

# Rehabilitation

SPRING 2007

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## Formulary Substitution

A candid look at the pros and cons ■ ROBERT J. KLECZ, M.D., AND NEIL SCHULMAN, PHARM.D

Substituting one drug for another is common among almost all large American hospitals, but the practice still is tinged with controversy. The question is, why?

The answer is far from simple.

The core rationale for substitution is that certain medications, or classes of medications, have multiple similar drugs. A hospital pharmacy could conceivably carry every drug in every class, but this would be costly and inefficient. So, the hospital's Pharmacy and Therapeutics (P&T) committee grants certain drugs a preferred status. The selection is driven by three factors: 1) efficacy; 2) ease of obtaining the particular drug; and 3) economics.

Consider the case of the common anti-hypertensive, the ACE inhibitor. At Kessler Institute for Rehabilitation, the ACE inhibitor of choice is Lisinopril. Any prescription written for a medicine of that class, such as Vasotec, will automatically be changed to Lisinopril.

Does this mean business analysts have abrogated medical therapeutic decisions? Hardly.

The process of selecting formulary substitutions is collective and always amicable. At Kessler, the P&T committee includes physicians and pharmacists, nursing directors, administrators and even a nutritionist who all talk candidly and at length about the science of any drug proposed for substitution. The discussions cover efficacy, the practicality of stocking alternates and cost.

Besides, formulary substitution does not apply to a large number of drugs. In all, there are probably only 15 to 20 substitutions. Most are common ones such as cough medicines, basic antibiotics and antihistamines. They are not drugs such as seizure or diabetes medications, which require specific therapeutic levels.

### Root of the Controversy

The practice of substitution is controversial mostly to referring physicians, to whom a rehabilitation hospital is something of a downstream provider. Patients are referred to rehab from acute care hospitals and by primary care physicians (PCPs) who may prefer one particular drug. If the rehabilitation hospital substitutes another of the same class, the PCP may object.

Formulary substitution also can be controversial when medicines are used off-label, or have off-label indications. A good example is Lovenox (enoxaparin), which is used for thromboprophylaxis. Many studies support its use in the spinal cord injured population. However, Lovenox can be substituted with Fragmin (dalteparin) in the formulary. Dalteparin is the same class, and is meant to serve as an anticoagulant. Such a substitution becomes an issue because the research to support the use of dalteparin among patients with spinal cord injuries has been relatively sparse in comparison to that involving enoxaparin. A referring physician may be opposed to (continued on page 7)



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#### MISSION STATEMENT

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**M-MURRY**



## Envisioning the Future of Inpatient Medical Rehabilitation

The world of hospital-based medical rehabilitation is under siege due to changes in Centers for Medicare and Medicaid Services (CMS) rules and the ways in which they are interpreted. These changes are forcing rehabilitation beds, whole rehabilitation units and even entire rehabilitation facilities to close. More than 8 percent of rehabilitation beds in the U.S. closed in fiscal year 2005-2006 alone.

Three factors are driving the decimation of inpatient capacity: the "75 Percent Rule," an increase in medical necessity denials by Fiscal Intermediaries (FIs) and additional denials by Recovery Audit Contractors (RACs).

The complete phase-in of CMS's 75 Percent Rule was delayed by one year, but its full impact is set to take effect on July 1, 2008. Also driving the reduction of inpatient capacity is the retrospective denial by FIs of payment for services that have already been rendered by rehabilitation hospitals. The FIs have become more aggressive in auditing facilities and issuing medical necessity-based denials if they believe patients could have been treated in a less-intensive setting. Lastly, the RAC system was initially a demonstration project, but is now mandated for all 50 states. Because RACs are paid a percentage of each dollar recovered, they have a strong financial incentive to deny reimbursement during their retrospective case reviews. Already, these factors have produced a dramatic reduction in overall utilization of rehabilitation facilities, especially by patients with contended diagnoses. Even more beds and facilities will close as their full impact comes into effect. Compounding these challenges, insurance companies are reducing payments for rehabilitation hospitalization through various strategies, such as pre-certification denials, preferred provider relationships and medical necessity denials.

Ironically, this loss of rehabilitation beds is occurring just as the need for rehabilitation services is increasing. While medical advances may reduce some of the need for inpatient rehabilitation care, in the area of joint replacement surgery, for example, the need is increasing in many other situations (such as cancer, pulmonary disease and cardiac conditions) that cannot be addressed under current CMS rules.

Despite these challenges, the field of rehabilitation has an incredibly bright future. As we create our vision of that future, we must consider political, economic and technical factors. Politically, to sustain and grow the rehabilitation capacity that this country needs, we must make the general public and our elected officials aware of the problem, and we must build a large, supportive constituency. The public at large does not yet understand that the rehabilitation hospital is becoming an "endangered species" on the verge of extinction.

Economically, we must continue to make our care more cost effective at a hospital level. We need to create a rational policy that protects our most effective and highest quality service providers, as well as the most essential components of the system, including academic centers, where the future providers are trained and much of the research is undertaken. In the technical arena, we must adopt more effective and efficient therapeutic strategies, whether they're robotic therapy devices, better medications to treat brain disorders or improved communication strategies within delivery teams. We must strengthen the quality of care being delivered in other settings, too, and look at new and innovative service delivery models and enterprises.

With a carefully crafted plan, we can create our vision of the future of inpatient rehabilitation. If we pay attention to the issues addressed here, we also can create a constituency around that vision—that is, our own dedicated army of believers.

Bruce M. Gans, M.D.

# Severe Brain Injury

Taking complications into consideration

■ C. MICHELE MILLER, D.O.

**W**hen a patient presents with a severe brain injury at an acute care hospital, the diagnosis and treatment of concomitant medical conditions may not be of primary importance. Once the patient transfers to a rehabilitation center, however, it becomes critical.

Brain injury tends to have a bimodal distribution by age. Younger patients, in their 20s or 30s, whose injuries usually relate to violent events such as car accidents or gunshot wounds, often have no medical history other than typical childhood illnesses. However, older patients, for whom falls are the likeliest cause of injury, are more prone to the chronic disorders common to senior populations, such as diabetes or hypertension. This patient population also may have had cancer, multiple surgeries or psychiatric disorders.

Kessler categorizes common medical complications of severe brain injury into four broad groups:

•**Neurological/neuroendocrine problems**, including seizures, hydrocephalus, sleep/wake disturbances, agitation, low arousal, autonomic dysregulation, SIADH, cerebral salt wasting and diabetes insipidus

•**Immobility-related problems**, such as deep-vein thrombosis, pulmonary emboli, decubitus ulcers and heterotopic ossification

•**Infections**, including *Clostridium difficile* overgrowth (from previous antibiotic use), catheter-related infections and pneumonia

•**Residual traumatic injuries**, including undiagnosed fractures and their associated pain

## Keeping a close watch

Because patients with brain injury often cannot express their symptoms, diagnosing other medical conditions can be complicated. Open communication with primary care physicians and family is essential for understanding family medical history. Equally important,

clinicians must rely on other methods of detection, such as monitoring vital signs, looking for signals of distress, applying screenings proactively and being vigilant in identifying symptoms of infection and other acute disorders.

Brain-injury patients also may not exhibit typical symptoms or signs of medical complications. For example, patients with autonomic dysregulation who develop fever may not have an infection, as might be expected. In such cases, diagnostic tests and the presence of other signs indicating infection or sources of fever lead to a more accurate diagnosis.

There are several unique factors to take into account when treating medical complications in this population. First, clinicians must consider the treatment's effect on cognition and arousal, particularly when administering pain and seizure medications. After a surgery, anticoagulation therapy must be carefully monitored, especially if pre-existing hemorrhage is a concern. Depending on the nature and location of the brain injury, pre-existing antidepressant or anti-anxiety treatment also might require adjustment.

Finally, it is important to schedule treatments around patients' rehabilitation schedules. This can be accomplished with practices such as giving tube feedings during the night, with a "bolus" feeding at noon.

## Evaluating care options

Beyond this population's unique physiological needs, there are other factors to take into account when making treatment choices. Clinicians must adopt aggressive prevention efforts, and they should have a high index of suspicion for the most common medical conditions and complications to allow for early intervention.

When considering treatment options and related side effects, benefits must always outweigh risks. Likewise, clinicians must evaluate pre-existing conditions and how they are being

treated, and adjust medications if necessary based on the nature and location of the brain injury.

Cost must be considered, especially at discharge. For patients with little or no insurance coverage, Kessler prioritizes the discharge medications accordingly and often uses generic drugs to help ease the financial burden. In New Jersey, for example, a prescription-assistance program is available, and some pharmaceutical companies offer discounts or other financial assistance.

Finally, clear and proactive communication is key. At Kessler, a daily morning conference covers every patient's current care and discharge plan. The patient's treatment team meets weekly, which helps keep everyone up to date. Clinicians also rely on and listen to the floor staff, the patient's family and friends, and the patients themselves when they notice changes that might need our attention.

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## Form Follows Function

Kessler Institute for Rehabilitation opens its 21st century NeuroRehabilitation Pavilion

**A**n institution is more than just brick and mortar, Henry H. Kessler, M.D., once said. "Its strength lies in the people—qualified, dedicated people with vision and imagination, as well as understanding and compassion."

That vision was the guiding force behind Kessler Institute for Rehabilitation's new 102,000-square-foot NeuroRehabilitation Pavilion. Opened in December 2006, this innovative addition to Kessler's West Orange campus represents a new model for inpatient rehabilitation care—an environment designed to provide optimum support for patients and their families, as well as the staff members dedicated to their recovery.

Vincent Knoll, vice president, construction and asset management, recently discussed the design considerations and building process for the Pavilion.

**Focus on Rehabilitation:** What was the impetus for the new building?

**Vincent Knoll:** There were a couple of key reasons for opening the NeuroRehabilitation Pavilion. First, Kessler's Centers of Excellence for Spinal Cord Injury and Brain Injury Rehabilitation had been occupying separate buildings in East Orange and West Orange. Because a large percentage of patients with spinal cord injury

(about 40 percent) also have brain injury, this created logistical issues for patients, their families and staff.

The new Pavilion combines both centers into one facility, offering access to comprehensive components of each rehabilitation program, such as equipment and research projects. By eliminating redundancies and making it easier for Kessler's team members to utilize these resources, the Pavilion optimizes treatment and outcomes for patients.

Also worth noting is the fact that the Pavilion is located in a suburban area, with the kind of wide-open space necessary to achieve the size and scope of the facility we envisioned. Undertaking a similar expansion in the urban setting of East Orange would have been much more difficult. Besides, the West Orange campus is only six miles from the East Orange hospital.

**Focus:** What considerations went into the design and building processes?

**VK:** Our primary goal was to create a rehabilitation environment that fosters healing and recovery. This was no small task, as it involved streamlining our operations while expanding our services. It also required a detailed transition plan to ensure that patients were not inconvenienced and had absolutely no disruption in care.

To achieve our goal, we assembled a design team that included a construction manager early in the preconstruction phase. We accepted competitive bids, with a guaranteed maximum price and estimated budget of \$25 million. Of course, price was just one criteria in the selection process. Equally important was finding an architectural/engineering firm with demonstrated expertise in hospital design and a deep understanding of the amenities that would help us achieve our goal.

The final design called for a three-story, 96-bed addition



Large day rooms offer sweeping views and comfortable space for patients and families to gather.

that would house all Brain Injury resources on one floor, and all Spinal Cord Injury resources on the other, with the ground floor reserved for admissions, a gift shop and administrative functions. We broke ground on the building in May 2005 and were finished 18 months later.

**Focus:** In what ways has the design achieved your goal?

**VK:** For patients and families, we wanted an environment that ensured privacy, dignity, comfort and convenience.

To that end, all the rooms are now either private or semiprivate. Whereas most hospital semiprivate rooms have a vertical design, requiring staff and visitors to pass one patient to get to the other, those in the Pavilion have a wider, more horizontal configuration. Besides creating truly personal space, this semiprivate-room design also provides each patient with the added benefit of a window with a view.

To optimize the early and often critical stages of care, when patients with spinal cord injury or brain injury may require ventilators, mechanisms for delivering oxygen and other medical gases are built into the wall. In addition, state-of-the-art lighting and HVAC systems adjust to individual sensitivities. Ceiling lifts enable staff to transition patients from their wheelchairs to their beds more safely and comfortably and with a significantly higher degree of dignity.



The new main entrance features a protective portico, and the hospital's glass façade brings natural light into the lobby, day rooms and therapy gyms above.



Above left: The West Orange addition went from raw space to completed construction in 18 months. Above right: Two nursing stations on each floor enhance responsiveness to patient needs, as well as overall safety and security.

There also is a high-tech security system to ensure everyone's safety, and two nursing stations on each floor feature the latest medication administration and dispensing systems.

Other important amenities: All rooms have private baths with showers designed to accommodate today's larger equipment and wheelchairs, as well as sinks, tables and furniture positioned at accessible heights. These accommodations help patients ease their way from dependency on staff to self-sufficiency—a critical aspect of recovery.

**Focus:** What technological innovations have raised the bar for patient care?

**VK:** Helping individuals who experience brain or spinal cord injuries build a sense of independence and get comfortable socializing again is essential to successful rehabilitation. The technologies we've employed in patient rooms, therapy gyms and public spaces help make this happen.

Spaces for activities of daily living (ADL), for example, have been enlarged to provide more opportunities for patients to practice everyday tasks, from personal grooming to preparing a family meal. Each floor has a large day room, with dining and sitting areas for socializing with other patients, family members and visitors. These areas feature computer stations and large,



Both private and semiprivate rooms optimize privacy, safety and comfort.

flat-panel televisions. We've also integrated the use of Environmental Control devices for patients who need them, such as TVs that operate by chin movements and lights that can be turned on and off with the blink of an eye.

Beyond technology, great care was put into creating an environment that's peaceful and uplifting. The day rooms and therapy gyms have full walls of windows, allowing natural light to flow throughout the space.

**Focus:** What recommendations do you offer those who are thinking of building, adding to or renovating hospital centers?

**VK:** I can think of several. First, get as many stakeholders involved in planning as you can. We sought extensive input from our physicians, nurses and therapy staff on design features, and also used focus groups and surveys to get feedback from patients and family members.

Second, when considering a location, weigh the unique challenges and opportunities it presents. Expanding our suburban campus enabled us to realize our full vision.

It's also smart to get the general contractor and design team involved at the preconstruction phase. By doing so, we were able to use the most efficient materials and building methods.

Be sure to keep everyone in the loop. Our communications plan included sharing ongoing progress reports with staff, patients and family members, as well as with our referrers. We even introduced a special newsletter, *Passport*, to serve as a guide for employees. By communicating regularly and often with these key audiences, we kept everyone well-informed of our progress.

And, of course, it's always important to maintain a good sense of humor.

## Kessler's NeuroRehabilitation Pavilion

### By the Numbers

3

number of stories  
in the Pavilion

138

total number of beds

102,000

total square footage

146.5

miles of wire used in construction

23,000

total feet of copper tubing

4,000

cubic yards of concrete  
in the foundation, walkways  
and curbing of the building—  
enough to create  
16 miles of sidewalks

18

number of months  
from start to finish

# Controlling Our Destiny

Collaboration is essential to ensuring a patient-focused future for post-acute care providers

■ BRUCE M. GANS, M.D.

The Centers for Medicare and Medicaid Services (CMS) is moving doggedly forward on a course to change post-acute care, both by implementing changes to inpatient rehabilitation facility regulations and by launching a series of contracts with external research groups to ultimately create a new single payment system for all post-acute care settings.

CMS has identified a legitimate problem of determining which patient requires a particular type of post-acute care setting for rehabilitation, and, therefore, a given level of payment. Unfortunately, “post-acute” care is a heterogeneous group of settings, with no simple common definition.

In effect, CMS is looking to lower the distinctions among various post-acute care facilities.

## Digging for the wrong details

To this end, CMS is awarding a series of contracts to do the work that will lead to the development of a new payment system. The first of these contracts has been awarded to an organization called Research Triangle Institute (RTI) to develop a uniform way of measuring functional status and outcome in all post-acute settings. The second contract, also awarded to RTI, uses that instrument to collect patient outcome and cost data across all post-acute care settings.

In addition, we currently have a system that provides too little regulatory control in some post-acute settings to assure equivalency of services. For example, rehabilitation hospitals must provide 24/7 physician coverage, round-the-clock professional nursing staff, high-level licensed therapists and three hours of rehabilitation therapies. None of these requirements is in place for SNFs, which can differ widely in the services they provide and still be treated in the same way by CMS.

The rehabilitation field should come together to initiate a conversation about what we feel the post-acute care world should entail, rather than letting CMS define it for us. Why not bring all stakeholders together to develop a consensus vision of how to change the healthcare system to better deliver post-acute care? In creating that joint vision, we should reframe the primary question, not as an issue of who wins or who loses in terms of CMS payments, but rather as our basic concern of how to best care for our patients.

In doing this, we have the opportunity to design a system that could cost less, yet provide our patients a better outcome. We could make very simple changes that our patients would greatly appreciate and that would save our healthcare system money. This might include, for example, eliminating the three-day hospital stay requirement for SNF admission, or incentivizing an ambulatory surgery benefit for joint replacement surgery that would include transportation and allow patients to be admitted directly into a rehabilitation hospital. If we try, we can invent a bright new world of care delivery for persons with disabling conditions.

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What we need to correct is, first, the process of selecting the proper, unique setting for post-acute care for an individual patient.

CMS includes several settings in its designation of “post-acute” care, including rehabilitation hospitals (which it calls inpatient rehabilitation facilities, or IRF), long-term acute care hospitals (LTACH), skilled nursing care facilities (SNF) and home healthcare agencies (HHA).

CMS has chosen to define the problem of identifying the correct site for post-acute care as an issue of proper payment policy. In its quest to reduce costs, CMS has launched a program to unify payment methodologies across the continuum of post-acute care providers. Its goal is to have payment follow the patient rather than be linked to the type of facility providing the care.

The third contract will develop a new data collection infrastructure to capture the information from all the post-acute providers.

Contrary to the CMS view, the payment systems are not the problem; in fact, the payment systems in each of the post-acute settings are actually quite effective at characterizing resource utilizations and costs. What we need to correct is, first, the process of selecting the proper, unique setting for post-acute care for an individual patient. Furthermore, when a patient could be cared for in more than one setting, we need a way to identify precisely which services are needed for that patient and how much they should cost.

## Formulary Substitution

(continued from page 1) the substitution because he or she feels more comfortable having strong backing from medical literature.

Although Kessler maintains an automatic substitution policy for various medications, this does not mean that substitutions cannot be overridden. That decision is the physician's prerogative. A doctor who feels strongly about any particular medicine can simply write "Do Not Substitute." Then it is the obligation of the pharmacy either to obtain that medication, or have the patient bring in his or her own supply, and not use the formulary substitution. No one contests the physician's or patient's right to insist upon this path.

Another medication that some physicians feel strongly about not having automatically substituted is the antibiotic Levaquin. Ciprofloxacin is a medication of the same family, and the Kessler formulary substitutes Ciprofloxacin for Levaquin. This decision was based on judgment of efficacy, because an increasing amount of bacterial resistance to Levaquin has been found in the northeastern U.S.

Some substitutions have met with resistance. For example, Levaquin is a top-selling drug in its class, partly due to aggressive marketing and pricing, but also because it's the easiest to prescribe. It's a once-a-day antibiotic, versus twice a day for Ciprofloxacin. This difference may not be significant in the hospital setting, but could be an issue after the patient has been discharged. Levaquin, coincidentally, is also the more expensive of the two drugs. Still, Kessler substitutes Ciprofloxacin for most uncomplicated infections, such as urinary tract infections, where the physicians generally feel that the bacteria sensitivity profile warrants the use of a quinolone.

### Keeping patients in the loop

Most of the time, patients support substitutions as long as they are made aware of the change and that the clinical equivalency remains intact. Those who take an established regimen of medications

### AT A GLANCE

## Formulary substitutions: arguments for and against

For	Against
The practice is <b>widely accepted</b> at major hospitals nationwide.	Doing something often <b>doesn't necessarily make it right</b> .
The <b>medical staff</b> in cooperation with pharmacy and therapeutics makes substitution <b>decisions</b> .	The practice can <b>appear to be dictated by pharmacy</b> .
The practice is <b>limited</b> to a relatively small number of medications.	There is a fear that the practice will <b>favor generics</b> over everything.
Substitution is <b>economically sound</b> , which benefits all parties. It allows the hospital to buy in bulk and thereby exert some control over high pharmaceutical costs.	Physicians should be <b>concerned with efficacy</b> , not cost.
Substitution is <b>not always financially driven</b> . It may reflect efficacy concerns (example: regional differences in bacteria driving the choice of antibiotic).	Substitution is perceived to put <b>cost considerations</b> before therapy.
The practice is driven by <b>amicable negotiations</b> between medical staff and pharmacy.	The practice is perceived as being <b>driven by MBAs</b> who know nothing about medicine and increasingly dictate healthcare.
<b>May be overridden</b> at any time with a doctor's "Do Not Substitute" order.	Some may perceive substitution as being <b>inflexible</b> .

at home can opt to have their preferred medications administered. Statins are among the most common examples. Patients who take Lipitor at home, for example, may receive Zocor in the hospital. These patients either support that substitution, or are given the opportunity to bring their own chosen brand with them to the hospital.

### Efficiency and cost challenges

Substitutions can cause extra work for the pharmacist, who may have to call the physician to determine whether a patient has his or her own medication, and whether the patient really needs to take it. Writing "Do Not Substitute" also may be expensive for the pharmacy, so again, the first

question will be whether or not the patient has a supply of the given drug.

The bottom line: Every organization has clinical and financial goals, and it's simply not practical to carry 30 different versions of a similar type of drug. A limited number of them will warrant substitution, and the P&T committee always reviews this at length in advance. Even then, the pharmacy still has to remain flexible for the patient who does not benefit from any particular course of medication.

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# Identifying and Treating Addiction

Risk, diagnosis and prevention ■ LORAN G. VOCATURO, ED.D., ABPP (RP)

**D**rug and alcohol addiction is a significant problem among patients in the PM&R population. But what leads to the behavior and how can it be prevented?

According to medical literature, the leading risk factor for substance abuse after trauma is a history of abuse. As many as 66 percent of patients with traumatic brain injury (TBI) and 49 percent with spinal cord injury (SCI) have a premorbid substance abuse problem. Other salient risk factors include personality characteristics, coping strategies (or their absence) and comorbid psychiatric disorders such as depression.

## Early identification and warning signs

For these reasons, early identification is crucial and begins with a psychologist's thorough evaluation for signs and symptoms of abuse. A primary goal of the evaluation is to obtain an understanding of the patient's perception of his or her sense of self and the world, as well as how he or she responds to life's stressors. When a disabling injury or illness alters these perceptions, it can reduce the patient's ability to cope or adjust, thereby heightening the risk for substance abuse.

A toxicology report is often the earliest information available to clinicians. Intoxication at the onset of injury is a trigger for a substance abuse problem and should be followed by an in-depth

assessment. But even in the absence of a toxicology report, it is prudent to evaluate every admission for history of substance abuse, at least with a pro-forma substance abuse screening measure (i.e., CAGE, MAST, SASSI). In order to get a comprehensive understanding of the patient's history, a family interview also should be part of the evaluation.

Signs of addiction post-injury may include compromised ability to cope and adjust to rehabilitation. Substance abusers tend to become more symptomatic in the hospital setting, which can confound adjustment. Abusers often have problems with motivation, participating in rehabilitation, and managing situational and interpersonal stressors.

The psychologist should remain alert for symptoms of depression or anxiety, irritability and sleep difficulty, all of which can signal adjustment challenges, as well as the early side effects of substance abuse withdrawal. Drug-seeking behaviors also may suggest a substance abuse problem. Individuals may look for anxiolytics or complain that their pain management regimen isn't effective. The psychologist walks a fine line, because physical disability frequently produces true physiological pain that requires pharmaceutical intervention.

## Education key to prevention

Counseling should include a psycho-educational component to inform the

patient of the risks and complications of substance abuse. It is important that they understand that abuse will not only compromise overall health, but also can heighten the risk of subsequent injury. In this population, even a simple fall can be serious.

Patients benefit from understanding the risk of addiction within physical disability. Coping and social skills training are important to help the patient regulate mood, manage stressors and fully participate in life. Supportive family and friends are key elements to help facilitate adjustment and community reintegration.

Although a decline in or complete abstinence from alcohol consumption may occur in the early months after injury, many patients will return to abuse one to two years post-injury. Given the ongoing danger of abuse, the psychologist must treat all patients as risks, and urge vigilance. The PM&R patient faces enormous physical and psychological challenges, and addiction can make overcoming them even more difficult. Substance abuse prevention, identification and treatment conducted by experienced psychologists are vital aspects of medical rehabilitation.

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