CareManagement

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Vol. 29, No. 3 June/July 2023

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JOURNAL OF THE COMMISSION FOR CASE MANAGER CERTIFICATION, THE CASE MANAGEMENT SOCIETY OF AMERICA, & THE ACADEMY OF CERTIFIED CASE MANAGERS

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Catherine M. Mullahy

Reflection, Rejoicing, Relaxation—the 3 Rs

Our Executive Editor Cathy Mullahy has stepped in to provide our Editor-in-Chief Gary Wolfe with some needed downtime this issue. Gary will return for the August-September issue.

This Summer issue of the journal typically motivates me to encourage each of us to take a bit of time for self-care. During what continues to be very busy schedules, it is so important to stop and consider how you are feeling, make a concerted effort to plan something that is non–work-related, and provide time for reflection, rejoicing, and relaxation.

We have had a few occasions to celebrate during the last few months including Mother's Day, Nurse's Day/Month, Social Work Day, Memorial Day, and Father's Day. Added to those are the likely graduations, birthdays, anniversaries, and other days that encourage us to remember those individuals in our lives who should matter more than the work we do every day.

As I'm doing a bit of reflection about what would seem to be conflicting priorities, I wonder just how we can manage all of them, or if we can.

While there are many articles and books that provide insight and guidance on how to manage competing priorities and challenges on both the professional front and in our personal lives, most of these articles and books are not that specific to health care or drilling down even further, to case management. The question central to those in health care and often asked is, "How do we prioritize when everything is a priority?" To that question, I remind you of the saying that "When everything is a priority, nothing is."

Health care organizations remain steadfast in their mission to care for and improve the health outcomes and quality of life of our patients. Over time, as health care has evolved, the complexity of achieving that mission has increased. We no longer just take care of patients. Rather, we meet the needs of "consumers" or "customers" or "clients." We don't simply treat illness but now examine ways that we can positively affect the social determinants of health—those endless issues that can result in poor health for large populations.

We have an increased number of stakeholders to whom we are accountable, and when these are added to this evolving mission, the complexity only increases. We are left asking ourselves, "What are we targeting? Quality of care? Patient safety? Outcomes?" And what should these be? Cost? Access? Employee retention? Enhanced patient satisfaction? Many organizations are targeting all of those and a growing list of many more.

To accomplish a multitude of

During what continues to be very busy schedules, it is so important to stop and consider how you are feeling, make a concerted effort to plan something that is non–work-related, and provide time for reflection, rejoicing, and relaxation.

objectives, there is often the addition of a plethora of services, programs, and technologies. Layered one on top of one another, the result is an avalanche of competing priorities, each with its own set of initiatives and metrics. As we have come to realize, all too frequently, these are added without an appropriate assessment of what is already being done, what is no longer working, or what is no longer needed. Valuable resources are wasted, and health care professionals including case managers suffer from burnout from working to meet too many objectives simultaneously in an industry that is facing increasing labor shortages and growing attrition rates.

The answer to the prioritization problem, as one would expect, is a challenging one that begins with health care leaders.

Case management professionals are leaders, and as such, need to be part of the solution. This holds whether a case manager is serving in a department overseeing case management staff, or as the case management representative for an organization's interdepartmental team itself. In a complex, high-urgency, high-impact environment like health care, prioritization will always be a challenge. Leaders can alleviate the impact of this environment by redefining their role. Instead of "getting into the weeds" to manage daily priorities for their teams, leaders need to pull back and rebuild the fundamentals. Leaders should focus on creating an environment that promotes regulatory compliance and adheres to standards of practice and evidence-based practices. Through their leadership, a clear strategic direction, backed by clear and effective communication, enables and empowers case management teams and individual case managers to establish their priorities.

There are a few recommendations that transcend business and health care communities for managing conflicting priorities that you might want to consider:

- ***Schedule work effectively:*** One thing is worth remembering. There will always be too much to do and never enough time to get it all done. You'll need to be flexible to adapt to the changes that will occur during each project's lifecycle.
- ***Prioritize your projects and goals:*** You can't do everything at once.
- ***Eliminate low-priority tasks and people from your day:*** When dealing with conflicting priorities, pay attention to the difference between an important task and an urgent one. Do you need to be at every meeting or zoom call? Probably not.
- ***Manage your time and set boundaries.***
- ***Consider what can be delegated to others and then delegate those tasks.***
- ***Keep others informed of your progress with regular reporting.***
- ***Be prepared to negotiate deadlines.***

While I began this column thinking about taking some well-deserved time to *reflect* upon our many accomplishments, and *rejoice* about the opportunities we will have to continue to make a very important difference in the lives of those entrusted to our care, I want to conclude by encouraging you to *relax* and enjoy time with your family and friends. Walking on the beach, reading a book in your favorite summer spot, gardening, attending concerts in the park, playing with the little ones in your family, participating in a family reunion, celebrating weddings and other special occasions, or just going to a movie will all help to renew your spirits and caring hearts.

We'll be here waiting for your return and will join you as we make a difference…one patient at a time!

Wishing each of you a Happy Summer! —Catherine

Catherine M. Mullahy, RN, BS, CRRN, CCM, FCM, Executive Editor
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Advocacy: Another Name for Case Management

Nina Mottern, RN, BSN, CCM

Advocacy is a cornerstone of professional and ethical case management practice as we seek to improve the health, wellness, and autonomy of the individuals we serve. So inherent in our practice of providing the right care and treatment at the right time, advocacy might be thought of as another name for case management.

Advocacy has long been impacted by the many pressures and challenges that span the health and human services continuum. As a result, how we as case managers put advocacy into action must become more intentional. Following are 4 such challenges with information on how advocacy can guide the case management response.

- **Cultural:** When advocating for patients within diverse populations, case managers will often encounter cultural differences regarding health goals, priorities, and care choices. A family's decision about how to best provide care for an elderly loved one is often influenced as much by culture as it is by the needs of the individual. To advocate for each patient and their respective support system, it is imperative that case managers actively strive to develop cultural literacy, with particular emphasis on the populations they serve. A case manager's intentional reach for cultural literacy allows for authentic and meaningful advocacy.
- **Gender Identity:** In my role as a case manager working for my local county department of public health, I may advocate for patients whose gender identity differs from the gender assigned at birth. This requires open-mindedness and a willingness to not make assumptions, whether about a person's preferred pronouns or life choices. I am often reminded of this while testing for sexually transmitted diseases as part of a county health outreach program. Functioning in this role, I am taken to many diverse locations ranging from homeless shelters to college campuses. My patient population spans sex workers to college students. In each encounter, I am focused on the individual, how they express their gender identity, and what their needs are—from homelessness and medical care to information about safe sex.
- **Financial:** Advocacy, inevitably, brings us to the intersection of what our patients want and the reality of the resources available to them. For example, someone may want to receive a particular treatment or be treated by a particular provider; however, their insurance (or lack thereof) makes that choice impossible. Recently, I encountered a young international student who came to a testing clinic. In our conversation, it became clear that she wanted and needed mental health services for depression. When I mentioned student health services as a possible resource, she became very upset and related to me that she did not find it to be a good fit for her needs. With no insurance and no money for resources, she seemed to have very limited options. By chance, I later met a vendor at a resource event who could provide access to free mental health services available in the community. In my role as an advocate, I was able to provide this information to the young woman and encourage her to reach out for this support available at no cost to her.
- **Health Literacy:** All the information we have at our fingertips will do no good if our patients cannot understand it. Health literacy can be

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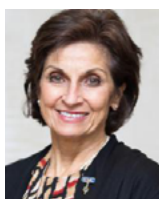

Nina Mottern, RN, BSN, CCM, *is a Commissioner with the Commission for Case Manager Certification, the first and largest nationally accredited organization certifying more than 50,000 professional case managers and disability management specialists with its CCM® and CDMS® credentials. With more than 20 years in professional case management, Nina has served a variety of care settings, including public health, geriatric care management, and the Veterans Administration.*

Coming Up: CMSA 2023 National Conference June 27–30

Colleen Morley, DNP, RN, CCM, CMAC, CMCN, ACM-RN, FCM

It's an electrifying time for the Case Management Society of America (CMSA)! Our annual conference (June 27-30 at Mandalay Bay Resort in Las Vegas) is just around the corner. If you have never been to a national CMSA conference, this is your invitation to check it out! If you have been to a conference, but not in recent years, this is your invitation to re-engage. If you come to the conference every year, we can't wait to see you and reconnect!

CMSA is excited to offer continuing education credits for conference registrants for the following: RN, ASWB, CCM & CCM Ethics, CDMS & CDMS Ethics, CRC & CRC Ethics, and CPHQ (pending approval).

Colleen Morley, DNP, RN, CCM, CMAC, CMCN, ACM-RN, FCM, *is current president of the Case Management Society of America National Board of Directors and principal of Altra Healthcare Consulting in Chicago, IL. She has held positions in acute care as director of case management at several acute care facilities and managed care entities in Illinois for over 14 years, piloting quality improvement initiatives focused on readmission reduction, care coordination through better communication, and population health management. Her current passion is in the area of improving health literacy. She is the recipient of the CMSA Foundation Practice Improvement Award (2020) and ANA Illinois Practice Improvement Award (2020) for her work in this area.*

The systems and routines we depended on for so long have disappeared. Let's identify the opportunities for innovation resulting from recent changes in health care delivery.

CMSA's 30 concurrent sessions are designed to spark conversations and innovations, and provide strategies and solutions along with practical tools and successful initiatives for professional case managers and case management systems.

Topics run the gamut of practice settings and include acute care, maternal/child health/pediatrics, mental/behavioral health, managed care/managed Medicare/managed Medicaid, ambulatory case management, older adult/geriatric care, post-acute/community care and of course, military services/DoD/Veterans Affairs dedicated programming.

Enhance your case management practice with subjects including communication techniques, value-based reimbursement, disease/condition-specific readmission prevention, transition management, technology, professional development, leadership, self-care, and legal/regulatory/ethical.

Presentations have been categorized to help you plan your educational program according to where you are in your career path.

NOVICE: New to case management practice, care coordination, and transition management culture, students, or health care professionals not familiar with case management as a specialty/profession.

INTERMEDIATE: Those with some case management practice experience and familiarity with the culture.

ADVANCED: Those who are very familiar with case management practice and culture. The individual may be in a leadership position or seeking leadership skills.

Back by popular demand! CMSA networking roundtables. Make the most of your in-person conference experience with this engaging and interactive session designed to help you make connections, expand your learning, share best practices, and have some fun! During this session, tables will be marked with a variety of topics, settings, and disciplines to help you find peers with similar interests, experiences, and challenges.

And our incredible keynote lineup is not to be missed!

- **Kai Kight,** *violinist turned composer, innovator:* "Compose Your World"
  The systems and routines we depended on for so long have disappeared. Let's identify the opportunities for innovation resulting from recent changes in health care delivery.
- **Bruce Berger, PhD,** *researcher, professor, communications expert:* "Living With Your Eyes Open: Recognizing & Addressing Self Deception"
  We know from health disparities research that sometimes we see patients (and others in our life) as objects and not people. Why does this happen,

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Advocacy: From Return-to-Work to Self-Advocacy

By Patricia Nunez, MA, CRC, CDMS, CCM

The goal of disability management is the "prevention and minimization of the human and economic impact of illness and disability" for both the employee and the employer. This is accomplished through a variety of services and solutions—all of which speak to advocacy in action.

Certified disability management specialists (CDMSs) have knowledge and expertise in workplace interventions. Primary among them are return-to-work (RTW) and stay-at-work programs to maintain the productivity of employees who are ill, injured, or have disabilities.

Years ago, many employers were reluctant to bring employees back to work or to keep them on the job unless they were "100 percent." Fortunately, this attitude has changed with regulations such as the Americans with Disabilities Act (ADA)—as well as greater recognition of the importance of maintaining the employee's connection to the workplace.

In addition, self-advocacy also encourages the employee to contribute their own ideas and creativity to the job modification process. After all, the individual knows their job better than anyone.

Increasingly, RTW and stay-at-work interventions are provided to employees who are ill, injured, or have disabilities that are work-related or that are nonoccupational in nature. As an advocate, the CDMS engages with the individual, the employer, and the health provider to facilitate a safe and timely RTW or stay-at-work plan.

These arrangements often involve job modifications, such as light duties or a reduced schedule. By utilizing their expertise, a CDMS can explore job modifications or accommodations that are reasonable and fair for the employer, while providing meaningful work that matches the employees' capabilities.

The Importance of Self-Advocacy

For the CDMS, advocacy does not end with a job modification or workplace arrangement. Interactions with the employee should also include the promotion of self-advocacy. This involves education and empowerment of the individual to help them pursue additional support and services, whether from the employer or within the community.

Consider the example of an employee who returns to work at a large company following a serious illness, such as cancer, after surgery, recovery, and chemotherapy or radiation. The person's RTW plan is facilitated by a disability manager who works for the employer, with light duties and other job modifications. Over time, the employee is able to return to their regular duties and full-time work.

However, follow-up appointments and ongoing treatment requires flexibility in scheduling and periodic changes in duties. The CDMS can coach the employee in how to articulate and request what they need, without having to disclose their entire medical history. The disability manager is there to intervene, when necessary, but the rapport built between the employee and the employer during the RTW process should allow for that communication and self-advocacy.

In addition, self-advocacy also encourages the employee to contribute their own ideas and creativity to the job modification process. After all, the individual knows their job better than anyone. An employee who is highly motivated can work collaboratively with the employer—and perhaps even with colleagues—to suggest solutions that

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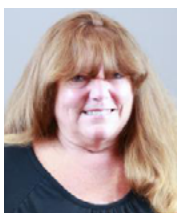

Patty Nunez, MA, CRC, CDMS, CCM, *is a Commissioner and serves as Secretary on the Executive Committee of the Commission for Case Manager Certification (CCMC), the first and largest nationally accredited organization certifying more than 50,000 professional case managers and disability management specialists. The Commission oversees the process of case manager certification with its CCM® credential and the process of disability management specialist certification with its CDMS® credential. Patty is also a director within the Claim Supply Management office of CNA, and is based in CNA's Orange County, California, location.*

OIG: Expanded FAQs

Elizabeth E. Hogue, Esq.

Beginning in March, 2023, the Office of Inspector General (OIG) of the US Department of Health and Human Services (HHS) has expanded the topics it considers for new FAQs submitted by providers as follows:

1. General questions about the Federal anti-kickback statute (AKS), prohibitions on remuneration to Medicare and beneficiaries of state health care programs, and the OIG's enforcement of these statutes
2. Questions about the general application of the AKS and prohibitions on inducements to beneficiaries to arrangements that may implicate these statutes
3. Questions about compliance considerations
4. OIG's Health Care Fraud Self-Disclosure Protocol
5. General questions about topics covered by existing FAQs; including advisory opinions, exclusions, and the OIG's whistleblower protection coordinator function

Providers should submit their questions to OIGComplianceSuggestions@oig.hhs.gov

The OIG's expansion of consideration of providers' questions in FAQs is important because providers may be able to obtain the necessary guidance without expending time and money to obtain an OIG Advisory Opinion.

In addition, the OIG has provided several FAQs that may be especially important to providers. Two of these FAQs are detailed below.

The OIG's expansion of consideration of providers' questions in FAQs is important because providers may be able to obtain the necessary guidance without expending time and money to obtain an OIG Advisory Opinion.

1. **"How does OIG differentiate between 'cash,' 'cash equivalents,' and 'in-kind' gift cards? How would OIG categorize a gift card to a big-box store? How would OIG categorize a gift card to a big-box store, the terms of which expressly limit the scope of items the consumer could purchase with such gift card (eg, the gift card could only be used to purchase fresh food items)?**

'Cash' refers to monetary payments in the form of currency. (Note that cash could be transmitted electronically, too, such as through a peer-to-peer application.) 'Cash equivalents' include items convertible to cash (such as a check) or items that can be used like cash, such as a general-purpose prepaid card such as a Visa or Mastercard gift card. Gift cards offered by large retailers or online vendors that sell a wide variety of items (eg, big-box stores) could easily be diverted from their intended purpose of converted to cash. Consequently, OIG considers such gift cards to be cash equivalents. (We note that the regulatory text of the Preventive Care Exception, found at 42 CFR Section 1003.110, uses the term 'instruments convertible to cash' not 'cash equivalents.' The phrase 'instruments convertible to cash' refers to a subset of 'cash equivalents,' which includes a broader range of remuneration. For example, OIG would consider a preloaded prepaid card to be a 'cash equivalent' but not an 'instrument convertible to cash.')"

2. **"Does remuneration exchanged between entities with common ownership implicate the Federal AKS?**

The Federal AKS is an intent-based, criminal statute that, as a general matter, prohibits payments in exchange for referrals or other Federal health care program business. Congress did not exempt from the statute's prohibitions remuneration exchanged between entities with common ownership. Consequently, such remuneration could implicate the Federal AKS. Furthermore, OIG has previously declined to provide safe harbor protection for remuneration exchanged between wholly owned entities, including parent entities and their wholly owned subsidiaries, indicating that common ownership does not eliminate the risk of improper referrals under the statute:

"…we are concerned…that integrated delivery systems, *including arrangements involving wholly owned subsidiaries* [emphasis added], may present opportunities for the payment of improper financial incentives that

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Elizabeth E. Hogue, Esquire, *is an attorney who represents health care providers. She has published 11 books, hundreds of articles, and has spoken at conferences all over the country.*

Fraud Enforcement Actions: Lessons for Providers

Elizabeth E. Hogue, Esq.

According to a recent press release, Progenity, Inc, fraudulently overbilled Medicaid and the VA by using a billing code that misrepresented tests performed. Fraud enforcers also claim that Progenity provided illegal kickbacks in the form of excessive fees to physicians, meals and happy hours for physicians and their staff members, and improper reductions or waivers of patients' coinsurance and deductible payments. The "price tag" for Progenity: $49 million!

First lesson: Fraud and abuse prohibitions apply to all federal and state health care programs, not just the Medicare program.

Enforcement action was taken against Progenity by multiple state and federal health care programs, including the VA, various state Medicaid Programs, TRICARE, and the Federal Employees Health Benefits Program. This means, for example, that companies that provide private-duty services that may be paid for, at least in part, by any federal or state health care program must comply with the federal False Claims Act and the Anti-Kickback Statute, and applicable state requirements. Many private insurers have followed the federal government's lead in terms of fraud and abuse enforcement.

Second lesson: Providers must pay physicians at fair market value for services actually rendered.

The government alleged that Progenity induced physicians to order lab tests by providing kickbacks. This claim was based on the fact that the "draw fees" that Progenity paid to physicians to draw blood for lab tests exceeded the fair market value of the services performed.

Fraud and abuse prohibitions apply to all federal and state health care programs, not just the Medicare program.

Providers must address the issue of payments at fair market value to physicians who both make referrals and provide services to them. The most effective way for many providers to meet this requirement is to pay physicians at an hourly rate at fair market value for services actually rendered. In other words, flat monthly amounts are likely inappropriate because providers run the risk of payment for services that were not rendered or payments for services at rates above fair market value.

Third lesson: Providers' gifts of nominal value to physicians cannot exceed the current federal limit of $489.00 per year.

Progenity also provided kickbacks in the form of food and alcohol to physicians and their staff at "gatherings," including happy hours and holiday parties. There was rarely any educational content provided during these events. One sales representative for Progenity, for example, spent $65,658 on meals and alcohol for physicians during a single year.

Providers may give referring physicians noncash, nonmonetary equivalent items of nominal value worth no more than $489.00 per calendar year in 2023. Monetary equivalents include gift cards and gift certificates. Providers must track what they give physicians to help ensure that they do not exceed this limit. Enforcers have repeatedly said that providers are responsible to show how much they spent.

Fourth lesson: Providers cannot routinely waive copayments and deductibles unless they make individualized determinations of financial need and/or make reasonable collection efforts.

Progenity provided kickbacks to patients in the form of waivers of coinsurance and deductible payments and had agreements with physicians to do so on a regular basis. This means that providers must have policies and procedures that govern the waiver of copayments and deductibles, including criteria that are used to determine financial need. These policies and procedures must be consistently applied.

The information above isn't new. Enforcement actions on the bases described above are "low-hanging fruit." Make it tougher for enforcers to take action by taking the steps described above! CM

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Whistleblowers Fight Back

By Elizabeth E. Hogue, Esq.

Don't shoot the proverbial messenger who brings information about possible fraud and abuse violations. There is a heavy price to be paid.

The US Department of Justice relies on whistleblowers for evidence to conduct enforcement actions. As providers certainly know, however, not all whistleblowers' allegations are correct. Regardless of the outcome, providers often expend significant resources defending whistleblowers' claims. The stigma of unfounded allegations may linger; damaging the reputations of providers.

Providers are now fighting back! In 2016, for example, individuals at Camden Clark Medical Center in West Virginia filled a whistleblower suit alleging false claims, kickbacks, and violation of the Stark law by a competing health system, Marietta Area Healthcare. The whistleblowers voluntarily dismissed the complaint prior to service on the competing health system.

Nonetheless, Marietta then sued the whistleblowers based on the common law, including claims for:

- Malicious prosecution that requires proof of malice
- Tortious interference that requires proof of improper purpose that goes beyond legitimate competition and efforts to succeed in business
- Abuse of process that requires evidence that a party willfully or maliciously misuses legal process to accomplish some purpose not intended by process

When Marietta moved for summary judgment, the Court focused on facts that show that the whistleblowers were not as interested in addressing fraud as they were in harming a competitor.

The goal of all providers should, of course, be to prevent whistleblower or qui tam lawsuits. In order to do so, providers must take seriously employees' concerns regarding possible fraudulent and abusive practices.

Most whistleblowers take their concerns to their employers first. It is only when employers ignore their concerns or, even worse, retaliate against them for raising issues in the first place, that employees turn to outside enforcers for assistance in pursuing their concerns. Whether or not the allegations of employees are valid, providers must take them seriously. Thorough, well-documented investigations are required in order to demonstrate to employees that there is no problem or that the problem has been corrected.

Private citizens may initiate so-called "whistleblower" or qui tam lawsuits to enforce prohibitions against fraud and abuse in the Medicare, Medicaid, and Medicaid Waiver Programs and other state and federal health care programs, such as VA and Tri-Care.

One of the federal statutes that allows for whistleblower actions is the False Claims Act. This Act generally prohibits providers from "knowingly" presenting or causing to be presented false or fraudulent claims for payment by the government.

To bring a qui tam action under the False Claims Act, private parties must have direct and independent knowledge of fraud by providers against whom suits are filed. Thus, current or former employees who are familiar with providers' practices may often initiate whistleblower actions under the False Claims Act. As you can imagine, employees who are ignored or retaliated against when they bring possible violations to their employers' attention by being fired, for example, are likely to initiate whistleblower suits. An example follows.

In *United States ex rel. Chorches v. American Medical Response* [No. 15-3920 (2d Cir. July 27, 2017)], Paul Fabula worked as an emergency medical technician (EMT) for American Medical Response. Fabula realized that his employer fraudulently sought reimbursement from the Medicare Program by falsely claiming that ambulance services were medically necessary when they were not. Specifically, EMTs were asked to falsify electronic Patient Care Reports (PCRs) to make it appear that services were medically necessary. Supervisors printed copies of PCRs, revised them, and directed staff members to signed the revised forms.

In one instance, Fabula provided services with another staff member who prepared the PCR. A supervisor directed the staff member to fraudulently revise the form. When the staff member refused, the supervisor directed Fabula to sign the revised form. When Fabula refused, he was fired.

And what did Fabula do? He filed a

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Building Therapeutic Relationships Telephonically

By Eric Bergman, RN, CCM

How do you connect when you can't see and barely know your patient? For telehealth professionals, this is a daily challenge and one that many of us have learned to overcome with careful listening and genuine conversation. As the COVID crisis moved more and more interaction to the virtual arena, a growing number of health care professionals had to learn how to convey genuine caring and therapeutic interaction without touch, eye contact, or, in many case, the opportunity to communicate nonverbally. There are ways to build that true connection and relationship, but it takes new skills and different perspectives.

I work as a population health case manager for a small insurance organization. I have helped to initiate and build our program, which is based on our organization's fundamental commitment to honor and care for our members as if they were our family. It was precisely this promise that drew me to join the company when I was recruited through my professional network grown by my engagement with CMSA—but that is another story for another day.

I have learned to use the power of conversation to ensure that my members feel heard and understood and to build trust and connection.

A big part of my daily job is to identify and reach out to members of the health plan who appear to need some additional support as they manage chronic illness or serious acute problems—meaning problems that are immediate, but likely to resolve. When I call, I offer our members the opportunity to engage with me to discuss and manage their issues. I provide them the insight and expertise I have gained from my years of work as a nurse to help them navigate the health care system.

The work I do is 100% telephonic and is based on building a relationship of trust with them over the course of our conversations. I am able to build these relationships by carefully listening and drawing them into conversation about themselves, their families, and their health challenges. My organization provides me with one of my most powerful tools, the mandate to devote a lot of individual time to each client. I have honed the skills of hearing in the silences and discerning the tone of voice that indicates hesitation or uncertainty, and then I make space to address and support them through that discomfort. I rigorously work to be nonjudgmental and meet our members where they are without preconceived ideas about what they should do or what they need.

I have learned to use the power of conversation to ensure that my members feel heard and understood and to build trust and connection. For example, I met John after noticing that he had a lot of claims for breathing-related issues, and a pattern of hospital stays and medical equipment claims that suggested he was in a late stage of a respiratory illness that was likely to end his life.

On my first call, I connected with John's wife who told me briefly that she and John no longer lived together, and she provided me with a new phone number for him. This was a valuable piece of information I filed away to help me understand and meet John where he was.

When I reached John, he had a hard time talking to me because each time he tried to give a lengthy explanation of his situation, he would get so winded he had to stop speaking to catch his breath. I quickly learned that he did not understand how to properly use the oxygen equipment that he had been provided when

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Veterans Affairs Polytrauma and Amputation Health Care and Comprehensive Case Management and Care Coordination

Lisa Y. Perla, PhD, RNB, CFNP, CRRN, CCM; and Patricia A. Young, MSPT, CP

Purpose

The purpose of this manuscript is to describe the background and evolution of programs supporting veterans in the Polytrauma System of Care (PSC) and Amputation System of Care (ASoC) in Veterans Affairs/Veterans Health Administration (VA/VHA) and supporting service member and veteran (SM/V) transitioning between the Department of Defense (DoD) and community health care settings. Also described is the integrated communication and care planning offered by polytrauma case managers and amputation rehabilitation coordinators.

Background

Established in 2005 to support the critical injuries seen in Operation Iraqi Freedom, Operation Enduring Freedom, and Operation New Dawn, the PSC is now a foundational service in the VA. For the past two decades, ongoing congressional mandates have called for the enhancement of rehabilitation services and the coordination of care for persons with traumatic brain injury (TBI). (Title 38 United States Code, sections 1710C–E) The recognition and request for the support of veterans with TBI requiring chronic disease management also became a priority for the VA. (Institute of Medicine 2010).

Consistent with the PSC, the ASoC provides specialized expertise for veterans with limb loss, incorporating the latest in rehabilitation management and prosthetic technology. (VHA Directive 1172.03 2018)

Introduction

The VA has a proven history of excellence in rehabilitation care and is committed to providing the best of both modern medicine and integrative therapies for combat injuries and noncombat-related incidents such as motor vehicle accidents and falls. (Longman 2012) Support for complex injuries requires integrated communication and care planning through assessment and treatment by rehabilitation specialists, specialty case management, patient and family education and training, psychosocial support, and advanced rehabilitation and prosthetic technologies. The rehabilitation requirements and clinical needs of SM/V for more than 2 decades directed the robust development of exceptional programs through the Office of Rehabilitation and Prosthetic Services in the VA. The PSC and the ASoC are two such distinguished systems demonstrating the importance of collaboration in case management and care coordination.

Polytrauma System of Care

Polytrauma programs are organized into a 4-tier system ensuring access to the appropriate level of specialized rehabilitation care at more than 110 VA medical centers across the country. Medical rehabilitation services in the PSC address the goals of recovery and community re-integration for veterans. In addition to the work done at each tier, a large portion of the work in the system includes mandatory TBI screening for post-9/11 combat veterans; those who screen positive are referred for comprehensive evaluations by specialty providers.

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The VA has a proven history of excellence in rehabilitation care and is committed to providing the best of both modern medicine and integrative therapies for combat injuries and noncombat-related incidents such as motor vehicle accidents and falls.

The PSC directs 5 Polytrauma Rehabilitation Centers (PRC) strategically co-located at medical centers near DoD Military Treatment Facilities (MTFs). A dedicated staff of specialized rehabilitation professionals and consultants are available to address polytrauma and complex associated TBI. Each of the 5 PRCs are designated Centers of Excellence (CoE) and include emerging consciousness programs, structured residential programs known as Polytrauma Transitional Rehabilitation Program (PTRP), and assistive technology labs. Additionally, the PRCs have implemented Intensive Evaluation and Treatment Programs (IETPs) to provide intensive intervention for SM/V with a history of multiple mild TBIs and complex comorbidities and with needs not met in traditional outpatient settings.

Twenty-three Polytrauma Network Sites (PNS) focus on outpatient services with inpatient beds available to address postacute and chronic complications. The PNS maintain a full complement of rehabilitation professional staff to address complex TBI and polytrauma-related symptoms and functional deficits. PNS staff provide clinical and administrative oversight of the PSC programs within their Veteran Integrated Service Network (VISN).

Within the PSC, 86 Polytrauma Support Clinic Teams (PSCT) provide and coordinate outpatient interdisciplinary rehabilitation care for SM/V typically within the catchment area of their medical facility. Most post-9/11 screening and evaluation for TBI occurs at this level within the system.

Within the system are 34 Polytrauma Points of Contact sites (PPOC) that deliver a more limited range of rehabilitation services including evaluations for TBI and polytrauma-related problems and treatments. The PPOCs refer SM/V to higher levels within the system, as needed.

- The PSC was the first clinical service that deployed a nationwide telehealth system dedicated to improving access to specialized rehabilitation and care coordination.
- The utilization of telehealth technologies has increased exponentially, particularly in the area of in-home telehealth. In 2022, 54.5% of patients treated in polytrauma clinic stop codes (Decision Support System identifiers used to specify outpatient care) had telehealth encounters, consistent with 55.3% in 2021.

Polytrauma leaders collaborate with Department of Health and Human Services' TBI Model Systems Program allowing for consistent patient outcomes, similar to or better than the community standard in rehabilitation. These outcomes reflect the outstanding rehabilitative care, prosthetic services, benefits, and adaptive modifications to the veteran's home and vehicle, helping those with severe disabilities maximize their independence and move toward opportunities in life that provide meaning. PSC collaborates with specialists in the DoD, academia, and private sector to develop and disseminate consensus guidance on optimal practices such as the *VA/DoD Clinical Practice Guidelines for the Management of Post-Acute Mild TBI and Amputations* (VA/DoD Clinical Practice Guidelines Home). PSC developed a framework for managing the long-term effects of TBI in response to recent research findings about their potential devastating consequences. Collaboration with the Chronic Effects of Neurotrauma Consortium (CENC) enabled the VA to perform multicenter research protocols in collaboration with the DoD, academic centers, and nonprofit organizations.

Amputation System of Care

Corresponding with the PSC, the ASoC incorporates a systems and teams-based approach to longitudinal care for veterans with limb loss. The Amputation System of Care (ASoC) provides specialized expertise in amputation rehabilitation incorporating the latest practices in medical rehabilitation management, rehabilitation therapies, and advances in prosthetic technology. The system facilitates patient-centered, gender-sensitive, lifelong care and coordination across the entire health continuum. (Webster et al 2020)

The ASoC is designed similarly to the PSC using a tiered approach. There are 7 Regional Amputation Centers (RACs) and 18 Polytrauma Amputation Network Sites (PANS) across the country aligning with many of the polytrauma specialty centers. These sites consist of a physician specializing in amputation care, an amputation rehabilitation coordinator (ARC), a Regional Orthotics & Prosthetics Clinical Director (RACs only), and a program support assistant. RACs and PANS provide the highest level of comprehensive care to the community of veterans living with limb loss including care and education in prevention and preparation for amputation. Additional tiers of the system include the more than 110 sites where Amputation Clinic Teams (ACT) and Amputation Points of Contact (APoC) are available to provide care for

ABBREVIATIONS

ACT	Amputation Clinic Teams
APoC	Amputation Points of Contact
ARC	Amputation Rehabilitation Coordinator
ASoC	Amputation System of Care
CENC	Collaboration with the Chronic Effects of Neurotrauma Consortium
CoE	Center of Excellence
DoD	Department of Defense
IETP	Intensive Evaluation and Treatment Program
IRCR	Individualized Rehabilitation Community Reintegration
M2PI	Mayo-Portland Participation Index
MTF	Military Treatment Facility
OPRA™	Osseoanchored Prostheses for the Rehabilitation of Amputees
PANS	Polytrauma Amputation Network Sites
PNS	Polytrauma Network Site
PPOC	Polytrauma Points of Contact Site
PRC	Polytrauma Rehabilitation Center
PSC	Polytrauma System of Care
PSCT	Polytrauma Support Clinic Team
PTRP	Polytrauma Transitional Rehabilitation Program
RACs	Regional Amputation Center
SM/V	Service member/veteran
VA	Veterans Affairs
VHA	Veterans Health Administration
VISN	Veteran Integrated Service Network

veterans living outside of the RAC and PANS catchment areas. See Appendix A for a list of legislation supporting TBI and amputee care.

VA Case Management and Care Coordination

The delivery of health care services in VA and the community can be complicated by the evolving demographics, social determinants of health, and diagnoses of veterans. The standards of practice for case managers in VA dictate provision of services to satisfy veteran health care needs while promoting the highest standards of case management resource utilization, crisis intervention, and veteran outcomes. (VHA Handbook 1110.04, 2020)

Veterans requiring case management services are assigned either a registered nurse or social worker case manager. Nurse and social worker case managers collaborate when both complex medical and psychosocial factors are identified that may adversely affect the veteran's health. A close, collaborative relationship between nurse and social worker case managers provides the most comprehensive approach to case management services. The dyad relationship between the disciplines minimizes duplication of services and unnecessary handoffs as each discipline brings their unique perspective to ensure biopsychosocial needs of a patient are met. (VHA Handbook 1110.04, 2020)

Impacting the complexity of case management within the VHA are the specialty populations for whom case managers provide services. Specialty populations are defined as those veterans who are at high risk for clinical decline or increase of resource utilization because of complex care needs and care coordination. Case management services are provided to those veterans determined to be at high risk. Programs in VA providing case management to specialty populations include veterans with polytrauma and amputation. (VHA Handbook 1110.04, 2020)

Polytrauma Case Management

Since the implementation of the PSC, polytrauma nurse and social worker case managers with specialty training in polytrauma and TBI have been pivotal members of the polytrauma team. The polytrauma case manager often serves as the single point of contact between the interdisciplinary rehabilitation team and the patient to coordinate resources supplementing VA benefits with the medical and psychosocial issues that often occur after severe injury and illness. Specialty case managers actively and continuously assess the needs of the veteran, the veteran's family, and caregivers, offering education and resources to maintain and restore the veteran's highest level of independent functioning. (VHA Handbook 1110.04, 2020) They are the point of contact for veterans and families in crisis and available to their peers nationwide.

Veterans receiving services in a PSC or with amputation also receive coordinated care through application of an Individualized Rehabilitation Community Reintegration (IRCR) plan of care. The IRCR care plan follows a comprehensive interdisciplinary team assessment and targets improvement of the physical, cognitive, vocational, scholastic, and psychosocial community reintegration of the veteran. Patient-driven goals follow the structure of the Whole Health Model, interdisciplinary, functional, and measurable by the Mayo-Portland Participation Index (M2PI). (Malec 2004) The communication, management, and data collection of the IRCR and the M2PI are the primary responsibilities of the polytrauma case manager.

- Since 2005, polytrauma case managers have supported and managed more than 1 million veterans screened for possible TBI.
- Approximately 6,000 veterans with the most complex TBI needs receive a templated community reintegration care

Nurse and social worker case managers collaborate when both complex medical and psychosocial factors are identified that may adversely affect the veteran's health.

plan provided by a small network of approximately 100 polytrauma case managers each year.

The VA Mission Act of 2018 supports veterans who seek health care in the private sector without restriction and has been an effective health care solution to the appointment challenges in the VA. (Isakson 2018) Specialty case managers from the PSC and ASoC are specifically trained in all aspects of VHA resources, military culture, and service, and they support veterans' clinical needs in the VA and the community. PSC and ASoC case managers and care coordinators promote the utilization of VA clinics, which provide a special milieu for veterans through:

- Social connection and support with peers
- A means to acknowledge the veteran's military service and sacrifice
- A connection between the veteran's military life, the community in which they live, and their clinical needs

Amputation Rehabilitation Coordinators

ARCs are the care coordinators at the RAC and PANS locations. The ARCs provide holistic rehabilitation care and coordination related to the veteran's amputation needs and focus on the prevention of secondary amputation. The role of the ARC is filled by physical therapists, occupational therapists, or prosthetists who are subject matter experts in the field of rehabilitation after amputation. These individuals are the main point of contact for veterans and their family and assist in supporting the veteran's physical and psychosocial needs through extensive education. They assist with coordination of care efforts across the continuum of care using a whole health approach throughout the lifetime of the veteran including benefits, durable medical equipment, integration in adaptive recreation and activities, peer support services, and so much more. The ASoC provides care coordination for veterans of all ages and causes of amputation.

- In fiscal year (FY) 2022 the VA system recorded more than 44,000 major limb amputations (major limb amputation defined as amputation at or above the wrist or ankle).
- In FY 22, 9,448 amputations occurred in the VA.
- Most amputations in the VA are related to disease processes (vascular/diabetes).
- 1.8 million veterans are at risk for amputation.

PSC and ASoC Specialty Programs and Education

Osseointegration

The ASoC boasts the latest treatment option in the VA system: the Osseoanchored Prostheses for the Rehabilitation of Amputees (OPRATM) Implant system. This specialty program provides training and support for the successful integration and use of advanced rehabilitation for those veterans living with transfemoral (above the knee) amputation. Assessment for this procedure is a 2-stage process led by the RAC and PANS sites performing in-person and virtual care assessments for accurate and timely referral and care coordination.

Patient Self-Directed Scheduling

Since 2018, ASoC has utilized a patient self-directed scheduling approach to improve access to veterans living with amputation. This approach allows the veteran to be scheduled into an outpatient amputation specialty clinic without the need for a consult by primary care, which facilitates timely communication and more timely scheduling in clinic.

Educational Resources for Veterans Undergoing Amputation

The Next Step: The Rehabilitation Journey After Lower Limb Amputation and *Within Reach: The Rehabilitation Journey After Upper Limb Amputation* are two resources created for the purpose of educating veterans and their family. It is through the collaboration efforts of the VA and DoD that these books were created; they can be found online at https://www.healthquality.va.gov/. They are also part of audiorecorded books offered through the National Library of Congress. In addition to the resources created through the VA and DoD, ASoC is fortunate to partner with the Amputee Coalition, an organization whose mission is "to support, educate, and advocate for the people impacted by limb loss and limb difference" (https://www.amputee-coalition.org/about-us/mission-vision/). As part of this collaboration, the Amputee Coalition provides resources to ASoC to support education of those living with amputation as well as opportunities to connect individuals through a certified peer visitor program.

Clinical Practice Guidelines

Equally important to VA clinicians and to veterans and their families are the clinical documents created through collaboration between the VA and DoD. Clinical Practice Guidelines

VHA is focusing on the future as it remains prepared to maintain capacity for specialized TBI and amputation care rehabilitation while allowing sufficient flexibility in the system to respond to potential upticks in demand for services.

(CPG) for TBI care and amputation care were created with the intention of providing a framework to evaluate, treat, and manage patients with amputation and TBI. The CPGs include a full guideline, a summary, a pocket card, and a patient summary. See Appendix B for CPG and website resources.

Whole Health

Both PSC and ASoC have adopted a whole health approach to the care of veterans with polytrauma injuries and amputation. The Whole Health Program encourages veterans to take a more active part in their health and rehabilitation by empowering them to set goals based on what is most important to them (Figure 1).

Future Concerns: Safety and Long-Term Management

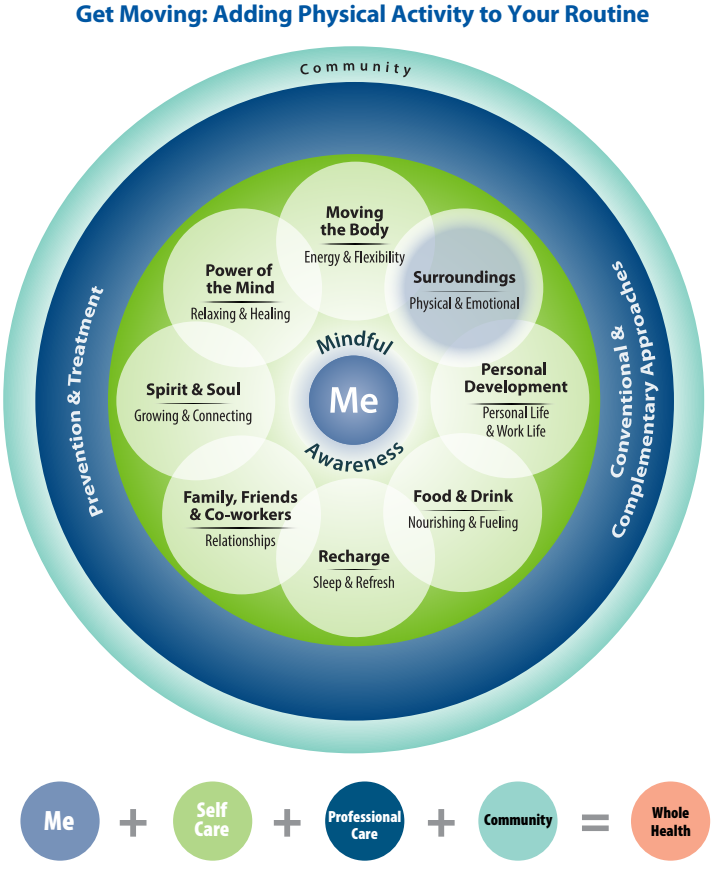
Between 2001 and 2020, the suicide rate among veterans aged 18 to 74 increased by 77% on average. During that same period of time, the suicide rate among veterans between the ages of 55 and 74 rose 58.2%. Firearm safety and suicide prevention is of particular concern in the brain injury population and is a public health priority for health care workers and for persons with TBI and their caregivers. The sequelae from brain injury can include impulsivity and mental health disorders such as anxiety and depression, leading to safety concerns. According to a 10-year study of veterans with moderate to severe TBI, findings reinforced the importance of mental health and suicide risk assessment during recovery from TBI. (Klyce et al 2022)

Surveillance for risk of suicide by VA case managers in PSC and ASoC remains an area of ongoing focus. The ASoC integrates annual follow-ups into the care of veterans with amputation to ensure comprehensive assessment of needs as they relate to care, prosthetic devices, equipment, and support. Polytrauma case managers screen veterans for suicidality during encounters per their professional scope and annually. (VHA Directive 1160.07, 2021)

Conclusions

VHA is focusing on the future as it remains prepared to maintain capacity for specialized TBI and amputation care rehabilitation while allowing sufficient flexibility in the system to respond to potential upticks in demand for services.

FIGURE 1 WHOLE HEALTH PROGRAM



Anticipated trends for the future include:

- Expanding access to the TBI and amputation experts through telehealth services
- Strengthening collaboration with community providers
- Enhancing long-term rehabilitation services for TBI-related chronic disabilities
- Enhancing lifelong rehabilitation services for veterans with amputation
- Collaborating with the Long-Term Impact of Military-related Brain Injury Consortium to advance the identification, treatment, and prevention of brain injuries CE1

APPENDIX A

Public laws and the United States Code governing rehabilitation provided by VA/VHA:

- P.L. 104-262, Veterans' Health Care Eligibility Reform Act of 1996, Section 104: Requires the VA to maintain its capacity to provide for the specialized treatment and rehabilitative needs of disabled veterans, including those with spinal cord dysfunction, amputations, blindness, and mental illness, within distinct programs dedicated to the specialized treatment of those veterans.
- P.L. 108-447, Consolidated Appropriations Act, 2005: Directs the VA to ensure that veterans with loss of limb and other very severe and lasting injuries have access to the best of both modern medicine and integrative holistic therapies for rehabilitation.
- P.L. 110-181, National Defense Authorization Act for Fiscal Year 2008, Section 1704(d): Directs the VA to collaborate with the TBI rehabilitation research community, grantees of the National Institute of Disability and Rehabilitation Research of the Department of Education, the Defense and Veterans Brain Injury Center ,and other governmental entities engaged in TBI rehabilitation.

Title 38 United States Code:

- §1710C–TBI: Plans for rehabilitation and reintegration into the community
- §1710D–TBI: Comprehensive program for long-term rehabilitation
- §1710E–TBI: Use of non-Department facilities for rehabilitation
- §7327–Centers for research, education, and clinical activities on complex multi-trauma
- §8111–Sharing of DVA and DoD health care resources
- §8153–Sharing of healthcare resources

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APPENDIX B

Public laws and the United States Code governing rehabilitation Clinical Resources

The Next Step: The Rehabilitation Journey After Lower Limb Amputation and Within Reach: The Rehabilitation Journey After Upper Limb Amputation. Version 2. 2022.

VA/DoD Clinical Practice Guideline for Rehabilitation of Individuals with Lower Limb Amputation. September 2017.

VA/DoD Clinical Practice Guideline for the Management of Upper Limb Amputation Rehabilitation. Version 2.0. March 2022.

VA/DoD Clinical Practice Guidelines for the Management and Rehabilitation of Post-Acute Mild Traumatic Brain Injury (mTBI). 2021.

Website Resources

Amputee Coalition

Rehabilitation and Prosthetic Services

Polytrauma/TBI System of Care

Traumatic Brain Injury Factsheets

Veteran Suicide Prevention

Whole Health in the VA System

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Reducing Readmissions Through Primary Care Interventions

By Sager Abu Inseir, DNP, RN, FNP-C, and Colleen Morley, DNP, RN, CCM, CMAC, CMCN, ACM-RN FCM

Introduction and Overview

The Centers for Medicare and Medicaid Services (CMS) data report that acute hospital 30-day readmissions account for over $26 billion in Medicare spending. For some chronic conditions, 30-day readmission rates were reported to be as high as 34%. (CMS 2019) The factors driving the need to reduce readmissions include cost containment, achievement of performance initiatives and penalty avoidance, and improvement of quality indicators and patient experience. CMS mandates that acute care facilities provide an active continuum of care and improved patient education to increase patient engagement and self-management of their conditions and decrease readmission rates. (CMS 2012) Readmission reduction has been in the public eye for over 10 years. Public awareness continues to rise as health care data become more transparent through quality data reporting and dedication to patient satisfaction surveys. The current literature points to a breakdown during the care transitions across settings.

The focus of this project was to adapt and evaluate an active support program providing coordinated care from the community clinic side with the goal of the readmission reduction for patients with chronic conditions. Evaluating the data available for the patient population of the clinic site, the population of hospitalized patients discharged from a single (highest utilized) facility were identified as the pilot focus group. This served both the needs of the clinic site and the acute facility because of the focus on quality initiatives and the financial implications to the facilities. The identified objectives for the program were to "provide support, resources, and increased education to discharged patients from time of inpatient discharge through the immediate 30-day post-acute period to increase self-management skills to decrease 30-day readmissions." (Morley 2019) The rationale for this project was to address the goals identified by the Institute for Health Improvement and Agency for Healthcare Research and Quality, through enablement of communication education to increase self-management skills for the patient population's health care with the aim of decreasing the avoidable readmissions.

Acute facilities face yearly penalties based on their overall readmission rates, and the risk is filtering down to the provider level, with primary care providers facing potential cost-sharing and penalties as are currently in place with some accountable care models. (CMS 2021) The Centers for Medicare and Medicaid (CMS) have charged hospitals to decrease readmissions through managing patients across the care continuum and providing better health education to patients and their caregivers to confidently master their care in the lowest level of care safely available with the ultimate goal of returning to the community. (CMS 2021)

PICOT Question

For hospitalized, established practice, engaged adult patients, aged 18 years and older (P), would the use of an evidence-based post discharge education and outreach protocol (I) compared to the immediate 8-week retrospective group who received standard follow-up protocol (C) decrease 30 day readmission rates (O) over an 8-week period (T)?

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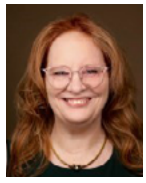

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Banerjee and colleagues (2017) report that only 52% of patients reviewed attended their post-hospitalization follow-up visit.

Desired Outcomes Summary

- Reduce hospital readmissions for the target population by 10%
- Increase attendance at 7-day post-hospitalization PCP visit by 10%

While hospital readmission was the primary desired goal and outcome, a secondary goal was identified as an increase in attendance at the post-hospitalization primary care provider follow-up appointment. Studies have demonstrated that patient attendance at follow-up appointments with their primary care provider is significantly low. Banerjee and colleagues (2017) report that only 52% of patients reviewed attended their post-hospitalization follow-up visit. Morley and Walker (2020) noted a similar trend in their review of readmitted patients, reporting that 46% of readmitted patients surveyed did not attend their scheduled follow-up appointment.

Literature Review and Synthesis of Sources

After the final assessment of the available articles, 38 studies were identified as resources for this project proposal. The study interventions were categorized into several main categories: follow-up telephone calls, services related to discharge planning interventions, enhanced patient education or teaching methods, and use of collaborative care coordination across the care continuum.

A recent survey conducted by the Center for Case Management reported that "patients want to influence their care but often do not understand their condition." (Owens & Garbe 2015) Hoyer and coauthors (2018) report "there are many reasons for readmissions, including underlying comorbidities, social issues, and poor health behaviors."

"Collaboration in health care delivery ensures patient safety, promotes self-care, and improves decision-making when providing care to patients with complex discharge needs; this process also helps patients avoid prolonged hospital stays and readmission." (Nnate et al 2021)

Hospitals frequently fail to complete or provide effective care transitions at discharge. Transitions of care activities such as comprehensive, understandable discharge instructions or efficient handoffs to the next level of care can decrease the risk of postdischarge complications, including avoidable readmissions. (Hoyer et al 2018)

Patients who lack support postdischarge are frequently readmitted due to complications. (AHRQ 2019) This proves to be an overarching theme in studies focused on readmission reduction. Kripalani and coauthors (2019) report that "lack of care coordination and continuum of care postdischarge increase the risk of readmissions to the hospital." Bamforth and co-researchers (2021) note that "these gaps place health care systems and patients at risk for growing financial burdens, higher morbidity and mortality rates, decreased quality measures, and poor patient satisfaction." Postdischarge phone call interventions have been shown to reduce readmissions and are a key part of established evidence-based readmission reduction programs. (AHRQ 2019)

Providing an integrated approach to transitional care can decrease care gaps between care settings. Active collaboration across the care continuum and patient-centered care coordination to include enhanced patient education can be completed by telephonic nursing follow-up calls after discharge. Call programs currently in place can be built on to further assess the patient's retention of knowledge and confidence of being able to self-manage their care at home. (Ryan et al 2019) Other areas of focus include ensuring a safe transition of care between providers and care settings. Issues such as improved clinician-to-clinician communication, consistent patient education messaging, overreliance on information technology systems, enhanced involvement of community-based providers, and arrangements for prompt follow-up and patient engagement to attend those post-hospitalization follow-up visits must be addressed. (Alper et al 2021) Ryan and coauthors (2019) report that "more than 31% of patients who received a discharge phone call were successfully enrolled in patient education, telephone, and in-clinic follow-up, medication reconciliation, and home visits that effectively reduced readmissions to the hospital."

Of interest for this project was a hospital-based case management program, the Post-Acute Care Coordination (PACC) Model. This model uses hospital-based staff, implementing a series of in-person and phone-based interventions designed to serve as reminders and reinforcement of discharge instructions, condition management education and gap-finding for any issues that could potentially result in a readmission. Readmission reduction for this program was noted at 65% for patients with chronic obstructive pulmonary disease and 45%

A recent survey conducted by the Center for Case Management reported that "patients want to influence their care but often do not understand their condition." (Owens & Garbe 2015)

for patients with congestive heart failure. (Morley 2019) The benchmarks available on a national level are housed with the CMS and under the Healthcare Cost and Utilization Project (HCUP) at the Agency for Healthcare Research and Quality. Current benchmarks demonstrate Medicare overall all-cause 30-day readmission rates at 17%. Additionally, acute care facilities receive quarterly PEPPER (Program for Evaluating Payment Patterns Electronic Report) reports from CMS that provide provider-specific data statistics for discharges that may be at risk for payment or penalty. For the acute care facility associated with the DNP project, the current 30-day all-cause unplanned readmission rate is 15.5%, which is in line with the national average. (CMS 2022)

Timeframes for Implementation/Re-evaluation

The timeframe for project implementation was August 1, 2022, through October 31, 2022. The intervention's success was measured based on lack of readmission within 30 days of discharge for the index admission of the target population member. Participants were recruited for 4 weeks to allow for readmission to be evaluated for the target population within the 8-week implementation period.

Project evaluation was completed by comparing pre- and postintervention data for the target population to evaluate for reduction of actual readmissions for the target population, including observation-status admissions. There can be a risk of these patients being placed in observation status so as not to "count" as a readmission. To evaluate the true impact of the intervention, observation readmissions were included in the data collection.

Intervention/Tools

The protocol for adapting the PACC program consisted of patient identification, assessment, and evaluation of social supports available to the patient with appropriate referrals made during the inpatient stay, condition management and discharge teaching, arrangement of follow-up appointments with the primary care provider appointment within 7 days of discharge, and a patient-centered follow-up program. The after-discharge program comprised a series of telephone interventions from the primary care practice to review discharge instructions and follows a scripted list of transitional factors to identify any new or ongoing gaps in care, such as transportation, medication adherence, or other social issues. These sessions also provided an opportunity for the patient to ask questions or seek clarification on issues identified or parts of the discharge plan and education provided. The first postdischarge contact occurred within 48 to 72 hours postdischarge and continued with 4 weekly scheduled calls through the 30-day post-hospitalization period. (Morley 2019)

Given the change in the location focus for this project, from hospital to primary practice, the follow-up work was managed by the practice staff, rather than hospital staff. All other parts of the PACC program were implementable for the provider practice location as written.

Challenges in Converting Setting of the Project

The sustainability of the project was dependent on the success in reducing readmissions and increasing the patient's adherence to the follow-up primary care visits. Readmission reduction activities have been the bailiwick of acute care facilities to this point. Explaining the concept, importance, and role of the primary care provider site were critical activities.

Leadership and physician provider dedication to the project was a crucial priority in promotion of acquiring new skills, building the new activities into the existing workflow, and providing on-the-spot education to answer questions related to different situations as they occurred. Change is not easy and team members can become easily frustrated and fall back into old patterns of work and behavior without the support of the practice owner and project leader.

As an adaptation of the acute facility-based PACC program, the nurse practitioner, through an already established therapeutic relationship with the patient "used the discharge process to build on the education previously given. This provided continuity of information, less confusion for the patient and the ability for the patient to ask more specific, personalized, condition-related questions." (Morley 2019)

Analysis and Recommendations

Data analysis for this project included the review and evaluation of the 30-day readmission rates for participants recruited to the project versus the facility's reported readmission rate. An additional metric of attendance at the initial primary care provider visit post-hospitalization was also evaluated. During the implementation phase of the project, 49

patients were recruited. After attrition, there were 44 patients who completed the program.

Data collected included:

- Number of patients meeting criteria who agreed to participate
- Attendance at initial postdischarge primary care provider visit
- Readmission events within 30 days from index admission
- Interventions completed during follow-up program calls

Data Analysis

The attendance at the post-hospitalization primary care provider visit was successful with 100% attendance within 7 days post-hospital discharge. Participants were given a choice between an in-person visit and a telehealth visit. Telehealth visits accounted for 46.9% or 23 visits and the traditional in-person visits, 53.01% or 26 visits (Figure 1).

FIGURE 1 PRIMARY CARE PROVIDER POSTDISCHARGE VISIT WITHIN 7 DAYS ADHERENCE

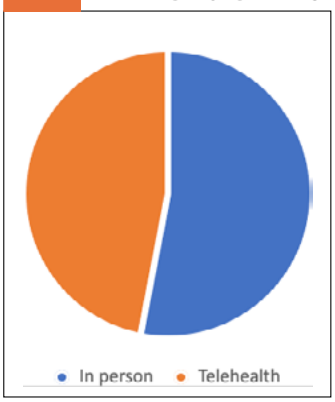
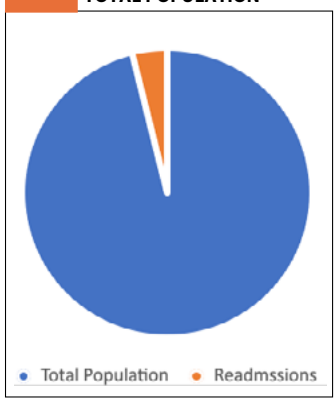


FIGURE 2 READMISSIONS VERSUS TOTAL POPULATION



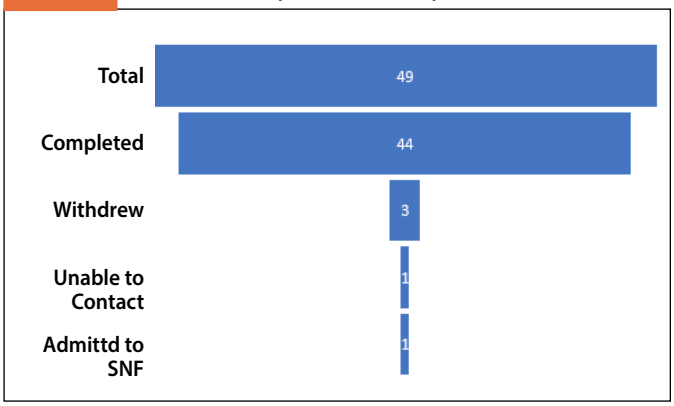
Of the 44 participants who completed the project program, there were only 2 hospital 30-day readmissions, for a percentage of 4.54% (Figure 2).

The attrition rate of the follow-up call program was noted to be 10.2% or 5 participants not completing the full 4-week follow-up call program. Three of the participants actively withdrew from the program after the first call, 1 participant was unable to be contacted after the initial call, and 1 participant was admitted to a skilled nursing facility from their home after discharge from the hospital (Figure 3).

Relationship of Results

The project results correlated directly to the project's framework to provide excellent care and contribute to financial viability for both the facility and primary care practice through reduction of 30-day readmission. Excellent care was demonstrated by the active care coordination that occurred during the follow-up calls to meet the postdischarge needs of

FIGURE 3 RECRUITMENT, COMPLETION, AND ATTRITION



the patients and the feedback received from the patients and their caregivers related to the follow-up calls.

Interventions provided for patients during the follow-up call program included coordinated transportation to specialist visits, work with community pharmacies for prescription delivery and medication management strategies, discussions about ongoing symptom management, facilitation of same-day in-person appointments to avoid an emergency department visit follow-up on durable medical equipment delivery, connection of the patient with community Senior Service programs for assistance in the home, and facilitation of placement in a skilled nursing facility directly from the community rather than readmission for placement. Each of these interventions also contributed to resolving patient issues that could have easily led to a hospital readmission if not addressed in a timely manner.

Positive takeaways from the project include the high follow-up appointment attendance, low readmission rate and low patient attrition rate. All patients were seen by the primary care provider within 7 days postdischarge as opposed to the national average of 50.2%. The ability to flex to telehealth visits was a key driver in this area of success. The lower-than-national-average readmission rate for the population (4.54% versus 15%) can be attributed to excellent patient engagement and early identification of issues or barriers through the weekly touchpoints. Patient attrition was surprisingly low, which demonstrated that patients were appropriately educated about and engaged in the program before discharge and found value in the weekly touchpoints.

The hospital facility engaged in the project has also expressed interest in the results and may be considering piloting this project at the facility's employed primary care clinic sites and recommending it to affiliated primary care providers as well. The decrease in readmissions is noteworthy, even with the number of 49 participants.

Every health care practitioner creates a plan focused on

Ryan and coauthors (2019) report that "more than 31% of patients who received a discharge phone call were successfully enrolled in patient education, telephone, and in-clinic follow-up, medication reconciliation, and home visits that effectively reduced readmissions to the hospital."

reducing readmissions and to date, the provider practice level has been absent from the conversation. This successful implementation of a readmission reduction program at the primary care provider site can help to bring the provider practice setting into the conversation where the patient seeks care more often in the primary care setting than any other and where the first level of intervention belongs.

Conclusion

Recommendations and Implications for Future Practice

Further study of this intervention should include a larger sample size and longer study period to determine if the successes noted are replicable and applicable to other practices. As the study of readmission reduction continues and facilities are involved in value-based purchasing models such as Bundled Care Payment Improvement Initiatives, where acute facilities are responsible for the longer-term management of patient care costs for up to 90 days post-hospital discharge, projects like this can be key patient management strategies. (CMS 2022).

For the last 12 years, readmission reduction has been in the scope of work for hospitals and other acute care facilities. As these types of facilities specialize in acute episodic care, usually lasting a short period of time, the Hospital Readmission Reduction Program under CMS has yielded minimal results in reducing all-cause hospital readmissions. Hospitals have been working tirelessly to institute programs to close care gaps once the patient leaves the hospital that have short-lived success. Since the focus of the issue is on patient education and ensuring a patient can be successful post-hospital discharge, it is time to shift the work of readmission avoidance into the community and primary care practices. Primary care practices have established therapeutic relationships with their patients, can be accessed more easily, frequently, and at lower cost than hospital level care, and are focused on prevention, wellness, and maintaining the patient in their chosen environment. The new flexibility that telehealth services give the primary care provider only serves to enhance this relationship, making it patient-centered and convenient. Research does note that interventions started in the hospital/acute facility and transitioned into the community level are more successful than interventions that are purely based in either one or the other.

While the evaluation of the project's results was found to be "not statistically significant," the target population did not experience a substantial number of readmissions and, when compared to national averages, demonstrated meaningful readmission reduction. The successful adaptation of this project from acute facility focus to primary care setting demonstrates that enhanced patient engagement touchpoints and interventions can help to reduce readmissions by leveraging the established therapeutic relationship and connection between the patient and their primary care provider. CE II

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CE3 Approved for 1 hour of CCM, CDMS, and nursing education credit
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Knowledge to Action…Driving Change Through Research Utilization

By Melanie Prince, MSN, BSN, RN, NE-BC, CCM, FCM, FAAN

Three reflections inspired this article on research utilization. First, I have reviewed more than 100 research articles in the past 12 months, and the plethora of rigorous studies in health care, public health, and clinical medicine is outstanding. Second, the continued interest in the influences of social determinants of health (SDOH) on individuals' ability to achieve optimal health is disseminating throughout academia, clinical practices, medical societies, and governmental agencies. For example, the Centers for Medicare & Medicaid Services (CMS), published the SDOH-related Z codes (Z55-Z65) as the ICD-10-CM encounter reason codes used to document SDOH data, such as housing, transportation, food insecurity, etc. (CMS 2021) The American Hospital Association (AHA) provides guidance on procedures for the medical team to collect data and document social needs of patient populations and how these nonmedical factors may influence individual health status. (AHA 2022) And third, the Case Management Society of America (CMSA) has championed the theme of case managers "Driving Change," and one of the best ways to drive change is through the utilization of evidenced-based research. (CMSA 2023)

There are different terms used to describe how one can take the results of a rigorous study and replicate the design or procedures in the actual practice setting. Curtis and colleagues (2017) found 6 terms/phrases to describe the activity of translating research into practice: *research utilization, research dissemination, knowledge diffusion, knowledge uptake, knowledge translation,* and my favorite, *knowledge-to-action.* Some studies may be generalized to settings where the population, environment, and other criteria are consistent with the research parameters. But many are not generalizable and clinicians may be hesitant to use research that cannot be replicated. However, the transfer of knowledge derived from study results should be embraced as a way to improve practice. It is possible to use 1 or 2 aspects of a study's outcomes to design a new program, revise an administrative procedure, or initiate a process improvement. The key is to implement a change in a methodical, measurable fashion.

There are streamlined frameworks a clinician can use when implementing a change. One popular methodology for process improvement is the Plan, Do, Check, Act (PDCA) cycle originally developed by Walter A. Shewhart and refined by W. Edwards Deming in the 1950s. (Swamidass 2000). This cycle has withstood the test of time as a way to drive change through process improvement. The PDCA cycle is as follows:

P=Plan stage where the clinician would study the problem in context, collect data, and plan the change initiative

D=Do stage is when the clinician implements the change as a trial or alpha test. For example, this change may be a new process, revised program, or streamlined procedures

C = Check stage requires the clinician to assess if the change is working and identify any concerns or new opportunities that should be incorporated

A = Act stage, which is the implementation of the conclusionary plan

PDCA is a continuous methodology that does not require an expert level of research design acumen. The PDCA cycle is straightforward and streamlined, which is why this methodology is popular in various industries such as manufacturing, education, and health care.

What is a practical example of how a clinical team can use the results of a research study? Consider a study by Kulie and co-researchers (2021) titled, "A health-related social needs referral program for Medicaid beneficiaries treated in an

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Curtis and colleagues (2017) found 6 terms/phrases to describe the activity of translating research into practice: *research utilization, research dissemination, knowledge diffusion, knowledge uptake, knowledge translation,* and my favorite, *knowledge-to-action.*

emergency department (ED)." This subject matter is squarely in the wheelhouse of case managers who advocate for the assessment of SDOH as the context for eliminating barriers in the continuity of care. The researchers conducted an SDOH survey on 505 Medicaid beneficiaries before their discharge from the ED, and 85% received a health-related social need referral, primarily for housing, medical issues, and food insecurity. The social needs identified spanned the SDOH domains and included referrals to agencies for medical, food, housing, transportation, behavioral health, wellness, legal, and job training. However, the agency referrals were passive, and unfortunately, less than 17% of patients received the intended assistance from the agencies. The researchers noted that other studies reported up to 25% success rates with patient-agency referrals when there was active intervention such as patient navigation.

Although this study has limitations, the results are detailed enough to inspire a new process or PDCA study at an acute care facility. Schon (1987) wrote about reflective transfer, which means considering the conditions under which the original study was done and analogizing the results to other places when conditions are "similar enough." The case management 6-step process is a standardized intervention that may be implemented in an ED, using the same methodology of Kulie and co-researchers in their 2021 study. For example, the case management supervisor or medical director can enroll Medicaid beneficiaries into the SDOH referral program, administer the survey, analyze the results, and assign case managers to the most at-risk patients. The case management process would be an active intervention rather than the passive referral intervention used in the original study. The AHA advocates for "employing a standardized approach to screening for, documenting and coding social needs as a way for hospitals to" (AHA 2023):

- Track the social needs that impact their patients, allowing for personalized care that addresses patients' medical and nonmedical needs
- Aggregate data across patients to determine how to focus a social determinants strategy (use of the research survey tool to guide agency referrals)
- Identify population health trends and guide community partnerships (based on your unique geographical location)

The case management supervisor and ED medical director can partner as co-leaders and the health care team can use PDCA to organize the targeted efforts for the Medicaid beneficiary cohort of ED patients. The administrative personnel can support the PDCA efforts with collecting and tracking the PDCA results. This example is feasible when there is a collaborative team approach to a methodology that has the potential for improving the lives of patients, engaging the community, and reducing the costs of emergency medical care. It is important to identify a defined timeframe for the PDCA process improvement. Plan to convey the results to as many stakeholders as possible and celebrate wins with staff recognition.

LEAN in Health Care

In addition to the PDCA method, another way to initiate process-improvement activities is to incorporate the principles of LEAN. LEAN is a quality improvement philosophy originating from the Toyota Motor Company in Japan where continuous improvement was built into the manufacturing processes. Toussaint and Berry (2013) wrote an excellent article where they capture several examples of how LEAN principles were used for process improvement in health care. They defined LEAN in health care as "an organization's cultural commitment to applying the scientific method to designing, performing, and continuously improving the work delivered by teams of people, leading to measurably better value for patients and other stakeholders." The article includes templates to illustrate how LEAN principles are incorporated into quality improvement within health care settings. A contrasting opinion by another group of researchers provides additional context for LEAN in health care. Radnor and colleagues (2012) also studied multiple examples of LEAN implementation as a continuous process-improvement strategy in health care, but found that LEAN initiatives were fragmented and not adopted as an institutional improvement within organizations at large. While they advocated for LEAN methodology as a process-improvement tool, the authors acknowledged that institutional barriers hamper system-wide implementation. Nevertheless, LEAN is another example of how case managers can use evidenced-based principles to advance process improvements within the practice of case management and supporting systems. Radnor

TABLE 1 LEAN WASTE EXAMPLES IN HEALTH CARE

1. Transportation	• Staff walking to the other end of a ward to pick up notes • Central equipment stores for commonly used items instead of locating items where they are used
2. Inventory	• Excess stock in storerooms that is not being used • Patients waiting to be discharged • Waiting lists
3. Motion	• Unnecessary staff movement looking for paperwork • Not having basic equipment in every examination room
4. Waiting (Delay) for:	• Waiting for patients theater staff results, prescriptions, and medicines • -Waiting for doctors to discharge patients
5. Overprocessing	• Requesting unnecessary tests from pathology • Keeping investigation slots "just in case"
6. OverProcessing	• Duplication of information • Asking for patients' details several times
7. Defects Correction	• Readmission because of failed discharge education/information • Repeating tests because correct information was not provided

Adapted from Radnor Z, Holweg M, Waring J. Lean in healthcare: the unfilled promise? *Soc Sci Med.* 2012;74(3):364-371.

and colleagues (2012) highlighted the central theme of LEAN as driving efficiencies through the elimination of "waste" or "non–value added" steps in a process. Table 1 is a depiction of 7 types of waste that may be addressed in a LEAN process-improvement initiative.

LEAN is customer focused, which makes it relatable to clinical teams as they drive process-improvement initiatives that are patient/client focused. NEJM Catalyst (2018) advocated for deploying LEAN in health care as a way for organizations to improve patient satisfaction as decisions and processes become patient focused, especially as hospitals strive for value-based health care. Using examples from Table 1, a case management or multidisciplinary team can consider some of the process challenges inherent in providing care for complex or complicated patient/client cases. The NEJM Catalyst described some of the waste examples in more detail, and 2 of them are notable representations of a "day in the life of a case manager." The two LEAN waste examples, according to the NEJM Catalyst article are:

1. **Eradicate Defects to Improve Quality of Care and Increase Reimbursement**: Process or system failures, medical mistakes, and misdiagnosis are examples of defect waste in health care. Healthcare-acquired conditions such as blood clots and infections, medication or surgical errors, avoidable readmissions, preventable allergic reactions, and incomplete or erroneous medical records all illustrate defect waste in health care. As payers move toward pay for performance models that reward/penalize outcomes, organizations can leverage lean principles to mobilize every employee to eradicate defect waste and improve quality to positively impact the bottom line and, most importantly, to avoid mistakes.
2. **Remove Waste from Overprocessing:** Overprocessing occurs when unnecessary work goes into treating patients. Needless tests, filling out different forms with the same information, and performing data entry in more than 1 system are examples. When time, effort, and resources do not add to the quality of care or improve patient outcomes, [they] have the potential to be changed or eliminated through lean analysis. By viewing all processes through the lens of lean health care, staff can help identify repetitive, redundant, or less-than-valuable processes to save time and money.

Now, review the Radnor table and the 2 NEJM Catalyst examples, and then consider the following case study.

Case Study

Mr R suffered a severe stroke resulting in mobility and speech deficits. After 8 days in the hospital, the plan was to transfer Mr R to an acute rehabilitation facility for continued therapies. Several missteps occurred. The case management staffing changed as part of the routine work schedule, and the new team was not aware of the original team's transfer plan. The patient did not appear to comprehend the plan, and the new hospitalist was unwilling to write new/revised orders for transfer. The hospital was located in an area that had limited availability for rehabilitation beds. The original case manager had given the facility a heads-up about a likely transfer, but nothing was documented. When the new team made the second inquiry, there were no beds available. The patient's family was not cooperative about the transfer because they did not understand why their father was moving to another facility when he should remain in the hospital to receive the services as an inpatient. There was family discord, health care team confusion, and an increasingly depressed patient. By the time Mr R was ready for discharge, there were no beds available and his avoidable inpatient stay was extended.

The case management team collaborated with the acute rehabilitation admissions team to map out the process of

The researchers noted that other studies reported up to 25% success rates with patient-agency referrals when there was active intervention such as patient navigation.

referrals and transfers between inpatient and acute rehabilitation. They discovered steps that were redundant (waste), actions that complicated the process, gaps in communication of pertinent information, and lack of patient/family involvement. The team isolated each challenge and designed new procedures to improve steps within the overall transfer process. One of the outcomes was the development of a transfer protocol that included timelines, milestones, and gates to drive efficient implementation of the transfer protocol. The protocol included validation of patient/family understanding of and involvement in the transfer process.

The transfer process mapping identified 3 of the 7 LEAN wastes: transportation, waiting/delays, and defects correction. The team used these principles to guide the redesign steps in the overall transfer process. The new transfer protocol was sustainable because both end-users cooperated in the design of the improved process. To Radnor's (2012) points about "isolated process improvements," the transfer protocol does not represent an institutional change. However, a LEAN mindset to address other process inefficiencies may lead to a change in organizational culture around continuous process improvement. It is okay to start small or to address 1 problem at a time. They key is to champion process-improvement methodology based on examples from the research literature.

Similar to PDCA, health care leaders must advocate for research utilization. When feasible, consider employing a research coach or consultant to champion research replication or process improvements using LEAN in health care. Organization recognition via staff meetings, infographics, personnel bonuses, or merit awards are excellent ways to institutionalize the concepts of research utilization and continuous process improvements. The process-improvement methodology and results can also be submitted for publication in professional journals such as this one. Also, the Case Management Society of America (CMSA) Foundation offers grants and research awards for clinicians who conduct research, display process improvements, or demonstrate research utilization practices. These are examples of award recipients and real change occurring within various health care settings:

2022 CMSA FOUNDATION AWARD RECIPIENT

- **Case Management Practice Improvement Award:** Kaiser Permanente of Washington for their program "Readmission Prevention of Patient Discharging with COVID"

2020 CMSA FOUNDATION AWARD RECIPIENTS

- **Case Management Practice Improvement Award #1:** West Suburban Medical Center for their program "Health Confidence & Simulation: A Novel Approach to Patient Education to Improve Patient Engagement & Reduce Readmissions"
- **Case Management Practice Improvement Award #2:** Anthem, Inc for their program "High Outreach to Promote Engagement (H.O.P.E)"

2019 CMSA FOUNDATION AWARD RECIPIENTS

- **Case Management Practice Improvement Award:** Coordinated Behavioral Care for their Program, "Pathway Home"
- **Case Management Research Award:** Kelson Zehr for his project "Case Study: Triad Case Management Model Applying Human Performance Technology"

More information about CMSA Foundation awards can be found at https://www.cmsafoundation.org/awards.

In conclusion, one need not be an expert in research, statistics, or program evaluation. Research articles are written in a way that makes replicating an aspect of a study or developing a new process based on a study feasible. The research provides a starting point for addressing challenges within an often-complex health care delivery system. Research studies can inspire multidisciplinary projects that use straightforward methodology to implement change. The Plan, Do, Check, Act methodology is an easy way to capture process improvements that are likely occurring every day as case managers address multi-ystem challenges. LEAN methodology in health care requires a little more time commitment, but the gains from understanding all aspects of an end-to-end process via process mapping provides invaluable insight into areas of inefficiencies, redundancies, gaps, and waste. The key is to formulate a continuous process-improvement mindset in which the challenge, changes, and outcomes are documented. After documentation, the next steps are to recognize the successes with staff recognition, journal publications, and award submissions. Finally, organizations can invest in coaches or consultants with expertise in continuous process improvement or LEAN in Healthcare certifications to jumpstart research utilization initiatives. This investment would go a long way toward promoting an evidenced-based

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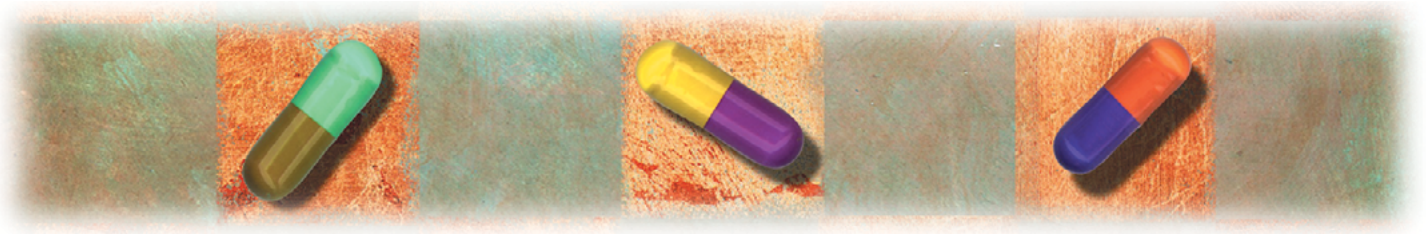
PharmaFacts for Case Managers



QALSODY (tofersen) injection, for intrathecal use

INDICATIONS AND USAGE

QALSODY is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene. This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain (NfL) observed in patients treated with QALSODY. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

DOSAGE AND ADMINISTRATION

Recommended Dosage

Administer QALSODY intrathecally using a lumbar puncture by, or under the direction of, health care professionals experienced in performing lumbar punctures.

The recommended dosage is 100 mg (15 mL) of QALSODY per administration.

Initiate QALSODY treatment with three (3) loading doses administered at 14-day intervals. Administer a maintenance dose every 28 days thereafter.

Missed Dose

If the second loading dose is missed, administer QALSODY as soon as possible, and administer the third loading dose 14 days later.

If the third loading dose or a maintenance dose is missed, administer QALSODY as soon as possible, and administer the next dose 28 days later.

DOSAGE FORMS AND STRENGTHS

Injection: 100 mg/15 mL (6.7 mg/mL) as a clear and colorless to slightly yellow solution in a single-dose vial.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Myelitis and/or Radiculitis

Serious adverse reactions of myelitis and radiculitis have been reported in patients treated with QALSODY. Six patients treated with QALSODY experienced myelitis or radiculitis in the clinical studies. Two patients discontinued treatment with QALSODY and required symptomatic management with full resolution of symptoms. In the remaining 4 patients, symptoms resolved without discontinuation of QALSODY. If symptoms consistent with myelitis or radiculitis develop, diagnostic workup and treatment should be initiated according to the standard of care. Management may require interruption or discontinuation of QALSODY.

Papilledema and Elevated Intracranial Pressure

Serious adverse reactions of papilledema and elevated intracranial pressure have been reported in patients treated with QALSODY. Four patients developed elevated intracranial pressure and/or papilledema. All patients received standard of care treatment with resolution of symptoms, and no events led to discontinuation of QALSODY. If symptoms consistent with papilledema or elevated intracranial pressure develop, diagnostic workup and treatment should be initiated according to the standard of care.

Aseptic Meningitis

Serious adverse reactions of aseptic meningitis (also called chemical meningitis or drug-induced aseptic meningitis) have been reported in patients treated with QALSODY. One patient experienced a serious adverse reaction of chemical meningitis, which led to discontinuation of QALSODY. One patient experienced a serious adverse reaction of aseptic meningitis, which did not lead to discontinuation of QALSODY. In addition, nonserious adverse drug reactions of increased CSF white blood cells, and increased CSF protein level have also been reported with QALSODY. If symptoms consistent with aseptic meningitis develop, diagnostic workup and treatment should be initiated according to the standard of care.

ADVERSE REACTIONS

The following clinically significant adverse reactions are discussed elsewhere in the labeling:

- Myelitis and/or Radiculitis
- Papilledema and Elevated Intracranial Pressure
- Aseptic Meningitis

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of QALSODY cannot be directly compared to rates in clinical trials of other drugs and may not reflect the rates observed in practice.

The safety of QALSODY 100 mg was evaluated in 147 patients with SOD1-ALS. The median patient exposure was 119.4 weeks (range, 4-212 weeks). QALSODY was evaluated in the placebo-controlled Study 1 and in the open label extension Study 2. In Study 1 Part C, approximately 43% were female; 57% were male; 64% were White and 8% were Asian. The mean age at entry in Study 1 Part C was 49.8 years (range, 23–78 years).

The most common adverse reactions (≥ 10% of patients treated with QALSODY and greater than placebo) were pain, fatigue, arthralgia, increased CSF white blood cells, and myalgia. Table 1 shows the common adverse reactions that occurred in at least 5% of patients treated with QALSODY and at a 5% or higher frequency than placebo.

TABLE 1 ADVERSE DRUG REACTIONS THAT OCCURRED IN AT LEAST 5% OF PATIENTS TREATED WITH QALSODY AND AT >5% HIGHER FREQUENCY THAN PLACEBO

	Study 1 Part C	
Adverse Reaction	QALSODY 100 mg (n = 72) %	Placebo (n = 36) %
Pain	42	22
Fatigue	17	6
Arthralgia	14	6
Increased CSF white blood cells	14	0
Myalgia	14	6
Increased CSF protein level	8	3
Musculoskeletal stiffness	6	0
Neuralgia	6	0

Less Common Adverse Reactions

Serious adverse reactions of myelitis and radiculitis; papilledema and elevated intracranial pressure; and aseptic meningitis have occurred in patients treated with QALSODY.

In the long-term extension study, nonserious adverse reactions of pyrexia have occurred with repeat administration of QALSODY.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no adequate data on developmental risks associated with the use of QALSODY in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. The background risk of major birth defects and miscarriage for the indicated population is unknown.

Lactation

Risk Summary

There are no data on the presence of tofersen or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. Tofersen was detected in the milk of lactating mice following subcutaneous administration. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for QALSODY and any potential adverse effects on the breastfed infant from QALSODY or from the underlying maternal condition.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

A total of 13.5% (22/162) of patients were 65 years of age and older and 1.2% (2/162) of patients were 75 years of age and older at initiation of treatment in clinical studies for ALS in patients who have a mutation in the superoxide dismutase 1 (SOD1) gene. No overall differences in safety or effectiveness were observed between these patients and younger patients, but a greater sensitivity of some older individuals cannot be ruled out. There is no evidence for special dosage considerations based on age when QALSODY is administered.

CLINICAL STUDIES

The efficacy of QALSODY was assessed in a 28-week randomized, double-blind, placebo-controlled clinical study in patients 23 to 78 years of age with weakness attributable to ALS and a SOD1 mutation confirmed by a central laboratory (Study 1 Part C, NCT02623699). One hundred eight (108) patients were randomized 2:1 to receive treatment with either QALSODY 100 mg (n = 72) or placebo (n = 36) for 24 weeks (3 loading doses followed by 5 maintenance doses). Concomitant riluzole and/or edaravone use was permitted for patients.

The prespecified primary analysis population (n = 60, modified intent to treat [mITT]) had a slow vital capacity (SVC) ≥ 65% of predicted value and met prognostic enrichment criteria for rapid disease progression, defined based on their preran-

domization ALS Functional Rating Scale–Revised (ALSFRS-R) decline slope and SOD1 mutation type.

The non-mITT population (n = 48) had a slow vital capacity (SVC) ≥ 50% of predicted value and did not meet the enrichment criteria for rapid disease progression.

Baseline disease characteristics in the overall intent-to-treat (ITT) population (combined mITT and non-mITT population) were generally similar in patients treated with QALSODY and patients who received placebo, with slightly shorter time from symptom onset and higher plasma NfL at baseline in the QALSODY group. At baseline, 62% of patients were taking riluzole, and 8% of patients were taking edaravone. Mean baseline ALSFRS-R score was 36.9 (5.9) in the QALSODY treatment group and 37.3 (5.8) in the placebo group. Median time from symptom onset was 11.4 months in the QALSODY treatment group and 14.6 months in the placebo group.

The primary efficacy analysis was the change from baseline to Week 28 in the ALSFRS-R total score in the mITT population, analyzed using the joint rank test to account for mortality in conjunction with multiple imputation (MI) to account for missing data for withdrawals other than death. Patients treated with QALSODY experienced less decline from baseline in the ALSFRS-R compared to placebo, but the results were not statistically significant (QALSODY-placebo adjusted mean difference [95% CI]: 1.2 [-3.2, 5.5]). Other clinical secondary outcomes also did not reach statistical significance.

Secondary endpoints of change from baseline at Week 28 in plasma NfL and CSF SOD1 protein were nominally statistically significant (see below). NfL reduction was consistently observed for all subgroups based on sex, disease duration since symptom onset, site of onset, and riluzole/edaravone use. (Table 2)

After completion of Study 1, patients had the option to enroll in an open-label extension study. At an interim analysis at 52 weeks, reductions in NfL were seen in patients previously receiving placebo who initiated QALSODY in the open-label extension study, similar to the reductions seen in patients treated with QALSODY in Study 1. Earlier initiation of QALSODY compared to placebo/delayed initiation of QALSODY was associated with trends for reduction in decline on ALSFRS-R, SVC percent-predicted, and hand-held dynamometry (HHD) megascore that were not statistically significant. Through all open-label follow-up at the time of the interim analysis, earlier initiation of QALSODY was also associated with a trend towards reduction of the risk of death or permanent ventilation, although it was not statistically significant. These exploratory analyses should be interpreted with caution given the limitations of data collected outside of a controlled study, which may be subject to confounding.

TABLE 2 BIOMARKER RESULTS OF QALSODY IN STUDY 1 PART C AT WEEK 28

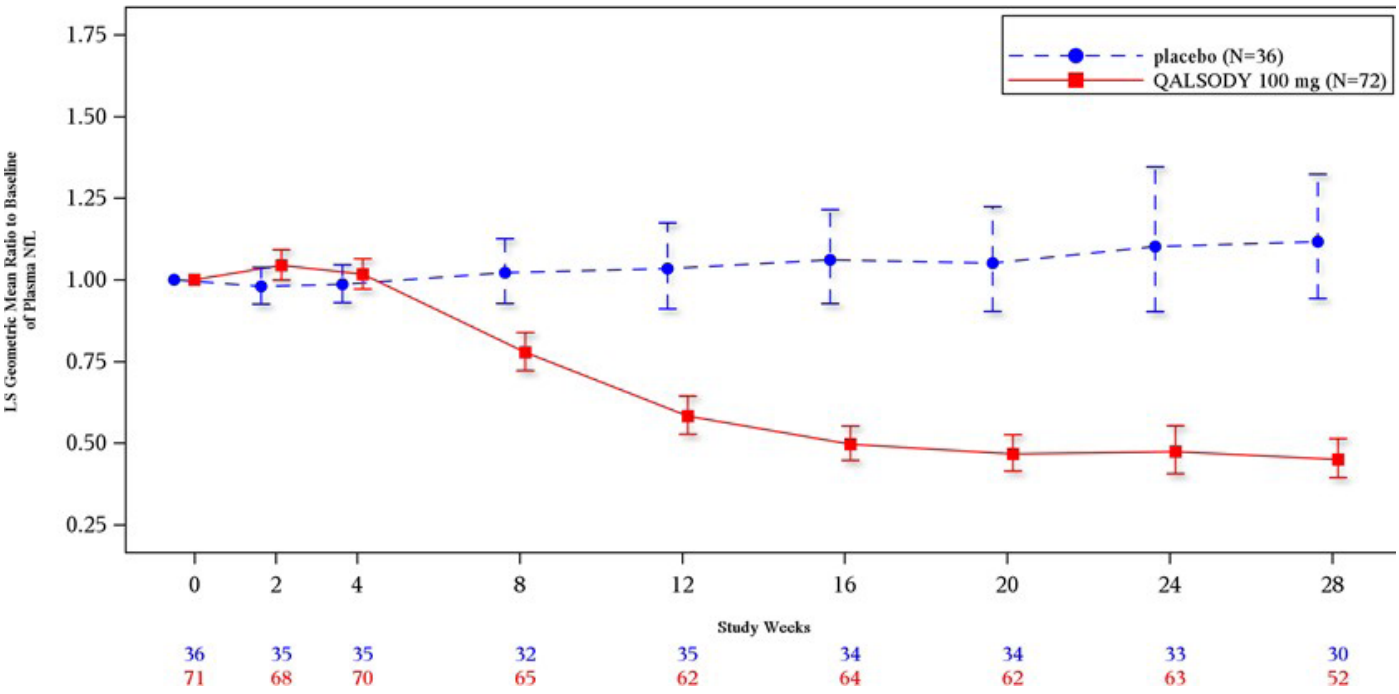
Biomarker Endpoints	QALSODY	Placebo
Plasma NfL		
ITT population	N=72	N=36
Adjusted geometric mean ratio to baseline	0.45	1.12
QALSODY to placebo difference in geometric mean ratio (95% CI	0.40 (0.33, 0.49)	
Nominal p-value (ANCOVA+MI)	<0.0001	
mITT population	N=39	N=21
Adjusted geometric mean ratio to baseline	0.40	1.20
QALSODY to placebo difference in geometric mean ratio (95% CI)	0.33 (0.25, 0.45)	
Nominal p-value (ANCOVA+MI)	<0.0001	
CSF SOD1 Protein		
ITT population	N=72	N=36
Adjusted geometric mean ratio to baseline	0.65	0.98
QALSODY to placebo difference in geometric mean ratio (95% CI)	0.66 (0.57, 0.77)	
Nominal p-value (ANCOVA+MI)	<0.0001	
mITT population	N=39	N=21
Adjusted geometric mean ratio to baseline	0.71	1.16
QALSODY to placebo difference in geometric mean ratio (95% CI)	0.62 (0.49, 0.78)	
Nominal p-value (ANCOVA+MI)	<0.0001	

Note 1: N is the number of patients with baseline value.

Note 2: MI was used for missing data. Model included treatment, use of riluzole or edaravone, relevant baseline score and post- baseline values (natural log transformed data). Separate models for mITT and nonmITT were used and combined for ITT analyses.

Note 3: Adjusted geometric mean ratios to baseline, treatment differences in adjusted geometric mean ratios to baseline and corresponding 95% CIs and nominal p-values were obtained from the ANCOVA model for change from baseline including treatment as a fixed effect and adjusting for the following covariates: baseline disease duration since symptom onset, relevant baseline score, and use of riluzole or edaravone. The analysis was based on natural log transformed data.

TABLE 2 **PLASMA NFL ADJUSTED GEOMETRIC MEAN RATIO TO BASELINE VALUES IN STUDY 1 PART C BY STUDY WEEK FOR THE ITT POPULATION**



HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

QALSODY injection is a sterile, clear and colorless to slightly yellow solution supplied as 100 mg/15 mL (6.7 mg/mL) solution in a single-dose glass vial free of preservatives.

Storage and Handling

Store refrigerated between 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze.

If no refrigeration is available, QALSODY may be stored in its original carton, protected from light at or below 30°C (86°F) for up to 14 days.

If removed from the original carton, unopened vials of QALSODY can be removed from and returned to the refrigerator, if necessary, for not more than 6 hours per day at or below 30°C (86°F) for a maximum of 6 days (36 hours).

PATIENT COUNSELING INFORMATION

Myelitis and/or Radiculitis

Inform patients and caregivers that QALSODY could cause myelitis and radiculitis. Instruct patients and caregivers to contact their healthcare provider if symptoms consistent with these adverse reactions develop.

Papilledema and Elevated Intracranial Pressure

Inform patients and caregivers that QALSODY could cause papilledema and elevated intracranial pressure. Instruct patients and caregivers to contact their healthcare provider if symptoms consistent with these adverse reactions develop.

Aseptic Meningitis

Inform patients and caregivers that QALSODY could cause aseptic meningitis. Instruct patients and caregivers to contact their healthcare provider if symptoms consistent with meningitis develop.

For full prescribing information, see Product Insert.

QALSODY is manufactured by Biogen MA, Inc.

Other Drugs Recently Approved

Elfabrio (egunigalsidase alfa–iwix) is a hydrolytic lysosomal neutral glycosphingolipid-specific enzyme indicated for the treatment of adults with confirmed Fabry disease manufactured by Protaix BioTherapeutics, Inc. Fabry disease (also known as alpha-galactosidase-A deficiency) is an inherited neurologic disorder that occurs when the enzyme alpha-galactosidase-A cannot efficiently break down fatty materials known as lipids into smaller components that provide energy to the body. The mutated gene allows lipids to build up to harmful levels in the body's autonomic nervous system (the part of the nervous system

continues on page 37

LitScan for Case Managers

LitScan for Case Managers reviews medical literature and reports abstracts that are of particular interest to case managers in an easy-to-read format. Each abstract includes information to locate the full-text article if there is an interest. This member benefit is designed to assist case managers in keeping current with clinical breakthroughs in a time-effective manner.

HIV Med. 2023 May 4. doi: 10.1111/hiv.13498. Online ahead of print.

Resistance rates among antiretroviral regimens in pregnant people living with HIV

Maria Isabel Fragoso da Silveira Gouvêa MIF, de Lourdes Benamor Teixeira M, Fuller T, et al.

OBJECTIVES**:** To update nucleoside reverse transcriptase inhibitor (NRTI), nonnucleoside reverse transcriptase inhibitor (NNRTI), and protease inhibitor (PI) resistance rates and describe the frequency of HIV subtypes in a cohort of pregnant people living with HIV (PPLH) at a national Prevention of Mother-To-Child HIV Transmission (PMTCT) center.

METHODS**:** We evaluated genotypic resistance among PPLH during prenatal care who were antiretroviral therapy-naïve or experienced. We determined mutations by the Surveillance of Drug Resistance Mutations (SDRM) dataset and also focused on studying participants with intermediate or high resistance defined through the Stanford score.

RESULTS**:** From 2018 to 2021, 1170 PPLH received prenatal care at the center and 550 were genotyped. Among the 295 SDRMs, with respect to NRTI-resistance mutations, there were 27/295 (9.2%) M184V/I, 14/295 (4.7%) T215Y/C/D/E/F/V/I/S, and 12/295 (4.1%) M41L. For NNRTI, there were 75/295 (25.4%) K103N, 18/295 (6.1%) M230, and 14/295 (4.7%) G190A/E/S mutations. For PI, the most frequent mutations were 13/295 (4.4%) V82A/S/F/T, 12/295 (4.1%) M46I/L, and 10/295 (3.4%) D30N. Based on the Stanford score, 36/224 (16%) naïve participants had one or more antiretroviral resistance mutations, 81% of whom had NNRTI resistance. In the treatment-experience group, 108/326 (33%) had one or more mutations, 91% of whom had NNRTI resistance. The most frequent HIV subtype was B (82.5%).

CONCLUSIONS**:** Our findings suggest that continuous surveys of HIV genotype appear to be important tools to map the distribution and evolution of HIV subtypes and resistance to provide information to support treatment policies. Furthermore, concerns about the use of rilpivirine-containing regimens underscore the importance of resistance surveillance.

Clin Infect Dis. 2023 May 3; ciad266. doi: 10.1093/cid/ciad266. Online ahead of print.

Vaccination status and trends in adult COVID-19-associated hospitalizations by race and ethnicity, March 2020-August 2022

Ko JY, Pham H, Anglin O, et al for the COVID-NET Surveillance Team.

BACKGROUND**:** We sought to evaluate whether race/ethnicity disparities in severe COVID-19 outcomes persist in the era of vaccination.

METHODS**:** Population-based age-adjusted monthly rate ratios (RR) of laboratory-confirmed COVID-19–associated hospitalizations were calculated among adult patients from COVID-19–Associated Hospitalization Surveillance Network (COVID-NET) during March 2020–August 2022, by race/ethnicity. Among randomly sampled patients, July 2021–August 2022, RRs for hospitalization, intensive care unit (ICU) admission, and in-hospital mortality were calculated for Hispanic, Black, American Indian/Alaskan Native (AI/AN), and Asian/Pacific Islander (API) versus White persons.

RESULTS**:** Based on data from 353,807 hospitalized patients, hospitalization rates were higher among Hispanic, Black, and AI/AN versus White persons during March 2020–August 2022, yet the magnitude of the disparities declined over time (for Hispanic, RR=6.7; 95% CI: 6.5-7.1 in June 2020 vs RR <2.0 after July 2021; for AI/AN, RR=8.4; 95% CI: 8.2-8.7 in May 2020 vs RR <2.0 after March 2022; and for Black persons RR=5.3; 95% CI: 4.6-4.9 in July 2020 vs RR <2.0 after February 2022; all $P \leq 0.001$). Among 8,706 sampled patients during July 2021–August 2022, hospitalization and ICU admission RRs were higher for Hispanic, Black, and AI/AN (range for both hospitalization and ICU admission: 1.4-2.4) and lower for API (range for both: 0.6-0.9) versus White persons. All other race and ethnicity groups had higher in-hospital mortality rates versus White persons (RR range: 1.4-2.9).

CONCLUSIONS**:** Race/ethnicity disparities in COVID-19–associated hospitalizations declined but persist in the era of vaccination. Developing strategies to ensure equitable access to vaccination and treatment remains important.

AIDS Res Hum Retroviruses. 2023 May 4. doi: 10.1089/AID.2022.0185. Online ahead of print.

Obesity modifies the relationship between raltegravir and dolutegravir hair concentrations and body weight gain in women living with HIV

Delille Lahiri C, Mehta CC, Sykes C, et al.

Integrase strand-transfer inhibitors (INSTIs) are associated with weight gain in women living with HIV (WLH). Relationships between drug exposure, baseline obesity, and INSTI-associated weight gain remain unclear. Data from 2006–2016 were analyzed from virally suppressed WLH enrolled in the Women's Interagency HIV Study who switched/added an INSTI to antiretroviral therapy: (raltegravir [RAL], dolutegravir [DTG], or elvitegravir [EVG]). Percent body weight change was calculated from weights obtained a median 6 months pre- and 14 months post–INSTI initiation. Hair concentrations were measured with validated LC-MS/MS assays. Baseline (preswitch) weight status evaluated obese (body mass index, BMI, ≥30 kg/m^2) vs nonobese (BMI <30 kg/m^2). Mixed models examined the drug hair concentration baseline obesity status interaction for each INSTI. There were 169 WLH included: 53 (31%) switched to RAL, 72 (43%) to DTG, and 44 (26%) to EVG. Women were median age 47–52 years, predominantly non-Hispanic Black, median CD4 counts >500 cells/mm^3, >75% with undetectable HIV-1 RNA. Over ~1 year, women experienced median increases in body weight: 1.71% (-1.78, 5.00) with RAL; 2.40% (-2.82, 6.50) with EVG; and 2.48% (-3.60, 7.88) with DTG. Baseline obesity status modified the relationship between hair concentrations and percent weight change for DTG and RAL (Ps <0.05): higher DTG, yet lower RAL concentrations were associated with greater weight gain among nonobese women. Additional pharmacologic assessments are needed to understand the role of drug exposure in INSTI-associated weight gain.

J Travel Med. 2023 May 3; taad065. doi: 10.1093/jtm/taad065. Online ahead of print.

Negligible risk of surface transmission of SARS-CoV-2 in public transportation

Alina Pilipenco, Michala Forinová, Hana Mašková, et al.

BACKGROUND**:** Exposure to pathogens in public transport systems is a common means of spreading infection, mainly by inhaling aerosol or droplets from infected individuals. Such particles also contaminate surfaces, creating a potential surface-transmission pathway.

METHODS**:** A fast acoustic biosensor with an antifouling nano-coating was introduced to detect SARS-CoV-2 on exposed surfaces in the Prague Public Transport System. Samples were measured directly without pretreatment. Results with the sensor gave excellent agreement with parallel qRT-PCR measurements on 482 surface samples taken from actively used trams, buses, metro trains, and platforms between April 7 and 9, 2021, in the middle of the lineage Alpha SARS-CoV-2 epidemic wave when 1 in 240 people were COVID-19 positive in Prague.

RESULTS**:** Only 10 of the 482 surface swabs produced positive results and none of them contained virus particles capable of replication, indicating that positive samples contained inactive virus particles and/or fragments. Measurements of the rate of decay of SARS-CoV-2 on frequently touched surface materials showed that the virus did not remain viable longer than 1 to 4 hours. The rate of inactivation was the fastest on rubber handrails in metro escalators and the slowest on hard-plastic seats, window glasses, and stainless-steel grab rails. As a result of this study, Prague Public Transport Systems revised their cleaning protocols and the lengths of parking times during the pandemic.

CONCLUSIONS**:** Our findings suggest that surface transmission played no or a negligible role in spreading SARS-CoV-2 in Prague. The results also demonstrate the potential of the new biosensor to serve as a complementary screening tool in epidemic monitoring and prognosis.

JAMA. 2023 May 2;329(17):1469-1477. doi: 10.1001/jama.2023.4809.

National trends in mental health-related emergency department visits among youth, 2011-2020

Bommersbach TJ, McKean AJ, Olfson M, Rhee TG.

IMPORTANCE**:** There has been increasing concern about the burden of mental health problems among youth, especially since the COVID-19 pandemic. Trends in mental health–related emergency department (ED) visits are an important indicator of unmet outpatient mental health needs.

OBJECTIVE**:** To estimate annual trends in mental health–related ED visits among US children, adolescents, and young adults between 2011 and 2020.

DESIGN, SETTING, AND PARTICIPANTS: Data from 2011 to 2020 in the National Hospital Ambulatory Medical Care Survey, an annual cross-sectional national probability sample survey of EDs, was used to examine mental health–related visits for youths aged 6 to 24 years (unweighted = 49,515).

MAIN OUTCOMES AND MEASURES: Mental health–related ED visits included visits associated with psychiatric or substance use disorders and were identified by International Classification of Diseases, Ninth Revision, Clinical Modification

(ICD-9-CM; 2011-2015) and ICD-10-CM (2016-2020) discharge diagnosis codes or by reason-for-visit (RFV) codes. We estimated the annual proportion of mental health–related pediatric ED visits from 2011 to 2020. Subgroup analyses were performed by demographics and broad psychiatric diagnoses. Multivariable-adjusted logistic regression analyses estimated factors independently associated with mental health–related ED visits controlling for period effects.

RESULTS**:** From 2011 to 2020, the weighted number of pediatric mental health–related visits increased from 4.8 million (7.7% of all pediatric ED visits) to 7.5 million (13.1% of all ED visits) with an average annual percent change of 8.0% (95% CI, 6.1%-10.1%; $P < .001$). Significant linearly increasing trends were seen among children, adolescents, and young adults, with the greatest increase among adolescents and across sex and race and ethnicity. While all types of mental health–related visits significantly increased, suicide-related visits demonstrated the greatest increase from 0.9% to 4.2% of all pediatric ED visits (average annual percent change, 23.1% [95% CI, 19.0%-27.5%]; $P < .001$).

CONCLUSIONS AND RELEVANCE: Over the last 10 years, the proportion of pediatric ED visits for mental health reasons has approximately doubled, including a 5-fold increase in suicide-related visits. These findings underscore an urgent need to improve crisis and emergency mental health–service capacity for young people, especially for children experiencing suicidal symptoms.

J Am Coll Cardiol. 2023 May 9;81(18):1766-1776. doi: 10.1016/j.jacc.2023.02.049.

1-year outcomes of transcatheter tricuspid valve repair

Kodali SK, Hahn RT, Charles J Davidson CJ, et al.

BACKGROUND**:** Surgical management of isolated tricuspid regurgitation (TR) is associated with high morbidity and mortality, thereby creating a significant need for a lower-risk transcatheter solution.

OBJECTIVES**:** The single-arm, multicenter, prospective CLASP TR (Edwards PASCAL TrAnScatheter Valve RePair System in Tricuspid Regurgitation [CLASP TR] Early Feasibility Study) evaluated 1-year outcomes of the PASCAL transcatheter valve repair system (Edwards Lifesciences) to treat TR.

METHODS**:** Study inclusion required a previous diagnosis of severe or greater TR and persistent symptoms despite medical treatment. An independent core laboratory evaluated echocardiographic results, and a clinical events committee adjudicated major adverse events. The study evaluated primary safety and performance outcomes, with echocardiographic, clinical, and functional endpoints. Study investigators report 1-year all-cause mortality and heart failure hospitalization rates.

Results**:** Sixty-five patients were enrolled: mean age of 77.4 years; 55.4% female; and 97.0% with severe to torrential TR. At 30 days, cardiovascular mortality was 3.1%, the stroke rate was 1.5%, and no device-related reinterventions were reported. Between 30 days and 1 year, there were an additional 3 cardiovascular deaths (4.8%), 2 strokes (3.2%), and 1 unplanned or emergency reintervention (1.6%). One-year postprocedure, TR severity significantly reduced ($P < 0.001$), with 31 of 36 (86.0%) patients achieving moderate or less TR; 100% had at least 1 TR grade reduction. Freedom from all-cause mortality and heart failure hospitalization by Kaplan-Meier analyses were 87.9% and 78.5%, respectively. Their New York Heart Association functional class significantly improved ($P < 0.001$) with 92% in class I or II, 6-minute walk distance increased by 94 m ($P = 0.014$), and overall Kansas City Cardiomyopathy Questionnaire scores improved by 18 points ($P < 0.001$).

CONCLUSIONS**:** The PASCAL system demonstrated low complication and high survival rates, with significant and sustained improvements in TR, functional status, and quality of life at 1 year.

PLoS One. 2023 May 3;18(5):e0283759. doi: 10.1371/journal.pone.0283759. eCollection 2023.

Associations between long-term fine particulate matter exposure and hospital procedures in heart failure patients

Catalano S, Moyer J, Anne Weaver A, et al.

BACKGROUND**:** Ambient fine particulate matter (PM2.5) contributes to global morbidity and mortality. One way to understand the health effects of PM2.5 is by examining its impact on performed hospital procedures, particularly among those with existing chronic disease. However, such studies are rare. Here, we investigated the associations between annual average PM2.5 and hospital procedures among individuals with heart failure.

METHODS**:** Using electronic health records from the University of North Carolina Healthcare System, we created a retrospective cohort of 15,979 heart failure patients who had at least 1 of 53 common (frequency > 10%) procedures. We used daily modeled PM2.5 at 1 x 1 km resolution to estimate the annual average PM2.5 at the time of heart failure diagnosis. We used quasi-Poisson models to estimate associations between PM2.5 and the number of performed hospital procedures over the follow-up period (12/31/2016 or date of death) while adjusting for age at heart failure diagnosis, race, sex, year of visit, and socioeconomic status.

RESULTS**:** A 1 $\mu g/m^3$ increase in annual average PM2.5 was associated with increased glycosylated hemoglobin tests (10.8%; 95% CI = 6.56%, 15.1%), prothrombin time tests (15.8%; 95% CI

= 9.07%, 22.9%), and stress tests (6.84%; 95% CI = 3.65%, 10.1%). Results were stable under multiple sensitivity analyses.

CONCLUSIONS**:** These results suggest that long-term PM2.5 exposure is associated with an increased need for diagnostic testing on heart failure patients. Overall, these associations give a unique lens into patient morbidity and potential drivers of health care costs linked to PM2.5 exposure.

Am J Cardiol. 2023 May 15;195:83-90. doi: 10.1016/j.amjcard.2023.02.029. Epub 2023 Apr 7.

Hemodynamic predictors of stabilization when using temporary mechanical support for cardiogenic shock from acute on chronic heart failure

Wolfe JD,Deych E, Sintek MA, Schilling JD.

Cardiogenic shock from acute on chronic heart failure is a lethal condition that frequently requires temporary mechanical circulatory support devices (tMCS) as a bridge to stabilization, durable support, or heart transplantation. However, there are limited data on methods to optimize use of tMCS in this population. We identified patients who received tMCS devices for cardiogenic shock from acute on chronic heart failure at a single center from August 2016 to July 2020. All the patients had invasive hemodynamic data before and immediately after tMCS placement. We classified patients according to whether they showed stabilization or decompensation with tMCS. We then evaluated hemodynamics pre-tMCS, post-tMCS, and the change in hemodynamics with tMCS (Δ-tMCS) and assessed their relationship with clinical outcomes. Among 111 patients who received tMCS, 71 stabilized, and 40 decompensated. Post-tMCS hemodynamics were more likely than were pre-tMCS or Δ-tMCS to predict stabilization. Post-tMCS cardiac index >2.1 (area under the curve: 92.2) and cardiac power index >0.3 (area under the curve: 89.6) were the best predictors of stabilization. Patients who decompensated had increased in-hospital all-cause mortality (hazard ratio 3.06 [1.29 to 7.24], $P = 0.011$), cardiovascular mortality, and increased hospital and intensive care unit length of stay and were less likely to receive left ventricular assist device or heart transplant (hazard ratio 0.56 [0.36 to 0.88], $P = 0.01$). In conclusion, among patients with cardiogenic shock from acute on chronic heart failure who received tMCS, post-tMCS cardiac index and cardiac power index were highly predictive of stabilization. Those who decompensated had increased mortality, hospital length of stay, and intensive care unit length of stay and were less likely to receive heart replacement therapy.

ASAIO J. 2023 Apr 20. doi: 10.1097/MAT.0000000000001937. Online ahead of print.

Improved 3 year heart transplant survival in Black recipients following the Affordable Care Act

Brandes RA, Liang CJ, Suerig B, Chen FY, Couper GS, Kawabori M.

To improve health care access, the US government implemented the Affordable Care Act (ACA) in 2014. Previous studies investigating its impact on health care inequities showed significant improvement in Black transplant recipient outcomes. Our objective is to determine the ACA's impact on Black heart transplant (HTx) recipients. Using the United Network for Organ Sharing database, we analyzed 3,462 Black HTx recipients pre- and post-ACA (January 2009 to December 2012, and January 2014 to December 2017). Black recipient numbers and rates of overall HTx, insurance effects on survival, geographic changes in HTx, and post-HTx survival were compared pre- and post-ACA. Black recipients increased from 1,046 (15.3%) to 2,056 (22.2%) post-ACA ($P < 0.001$). Three year survival increased among Black recipients (85.8-91.9%, $P = 0.01$; 79.4-87.7%, $P < 0.01$; 78.3-84.6%, $P < 0.01$). Affordable Care Act implementation was protective for survival (hazard ratio [HR] = 0.64 [95% confidence interval [CI], 0.51-0.81], $P < 0.01$). Publicly insured patient survival increased post-ACA to match that of privately insured (87.3-91.8%, $P = 0.001$). United Network for Organ Sharing (UNOS) Regions 2, 8, and 11 experienced improved survival post-ACA ($P = 0.047$, p = 0.02, and $P < 0.01$, respectively). The post-ACA era showed improved HTx access and survival in Black recipients, indicating that national medical policy may play a strong role in eliminating racial disparities. Further attention is required to improve inequities in medical care.

Am J Manag Care. 2023 Apr;29(4):196-202. doi: 10.37765/ajmc.2023.89348.

Multilevel influences on patient engagement and chronic care management

Miller-Rosales C, Brewster AL, Shortell SM, Rodriguez HP.

OBJECTIVES**:** Physician practices are increasingly owned by health systems, which may support or hinder adoption of innovative care processes for adults with chronic conditions. We examined health system- and physician practice-level capabilities associated with adoption of (1) patient engagement strategies and (2) chronic care management processes for adult patients with diabetes and/or cardiovascular disease.

STUDY DESIGN: We analyzed data collected from the National Survey of Healthcare Organizations and Systems, a

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Coming Up: CMSA 2023 National Conference June 27–30

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and how can we maintain a patient-centered approach more often?

- **Jean Watson, PhD,** *nurse theorist, award-winning author, legend:* "Humanization of Health Care: Philosophy & Practice of Human Caring /Healing/Health"
  Considered to be a legend in the industry, Dr. Watson will lead us through the humanization of health care using authentic practice and her research exemplars of Caring Science/ Theory of Human Caring.

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Have an idea for an article? Send your suggestions for editorial topics to: Catherine Mullahy, cmullahy@academyccm.org.

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Advocacy: Another Name for Case Management

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affected by many variables including English as a second language, education, literacy skills, and attitudes toward health care. As advocates, we know that it's not enough to provide information about an illness, treatment, or other care choice. We need to engage our patients in conversation—by asking open-ended questions, for example—with the objective being to ascertain what they understand and probe for questions they might be reticent to ask. Once a care plan is put in place, asking the individual to repeat the details can provide assurance that they understand, while correcting any misperceptions before they become an issue. All these efforts will allow for better patient outcomes.

While the intention behind advocacy is universal and consistent, what that looks like in every interaction is unique to the individual involved. To that end, listening and hearing are imperatives for anyone who advocates for others.

No matter how experienced we are as case managers, we can never assume that we know best or have all the answers. Only by listening can we prioritize the patient's goals and ensure that the care plan moves in the direction of pursuing those goals. In the complex and often confusing world of health and human services, case managers are uniquely positioned to demonstrate our advocacy by seeing, hearing, and understanding our patients and what they need. CM

OIG: Expanded FAQs

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result in overutilization of services and increased program costs and that may adversely affect quality of care and patient freedom of choice among providers…" [See 64 Fed. Reg. 63,518, 63,520 (Nov. 19, 1999)].

"However, we recognize that as the health care industry moves away from a fee-for-service payment model toward value-based care, providers may need additional flexibility to support legitimate, collaborative arrangements. Through our final rule at 85 Fed. Reg. 77,684 (Dec. 2, 2020), we finalized safe harbors that provide additional flexibility to providers and suppliers pursuing value-based arrangements. Illustratively, providers and suppliers with common ownership may be able to establish a 'value-based enterprise' and utilize the safe harbors that are available to those entities" [See e.e., 42 CFR Section 1001.952(ee)-(gg).]

We note that compliance with a safe harbor is voluntary and that the advisory opinion process remains available for those who wish to obtain OIG review of a particular arrangement involving common ownership."

The OIG certainly seems to "beg the question" in this FAQ. Questions about remuneration exchanged between entities with common ownership often occur outside of value-based arrangements. And, yet, if such remuneration is impermissible, what are the practical effects on the ability of multi-provider systems to operate?

FAQs from the OIG are another way for providers to gain knowledge and insight into important fraud and abuse compliance issues. Definitely worth reading! CM

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nationally representative survey of physician practices (n = 796) and health systems (n = 247) (2017-2018).

METHODS: Multivariable multilevel linear regression models estimated system- and practice-level characteristics associated with practice adoption of patient engagement strategies and chronic care management processes.

RESULTS: Health systems with processes to assess clinical evidence (β = 6.54 points on a 0-100 scale; *P* = .004) and with more advanced health information technology (HIT) functionality (β = 2.77 points per SD increase on a 0-100 scale; *P* = .03) adopted more practice-level chronic care management processes, but not patient engagement strategies, compared with systems lacking these capabilities. Physician practices with cultures oriented to innovation, more advanced HIT functionality, and with a process to assess clinical evidence adopted more patient engagement strategies and chronic care management processes.

CONCLUSIONS: Health systems may be better able to support the adoption of practice-level chronic care management processes, which have a strong evidence base for implementation, compared with patient engagement strategies, which have less evidence to guide effective implementation. Health systems have an opportunity to advance patient-centered care by expanding practice-level HIT functionality and developing processes to appraise clinical evidence for practices.

Retina. 2023 May 1. doi: 10.1097/IAE.0000000000003827. Online ahead of print.

Better baseline vision leads to better outcomes after the 0.19-mg fluocinolone acetonide intravitreal implant in diabetic macular edema

Gonzalez VH, Luo C, Almeida DRP; for the PALADIN Study Group.

PURPOSE: Analysis of a 3-year, phase 4, open-label, observational study evaluating the association of baseline best-corrected visual acuity (BCVA) with visual, treatment burden, and retinal thickness variability (RTV) outcomes and intraocular pressure (IOP)-related events following the 0.19-mg fluocinolone acetonide (FAc) intravitreal implant.

METHODS: Data from patients with diabetic macular edema (DME) who did not have a clinically significant rise in IOP following previous corticosteroid treatment (N=202 eyes from 159 patients) were segregated by baseline BCVA of ≥20/40 or <20/40 and analyzed for BCVA, number of yearly supplemental DME treatments, RTV, and incidence of IOP-related event.

RESULTS: At 36 months post-FAc, eyes with better baseline BCVA (≥20/40) maintained baseline BCVA, while vision in eyes with worse baseline BCVA (<20/40) increased by approximately 7 letters to 61.34 letters (Snellen equivalent approximately 20/60; *P*<0.05). Treatment burden and RTV decreased post-FAc regardless of baseline BCVA. Eyes with better baseline BCVA (≥20/40) had numerically fewer IOP-related events post-FAc vs eyes with worse baseline BCVA (<20/40), including a lower incidence of incisional IOP-lowering surgery.

CONCLUSIONS: The 0.19-mg FAc implant improved RTV and treatment burden regardless of baseline BCVA. Better baseline BCVA (≥20/40) was associated with long-term BCVA maintenance. Though eyes with worse baseline BCVA (<20/40) experienced significantly improved BCVA, it never rose to the level of those with better baseline BCVA. These data indicate that early, effective intervention in DME, before significant vision loss occurs, is key to maintaining visual outcomes.

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Building Therapeutic Relationships Telephonically *continued from page 10*

he returned to his apartment from a recent hospital stay. Not only did this constitute an emergency but also provided me the opportunity to gain John's trust as I gave him instructions over the phone about how to improve his breathing and run the oxygen system. I helped him to get the supply company to return to his home right away to ensure the equipment was properly set up and to give John better instructions on how to use it.

On my next call John was breathing much more easily and was clearly much more clearheaded, since his oxygenation was adequate. John was quick to thank me for my assistance and was ready to tell me more about his situation. We talked about what I could offer him, and he told me what his goals and hopes were as he came to terms with his eminent death.

I did not shy away from his desire to speak directly about dying and his concerns about what would happen to him in the coming months. My background as a hospice nurse provided me with lots of experience to draw on and comfort to offer during these conversations as John asked questions and discussed his feelings. One of the things I learned was that John has support from his wife and daughter, although they were estranged. Despite the support, he was feeling rather alone. I offered to make a regular schedule for our calls, and John enthusiastically asked if I would call every week on Tuesday afternoon. I set up the schedule and arranged my Tuesdays so that I would never miss a call with him.

Over the course of a month, John began to speak more and more frankly with me about his needs, and I was able to provide meaningful guidance, support, and tools to help him resolve some problems—like getting the oxygen company to provide appropriate humidification equipment for his oxygen concentrator. Then one day, John confided in me the serious error he had made that had resulted in his separation from his wife and his estrangement from his grownup daughter and her child. He was so ashamed of what he had done that he expressed concern that I would stop helping him as a result. Since none of this had any bearing on the help I was providing John, I explained it would not change any aspect of our relationship. His relief at my response was so strong I could feel it over the phone.

By listening carefully to what John had to tell me and asking careful questions about the things I thought he might not be expressing, I had built a relationship of trust and comfort with John that allowed him to share his worries and problems, and allowed me to help him find solutions. The combination of reliably following through on my commitments—calling each week at the appointed time and providing useful advice, educational tools, and direct intervention with providers—as well as listening carefully and respectfully to John, I had earned his trust and respect. That allows me to continue to provide him meaningful support as his disease progresses and to help him though this difficult period of his life. CM

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Advocacy: From Return-to-Work to Self-Advocacy *continued from page 6*

are acceptable to everyone.

Self-advocacy may shift the employee's attention to services available in the community. Such services might range from health and wellness programs to developing new skills that make them even more valuable in the workplace.

At the same time, there may be cultural sensitivities to be considered, as well. For some employees, self-advocacy and speaking up about their needs may run contrary to their cultural attitudes that see the workplace as hierarchical. Therefore, the CDMS needs to be culturally aware of potential barriers, while keeping an open mind to the employee's beliefs, attitudes, and values.

For a CDMS, advocacy is grounded in the twofold goal of keeping employees on the job and maintaining productivity for the employer. Perhaps even more satisfying is supporting employees in taking the next step, to self-advocate for what they need to thrive. CM

Whistleblowers Fight Back *continued from page 9*

whistleblower suit, of course! The message from this case and many others is clear: Don't shoot the proverbial messenger who brings information about possible fraud and abuse violations. There is a heavy price to be paid. CM

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continued from page 29

that controls involuntary functions such as breathing and heartbeat), as well as in the eyes, kidneys, and cardiovascular system.

Arexvy (respiratory syncytial virus vaccine, adjuvanted) Suspension for intramuscular injection is a vaccine indicated for the prevention of RSV infection manufactured by GlaxoSmithKline.

Lumryz (sodium oxybate) Granules for Extended Release Oral Suspension is a once-nightly formulation of the approved central nervous system depressant sodium oxybate indicated for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy manufactured by Avadel Pharmaceuticals plc.

Uzedy (risperidone) Extended Release Injectable is a long-acting atypical antipsychotic indicated for the treatment of schizophrenia in adults manufactured by Teva Pharmaceuticals and MedinCell.

RizaFilm (rizatriptan) Oral Film is a serotonin (5-HT) 1B/1D receptor agonist (triptan) oral film formulation for the acute treatment of migraine manufactured by IntelGenx Corp.

New Research

Medical Cannabis May Be Tied to Improved Health-Related Quality of Life

Findings from a recent study conducted by Thomas R. Arkell PhD and colleagues, from the Swinburne University of Technology in Melbourne, Australia, have found that medical cannabis may improve quality of life according to a study published in *JAMA Network Open*. Some 3148 patients participated in this study. The most common indication for the use of medical cannabis was for the treatment of noncancer pain (68.6%), followed by cancer pain (6.0%), insomnia (4.8%), and anxiety (4.2%). Using the 36-Item Short Form Health Survey, all patients reported significant improvements over baseline in all domains of the Short Form Health Survey. These improvements were mostly sustained over time.

CE1

Veterans Affairs Polytrauma and Amputation Health Care and Comprehensive Case Management and Care Coordination *continued from page 16*

VADoDLLACPG092817.pdf

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CE2

Reducing Readmissions Through Primary Care Interventions *continued from page 20*

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CE3

Knowledge to Action…Driving Change Through Research Utilization *continued from page 24*

culture of process improvement and research. Driving change is possible when clinicians transform knowledge to action, and the opportunities for case management to be at the forefront of change are exceptional! CM

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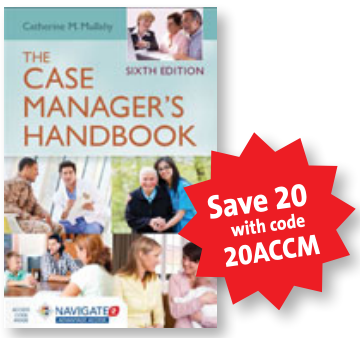

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