT (Co-chair)

Professor and Chair
Department of Physical Therapy
Arcadia University

Thomas S. Buchanan, Ph.D.

Director, Delaware Rehabilitation Institute
George W. Laird Professor of Mechanical
Engineering and Biomedical Engineering
University of Delaware

Steven C. Cramer, M.D.

Associate Professor of Neurology, Anatomy,
and Neurobiology
Director of Neuroimaging Core
General Clinical Research Center
Associate Clinical Director of Stem Cell
Research Center
University of California, Irvine

Anthony Delitto, Ph.D., PT

Professor and Associate Dean for Research
School of Health and Rehabilitation Sciences
University of Pittsburgh
Director of Research Comprehensive Spine
Center at the University of Pittsburgh Medical
Center

Walter R. Frontera, M.D., Ph.D.

Professor & Chair
Department of Physical Medicine and
Rehabilitation
Vanderbilt University

Naomi Lynn Gerber, M.D.

University Professor Health Director of the
Center for Study of Chronic Illness and
Disability
George Mason University

Richard M. Greenwald, Ph.D.

Co-Founder and President, Simbex
Adjunct Associate Professor
Thayer School of Engineering
Dartmouth College

Alan M. Jette, Ph.D., PT

Director, Health & Disabilities Research
Institute
Professor of Health Policy and Management
Boston University

Michael V. Johnston, M.D.

Senior Vice President and Chief Medical
Officer
Director, Division of Neurology and
Developmental Medicine
Director, Neuroscience Laboratory
Kennedy Krieger Institute
Professor of Neurology and Pediatrics
Johns Hopkins University School of Medicine

Randolph J. Nudo, Ph.D.

Director, Landon Center on Aging
University of Kansas

Kenneth J. Ottenbacher, Ph.D., OT

Russell Shearn Moody Distinguished Chair in
Neurological Rehabilitation
Senior Associate Dean for Graduate Research
Education
University of Texas Medical Branch

NICHD Staff Support:

Chanya Liv, M.S.

Public Health Analyst
NICHD Office of Science Policy,
Analysis, and Communication

Katie Rush, M.A.

Special Assistant to the Director, NICHD

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II. Process

The Blue Ribbon Panel met 3 times via face-to-face meetings and 6 times via teleconferences. The first face-to-face meeting occurred on October 10, 2011. After an in depth discussion, Medical Rehabilitation was defined via consensus. The history of the NCMRR was reviewed with the goal of understanding the language and intent of the original legislation that established NCMRR in 1990 (Public Law 101-613), and how the Center has evolved since inception. In order to assess the present status of NCMRR, the Panel sought to understand the nature of congressional legislation with a focus on identifying elements that are required by law, elements that are desirable, but not required, and elements that are actionable. In order to assess the scope of medical rehabilitation research across the NIH, total funding levels supporting medical rehabilitation research at each IC were presented and reviewed. Finally, in order to place the work of the Panel in its proper historical context, the recommendations of the 2007 IOM, *The Future of Disability in America*, were reviewed.

The second face-to-face meeting occurred on January 12 and 13, 2012. Representatives from ICs outside of the NCMRR reporting the largest amount of funding support for rehabilitation research, the National Eye Institute (NEI), the National Heart Lung and Blood Institute (NHLBI), the National Institute on Aging (NIA), the National Institute of Arthritis and Musculoskeletal and Skin Disease (NIAMS), the National Institute of Biomedical Imaging and Bioengineering (NIBIB), the National Institute on Deafness and other Communication Disorders (NIDCD), the National Institute of Nursing Research (NINR), and the National Institute of Neurological Disorders and Stroke (NINDS), were invited to address the following questions:

- Describe the scope of rehabilitation research in your IC.
- Identify the elements of rehabilitation research that are unique to your IC.
- Describe how rehabilitation research in your IC addresses the World Health Organization-International Classification on Function, Disability and Health (WHO-ICF) domains.
- Describe how your IC coordinates with NCMRR.

Members of the NIH Coordinating Committee for Rehabilitation Research were interviewed as a group to ascertain the scope and depth of their activities, and how the committee contributes to the advancement of rehabilitation research across the NIH. Finally, in order to carry out a comparative assessment of NCMRR's coordinating function, other Coordinating Bodies within the NIH were reviewed with respect to their charge, the nature and success of their coordination function, and resource allocations. The specific coordinating bodies included the Office of AIDS Research (OAR), Office of Research on Women's Health (ORWH), Office of Behavioral and Social Sciences Research (OBSSR), Interagency Autism Coordinating Committee (IACC), Muscular Dystrophy Coordinating Committee (MDCC), NIH Down Syndrome Consortium and the NIH Pain Consortium.

Two teleconferences were conducted with the NICHD staff and leadership. The March 17, 2012 teleconference focused on Coordinating Bodies and budget trends for NCMRR relative to other centers within NICHD. The following questions were addressed regarding the various Coordinating Bodies within the NIH:

- Which Coordinating Bodies are effective?
- What are the common features of "successful" Coordinating Bodies?
- What are the unique features of those residing in the Office of the Director vs. an IC?
- Which Coordinating Bodies should be interviewed?

In reviewing the budget for NCMRR relative to the rest of NICHD, the following questions were addressed:

- What constitutes the budget numbers for each Center within the NICHD?
- How are budget allocation decisions made?
- What funds were allocated to NCMRR for "coordination" in the last 4-yrs?

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- What accounts for the reduction in the NCMRR budget in the last 4-yrs?

The March 21, 2012 teleconference with NICHD staff and leadership focused on additional quantitative data comparing NCMRR and the rest of NICHD. Funding opportunity announcements (FOA) across NICHD Centers were reviewed. Specific parameters included the number of proposed NICHD primary initiatives approved and published, the number of all NICHD primary and secondary initiatives, approved and published, and the total number of program officer level staff at each Center. The total number of Request for Applications (RFA) or Program Announcements (PA), application success rates for each RFA/PA, and investigator-initiated application success rates across Centers were reviewed and compared.

The role of NCMRR as a Coordinating Body was further evaluated by identifying key Coordinating Bodies within the NIH that appear to be most similar to NCMRR with respect to purpose and function, and have demonstrated reasonable success. A series of 4 teleconferences were held with the leadership of the following Coordinating Bodies:

- 3/22/12: Office of Behavioral and Social Sciences Research
- 3/23/12: Office of Autism Research Coordination
- 3/28/12: Office of AIDS Research
- 3/30/12: Office of Research on Women's Health

The teleconferences addressed the following questions:

- How does your Office coordinate?
- What is your grant awarding role, if any?
- How are you funded and at what level?
- What is your staff make up?
- Why are you successful?
- What are the barriers?
- How do you get all the ICs to "play"?

The final meeting of the Blue Ribbon Panel was a face-to-face meeting on April 12-13, 2012. The content of the prior face-to-face meetings and teleconferences, including all quantitative data, were reviewed and summarized. These data were further discussed with respect to the 6 specific questions in the charge, and preliminary recommendations were formulated via consensus. A preliminary report of the Blue Ribbon Panel's findings and recommendations were presented to the Advisory Board of the NCMRR on May 3, 2012 and to the Advisory Council of the NICHD on June 7, 2012. The final report was submitted to Dr. Alan Guttmacher, MD, Director of NICHD, on August 31, 2012. The co-chairs of the Panel met one final time with the Advisory Board of the NCMRR on December 3, 2012 to discuss the final report. A minor error was noted in the final report regarding recommendation 1. After consulting with the entire panel and achieving unanimous consensus, a revised final report was submitted to Dr. Alan Guttmacher, MD on December 18, 2012.

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III. Findings

A. What is the Definition of Rehabilitation Research?

The Panel's working definition of rehabilitation research: **The study of mechanisms, modalities and devices that improve, restore, or replace lost, underdeveloped, or deteriorating function**, where "function" is defined at the level of impairment, activity, and participation according to the World Health Organization International Classification on Function Model (see below).

World Health Organization International Classification on Function:

The International Classification of Functioning, Disability, and Health (ICF) describes functioning at three perspectives: body, person, and societal (Figure 1). The ICF organizes information in two parts. The first part deals with functioning and disability, and the second part covers contextual factors.

Components of Functioning and Disability:

1) Body component including body functions and anatomical structures. A problem in body function or structure is noted as an impairment. For example:

- Specific examples of impairment following stroke include hemiparesis, joint contractures, spasticity, reduced range of motion, dysphagia and aphasia.
- Specific examples resulting from rheumatoid arthritis include pain, joint stiffness, joint swelling, fatigue, reduced range of motion and reduced strength;

2) 'Activity' and 'Participation' components where Activity is defined as the execution of a task or action by an individual and Participation is defined by involvement in a life situation. A difficulty at the person level would be noted as an activity limitation, and at the societal level as a participation restriction.

- Examples include reduced mobility (ambulation, transfers, elevations), reduced basic activities of daily living (ADLs) (feeding, grooming, hygiene, dressing, bathing, toileting, etc.) instrumental IADLs (money management, cooking, household tasks, purchasing, etc.), and inability to return to work.

Contextual Factors:

The contextual factors are independent and integral components of the classification and are divided into:

1) 'environmental factors' and 2) 'personal factors'. 'Environmental factors' have an impact on all components of functioning and disability but 'Personal factors' are not classified in the ICF.

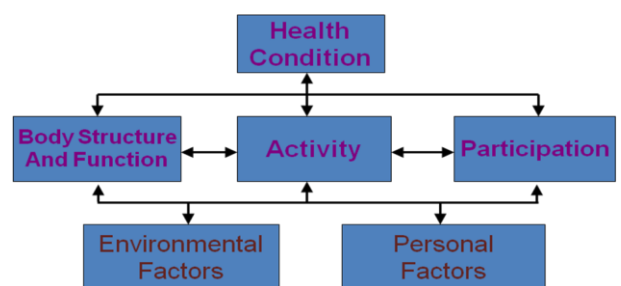


Figure 1: Components of International Classification of Functioning, Disability and Health

B. What is the Scope of Rehabilitation Research at the NIH?

NIH adopted an official *Research, Condition, and Disease Category (RCDC)* definition of Rehabilitation (2008) that contains 380 terms. The official definition includes Alcohol and Drug Rehabilitation, Cardiovascular prosthetics/valves, Dental implants, Psychiatry disability and rehabilitation, and Physical medicine and rehabilitation. NCMRR developed a more specific definition of Medical Rehabilitation that includes ~300 keywords and their synonyms. The Panel asked the 8 Institutes (NEI, NHLBI, NIA, NIAMS, NIBIB, NIDCD, NINR, NINDS) invited on January 12, 2012, to present the scope of rehabilitation research in their portfolios to use these search terms. The Panel requested that research projects primarily focused on the following areas be excluded from the project listings: dementia, substance abuse, alcohol/drinking, drugs, nicotine, psychiatry, mental disorders, and schizophrenia.

Figures 2 and 3 show the total and institute specific funding for rehabilitation research, respectively, for 2009, 2010, and 2011. The dotted lines in Figure 2 represent the estimated total NIH funding for rehabilitation research using the *Research, Condition, and Disease Category (RCDC)* definition adopted in 2008. The red bars in 2009 and 2010 indicate the funding provided by the American Recovery and Reinvestment Act (ARRA). The blue bars indicate the estimated funding for rehabilitation research deleting 80 of the 380 search terms. The Panel concluded that when the ARRA funding was not included, funding for rehabilitation research across the NIH was flat during 2009-2011. Figure 3 shows the distribution of rehabilitation research funding in 2009, 2010, and 2011 across the 9 ICs with the highest level of funding. NINDS and NIDCD were the highest funders of rehabilitation research at the NIH during FY 2009-2011. The NCMRR within NICHD funded approximately 20% of rehabilitation research at the NIH.

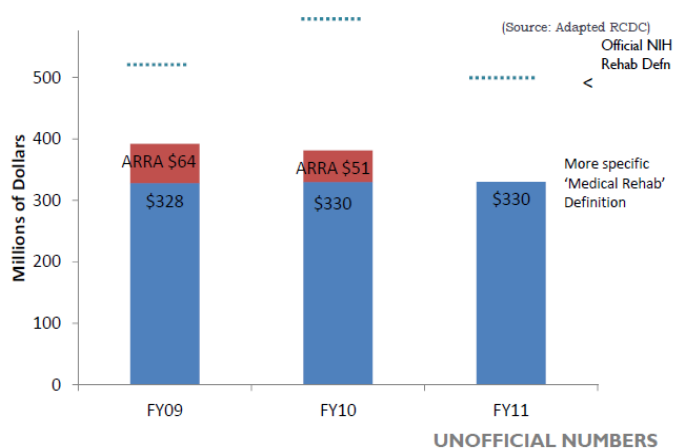


Figure 2: Total NIH funding dedicated to medical rehabilitation research.

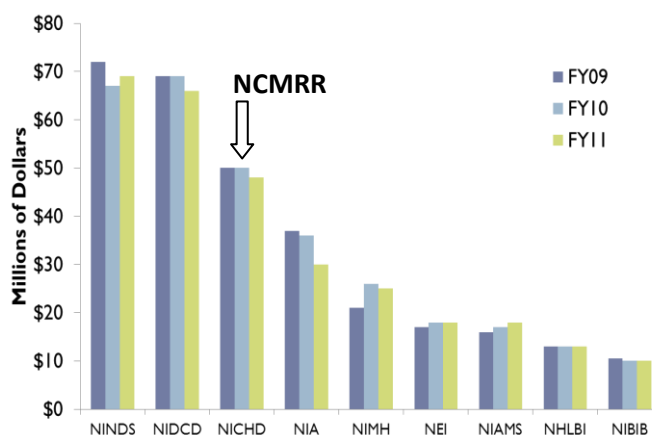


Figure 3: The NIH Institutes with the highest level of funding for rehabilitation research.

C. Is NCMRR Doing What it is Supposed to be Doing?

The performance of the NCMRR was initially assessed with respect to Public Law 101-613, now referred to as PL 101-613. According to PL 101-613, “The general purpose of the Center is the conduct and support of research and research training,...the dissemination of health information, and other programs with respect to the rehabilitation of individuals with physical disabilities resulting from diseases or disorders of the neurological, musculoskeletal, cardiovascular, pulmonary, or any other physiological system...” PL 101-613 indicates the following “shall” statements, which were interpreted by the Panel as required by law:

- Develop a comprehensive Research Plan. The Plan identifies current research activities, opportunities and needs for additional research and priorities and makes recommendations for coordination of rehabilitation research across the NIH and the federal government.
- Periodically revise and update the Research Plan.
- Establish the Medical Rehabilitation Coordinating Committee. The Committee makes recommendations to the directors of the NICHD and the NCMRR regarding the content of the Research Plan and the activities of the NCMRR that are carried out in conjunction within the NIH and other federal agencies.
- Establish a National Advisory Board on Medical Rehabilitation Research. The Board reviews and assesses federal research priorities, activities and findings regarding medical research, and advises the Directors of the NICHD and the NCMRR on the provisions of the Research Plan.

PL 101-613 also indicates the following “may” statements, which were interpreted by the Panel as recommendations and possible activities of the Center, but not required by law:

- Provide for clinical trials
- Provide for research regarding model systems of medical rehabilitation
- Coordinate the activities of the NCMRR with similar activities at the NIH and other agencies of the Federal Government
- Support multidisciplinary research conducted or supported by more than one agency
- Support research and training centers

In accordance with PL 101-613 NCMRR developed a comprehensive Research Plan, organized a Medical Rehabilitation Coordinating Committee, and established a National Advisory Board on Medical Rehabilitation Research. However, the Research Plan has not been periodically revised and updated since the original Research Plan, which was written in 1993. The NCMRR has funded clinical trials, supported multidisciplinary research conducted or supported by more than one agency, established peer-review groups and appointed members, and supported research and training centers. As shown in Figure 4, the NCMRR funding of research grants has grown tremendously since its inception. Thus, with the exception of the periodic revision of the Research Plan, the NCMRR has satisfied the “letter of the law,” and even provided important services that were recommended, but not required by PL 101-613.

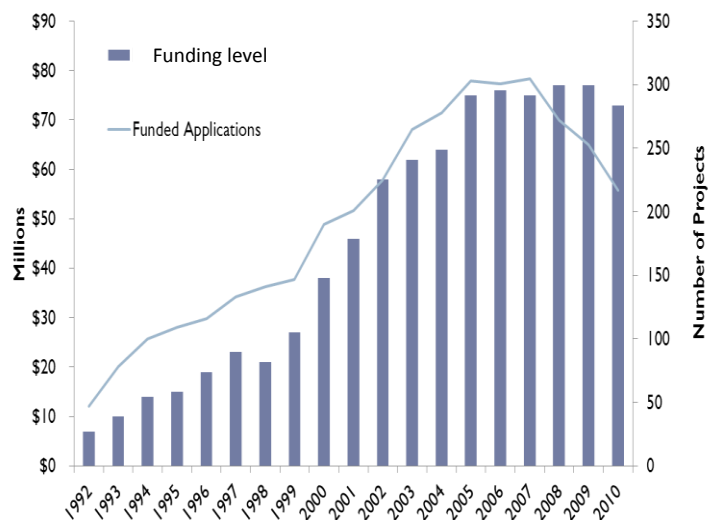


Figure 4: Total NCMRR grant funding from 1992-2010.

After this initial assessment of the performance of NCMRR based on the legal requirements of PL 101-613, the Panel evaluated the NCMRR with respect to the following broader set of criteria:

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- How has the NCMRR performed with respect to the spirit or intent of PL 101-613?
- How do we best advance rehabilitation science?
- How do we best improve the function and quality of life of Americans with disabilities?

As noted above, although a Comprehensive Research Plan was developed in 1993, the Plan has not been revised or updated as indicated by the website (http://www.nichd.nih.gov/about/org/ncmrr/prog_priorities.cfm - accessed on 8-10-12). Thus, current research activities across the NIH have not been consistently tracked, and opportunities and needs for additional research and priorities have not been identified in a comprehensive and iterative manner.

As shown in Figure 3, 80% of all rehabilitation research at the NIH occurs outside of the NCMRR. Thus, there are significant opportunities for coordination across the NIH in order to maximize efficiency, identify priorities, and co-fund promising applications. Although a Medical Rehabilitation Coordinating Committee exists, it lacks the participation of high level leadership from other ICs and the necessary resources for effective coordination. The Committee meets infrequently and meeting minutes were not available for review. Some coordination occurs at the NCMRR; however, the extent of coordination and joint funding is limited primarily to NINDS and NIBIB and rarely with other ICs. The Coordinating Committee Table 1 shows the staff and budget allocations for trans-NIH coordination for 4 selected Coordinating Bodies. In comparison, the NCMRR has no dedicated personnel and no budget for coordination.

| Table 1: Estimated Number of Personnel* and Overall Budget of Selected Coordinating Bodies, FY 2011 | | |
|---|--------------|--------------------|
| Body | Staff | Budget (\$) |
| Office of Behavioral and Social Sciences Research | 14 | 27.0M |
| Office of Autism Research Coordination/Interagency Autism Coordinating Committee | 6 | 1.9M |
| Office of AIDS Research | 38 | 3B/63.3M* |
| Office of Research on Women's Health | 18 | 42.3M |
| *Estimated staff figures include a wide range of personnel categories--scientific and administrative. In the case of the Office of AIDS Research, the figure also includes staff funded by OAR but working in other NIH offices (budget, contracts, legislative affairs, etc.) and assisting with AIDS-related research activities. | | |
| *The total AIDS appropriation for NIH is ~\$3B each year, most of which OAR distributes to the ICs. In FY2011, OAR retained ~\$63.3M for its own operating expenses, research coordination activities, and co-sponsorship of initiatives and programs. | | |
| -Unofficial estimates - | | |

As required by PL 101-163, the National Advisory Board on Medical Rehabilitation Research was established and meets twice yearly. However, since the Research Plan has not been revised since 1993, the Board has not had the opportunity to advise the Directors of the NICHD and the NCMRR on the provisions of an updated Research Plan. Members of the Board who were also members of the Blue Ribbon Panel are unclear regarding their role, and the Board's impact is uncertain.

The Panel examined NCMRR's relative emphasis on different diseases and conditions. According to PL 101-613, rehabilitation research funded by NCMRR should address a wide range of diseases and conditions that

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cause physical disabilities, including “...diseases or disorders of the neurological, musculoskeletal, cardiovascular, pulmonary, or any other physiological system...” NCMRR and NIH rehabilitation research portfolios do not appear to be addressing the scope of disorders equitably or related to prevalence. Figure 5, for example, illustrates the distribution of applications across various conditions received and awarded by the NCMRR. A large majority of applications appear to be devoted to neurological conditions. In addition, Figure 6 displays the NIH Institutes with the highest level of funding for rehabilitation research; NINDS, NIDCD and NICHD support ~50% of the rehabilitation research conducted at the NIH and the research at the three institutes is also predominantly neurological in nature. This emphasis is not congruent with the breadth of diseases and conditions identified in PL 101-613, or with the actual practice of clinical rehabilitation where a large majority of conditions being treated are not neurological in nature. For example, although musculoskeletal conditions and pain syndromes make up nearly half of clinical rehabilitation practice, only a fraction of applications to the NCMRR are musculoskeletal in nature.

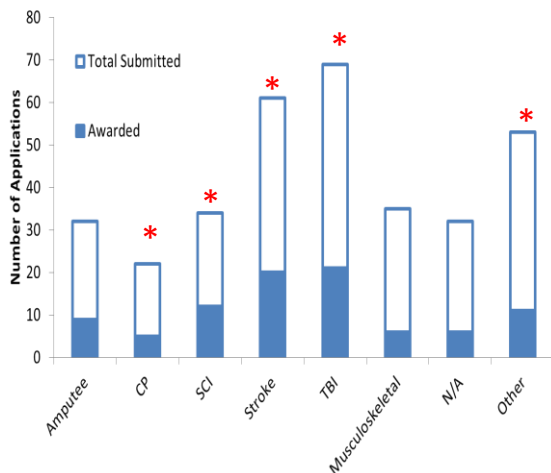


Figure 5: Total number of applications received and awarded by NCMRR during FY 07-11. “Other” indicates Parkinson Disease, MS, other paralysis and other neurological conditions. * indicates neurological conditions.

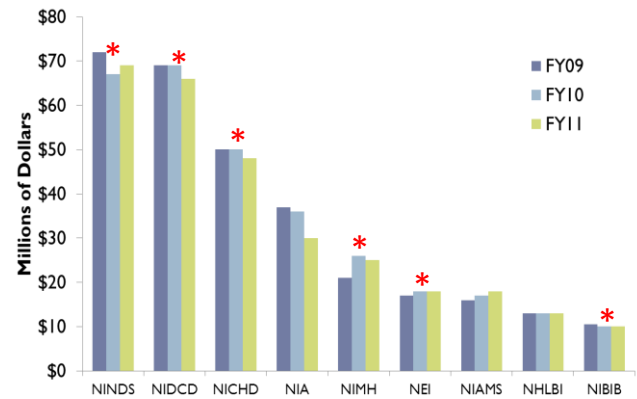


Figure 6: The NIH Institutes with the highest level of funding support for rehabilitation research. * indicates Institutes with primary neurological focus. (unofficial numbers)

Although funds allocated to the NCMRR from NICHD for grant support have grown tremendously since its inception (Figure 4), the NCMRR has experienced a steady decline in their grant funding levels and the number of Funding Opportunity Announcements (FOAs) relative to other Centers in the NICHD over the past 4 years. Figure 7 shows the grant funding levels for each NICHD Centers during 2007-2011. The NCMRR funding level was substantially lower than that of the other NICHD Centers, on the order of less than a third. While funding levels for the other NICHD Centers increased or remained stable during 2007-2011, the NCMRR funding level decreased substantially.

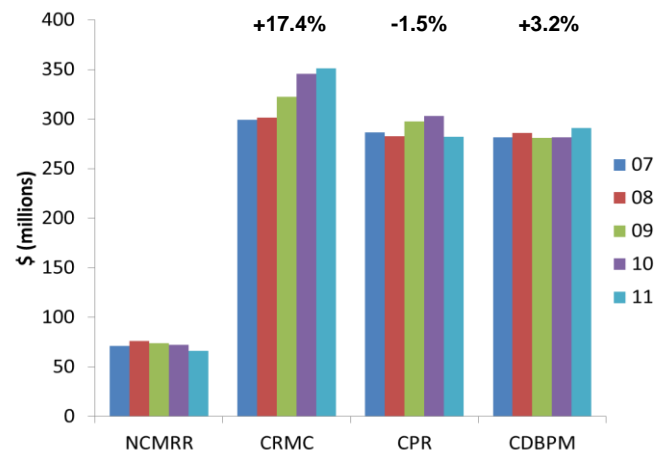


Figure 7: Annual grant funding levels for each NICHD Center during FY 2007-2011. Percent change indicates change between 2007 and 2011. CRMC: Center for Research for Mothers & Children; CPR: Center for Population Research; CDBPM: Center for Developmental Biology and Perinatal Medicine.

Figure 8 shows that the NCMRR funding level decreased by 7.3% since 2007 (by 13.2% since 2008), while during this same period the NICHD budget increased by 5.5% as shown in Figure 9. Figures 10 and 11 show the total number of FOA

proposals and total staff, respectively, for each NICHD Center during 2009-2012. Although the NCMRR staff comprised only 9% of NICHD program staff, they wrote 18% of all FOA proposals during this time period. Figures 12 and 13 show the total number of published FOAs and the FOA success rates (published FOAs/proposed FOAs), respectively for each NICHD Center during 2009-2012. The total number of published FOAs decreased each year for NCMRR, while the other Centers remained stable. The NCMRR success rates were lowest of all NICHD Centers; in 2012, the success rate for NCMRR was 33% while the combined success rate for the other NICHD Centers was 66%.

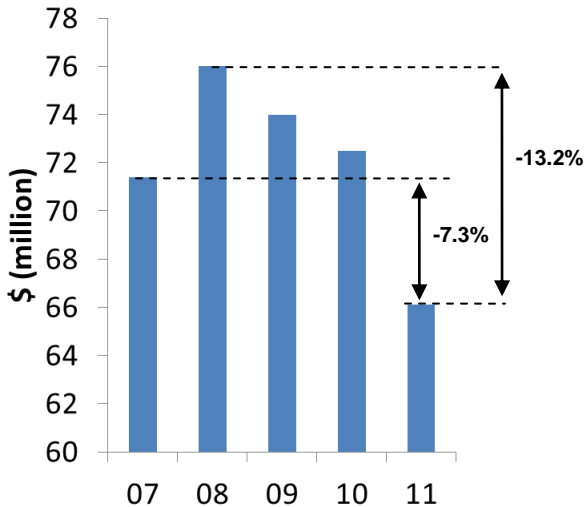


Figure 8: Annual NCMRR extramural award funding for 2007-2011.

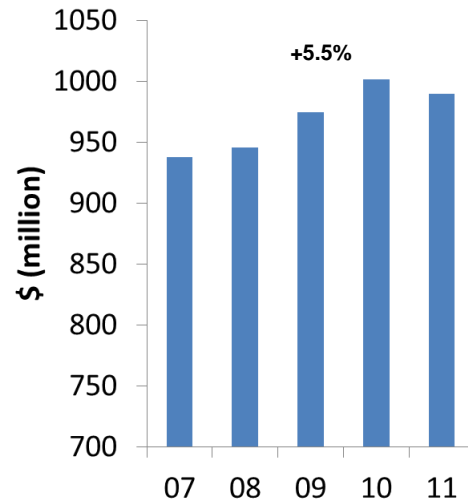


Figure 9: Annual NICHD extramural award funding for 2007-2011. Percent indicates change between 2007 and 2011.

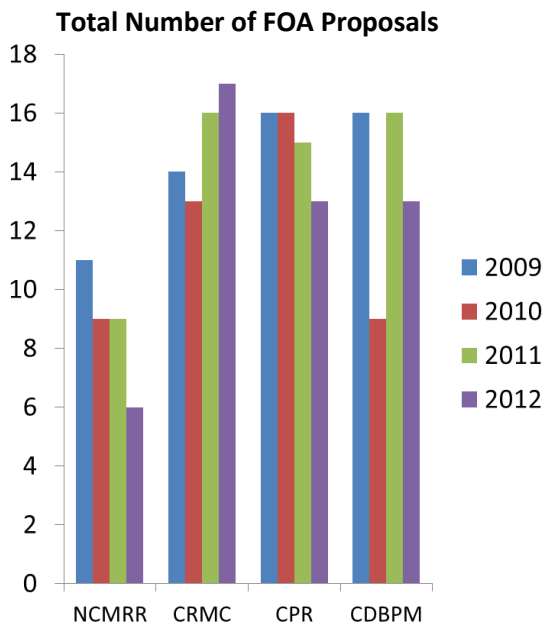


Figure 10: Total number of FOA proposals submitted by each NICHD Center.

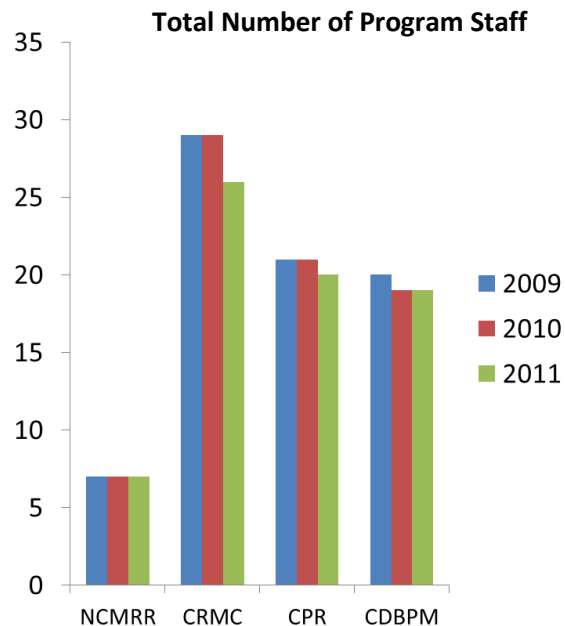


Figure 11: Total number of program staff by each NICHD Center. (Does not include administrative support staff.)

[Note: Figures in this report may not tie to published figures due to variations in inclusion/exclusion criteria.]

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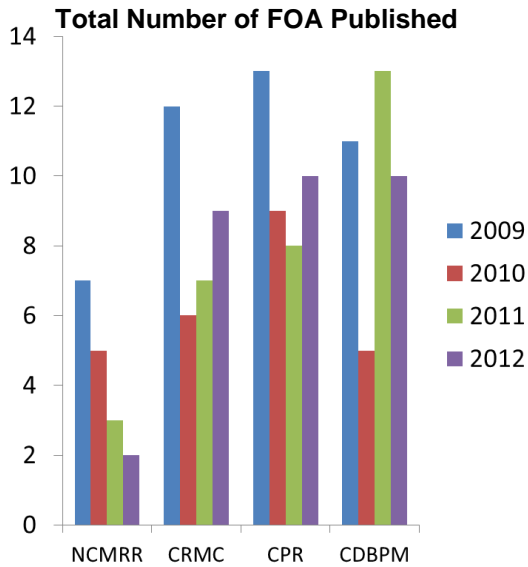


Figure 12: Total number of FOA proposals published by each NICHD Center.

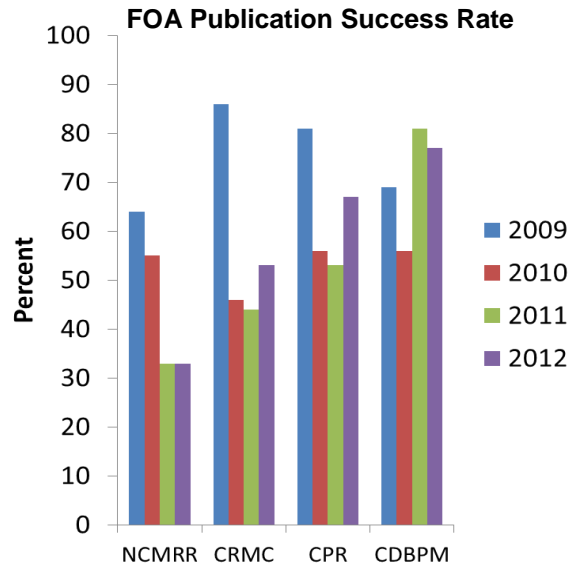


Figure 13: FOA publication success rates by each NICHD Center.

In summary, based on its analysis over the past year, it is the Panel's judgment that the NCMRR is functioning, but not thriving within the NIH. With the exception of the periodic revision of the Research Plan, the NCMRR is satisfying the "letter of the law," and is providing important services that were recommended by PL-101-613, but not required by law. Given the limited number of staff and resources at its disposal, the NCMRR should be commended for what it has been able to accomplish. Nevertheless, it is the Panel's view that there are important missed opportunities and significant new initiatives that are needed to help the NCMRR meet the broader performance criteria with respect to the spirit or intent of PL 101-613 – the advancement of rehabilitation science, and the improvement of function and quality of life of Americans with disabilities.

D. Can or Should there be Coordination of All Rehabilitation Research within the NIH?

The panel initially addressed the question, “**Can** there be coordination of all rehabilitation research within the NIH?” Conversations with the various NIH Coordinating Bodies and review of their activities demonstrated that a track record already exists for successful trans-NIH coordination. The NIH Office of AIDS Research, for example, works with *every* IC and *every* IC has AIDS research dollars. During interviews with the leadership of Coordinating bodies including the Office of Behavioral and Social Sciences Research (OBSSR), Office of Autism Research Coordination (OARC), NIH Office of AIDS Research (OAR), and Office of Research on Women’s Health (ORWH), potential barriers to the initial coordinating efforts within the NIH were identified. These include IC silo mentality and individualism that impeded initial coordination. Behavior will not change for a coordinating effort if collaboration and coordination activities are inadequately rewarded or not recognized during performance reviews and do not influence funding allocation. Support from high level NIH leadership that strongly encouraged trans-NIH collaboration and coordination was viewed as contributing to the coordinating bodies’ success. There were several key factors identified that characterized successful coordination. Public advocacy, congressional influence and high level NIH and IC leadership participation were major facilitators. Strong interpersonal skills characterized by negotiation skills, diplomacy and frequent social interactions were identified as key features of effective leadership in coordination. Finally, successful coordination was almost uniformly associated with dedicated funds available for “topping off” opportunities, co-funding, and “motivating” ICs to participate. “Topping off” refers to the use of funds to support an application at another IC that would otherwise go unfunded. Based on the success of other Coordinating Bodies, the Panel concluded that there **can** be coordination of all rehabilitation research within the NIH.

The Panel then directed their attention to the question, “**Should** there be coordination by NCMRR of all rehabilitation within the NIH?” As noted previously, a significant portion of rehabilitation research at the NIH occurs outside the NCMRR. Presentation by the various Institutes revealed a high degree of redundancy with Institutes unaware that other Institutes were funding very similar applications. Most Institutes were unaware of the WHO-ICF framework or worked outside the WHO-ICF framework. Finally most Institutes did not coordinate with NCMRR, and one Institute representative did not even know that NCMRR existed.

A more thorough review of the evolution of the Office of AIDS Research revealed important parallels with rehabilitation research: “Most of the earliest AIDS research was conducted by the National Cancer Institute (NCI) and the National Institute of Allergy and Infectious Diseases (NIAID), which, by 1985 was the lead Institute conducting and sponsoring AIDS research. ...the challenges posed by AIDS exceeded the mission of any individual Institute. AIDS is a multi-system and multi-organ disease, involving malignancies, opportunistic infections, and cardiovascular, neurological, gynecological, ocular, oral, dermatological, and gastrointestinal complications. It affects people across the life span from infancy to old age. Both behavioral and biomedical interventions are required to prevent new infections. Consequently, virtually every NIH Institutes and Centers (IC) became involved in conducting or supporting AIDS research. This burgeoning effort required coordination.” (<http://www.oar.nih.gov/about/history.asp>)

There are striking similarities between rehabilitation research and AIDS research. Rehabilitation research is not organ or disease specific, and as noted in PL 101-613, rehabilitation research focuses on “...individuals with physical disabilities resulting from diseases or disorders of the neurological, musculoskeletal, cardiovascular, pulmonary, or any other physiological system...” Rehabilitation needs affect people across the life span from infancy to old age. Societal, environmental, behavioral, and biomedical interventions are required to prevent and treat disabilities. As with AIDS research, rehabilitation research is cross-cutting, and virtually every NIH IC should be involved in the conduct or support of rehabilitation research. This requires coordination. The Panel concluded that rehabilitation research across the NIH **should** be coordinated.

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E. What are the Scientific Opportunities?

Scientific opportunities in rehabilitation research at the NIH were assessed in the context of 1) stages of translational research; 2) framework of the WHO-ICF; 3) the spectrum of clinical rehabilitation; and 4) prevalence of disability. Definitions of the stages of translational research are shown in Table 2.

Table 2: Stages of translational research

(http://casemed.case.edu/ctsc/cores/documents/CTSC_Projects_and_Translational_Research_2010-0111%20Final.pdf)

| Stage | Description |
|-------|--|
| T0 | Pre-clinical or “bench” research, all directed at mechanisms and presentations of human disease. |
| T1 | Translates discoveries made at the bench to first testing in humans, phase 1 and 2 clinical trials that take place at the patient bedside in an academic medical center. |
| T2 | Second phase of the translation process, builds on the clinical efficacy work conducted in T1, and translates results from early clinical studies to controlled observation studies and phase 3 clinical trials for bedside patient care and health decision making. |
| T3 | Third phase of the translation process, builds on the clinical efficacy work conducted in T2, and translates T2 research into clinical practice. |
| T4 | Fourth phase of the translation process, builds on the results of T3, helps identify the best approach to reach clinicians and patients nationwide so that they not only understand the new treatment but will start to use it. |

In general, the NIH has invested larger amount of resources in the basic sciences (T0) and early human trials (T1), and considerably less so on larger clinical trials (T2), including comparative and cost-effectiveness trials, which are essential for the translation of T0 and T1 discoveries to actual clinical practice (T3) and policy development (T4). At the NCMRR, this is reflected in the preponderance of applications that focus on mechanisms, which comprised 57% of all applications, compared to 43% for interventional studies (Figure 14). Mechanistic studies also have a slightly higher success rate (29 vs. 23%). Classification according to the WHO-ICF shows that applications submitted to the NCMRR were heavily weighted toward pathophysiology and the reduction of impairments, and considerably less so on more clinically relevant domains of activity and participation (Figure 15). Thus there are tremendous opportunities to increase the clinical and societal relevance of rehabilitation research throughout the NIH, and thereby enhance the quality of life of persons with disability, by addressing the gaps in the continuum of translational research and the WHO-ICF framework.

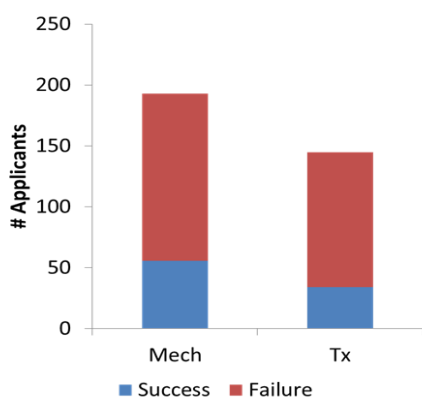


Figure 14: Number of applications submitted to the NCMRR during 2007-2011 classified as mechanistic (Mech) or treatment (Tx) and their relative success rates.

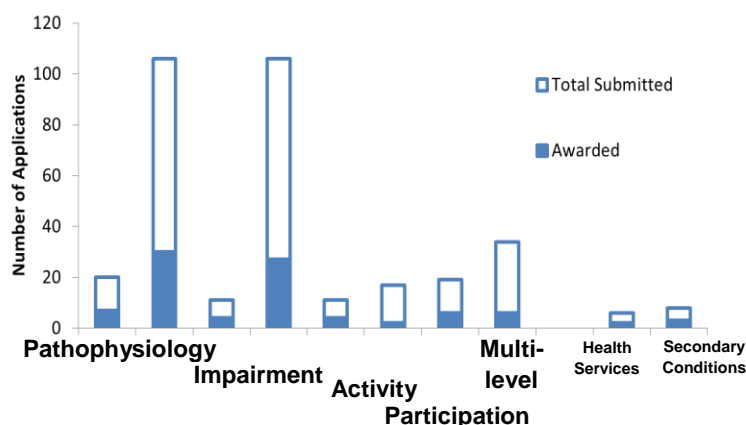


Figure 15: Number of applications submitted to the NCMRR during 2007-2011 classified according to the WHO-ICF domains and their relative success rates.

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As already noted, clinical rehabilitation spans the life span from infancy to old age, is based on the biopsychosocial model of the WHO-ICF, includes multiple diseases and organs, and embraces the transdisciplinary approach. However, survey of rehabilitation research at the NIH demonstrates disease or organ specific approaches that remain isolated in individual ICs with minimal interaction and coordination across institutes, a predilection toward neurological conditions and the non-pediatric population, and emphasis on biologic and engineering solutions. Despite this relatively narrow focus, major advances have been made in understanding the neurobiological underpinning of recovery, and it is likely that new interventional targets will be identified close on the heels of these discoveries. Likewise, technological innovations have provided new tools for monitoring function as well as controlled interventional modalities that may revolutionize clinical trial design in rehabilitation. But now there is significant opportunity for trans-NIH endeavors to tackle rehabilitation problems that span the life-span across a myriad of conditions (beyond neurological conditions) in a transdisciplinary manner with a focus on patient oriented outcomes. To this end, there are significant opportunities to expand the translational research spectrum in rehabilitation by conducting comparative effectiveness research and partnering with the Patient Centered Outcomes Research Institute. This transdisciplinary approach, by necessity, requires a coordinated strategic plan that includes multiple NIH ICs and investigators from numerous, even disparate, disciplines, including basic, social and clinical sciences, public health, health services research, engineering, biostatistics, and clinical trials methodology. In order to further facilitate translation, practicing clinicians, public health professionals, public advocates and persons with disabilities should have active roles in developing the strategic plan.

Finally, the above opportunities must be considered in the context of the prevalence of disability. Disability affects 13-14 percent of Americans (IOM, 2007) with a global prevalence of 15% (WHO, 2011). With the aging population in the US, this prevalence is expected to grow substantially. Yet, the NIH expenditure on rehabilitation research is less than 1.2% of total budget. Thus, while the above opportunities focus on “relative” gaps, the incongruity between prevalence and expenditure must be reconciled. This means that even though basic science and early efficacy trials that focus on discovery, mechanisms of disease and impairments have received more resources than other types of rehabilitation research, there are still substantial opportunities in these types of research that should be pursued. Thus there is a critical need to substantially increase ALL aspects of rehabilitation research across the continuum of translational research and the WHO-ICF framework in order to meet the growing rehabilitation needs of Americans.

The Future of Disability in America, Institute of Medicine, 2007 (Report Brief: <http://www.iom.edu/~media/Files/Report%20Files/2007/The-Future-of-Disability-in-America/Disabilityreportbrief.pdf>)

World Report on Disability, World Health Organization, 2011 (Full Report: http://whqlibdoc.who.int/publications/2011/9789240685215_eng.pdf)

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F. What Barriers Prevent Rehabilitation Science from Progressing?

The Panel agreed that a barrier to progress in rehabilitation science has been the self-focus of the rehabilitation scientists on advocating for their own disciplines with limited advocacy for the consumers of rehabilitation science. For example, NCMRR is the National Center for *Medical Rehabilitation* Research placing the focus on the researchers rather than the target populations. The 2000 U.S. Census (<http://www.census.gov/prod/2003pubs/c2kbr-17.pdf>) estimated that 49.7 million people in the U. S. age 5 and over have a disability -- nearly 1 in 5 U.S. residents.

1. 2.6 million were between the ages of 5 and 15. This was 5.8 percent of people in this age group.
2. 33.1 million were between the ages of 16 and 64. Only 36 percent of them were employed.
3. 14.0 million were 65 and over. Those with disabilities comprised 42 percent of people in this age group.

Focus on the need for rehabilitation science to develop interventions to reduce disability and to promote participation in society may enhance public awareness of the critical need for funding in this arena.

Another current barrier is that rehabilitation science faces a lack of understanding by those who are in a position to commit the resources. NIH is a disease-driven organization which frequently leads to fragmentation of rehabilitation research. In addition, NIH is primarily a biomedically-oriented organization, but much of rehabilitation is broader than biomedicine, preventing it from being fully accepted and respected within NICHD and across the NIH.

There is also a current lack of adequate outcome tools to measure effectiveness of rehabilitation interventions. Investing in tools is an opportunity, especially in a field that is often accused of using “soft” tools and outcomes. The field of mental health was able to take “soft” tools and have them accepted as hard evidence; rehabilitation science needs better outcome tools and needs to conduct the research to establish their psychometric utility. That will lead to making them more accepted.

The lack of coordination of rehabilitation science within and outside the NIH (VA, DOD, NIDRR, NSF) inhibits the development of rehabilitation research priorities and contributes to redundancies and duplication of effort. For example, exercise was a common topic when each of the 8 Institutes presented examples of funded research from their respective portfolios. Without coordination across these efforts, emphasis is on the need for exercise rather than on the type of exercise, the effective dose of exercise, or the most effective mode of exercise. Since a significant portion of rehabilitation research at the NIH occurs outside of NCMRR, coordination is critical to maximize the impact of available resources.

Due to the relatively low number of scientists devoted to rehabilitation, minor changes in funding level have a major impact on research, especially for the new investigators. The number of rehabilitation publications has increased, as have the number of researchers during the past decade, yet the amount of funding has decreased. The challenge will be to maintain sufficient funding to enable rehabilitation research to continue to progress and fill in some of the gaps across the continuum of rehabilitation research. While rehabilitation has been successful in developing a cadre of researchers, another challenge will be keeping them sufficiently funded so they will stay in the field. While keeping researchers in the fold may not be unique to rehabilitation research, the impact may be greater in the rehabilitation field because it has fewer researchers to start with.

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IV. Recommendations

Based on the data gathered, the Panel developed the following recommendations:

1. Functional Requisites

Over the past 20 years, the NICHD has served as an effective incubator for the NCMRR. The NCMRR has grown tremendously since its inception and has given legitimacy to rehabilitation science as evidenced by the growth and scope of rehabilitation research throughout the NIH. However, as the NCMRR emerges out of its “teenage years,” the Panel’s analysis suggests that while the NCMRR is functioning, it is not thriving, and is in need of significant revitalization. While rehabilitation research throughout the NIH has also grown, and has become important strategic elements of many NIH Institutes, it remains fragmented, uncoordinated, and without a trans-NIH strategic plan. Finally, although more than 10% of Americans are considered disabled, less than 1.2% of the NIH budget is dedicated to rehabilitation research.

In order to satisfy the broader performance criteria, NCMRR, as an entity, must satisfy the following functions:

- Granting – with independent control
- Coordination – within NIH, across federal agencies
- Budgetary control and stability for granting and coordination function
- Reporting mechanism – opportunity for negotiation for budgetary control and stability
- Capacity building
- Advocacy (persons with disability centered, not “us”)
- Single-entity

NIH investment, with dedicated funding, in strategic, comprehensive, and systematic coordination of rehabilitation research is a priority. It requires strategic collaborations among other institutes and agencies and networking with the rehabilitation research and advocacy communities to more broadly and comprehensively identify rehabilitation research needs and to help these institutes prioritize rehabilitation research with the goal of:

- Co-writing RFAs, RFPs, with or without dedicated funds
- Co-writing funding opportunities for training
- Planning and organizing conferences to identify opportunities with advocacy groups and interested ICs/Offices
- Avoiding duplication of efforts
- Defining priorities
- Coordinating study groups

The Panel recommends that dedicated funding be allocated for this coordination function; bringing “money to the table” when working with other NIH entities would ensure better success.

2. Structural Change

In order to satisfy the functional requisites, the Blue Ribbon Panel recommends a structural change where the NCMRR is transitioned into an independent IC or a new Office in the Office of the Director.

The independent IC should function in a manner similar to the other NIH ICs with the following unique features. A major objective of the new IC is to provide trans-NIH coordination. The new IC develops and implements a trans-NIH strategic plan with input from all ICs and other stakeholders. Rehabilitation research is centrally coordinated by the new IC as a “cross-cutting” element distributed across all NIH ICs. Thus, significant portion

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of the budget should be dedicated toward this coordination function. Given this strategic importance of coordination, the performance criteria and budget allocation for the new IC should include:

- Number of grants co-funded with other ICs
- Number of “topping off” grants with other ICs
- Growth of rehabilitation research across the entire NIH
- Growth of new investigators in rehabilitation research across the entire NIH

An alternative to an independent IC is a new Office of Rehabilitation Research (ORR) in the Office of the Director. Given the parallels between AIDS and rehabilitation, the Office of AIDS Research serves as the model for the proposed ORR. The ORR develops an annual trans-NIH strategic plan with input from IC program staff and senior leadership, trans-NIH coordinating committees, advisory council, representatives from other federal agencies, outside organizations and advocates, and community stakeholders. Unlike ICs, the ORR does not have grant-making authority, but helps coordinate research across the NIH. Every IC has a designated Rehabilitation Research Coordinator (with access to the IC Director) to liaise with the ORR. Institutes and Centers submit funding proposals to the ORR, and the Office distributes funds to ICs based on scientific priorities as outlined in the strategic plan.

3. Rehabilitation Research Definition

“The study of mechanisms and interventions that prevent, improve, restore or replace lost, underdeveloped or deteriorating function, where “Function” is defined at the level of impairment, activity and participation according to the WHO-ICF Model.

- 4. Develop, implement, and periodically update a NIH Rehabilitation Research Plan that includes a trans-NIH strategic plan to tackle rehabilitation problems that span the life-span across a myriad of conditions in a transdisciplinary manner.**
- 5. Network strategically with (1) staff of other institutes and (2) selected members of the rehabilitation research community to broadly and comprehensively identify rehabilitation research needs and opportunities worth pursuing, and to facilitate prioritizing rehabilitation research within each relevant Institute and Center. This role of joint or coordinated funding would be equivalent to the current NCMRR granting authority role.**
- 6. Increase the clinical and societal relevance of rehabilitation research throughout the NIH by addressing the gaps in the continuum of translational research and the WHO-ICF framework.**
- 7. Substantially increase funding for ALL aspects of rehabilitation research across the continuum of translational research and the WHO-ICF framework, including basic science and early phase clinical trials.**
- 8. Continue to build research capacity.**
- 9. Increase participation of persons with disability and public advocates in the development and implementation of the Research Plan.**
- 10. Change name of the Center to National Center for Rehabilitation Research.**

The Panel agreed to recommend replacing the medical aspect of the label “medical rehabilitation” or “rehabilitation medicine” because this implied profession and was perceived as very narrow in the field. We recognize the history of the term “rehab” implying drug and psychiatric rehabilitation. Given the maturation of the field and the growing body of knowledge, the Panel agreed that rehabilitation was strong enough to stand on its own.

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