Disturbed sleep is highly prevalent among traumatic brain injury (TBI) populations, with estimates ranging from about one-third to one-half or more of head injury cases. Despite the seriousness of the sequelae, our understanding of sleep-wake disturbances in rehabilitation research and practice is still nascent. But as our knowledge of these complex conditions improves, so too will our ability to provide comprehensive, evidence-based care for TBI patients.

**EYE-OPENING FACTS**

A common misperception of sleep disturbance in TBI is that it largely refers to just insomnia. In reality, other diagnoses occur frequently, including excessive daytime somnolence, impaired sleep maintenance, sleep-related breathing disorders (e.g., apnea) and overall poor rest due to factors such as decreased sleep efficiency, fragmentation and frequent wakening. Prevalence of specific disorders and symptoms varies but, in general, is relatively high. Approximately 30 to 60 percent of TBI patients are reported to experience insomnia; 25 to 50 percent, excessive daytime sleepiness; 10 to 30 percent, hypersomnia (narcolepsy); and 30 percent, sleep-related breathing disorders. TBI populations are two to four times more likely than individuals without head injuries to have impaired sleep maintenance and efficiency, excessive daytime drowsiness, sleepwalking and early awakening.

The precise pathophysiological mechanisms underpinning disordered sleep after TBI are unclear. Putative causes include hypothalamic lesion, reduced hypocretin-1 secretion, decreased melatonin production, impaired parasympathetic functioning, and alterations in the sleep cycle that deprive patients of restorative rapid eye movement sleep. One of the primary culprits concerns the body’s natural central timing mechanism. Indeed, TBI is known to induce alterations in the circadian rhythm through hippocampal (continued on page 2)
injury, causing interference with signaling from the suprachiasmatic nuclei. This disrupts not only sleep-wake functions but also hormone, metabolic, heart rate and temperature regulation.

WELL-TIMED TREATMENTS

Research suggests that sleep symptoms might be more pronounced during the acute recovery phase, with some impairments gradually diminishing. Nonetheless, treatment during any phase of rehabilitation should be considered, as sleep disturbance is associated with significant detriments in cognition, mood and daily functioning.

Pharmacological and behavioral interventions are the primary tools for treating sleep disturbance. Sedating agents such as benzodiazepines; neuro-stimulants like methylphenidate and modafinil; and melatonin agonists have been investigated but yielded mixed findings. Recommended behavioral practices are aimed at establishing good sleep hygiene. This includes, but is not limited to, setting and maintaining a regular sleep-wake routine; avoiding stimulating foods or beverages (such as caffeine) at night; reducing exposure to blue light from mobile phones, tablets and computers at least one hour prior to bedtime; and ensuring the bedroom is dark and cool in temperature. Environmental control is harder to establish once a patient is discharged to home, although the hospital is often a less-than-ideal place to achieve optimal rest. In neurointensive care, for instance, patients are exposed to light 24 hours a day and regularly disrupted to undergo neurological checks. Although mapping is not a standard feature of the sleep hygiene prescription for most patients, those with TBI may find dozing necessary. Even when sleep quality is good, brain injury populations usually experience daytime somnolence and require additional rest due to increased metabolic demand from the healing brain.

UNRAVELING THE MYSTERIES

As with other neurological and musculoskeletal conditions, sleep disturbance in TBI can impinge on rehabilitation outcomes and global functioning. However, variations in specific symptoms and disorders exist. For instance, individuals with spinal cord injuries are more likely than TBI patients to exhibit hypoventilation presenting with brain injury, particularly when damage has occurred to the reticular activating system, prefrontal cortices, anterior cingulate, hippocampus or parietal cortices.

THE FUTURE OF SLEEP AND TBI

The degree to which pharmacological and behavioral sleep interventions can safely and effectively address short- and long-term rehabilitation outcomes in TBI patients is unknown but being studied. Clinicians at Kessler Institute for Rehabilitation are contributing to the research base through medication trials (see sidebar “A Promising Role for Melatonin?”). Medication, behavioral and environmental interventions are utilized as appropriate. For instance, Kessler Institute clinicians help inpatients re-establish normal circadian rhythms and improve sleep consolidation by exposing them to bright light during the day and encouraging engagement in supervised, low-intensity exercise in the context of a structured therapy plan. Trazadone is dispensed at night to help individuals achieve deeper stages 3 and 4 sleep.

Brain injuries and sleep disorders are significant public health concerns in their own right, each imparting a unique effect on mortality, morbidity, and health care spending and use of resources. Taken together, they pose a serious risk for patients’ long-term functioning. And in the absence of preventive or curative measures, the rehabilitation field will continue to rely on growing research to lead us out of the dark.

A PROMISING ROLE FOR MELATONIN?

In 2015, clinicians from Kessler Institute for Rehabilitation and investigators from Kessler Foundation teamed up for what is currently the only published randomized controlled trial of ramelteon (a melatonin agent) in brain-injured patients. The six-week crossover study demonstrated a benefit of 8 milligrams of ramelteon taken nightly for three weeks on total sleep time and increased sleep latency compared with placebo. Treatment was also associated with improved scores of cognition, particularly executive functioning, reaction time and complex attention. Kessler physicians and researchers are now collaborating on a study drawing from a larger sample of participants.

In 2016, a working group of the American Society for Experimental Neurotherapeutics and the International Society for CNS Clinical Trials and Methodology released a set of recommendations to advance the science and treatment of sleep disturbance in mild TBI. Read more about them here: link.springer.com/article/10.1007%2Fs13311-016-0429-3.

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Raising their voices in protest

The news images of protesters on crutches and in wheelchairs being dragged from outside Sen. Mitch McConnell’s office, where they were protesting the potential decimation of health care, was both heartbreaking and heartening. Heartbreaking because of why they were there, but heartening because it demonstrated the freedoms of a nation that permits this type of activism.

Civil disobedience clearly helps raise public awareness and empathy for issues that affect minority populations, which is why it has been a core tactic for more than 50 years. Indeed, the disability rights era, which began in the 1960s, was modeled on the African-American civil rights movement with similar nonviolent protests. That’s because the disability community understands that disability rights are civil rights, the same liberties other minority groups have struggled to achieve.

Just consider some of the actions taken during the past half-century and more:

- The Independent Living Movement, which more than 100 people with quadriplegia launched in the 1960s in Berkeley, California, pushed for removal of barriers and for the rights of individuals with disabilities to determine their own fate.
- The Architectural Barriers Act, passed in 1968, mandated that federally constructed buildings and facilities be accessible to people with physical disabilities. The act was also spurred by Berkeley activists who smashed curbs in the city to create ramps and established a wheelchair route through the town and University of California campus.
- The Rehabilitation Act of 1973, among its tenets, prohibited discrimination against people with disabilities in programs and services that are federally run or that receive federal funds. Although signed into law, it took a sit-in of government buildings, including taking over the Department of Health, Education, and Welfare building in San Francisco for 25 days, before regulations were issued to implement sections related to antidiscrimination.
- During the transit protest in Denver in the 1970s, disability activists shut down the city’s bus system for two days. The next year, all city buses had wheelchair lifts.
- And, of course, there is the Americans with Disabilities Act (ADA), the most sweeping disability legislation in American history. When it stalled in Congress in the late 1980s, activists crawled up the Capitol steps in protest. The ADA was finally signed into law in 1990.

It is far from surprising to see the tactics of civil disobedience being reinstated given the devastating changes that have been proposed for the nation’s health care system, including massive cuts to Medicaid, which millions in the disability community depend on. These are civil rights matters for a potentially vulnerable class of people.

The ongoing efforts to protect access to health care are a statement of the positive aspects of a democracy, which allows citizens to express their political views even if the result is disruptive, albeit peaceful, behavior.
Regenerative medicine is a field in which the patient’s own healing factors are used to treat degenerative conditions. It is, in essence, a modern application of Chinese and other ancient Eastern methods. Western physicians have been slow to embrace this approach to treatment as anything more than alternative therapy, but that could be changing. Over the past decade, there has been a significant increase in the science and practice of regenerative interventions, which have now been introduced into a limited number of medical practices. These treatments offer alternatives for people with musculoskeletal and neuromuscular conditions causing pain and disability—putting an interesting twist on the term “personalized care.”

INSIDE INSIGHTS
The variety of cells in the body that are capable of healing injuries include growth factors contained on platelets as well as stem cells. A significant concentration is found in our bone marrow and adipose tissues. These are more plentiful when we are young and in those without medical conditions. Regenerative medicine is now taking those core concepts a step further by offering scientists and clinicians a way to turn our innate healing abilities into treatments for spine and orthopedic injuries.

The science behind regenerative medicine is based upon well-known human cellular physiology. On the surface of platelets sit alpha granules that release cytokine growth factors, which initiate healing through cell replication whenever an injury occurs such as a cut, strain, sprain or fracture. Stem cells are also recruited to the area of injury to assist with the reparative process. Thus, we commonly heal ourselves after most injuries. In some cases, however, there is an inadequate healing response, and a patient is left with a chronic, painful condition. In these cases, regenerative treatments can be quite helpful. By harvesting and concentrating these cellular components through the use of specialized equipment, doctors can inject them into an injured area and inundate the affected tissue with these restorative growth factors. Term platelet-rich plasma (PRP), this technique requires little more of patients than a blood draw.

A similar approach called bone marrow concentrate capitalizes on the body’s natural healing architects and engineers—the stem cells. These are harvested by aspiration, usually from the lower pelvis; concentrated by means of density gradient centrifugation that isolates the stem cells from platelets, red blood cells and granulocytes; and then injected back into the tendon or cartilage. Stem cells can also be harvested from a patient’s adipose cells. The Lipogems® system, from a company of the same name, is a novel method of harvesting stem cells from adipose tissue, which is rich in the mesenchymal stromal cells. The cells contain and release multiple healing factors that reduce pain and inflammation and facilitate tissue healing. These cells are again concentrated into a small volume and injected using fluoroscopy or ultrasound guidance.

ALTERNATIVE OPTIONS
Traditional orthopedic treatments have been found to have adverse effects but continue to be used because of a lack of other options. Cortisone injections, for example, can be effective in the short term but with repeated use are harmful to cartilage and tendons, ultimately interfering with tissue healing. Anti-inflammatory medications produce only transient benefits and are associated with an increased risk of mortality due to potential side effects, including gastric ulcers, myocardial infarction and stroke. This has led to multiple Food and Drug Administration warnings to physicians and the public. Surgeries such as arthroscopic knee surgery, rotator cuff repair, and knee and hip replacement are typically recommended to patients after conservative measures like medications, injections and physical therapy fail to relieve symptoms. The surgeries can be helpful in certain cases, but current research questions the value and effectiveness of many of these procedures, particularly arthroscopic surgery for meniscal tears.

Regenerative medicine’s expansion into orthopedics and rehabilitation is in the early stages. Cardiologists and dentists have been using PRP for
Regenerative techniques are considered highly safe and have not been found to result in significant adverse effects other than minor pain at the injection site. A careful history and examination and a review of X-rays and MRIs are needed to determine whether any of these treatments might benefit a particular individual. Major exclusions are incomplete cancer treatment within the past five years; infection in the injury site; chronic, complex comorbidities such as autoimmune diseases; and patients on multiple medications. The populations that have demonstrated the best outcomes include people with arthritic conditions (particularly of the knee, hip and shoulder), cartilage injuries, meniscal tears and rotator cuff pathology. In our recent study on meniscal tears, a vast majority of subjects reported significant improvement in their symptoms and quality of life, with all patients avoiding additional surgery. And to date, no adverse effects have been observed. To monitor patient outcomes and any adverse reactions, we have for several years maintained a database on the regenerative procedures we have performed. It is hoped that this database will be expanded to include centers throughout the United States.

**PAVING NEW PATHS**

Knowledge about the availability and applicability of regenerative therapy for musculoskeletal populations is lagging. Only a modest number of orthopedists and other physicians nationwide offer these interventions, and those who do so often have limited understanding and experience. Technology is advancing at such a pace that even someone knowledgeable of regenerative techniques from five years ago would now be behind the learning curve. Consequently, there is a dearth of definitive orthopedic experts in these groundbreaking treatments.

Kessler Institute for Rehabilitation hopes to change this and is on the path to become the leading center in regenerative approaches. Last spring, for instance, Kessler became one of only a handful of medical centers in New Jersey to offer the Lipogems procedure for various orthopedic conditions. Many of the patients seen at rehabilitation centers such as Kessler Institute have orthopedic conditions and are felt to be poor candidates for surgery because of their advanced age and disease process. For such individuals, regenerative therapy is not just a game changer but potentially a life changer.

**CAUTIOUSLY OPTIMISTIC**

The notion of your body being its own medicine cabinet is an exciting area of health care, and we are only in the early phases of learning how best to harness and use these innate healing functions. Research at Kessler Foundation and elsewhere is investigating the application of regenerative medicine to neurological rehabilitation patients, such as those with nerve damage, post-stroke effects or traumatic brain injury (see “A New Option May Keep SCI Patients Active”).

Spinal cord injury is an appealing area of focus, as one of its most frustrating consequences is the development of scar tissue, which inhibits nerves from regenerating. Stem cells contain properties that can signal to reduce scar formation and inflammation. Over time, we likely will see stem cell applications used more frequently in these patients to facilitate and enhance recovery. There are numerous other ways to employ these regenerative treatments, ranging from wound healing to neuromuscular repair.

Advances are occurring so swiftly that federal officials and oversight groups have responded accordingly. As of 2017, the FDA monitors certain human cell and tissue therapies through its Regenerative Medicine Advanced Therapy Designation program for Investigational New Drug application submissions. And in December 2016, Congress added to its 21st Century Cures Act specific provisions that, among other things, give FDA the authority to accelerate approval of regenerative treatments, bypassing phase I, II and III testing and jumping straight to postmarket surveillance. Those involved in regenerative treatments must be aware of and fully compliant with these FDA regulations.

Scientists and clinicians must be careful about how to most appropriately implement regenerative therapies. At the same time, the field must keep pushing forward through data collection and clinical research. Regenerative medicine has the potential to revolutionize the treatment options for many chronic, disabling orthopedic and neurological conditions.

**A NEW OPTION MAY KEEP SCI PATIENTS ACTIVE**

Approximately 70 percent of the spinal cord injury (SCI) population, particularly those who use wheelchairs, develops rotator cuff and shoulder damage due to overuse injuries. Nonsurgical intervention is preferred, as traditional repair immobilizes the affected area, leaving most individuals with SCI temporarily bedbound. This further increases risk of weight gain, heart disease, hypertension and mortality.

Kessler Foundation is enrolling participants in a small clinical trial (ClinicalTrials.gov Identifier: NCT03167138) exploring the safety and efficacy of autologous, microfragmented adipose tissue (Lipogems) injection for chronic shoulder pain in persons with SCI. It is the first of its kind and will track outcomes of discomfort and shoulder functioning for six months following treatment.

To refer patients for possible enrollment in the Lipogems clinical trial for SCI patients with shoulder pain, contact Trevor A. Dyson-Hudson, M.D., at 973-324-3576 or Matthew Weiner at 973-324-3515.
In late July, the U.S. Senate ended a “vote-a-rama” of proposed bills designed to “fix” the perceived flaws of the Affordable Care Act (ACA). One defeated bill would have simply repealed the ACA and then, within two years, “fixed” the resulting problems with a replacement (which legislators had not accomplished in seven years). Another would have repealed certain components of the existing law, then left it to a joint committee of Senate and House members to make additional changes to the bill through reconciliation.

The entire effort laid bare an often-unnoticed approach in the legislative and regulatory process: approving a stop-gap measure with the stated intent of returning to the issue at some future time to implement the “fixes” needed.

In reality, history is replete with examples of how unlikely this sequence of events is and the risks involved in temporizing an issue, particularly for the disability community. That is why it is so important that we do not settle for anything in any new legislation that could seriously and adversely affect our access to medical rehabilitation services and devices, even if proponents assure us that it is a temporary change.

We’ve seen this before in the disability community. The Tax Equity and Fiscal Responsibility Act of 1982 established the prospective payment system for short-term acute care hospitals using the diagnosis-related group coding system.

At the time, it embodied a “temporary” payment system for rehabilitation and other specialty hospitals because data were insufficient to model payments that reliably related to the costs of care. That temporary solution lasted nearly 30 years, until the inpatient rehabilitation hospital prospective payment system was implemented in 2002.

Since laws are passed through a group consensus process, compromise is almost always involved in coming to closure and passing a bill. Thus, it is common for each side to yield from its “perfect” solution to one good enough to make progress toward a desired goal. Indeed, the measure of a good compromise is when both sides are a bit unhappy but still satisfied.

Deciding what’s good enough is a big decision but extremely important. It can take many years, even generations, to return to legislative or regulatory issues. Consider that after seven years, the perceived needed fixes for the ACA had yet to materialize.

One of the near-term potential risks to our field is the Medicare Post-Acute Care Value-Based Purchasing Act. It attempts to influence Part A providers of post-acute care to reduce costs by evaluating their performance primarily on the Medicare Spending Per Beneficiary standard.

The previously introduced version of this bill would withhold 5 percent of a rehabilitation hospital’s payments from fee-for-service Medicare while allowing some recovery of those funds based on cost reductions for other aspects of the patient’s care, such as acute care expenses or those occurring after discharge from the rehabilitation hospital. Coupled with other cuts in reimbursement that the Medicare Payment Advisory Commission has suggested, the collective payment reductions to rehabilitation hospitals could be devastating, forcing many to close.

The legislation has gone through at least three drafts and revisions, with the most recent version still unacceptable to the post-acute care community. While the bill has yet to be reintroduced in this Congress, we expect that legislators will come forward with yet another version they consider “good enough.” Depending on the details, the field will need to vigorously object to “good enough” since it is, in fact, not good enough. If passed as it now stands, it would take years of debate to make the changes necessary to improve it.

The disability community deserves more than “good enough.” It deserves what’s right. A “temporary” solution may be around for a very long time and, in legislation as in medicine, our elected officials’ essential responsibility should be “first do no harm.”
As any pet owner can attest, animals have the ability to significantly enhance our lives and well-being. For people with physical and cognitive disabilities, additional improvements in functioning and symptoms are not uncommon. But potential health risks from exposure to animals in hospitals are present and must be taken seriously.

PROCEEDING WITH CAUTION

Therapy animals have been increasingly utilized in health care settings because of the physical, emotional and social benefits they confer to patients. Despite this, infection control must be prioritized given that many inpatients are immunocompromised or otherwise susceptible to potentially devastating diseases. Transmission of pathogens can occur from direct or indirect contact or, less likely, via droplet or aerosol routes. Methicillin-resistant *Staphylococcus aureus* is particularly worrisome given its virulence. Other serious skin and diarrheal illnesses of concern are *Clostridium difficile*, multidrug-resistant *Enterococcus*, extended-spectrum β-lactamase-producing *Enterobacteriaceae*, *Campylobacter* and *Salmonella*.

Minimizing infection risk can be challenging given the dearth of evidence-based practice recommendations and substantial variation in policies among medical institutions. Hand washing is the most powerful method of avoiding the transmission of a zoonotic disease but can be difficult to enforce as staff and patients might simply forget to engage in appropriate and consistent hand hygiene. Since early detection is essential in preventing outbreaks, regular evaluations by veterinarians, including rabies vaccinations, physical exams, dietary assessment (e.g., prohibiting raw meat), fecal testing and parasite control practices, are vital. However, veterinary screening is not always carried out and enforced across facilities.

Pets visiting patients in health care settings has been a source of controversy as companions and their owners do not undergo the same degree of training, monitoring, health assessment or exclusion practices as animals in therapy programs. As a result, visitation with pets tends to be more restricted and allowed only under specific circumstances, with close supervision.

A WATCHFUL EYE

Kessler Institute for Rehabilitation’s Animal Assisted Program, which only uses canines, has implemented evidence-based policies to ensure the safety of our patients and employees. For instance, dog handlers must undergo screening and safety training prior to being accepted into the program. Handlers train animals to avoid body parts and objects that are susceptible to contamination, such as invasive medical devices, bandages, ports and damaged skin. Kessler also conducts continuous surveillance activities to facilitate better monitoring and oversight, including collecting data on all types of hospital-acquired infections as well as targeted checks for a specific disease or pathogen. Direct observation and tracking of infection rates inform the degree to which safety policies are effective and where to course correct. Visitation by Canine Companions for Independence Inc., a nonprofit that trains and provides therapy dogs, is also performed annually.

To optimize the integration of therapeutic animals into health care settings, more attention must be paid to establishing universal screening, safety and monitoring practices. By protecting the health of staff and patients, we also can help preserve these therapy programs and the numerous benefits they provide.
Horticultural therapy (HT) entails the treatment-related use of gardening activities, such as watering, seeding and maintaining plant life. It has been in use since the 1940s, when rehabilitation hospitals tapped HT to treat military combat veterans, according to the American Horticultural Therapy Association. The initial application of therapeutic gardens was in the treatment of mental illnesses; however, it has expanded as researchers and clinicians have witnessed its utility for other patient populations, including those with acquired brain injuries and cognitive impairments.

Modest empirical literature speaks to the therapeutic benefits of HT among populations with musculoskeletal and neurocognitive deficits, inclusive of stroke and spinal cord injury, as well as individuals with dementia due to Alzheimer’s disease or other neurodegenerative disorders. Gardening has been shown to be an advantageous and effective therapeutic modality because it provides sensory stimulation and exercise. It also assists patients with neurocognitive impairments by helping them acquire new skills or regain lost abilities. Enhanced memory, attention, sensory-motor functioning, task initiation, communication and socialization have been reported to occur with exposure to HT, as have reductions in pain, stress, agitation and other dementia-related behavioral disturbances. Participation in HT is also associated with improvements in psychological outcomes, such as mood, overall well-being and quality of life.

**SOWING BENEFITS**

A garden can be described as therapeutic when it has been designed to meet the needs of a specific population to address individual goals. HT is widely used within a broad range of rehabilitative, vocational and community settings. Every program has unique attributes, such as the type of patients served, amount of space allotted, and activities and opportunities offered.

As a reflection of Kessler Institute for Rehabilitation’s interest in offering therapies that are evidence-based but also engaging and inventive, its Cognitive Rehabilitation Program (CRP) at the West Orange campus initiated HT in 2009. The rollout of garden therapy was born from a desire to provide a novel approach to treatment wherein individuals could engage in physical activity while working on specific therapeutic skills. Additionally, staff members of the CRP as well as those in Psychology & Neuropsychology Services were seeking a program in which patients’ progress could be easily monitored over time and through visible feedback, providing important reinforcement.

The primary component of the HT program is individual or group engagement in the planning, planting, watering and maintaining of indoor and outdoor annuals, perennials, vegetables and herbs in and around the hospital. As with any other rehabilitation intervention, a trained therapist develops and monitors each patient’s HT treatment plan to ensure it addresses individual needs and functional and cognitive deficits. Participants are supervised but largely independently responsible for the plants. Referrals generally come from Kessler Institute’s Brain Injury Rehabilitation Center, although HT is open to everyone.

Anecdotal evidence suggests that individuals in HT generally demonstrate positive effects, such as increased independence and better well-being. Successfully functioning at work, school and home and in the community requires one to interact and collaborate, problem solve and be autonomous. These skills are important aspects addressed in the horticulture initiative and help patients thrive outside of the rehabilitation setting. Many people report HT to be stimulating yet relaxing, while others express excitement at seeing their foliage flourish.

Although more formal qualitative and quantitative research is needed, evidence to date from therapeutic gardens should not be undervalued. HT is a promising adjunct to traditional rehabilitation that may help patients improve their skills, functioning and quality of life.