



Opportunities and Priorities for Headache Research

NIH Headache Research Planning Meeting Report

Introduction

The prevalence of headache is enormous with more than 45 million Americans suffering from chronic, recurrent headaches. Migraine alone affects 15% of this population who have moderate to severe disability and often are not responsive to current therapies. Genetic, physiological, environmental, sex, lifestyle, and cultural factors all contribute to headache severity, disability, and responsiveness to treatment. Whereas advances in understanding the mechanisms underlying headaches have led to the development of new therapeutic strategies, research has been hampered by both the complexity and variability of the disorder. Headache treatments, therefore, remain inadequate.

Given this background, the National Institutes of Health (NIH) sponsored a workshop in May 2010 to guide a strategic planning effort to facilitate headache research. This effort was supported by NIH institutes with interests in headache research, private and public organizations, health care providers, researchers in the headache and other relevant fields, and patient advocates. The goal of the meeting was to develop a strategy that would engage all relevant partners to advance the field of headache research. A full list of participants is included at the end of this report.

The agenda for the workshop was based on recommendations of experts who participated in a pre-planning meeting sponsored by the National Institute of Neurological Disorders and Stroke (NINDS) in May 2009. Participants were asked to identify gaps in the research portfolio and to prioritize topics for discussion at the May 2010 workshop. Their recommendations were used to develop the participant list and select topic areas to be addressed by working groups at the planning workshop. The topics included: Animal Models and Research Resources, Translational Research and Drug Development in the Public and Private Sectors, Clinical Research Partnerships and Resources, Pediatric Headache, and Academic Headache Centers.

Experts at the May 2010 workshop were asked to describe the scientific knowledge gaps and recommend approaches to address the gaps to advance research. The groups also were tasked with noting available resources and technologies, suggesting means to share them, and recommending additional resources needed to advance the science. This report represents the recommendations and expectations of the multidisciplinary working groups relevant to basic, translational, and clinical headache research.

Several shared concerns and recommendations to address them were noted by all five working groups and are presented in a section below entitled “Global Findings and Recommendations.” The comments and discussions relevant to the specific working group topics are presented in later sections. The targeted audience for this report includes researchers in the public and private sector, health care providers, patients and patient advocates, and funding sources. The recommendations of the group are directed at all stakeholders in headache research and address some of the unmet needs which have hampered advances in research. Implementing the recommendations outlined in this report requires the effort of not only the NIH, but also the involvement and coordination of efforts by other Federal agencies, such as the Food and Drug Administration (FDA), Department of Veteran’s Affairs (VA), and the Department of Defense (DoD), as well as the pharmaceutical industry, professional organizations, research foundations, and patient advocates.

Global Findings and Recommendations

A number of findings and recommendations were shared by all working groups and highlighted cross-cutting needs in basic, translational, and clinical aspects of headache research.

Expand the Pool of Qualified Headache Researchers

Formal training opportunities in headache research for scientists and clinicians are not adequate to establish a robust, interactive, and sustainable pool of qualified researchers. Training opportunities need to be established and supported by academic institutions, pharmaceutical programs, public funding agencies, and professional societies. The lack of a well-trained pool of researchers and clinicians contributes to an environment in which skills needed to compete for research funds are lacking. In addition, there are not enough investigators to boost the volume of quality proposals for research dollars, provide the expertise to review research proposals, and mentor young scientists and clinicians. These hurdles contribute to the limited ability of the field to address research needs effectively.

One means to expand the field is to recruit and enhance collaborations with researchers in related (e.g., plasticity, epilepsy) and relevant (e.g., genetics, pharmacology) fields. These efforts are hampered by the lack of a forum for communicating with experts outside the headache research community. Effective clinical research partnerships with outside experts would also help the field to expand, but these partnerships depend on a strong infrastructure base and large research community.

For pediatric headache research, in particular, the greatest hurdle to advancement is the lack of interested clinicians and scientists at all levels of expertise and experience. The problem is exemplified by the current lack of fellowships in this field. Only one of ten fellowships accredited by the United Council for Neurologic Subspecialty in Headache Medicine is for pediatrics. Interest could be increased through training opportunities in Headache Medicine at the resident, fellowship, graduate, and post-doctoral levels by pediatric, neurology, psychology, and other programs, particularly those outside of neurology departments. Coordinated efforts among pediatric and adult headache scientists and other pain scientists would diminish hurdles to expanding the headache research effort.

Recommendations:

- Establish an environment for improved interaction with scientists whose interests relate to disorders that are co-morbid with migraine to help establish collaborations and provide new interest in headache research. Scientists and clinicians involved in headache research may be in many different academic departments besides neurology.
- Support collaborations across pediatric and adult headache investigators, and with pain scientists to address the unique needs of pediatric headache research.
- Support junior clinical investigators interested in headache research and increase research support for all levels of clinical investigators in headache-related research to catalyze movement of people into the headache field.
- Support integration of the pain and headache research communities, and create an increased awareness of the burden of headache among researchers in related fields and across funding sources. The goal of these efforts would be to attract researchers in other fields to develop headache research programs and encourage funding groups to support non-headache researchers entering the field.
- Disseminate information on funding opportunities and sponsor training sessions for grant writing skills.

Expand Support of Infrastructure for Headache Research

Adequate institutional support is recognized as a crucial element to provide an infrastructure base upon which to build strong and effective research programs that are competitive for funding sources, successful in training researchers, and effective in pain medicine. As a rule, headache clinics do not generate the financial resources needed to support a strong environment or infrastructure for research. Academic centers (real and virtual) need to provide support for basic through clinical research, including data management and analysis and clinical coordination support for interactions with other clinical sites. Furthermore, public funding mechanisms targeted for individual research grants and pharmaceutical support for clinical studies are not the most appropriate or sufficient ways to support infrastructure development. These factors influence the current status of many academic institutions in which headache research programs have shrunk or been eliminated entirely. The need for resources to support the special requirements of clinical pediatric headache research was highlighted. Opportunities for interactive, multidisciplinary teams to span the bench to bedside and bedside to bench gaps in communication also were recognized as essential to a successful research effort. Support for the establishment and maintenance of clinical research partnerships which focus on migraine/headache research was identified as an important need as well.

Recommendations:

- Develop partnerships to leverage resources, funding opportunities, and research support to strengthen the infrastructure base.
- Develop a model business plan for academic associations that would provide compelling arguments for institutional support for infrastructure.
- Encourage academic researchers to tap into diversified funding sources. Make available a coordinated source of information on available funding opportunities (through NIH, private foundations, industry, etc.). An omnibus NIH announcement was cited as an example of a helpful resource to identify areas of research supported by NIH. Enhanced research funding opportunities and applicant success in obtaining funding will promote interest in institutional support to develop and maintain infrastructure.

Promote Integration of Headache Research Efforts

The lack of a unified focus and strategy for headache research was recognized as a hindrance to advancement of the field. Collaborative efforts to develop headache research priorities will help to foster needed research partnerships and to direct funding opportunities. These issues were felt to be fueled by poor communication not only among the bench to bedside researchers within a given research or academic center, but also by barriers to communication between academic and pharmaceutical research facilities. These hurdles were considered to have hindered all areas of headache research but particularly translational research, where communication and interaction all the way from the bench to the bedside are needed to facilitate a pipeline for successful therapy development.

Recommendations:

- Convene a panel of experts in headache research who can provide leadership and guidance to prioritize areas of investigation with the goal of enhancing the headache research environment and improving infrastructure to support headache research. The formation of the panel, annual meetings, and all other activities of the panel should be managed by an impartial academic group

or scientific organization(s) to provide an open and unbiased forum for discussion. The panel should include representation from all partners in the headache research arena, including academia, industry, Federal agencies, private foundations and patient advocates. Their recommendations could be shared through a public forum and implemented through appropriate mechanisms and partnerships among patient advocacy groups, industry, government agencies, headache foundations, and professional organizations.

- Create an interactive environment through which researchers across and within academic institutions and industry can discuss and develop a common vision for research strategies and share current data, updates, and technological advances (e.g., a symposium at the Society for Neuroscience meeting or a Gordon Research Conference were suggested as a starting point for this effort).
- Provide a forum for industry and academic headache researchers to share ideas and timely advances in headache research (e.g., an annual meeting hosted by a non-pharmaceutical, non-academic sponsor).
- Develop and maintain a working relationship between NIH Institutes and Centers and the headache research community through research symposia and other interactive events.

Working Group Findings and Recommendations

Basic and Translational Research

The Animal Models and Research Resources and the Translational Research and Drug Development in the Public and Private Sector working groups highlighted a number of common challenges and opportunities for advancing basic and translational headache research. The findings and recommendations of these two groups were closely related and are integrated in this report under one heading.

Improved understanding of headache pathophysiology depends on availability and validity of appropriate animal models that accurately reflect the human condition. An ideal model of migraine headache would need to address the acute, recurrent, and chronic nature of headaches, as well as reflect the multiple and varied symptoms (e.g., cortical spreading depression, vasodilation, altered brain activation patterns, and sensitivities to chemical stimuli). Development of such a behavioral/physiological model is not considered a realistic goal at present and is not needed to attain the goals of headache research. The currently accepted mechanistic models for headache rely on measures of headache-related symptoms such as hypersensitivity to touch or light, which are exhibited by human migraineurs. The pain assays applied to these models, however, were not developed for and are not appropriate for headache conditions. Genetic models are perhaps even more problematic in that models based on single gene mutations are relevant only to rare forms of migraine. The multiple genetic contributions associated with common forms of migraine are poorly understood, difficult to isolate, and too complex to serve as useful models. It is not surprising then, that findings on therapeutic targets in animal models are not good predictors of clinical outcomes in humans.

Translational research is hampered not only by a lack of understanding of basic headache neurobiology and mechanisms of target drugs, but also by a lack of useful screening assays for drug development. The current models and assays that are accepted and validated for basic research are not optimal for the drug discovery process. Whereas surrogate markers for headache are essential for translational research, those used in basic research such as photophobia and cutaneous allodynia need further consideration and exploration for use in translational research. They may be useful as low

throughput drug screens, but high throughput assays, which are essential for drug screening, do not exist for headache.

Resources currently exist that provide opportunities to advance basic and translational research. Several behavioral and physiological models have emerged recently as accepted headache models by the research community and have potential to improve relevance of preclinical research to clinical phenomenon. Furthermore, many basic headache research laboratories are adopting headache-appropriate behavioral assays in their research (e.g., relevant pain thresholds, food intake, and light and sound sensitivity), which can be used in conjunction with classical physiological measures (e.g., electrophysiology, microdialysis, and molecular studies) to advance preclinical research findings. Moreover, human studies are providing opportunities to advance preclinical work. Imaging studies showing migraine-induced changes in brain states have the potential to be surrogate markers in animal models, and imaging results of rare headache related gene mutations have identified key areas in the brain for further analysis. Many compounds have been tested for efficacy in headache clinical trials and findings of their negative or positive effects can be used to validate animal models and assays. Basic genetic research will benefit from the high-throughput sequencing of migraineurs that are yielding a multitude of candidate genes for further exploration.

Recommendations:

Basic Research:

- Develop and improve animal models and assays to better reflect the human condition. Symptoms of migraine (e.g., photophobia and phonophobia) need to be validated as surrogate markers. Clinical phenomenon (e.g., cortical spreading depression, vasodilation, altered brain activation patterns, and sensitivities to chemical stimuli), relevant neural circuitry (e.g., pain modulation pathways and the trigeminal system), and the episodic nature and spontaneous pain of migraine need to be reflected in models. Models with known genetic alterations and their mechanisms are needed, but should be developed only as their contributions to headache are understood. Opportunities should be developed to train researchers to use and share accepted models created in expert laboratories and apply appropriate assays in their own research programs.
- Establish a functional imaging consortium to consolidate and standardize data and data collection. Develop partnerships across industry, academia, and relevant consortia (e.g., the Foundation for NIH Biomarker Consortium) to share imaging resources and foster collaborations. Expand animal imaging resources to support studies using behavioral models of pain and other symptoms of migraine.

Translational Research:

- The headache research community needs to develop a cogent strategy to standardize criteria for evaluation, validation, and determination of the predictive values of models for screening and testing potential therapeutic compounds. These steps need to occur before a large scale drug screening program can be launched effectively. A scientific consensus meeting should be convened for further discussion of the field's needs and priorities at this stage in translational research to address the following issues:
 - Current behavioral models need to be validated as potential low throughput screening tools for translational studies before developing new models and assays. Their

- responsiveness to drugs effective in the acute and preventive treatment of headache in humans should be one tool for validation.
- Mechanistically based assays (e.g., CSD slice model) need to be evaluated for validity and accepted or rejected.
 - Validated and accepted pharmacological criteria for drug target engagement are needed. A link between molecular mechanisms of headache and drug targets most likely to alter their pathophysiology will facilitate the likelihood of successful trials for clinical efficacy.
 - Models for rapid throughput drug screening need to be prioritized and developed. Sensitive assays to screen for negative effects of drugs are also needed.
- New compounds for screening and testing need to be generated. Relevant molecular libraries are needed to generate compounds to study mechanisms of headache and development of drug targets.
 - Pharmaceutical companies should make relevant compounds and data on the compounds available for further headache research and testing.
 - Evaluate and improve criteria for the preclinical research phase of drug development to facilitate approval for safety studies in humans and to support clinical trials. Guidance for harmonization and standardization of preclinical research studies, validation and acceptance of new methods for safety evaluation, and marketing authorization would focus preclinical research resources and facilitate trial implementation. FDA input and support are needed to facilitate these changes.

Clinical Research Partnerships and Resources

To advance clinical headache research, effective partnerships between academia, industry, Federal agencies, private foundations, and patient advocates are needed. Successful partnerships could facilitate numerous aspects of clinical research including consistency and sharing of data across trials, sharing information on failed or pending trials, repurposing of trial drugs, and centralizing strategies for clinical research. Effective collaborative research efforts and teams within academic institutions are sparse and, therefore, limit the ability to develop partnerships outside of their institutional settings. Existing and new potential partnerships are limited by financial constraints, a small pool of qualified and trained researchers, and lack of necessary infrastructure. Opportunities for academic and pharmaceutical communities to interact are increasingly limited by potential or perceived conflicts of interests.

Resources that provide opportunities to expand clinical research partnerships currently are available through the NIH Clinical and Translational Science Awards (CTSAs) which support research training, as well as basic and clinical research. Many of the academic centers where headache research is ongoing have access to currently funded CTSAs, which are designed to partner with academicians for research support. Programs to better integrate the C TSA research resources with the pain and headache community have been initiated. The Foundation for the NIH may provide partnership opportunities to develop initiatives for headache research support. The Foundation can provide a means to bring industry, academia, NIH, and private foundations together to support research. Patient Advocacy Groups/Headache Research Foundations are providing increasing opportunities for research support, patient registries, and educational programs.

Recommendations to Enhance Clinical Research Partnerships and Resources:

- Establish a partnership among non-profit organizations, academia, government, advocacy, and industry specifically to facilitate therapy development and testing for headache. An example is the American Society for Experimental NeuroTherapeutics (ASENT), which engages in scientific exchanges to encourage contacts between those involved in the discovery and development of neurotherapeutics for diseases of the nervous system and provides opportunities for dialogue between the interested groups. <http://asent.org/go/about-asent>
- Explore and support training experiences that cross partner boundaries with the goal of broadening clinical research skills, providing opportunities for resource sharing, and expanding the pool of experienced mentors and the research knowledge base. An example is to provide for visiting clinical fellowships in pharmaceutical research facilities with preclinical laboratory and/or clinical research and/or biostatistical training experiences.
- Promote partnerships between academic and industry research programs to facilitate access to existing pharmaceutical and academic databases, which is an important resource to optimize clinical trial design and approaches. The pharmaceutical industry's repositories of patient samples could be tapped for further exploration as new molecular or genetic drug targets emerge.
- Design and promote educational programs to inform clinicians on how to develop trial design elements, implement trials, and interpret results from trials. This could be part of a larger effort for clinicians in other fields – in addition to headache - as well.
- Design and implement educational programs for patients to better understand trial goals, patient roles in clinical research and to foster patient participation in trials.
- Create an open and interactive environment across the clinical headache research partners to facilitate sharing and development of knowledge, data, resources, infrastructure, and patient populations. A roadmap for this environment should include planning and working meetings, symposia, and other events that reach across the potential partners in headache research.
- Facilitate partnerships between clinical researchers and FDA staff to investigate possibilities for changes in trial design and measures to optimize investment in headache clinical trials.

Pediatric Headache Research

Headache in young children, adolescents and young adults affects a significant proportion of society, including patients and their families. Pediatric headache is recognized as a progressive disorder with a changing phenotype over a lifetime. Challenges in pediatric headache research include a poor understanding of neurophysiological processes underlying acute and chronic headaches, the complex genetic nature of primary headaches, lack of biomarkers, and need for standardized and validated clinical evaluation tools.

There are gaps in the understanding of pediatric headache disorders and limitations to interventions that may improve management and long-term outcomes. Developmentally appropriate clinical study designs are limited as to how they can incorporate biological, sociological, and developmental aspects of treatment because of the unique nature of the pediatric population. Similar to the headache field in general, there is a limited number of stakeholders in pediatric headache, both clinically and scientifically, which results in insufficient research and an inadequate knowledge base. Evidence-based ways to change the impact of this disease in children, adolescents, and young adults are not known, and will not advance without well-designed research across the spectrum of investigation.

Opportunities to advance pediatric headache research are provided by the resources and data generated from adult headache research. Tools to evaluate comparative outcomes and treatment responses at both clinical and population levels exist for adult populations. Epidemiological tools and headache questionnaires for adults are well established. These resources can be leveraged to optimize pediatric trials. In addition, data sets to examine headache characterization and treatment response patterns to determine best therapies exist for adults and can be modified to improve pediatric headache management. Medicines tested in adult headache trials that have a proven safety profile, but lack effectiveness data in children, provide a unique opportunity for efficient development and execution of pediatric trials. Pediatric headache studies offer a unique opportunity to understand headache across the lifespan, because they can be initiated at the early stage of the disease before progression and refractoriness has occurred. The relative lack of co-morbid conditions and limited exposure to treatments that may alter disease presentation helps in interpretation of disease manifestations and helps facilitate study of headache effects on population and family, longitudinal and cross-sectional outcomes, and burden of disease over the life span.

Recommendations:

- A consensus by the headache community should establish standardized and validated diagnostic, evaluation (including neuroimaging) and outcome criteria (significant vs. incidental) for clinical studies.
 - Include the development of pediatric specific headache questions and endpoints for appropriate assessment of impact and outcome.
 - Develop tools for improved phenotyping of pediatric populations to include co-morbid conditions.
- The community should establish pediatric-specific methodology for trials.
- A consensus by the headache community should improve evidence-based treatment guidelines for pediatric populations. Clinical research will support this effort.
- Opportunities to run efficacy trials to evaluate existing adult therapies for both acute and preventive treatment should be expanded. Trial design guidelines that address unique aspects of pediatric headache must be applied and should include biological efficacy and cost-effectiveness.
- Opportunities to implement rigorously designed studies by relevant funding bodies to assess the global impact of pediatric headache at the individual, family, and society levels are needed. Clinical studies should include influence and impact of headache and treatment intervention on socioeconomic status, educational status and school intervention, and/or employment success, and reproductive influences. At the patient level they should provide assays for neurological changes, and risk of disease progression.
- A pediatric focused biorepository should be established to facilitate identification of genetic markers and biomarkers and seed future static and longitudinal studies on the genetics, gene expression, and metabolic activity in a subject population that is naive and developing with a changing phenotype. The repository should include well characterized phenotypic data.
- Determination of the epidemiology and natural history of pediatric headache, especially migraine, will help to identify individuals at risk for progression of disease and determine whether progression is modifiable or reversible. Data points should include changes in phenotypic expression over developmental and life stages, to address the potential for reversing progression and the impact of interventions on headache progression.

Academic Headache Centers

Very few academic headache centers exist, and those that do exist often struggle financially. Medical schools lack faculty with expertise in headache disorders, as compared with other neurological disorders, and few post-graduates choose to pursue a clinical research career in Headache Medicine let alone basic research. Academic headache centers could improve understanding, diagnosis and treatment of headache and advance patient care by: conducting and expanding basic and clinical research; establishing an environment conducive to translational research; improving education of medical students, residents and fellows in headache; improving standards of care; introducing interdisciplinary approaches to the lab and clinic; and establishing a system to measure treatment outcome and enhance individualized patient care. Institutional support of existing infrastructure for academic headache research centers is needed. Establishing new centers where infrastructure is lacking (i.e., headache clinics and research laboratories) currently is unrealistic. The working group recognizes that without this base, the ability to undertake such a venture is well beyond the ability of any potential funding source or mission of any single partner. The stakeholders, including multidisciplinary academic teams, who are interested in developing centers to support research and patient care, could develop a model business plan that could be used to make the argument for institutional support. Institutional support could include such things as: means to attract residents and students from related disciplines to headache research; institutional training fellowships and career development support; awards and venues for rotating residents; and resources for design and development of an education and training syllabus in undergraduate, graduate, and medical schools. While traditional, single-site academic headache research centers are one model, virtual headache centers could also play an important role in filling this niche. Virtual centers, which incorporate resources of multiple sites, could offer the opportunity to collaborate with scientists/clinicians who are most appropriate and well-equipped to tackle specific questions which lay outside the expertise of the core institute.

Recommendations for Design and Development of Centers:

- Translational research: An academic headache research center should be designed around: (a) basic and clinical science researchers; (b) mentors who are qualified to attract, educate, and train fellows; and (c) academic clinicians. Creating a natural environment for interactions between scientists and clinicians will facilitate bi-directional translational research and cultivate partnerships in which clinical observations can be tested in the laboratory, while laboratory findings can be brought to the clinic. These partnerships are crucial for the success of translational research.
- Education and training: An academic headache research center should offer a comprehensive education and training program that includes basic and clinical research, advanced patient care, exposure to all available therapeutic approaches, and training in outcome measures. The mission is to produce well-trained and educated headache clinicians and researchers and will be achieved by training at all levels of medical education.
- Patient care: The complexity of headache disorders dictates that academic headache research centers offer a multidisciplinary approach, encompassing neurology, psychology, and psychiatry. In addition, anesthesia, physical medicine and rehabilitation, nutrition, gynecology, dentistry or oral surgery, otolaryngology, ophthalmology, and mind-body medicine are useful and important adjuncts. Communication and collaboration across these departments would be encouraged at and facilitated by academic headache research centers.

- Individualized patient care using outcome measures: An academic headache research center should offer sufficient time with patients to extract all information about clinical symptoms and to collect data on successful and failed treatment approaches. Such data (conducted as prospective observational studies), if collected by multiple headache centers and added to a nation-wide database, would establish a substantial basis for evaluating effectiveness of treatment. Such a database, when collected along with individual neurological profiles of the patients, could help to identify responders/non-responders to treatments.
- Expand the field of researchers and clinicians from within and outside the headache field: An academic headache research center should play a crucial role in attracting researchers and clinicians to the field. To attract new clinicians, the center should offer 1-3 month headache rotations to residents in neurology, anesthesiology, internal medicine, family medicine, gynecology, psychiatry, psychology, physical medicine and rehabilitation, otolaryngology, and oral surgery. To attract new researchers, the center should offer undergraduate and graduate classes on headache research and opportunities for research in appropriate laboratories.

Conclusion and Future Directions

The participants at the May 2010 meeting made a number of important recommendations regarding headache research priorities and future scientific directions that are outlined in this report. These recommendations encompass many aspects of headache research including basic, translational, and clinical research issues, training and career development for students, clinicians, and researchers, and infrastructure needs to move the field forward. The recommendations may be used as a guide and starting point for all stakeholders – including Federal agencies, the pharmaceutical industry, academia, professional organizations, and patient groups – to consider as they implement new programs or expand and refine existing opportunities. A commitment from all these partners, working together, is needed to help relieve the burden of headache disorders and provide new and improved treatments for headache sufferers.

NIH Headache Research Planning Meeting

May 2010

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