

Focus on Rehabilitation

A PUBLICATION FROM THE KESSLER REHABILITATION CORPORATION

Intrathecal baclofen therapy decreases spasticity, improves function in brain-injured patients

Spasticity in patients with acquired brain injury can be greatly relieved with the use of intrathecal baclofen therapy.

Jonathan L. Fellus, M.D.



Intrathecal baclofen (ITB) therapy can offer dramatic improvement for individuals with spasticity related to acquired brain injury. Nonethe-

less, the treatment is greatly under-recognized, and relatively few physicians are aware of its applications and advantages.

Intrathecal baclofen therapy has been in use for more than 20 years, mostly to treat children with cerebral palsy. It was approved by the FDA for spasticity of spinal cord origin in 1992 and for spasticity of brain origin in 1996. With those approvals came the increased use of ITB therapy for multiple sclerosis, traumatic brain injury, stroke and anoxic-ischemic encephalopathies.

Why adjustable dosing helps

Intrathecal pumps are currently used to deliver a number of drugs, including pain medication. The most common agent used with the pump to manage spasticity is the muscle relaxant baclofen. Candidates for the therapy are first given a test dose of baclofen via spinal tap to ensure that they respond favorably to the drug. Then a programmable pump is surgically implanted in the abdominal wall. Attached to the pump is a catheter that is placed under the skin and inserted

between the vertebrae into the intrathecal space. The pump delivers continuous, programmed doses of baclofen directly into the spinal fluid. Adjustments in dosage are made telemetrically, by placing a "wand" above the site of the pump to change the dosage and time of delivery programmed into the pump's computer.

Fine-tuning the delivery of baclofen often takes months. The adjustability of the pump is a critical advantage, however, since spasticity tends to fluctuate

Direct delivery to the spinal fluid permits lower doses – and therefore reduced side effects.

during the course of the day and is a highly individual symptom. In addition, some patients with multiple sclerosis often use the muscle tone that spasticity provides in order to perform certain functions, such as transferring and other daily living activities. Adjustments to dosage and timing of administration allow us to accommodate these fluctuations and needs.

When it's time to refill

The pump placement is generally long-lasting, with replacement needed approximately every 5 years. Refills of baclofen are required up to every 90 days and may be done in the doctor's

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LETTER FROM THE EDITOR

View from the ‘back door’

Bruce M. Gans, M.D.



Usually, I can’t stand the way medicine is portrayed in TV series. Watching physicians rush through the halls, tipping the scales between life and death in seconds, reminds me too much of my internship in Philadelphia.

But these dramas also highlight a key difference between acute care and rehabilitation: time. Acute care, particularly the kind delivered in academic health systems with their powerhouse technology, affects patients’ lives in minutes or hours, while those of us in rehabilitation may see success only after weeks or months of hard work.

Now, however, academic health systems and rehab hospitals seem separated by more than just approaches to care and sense of time. While rehab facilities remain an important “back door” for academic systems, a place to discharge disabled patients, our two enterprises act as if we are distant therapeutic cousins, interacting only briefly during patient hand-offs.

Our relationship has not always been so detached. Over the years, many academic health systems have evolved from single teaching hospitals tied to medical schools into vast networks of hospitals and other health services. Many such systems developed their own rehab programs, particularly after the advent

**Needed: partnerships
between acute care and
rehab facilities.**

of Medicare, or partnered with the growing number of freestanding rehab hospitals.

The rage to partner with—or even acquire—rehabilitation sites got a big boost during the heyday of managed care risk contracting. But academic systems have since found that risk is too difficult to manage and the continuum of care is extraordinarily difficult to integrate. Instead of expanding their involvement with rehabilitation, academic systems have more often decided to intensify their focus primarily on their core acute care business. They must view rehab as a lower priority, not an opportunity—a trend I’d like to see reversed.

I see real value for both our patients and our institutions in restoring a more robust focus on rehabilitation in academic medical centers through partnerships with equally focused providers of medical rehabilitation. Having access to a rehab program would, for instance, make acute care physicians and patients more aware of rehab benefits. That could lead to earlier transfers of patients to the post-acute setting—giving patients earlier rehabilitation interventions, freeing up hospital beds and improving the academic center’s bottom line.

There is, in fact, a reciprocal value of rehabilitation to the acute care system. Strong partnerships would give them access to patients who are high users of ancillary medical services and are likely to need repeat hospitalizations. And an active rehab component would enhance academic medicine’s research, teaching and community service missions. Researchers could more freely design research protocols that include measures of function and long-term outcomes—a distinct advantage when seeking grants.

Partnering with rehab hospitals would enhance academic systems’ community standing, making clearer their commitment to comprehensive care for all. It would also educate medical students and residents about rehab options.

Kessler is actively developing partnerships with academic systems—and we’re looking for more. It is time our brief back-door exchange evolves into a thriving and vigorous partnership.

—Bruce M. Gans, M.D., Editor-in-Chief



Body weight-supported training on a treadmill offers promise

With this emerging therapy, an overhead harness and treadmill are used to improve mobility for individuals with stroke or spinal cord injury.

Sue Ann Sisto, Ph.D., and Ross Bogey, D.O.

People with mobility deficits following spinal cord injury or stroke have few useful therapy options after traditional rehabilitation. Now, however, a new therapy called body weight-supported treadmill training shows great promise for improving walking in these patients.

The therapy uses an overhead harness that relieves weight bearing while the patient exercises on a treadmill. The harness usually supports about 40 percent of the patient's body weight. In early sessions, that weight is borne by the harness, and therapists move the patient's limbs manually while the patient is stepping on the treadmill. Over time, the harness is adjusted to increase the weight borne by the patient and less manual assistance is given to move the patient's legs.

Using the spinal cord

The therapy involves three environments in which ambulation training with body weight support is performed at each session:

- **treadmill training**, in which the patient is given manual assistance to move the legs while body weight is relieved using the harness.

- **over ground training**, in which the patient takes steps while off the treadmill, without the harness and with some manual support.

- **community ambulation**, including the use of assistive and/or orthotic devices, in which traditional physical therapy is used to facilitate gait training, endurance and speed.

The therapy is based on the finding that crude walking, without impulses from the brain, can be generated and sustained via a group of cells located at the base of the spinal cord, sometimes referred to as a cen-

tral-pattern generator. There appears to be a loop in which information from the periphery, such as sensation experienced during walking, is transmitted to the spinal cord where it is mediated to produce a stepping pat-



The new therapy stems from the finding that crude walking can be generated from the spinal cord.

tern without input from higher levels, such as the brain. Animal studies in the U.S., Canada and Europe led to this discovery, and the concept has been shown to apply to humans as well. As a result, national and international studies are now under way to develop protocols for the therapy, including several being conducted at Kessler Medical Rehabilitation Research and Education Corporation (KMRREC) in the Human Performance and Movement Analysis Laboratory.

A critical element of the therapy is to optimize the sensory cues used for walking, and one of the main cues is the physical sensation of normal

walking. For this reason, use of the treadmill provides an optimal environment for training. In addition, the hand contacts used to move the limbs are extremely crucial and it is important for therapists to be trained to learn how to move the limbs correctly.

Getting the gait

Dr. Sisto is studying the method with patients who have had spinal cord injuries at lesions from C6 to T6 for at least one year and no longer than 3 years. The therapy can be used at any lesion level and in patients with relatively new or more chronic injuries.

The goal is to develop a normal walking pattern and increase endurance and speed. For persons with spinal cord injury, one must determine how much weight support should be used with complete versus incomplete injuries. The methodology for these patients is to gradually decrease the mechanical body weight support and the hand contacts from the therapists who guide the legs.

Patients with spinal cord injury who may not be candidates for this therapy include those who are unable to tolerate the physical exertion due to cardiac conditions and those with heterotopic ossification, bone fractures, severe osteoporosis or wounds where the harness is applied.

Dr. Bogey is studying the effectiveness of the therapy with acute stroke patients. (Previous studies have shown that body weight-supported treadmill training can be helpful in chronic stroke patients.) He is also testing the concept that increasing the weight-bearing over time is the most effective methodology for these patients. For stroke patients, weakness

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An Interview with Todd Linsenmeyer, M.D.

Guideline helps treatment of patients with spinal cord injuries

A revised guideline sheds light on an often unrecognized problem, autonomic dysreflexia.

Autonomic dysreflexia is a serious medical condition that can occur in those with spinal cord injuries at thoracic level 6 and above. To help professionals, patients and caregivers recognize and manage this condition, the Consortium of Spinal Cord Medicine assumed the task of revising the first edition of its guideline to include updated and new information on the condition. There are now two new editions available: one for professionals and one for consumers. *Focus on Rehabilitation* spoke recently with Todd Linsenmeyer, M.D., director of urology at the Kessler Institute for Rehabilitation and chairman of the development panel for the guideline, about the new edition and its importance to spinal cord injury medicine.



Shown here with patient Michael Rojek, Todd Linsenmeyer, M.D., (right) has been involved in developing treatment guidelines for spinal cord injury since 1993.

FOCUS: First of all, could you explain what autonomic dysreflexia is and how it develops?

LINSEMEYER: It is an abnormal response to a problem in the body in those with spinal cord injuries at thoracic level 6 and above. The cause is often an overfull bladder or bowel, which can result from a catheter blockage. The condition triggers messages to the spinal cord, but because

of the injury, these messages are obstructed. In response, they activate autonomic nerves that constrict blood vessels in the intestines, causing a rapid and potentially fatal rise in blood pressure. The person may experience no symptoms or may have

pounding headache, heavy sweating, flushing, goose bumps, blurry vision, nasal congestion, anxiety or difficulty breathing. The dysreflexia will go away as soon as the problem in the body is taken care of. Clinicians should treat patients immediately by alleviating the underlying cause of the dysreflexia and administering treatment for the hypertension.

The Acute Management of Autonomic Dysreflexia: Individuals with Spinal Cord Injury Presenting to Health Care Facilities, 2nd ed.

(40 pages), is available from the Consortium for Spinal Cord Medicine for \$19.95, plus shipping and handling. The guideline includes peer-reviewed, evidence-based information on the diagnosis, treatment, and management of autonomic dysreflexia. Search online at www.scicpg.org (where downloads are available for \$8) or call 888-870-7244. A guide for consumers (*Autonomic Dysreflexia: What You Should Know*, 14 pages plus a wallet card) is also available (for \$9.95 plus S&H, or \$5 for downloads from the web site). Dr. Linsenmeyer is chairman of the development panel for the guidelines, as well as a member of the steering committee for the Consortium for Spinal Cord Medicine representing the American Paraplegia Society. He is board-certified in both urology and physical medicine and rehabilitation.

FOCUS: Why was a guideline needed for this condition?

LINSEMEYER: The main reason was that physicians generally do not see many spinal cord injury patients and are relatively unfamiliar with their medical conditions and needs. Emergency room personnel, for example, tend to have very little knowledge of the condition, which can in some cases

New subspecialties in physical medicine

Joel A. DeLisa, M.D., M.S.



Psychiatry's first subspecialty—approved by the American Board of Medical Specialties (ABMS) in March 1995—was spinal cord

injury medicine. As of the end of 2001, 294 individuals had earned this subspecialty certificate. The second subspecialty, pain medicine, was approved in March 1998. Through 2001, 203 of these subspecialty certificates had been awarded. Our newest subspecialty, pediatric rehabilitation medicine, was approved by the ABMS in March 1999, and the first examination is set for November 2003.

A fourth subspecialty may also be approved for physical medicine and rehabilitation, although this could take a year or more. In September 2002, the American Board of Physical Medicine and Rehabilitation (ABPMR) resubmitted a letter of intent for the designation of a new subspecialty to be known as sports medicine rehabilitation. The original letter of intent was submitted in 1995. The specialties of internal medicine, family practice and emergency medicine were approved by ABMS in 1994 to issue certificates in sports medicine, while pediatrics was approved for the certificate of pediatric sports medicine. More recently, orthopedic surgery has applied for approval to issue a similar certificate, to be entitled orthopedic sports medicine. I suspect that the latter request will be approved at the March 2003 meeting of the ABMS Assembly.

A debate exists on whether subspecialty certificates weaken the primary specialty certificate. In most areas of the country, accepted medical practice overlaps specialties. As a result, when other boards receive permission to grant a subspecialty certificate, pressure is placed on the ABPMR

to do the same. An example is sports medicine. If we do not obtain this subspecialty certificate, we will be the only specialty whose diplomates treat this group of patients but lack the "extra" certificate of expertise.

The ABPMR is a small certifying board within ABMS, accounting for only three out of 111 votes. Most issues require a simple majority vote, while a few issues require a two-thirds majority. Thus, it will be difficult for us to prevent other boards from obtaining subspecialty certificates in areas that overlap with our practice. Once an area has been declared a subspecialty in one disci-

When other fields add subspecialty certifications, it puts more pressure on ours to do the same.

pline, however, it is easier for another board to obtain approval for granting a corresponding subspecialty certificate. For example, it will be easier to encourage organized medicine, through ABMS, to approve sports medicine rehabilitation as an ABPMR subspecialty than it would be to receive approval for spine medicine.

There are other areas where the ABPMR may want to seek subspecialty certification, such as in brain injury and geriatrics. But significant effort and resources are required to develop multiple examinations in different areas on an annual or even less frequent basis. Thus, I suspect we will not see initiatives for further subspecialization beyond sports medicine rehabilitation for a few years. **FOCUS**

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be life-threatening without prompt diagnosis and treatment. In addition, payers were unable to reach a consensus on the needs of these patients, and the guideline gives them the evidence they need to justify providing insurance coverage for this as well as other conditions related to spinal cord injury. We also wanted to equip consumers and those with spinal cord injuries with good, evidence-based information, since they are the ones who have the greatest need to recognize the condition when it arises.

FOCUS: How did the guideline for autonomic dysreflexia come about?

LINSENMEYER: In 1993, the Eastern Paralyzed Veterans of America (EPVA) developed the guideline for use in a hospital. I was asked to be one of the reviewers for this document. The American Paraplegia Society (APS), which is supported by the EPVA, saw a need to refine these for general use. The Paralyzed Veterans of America (PVA) agreed to coordinate the project, and representatives from 17 organizations were involved in gathering, reviewing and writing the guideline. They included groups of physicians, nurses, payers and the U.S. Department of Veterans Affairs. In addition, all the major spinal cord injury organizations have contributed by providing field reviews and by endorsing the guideline.

FOCUS: What other guidelines have been developed by the consortium?

LINSENMEYER: It has also produced guidelines for thromboembolism prevention, neurogenic bowel management, treatment and prevention of pressure ulcers, treatment of depression related to spinal cord injury, and outcomes following traumatic spinal cord injury. In January 2003, the consortium will be releasing two new guidelines, on the preservation of upper extremity function and respiratory management.

The consortium also sees that the guidelines are disseminated and used effectively. It has sent 70,000

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Designing— and fighting for — ideal coverage

Bruce M. Gans, M.D.



As physiatrists, we have fought hard to break down barriers that restrict patients' access to rehabilitation.

One obstacle we have worked to remove is the lack of awareness within the medical community. Because we have historically been a small specialty with limited numbers of practitioners and facilities, many health care professionals simply did not know the range of rehab services that exist. Slowly but effectively, we are convincing the medical community that we have a lot to offer patients.

Mindset has been another barrier: Many providers have stubbornly believed that only cure counts, not functional improvements. But again, with a lot of effort, we are shifting that paradigm. Now both physicians and consumers are starting to realize that helping patients to use a wheelchair improves their quality of life and independence dramatically—even if we cannot enable them to walk again.

But perhaps the highest hurdle we continue to face is money. Even when providers and patients fully endorse the benefits of rehabilitation, insurers are reluctant to step up to the plate. They argue that rehab is not a necessary medical expense, and they are not motivated to make short-term investments to gain long-term patient improvements—particularly when plans do not expect to cover any given patient for more than a year or two.

As a result, rehab benefits vary enormously from state to state and from plan to plan, with one thing in common—they do not begin to cover the range of rehabilitative costs. Oddly, Medicaid provides the best coverage in many states, not commercial insurance. The fact that patients must impoverish themselves after a cata-

strophic event to qualify for rehabilitation benefits is a disgrace—particularly if the coverage they get is still not adequate.

How much does effective rehabilitation cost? Some expenses are obvious, like salaries for physicians and nurses, and the cost of bed days, medications and medical equipment. But other costs are less obvious, although the services they buy bring vast improvements in clinical function and quality of life. They include home health services, personal care assistance and home modification expenses that make it possible for patients to live at home.

The fact that patients must impoverish themselves to be covered is a disgrace.

They also include the costs of wheelchairs and other motorized devices and the transportation patients need for medical or rehab care. Then there is the expense of accommodating patients' disabilities in educational or vocational rehab, to give them the chance to work again. The true costs associated with successful rehabilitation are greater than many health policy makers are willing to acknowledge.

So how do we move toward acquiring the kind of coverage our patients need? One good approach is to define what an ideal health insurance benefit package looks like, and then to advocate its adoption through legislative and regulatory actions.

The American Medical Rehabilitation Providers Association (AMRPA) is now developing a model health insurance coverage description—to be rolled out within the next year—that will detail the ideal rehabilitation benefit plan. The model will cover the full range of rehabilitative costs: inpatient and outpatient services; mainte-

nance and environmental needs; home health and personal care assistance; and even medically necessary transportation expenses.

To get the plan adopted, AMRPA will work with a broad coalition in the disability community—including the American Academy of Physical Medicine and Rehabilitation, the American Academy of Neurology and the Consortium for Citizens with Disabilities—to support the model as the gold standard of how health insurance should be structured. Institutions and physicians will be called upon to argue for adopting elements of the plan on the federal level, in states, and by commercial insurers.

In designing the ideal benefit model, we look closely at existing coverage approaches, particularly benefits for patients with chronic illnesses.

Among government programs and health plans, the wisdom of managing chronic illness—to improve outcomes and cut costs—is taking hold. There is growing recognition that early preventive care can avoid the expensive late consequences of many disabling conditions. Further, if health plans are assured of economic advantages in the long run from investing in near-term care, the interests of patients and insurers become more clearly aligned.

The elements of this model program will not be adopted without a fight. But we should ultimately succeed with a broad coalition of professional organizations—and another powerful force we will have on our side: consumers. Opposition to full and necessary health insurance coverage is just one more barrier that we have to continue to work to bring down. **FOCUS**

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office or patient's home. The baclofen is injected through the skin into a reservoir port, a process that takes approximately 15 minutes. An alarm alerts the user if the pump requires refilling or replacing. The treatment is reversible, and the pump can be removed at any time.

Who's right for this treatment

Among individuals with acquired brain injury, candidates for ITB therapy include those with spasticity in more than one limb and those who require excessive medications or injections to manage their spasticity. The therapy is generally more effective in controlling leg spasticity than arm spasticity. It is also appropriate for those who have not responded to oral medications or are unable to tolerate the side effects of oral medications. One crucial advantage of ITB therapy in acquired brain injury patients is that the pump delivers the baclofen to the spinal fluid, rather than to the brain. The dosage is therefore lower, which in turn reduces or eliminates side effects that often exacerbate the cognitive, arousal or behavioral problems that can occur in these patients.

Candidates for ITB therapy must be reliable and motivated to adhere to follow-up care. The patients must also be willing to play an active role in setting and achieving new goals. They should be informed that they will not be stronger after the therapy, but will have improved control and function. Patients will therefore require new

evaluation and possibly targeted therapy to take advantage of this new window of opportunity.

For reasons that are little understood, improvement can continue for a number of years. This improvement may be a result of the fine-tuning that the pump allows, or the follow-up therapies that patients are able to undergo. One Kessler patient, a young man with a traumatic brain hemorrhage that compressed the brain stem, came to us with no limb movement and some ataxia and spasticity

Some patients have reduced pain, improved skills and better urinary, bowel and sexual function.

in the legs. He had completed the course of therapy at another facility and reached the goals that had been set. The young man responded to the test dose of baclofen and was initiated on ITB therapy. He subsequently gained more control and was able to walk with a walker. This made it possible for him to complete college.

Helping in several ways

ITB therapy offers a number of other potential benefits. The bedridden patient may be better able to change positions, for example, which can help to reduce bed sores and the need for orthopedic surgeries to repair contractures. The caregiver burden may also be decreased, which is

extremely important in both the nursing home and home care setting. Some patients will experience decreased pain, improved skills, greater sexual function and better bowel and urinary function, as well as improved control of joint movement.

What's the downside?

The risks of the pump are those that accompany any surgical procedure, although the surgery is fairly minor. As with any surgery, post-operative care is required to prevent infection. In addition, the catheter can become kinked, twisted or detached, but this is a rare occurrence. If the therapy is discontinued, the patient should be withdrawn from the drug carefully and gradually, to avoid seizure.

Although the implantable pump is not a first-line therapy for spasticity in acquired brain injury patients, it is an advanced and effective therapy that should be considered before the patient experiences the onset of contractures and other severe consequences of spasticity. **FOCUS**

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The next issue will feature a related article on the use of Botox to manage spasticity by Elie Elovic, M.D., co-author of a recent *New England Journal of Medicine* article on the topic.

Autonomic dysreflexia continued from page 5

copies of the autonomic dysreflexia guideline to organizations, individuals and libraries to get the word out.

FOCUS: What is your role in the development of these guidelines for the treatment of spinal cord injury?

LINSENMEYER: I was asked by the Spinal Cord Consortium to chair the

group that put together the autonomic dysreflexia guideline. I am also on the steering committee of the consortium. As such I am one voice in the process and in choosing the topics..

FOCUS: Why was a new edition of the autonomic dysreflexia guideline needed?

LINSENMEYER: It was necessary to

assure that the information in the guideline was still current. In addition, the guideline was revised to include three timely new sections—on pediatrics, pregnancy and Viagra. In the future, we plan to update the guideline and release a new edition every five years. **FOCUS**

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Treadmill training

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is not the main obstacle to walking. An analogy is with driving a car in which the engine works (the muscle), but being unable to find the gas pedal. Thus the emphasis of Dr. Bogey's research is less on increasing weight-bearing over time and more on developing a normal gait.

Questions that remain

Stroke patients who are unable to follow directions and those with orthopedic and cardiac problems are probably not candidates for the therapy. Most stroke patients, however, should be able to tolerate body weight-supported treadmill training.

The therapy is currently being used clinically for stroke and spinal cord injury patients at Kessler's inpatient facilities. Plans are under way to incorporate it into outpatient programs as well.

Therapy for most patients may take four weeks to six months, but this is one of many questions the studies will address. How often should therapy be given and for how long? What speeds and weight support levels are most effective? How soon after injury or stroke should therapy begin? Resolving these and other questions may help make this emerging therapy available as routine treatment within this decade. **FOCUS**

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Clinical Pearls

Keeping patients with acute medical conditions in the rehabilitation facility

Samuel P. Grissom, M.D.

Patients who develop acute medical problems during the course of their rehabilitation stay require a certain degree of flexibility on the part of the rehab facility. In managing patients who develop pneumonia, urinary tract infection, fluid imbalance or severe constipation, for instance, the goal is to prevent significant functional loss that can occur if the individual is transferred to acute care. Patients in the hospital may receive some rehabilitation therapy, but generally only a very limited amount. The challenge is therefore to care for the patient medically while still providing the required rehabilitation.

The first requirement is flexible staffing. Patients with acute conditions may well require more nursing care, and the nursing staff should therefore be sufficient and flexible enough to accommodate these situations.

Therapy staff should also be able to meet the needs of the acutely ill patient. This means providing bedside therapy when the patient is not well enough to go to the gym and being able to adjust the intensity of therapy for the patient who is ill. Indeed, the goal that patients should receive three hours of therapy a day may have to be suspended for a few days in these cases.

There is also a need for physiatrists who know how to manage medically ill patients and are comfortable doing so. And it is useful to have an internist on staff. Kessler Institute has one internist at each of its inpatient facilities to help manage patients with acute illness or complex medical conditions.

Also important is access to ancillary

services, such as lab and radiology, that can come to the patient. Radiology should be on the premises, although readings can be done by a radiologist who is not on-site. And if the facility lacks CT and MRI capabilities, medical transport should be available for patients who require these services.

Finally, a key element to keeping the ill patient in rehab is effective and thorough pre-admission assessment. This critical tool helps physicians anticipate the medical needs of patients and have both the staff and the resources in place to prevent medical complications. This need can be filled in a number of ways; at Kessler, a nurse liaison performs full assessments before each admission to help anticipate a patient's particular needs. This assessment includes not only the rehabilitation status of the patient, but medical conditions as well.

Smaller facilities, however, may not be able to send a nurse to the acute care hospital to assess each patient before admission. For these facilities, a system should be in place to perform adequate assessment of patients admitted for inpatient rehabilitation, including gathering and reviewing patient records, physicians' notes and all pertinent information. Such a system will allow even the smaller facility to obtain a clear picture of the medical status of each patient before he or she is transferred to rehabilitation. **FOCUS**

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