

Rehabilitation

SUMMER 2009

2 Editor's Letter

Bruce M. Gans, M.D., explains how technological advances are providing opportunities to differentiate our services from non-rehabilitation settings and improve patient outcomes.

3 Going Beyond Treatment

Choosing to pursue palliative care is a difficult process not just for patients, but also for the individual's health care team.

Loran Vocaturo, Ed.D., ABPP (RP), gives a guide for dealing with the sensitive issues surrounding end-of-life decisions.

4 An Exercise in ... Exercise

Functional electrical stimulation provides a means for patients with paralysis to participate in cardiovascular exercise. **Monifa Brooks, M.D.**, and **Liz Caputo, P.T., DPT**, discuss how to effectively implement this activity.

6 Deciding on a Definition

Payors often use medical necessity as a reason for coverage denial. **Bruce M. Gans, M.D.**, argues that the PM&R field should promote an objective standard that is not so open to interpretation.

8 Thinking Outside the Box

Allison Averill, M.D., describes how psychiatry can bring an important perspective to the trauma care setting, helping patients with an early transition to rehabilitation that results in better long-term recovery.

Breathing Easier

Alternatives to mechanical ventilation offer more natural respiration, but are not appropriate for all patients

■ **STEVEN KIRSHBLUM, M.D.**

For many of the 12,000 people who sustain acute spinal cord injury (SCI) each year, taking a breath is a major challenge: About 20 percent will have initial weakness of the respiratory muscles, and up to 5 percent will develop chronic respiratory insufficiency. Traditional management of these individuals has included mechanical, positive-pressure ventilation (MV) through a tracheostomy. The risks and drawbacks associated with MV, however, have spurred the development of alternative methods of respiratory support.

Because most people who sustain SCI are young and expected to live a near-normal life span, MV use can continue for decades. Although MV saves lives, it also is associated with increased mortality, morbidity and disruptions in daily activities such as eating, drinking and speaking. Other means of artificial ventilation, including direct diaphragm pacing and phrenic nerve pacing (PNP), can eliminate many of these problems and provide a more natural form of breathing.

Direct Phrenic Nerve Pacing

The Avery Mark IV Breathing Pacemaker System is the only PNP device approved for use in the U.S. This system involves implanting electrodes via thoracotomy into each phrenic nerve. The electrodes are wired to internal radio frequency (RF) receivers in the anterior thorax, which are in turn coupled to external antennas. An external transmitter broadcasts an RF signal that is picked up by the antennas, converted to an electrical signal by the receivers, and delivered to the electrodes,

causing contraction of the diaphragm and inspiration. Upon cessation of the RF signal, the diaphragm relaxes, causing exhalation. The signal's frequency and amplitude can be adjusted according to the patient's tidal volume as needed.

Compared with MV, PNP systems are generally associated with improved comfort, mobility and speech and reduced anxiety. Their duration of use has also been comparable to that of MV, lasting up to 15 years in some cases. However, handling the phrenic nerve during the implantation procedure does carry a risk of nerve injury, and the requirement for thoracotomy involves typical risks associated with major surgery and a prolonged hospital stay.

Diaphragm Pacing

With an intramuscular diaphragm pacing system (DPS), two electrodes are placed laparoscopically into each half of the diaphragm, allowing direct stimulation of the phrenic nerve motor roots. The implanted electrode wires exit the skin and connect to an external, battery-operated pulse generator. The pulse amplitude, frequency (continued on page 7)



FOCUS ON

Rehabilitation

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Giving Our Patients More

Traditional rehabilitation has accepted the patient “as is,” with treatment focusing on adapting, coaching and enhancing the individual’s remaining mental and physical capacities. Also, over the years some elements of rehabilitation services began to be offered in less intensive inpatient settings, rather than in rehabilitation hospitals and units (IRH/Us). As a result, payors have developed the view that many services are interchangeable, without regard to the setting in which they are delivered.

However, IRH/Us should no longer settle for this commodity approach. We now have opportunities to offer exciting new medical and surgical interventions that can improve the patient medically as well as functionally. Some of these modalities are already available; others are in development but should become part of our rehabilitation repertoire soon. These advances will further differentiate the rehabilitative services we offer from those available in other settings.

Advances in neurosciences, biomedical sciences, engineering, and molecular and genetic technologies are constantly providing us with these new tools that focus on changing and improving a person’s status. For example, we already can repair joints with cartilage transplants and injections of joint lubrication, or even completely replace joints surgically. Powered orthotic devices currently are available to augment residual upper extremity function in some patients.

Neurological examples include implantable bionic neurons for restoring or improving muscle function. Transcranial magnetic stimulation (TMS) and similar technologies are being used to improve brain function (including, for example, cognitive arousal), without surgical placement of stimulating electrodes.

These are examples of how rehabilitation services can now enhance function in our patients, not just improve impairments that remain after disease or injury. Other cases include implantable stimulators for pain control, spasticity management, improved motor function, and bladder and bowel function. Deep brain stimulation is being used to augment the rehabilitation of those with Parkinson’s disease. Work continues on implantable devices that connect directly into the brain cortex to capture visual information or motor intent. Implantable surface electrodes have been devised to give individuals the ability to communicate and to control devices with their thoughts.

Regenerative and restorative therapies such as stem cells and other biologicals will soon allow us to reestablish tissue function, regrow components of tissue, and perhaps in the future replace full body parts. We are already close to improving the vascular system in this way.

The bottom line is that we no longer have to settle for keeping the patient “as is”; rather, we can use technology to further impact patient outcomes. We will be able to help an individual change physically, not just adapt to loss of function due to injury or disease. IRH/Us will have the unique opportunity to translate these exciting scientific developments into practice that will change the function of our patients. In doing so, we will continue to differentiate ourselves from less intensive settings for rehabilitation.

Bruce M. Gans, M.D.
Chief Medical Officer



Going Beyond Treatment

A look at end-of-life issues in medical rehabilitation

■ LORAN VOCATURO, ED.D., ABPP (RP)

Palliative care, which seeks to comfort rather than to cure, raises a difficult existential question: When is life with a chronic, debilitating disorder not worth living? Although such care was originally developed for patients with terminal medical conditions, health care professionals in the rehabilitation setting increasingly are faced with end-of-life issues.

It's important to understand how to address such challenges to help ensure quality care for individuals—respecting their dignity and choices while adhering to ethical, legal and regulatory standards. A closer look at these principles and the pragmatic application of palliative care, or PC, will help providers better serve their patients.

A Question of Timing

The need for PC can emerge early after injury or illness or after years of living with a condition. At least one of the following criteria generally is present:

- There is an underlying incurable condition.
- Death is expected and imminent.
- Further treatment is considered futile.
- Life-support efforts would only prolong the dying process.

Palliative care might also be appropriate for those with chronic or debilitating

disorders for whom the burdens of treatment significantly outweigh the benefits. In a physical medicine and rehabilitation (PM&R) environment, such disorders likely would represent static and irreversible disabling conditions such as spinal cord injuries or severe disorders of consciousness.

Who Decides?

PM&R clinicians, rehabilitation psychologists and disability activists are trained to improve or maintain the quality of their patients' lives and preserve their abilities. By law, however, a competent person can refuse treatment, even if it is life sustaining.

In this context, *competent* is a legal term, not a medical one. All adults are assumed to be competent unless a court judges them otherwise. The *capacity* to make informed health care decisions, on the other hand, must be assessed by medical staff at the time of each decision. Patients have capacity only when they can comprehend relevant information, deliberate according to their own values and goals, and communicate (verbally or otherwise) with caregivers.

Tools such as the Aid to Capacity Evaluation allow clinicians to state the level of certainty regarding decision-making ability. Patients lacking the capacity to make informed decisions, including those regarding PC, might

require referral for a competency hearing or appointment of a guardian.

Some individuals have an advance directive in place, which can assist medical providers in carrying out end-of-life wishes. Such directives are often based on hypothetical situations, however, and choices can change over time and in differing circumstances.

A Range of Factors

The decision to request PC is complicated. It is not simply a question of the person's prognosis, functioning or quality of life; it also encompasses his or her beliefs, culture, values, wishes and autonomy.

The entire rehabilitation team may be involved with the determination to begin PC, including physicians, nurses, case managers and social workers. Any of these professionals can receive a request for PC from the patient, a family member or the patient's representative. Therefore, PM&R practitioners must be aware of their own values, biases and attitudes about disability and end-of-life care, to avoid any undue influence.

Also, staff may believe that they have failed in their rehabilitation role if an individual chooses to begin palliative care. These team members should receive assistance to work through this perception, which also will help to garner their support in implementing the patient's decision.

Once the choice has been made to begin PC, the goal of treatment changes to providing support for the patient and family. Psychology professionals play a prominent role not only in the initial decision, but also in guiding individuals through the course of care and assisting the family after death. Specific treatment principles include optimal control of pain and other distressing symptoms; application of dedicated spiritual, social and psychological resources; and education about the disease process, so that care can be patient-directed and focused on providing the best quality of life possible to patients and their loved ones.

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An Exercise in ... Exercise

Electrical stimulation devices help decrease disease risk and improve quality of life

When a person develops permanent paralysis, attention is focused first on immediate medical needs and then on learning to cope with a disability. Because these patients are living longer, however, they also are developing the same diseases that occur in the aging able-bodied population, including heart disease, diabetes and hypertension. When the ability to exercise regularly is lost, an individual with paralysis may be left with a very sedentary lifestyle that further increases the risk for these diseases.

To help address this challenge, functional electrical stimulation (FES) allows someone with little or no voluntary leg movement to pedal a stationary bicycle for cardiovascular exercise. Surface electrodes are placed over the leg muscles, and low-level electrical pulses generated by a computer move through the electrodes to the muscles, enabling them to contract in a coordinated fashion. Even a patient with complete lower body paralysis may be

able to pedal one of these specialized FES cycles and once again engage in regular exercise.

Kessler Institute for Rehabilitation offers FES for persons with paralysis through both inpatient and outpatient programs at its campuses. *Focus on Rehabilitation* spoke with Kessler's Monifa Brooks, M.D., staff physiatrist, and Liz Caputo, P.T., DPT, senior physical therapist, to learn more about exercise using FES.

Focus: Who can benefit from FES?

Monifa Brooks, M.D.: FES exercise devices are often appropriate for many individuals with upper motor neuron lesions, including those who have had a stroke, a spinal cord injury, multiple sclerosis with paralysis, and certain traumatic brain injuries that lead to paralysis. The typical patient has damage to the central nervous system and is no longer able to control muscle contraction in the affected limb.

Focus: Why is lower body exercise, like that provided with FES cycles, important for people with paralysis?

Liz Caputo, P.T., DPT: Lower body training using FES provides more intense exercise, using larger muscles, than upper body exercise alone. This type of FES has many benefits for those with paralysis, including cardiovascular effects and control of pain and spasticity. I also find it helps to improve a patient's

mood and overall quality of life.

Brooks: I would like to emphasize that, in terms of rehabilitation, so much of what we do after the injury is to try to compensate for what has happened,

while also looking to improve quality of life. This intervention is one of the few we have that actually can be preventative in terms of decreasing cardiovascular disease and onset of type 2 diabetes, both of which are increased in people who have paralysis as compared to the able-bodied population. So FES is, in my mind, more of a preventative intervention.

As these patients are living longer, you are going to see all of the disease processes that exist in the general population, including cardiovascular disease, diabetes, metabolic syndrome and hypertension. FES lets us help patients focus not only on coping with disability but also on preventing long-term disease.

Focus: What are some of the specific health benefits from regular exercise with FES cycles?

Brooks: Using an FES cycle can increase general fitness and reduce cardiovascular risk factors. It decreases heart rate (HR) and blood pressure (BP) over time, and may significantly reduce bone loss. A variety of quality-of-life measures have been shown to improve with regular use of an FES cycle in persons with paralysis. We also see decreases in spasticity and tone that limit movement, reduction in pain, and improved strength in partially innervated muscles.

Caputo: We educate patients about the fact that although FES cycling doesn't establish connections that aren't there, it can, as Dr. Brooks mentioned, strengthen partially innervated muscles. For those people with more complete paralysis, we stress the cardiovascular benefits. We emphasize to our patients that if they discontinue regular exercise with the FES systems, the benefits will disappear. Just as with any other fitness program, it is important to exercise regularly.

Focus: How do you initiate an exercise program using an FES cycle?

Caputo: We can set the amount of stimulation applied to muscle, that is, over the hamstrings, gluteals and quadriceps. Stimulation is applied to produce a muscle contraction for cycling. We also monitor HR and BP at the same time. If a patient has residual sensation in the areas we are stimulating, they may feel pain that can limit their ability to participate in FES cycling.



Patients participating in a functional electrical stimulation program can benefit from improved cardiovascular function, as well as a significant decrease in bone loss.



A physical therapist works closely with a patient during an FES session, which can progress to 60 minutes for some individuals.

Brooks: If someone is significantly deconditioned, we may observe very exaggerated responses in HR and BP initially, even after just a few minutes of cycling, but these are being closely monitored by the physical therapist. As conditioning improves, people are able to tolerate longer periods of exercise on the apparatus. There is no set rule, however; the amount of exercise is tailored to the individual.

Focus: Where are FES cycles used?

Brooks: Some patients have them at home, and family members are trained to apply the electrodes. Because of the expense, however, FES cycles are not generally available. We have them at our Kessler facilities, and our patients use them in both inpatient rehabilitation and special outpatient programs, including fitness and wellness programs. Kessler is doing long-term research and gathering evidence that further supports the benefits of FES in persons with paralysis.

Focus: What are the differences among the various FES cycles?

Caputo: Systems like the REGYS and ERGYS require the patient to transfer from a wheelchair onto the cycle. For those who can do so easily, these systems are fine. With a patient for whom transferring is more difficult, such as someone

with tetraplegia, then it is easier to use a machine from his or her wheelchair, such as the RT-300. In terms of overall technology, however, one type of FES cycle is not superior to another.

Focus: Are there limitations to the use of FES cycles?

Brooks: Under certain conditions, we would not use electrical stimulation in patients in whom it might otherwise be appropriate. For example, if there is an untreated blood clot

in the leg, we wouldn't use FES. It is also not suitable for someone who has heterotopic ossification [bone growth in abnormal areas, usually in soft tissues], because FES would stimulate extra bone growth. If a person has sensation to the point that the electrical stimulation is painful, then obviously they would not be candidates. Finally, if a patient has any open sores in places where the electrodes need to be placed, then FES would be inappropriate.

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Kessler's FES Protocol

At Kessler Institute for Rehabilitation, patients being considered for a functional electrical stimulation (FES) program are evaluated and monitored to ensure the best possible rehabilitative outcome. The primary goal of inpatient therapy is functional independence and safety for discharge to home.

With these objectives in mind, a physician first must determine that a person is medically appropriate for FES. A physical therapist then incorporates the FES cycle into the regular therapy session on a trial basis to assess if the lower extremities will respond to stimulation. The therapist will be able to see or palpate a muscle contraction when the process is working—if there is any lower motor neuron impairment, the stimulation may not be effective. If the patient has lower extremity sensation, he or she is assessed to determine tolerance for the stimulation, which may be painful and possibly prohibit any further use of FES.

Once it is established that the person is a good candidate, the individual typically is started on an FES-based program of two to three days per week. The initial exercise duration on the cycle is 30 minutes, or as long as tolerated, with the therapist monitoring vital signs before, during and after the session. The Karvonen formula—a calculation that incorporates maximum and resting heart rates—can be used to obtain target heart rate for a desired intensity. Depending on the patient's endurance and how vital signs are responding, the therapist may progress the session to 60 minutes in duration.

As with any type of exercise, this program must be continued at home or on an outpatient basis, or the results will not be maintained.

Deciding on a Definition

Medical necessity standards are needed to reduce disputes between providers and payors

■ BRUCE M. GANS, M.D.

One of the most contentious subjects in the rehabilitation hospital community is the issue of coverage denials based on a lack of medical necessity. Providers and payors have very different views of what should be covered and how costs should be constrained. All too often coverage is denied after the fact on the grounds that either the services could have been delivered in a less intensive setting or they were not “medically necessary.” As the Recovery Audit Contractor (RAC) program ramps up, rehabilitation facilities fear that denials will only increase.

We need much more clarity around the coverage criteria, especially concerning the complex concept of medical

even provide preliminary approval for a hospital stay through a pre-certification process but may later decline to cover the costs, citing medical necessity. Although a rehabilitation hospital can appeal adverse rulings, even in court, the process is long and expensive. There is no guarantee that the medical appropriateness of an action will translate, in legal terms, into medical necessity and, therefore, payment.

No gold standards are available to define medical necessity. The clinical decision-making processes are too complex to be broken down into a series of univariate, linear questions that would allow payors and physicians to easily reach the same conclusions about patient care. Unfortunately,

it is invoked, services may be denied with the statement that they could have been provided in a less intensive setting. Legal challenges are being brought forward to try to establish the primacy of 85-2 as the legal standard to apply in these situations.

A Better Way

The clinical decision-making challenges remain. In addition to the Medicare standards, proprietary medical necessity instruments are available, but these have not been endorsed through a professional consensus. A different method is needed to demonstrate that a patient must be in the hospital to get appropriate care. This approach should be clear and easy to apply consistently by both the inpatient rehabilitation hospital/unit and the payor so that the right patient gets the right treatment in the right facility, with a reduced likelihood of disputes between provider and payor. Several approaches to developing a better method have been taken already. For example, the AAPM&R has published a Standards Position, but this method still relies heavily on professional judgment, which means that the standard is not easily and unambiguously applied by less specialized professionals.

The field of rehabilitation should work to develop objective, evidence-based and consensus-“blessed” medical necessity standards and tools that are accurate, unambiguous, unlikely to be misinterpreted, and readily used by a variety of professionals in health care. Whether that goal is achievable is an interesting question, but only by encouraging groups to try to reach such a consensus will we know the answer.

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A different method is needed to demonstrate that a patient must be in the hospital to get appropriate care.

necessity, which is a legal term, and, unfortunately, not equivalent to “medical appropriateness.” What the physician thinks is the right thing to do for a patient and what the health insurer believes it is contractually obligated to pay for are inextricably intertwined in this deceptively simple phrase.

Lost in Translation

Payors control expenditures both prospectively and retrospectively, which means the physician or rehabilitation facility must often fight with the insurance company to establish that something either is (prospectively) or was (retrospectively) not just appropriate, but also necessary. Some payors may

Medicare’s 60% Rule has been used erroneously as a proxy for medical necessity by some carriers and Medicare Administrative Contractors, even though the rule is clearly not a set of standards to define which patients need care in a rehabilitation hospital.

Instead, HCFA Ruling 85-2 has been cited as the most explicit legal standard available and has been used in the courts by providers appealing denial of payment based on medical necessity. This 1985 rule defined eight criteria that, if satisfied, establish an inpatient rehabilitation hospital stay as medically necessary.

Yet this rule is often not cited by Medicare contractors, and even when

Breathing Easier

(continued from page 1)

and width can be altered through a separate, stationary console.

The NeuRx DPST[™] was approved for use in the U.S. in June 2008. Kessler Institute for Rehabilitation, the first facility in New Jersey to use NeuRx, has successfully implanted the system in two patients. Overall success rates with DPS appear similar to those of conventional PNP systems, but DPS implantation is less invasive than thoracotomy, can be performed on an outpatient basis, and nearly eliminates the risk of phrenic nerve injury. A significant limitation of this percutaneous system is the risk of infection along the electrode wires exiting the skin.

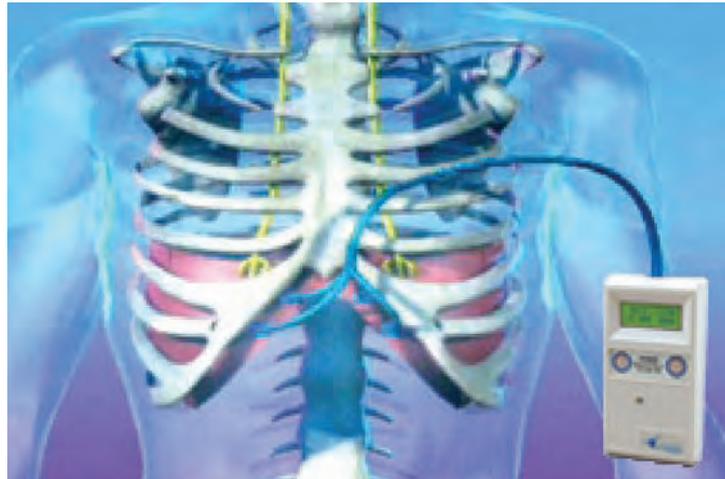
Selecting the Right Patient

PNP is not appropriate for those with significant lung or primary muscle disease. Candidates also must have complete function of both phrenic nerves for optimal outcomes, which may not be the case for many SCI individuals. Phrenic nerve studies should be performed before considering PNP.

Psychosocial conditions are also important for favorable PNP or DPS results. Success is most likely to occur when the candidate and family members are motivated to improve the patient's overall health, mobility, social interaction and occupational potential.

Changing Over

No definitive guidelines exist to guide the transition from mechanical



DPS implantation is less invasive than thoracotomy and can be performed on an outpatient basis.

ventilation to PNP or DPS, which should occur as quickly as possible (given the risks of MV) but without straining the diaphragm. Because the diaphragm tends to weaken from disuse during MV, it must be conditioned before full-time pacing can commence. Generally, conditioning begins with pacing that continues until symptoms or signs of poor oxygenation develop. After a rest, PNP or DPS use is resumed for a shorter period every hour during the day. After full-time pacing is achieved during waking hours, PNP or DPS is applied during sleep. The conditioning phase can take 10 weeks or longer, but full-time support can be achieved in as few as two weeks.

Most patients cap the tracheostomy tube during daytime pacing. While sleeping, however, the

tracheostomy should be capped with a valve allowing airflow. In addition, sitting may require greater stimulation than supine postures, because of diaphragm shortening and increased resting lung volume.

Both DPS and PNP can offer significant advantages over mechanical ventilation in providing respiratory support for patients with high-level SCI. Future refinements might include development of a fully implantable system to reduce the risks of infection and decoupling between the transmitter and receiver.

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THE IMPACT OF MECHANICAL VENTILATION

- Annual expenses approach \$200,000.
- Insufficient venting can lead to atelectasis in the lungs, increasing susceptibility to infection.
- A tracheostomy confers the risks associated with anesthesia and surgery.
- The tracheostomy tube may interfere with eating, drinking and speaking.
- The ventilator apparatus is not readily portable, reducing mobility.
- Use of mechanical ventilation can lead to atrophy of the diaphragm.
- Pressurization of the lungs adversely affects venous return.
- Fears of ventilator disconnection can lead to considerable anxiety.
- Individuals may feel self conscious over dependence on the ventilator.

Thinking Outside the Box

A psychiatry perspective in trauma care can be vital for long-term recovery

■ ALLISON AVERILL, M.D.

When it comes to the care of trauma patients, psychiatrists are trained to notice everything, helping to fine-tune treatment and facilitate the transition from an acute setting to rehabilitation. To maximize this process, constant vigilance is needed to determine how acute measures may impact the patient's long-term prognosis and recovery. Because of this, psychiatrists can play a key role by collaborating with other trauma professionals to develop a comprehensive approach to care.

Intervening Early

Special attention is needed for patients who have experienced neurological insult, such as traumatic brain injury (TBI) and spinal cord injury (SCI). Individuals with TBI are susceptible to cognitive problems such as memory loss, as well as behavioral deficits such as agitation. Both issues can impede recovery, yet how symptoms are treated early on can affect how quickly a patient progresses through the continuum of care. A psychiatrist can help the trauma team understand the critical need to consider present and future rehabilitation demands.

For example, a patient with agitation may require medication, but if he or she is too sedated to participate in physical therapy, what are the benefits in the long run? In fact, early entry into rehabilitation has been associated with better outcomes in functional capacity versus delayed entry. Simply put, the

longer patients are inactive, the more time they will require for recovery.

Although management of acute medical issues is paramount, consideration must be given to treatments that minimize side effects, which may impede rehabilitation. Medications often are necessary for reducing agitation and cognitive symptoms, but the goal is to avoid administering drugs that will lengthen the patient's time to recovery. The injured brain is like the elderly brain in that it is more sensitive to effects and side effects.

Trauma teams need to assess medication usage and determine whether alternate drugs can reduce symptoms, but in a manner that is less detrimental to long-term recovery. Again, a psychiatrist's expertise is helpful. For example, use of the neuroleptic ziprasidone in place of older antipsychotics, such as haloperidol, has been successful in treating agitation with fewer side effects. If older neuroleptics are necessary, doses often can be reduced while still getting the desired effect.

More than Medicine

Patients who are in acute settings simply because of behavioral management are having their treatment delayed and are not benefiting from the best our health care system can provide. To improve the ability to transition individuals to a rehabilitation facility as soon as possible, the psychiatrist can educate the trauma team about techniques used in the rehabilitation setting, such as allowing the patient

to walk while supervised to help alleviate restlessness and increase mobility.

Further, nursing education is critical to patient care. Toward that end, TBI nurses from Kessler Institute for Rehabilitation have provided instruction to acute care nurses on behavioral management. Information from the nurses and families may also help determine which medications are trialed first. This includes details about sleep/wake cycles and patterns of agitation. In SCI populations, where cognitive deficits are less common, education about therapeutic interventions and their effect on transitioning to rehabilitation must also occur at the patient level.

Beyond providing medical treatment, multidisciplinary care that includes psychiatry relies on assessment of the larger clinical picture and attempts to answer important questions. Where will the patient live after discharge? Does he or she have family support? What is needed to maximize recovery beyond the acute environment?

By taking a wider perspective and having a psychiatrist play a role within the trauma team, we can address both short- and long-term goals and help provide the comprehensive care that all patients deserve.

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