Advancing the Science of Neurorecovery

A model system grant holds promise for patients with traumatic brain injury

• ELIE ELOVIC, M.D., AND JONATHAN FELLUS, M.D.

More than 5 million Americans currently experience problems secondary to traumatic brain injury (TBI), and many do not receive the appropriate diagnosis and treatment.

But that’s about to change.

With a five-year grant from the National Institute on Disability and Rehabilitation Research (NIDRR), a model system has been established to fund studies devoted to the evaluation and treatment of individuals with TBI. Collectively known as the Northern New Jersey Traumatic Brain Injury System (NNJTBI), it consists of Kessler Medical Rehabilitation Research and Education Center (KMRREC) and Kessler Institute for Rehabilitation, Hackensack University Medical Center, Morristown Memorial Hospital, St. Joseph Medical Center and the University of Medicine and Dentistry of New Jersey-University Hospital.

One of only 14 model systems devoted to brain injury care in the country, the NNJTBI will focus on the continuum of treatment, from the onset of injury through acute care and rehabilitation to community reintegration and long-term follow-up.

As part of this effort, the model system will be involved in a number of key research projects that will ultimately benefit patients both in the United States and abroad. The information will be shared with the Traumatic Brain Injury National Data Center, which maintains a standardized database for innovative analyses of TBI treatment and outcomes.

In addition to helping advance patient outcomes, the five-year grant and resulting studies serve as recognition by federal agencies that fund rehabilitation research that brain injury is an epidemic worth studying. It also enables KMRREC and Kessler to remain at the forefront of innovative brain injury treatment and clinical research.

Currently, KMRREC, Kessler and University Hospital also collaborate in a model systems grant in the area of...
First, the disclaimers: I am currently president of the Foundation for Physical Medicine and Rehabilitation (PM&R), a charitable foundation operated by the American Academy of Physical Medicine and Rehabilitation (AAPM&R). And no, this is not a pitch for contributions (although my feelings would not be hurt if this article stimulates your giving gene a bit).

What I want to discuss is the premise of charitable support—the old saying that charity begins at home. We know that people are most likely to donate time and money to issues they deem especially important. For example, all of us know patients who have experienced a catastrophic event, and that led their friends and family down a path of intense charitable support. Local fundraisers and the creation of private trusts are prime examples of this type of charitable activity. Also, in PM&R, we often work with institutions that provide charitable support for nonprofit institutions such as hospitals or schools, or with foundations devoted to specific causes.

Our specialty actually developed in no small part because of philanthropic support. Bernard Baruch sponsored training fellowships in the 1950s and ’60s; Baruch Fellowships promoted the careers of many early PM&R pioneers. Also, community rehabilitation hospitals were often established through the interest and donations of local charities (the Junior League, for example). Many hospitals later formed their own charitable organizations to further support their missions. The Kessler Institute for Rehabilitation formed the Henry H. Kessler Foundation as a way of giving back to the world of rehabilitation. Other examples include United Way, the Muscular Dystrophy Association, the Spina Bifida Association and the ThinkFirst Foundation. Professional organizations, such as the AAPM&R, formed their own foundations (the Foundation for PM&R) to support research and education in PM&R.

Many of us who work in the field of PM&R find ways to get involved in charitable activities through such organizations that leverage our donated dollars by focusing on specific problems of interest to us. Why should we support these efforts? Because if we do not care about our own field, why should anyone else? Objectivism, a form of enlightened self-interest, guides us to give money to promote activities we believe in. We can give back to our society in a manner that is respectable and enlightened yet self-interested by supporting those things we know and care about, both professionally and personally.

While everyone should give to the degree that they can, we often wonder how much giving is enough. Should we tithe a certain percentage of our income, “give till it hurts,” or use some other model? Perhaps we don’t need to worry so much about the optimal formula, because there is no perfect model for giving; rather, we should select our causes carefully and support them regularly. We can enhance our giving for special situations. We can plan to make major contributions from our estates, incorporating giving into our wills or estate plans, creating a legacy of support for our favorite charitable causes. Most important, we can influence others to give, too.

I urge you to spread the word that giving is a good thing!
It is common for individuals to feel depressed, even to the point of hopelessness, after amputation. This depression has everything to do with a perceived loss of functional independence, and addressing it successfully involves a complicated mix of education and trust. At Kessler Institute for Rehabilitation, a combination of peer mentoring and self-management education has been shown to significantly help the new amputee rehabilitate both body and mind.

Because of its success in this area, Kessler has been a pioneer in training and certifying peer visitors, as well as in amputee education. Its current 10-week program anticipates and addresses common challenges faced by this patient population, including:

**Dealing with aches and pains.** Few if any amputees are prepared for the experience of postoperative pain or pain in the phantom limb. Kessler addresses the physical and psychological aspects of this pain.

**Envisioning the future.** A road map to recovery is essential to making the future both tangible and realistic. By removing the element of surprise, this helps minimize dread. Peer counseling is critical in this area.

**Interacting with family and friends.** While recent amputees haven’t changed as people, they may be perceived or treated differently. As a result, they often need guidance in understanding possible changes in behavior among family and friends, and in how to interact with them.

**Communicating, networking and taking advantage of community resources.** Withdrawal is a common emotional reaction for new amputees; the changes they’ve experienced often seem overwhelming. Kessler supports and encourages individuals to pursue activities they have always enjoyed.

**Maintaining a healthy outlook.** A positive attitude means getting comfortable with differences and understanding that amputation does not limit the opportunities for personal and professional fulfillment.

**Accepting support.** Learning to live with an amputation is an ongoing challenge. Patients commonly feel depressed and need steady emotional and practical support.

**Connecting for the long term.** The new patient will enter rehabilitation and participate with a group of other amputees. By learning from one another, patients at Kessler build long-lasting relationships and often hold “class reunions” where they continue to share experiences. These connections help pave the to a more successful recovery.

**Beyond Anecdotal Evidence**
While current successes of such peer mentoring rehabilitation programs are anecdotal, the PALS-Plus study will lend scientific support to the methods.

Expected to involve 400 patients at six sites nationwide, the study will divide subjects into two groups: one to receive the PALS intervention (including both peer mentoring and self-management education), the other a control. Both groups will be issued problem-solving worksheets and will be asked to keep a pain diary. They’ll be evaluated shortly after amputation, then at four months and again at 12 months. The primary outcome measures are function, self-efficacy and depression.

Researchers plan to complete recruitment by the end of 2008, with data compiled by the end of 2009. In addition to supporting patient outcomes, the most important dimension of this study is its potential for wider application. Ideally, the results will indicate that a peer mentoring program can be adapted to help those affected by other diagnoses, such as individuals who have experienced a stroke, spinal cord injury or brain injury.

**Bruce Pomeranz, M.D.** is medical director and director of Amputee Rehabilitation at Kessler. You can reach him at bpomeranz@kessler-rehab.com.

---

**Benefiting from Shared Experiences**
The role of peer counseling in amputee rehabilitation

---

**Why Peer Relationships?**
Amputees do not wholeheartedly respond to professional support and counseling, no matter how sensitive or empathetic a practitioner may be. However, they do relate to amputee peer visitors, as these individuals clearly understand their experiences.

Kessler has been a pioneer in training and certifying peer visitors, as well as in amputee education. Its current 10-week program anticipates and addresses common challenges faced by this patient population, including:

**Dealing with aches and pains.** Few if any amputees are prepared for the experience of postoperative pain or pain in the phantom limb. Kessler addresses the physical and psychological aspects of this pain.

**Envisioning the future.** A road map to recovery is essential to making the future both tangible and realistic. By removing the element of surprise, this helps minimize dread. Peer counseling is critical in this area.

**Interacting with family and friends.** While recent amputees haven’t changed as people, they may be perceived or treated differently. As a result, they often need guidance in understanding possible changes in behavior among family and friends, and in how to interact with them.

**Communicating, networking and taking advantage of community resources.** Withdrawal is a common emotional reaction for new amputees; the changes they’ve experienced often seem overwhelming. Kessler supports and encourages individuals to pursue activities they have always enjoyed.

**Maintaining a healthy outlook.** A positive attitude means getting comfortable with differences and understanding that amputation does not limit the opportunities for personal and professional fulfillment.

**Accepting support.** Learning to live with an amputation is an ongoing challenge. Patients commonly feel depressed and need steady emotional and practical support.

**Connecting for the long term.** The new patient will enter rehabilitation and participate with a group of other amputees. By learning from one another, patients at Kessler build long-lasting relationships and often hold “class reunions” where they continue to share experiences. These connections help pave the to a more successful recovery.

**Beyond Anecdotal Evidence**
While current successes of such peer mentoring rehabilitation programs are anecdotal, the PALS-Plus study will lend scientific support to the methods.

Expected to involve 400 patients at six sites nationwide, the study will divide subjects into two groups: one to receive the PALS intervention (including both peer mentoring and self-management education), the other a control. Both groups will be issued problem-solving worksheets and will be asked to keep a pain diary. They’ll be evaluated shortly after amputation, then at four months and again at 12 months. The primary outcome measures are function, self-efficacy and depression.

Researchers plan to complete recruitment by the end of 2008, with data compiled by the end of 2009. In addition to supporting patient outcomes, the most important dimension of this study is its potential for wider application. Ideally, the results will indicate that a peer mentoring program can be adapted to help those affected by other diagnoses, such as individuals who have experienced a stroke, spinal cord injury or brain injury.

Bruce Pomeranz, M.D., is medical director and director of Amputee Rehabilitation at Kessler. You can reach him at bpomeranz@kessler-rehab.com.

---

**Why Peer Relationships?**
Amputees do not wholeheartedly respond to professional support and counseling, no matter how sensitive or empathetic a practitioner may be. However, they do relate to amputee peer visitors, as these individuals clearly understand their experiences.

Kessler has been a pioneer in training and certifying peer visitors, as well as in amputee education. Its current 10-week program anticipates and addresses common challenges faced by this patient population, including:

*Dealing with aches and pains.* Few if any amputees are prepared for the experience of postoperative pain or pain in the phantom limb. Kessler addresses the physical and psychological aspects of this pain.

*Envisioning the future.* A road map to recovery is essential to making the future both tangible and realistic. By removing the element of surprise, this helps minimize dread. Peer counseling is critical in this area.

*Interacting with family and friends.* While recent amputees haven’t changed as people, they may be perceived or treated differently. As a result, they often need guidance in understanding possible changes in behavior among family and friends, and in how to interact with them.

*Communicating, networking and taking advantage of community resources.* Withdrawal is a common emotional reaction for new amputees; the changes they’ve experienced often seem overwhelming. Kessler supports and encourages individuals to pursue activities they have always enjoyed.

*Maintaining a healthy outlook.* A positive attitude means getting comfortable with differences and understanding that amputation does not limit the opportunities for personal and professional fulfillment.

*Accepting support.* Learning to live with an amputation is an ongoing challenge. Patients commonly feel depressed and need steady emotional and practical support.

*Connecting for the long term.* The new patient will enter rehabilitation and participate with a group of other amputees. By learning from one another, patients at Kessler build long-lasting relationships and often hold “class reunions” where they continue to share experiences. These connections help pave the way to a more successful recovery.

**Beyond Anecdotal Evidence**
While current successes of such peer mentoring rehabilitation programs are anecdotal, the PALS-Plus study will lend scientific support to the methods.

Expected to involve 400 patients at six sites nationwide, the study will divide subjects into two groups: one to receive the PALS intervention (including both peer mentoring and self-management education), the other a control. Both groups will be issued problem-solving worksheets and will be asked to keep a pain diary. They’ll be evaluated shortly after amputation, then at four months and again at 12 months. The primary outcome measures are function, self-efficacy and depression.

Researchers plan to complete recruitment by the end of 2008, with data compiled by the end of 2009. In addition to supporting patient outcomes, the most important dimension of this study is its potential for wider application. Ideally, the results will indicate that a peer mentoring program can be adapted to help those affected by other diagnoses, such as individuals who have experienced a stroke, spinal cord injury or brain injury.

Bruce Pomeranz, M.D., is medical director and director of Amputee Rehabilitation at Kessler. You can reach him at bpomeranz@kessler-rehab.com.
Treating the Challenges of Multiple Sclerosis

Kessler’s comprehensive rehabilitation program focuses on three critical areas of care.

As individuals learn how to manage issues ... their symptoms become more predictable and they are able to take charge of their illness.

One of the few constants with multiple sclerosis (MS) is its variability. Its unpredictable progression and the myriad issues involved make it a rehabilitation challenge. Kessler meets that challenge with one of the country’s most comprehensive programs for MS—an approach that unites three disciplines into one dedicated effort: physical medicine, cognitive rehabilitation and psychosocial education/support.

The three Kessler team members who lead each program—Allison Averill, M.D., director of NeuroRehabilitation; Monique Tremaine, Ph.D., senior neuropsychologist/clinical manager for Kessler’s Cognitive Rehabilitation Programs for Acquired Brain Injury and Multiple Sclerosis; and Kimberly McGuire, Ph.D., staff psychologist in the Department of Psychology and Neuropsychology and chief psychologist for the MS program at Kessler—discuss what makes each component unique.

PHYSICAL MEDICINE

Focus: First, is it inevitable that people with MS become incapacitated? Allison Averill, M.D.: Not necessarily. About 70 percent of patients have some kind of mobility dysfunction, but up to two-thirds can remain mobile for decades. The numbers are more encouraging than people think and therapy contributes to that.

Focus: How does Kessler’s physical medicine program for MS patients differ from other treatment approaches? Averill: We have equipment that other facilities don’t. For example, we use a body-weight-supported treadmill to help treat gait disorders. It’s expensive, but it produces results. One ataxic patient came to us totally wheelchair-bound and walked out of here using a walker. We also use Vital Stimulation, which is like TENS for the throat, to stimulate those muscles to build up strength.

Focus: What are the most promising MS treatments on the horizon? Averill: Cladribine and Fingolimod are showing promise in diminishing clinical symptoms and lesions. They may become the first oral medications for MS.

Focus: What clues can help you determine how MS will progress in an individual? Averill: That’s the million-dollar question. It’s like an investment portfolio disclaimer: “Past performance is not indicative of future results.” That’s probably the hardest thing for these people to live with. If we could give them a prediction, then they could have a plan. But there’s no way to predict disease progression. The only fact is that a poor prognosis is easier to predict than a good one.

Averill: Muscle weakness is the most challenging to treat? Averill: We have equipment that that a poor prognosis is easier to predict than a good one.

Fatigue is our patients’ biggest complaint. They describe this sudden, overwhelming, feels-like-I’m-going-to-drop-right-now fatigue—no matter how much sleep they get. Fatigue is worsened by increased body temperature. Some patients are so sensitive to this that they must eat their biggest meal early in the day. Or they may need a scooter to get around at work but they’re OK walking around their house. Fatigue is often addressed medically, but we also look for vegetative signs of depression [changes in eating, sleeping] and collaborate with the psychosocial group as needed.

Focus: What aspects of MS are the most challenging to treat? Averill: Physically, it would be ataxia. Looking at the whole picture, probably the constellation of the cognitive/behavioral/psychological issues is the worst to deal with, especially when they’re combined, which they often are.

COGNITIVE REHABILITATION

Focus: How does Kessler use cognitive rehabilitation to benefit patients with MS? Monique Tremaine, Ph.D.: Ours is a neuropsychologically driven, multidisciplinary program that represents the collaborative work of researchers and clinicians. Our methodology is derived from 15 years of study in the Kessler Medical Rehabilitation Research and Education Center (KMRREC), the research affiliate of Kessler, combined with years of clinical practice.

Focus: Why does MS warrant its own cognitive rehabilitation program—versus combining it with one for TBI or stroke? Tremaine: MS deficits typically are more subtle and less global than with...
TBI or stroke. Also, individuals with MS generally show a greater level of insight into the functional effects that such deficits have on their lives. Finally, many individuals with MS are actively working; treatment needs to be tailored to helping people adapt within their work environment to remain active in the labor force.

Focus: John DeLuca, Ph.D., the director of Neuroscience Research at KMRREC, has shown that people with MS process information slower than healthy people. What does that mean for MS cognitive rehabilitation?

Tremaine: It means patients have impaired information acquisition, but they have normal recall. If we can make their learning process more efficient, better planned and more organized, then we can improve their cognitive skills. Memory scores can improve with guided imagery, environmental control and contextually based learning, among other methodologies.

Focus: How do you use these techniques in your program?

Tremaine: We follow a tutorial, application and review format whereby each topic builds on the next and is presented serially to enhance learning, retention and implementation. Typically, we meet for two hours a day, three times a week, over eight weeks. And we often add “booster sessions.”

Focus: What quantifiable gains do you expect to see?

Tremaine: They will be more subtle than physical gains. While repeat neuropsychological testing may be one quantitative indicator of cognitive change, quality-of-life issues such as driving, maintaining a job or meeting the demands of a family should not be overlooked.

Focus: Two-thirds of all patients with MS have mild cognitive dysfunction. What is the biggest takeaway message you can give to those who are unaware of this prevalence?

Tremaine: Individuals diagnosed with MS have well-preserved verbal intelligence, which can mask direct observation of cognitive deficit. During diagnostic and follow-up evaluations, patients should be questioned directly about changes in thinking or mistakes made in daily life. Referral to appropriate cognitive rehabilitation programs may sustain individuals with MS longer in the workforce and increase their sense of empowerment as they navigate through the many changes brought about by this disorder.

PSYCHOSOCIAL PROGRAM

Focus: The third component of Kessler’s MS rehabilitation, which has been in place for two years, is its Psychosocial Program. Formally known as the Living with Multiple Sclerosis Support Group Series, it’s open to all patients with MS. How would you describe it?

Kimberly McGuire, Ph.D.: We use psychoeducational and emotional support to increase awareness of the changes that individuals with MS experience—and give them tools to deal constructively with those changes.

Focus: One of the most distressing aspects of living with MS is its unpredictable nature. How does the program address that?

McGuire: We help patients face their fears. We try to increase their awareness of how they perceive their illness, what that perception is based on, if the perception is counterproductive, and, if so, what can be done to modify it so that they can improve their quality of life. As individuals learn how to manage issues such as fatigue, depression and cognitive challenges, their symptoms become more predictable and they are able to take charge of their illness. Encouraging self-advocacy and involvement in every aspect of their care helps patients reclaim control over their lives.

Focus: What additional strategies do you employ to help MS patients?

McGuire: We talk about the mind-body interaction, identity changes and adjusting to the new self. We also discuss how to identify thoughts and feelings in the moment, as well as how to empower oneself to communicate effectively.

We provide a safe environment where patients can share their thoughts and feelings with others who have MS. Because family members should know about the symptoms and struggles of MS, we welcome them to participate in the first half-hour of each session—the psychoeducational component. However, the remainder, the support group portion, is for patients only.

Focus: Studies cite that 40 percent to 60 percent of all MS patients experience clinical-level depression. How do you distinguish that from MS-related fatigue, over-somatization or a cognitive dysfunction?

McGuire: You look at the patient’s entire history: academic, health, work. We recommend and conduct neuropsychological testing during our initial intake with patients. The results help us distinguish between MS-related cognitive deficits and those related to mood states or somatic symptoms. It’s a collaborative process with the other parts of the MS program.

We also talk about fatigue in the group setting. We “tease it apart”: What’s the basis of it? Not sleeping well? Having spasms? If you have a burst of energy one day, let’s talk about energy conservation because you might need that extra energy for work or your family.

Focus: How long do you follow patients who come through the psychosocial program?

McGuire: The program is eight weeks, 1.5 hours each week. We ask patients to self-report the value of the program a week after finishing it; then we do follow-ups three and six months later. If anyone wants to repeat the series or utilize psychotherapy, they can.

Focus: What excites you most about psychosocial MS research?

McGuire: Psychoneuroimmunology: the association between stressful life events and effects on MS exacerbations. Interventions that can prevent the body’s stress-induced activities, such as release of cytokines, could positively affect the immune system. So, teaching stress management or similar interventions may help prevent negative health effects.

You can reach Allison Auverill, M.D., at auverill@kessler-rehab.com; Monique Tremaine, Ph.D., at mtremaine@kessler-rehab.com; and Kimberly McGuire, Ph.D., at kmcguire@kessler-rehab.com.
The International Approach to Joint Rehabilitation

Will it work in the U.S.?

BRUCE M. GANS, M.D.

The raging dispute regarding the proper setting where patients should receive care for restoring function after an elective joint replacement procedure is well known. In the United States, we have traditionally cared for these patients in inpatient rehabilitation hospitals/units (IRH/U). However, the Centers for Medicare and Medicaid Services (CMS) and some private insurers see skilled nursing facilities (SNF) as a preferred, less-expensive setting. Since little compelling data appear to exist to support either care setting, I wondered if we might gain perspective by considering the manner in which other countries provide this care.

I have learned that there is a broad range of “proper” care pathways worldwide. Other nations seem to have a lower frequency of joint replacement surgery, and many of those patients have a longer post-surgical stay in hospital (around seven days, compared with our three or four) and are simply discharged home. Typically, no or very limited outpatient rehabilitation services are available, with minimal to almost no use of SNF for home healthcare unless the patient has a very serious problem such as wound healing.

While differences in care practices provide us with interesting opportunities for research (such as cross-cultural studies that evaluate risk-adjusted outcomes, cost-benefit and cost-effectiveness of care), most other countries do not routinely measure outcomes as we do, making pooling cross-cultural data quite difficult. This type of research is still in its early stages. Gerben DeJong, Ph.D., from the National Rehabilitation Hospital in Washington, D.C., is currently pooling international data in several of his studies, but the results have not yet been published.

Delivering to Expectations

Even without research data, we can conclude that strikingly different patterns of care worldwide arise largely from drastically varying expectations of the right way to proceed. For example, I recently visited a five-story nursing home in China that has no elevator. People are only expected to enter that building once; they are never expected to leave. While that is not our expectation of care in the U.S., it is quite acceptable in China. This difference is not a reflection of a wrong or right way to serve patients; rather, it illustrates the strong cultural bias that influences each country’s decision about how to provide care, including that for joint replacement patients.

In the U.S., we expect to be served, to be catered to and to have instant gratification. It is not at all surprising that we have a strong belief in a healthcare delivery system that provides the most rapid recovery of function. Expectations are an important bias for the care delivery process, after all. If we have high expectations of being served, of resuming normal function quickly, of having help and having it done in the most convenient way without disrupting home and family, then we think in terms of IRH/U as the best setting for rehabilitation after joint replacement surgery. If we only expected slow, laborious recovery at home without assistance, then we would envision a very different model of care as appropriate, with different associated costs.

Measuring Success

Another issue relevant to this debate is how we choose to measure outcomes and the criteria we use to do so. Focusing only on survival after surgery, for example, ignores rate of recovery of function and blurs the value and impact of care delivery settings. Measuring how many days until becoming pain-free postoperatively, on the other hand, would likely pick up a dramatic difference in comparisons of care delivery settings.

In the U.S., care providers expect to deliver the highest, most efficient, most rapid recovery of function, but it seems that payers have the expectation that less costly care is preferred even if it means slower, more painful and laborious recovery, with patients bearing more of the burden. Do we really wish to base our care model on low expectations that might be acceptable in some other countries but that do not reflect our culture and our expectations of the right way to proceed?

Bruce M. Gans, M.D., is chief medical officer of Kessler Institute for Rehabilitation. You may reach him by e-mail at bgans@kessler-rehab.com.
Advancing the Science of Neurorecovery

(continued from page 1) Spinal cord injury (SCI). This is one of only seven systems in the country recognized by NIDRR as a model system for both SCI and TBI.

A Three-Part Study
The NNJTBIS grant will cover three categories of research:

- **Cognitive Therapy:** A randomized, double-blinded, placebo-controlled trial will evaluate the effectiveness of cognitive retraining in individuals who have suffered TBI. The research will examine cognitive treatment in real-world environments, with the ultimate objective of helping injured patients resume their day-to-day activities. In addition to examining the benefits of intervention and booster therapy, the study will evaluate the effects of treatment six months after it’s concluded.

- **Mining Data to Extract Trends:** Researchers will collect data on patients from 14 centers nationwide to study patterns of recovery among people with TBI. In addition to identifying trends related to brain injury over time, they’ll weigh data to determine if there is a need to influence public policy and to advise volunteer organizations on how to best allocate their limited resources. The goal is to explore the many factors affecting patient outcomes while also evaluating the medical economics of brain injury.

- **Collaboration:** Model system healthcare centers will team up to study research critical to the treatment of TBI. One study, for example, involves geographic localization of patients with TBI. Using GPS to track locations where injuries occur and are treated, researchers will determine whether socioeconomic factors affect outcomes after brain injury. Another study will explore the effect of TBI on sleep disturbance and insomnia. Patients who have suffered brain injury often experience a disruption in their sleep-wake cycles and complain of fatigue affecting their quality of life and everyday functions. This project will study the impact, prevalence and types of insomnia as a way of identifying possible treatments. These and other collaborative studies will provide opportunities for brainstorming and knowledge sharing that might not otherwise exist among healthcare institutions.

In all research areas, the NNJTBIS will ensure the validity of data through rigorous entry criteria. For example, patients who have sustained serious brain injury must first have been treated at one of four designated trauma centers and must then have been admitted as an inpatient to Kessler Institute for Rehabilitation.

Leadership and Innovation
Each of the components of this five-year research effort has a common theme: taking a scientific, evidence-based approach to the clinical and medical problems of people who have sustained TBI. This is the core of the model system, and it is why all participating centers expect to emerge with demonstrated criteria for treatment of this patient population.

Efforts are already motivating greater communication with upstream providers in the U.S. who are receiving more information about their former patients’ prognoses and outcomes. That alone is an important byproduct of the grant. But as the database steadily accrues information (at present it contains data on more than 7,000 people throughout the U.S. who have sustained TBI), the benefits of this research will extend to millions of people around the world who have sustained brain injury.

Elie Elovic, M.D., is director of TBI research at Kessler Medical Rehabilitation Research and Education Center and a consulting physician at Kessler Institute for Rehabilitation. You can reach him at eelovic@kmrrec.org. Jonathan Fellus, M.D., is director of Brain Injury Rehabilitation at Kessler Institute for Rehabilitation. You can reach him at jfellus@kessler-rehab.com.

Studying TBI in Patients with Spinal Cord Injury

It is estimated that between 40 percent and 60 percent of patients with spinal cord injury also have some degree of brain injury. Often, because the spinal injury may be more dramatic, in the urgency of the moment the brain injury may be treated as a secondary problem. Sometimes it may even go undiagnosed. Unfortunately, cognitive problems caused by the brain injury may subsequently affect the recovery from spinal cord injury. However, the NNJTBIS model system’s capabilities, including strong clinical and research teams, make it uniquely qualified to address issues related to this dual diagnosis of TBI and spinal cord injury. The NNJTBIS is working with the NNJSCI system on this issue.

Elie Elovic, M.D., is director of TBI research at Kessler Medical Rehabilitation Research and Education Center and a consulting physician at Kessler Institute for Rehabilitation. You can reach him at eelovic@kmrrec.org. Jonathan Fellus, M.D., is director of Brain Injury Rehabilitation at Kessler Institute for Rehabilitation. You can reach him at jfellus@kessler-rehab.com.

kessler-rehab.com • 7
From Bench to Bedside

The eight essential elements of clinical research

STEVEN KIRSHBLUM, M.D.

Improving patient outcomes is the primary objective of a clinical research study. And the steps that lead from bench to bedside practice—ideation to implementation—are critical.

1. Determine the subject. Everything begins with a great idea. In clinical research, these always stem from patient needs. For example, one study currently under way at Kessler is a randomized, controlled trial examining the prevention of long-term respiratory complications of spinal cord injury (SCI). Diseases of the respiratory system are the leading cause of death following SCI in the chronic stages. Respiratory complications such as pneumonia, caused by a generalized weakness of inspiratory and expiratory musculature, are also a major source of morbidity and hospitalization. This study is expected to improve quality of life and reduce total costs.

2. Conduct pre-research and develop a plan. With a strong idea in place, investigators review the medical literature, looking for similar studies to identify research gaps and justify the background and significance of the effort. A complete proposal, including the specific aims, hypotheses, study design, subject selection, study interventions and outcome measures, is written prior to submission for review.

3. Identify team members and partners. Putting the right experts on the project is essential to completing the overall research design. Some may come from inside your organization, but outside collaborators also may be important in defining the study methodology. Choose a team based on alignment of skills and experience with the proposed study. In the respiratory study, Kessler’s team is collaborating with John Bach, M.D., of New Jersey Medical School’s University of Medicine and Dentistry, whose expertise in noninvasive management of respiratory disorders in people with neuromuscular diseases is essential to the project. Other collaborators include pulmonologists Greg Schilero, M.D., of the Bronx VA Medical Center, and Douglas Green, M.D., of Kessler Institute for Rehabilitation; statistician Eugene Komaroff, Ph.D.; physician researcher Trevor Dyson-Hudson, M.D.; and David Tulsky, Ph.D., an expert in quality-of-life issues, all with Kessler Medical Rehabilitation Research and Education Corporation (KMRREC).

4. Obtain funding. This is a challenge faced by all primary investigators. The two most common options involve applying for grants from national agencies, foundations or smaller organizations dedicated to sponsoring research, or securing funds from industry. For the respiratory study, most funding is part of the Model SCI System sponsored by the National Institute on Disability and Rehabilitation Research (NIDRRN), as well as additional resources from Kessler and KMRREC.

5. Approvals. After initial review by the Subject Safety Board (SSB) to ensure that patient safety and rights are not compromised, all clinical studies require Institutional Review Board (IRB) approval. The IRB evaluates the scientific, ethical and regulatory validity of the study, looking at the overall risks and benefits.

6. Educate the team. Upon approval, everyone involved must be trained to follow the study protocol.

7. Identify study participants and commence research. Subjects are randomized and treated according to the protocol, and monitored for endpoints. The respiratory study is currently at this stage, having enrolled its first few patients. The study is expected to continue for five years. Researchers conduct periodic compliance and patient-safety reviews, and, depending on study design, the team statistician may perform interim data analysis.

8. Present findings and incorporate into patient care. Once the results of the study are presented or published, and peers provide feedback, practices can be changed. Following through on research from the bench to bedside is one of the most gratifying aspects of being a clinician-investigator.

Steven Kirshblum, M.D., is medical director and director of Spinal Cord Injury Rehabilitation at Kessler. You can reach him at skirshblum@kessler-rehab.com.