

Rehabilitation

Who belongs in an inpatient rehabilitation hospital?

RESPONDING TO THE CHALLENGES OF OUR RAPIDLY EVOLVING HEALTH CARE LANDSCAPE BY BRUCE POMERANZ, M.D.

THE CHANGES OCCURRING in our health care system today are unprecedented, bringing a significant shift to the practice of medicine as well as its economics.

While managed care has long been a part of health care in this country, the concept of “managed care” has shifted from insurance companies alone. Providers now use accountable care organizations and bundled payment models, employers use reference-based pricing and purchasing, and even businesses, such as large pharmacy chains, are affected.

The key words today are quality, value (defined as the ratio of quality to cost), patient-centeredness and coordination of care—all of which inpatient rehabilitation hospitals have long been familiar with and are excellent at providing.

However, increased competition from other levels of post-acute providers and the intense pressure to reduce costs are straining rehabilitation hospitals’ resources, potentially leaving patients at risk.

BENEFITS OF AN INPATIENT REHABILITATION FACILITY

Overcoming these challenges requires education about the unique characteristics of inpatient rehabilitation hospitals compared with other post-acute options such as nursing homes and home health agencies. The goal should be to ensure that patients receive care in the most appropriate setting. Yet too often patients

who would do best in a rehabilitation hospital are denied access because of a lack of understanding about the facility’s role or inappropriate barriers to admission.

That’s why educating managed care administrators and others is so important. Among the key points to highlight about inpatient rehabilitation hospitals:

- They are the only post-acute care setting with specialized expertise in rehabilitation provided by a team of physicians, nurses, therapists and others. Their focus is helping patients achieve the best health, functional outcomes and quality of life.

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MEDICARE REQUIREMENTS FOR INPATIENT REHABILITATION ADMISSION

Patients:

- Require the active and ongoing therapeutic intervention of multiple therapy disciplines, one of which must be physical or occupational therapy
- Require an intensive rehabilitation therapy program, typically defined as at least three hours of therapy per day for at least five days per week
- Must reasonably be expected to actively participate in and benefit significantly from the intensive rehabilitation therapy program
- Should be expected to make measurable improvement
- Must require supervision by a rehabilitation physician
- Must require an intensive and coordinated interdisciplinary approach to providing rehabilitation

Following these guidelines protects facilities if they are audited. Note, however, that nowhere do these regulations mention the 60 percent rule as criteria for admission.



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- They are required by the Centers for Medicare & Medicaid Services (CMS) to provide coordinated care under the supervision of a rehabilitation physician.
- They are, by their very nature, hospitals, and are capable of caring for the most complex medical needs of patients while working to return them to their communities with optimized function.
- They can prevent complications and readmission to the acute care hospital. Patients in a lower-acuity setting are more likely to experience a gradual or even sudden decline if complications are not addressed in a thorough and timely manner. This increases the risk that they will progress to chronic and irreversible disability and, of course, also increases costs.
- They have lower acute care transfer and hospital readmission rates. Indeed, CMS's own figures demonstrate that rehabilitation hospitals discharge 81 percent of their patients to the community compared with skilled nursing facilities' rate of 41 percent. They also have an acute care readmission rate of 9.4 percent compared with 22 percent.¹
- They provide better outcomes. A study by Dobson DaVanzo & Associates, with support from the American Medical Rehabilitation Providers Association, demonstrated that patients treated in inpatient rehabilitation hospitals and units had better long-term clinical outcomes, were discharged earlier, and lived in a community setting an average of two months longer than those treated in nursing homes.²

CLARIFYING THE 60 PERCENT RULE

To be considered an inpatient rehabilitation hospital, at least 60 percent of patients must have one of 13 diagnoses. Unfortunately, too many insurers and others associated with post-acute care assume this means that the absence of one of these diagnoses should prevent admission to a rehabilitation hospital.

What they don't understand is that the 60 percent rule does not define who should be admitted or cared for in an inpatient rehabilitation

hospital. The CMS criteria that delineate appropriate candidates for rehabilitation hospital admission do not mention anything about the 60 percent rule, nor do they list specific diagnoses (see the sidebar at left).³ In fact, the rule should not even be part of the conversation when considering the most appropriate setting for an individual patient's post-acute care.

In addition, 40 percent of patients can be admitted to a rehabilitation hospital without a diagnosis from the 60 percent rule list as long as they meet the CMS criteria.

BROADENING OUR FOCUS

To serve the medically complex patients who require the more intensive setting of a rehabilitation hospital, we should partner with acute care teams that treat patients who have specialized needs. At Kessler Institute for Rehabilitation, for example, we have established partnerships with programs for patients with left ventricular assist devices and those undergoing deep brain stimulation for Parkinson's disease. Further areas to consider include oncology, transplantation and other cardiovascular conditions.

This is particularly important given that the number of joint replacement patients admitted to rehabilitation hospitals is expected to decline in association with the Comprehensive Care for Joint Replacement (CJR) model that CMS released in November (read more about it on page 3). This will likely shift the referral patterns of acute care hospitals toward other post-acute care settings. Yet any approach that fails to focus on the circumstances and needs of each patient will also fail to deliver the best quality care and health care value.

Only by sharing information about the unique capabilities of inpatient rehabilitation hospitals compared with other post-acute settings will our patients receive optimal treatment.

¹ American Hospital Association. Fact Sheet: Inpatient Rehabilitation Hospitals. 2015. <http://www.aha.org/content/15/fs-rehab.pdf>.

² DaVanzo JE, El-Gamil A, Li JW, et al. Assessment of Patient Outcomes of Rehabilitative Care Provided in Inpatient Rehabilitation Facilities and After Discharge. Prepared for the ARA Research Institute. 2014. Available at: <https://www.amrpa.org/newsroom/Dobson%20DaVanzo%20Final%20Report%20Patient%20Outcomes%20of%20IRF%20v%20SNF%20-%202010%2014%20redated.pdf>

³ Medicare Benefit Policy Manual. Chapter 1 - Inpatient Hospital Services Covered Under Part A. Section 110. 2010.

FOCUS ON

Rehabilitation

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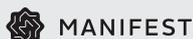
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Time to bundle up:

MEETING THE CHALLENGE OF BUNDLED PAYMENTS

In November, the Centers for Medicare & Medicaid Services (CMS) issued the final rule for the Comprehensive Care for Joint Replacement (CJR) model. Under this mandatory demonstration program, participant hospitals will receive additional payments—or reduced payments—based on quality outcomes for patients undergoing hip or knee replacements. The episode of care begins with the hospital admission and ends 90 days post-discharge.¹ The federal agency is introducing the program as a pilot in 67 geographic areas effective April 1, but it is only a matter of time before it is implemented throughout the country. It is reasonable to expect that similar models will follow from commercial insurers.

Nationally, total joint replacements are one of the most common reasons for admission to rehabilitation hospitals. Thus, this change will significantly affect many providers.

The expectation is that acute care hospitals will try to avoid sending patients to rehabilitation hospitals or even nursing homes in order to reduce total episode spending. Instead, there will be an increased effort to send patients home so they consume fewer resources.

This means rehabilitation hospitals must think strategically about the following:

1. What business are you in? Are you in the rehabilitation hospital business or are you in the rehabilitation care business? The latter means you offer a variety of models, from day treatment to home health, in addition to the traditional hospital program.
2. Who is your customer? Is it the patient? The payer? The other participants in the payment stream? The answer, of course, is all three, but the relationship with each is different.
3. Are you a vendor or a partner? Vendors wait for referrals to come to them. Partners identify opportunities to build and provide value with other providers to become a tighter part of the health care tapestry.
4. How much risk can you bear? Any risk model should consider patient complexity, duration of treatment, amount and level of care delivered by others outside of your control, and the range of services and outcomes you are responsible for. Also, larger volume improves the risk outlook since it is easier to manage cost outliers.
5. How will you fill your beds? The reality is that many rehabilitation hospitals will feel increased pressure to reduce occupancy. Some will also see reductions in market share, although others will see growth. Since fixed costs remain the same, rehabilitation hospitals need to find other patients or reimagine their facilities to provide different services.

The picture is not all bleak. There may be some positive results from this market shift, including:

- Improved coordination of care and outcomes for patients across the care continuum
- More referrals from acute care settings that want to minimize the number of organizations they work with and partner with those that can deliver value
- The opportunity to create new service programs and provide care for more varied patient populations
- Market share growth and increased strength for providers that survive

Times have changed and will continue to change. For rehabilitation hospitals, that means meeting new challenges in order to best leverage new opportunities.

¹ Centers for Medicare & Medicaid Services. The Comprehensive Care for Joint Replacement Model. Available at: <https://innovation.cms.gov/initiatives/cjr>. Accessed Jan. 31, 2016.

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AUTONOMOUS AUTOS: Are they the key to independence?

BEN SEIDEL, D.O., AND GUANG YUE, PH.D.

THE EVOLUTION OF THE AMERICAN AUTOMOBILE has achieved more than merely expanding the limits of human transport; it has revolutionized this country's economic and social systems and, on an individual level, allowed people to live more independent and rewarding lives.

The advent of driverless technology essentially circumvents the need for human involvement, regardless of whether that input is tactile, auditory or visual. This concept could significantly enhance the quality of life for people with physical, sensory or cognitive dysfunction. Although it is unclear how and when this technology may become regularly integrated into public life, it is easy to speculate about its potential in offering rehabilitation populations unprecedented access to the world around them.

OPENING NEW WORLDS

Robotic, or autonomous, automobiles operate independently of the operator, which represents a major complex technological feat compared with models requiring drivers. Infrared proximity sensors, lasers, radars, GPS technology and rooftop cameras help scan and detect objects in the environment, both immediately and in the distance, so that changes in vehicle speed, steering and braking can be applied appropriately. Advanced altimeters, gyroscopes and tachometers provide more accurate and detailed measurements of the car's location. Software gathers data on position and objects in the road, including other vehicles, to help the automobile respond accordingly, such as when it is clear to enter an intersection with a stop sign.

For many individuals with physical or cognitive limitations, mobility is critical for optimal everyday functioning. It enables them to travel to work, school or community activities; and it helps to both prevent social isolation and maintain overall well-being. While standard vehicles are usually inadequate, even specialized cars designed specifically for persons with disabilities are often insufficient. Someone with a spinal cord injury and no lower limb functioning, who subsequently cannot use pedals for propulsion, could operate a vehicle outfitted with hand controls. For an individual with tetraplegia and no upper motor abilities, however, this is not an option. Similarly, people with significant visual or cognitive deficits cannot necessarily benefit from current adaptive automobiles. Clearly, for these groups, an autonomous car could profoundly improve engagement in professional, academic or social activities that might previously have been difficult, if not impossible.

Mass transportation remains the current solution for many people with physical impairments, but it is far from ideal, as not all transit needs are addressed. The Americans with Disabilities Act (ADA) has attempted to improve transportation for this population, but there have been many obstacles. For instance, ride-booking companies, like Uber and Lyft, have argued that they are not covered by the ADA and thus are not required to serve clients with physical disabilities.¹ This is particularly problematic for rural and even suburban residents, who tend to have more restricted access to buses and trains. Further, many patients are frustrated with transportation companies, which are often hard to



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schedule and frequently not timely, and may only be available for “essential” tasks, such as doctor appointments. Unassisted cars could present an alternative to public transportation for individuals for whom driving is simply not an option.

SAFETY CONCERNS

From a rehabilitation perspective, anything that allows patients to be more independent, be involved in the community and have greater access to medical services will likely help to improve their quality of life and should be supported. Despite the clear potential benefits, though, robotic automobiles are not without their pitfalls.

Some of the greatest concerns relate to safety and the ability of the technology to appropriately detect, react to and avoid incidents that might lead to an accident. As anyone who has swerved to miss a deer can attest, human operators cannot always successfully prevent crashes, even in cases where driver error is not a factor. This has led to questions as to whether computerized technology can truly outperform or replace people under all circumstances.

Will the software react quickly enough to a child darting into the road? What happens if a sensor cannot pick up a small object in its path until it is too late to avoid a collision? What if the vehicle has to choose between two less-than-ideal situations, such as striking a pedestrian in a crosswalk or hitting a telephone pole while veering to avoid that person? Will these automobiles operate reliably? Or, like the Internet connection on your home computer or the cable on your television, will it experience occasional hiccups in buffering, coverage and wireless connectivity? The need for these devices to perform seamlessly is significantly higher than with other forms of daily technology, such as phones and tablets. It is imperative to answer these queries before these vehicles enter the market.

For people with physical or cognitive limitations, an additional barrier exists. Robotic cars for able-bodied, healthy individuals are highly complex and may still be years away from being ready for the public. But people with rehabilitation needs will likely require cars with further adaptations, like customized operating systems and additional sensors. A person with visual impairments may need an automobile with a greater range of voice commands. And even within the spectrum of disabilities, further tailoring may be necessary. Voice controls, for instance, will be insufficient for people with dysarthria or expressive aphasia, who may require more tactile inputs. These additional specifications would undoubtedly lengthen the time that adapted products take to come to market and realistically would impose a higher price tag.

For people with cognitive impairments, even more uncertainty lingers because, though driverless in principle, automated cars may still require some human interaction, which may be too difficult for some patients. For instance, a destination can be programmed, but what if the driver needs to change the endpoint en route to the final location? In California, where many companies are testing their cars (see sidebar “Buckle Up”), vehicles must be equipped with manual backup controls in case of an emergency, which could limit their suitability to all drivers with disabilities, not just those with cognitive difficulties. It is reasonable to speculate that future regulations may require people with limitations to have an able-bodied, healthy passenger with them at all times, which negates the concept of autonomy in many ways.

THE ROAD AHEAD

The imminent future of driverless cars is suggested by advanced driver features that appear to be creeping into many of today’s higher-end model vehicles, including automated, hands-free parallel parking; lane-keeping systems; adaptive cruise control; forward collision alerts; speed regulation; curve warnings; and blind spot monitoring. At this stage, the automobile industry is still assessing whether computers can safely drive a vehicle without major participation by a human, but the likelihood of public integration of such technology remains high. In contrast, consumers do not appear to be as confident. A 2014 poll from the Pew Research Center² indicated that only 48 percent of Americans said they were interested in riding in driverless cars. While many individuals with physical or cognitive disabilities might revel at the opportunity for greater freedom, other people have expressed hesitancy and skepticism that the technology would be a safe and efficient alternative to their current driving experience.

Time and further research will demonstrate the extent to which these innovations are adoptable by the American public. For rehabilitation patients, the automobile industry should have an economic interest in developing as wide a customer base as possible. History suggests the industry may even have a personal interest in helping individuals with physical disabilities lead productive lives: One of its greatest innovators, engineer Ralph Teetor, who invented cruise control, was blind.

¹ Wiczner J. Why the disabled are suing Uber and Lyft. May 22, 2015. *Fortune Magazine*. Available at: fortune.com/2015/05/22/uber-lyft-disabled/

² Smith A. U.S. Views of Technology and the Future. April 17, 2014. Pew Research Center. Available at: pewinternet.org/2014/04/17/us-views-of-technology-and-the-future

³ Moscaritolo, A. Google’s Self-Driving Car Takes Blind Man for a Ride. *PC Magazine*. March 29, 2012. Available at: pcmag.com/article2/0,2817,2402340,00.asp



BUCKLE UP

In the past five years, the technology for robotic cars has advanced dramatically. Numerous companies have built or are developing testable prototypes. These include Mercedes-Benz, General Motors, Bosch, Nissan, Renault, Toyota, Audi, Volvo, Tesla Motors, Peugeot, AKKA Technologies and Oxford University.

Some of the most publicly visible research has been conducted by Google, which began testing its robotic vehicles in 2009. Google’s fleet has accumulated more than 1 million miles in California and Texas. In 2012, tests of self-driving cars were successfully performed with a legally blind driver.³

Fighting managed care denials

BY BRUCE M. GANS, M.D.

MANAGED CARE HAS BECOME one of the biggest barriers to patient access to inpatient rehabilitation hospitals. It doesn't matter if it's a commercial plan, Medicaid managed care or Medicare Advantage—all are limiting admissions and steering patients into less expensive settings, seemingly regardless of individual needs.

In 2014, the Medicare Payment Advisory Commission (MedPAC), a nonpartisan agency that provides Congress with analysis and policy advice on the Medicare program, found that the rate of use of rehabilitation hospitals by Medicare Advantage (MA) enrollees was less than half that of fee-for-service Medicare beneficiaries despite the higher acuity of MA patients. This is particularly concerning given that one out of every three people covered by Medicare is now in an MA plan, and the number is growing.

Managed care companies use a variety of approaches to limit care in rehabilitation hospitals:

- They refuse to provide pre-authorization or prior approvals. If the denial is issued late in the week or late in the day, by the time the acute care hospital tries to appeal the decision, the office may be closed. The hospital wants to proceed with the discharge, so the patient is sent to a lower-acuity setting with limited attention to the individual's needs or wishes.
- They use biased, proprietary clinical screening tools that have never been objectively validated and that seem to invariably classify a patient as needing only skilled nursing or home health care.
- They don't inform patients that they are entitled to the full panoply of Medicare benefits, and have a right to appeal.

Even when a patient is approved for a rehabilitation hospital admission, the managed care organization exercises extremely tight case oversight, putting tremendous pressure on the clinical team to discharge the patient, often before the team believes the step is appropriate.

Finally, even if a stay has been authorized, the plan may issue a retroactive denial and refuse to pay a hospital's bill.

WHY THE DENIALS?

Plans deny appropriate admissions to rehabilitation hospitals for numerous reasons. The first, of course, is to spend less money. Others include: a lack of understanding about the differences in post-acute settings; the use of biased screening tools; and the fact that they rarely involve expert rehabilitation clinicians in the medical review process. People don't know what they don't know—so they don't realize the risk these decisions represent for patients.

OVERCOMING MANAGED CARE BARRIERS

There are several potential paths to improve the approval rate for patients who require care in a rehabilitation hospital:

- Partner with referring entities and educate them as to the unique offerings the rehabilitation hospital provides. Ensure that they understand that rehabilitation hospitals are integral to the post-acute continuum, and that planning for discharge to a rehabilitation hospital should begin at admission, and not be left to the last minute.
- Work with the referrer to provide the information managed care companies require for approval.

- Inform patients and families of their rights and appeal options and encourage referring hospitals to appeal on behalf of their patients.
- Offer to become authorized to appeal for the patient.
- Continue to appeal until you reach the medical director level. A physician-to-physician discussion, especially if it is repeated, usually helps.
- Develop relationships with administrative and medical leadership of the insurance plans, dealing with them as allies rather than enemies. Educate them as to the benefits of inpatient rehabilitation hospitals and the types of cases that require this level of care.
- Seek intervention from the state insurance commissioner, the media or elected officials when you see inappropriate denials or the possibility of patient harm.
- Be consistent in selecting appropriate patients for admission and be persistent in appealing adverse actions.

As always, it is up to us to advocate for our patients.

FEE-FOR-SERVICE (FFS) PATIENTS HAVE HIGHER IRF USE RATE, LOWER SEVERITY THAN MEDICARE ADVANTAGE (MA) PATIENTS, 2012

	FFS patients	MA patients
Use rate	1.04%	.41%
Average length of stay	12.90	13.60
Case-mix weight	1.30	1.37

Discharged home	69.4%	72.1%
Discharged home with home health	51.3%	52.1%
Discharged to skilled nursing facility	10.2%	7.9%

Note: IRF (inpatient rehabilitation facility). Use rate is calculated as the number of FFS or MA patients divided by all FFS or MA patients. Patients in the discharged home category also appear in the discharged home with home health category. Discharge destinations do not total 100 percent. Not all discharge destinations are represented herein.

Source: MedPAC analysis of Inpatient Rehabilitation Facility-Patient Assessment Instrument data from CMS. Source for the denominator for the use rates is the 2012 annual report of the Boards of Trustees of the Medicare trust funds.

When is less more?

MEETING THE UNIQUE PROSTHESIS NEEDS OF GERIATRIC AMPUTEE POPULATIONS IN A CHANGING REGULATORY ENVIRONMENT BRUCE POMERANZ, M.D.

Prosthetic devices offer individuals with upper or lower limb amputations the opportunity for greater function, independence and quality of life. Adaptation to limb loss is challenging—physically, emotionally and economically—which raises concerns about how to achieve the best possible outcomes for older individuals who may struggle without expert care, guidance and support, such as that provided by rehabilitation professionals. As the number of elderly amputees continues to grow, clinicians must remain aware of the unique demands and regulatory considerations of this population in order to give them the same prospects from treatment as their younger peers.

A VOICE FOR PATIENTS

Prostheses are a significant expense, and the elderly are highly dependent on public and private insurers in this regard. Clinicians play a vital role in helping to ensure continuity of care through appropriate documentation for Medicare and other insurance coverage. Physicians and therapists at Kessler Institute for Rehabilitation work closely with patients with prostheses to monitor their medical needs and collaborate with primary physicians, as warranted, who may not have expertise in prostheses and the documentation requirements.

Similarly, clinicians must keep pace with changes in the health care system, including new policies affecting Medicare coverage, in order to serve as advocates for older patients, who often lack the knowledge and confidence to do so for themselves. This need for advocacy became even more evident in July 2015, when the four regional Medicare contractors that operate the durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) program proposed the Local Coverage Determination (LCD): Lower Limb Prostheses (DL33787), which recommended significant

changes to Medicare coverage, coding reimbursement and documentation requirements for lower extremity prostheses. Stakeholders and patient groups heavily criticized the draft regulations for potentially limiting access to necessary care and equipment.

Among concerns expressed were that, under the proposal, K-levels—historically utilized to align prosthetic selection and coverage with a person's functional potential—would instead become a tool for denying access to appropriate prostheses and equipment. Other concerns pertained to limitations on which socket systems or liner inserts could be utilized and coverage determinations based on “the appearance of a natural gait” as opposed to actual functional mobility and potential. In response to feedback from the profession and numerous stakeholders, the Centers for Medicare & Medicaid Services (CMS) announced in November that the proposal would not be adopted at this time and that a Lower Limb Prostheses Interagency Workgroup would be convened in 2016 to revisit the issue.

ADDITIONAL BARRIERS

Beyond financial and access difficulties, geriatric amputee populations also face major challenges to prosthetic rehabilitation due to medical conditions and comorbidities (such as vascular disease), general debility and a higher incidence of neurocognitive impairment in comparison to their younger cohorts. Limitations in social support may also obstruct successful community reintegration. In order to achieve optimal functional and prosthetic outcomes, these unique factors have to be considered in the selection of devices and lifelong provision of clinical care.

It is imperative that clinicians know how best to adjust treatment to account for potential impediments. For instance, to the extent that cardiovascular disease

may be present, an elderly patient may experience diminished cardiac reserve and exercise tolerance that can make gait training and prosthetic management more physically taxing and less efficient. Neuropathy and visual deficits pose safety threats and risk of falling. The rehabilitation team should work together to implement clinical decisions and a treatment program that is optimal for each patient.

Clinicians must diligently attend to the individual issues which, taken together, result in better outcomes and fewer complications after limb loss. These include extensive prosthesis training for patients, inclusive of proper donning and doffing, management of swelling of the residual limb with strategic prosthetic sock management, techniques to avoid skin breakdown and how to prevent contractures and other musculoskeletal complications. This applies to all amputee populations but is especially important for older individuals given their high level of medical comorbidities and potential for poorer outcomes.

Ideally, clinicians should work closely with patients and families, and, as needed, insurance companies to develop an individualized rather than “one-size-fits-all” approach to care. Geriatric amputee populations may not have the ability to advocate on their own behalf, placing the onus on health care providers to use their expertise both inside and outside the treatment setting to help patients overcome hurdles.



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Contamination concerns

BY JEFFREY COLE, M.D.

CONTAMINATION, THOUGH PREVENTABLE, is unfortunately still encountered in the health care setting. While the focus of staff training and safety awareness often centers on hospital sources of infection, such as suboptimal hand-washing hygiene or the spread of bacteria from patient to patient, an additional and seemingly innocuous source also deserves attention.

In recent years, the contamination of injectable products at the manufacturing level has proved not just dangerous but also fatal to dozens of patients. By increasing awareness of the previous lapses in pharmaceutical production standards, clinicians can make better-informed decisions for the safety and quality of care of their patients. Hospital pharmacy policies, standards and sterility procedures have been in place and have been strictly enforced through institutional quality assurance and outside overseers. This same standard of production sterility is expected of major manufacturers. However, smaller and lower-volume pharmaceutical suppliers have not always received the same supervision.

UNEQUAL STANDARDS

Contamination of medications by manufacturers is problematic given that not all developers are held to the same safety standards. Large, well-known pharmaceutical producers that make name brand drugs perform the necessary research and testing to comply with the demanding requirements of the Food and Drug Administration (FDA) and other governing bodies. Smaller manufacturers, however, are not subject to the same rigorous, ongoing oversight; their products are only required to be approximately bioequivalent and dissolve at the same rate as their nongeneric counterparts.

Further, some pharmacies mix their own compounds, but this requires meticulous

sterilization and testing procedures that, until 2013, were not regularly enforced by the FDA and consequently were not always performed. US Pharmacopeia mandates that a compound be tested for pathogens. If the compound fails, the entire batch must be disposed of unless the manufacturer can show cause for retesting, such as a bad growth medium or a technician error. But for smaller producers, the economic incentive to salvage a batch is high, which could lead to dubious behavior. This is precisely what occurred in 2012, when the New England Compounding Center (NECC) was found to be distributing injectable medications for spinal procedures that were known to be contaminated with a fungus—*Exserohilum rostratum*—causing an outbreak of meningitis that led to 64 deaths and left hundreds seriously ill.¹ The company was eventually shut down after investigations by the Centers for Disease Control and Prevention (CDC), the FDA and the state health board.

MAINTAINING QUALITY CONTROL

In an otherwise healthy individual, a functioning immune system can usually fight off most bacteria and pathogens when exposure is in small doses. But injectable medications can bypass some of the body's defenses by going directly into deeper structures, allowing them to more easily take hold in much larger quantities. In the case of the NECC, many of the patients who were receiving the epidurals were older, and the injectables themselves included steroids, which suppress the immune system. These factors increased the risk of dangerous side effects and fatalities. As a result of this incident, the FDA and state agencies that license compounding pharmacies are now requiring far more stringent oversight on the mixing, distribution and testing of these products.

Although clinicians cannot control what happens outside of their hospitals, their primary defense comes in the form of only using reputable and name brand injectables. These medications are usually significantly more expensive than generic versions. The higher price may be justified, considering the potential cost of exposure to pathogens. At Kessler Institute for Rehabilitation, we strive to avoid generics and compound materials in order to achieve a higher level of certainty about the quality of medications we are giving our patients. Clinicians must remain diligent about their medication sources and avoid buying potentially inferior products from pharmacies that aren't being held to the same high standard of cleanliness and research as expected. If a clinician does suspect a compromised product has been supplied, it is important to save the vials for testing and report suspicions to the local health boards and the CDC.

In today's world of medical practice, financial austerity is the reality under which we must provide the best care possible. But it is equally important to be prudent about investigating the quality of our products.

¹ Bidgood J, Tavernise S. Pharmacy Executives Face Murder Charges in Meningitis Deaths. *The New York Times*. Dec. 17, 2014. Available at: nytimes.com/2014/12/18/us/new-england-compounding-center-steroid-meningitis-arrests.html?_r=0



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