CareManagement

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

Vol. 28, No. 6 December 2022/January 2023

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Gary S. Wolfe

Becoming an FCM–A Fellow in Case Management

The Case Management Fellow Program recognizes case management professionals who have made a significant contribution to case management through leadership, service, innovation, and scholarship.

In 2021 the Case Management Society of America (CMSA) inaugurated the Case Management Fellow Program. Founding Fellows were announced in 2021, and Fellows in the Class of 2022 were announced at the CMSA Annual Conference this year. The Case Management Fellow Program is an exciting development in the professional practice of case management.

The Case Management Fellow Program recognizes case management professionals who have made a significant contribution to case management through leadership, service, innovation, and scholarship. Fellows are the people who make a difference in case management. Those who are selected to Fellowship demonstrate to peers and others their commitment to quality case management. As recognized case management leaders, Fellows act as ambassadors by raising the standards of practice through consistent participation in professional development activities and service to case management. Fellows teach, lead, present, publish, participate, and attend activities. The essential essence of becoming a Fellow is making a significant contribution to the professional practice of case management. Fellows make a difference, either through leadership, service, or scholarly activities. It is a humbling honor to be selected and recognized as a Fellow.

Case Management Fellows represent a diverse community of thought leaders who play an active role in case management; they identify future trends and issues and advance the standards of case management practice through excellence, all with a passion for the professional practice of case management. Being awarded the FCM™ demonstrates a high degree of demonstrated proficiency in professional case management practice and an important contribution to advancing the professional practice of case management. Case Management Fellows show a commitment to knowledge through continuing education and publication and influence the growth of the professional practice.

To apply to become a Fellow, you must submit a written application that details

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CMSA Founding Fellows

Patricia Agius, BS, RN, CCM, CPHQ, FCM

Jeanne Boling, MSN, RN, CCM, CRRN, FCM

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Melanie Prince, MSS, MSN, BSN, NE-BC, CCM, FAAN, FCM

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Vol. 28, No. 5, December 2022/January 2023. *CareManagement* (ISSN #1531-037X) is published electronically six times a year, February, April, June, August, October, and December, and its contents are copyrighted by Academy of Certified Case Managers, 2740 SW Martin Downs Blvd. #330, Palm City, FL 34990; Tel: 203-454-1333; Fax: 203-547-7273.

Subscription rates: $120 per year for ACCM members; $150 for institutions.

CareManagement is indexed in the CINAHL® Database and Cumulative Index to Nursing & Allied Health Literature™ Print Index and in RNdex.™

Catherine M. Mullahy

Complex Patients with Complex Discharge Needs: The Continuing Challenge

As I contemplated, during this very busy time of year, just what to address in this last issue of *CareManagement* for 2022 and the first issue for 2023, it occurred to me that there is a continuing problem facing some of our patients and their case managers. It has become an accepted belief that not every patient needs a case manager. Surely those with seemingly insurmountable problems and issues that impact their care require more than what may still be the "norm" in our healthcare system.

We've done a great job using data analysis, predictive modeling, and other metrics to identify the kinds of patients that would benefit most from a professional case manager's intervention and care. We have achieved some success in identifying individuals who are sometimes called "frequent flyers" or "high utilizers." The most common reasons for hospital readmissions have been determined to be disengagement and noncompliance, condition complications, inadequate transition of care, misinterpretation of discharge instructions, and demographic factors. We have created programs that have greatly reduced the rate of hospital readmissions and length of stay for conditions that are most problematic (e.g., sepsis, congestive heart failure, kidney disease, chronic obstructive pulmonary disease, diabetes). It would seem, however, that as soon as some success is achieved, we need to turn our attention to other matters. Given that the number of complex patients with complex needs are increasing, it might be time to reexamine key factors relating to the case manager's involvement in treating complex patients. For instance, should we reconsider the duration of contact from a case manager, the frequency of that involvement, and the types or components of the case management process that are most effective? I believe we should.

As hospitals and case management leaders all across the country were creating the Hospital Reduction Readmission Programs (HRRP) to address conditions most responsible for hospital readmissions (e.g., septicemia, heart failure, diabetes with complications, and chronic obstructive pulmonary disease) (Overview of Clinical Conditions With Frequent and Costly Hospital Readmissions by Payer, 2018 #278 (ahrq.gov), there was increasing recognition of the need to expand the preparation and education of case managers. The number of individuals obtaining and pursing their CCM (certified case manager) certification and continuing education has increased. As of March 2022, that figure reached 50,000. These are the true hallmarks of professional accountability and the growing evidence of the importance of our role across the health care continuum. There has been significant progress in avoiding hospital readmissions and the subsequent complications that patients experience, not to mention the costs incurred. Now, however, we must examine just how we are accomplishing those goals. Are there components of the process that are more valuable than others? Does every patient need the same kind of intervention? We recognize the need to adhere to the core components of the process, with advocacy at its heart and center, but we also need to periodically examine the effectiveness of that process. Of significance, in the last several years an integrated case management model has emerged that incorporates the behavioral health and social determinants of health components of patients and their caregivers, along with their medical problems. This model has resulted in a more comprehensive and inclusive process with favorable results.

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Our patients, however, continue to experience problems. They are confused about their discharge and treatment instructions, their physicians and other members of their care team don't communicate and coordinate their care, they don't adhere to prescribed treatment and medications, and they are resistant to recommended lifestyle changes. In addition, they experience growing dissatisfaction and frustration with the quality of care they are receiving, the medical errors that are occurring, and the overwhelming number of providers and settings that are involved in their care.

It's no small wonder that our patients and case management colleagues are continually frustrated. If we're working so hard, why are the problems continuing and how can we

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Providers Liable for Harm to Patients and Fraudulent Conduct Despite Physicians' Orders

Elizabeth Hogue, Esq.

The steadily expanding authority, recognition, and independence of practitioners makes it clear that non-physician practitioners have the ability to collaborate with other health care providers to determine appropriate health care for patients and to implement plans of care.

In *Connette ex. Re. Gullatte v. Charlotte Mecklenburg Hospital Authority* [Case No. 331PA20, Supreme Court of North Carolina (August 19, 2022)], the Court said that practitioners owe a duty of care in the diagnosis and treatment of patients even though they are working under the supervision of licensed physicians. Here's what happened in this case: On September 11, 2010, a three-year-old child who had an upper respiratory infection went to the emergency room at the Hospital and was diagnosed with tachycardia. She was referred to a cardiologist who diagnosed cardiomyopathy and recommended an ablation procedure.

Shortly after the procedure began, the child went into cardiac arrest. She was revived, but suffered permanent brain damage, cerebral palsy. and profound developmental delays. The child's family sued the cardiologist, the nurse anesthetist, and the Hospital. Experts for the child's family concluded that the use of sevoflurane mask induction of anesthesia instead of an intravenous introduction of a drug other than sevoflurane breached applicable standards of care.

Historically, courts in North Carolina concluded that practitioners did not owe an independent duty to patients in the selection and planning of treatment. This meant that practitioners were not liable for the performance of their roles in administration of any negligent treatment of patients. Practitioners could be held liable only for the execution of their primary function, which was to obey and diligently execute the orders of physicians in charge of patients. Exceptions to this rule occurred when physicians' orders were so obviously negligent as to lead any reasonable person to anticipate that substantial injury would result.

Consequently, practitioners were sheltered from exposure to liability for negligence when performing duties under the supervision of physicians. They were vulnerable to claims of negligence due to the performance of their professional duties and responsibilities only when substandard execution of such activities was obvious.

The Court concluded its opinion by recognizing the "elevated station" of non-physician providers in the healthcare industry today that should result in "elevated responsibility." The steadily expanding authority, recognition, and independence of practitioners makes it clear that non-physician practitioners have the ability to collaborate with other health care providers to determine appropriate health care for patients and to implement plans of care.

Despite this court decision and many others that reached the same conclusion, providers may still be tempted to claim that they should not have liability because they were following physicians' orders. As indicated above, this argument is increasingly unlikely to fly!

Healthcare providers have also responded to allegations of fraud by arguing that they had orders for the care rendered from physicians that shield them from responsibility. Patients must, for example, be homebound or terminally ill because physicians certified to this fact. Care provided must be reasonable and necessary because physicians ordered it. Court decisions related to fraud and abuse, however, also make it clear that the "say so" of physicians may be insufficient when it comes to fraudulent conduct.

Providers must continue to make independent decisions about care provided to patients and work with physicians to modify orders as needed. CM

Elizabeth 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.*

What About Gifts to Patients During the Holiday Season?

Elizabeth Hogue, Esq.

Effective on December 7, 2016, the OIG increased the limits of items and services of nominal value that may be given by providers and suppliers to beneficiaries to a retail value of no more than $15 per item or $75 in the aggregate per patient on an annual basis.

The Office of Inspector General (OIG) of the U.S. Department of Health and Human Services, the primary enforcer of fraud and abuse prohibitions, increased the limits on free items and services that can be given to patients and potential patients effective on December 7, 2016. Specifically, according to the OIG, items and services of nominal value may be given to patients or potential patients that have a retail value of no more than $15 per item or $75 in the aggregate per patient on an annual basis. The previous limits were $10 per item or $50 in the aggregate per patient on an annual basis.

Under section 1128A(a)(5) of the Social Security Act, persons who offer or transfer to Medicare and/or Medicaid beneficiaries any remuneration that they know or should know is likely to influence beneficiaries' selection of particular providers or suppliers of items or services payable by the Medicare or Medicaid Programs may be liable for civil money penalties for up to $10,000 for each wrongful act. "Remuneration" includes waivers of copayments and deductibles and transfers of items or services for free or for other than fair market value.

In the Conference Committee report that accompanied the enactment of these requirements, Congress expressed a clear intent to permit inexpensive gifts of nominal value from providers to beneficiaries. In 2000, the OIG initially interpreted "inexpensive" or "nominal value" to mean a retail value of no more than $10 per item or $50 in the aggregate per patient on an annual basis. The OIG also

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Not Just One Week A Year! Case Management Appreciation

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

Each year, during the second full week of October, we celebrate National Case Management Week and recognize the invaluable work of case managers and those that support the case management community in improving health outcomes.

The theme for the most recent National Case Management Week, which was held October 9–15, 2022, was "Setting the Standard for Patient-Centered Care"; this theme truly encapsulated the professional practice of case management and the amazing work case managers do. #CMWeek2022 was the perfect opportunity to not only recognize our tireless case managers and their commitment to upholding the standards of practice but to also educate the healthcare community across the continuum of care in a myriad of settings as well as the public at large about the important role and incredible value that case managers bring to the patient-centered care table.

Case Management Week was the perfect opportunity to not only recognize our tireless case managers and their commitment to upholding the standards of practice but to also educate the healthcare community across the continuum of care in a myriad of settings as well as the public at large about the important role and incredible value that case managers bring to the patient-centered care table.

CMSA planned some wonderful activities to showcase case management, provide self-care, network with peers, and add more skills to the case manager's already overflowing toolbox. Locally, CMSA chapters, employers, providers, communities, and more participated in the celebrations.

#CMWeek2022 Celebration Round Up of activities included the following:

- Many CMSA chapters received official proclamations declaring National Case Management Week from their local and state legislators and held events and celebrations across the county.
- Case managers spoke at local community events and spread the word to other professionals on the importance of their work.
- Personal stories were shared that illustrated the impact case managers have every day both in person and on social media outlets.
- Employers hosted appreciation events and profiled case managers in their company newsletter to help raise awareness of the practice.
- Other healthcare professionals were encouraged to celebrate and acknowledge case managers.
- Health providers recognized case managers as critical members of healthcare teams and showed appreciation for their work and what they do for patients.
- Case management was promoted at local health fairs, preventative health screenings, and other community activities.
- Professional seminars and workshops were hosted that featured and benefited case managers.
- Case managers were recognized and featured on social media and in other communication outlets.
- Receptions and coffee connect virtual gatherings were held to celebrate case managers.
- Self-care sessions were offered to honor the tireless work of the case manager.

As much fun as #CMWeek2022 was, we encourage everyone to realize that our celebrations do not stop there. Case managers, regardless of discipline, should be appreciated all year long!

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Dr. Colleen Morley, DNP, RN, CCM, CMAC, CMCN, ACM-RN, FCM, *is the current President of the Case Management Society of America National Board of Directors and Associate Chief Clinical Operations–Continuum of Care at University of Illinois Hospital and Health Sciences System. Her current passion is in the area of improving health literacy. She has recently authored her 1st book, "A Practical Guide to Acute Care Case Management." Dr. Morley has over 20 years of nursing experience. Her clinical specialties include medical/surgical, oncology, and pediatric nursing.*

What "Quiet Quitting" Really Means—and 6 Ways to Respond

MaryBeth Kurland, MPA, CAE, ICE-CCP

"Quiet quitting" continues to dominate much of the workforce discussion as employers and employees alike grapple with this term and what it really means. The starting place is realizing that this phenomenon is nothing new. Whether we call it quiet quitting, burned out, stressed out, or low morale, the meaning is essentially the same: a desire to dial back the number of hours or take a break after an intense period of seemingly working nonstop.

We're seeing this across the care continuum, where the strains caused by the pandemic have created a widespread need for better work/life balance among many professionals. For example, the Commission for Case Manager Certification (CCMC) responded to this need with our ongoing "Push Pause" campaign to help others find moments of grace amid the grind.

For many, though, feelings of being overworked and overwhelmed are particularly acute, sometimes compounded by a difficult boss or diminished job satisfaction. All these factors point to the fact that quiet quitting is, at its core, a leadership issue. This applies to all of us—both Certified Case Managers (CCMs) and Certified Disability Management Specialists (CDMSs)—whether we lead a small team, a department, an entire company, or only ourselves.

Here are six ways that we can respond to quiet quitting by providing more support to ourselves and others:

"Quiet quitting" continues to dominate much of the workforce discussion as employers and employees alike grapple with this term and what it really means. Whether we call it quiet quitting, burned out, stressed out, or low morale, the meaning is essentially the same: a desire to dial back the number of hours or take a break after an intense period of seemingly working nonstop.

1. **Be honest about our own feelings.** We need to look internally before we can offer any help and direction externally. The fact is, leaders experience quiet quitting, too! We need to be honest about whether we are feeling tired or burned out. By addressing our own needs first, we can better support others. For example, by not sending emails after hours or on weekends, we show that we are putting limits on our own work hours while also demonstrating—in actions, as well as words—that work need not be 24/7. We can become role models for others as they strive to recharge and reengage.
2. **Reconnect with the mission.** Why do we do what we do? The organizations we work for have mission statements—and we may have them as well. For me personally, I have a strong sense of purpose around helping to develop and certify the professionals who are so greatly needed within our fractured healthcare system. As we reflect on our organizational and personal missions, we can become more engaged and rediscover our deeper motivations.
3. **Express empathetic leadership.** The more we understand where we're coming from, the better we can meet people where they are. Our shared humanness allows us to express empathetic leadership. But there's one important caveat: what worked in the past—for example, "pizza Fridays" at the office or ordering in lunch—clearly does not suffice, especially in a remote/hybrid environment. As leaders, we need to be more intentional in our outreach to help people feel connected and appreciated. For example, early on

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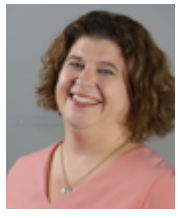

MaryBeth Kurland, MPA, CAE, ICE-CCP, *is the CEO of the Commission for Case Manager Certification, the first and largest nationally accredited organization that certifies more than 50,000 professional case managers and disability management specialists. The Commission oversees the process of case manager certification with its CCM® credential and the process of disability management specialist certification with its CDMS® credential.*

Jeff

Anne Fortenberry, LMSW

The types of innovative solutions that make me passionate about case management are identifying a problem, brainstorming solutions, and implementing, assessing, and driving change for better patient outcomes.

I met Jeff in the hospital. He told me he had been working at a construction job when he had a sudden and intense pain in his abdomen. At the hospital he learned it was cancer. Jeff had a decent paying job and a home, but he could no longer work. He did not have a support system or family to help him. He needed aggressive treatment. I arranged to accept him into our new housing program for homeless people because he was going to lose his apartment.

He started his treatment and I connected him to a colleague in our case management department who helped him file for expedited disability income. I took Jeff to the welfare office to apply for SNAP benefits. When he couldn't fit into his old clothing due to weight loss, we went to the Salvation Army to get new clothes. I took him grocery shopping for his specific food needs and for the Ensure protein shakes he needed to help maintain his weight and strength. We had 24/7 staff, and Jeff built friendships with them and the other residents.

I started my journey as a case manager in a city in the western United States that has a large homeless and transient population. During my interview at a medical and behavioral clinic that also provides transitional housing for people with mental health and/or substance use disorder diagnoses, my soon-to-be supervisor gave me the rundown of the many barriers people face in obtaining basic services for behavioral health or substance use disorder while being homeless. In addition to providing wraparound services in their clinic, they also had several transitional housing locations for those who met criteria and were committed to an intensive outpatient program. I was interviewing for a targeted case management position to provide case management to clients in one of those houses. I would also spend part of each day at the clinic's crisis drop-in center, where I would complete needs assessments and start the intake process for new housing clients.

During my interview, we discussed another problem the homeless population had and what the clinic was hoping to do about it. People who have cancer or who need outpatient wound care, physical and occupational therapy, or intravenous antibiotics and who are also homeless face barriers to obtaining outpatient follow-up services once they leave the hospital. My soon-to-be supervisor told me they were partnering with one of the Reno medical hospitals to provide short-term transitional housing to patients who needed a safe place to go at discharge so they could continue their medical care. Patients can't get intravenous antibiotics at a shelter, and it is unlikely they will get to their oncology and chemotherapy appointments while living on the streets without their basic needs being met.

Thus I was hired to provide targeted case management services and asked to spearhead this contract with the hospital. The directors and I created a minipsychosocial assessment and processes and procedures for receiving referrals from the hospital, assessing the patients face to face in the hospital and coordinating their discharge into our housing. Once in our housing, I provided ongoing case management services until their hospital housing contract expired (ie, when their outpatient follow-up care needs had been met—antibiotics completed, physical and occupational therapy completed, outpatient wound care clinic appointments completed). With each referral received, I would assess the patient and use my discretion along with feedback from directors as needed to accept or decline a patient and coordinate their postdischarge plan. Process improvements and feedback were continuous throughout the first few months while I figured out what was and was not working while best meeting the needs of the patient. Most of these patients were in our housing for 30 days and would discharge back to the street once their outpatient needs were met. Some were connected to group homes or able to be reconnected with family. During the short time I had with these patients, we worked hard

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***Anne Fortenberry, LMSW, is a** medical social worker with a passion for case management and strong interest in transitions of care. She graduated with her masters in social work from the University of Nevada, Reno, and is a board-certified case manager.*

CE1 Approved for 1 hour of CCM, CDMS, and nursing education credit
Exam expires on June 15, 2023

Reducing Hospital Length of Stay by Expediting Precertification

Eleanor Dashnaw, MSN, RN, CCM, Adria Grillo-Peck, RN, MS, CNS, CMC, Nikki Greisl, RRT, Kasey Burke, MSN, RN, CCM, ACM-RN, and Elizabeth Altenburger, PT, MSPT, CWS

Hospitals across the United States are being challenged to overcome a consistent and pervasive issue: well-timed insurance authorization and the associated hospital discharge delays. Seeking to address such delays, Indiana University (IU) Health, a 17-hospital healthcare system in Indiana, set about to fix the situation by taking a systematic approach to define and dissect the problem, develop a multifaceted solution, institute an implementation team, and generate a model to accurately evaluate for success.

Background and Purpose

Defining and Dissecting the Problem

Prior authorization, sometimes called precertification (precert), is a payment qualification process used by health plans by which health care providers must obtain advance approval from a health plan before a specific service or medication can be delivered to the patient (American Medical Association, 2019). This process can delay access to services, surgical interventions, and medications that have been deemed medically necessary by a patient's medical team (Menger et al., 2017; Shams et al., 2020).

Preliminary Research

To understand if precert delays were causing discharge delays, IU Health first turned to data from their electronic medical records (EMRs). Standard work across the system dictates that nurse case managers and medical social workers document "avoidable days" when they experience avoidable barriers to discharging their patients. A report categorizing these days for the year 2019 was pulled to reveal a total of 11,772 documented delays. Historical data from 2019 was used because of the prevalent precert waivers occurring in 2020 and 2021 because of the COVID-19 pandemic. IU Health determined that skilled nursing facility (SNF) and/or subacute rehabilitation (SAR) precert delays accounted for a total of 3,786 documented avoidable days.

A literature review revealed no best-practice evidence of

Eleanor Dashnaw, MSN, RN, CCM, *is a Clinical Program Manager for the statewide Integrated Care Management team at Indiana University Health. Her 12+ years of nursing experience across the continuum of patient care served her in the development and implementation of the Indiana University Health precert program.*

Adria Grillo-Peck, RN, MS, CNS, CMC, *serves as the Vice President of Integrated Care Management for Indiana University Health. As a certified case manager with over 25 years of case management experience, Adria's expertise is in care transitions, throughput, utilization management, and readmission prevention.*

Nikki Greisl, RRT, *is the Director of Indiana University Health Care Alliance Services, a statewide team of nonclinical support staff and transitional nurse case managers. Nikki has over 30 years of experience in healthcare, including 20 years in the post-acute setting, and a certification in leadership coaching.*

Kasey Burke, MSN, RN, CCM, ACM-RN, *also serves as a Clinical Program Manager for the statewide Integrated Care Management team at Indiana University Health. Kasey has 15 years of health care experience, and she has spent the last 6 years leading team members in both acute and population health case management.*

Elizabeth Altenburger, PT, MSPT, CWS, *currently serves as the Director of Acute Care and Wound Management for Rehabilitation Services at Indiana University Health's Adult Academic Health Center. She supports physical, occupational, and speech therapy and both inpatient and outpatient wound and ostomy programs at 3 hospitals. Beth is a licensed PT and Certified Wound Specialist.*

Hospitals across the United States are being challenged to overcome a consistent and pervasive issue: well-timed insurance authorization and the associated hospital discharge delays.

a hospital system internalizing their own postacute placement precert process. The literature review did confirm that awaiting health plan authorization for SNF/SAR placement is a common contributor to acute hospital discharge delays and increased length of stay (LOS) (Cai et al., 2020; Menger et al., 2017; Smith et al., 2017; Sorensen et al., 2020). Patients who experience discharge delays are at increased risk for hospital-associated deconditioning, delirium, and hospital-acquired infections. Since inpatient hospital rehabilitation services are often not equipped to provide daily physical/occupational/speech therapy, delays in discharge can also deny patients access to needed rehabilitation services (Cai, et al., 2020). Combined, these factors result in higher mortality and morbidity among patients who are medically ready yet unable to discharge to the most appropriate level of care in a timely manner (Rosman et al., 2015). The need for a viable solution was made evident by the preliminary research. The next step was to figure out how to make it happen.

Developing a Multifaceted Solution

Before this study, IU Health required SNF/SARs to manage all precerts for admission to their individual facilities. As per the SNF/SAR precert departments, established expectation for turnaround time (TAT) for precert determination averaged 48-72 hours. Internalization of the precert process offered a potential solution aimed at decreasing turnaround times, and Integrated Care Management (ICM) leadership decided to explore this option. However, internalization of the precert process would be a significant change that caused workflow alterations for multiple departments, both internal and external to the IU Health system. As change in healthcare can be challenging, it is important to begin with a team-based collaborative approach for process planning and implementation; this approach is vital to the success of process improvement in healthcare (Harrison, et al., 2021).

Identifying Stakeholders

The ICM department at IU Health is comprised of ICM leadership, nurse case managers (CMs), medical social workers (MSWs), and skilled ICM support staff. These individuals, along with rehabilitation services leadership and team members as well as postacute facility liaisons, were identified as stakeholders who would be vital to the success of the proposed process changes. One clinical program manager within ICM was designated as the lead project developer and tasked with coordinating stakeholder cohesion. Later in the development phase, there would also be 4 skilled ICM support team members who would become the core IU Health precert team, making them perhaps the most vital stakeholders. Patients and their family members were deeply affected by the process changes but were not identified stakeholders.

8-Month Pilot Program

Once stakeholders were established, a precert pilot program was initiated at seven IU Health hospitals. To focus attention on a manageable precert volume, the top 10 insurance payers for patients who were placed in an SNF/SAR during 2020 were identified. It was found that 3 of the top 10 payers were managed Medicare plans whose precerts were managed by the same 3rd party organization, and therefore a decision was made to proceed with only those 3 managed Medicare payers for the precert pilot. Contact with that 3rd party organization was established, and the 3rd party organization provided training on how to use their online portal for precert submission. Although the online portal was a no-cost solution, sensitive patient information would need to be uploaded on the portal, and thus the IU Health Information Services department was engaged to ensure that the portal met IU Health standards for information security. IU Health legal services was also involved in the early stages to ensure system compliance and legality before beginning to use the 3rd party organization online portal. Once the portal was cleared for use, the first precert request was submitted on 3/16/21. The pilot would span almost 8 months (3/16/21-10/31/21) and involved precert submission for 106 SNF/SAR admission cases. During the pilot period, standard work was developed, and necessary EMR modifications were designed and implemented.

Precert Pilot Results. A time study completed on each case revealed that the average time spent on each precert case was 75 minutes. Of the 106 cases submitted by the IU Health clinical program manager, 99 were approved with initial submission, 5 were approved after appeal, 1 was denied, and 1 was withdrawn or cancelled because of a change in the discharge plan. This high rate of approval was notably better when compared with SNF/SAR approval rates for the same payers within the same timeframe. While IU Health–initiated precerts resulted in a 99% approval rate, SNF/SAR–initiated precerts resulted in only an 83% approval rate. The pilot TAT results were also very favorable, especially when compared to the 48-72-hour TAT that our systemwide CMs

Prior authorization, sometimes called precertification (precert), is a payment qualification process used by health plans by which health care providers must obtain advance approval from a health plan before a specific service or medication can be delivered to the patient.

and MSWs were accustomed to. Even including the outlier of an approval requiring an appeal, the total average TAT for precert determination was only 3.3 hours. The precert pilot results were shared with statewide ICM director level leadership at their monthly steering committee meeting, and it was unanimously decided that the pilot should transition to a statewide program.

Personnel Resources. A validated cost-benefit analysis was completed, and historical data was used to establish the expected precert volume that helped inform productivity benchmarks. Based on time studies completed during the pilot phase and past precert volume information gathered from the 3rd party organization managing the precert determination process, it was determined that 3 precert team members and 1 team lead would be required for program initiation. A situation-background-assessment-recommendation (SBAR) was completed and approved for 3 new full-time equivalent positions within ICM. During the final month of the precert pilot, these team members were hired and turning the pilot into a systemwide fully operational program began to take shape.

Methods

Instituting a Solution Implementation Team

As stated, the pilot program involved only 7 of the 17 hospitals within the IU Health system. The standard work and initial process developed during the pilot phase was deliberately created to be scalable. There were, however, several enhancements to the established precert process that needed to occur to ensure expansion success.

Technology Tools

EMR modification was not necessary or available during the pilot phase, but it became the first important piece for program expansion. Before a go-live date of 11/1/21, a new "Precert Screen PowerForm" document was introduced and tested for viability within the IU Health EMR system. This new form was built to allow bedside CMs and MSWs across the IU Health system to quickly and easily submit a precert initiation request. Once signed, the ICM precert team was immediately alerted in the form of an electronic task within the EMR. The electronic form also gives each CM and/or MSW the opportunity to describe why SNF/SAR placement is the most appropriate discharge option for their patient. Having this depth of information provided directly from the ICM team member who is intimately familiar with the patient's situation assists in expediting the precert submission process for ICM precert team members. Additionally, the form allows for EMR reporting capabilities and provides much needed insight into each hospital's precert program utilization and compliance.

Other technologies that have proven to be essential to program success include a systemwide secure texting platform, an integrated electronic referral system (available at a limited number of hospitals), and secure email. Because the integrated electronic referral system is available at only 7 of the 17 IU Health hospitals, standard work also needed to be adapted to guarantee timely communication with every precert case, regardless of communication modes related to patient location.

Precert Team Member Education

Before go-live, the ICM team members underwent extensive orientation and education. They were trained on how to use the precert submission portal, electronic faxing, virtual printing, secure texting, EMR task lists, and additional EMR navigation specific to their role. They met with rehabilitation team members of both physical and occupational therapy disciplines to receive in-depth training about how to interpret rehabilitation progress notes. They spent time with a CM who provided education aimed at developing their understanding of rehabilitation and skilled nursing criteria for insurance approval of SNF/SAR admission. They also learned how to follow the standard work for management of precert requests, precert submission processes, appeal processes, and communication practices for each unique hospital. Most importantly, the ICM precert team learned how to recognize and build a solid case for SNF/SAR admission as well as the best practices of how to communicate approvals, peer-to-peer requests, denials, and appeal determinations to each bedside CM and/or MSW across the IU Health system.

CM, MSW, and Rehabilitation Team Member Education

Interprofessional communication methods were proposed, tested, and established, underscoring the shared ownership of program success between ICM and rehabilitation team members. Champion physical therapy, occupational therapy,

CM, and MSW team member stakeholders were identified during the pilot process, and these champions assisted in solidifying and socializing best practices for effective precert related communication. Systemwide CM and MSW team members were then educated about how to use the newly instituted "Precert Screen PowerForm" within the EMR. Multiple education sessions were offered by region to ensure that communication variations by region did not cause confusion. These presentations were recorded and shared to ensure all team members were fully informed. Job aids outlining communication flows and standard work were provided. ICM and rehabilitation teams were informed about their own responsibilities and expectations related to changes to their existing workflows. All education sessions were focused on enhancing interprofessional collaboration while fostering partnership and buy-in for precert process changes.

Teamwork as a Context

From the first conversations about how to design and implement this program, the extreme importance of every team member involved was deeply understood. It cannot be stressed enough that this context was to inform every aspect of the program. ICM leadership, rehabilitation services leadership, and team members in each of these departments across the state were involved in the development of their own standard work. Their continued feedback was asked for and listened to every step of the way. New avenues for open communication were cultivated and promoted that led to unprecedented collaboration between the two disciplines (care management and rehabilitation services). This level of teamwork has proven to be invaluable.

Evaluating for Success

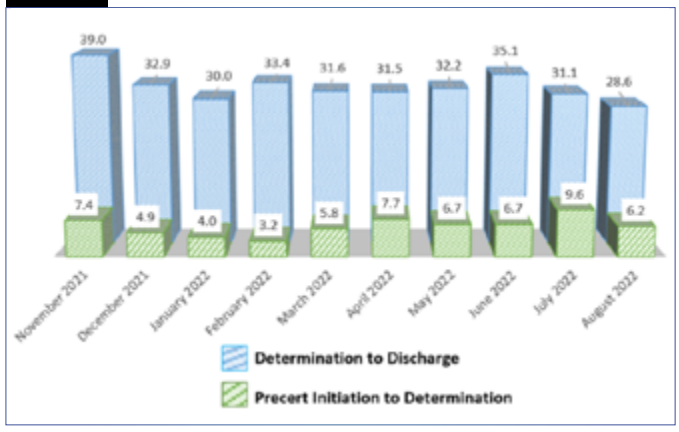
Precert Program Results

Data collection methods were built into the initial design of the precert program so that evaluating efficacy would be possible. ICM precert team members record 21 unique pieces of information for each precert submission. The information is collected on a shared spreadsheet. Included in the information is patient location, medical record number, exact date and time of precert submission, exact date and time precert determination is received, precert status outcome, exact discharge date and time, and several other pertinent items. This thorough collection of data reveals much.

Turnaround Time (TAT)

As predicted during the 8-month pilot phase, turnaround times remained consistently low. As seen in Figure 1, the monthly average TAT ranged from 3.2 to 9.6 hours, with a total average TAT of 6.4 hours. One possible explanation for seeing such a dramatic decrease in TAT when compared to SNF/SAR submission results is what the managing 3rd party organization calls "Additional Clinical Requests" (ACRs). ACRs can delay determination while the insurance reviewer waits for adequate clinical documentation. During the first 10 months of the precert program, only 17% of IU Health precert team submissions resulted in an ACR, while SNF/SAR precert submissions within the same timeframe resulted in ACRs for 48% of their total cases.

FIGURE 1 PRECERT PROGRAM TURNAROUND TIME—EXCLUDING OUTLIERS.



Approval and Denial Rates

Comparing approval and denial rates also demonstrates precert program success. While SNF/SAR submission resulted in a 16% denial rate from 11/1/21 to 8/31/22, the IU Health precert team had an overall denial rate of only 9% during the same period. This IU Health data was collected by the internal precert team and validated by data collected by the 3rd party organization. While a 91% approval rate is excellent, the goal is to have a 100% approval rate. To better interpret denial trends, denial reasons are captured and analyzed on each case. This research has shown that 84% of all denials occurred due to insufficient criteria to justify a SNF/SAR admission per Medicare guidelines. This realization prompted additional educational sessions for statewide ICM and rehabilitation team members to provide in depth information about Medicare guidelines for SNF/SAR placement. Interestingly, the education was provided in July and a sharp decline in denial rates was immediately recognized. It is believed that the statewide education session caused fewer precert requests to be submitted for patients who simply did not meet criteria.

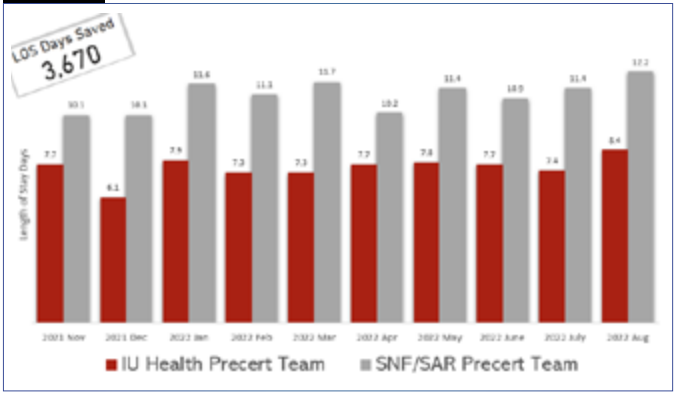
Increased Efficiencies

IU Health ICM leadership partnered with financial analysts within the Strategic Financial Planning department to develop a way to understand if these fast turnaround

Patients who experience discharge delays are at increased risk for hospital-associated deconditioning, delirium, and hospital-acquired infections. Since inpatient hospital rehabilitation services are often not equipped to provide daily physical/occupational/speech therapy, delays in discharge can also deny patients access to needed rehabilitation services.

times and high approval rates were having a positive impact on LOS and throughput. With the creation of a "Precert Dashboard," it was discovered that the impact was unquestionable. The new dashboard uses an algorithm that first examines patients who required a precert for a discharge disposition of SAR/SNF, analyzing LOS, diagnosis, and acuity. It then compares outcomes for patients whose precert was completed by the IU Health precert team vs. those not completed by the IU Health precert team. The dashboard revealed that from 11/1/21 to 8/31/22, precerts completed by IU Health resulted in 3,661 LOS days saved, which led to 687 backfilled cases, resulting in a variable direct cost savings of $7,495,407. Perhaps the most remarkable impact can be seen in a LOS comparison (Figure 2) that shows an overall differentiation of 7.5 vs. 11.1 days. Patients are benefiting from this expedited process by getting to the most appropriate level of care more quickly. And patients who are awaiting a bed in the emergency department or post-anesthesia care unit also benefit as they can backfill a bed and receive the care they need.

FIGURE 2 LENGTH OF STAY (LOS) COMPARISON WITH DAYS SAVED



Limitations

"Capture Rate." As stated, the IU Health precert program currently focuses on 4 managed Medicare payers. It is estimated that the IU Health ICM precert team is currently submitting only 16.6% of the total SNF/SAR placement precerts across the system for all payers. While there is a plan for the program to ultimately handle precerts for all levels of care and all payers, the program is currently limited by insufficient personnel to carry out such expansion.

SNF/SAR Initiating Precerts. Skilled nursing facilities submitting their own precerts has continued to be a frustration. According to the 3rd party organization that manages the authorization requests, IU Health is completing an average of 67% of the total precerts, while the SNF/SAR is continuing to average 33% of precert submissions initiated for IU Health patients. In some cases, this is happening when the SNF/SAR facility initiates a precert without being asked to do so. Other cases are caused by the CM or MSW forgetting to submit the precert PowerForm and instead asking the facility to initiate precert.

Communication Variations across IU Health System. Various forms of communication are required at different hospitals due to variations in standard work across the system. Some hospitals rely on secure email for team communication, while others rely on a secure texting platform. Yet another variation is use of an electronic referral system. Communication flow charts have been built and are being used by the ICM precert team members so that they can ensure that each individual hospital's communication preferences are being honored. Standardizing communication platforms across the system would reduce confusion and ultimately improve consistent transmission of urgent precert-related messages.

Next Steps

As program efficacy and impact has been established, the clear path forward is expansion. This will begin by partnering with more health plans to increase the overall capture rate. As the precert volume increases, so too will the number of team members on the IU Health precert team.

Conclusion

ICM team members across the IU Health system have been profoundly impacted by this internalized precert program. CMs, MSWs, and the skilled ICM support staff are responsible for the daily work required to maintain the precert

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CE2 Approved for 1 hour of CCM, CDMS, and nursing education credit
Exam expires on June 15, 2023

Fentanyl: The Silent Opioid Epidemic

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

A recent news story in Chicago highlighted the dangers of fentanyl and the high risk of overdose for concertgoers at the Lollapalooza event in July 2022. The news story urged concertgoers to test their substances for fentanyl with "test strips" that were made available at the event for free, no questions asked.

Miller (2021) states, "Regardless of whether they know it, many case managers are faced with patients and clients each day who are struggling with opioid use disorder (OUD). As rates of OUD continue to increase, it is essential for case managers to hone their skills of confidently recognizing and addressing the disorder."

What is already known about fentanyl?

The addition of fentanyl to other "recreational drugs" has resulted in an increase in fentanyl overdoses and deaths. Synthetic opioids accounted for more deaths than any other type of opioid.

Fentanyl contamination of other substances accounts for most of the opioid-related overdose deaths, and the numbers continue to rise year after year. Higher-risk populations include older Black and Native American/Alaskan males and younger Hispanic males. Social determinants of health, including access to care (mental health and substance treatment programs) have a negative influence on overdose prevention.

Background

Although the origins of increased opioid use were well-intended attempts at optimal pain management, the result has become a costly increase in OUD diagnoses and related deaths, with little evidence of reduction in chronic noncancer pain. OUD is the chronic use of opioids that causes clinically significant distress or impairment. Opioid use disorders affect over 16 million people worldwide and over 2.1 million people in the United States. Over 120,000 deaths worldwide annually are attributed to opioids.

OUD is a chronic medical condition.

- The diagnosis of OUD is based on the American Psychiatric Association DSM-5 and includes a desire to obtain and take opioids despite social and professional consequences.
- Examples of opioids include heroin, morphine, codeine, fentanyl, and synthetic opioids such as oxycodone.
- OUD consists of an overpowering desire to use opioids, increased opioid tolerance, and withdrawal syndrome when discontinued.
- OUD includes dependence and addiction, with addiction representing the most severe form of the disorder (CMSA, 2018).

The Centers for Disease Control and Prevention (CDC) approximates that the economic burden of opioid misuse in the United States is $78.5 billion a year. The statistics are overwhelming. Historical data shows the following:

- Nearly 29% of those prescribed opioids will misuse them
- Up to 12% develop an OUD, and an estimated 6% who misuse prescription opioids will transition to heroin
- Opioid overdoses rose by 30% in over 45 states, while the Midwest experienced overdose increases of 70% (CareExcellence, 2021).

A subset of the opioid epidemic has been the recent development of increased fentanyl overdoses. Fentanyl is a synthetic opioid that is 100 times more potent than morphine and 50 times more potent than heroin (National Institute on Drug Abuse, 2021). Fentanyl can be taken as a powder, as liquid used on blotter paper, as a patch for transdermal use, or as eye drops or nasal sprays; it can also be added into other drugs (National Institute on Drug Abuse, 2021). Fentanyl requires very little drug intake to create a "high" and costs significantly less, making it attractive to drug dealers as a cheap but dangerous additive to other drugs. Common

Dr. Colleen Morley, DNP, RN, CCM, CMAC, CMCN, ACM-RN, FCM, *is the current President of the Case Management Society of America National Board of Directors and Associate Chief Clinical Operations–Continuum of Care at University of Illinois Hospital and Health Sciences System. Her current passion is in the area of improving health literacy. She recently authored her 1st book, "A Practical Guide to Acute Care Case Management." Dr. Morley has over 20 years of nursing experience. Her clinical specialties include medical/surgical, oncology, and pediatric nursing.*

Opioid use disorders affect over 16 million people worldwide and over 2.1 million people in the United States. Over 120,000 deaths worldwide annually are attributed to opioids.

substances that fentanyl have been noted to be mixed with include heroin, cocaine, methamphetamine, and 3,4-Methyl enedioxymethamphetamine (MDMA) (National Institute on Drug Abuse, 2021). Fentanyl is hard to detect, and even a small amount can be lethal.

The addition of fentanyl to other "recreational drugs" has created an increase in fentanyl overdoses and deaths. According to the CDC, over 56,000 synthetic opioid deaths in 2020 were reported in the United States. Synthetic opioids accounted for more deaths than any other type of opioid. Additionally, the CDC reported that "synthetic opioid-involved deaths rates increased by over 56% from 2019 to 2020 and accounted for over 82% of all opioid-related deaths in 2020" (Centers for Disease Control and Prevention, 2022).

Discussion

A search of the key words "fentanyl" and "overdose" led to articles from Departments of Public Health or Human Services from across the United States that described the impact that fentanyl is having. Fentanyl remains the deadliest drug threat facing this country. According to the CDC, 107,622 Americans died of drug overdoses in 2021, with 66% of those deaths related to synthetic opioids like fentanyl. Drug poisonings are the leading killer of Americans between the ages of 18 and 45 (Centers for Disease Control and Prevention, 2022).

In Illinois, the Illinois Department of Public Health (2022) reported that in 2021 there were 3,013 deaths attributed to fentanyl overdose, a 35% increase from 2019. The Wisconsin Department of Health Services (2022) reported 1,280 deaths from fentanyl in 2021, a 97% increase from 2019 numbers. The Massachusetts Department of Public health noted that approximate 2,290 people died from an opioid-related overdose in 2021, an 8.8% increase from 2020 (Komaromy, 2022). Similarly, North Carolina had 3,163 deaths, an increase of 616% over 2016, and Colorado reported that fentanyl-related deaths increased over 1200% over a 5-year period (Hudson-Matthew et al., 2022); the increase in deaths shows that every state is impacted by the fentanyl epidemic (Killian, 2022). National statistics note that from "May 2020 to April 2021, overdose deaths topped 100,000 for the first time, with 64% of deaths involving fentanyl" (Killian, 2022).

The CDC "Synthetic Opioid Overdose Data" reports that "increases in the synthetic opioid deaths have been associated with the number of drug submissions obtained by law enforcement that test positive for fentanyl but are not consistent with fentanyl prescribing rates" (Centers for Disease Control and Prevention, 2022). These data suggest that most recent cases of fentanyl-related overdoses are linked to illicitly manufactured fentanyl than to fentanyl obtained through prescription or pharmacy routes. Populations affected are widespread. CDC data report increases in fentanyl-related deaths in diverse areas, including all settings from rural to large metropolitan (Centers for Disease Control and Prevention, 2022).

Additionally, the Drug Enforcement Administration is advising the public of an alarming emerging trend of colorful fentanyl available across the United States. Since August 2022, DEA and our law enforcement partners seized brightly colored fentanyl and fentanyl pills in 26 states. Dubbed "rainbow fentanyl" in the media, this trend appears to be a new method used by drug cartels to sell highly addictive and potentially deadly fentanyl made to look like candy to children and young people.

"Rainbow fentanyl—fentanyl pills and powder that come in a variety of bright colors, shapes, and sizes—is a deliberate effort by drug traffickers to drive addiction amongst kids and young adults" (United States Department of Justice, Drug Enforcement Agency, 2022).

As fentanyl is highly lethal, people who do not use drugs regularly are at the same risk as those who do. First-time users of recreational drugs are just as susceptible to a fatal overdose as regular users if the substance has had fentanyl added. Overdose deaths increased in all racial and ethnic groups, although Massachusetts reported an "extreme escalation of overdose deaths in 2020 for Black Americans." This study suggests that Black Americans, historically marginalized, are more vulnerable because they often rely on illicit drug supplies that are more likely to include fentanyl (Komoromy, 2022). CDC data report that overdose deaths increased the most in Black (44% increase) and Native American/Native Alaskan (39% increase) populations (Kariisa et al, 2022). The highest rate of reported overdose deaths in 2020 was in Black males between 45-64 years of age (52.6%), a rate that was nearly 7 times higher than their White counterparts. Hispanic males between 25-44 years of age demonstrated a risk of 47.6% and alarmingly, the overdose death rate for Hispanic males between 12–24 years of age increased

by 47% between 2019 and 2020 (Kariisa et al, 2022).

Individuals who have been recently released from institutions such as correctional facilities, inpatient rehabilitation programs, or psychiatric facilities are at additional risk for fentanyl overdoses. Individuals who have experienced a previous overdose are at higher risk than those who have not. A mental health diagnosis or substance use disorder diagnosis was recorded in the medical records of 20%-25% of individuals whose deaths were due to drug overdoses (Kariisa et al, 2022).

Social Determinants of Health Impact

The impact of the social determinants of health (SDOH) cannot be overlooked. SDOH are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. Resolution of gaps related to SDOH, such as access to care in the form of mental health services or opioid treatment programs, can play a large factor in overdose death prevention.

"Examples of SDOH include (but are not limited to) gender inequality, structural racism, stigma, poverty, citizenship status, education, housing, transportation, health systems and services, social safety network, food insecurity, unemployment/employment and working conditions, public safety, and social exclusion/inclusion" (Opioid Response Network, 2021).

Local communities are called upon to address the opioid crisis through filling the gaps related to an individual's SDOH risks. These SDOH are responsible for approximately 80% of health outcomes. Addressing the SDOH can help prevent opioid addiction and decrease overall overdose deaths while improving the lives of individuals with OUD. The gaps may involve interventions across the continuum of care: prevention, harm reduction, treatment, and recovery. They postulate that primary prevention and ongoing treatment of those with OUD can be supported, in large part, by addressing SDOH. The categories for SDOH are shown in figure 1.

The Opioid Response Network states "there are clear linkages between poor health and structural factors such as poverty, lack of opportunity, and substandard living and working conditions. Counties with the lowest levels of social capital have the highest overdose rates. Economic hardship, social isolation, and hopelessness are key reasons for drug use. Poverty and substance use, reinforced by untreated mental health disorders and lack of stable housing, are correlated with OUD in underserved communities. Therefore, viable employment, safe housing, and community reinvestment initiatives are needed to reduce high overdose deaths" (Opioid Response Network, 2021).

Every community is different, every person is different. There is no "one-size-fits-all" solution. It is important to recognize that unhealthy substance use and addiction do not happen in a vacuum. Previous strategies of addressing OUD tended to focus on a single solution for addiction response rather than addressing creating conditions that can prevent unhealthy substance use and support recovery simultaneously. Primary prevention efforts that address SDOH can also support recovery efforts and are recommended for implementation.

Strategies

Strategies to address the fentanyl overdose epidemic include raising awareness through multichannel outreach and community education on the dangers of fentanyl, increasing accessibility of testing kits, and increasing mental health resource availability.

CDC's Overdose Data to Action (OD2A) notes the 5

FIGURE 1 SOCIAL DETERMINANTS OF HEALTH CATEGORIES

ECONOMIC STABILITY	NEIGHBORHOOD AND PHYSICAL ENVIRONMENT	EDUCATION	FOOD	COMMUNITY AND SOCIAL CONTEXT	HEALTHCARE SYSTEM
Employment	Housing	Literacy	Hunger	Social Integration	Health Provider Availability
Income	Transportation	Language	Access to Healthy Options	Support Systems	Provider Linguistic and Cultural Competency
Expenses	Safety	Early Childhood Education		Community Engagement	Quality of Care
Debt	Parks	Vocational Training		Discrimination	
Medical Bills	Playgrounds	Higher Education			
Support	Walkability				

HEALTHY OUTCOMES

Mortality, Morbidity, Life Expectancy, Health Care Expenditures, Health Status, Functional Limiations

Adapted from Healthy People 2030.

A subset of the opioid epidemic has been the recent development of increased fentanyl overdoses. Fentanyl is a synthetic opioid that is 100 times more potent than morphine and 50 times more potent than heroin.

strategies to address the opioid crisis: (1) conduct surveillance and research to track data trends and bring attention to the issues; (2) build state, local, and tribal capacity to address overdose issues based on data; (3) support providers, health systems, and payers through provision of clinical tools and resources, online training modules, and encouragement to utilize the Prescription Drug Monitoring program; (4) partner with public safety to offer evidence-based strategies that can be implemented at any level and (5) empower consumers to make safe choices through education, shared stories, and public awareness campaigns (Centers for Disease Prevention and Control, 2022).

The Legislative Analysis and Public Policy Association (2022) reports that as of July 2022, all 50 states in the United States and the District of Columbia have enacted "some form of naloxone access law" (Legislative Analysis and Public Policy Association, 2022). In general, a core group of individuals (physicians, advanced practice nurses, pharmacists, individuals at risk of opioid overdose, and friends and family of those individuals) are authorized to prescribe, dispense, and /or administer naloxone, after completing the appropriate training program.

The National Coalition Against Prescription Drug Abuse has created educational materials with "safer drug use tips" for the public. The "Expect Fentanyl" campaign notes that fentanyl is "contaminating fake prescription pills, heroin, methamphetamine, cocaine, and other drugs" (National Coalition Against Prescription Drug Abuse, 2022). Recommendations include to carry naloxone, use one substance at a time, never use alone, always assume contamination and test your substances prior to use, and to go "low and slow," using a small amount at first (National Coalition Against Prescription Drug Abuse, 2022).

The National Academy of Medicine has created the "Action Collaborative on Countering the U.S. Opioid Epidemic." The collaborative is "a public-private partnership made up of 60 participants representing federal, state, and local governments; health systems; associations and provider groups; health education and accrediting institutions; pharmacies; payers; industry; nonprofits; and academia. The Action Collaborative is committed to developing, curating, and disseminating multisector solutions designed to reduce opioid misuse and improve outcomes for individuals, families, and communities affected by the opioid crisis (National Academy of Medicine, 2021). The Collaborative's focus is on 4 core priority areas: health professional education and training; pain management guidelines and evidence standards; prevention, treatment, and recovery services; and research, data and metrics needs. The goals of the Action Collaborative include:

- Identify and raise the visibility of complex challenges, outstanding research gaps, and needs of the opioid crisis that require a collective multisectoral response
- Elevate and accelerate evidence-based, multisectoral, and interprofessional solutions to improve outcomes for those affected by the opioid crisis
- Catalyze action on shared priorities and solutions to help overcome the crisis and improve outcomes for all

Case Management's Role

"Case managers have the expertise and knowledge to assess individual needs, identify treatments, and provide education to the patient and family system. Since an opioid addiction is complicated by life-or-death consequences, a comprehensive and timely approach is essential" (CareExcellence, 2021). The role of the professional case is multifocal. Case managers provide the needed assistance, support, facilitation, and coordination of the precise details of the treatment (CMSA, 2018). Case managers must be part of the care team from the beginning to help create patient-centered care plans. "One of the strongest rationales for case management in opioid addiction evaluation and treatment may be that care managers consolidate a single point of contact for clients who receive services across multiple agencies. This reduces a haphazard communication structure and increases the potential for success" (CareExcellence, 2021).

The professional case manager should:

- Assess patients/clients/members using evidence-based assessment tools such as CAGE, TAPS, ORT and the 5 A's.
- Avail themselves of the tools, resources, and training available at the CDC site
- Understand the naloxone laws and your discipline's Practice Act in your state for guidance in treatment of high-risk patients
- Be aware of the issues related to caring for potential

Strategies to address the fentanyl overdose epidemic include raising awareness through multichannel outreach and community education on the dangers of fentanyl, increasing accessibility of testing kits, and increasing mental health resource availability.

fentanyl overdose patients; naloxone can be effective, but fentanyl-related overdoses may require more than one dose of naloxone. Educate appropriately.
- Ask your patients/clients/members about substance use, using motivational interviewing techniques and a nonjudgmental approach.
- Educate patients about the dangers of fentanyl being mixed into drugs without their knowledge and use the National Coalition Against Prescription Drug Abuse recommendations on substance use
- Educate patients about testing their drugs and direct them to locations where they can get testing kits. Know the resources available in your area for recovery support

Conclusion

Miller's (2021) interview with Rebecca Perez sums it up very well: "Due to the all-encompassing nature of their role, case managers play an integral part in helping patients access treatment options. Case managers should continue educating themselves about opioid use and its effect on their patients and community." "Case managers are life-long learners," Perez explains. "They need to stay on the cutting edge of how best practices evolve. Providing resources on how and where to guide patients to treatment is one of the most critical interventions."

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Medical Cannabis and Workers' Compensation: Ethical Considerations for the Care Manager

Chikita Mann, MSN, RN, CCM

Scenario: Mr. Strange, a construction worker, fell 250 feet and sustained a traumatic brain injury (TBI) and spinal cord injury (SCI). He has undergone rehabilitation for both the TBI and SCI. He has been receiving long-term opioid therapy and wants to discontinue taking opioids. He would like to use medical marijuana for treatment. He admitted to the board-certified case manager who is coordinating his care that he has been smoking marijuana and prefers using marijuana instead of opioids. The client does not live in a state that has legalized medical cannabis. How should the board-certified case manager proceed?

The use of medical marijuana (or cannabis) for medical conditions has been gaining traction in the past 20 years. It is estimated that over 3 million Americans use cannabis in some form for different illnesses (Ryan et al., 2021). The opioid epidemic is now a public health crisis and national emergency. Since 2003, opioid prescriptions for work-related injuries have been steadily rising (O'Hara et al., 2018). It is estimated that overdose deaths from opioids in the United States increased to 75,673 in the 12-month period ending in April 2021. The annual costs of opioid overdose, misuse, and dependence were estimated to be $35 billion in health care costs and $92 billion in lost productivity (Pew Charitable Trust, 2021). Opioid overdose, misuse, and dependence directly and indirectly affect the workforce in the form of absenteeism (time missed from work) and presenteeism (being at work but not being productive).

Another reason for the increase in use of medical cannabis is the effect that long-term opioid use can have on the client psychologically, emotionally, and physically. The most obvious results are dependence, abuse, and misuse. Medical risks include chronic constipation, bowel obstruction, erectile dysfunction, osteoporosis, and immunosuppression. Psychological sequalae include depression and anxiety (Darnall et al., 2012; Von Korff et al., 2011).

The use of medical marijuana is complicated, especially when it comes to the workplace. What is legal (ie, what is permitted by law) and what is ethical (ie, morally right or wrong) can vary greatly. This can pose a range of ethical quandaries for the board-certified case manager who is coordinating care.

A major concern for using marijuana and/or medications derived from cannabis is that marijuana and/or medications derived from cannabis are classified as a Schedule 1 drug by the U.S. Drug Enforcement Administration (DEA). A Schedule 1 drug has a high potential for addiction and abuse. In addition, there is a lack of research to substantiate a request to use medical cannabis for medical conditions. Another major deterrent to using medical cannabis is the national zero-tolerance stance toward illicit drugs (Clark et al., 2011; Russell, 2019).

A state can legalize the use of medical and recreational cannabis, but it does not mean it is legal for the workplace. For employers who are federal contractors, the Drug-Free Workplace Act (DFWA) mandates a drug-free workplace. These employers must have protocols in place that ban the use of cannabis—medical or recreational. But for employers who are not federal contractors, there are questions that present complex situations that are neither black or white, but different shades of gray. What if the employee uses recreational marijuana in a state that has legalized it but they drive a company vehicle or operate heavy machinery? What if an employee has a documented approved medical condition that allows the use of medical cannabis? What if the employee lives in a state that has legalized medical cannabis but they work in a state that has not legalized medical cannabis? The employee could attempt to justify use of medical cannabis under the American Disabilities Act (ADA). However, the ADA does not provide immunity since medical cannabis is still classified federally as an illicit drug. Therefore, the employer is not obligated to accommodate its use, even if the state has legalized its use (Legal issues: Marijuana in the Workplace 2022).

Chikita Mann, MSN, RN, CCM *served as a Commissioner of the Commission for Case Manager Certification (CCMC). The CCMC is the first and largest nationally accredited organization that certifies case managers with its Certified Case Manager® (CCM®) certification. With more than 25 years of experience in case management, Chikita is currently a complex/catastrophic worker compensation case manager with a multinational property and casualty insurer and carrier.*

The use of medical marijuana (or cannabis) for medical conditions has been gaining traction in the past 20 years. It is estimated that over 3 million Americans use cannabis in some form for different illnesses.

In this article, we describe cannabis and discuss why it is being considered as appropriate treatment for some work-related injuries. We also discuss why cannabis use in the workplace can present ethical dilemmas for the board-certified case manager when coordinating care for the client. Last, we explore how to navigate ethical situations that can arise with regard to the use of cannabis.

Cannabis Description

The two major active ingredients in cannabis (cannabinoids) are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is the psychoactive component, and CBD has no psychoactive effects (Argueta et al., 2020). Marinol and Cesamet are THC-based; therefore, the client may experience a slight euphoria from using these medications. Syndros is a liquid form of Marinol; therefore, it contains THC. These are all oral forms of cannabis. One major disadvantage to oral administration is the delayed effects due to slow absorption (Russell, 2019).

The most common route of cannabis administration is by inhalation (smoking the plant, oils, or resin). This method takes effect within 15–45 minutes of inhalation and is rapidly absorbed into the bloodstream. A major disadvantage of this method is intake of carbon monoxide and its consequent effect on the respiratory system. Another disadvantage is that inhaled cannabis is not regulated and can contain other products that can prove detrimental to the client's health.

Transdermal application of cannabis is another route for consideration. There are benefits associated with this route that can make it an attractive option, and this route has been found to reduce the potential for abuse and improve dosing regimens. The client would not be subject to pulmonary irritants that are often present with inhaled administration (Goldsmith et al., 2015).

The U.S. Food and Drug Administration (FDA) has approved one cannabis-derived medication, Epidiolex, and three synthetic cannabis-related medications (Marinol, Syndros, and Cesamet). These medications can only be prescribed by a licensed healthcare provider (FDA and cannabis: Research and Drug Approval Process, 2020). Epidolex is classified as Schedule V because it has an accepted medical use for treatment. Syndros and Cesamet are classified as Schedule II (high potential for abuse); Marinol is classified as Schedule III (low to moderate potential for psychological and physical dependence) (Russell, 2019).

Uses for Medical Cannabis

Clients who have a condition that validates the reason for receiving medical cannabis (medical marijuana) must be treated by a licensed physician who must certify their qualifying condition (Boehnke et al., 2019). Even with certification by a physician, an employer may be hesitant to allow a client who uses medical marijuana to work because it could pose a safety risk to the worker and their coworkers. Medical marijuana has been documented for treating glaucoma, chronic pain, headaches, and migraines (which could result from a moderate to severe TBI), spinal cord injuries, and psychological disorders (posttraumatic stress disorders, anxiety, depression) (Russell, 2019).

On-the-job injuries that can lead to an inquiry into medical cannabis as a treatment choice are musculoskeletal injuries, spinal cord injuries, traumatic brain injuries, and posttraumatic stress disorders resulting from a traumatic work-related event. Chronic musculoskeletal pain is a major cause of disability. These range from simple sprains and strains to complex injuries such as spinal cord injuries. It is posited that chronic musculoskeletal pain is a leading reason for opioid therapy (Johal et al., 2020). Complex injuries can lead to chronic pain, which would usually be treated by long-term opioid therapy.

Medical Cannabis and the Workplace

Workplace safety is a growing concern, and use of medical marijuana further complicates the matter. The Occupational Safety and Health Administration (OSHA) and DFWA have normally taken an unwavering stance against drug impairment in the workplace. This stance is understandable because there is a correlation between workplace accidents and illicit drug use. Federal law can prohibit employees from working under the influence. Studies have shown an association between cannabis use and increased risk for motor vehicle accidents and fatal collisions (Goldsmith et al., 2015). The National Safety Council (NSC) presented a position statement of cannabis' negative effect on cognitive function and

The use of medical marijuana is complicated, especially when it comes to the workplace. What is legal (ie, what is permitted by law) and what is ethical (ie, morally right or wrong) can vary greatly. This can pose a range of ethical quandaries for the board-certified case manager who is coordinating care.

psychomotor skills. This poses a safety risk to the client and their coworkers. The National Institute on Drug Abuse (NIDA) reported the results of a study showing that cannabis use contributed to increased absenteeism among employees. The National Institute for Occupational Safety & Health (NIOSH) and National Council on Compensation Insurance (NCCI) are working to conduct research to examine cannabis' positive and negative impact on workplace safety (CDC, 2020).

States that permit medical and recreational cannabis use present another indirect, but concerning, situation for employers. It has been common practice for employers to perform drug testing. Depending upon the work-related injury (eg, fall, motor vehicle accidents), a drug screen is usually requested. Employers could be prohibited from testing employees. For states that still classify cannabis use as illegal, they may maintain the right to upholding a zero-tolerance stance. Regarding recreational cannabis use, employers can enforce policies that prohibit employees from coming to work under the influence (Legal issues: Marijuana in the Workplace 2022).

Considerations for the Board-Certified Case Manager

The guidelines in the Code of Professional Conduct for Case Managers/CDMS (Certified Disability Management Specialist) Code of Professional Conduct provide a solid foundation for the board-certified case manager to guide their practice with a controversial subject like medical cannabis and worker compensation (CCMC®, 2015) (Table 1).

TABLE 1 PRINCIPLES OF THE CODE OF PROFESSIONAL CONDUCT FOR CASE MANAGERS

1. **Board-certified case managers will place the public interest above their own at all times.**
2. **Board-certified case managers will respect the rights and inherent dignity of all of their clients.**
3. **Board-certified case managers will always maintain objectivity in their relationships with clients.**
4. **Board-certified case managers will act with integrity and fidelity with clients and others.**
5. **Board-certified case managers will maintain their competency at a level that ensures their clients will receive the highest quality of service.**
6. **Board-certified case managers will honor the integrity of the CCM designation and adhere to the requirements for its use.**
7. **Board-certified case managers will obey all laws and regulations.**
8. **Board-certified case managers will help maintain the integrity of the Code, by responding to requests for public comments to review and revise the code, thus helping ensure its consistency with current practice.**

Assessment

It is important for the board-certified case manager to use a person-centered approach when interacting with a client. If during the assessment the client states they are taking medical marijuana, the board-certified case manager should ask if they are registered with their state's medical marijuana program. Clients who are considered to have a qualifying condition should be registered with their state's medical marijuana program (MMP). This program specifies the qualifying condition, the certifying process, and the health care provider who is certified to designate the qualifying condition. The MMP will also designate the caregiver who can administer and obtain the medical cannabis for the client (Nursing care of the patient using medical marijuana, 2018).

The board-certified case manager should confirm with the client that all their treating physicians are aware of medical cannabis being a part of their treatment plan. Because this could be a sensitive subject to address with the client, the motivational interviewing process will enable the board-certified case manager to develop a trusting therapeutic relationship with the client. Because of the psychoactive component, the board-certified case manager should put extra emphasis on assessing the client's psychosocial status as well as their substance use history. The board-certified case manager should be clear in informing the client that they are not an expert and that they need to direct all their questions to the certified health care provider.

Medical reconciliation is paramount in performing the assessment of the client. The client could be using medical marijuana for a non-work-related injury. The ethical dilemma comes with the board-certified case manager disclosing this to the payor source. The client may not be allowed to return to work because he or she is using medical marijuana. As

The guidelines in the Code of Professional Conduct for Case Managers/CDMS (Certified Disability Management Specialist) Code of Professional Conduct provide a solid foundation for the board-certified case manager to guide their practice with a controversial subject like medical cannabis and worker compensation.

discussed before, the ADA does not provide protection for these situations because cannabis is classified federally as an illegal drug.

Ethical Considerations

The use of medical cannabis creates a unique ethical issue because it can be viewed as both good and evil. It can present issues that cause a battle between what is legal and what is ethical, and which one should prevail. For instance, a client with a qualifying condition may live in a state that has not legally approved cannabis, yet they live 10 minutes from the border of a state that has legalized medical cannabis. The "good" effect could be smoking marijuana because it is quick-acting, and the "evil" effect is exposure to possible toxins.

The board-certified case manager is required to obey all state and federal laws that govern their duties. Use of medical cannabis is complicated because some states allow use of medical cannabis but the federal government classifies medical cannabis as a Schedule 1 drug. Medical marijuana is legal in the following states: Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Illinois, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Utah, Vermont, Virginia, Washington, and West Virginia. The only states that have not legalized medical marijuana are Alabama, Idaho, Nebraska, North Carolina, South Carolina, Tennessee, and Wyoming (States with medical marijuana 2022, n.d.). This is important for the board-certified case manager to know because medical treatment for worker compensation is often guided by state jurisdictional guidelines. However, as stated previously, federal law supersedes state law with this unique issue. Knowing this can help guide the board-certified case manager navigate ethical scenarios that could arise related to care coordination for clients who use medical marijuana.

Another factor to contemplate is the payor source agreeing to pay for medical cannabis treatment. Obtaining reimbursement for cannabis treatment requires a thorough look at several elements. There must be evidence of a qualifying medical condition. As stated previously, the client should provide proof of being enrolled in their state's medical cannabis program. There should also be documentation that all other treatment has been tried and proven to be ineffective. The board-certified case manager should additionally explain to the client that there is a possibility that the payor source could decide not to pay for the prescribed medical cannabis because medical cannabis is still classified as an illicit drug.

Veracity

For worker compensation cases, the payor source is privy to health information for those injured on the job to coordinate care and process claims. If the board-certified case manager is not a direct employee of the payor source, then he or she will need to disclose to the client that they will need to inform the payor source (third party) of everything that pertains to their treatment. Along with this, the CCMC Code of Professional Conduct states that the board-certified case manager should explain all dual relationships that may exist. It is imperative that the board-certified case manager thoroughly explain their role and responsibilities so that the client understands who makes the final decision about what is/is not being financially covered.

Maintaining confidentiality for clients who are using medical cannabis can be challenging for the board-certified case manager. If the client is using medical cannabis for a non-work-related condition, the board-certified case manager should inform the client of the need to share this information with the authorized treating physician for their work-related injury. Even if the client is taking medical cannabis for a non-work-related injury, it could still affect the client's ability to return to work. Cannabis causes cognitive impairment in the areas of memory, attention, and executive function (Urits, et al, 2021). If a medication affects how one thinks, it could affect a client's ability to drive and operate machinery.

Another issue that could arise related to veracity is if the client has not registered with their state's medical cannabis program. Because of the dual relationship that the board-certified case manager has with the payor source, they must disclose to the client that this will be relayed to the payor source. Because the payor source assumes responsibility for approved medical treatment, they must be informed if the client is/is not in compliance with mandates concerning a

treatment. This should also be discussed with the client's treating physician who prescribed medical cannabis for treatment.

Advocacy

To be a true advocate, the board-certified case manager must know about available treatment options and be prepared to learn about treatment options that they are not aware of. For worker compensation, the board-certified case manager is usually educating both the payor source and the client and will need to have detailed conversations with the authorized treating physician about the benefits and risks associated with medical cannabis. These conversations need to be conveyed to the client and payor source. The board-certified case manager also needs to deal with their own views about medical cannabis and not allow their views to affect their ability to be an effective advocate. The focus should be on providing material to educate the client that enables the client to make an informed decision about their medical treatment. Case managers in disability management come from different backgrounds (ie, nurses, social workers, rehabilitation), but these guidelines from the National Council of State Boards of Nursing provide an excellent foundation for care coordination (https://www.ncsbn.org/nursing-regulation/practice/marijuana-guidelines.page).

Another ethical quandary the board-certified case manager may face is if they agree with the use of medical cannabis. They should keep in mind that the board-certified case manager is not able to direct care. This must be conveyed to the client because the client may see the board-certified case manager as a means to get the medical cannabis approved. The board-certified case manager should maintain objectivity and refrain from imposing their opinions for or against medical cannabis treatment. If the client decides to self-medicate, the board-certified case manager must disclose that this information could be provided to the payor source and to the treating physician.

Autonomy

Acknowledging and respecting the client's autonomy helps build the therapeutic relationship between the board-certified case manager and the client, providing a foundation to guide conversations between the client and board-certified case manager regarding the use of medical cannabis. Acknowledging the client's autonomy also means understanding the client's right to choose and refuse treatment. The client may refuse to accept prescribed opioids and decide to self-medicate by smoking cannabis. If the client does choose to do this, the board-certified case manager should inform the client that this needs to be discussed with the authorized treating physician.

Conclusion

As stated before, use of medical cannabis for treatment can raise several questions for the board-certified case manager coordinating care for a work-related injury. Medical cannabis is still viewed as an illicit drug and a new treatment option for certain medical conditions. The board-certified case manager needs to know which conditions are approved for medical marijuana. The board-certified case manager will have to engage in unbiased, objective, and clear communication with the payor source, client, and authorized treating physician. CE III

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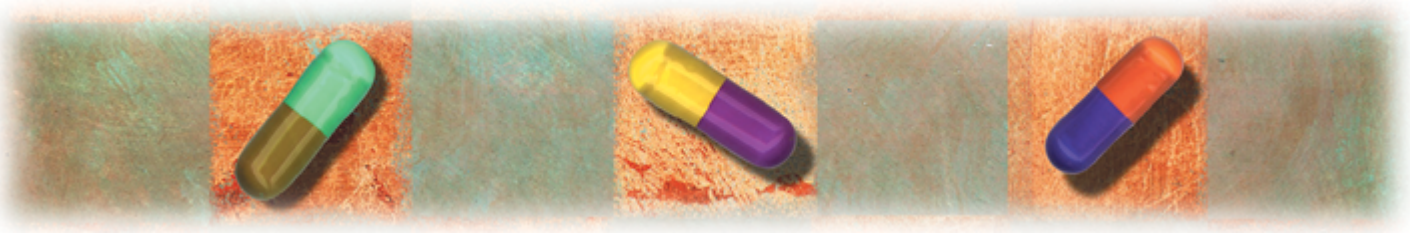

Tzield™ (teplizumab-mzwv) injection, for intravenous use

INDICATIONS AND USAGE

Tzield is indicated to delay the onset of Stage 3 type 1 diabetes in adults and pediatric patients 8 years of age and older with Stage 2 type 1 diabetes.

DOSAGE AND ADMINISTRATION

Patient Selection

Select adult patients and pediatric patients 8 years of age and older for Tzield treatment who have a diagnosis of Stage 2 type 1 diabetes.

- Confirm Stage 2 type 1 diabetes by documenting:
  - —At least two positive pancreatic islet cell autoantibodies
  - —Dysglycemia without overt hyperglycemia using an oral glucose tolerance test (if an oral glucose tolerance test is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be appropriate)
- Ensure the clinical history of the patient does not suggest type 2 diabetes.

Laboratory Evaluation and Vaccination Prior to Initiation

- Prior to initiating Tzield, obtain a complete blood count and liver enzyme tests.
- Use of Tzield is not recommended in patients with:
  - —Lymphocyte count less than 1,000 lymphocytes/mcL
  - —Hemoglobin less than 10 g/dL
  - —Platelet count less than 150,000 platelets/mcL
  - —Absolute neutrophil count less than 1,500 neutrophils/mcL
  - —Elevated ALT or AST greater than 2 times the upper limit of normal (ULN) or bilirubin greater than 1.5 times ULN
  - —Laboratory or clinical evidence of acute infection with Epstein-Barr virus (EBV) or cytomegalovirus (CMV)
  - —Active serious infection or chronic active infection other than localized skin infections
- Administer all age-appropriate vaccinations prior to starting Tzield:
  - —Administer live-attenuated (live) vaccines at least 8 weeks prior to treatment.
  - —Administer inactivated (killed) vaccines or mRNA vaccines at least 2 weeks prior to treatment.

Recommended Dosage and Administration

Administer Tzield by intravenous infusion (over a minimum of 30 minutes), using a body surface area-based dosing, once daily for 14 consecutive days as follows:

- Day 1: 65 mcg/m2
- Day 2: 125 mcg/m2
- Day 3: 250 mcg/m2
- Day 4: 500 mcg/m2
- Days 5 through 14: 1,030 mcg/m2

Do not administer two doses on the same day.

Recommendations Regarding Missed Dose(s)

If a planned Tzield infusion is missed, resume dosing by administering all remaining doses on consecutive days to complete the 14-day treatment course.

DOSAGE FORMS AND STRENGTHS

Injection: 2 mg per 2 mL (1 mg/mL) clear and colorless solution in a single-dose vial.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome

Cytokine release syndrome (CRS) has been observed in Tzield-treated patients. In clinical trials, CRS was reported in 5% of Tzield-treated patients compared to 0.8% of control-treated patients during the treatment period and through 28 days after the last study drug administration. CRS manifestations in Tzield-treated patients included fever, nausea, fatigue, headache, myalgia, arthralgia, increased alanine aminotransferase (ALT), increased aspartate aminotransferase (AST), and increased total bilirubin. These manifestations typically occurred during the first 5 days of Tzield treatment. To mitigate CRS:

- Premedicate with antipyretics, antihistamines and/or antiemetics prior to Tzield treatment.
- Monitor liver enzymes during treatment. Discontinue Tzield treatment in patients who develop elevated ALT or

AST more than 5 times the upper limit of normal (ULN) or bilirubin more than 3 times ULN.
- Treat symptoms of CRS with antipyretics, antihistamines and/or antiemetics. If severe CRS develops, consider temporarily pausing dosing for 1-2 days (and administer the remaining doses to complete the full 14-day course on consecutive days) or discontinuing treatment.

Serious Infections

Bacterial and viral infections have occurred in Tzield-treated patients. In clinical trials, Tzield-treated patients had a higher rate of serious infections (3.5%) than control-treated patients (2%), including gastroenteritis, cellulitis, pneumonia, abscess, sepsis. Use of Tzield is not recommended in patients with active serious infection or chronic infection other than localized skin infections. Monitor patients for signs and symptoms of infection during and after Tzield treatment. If serious infection develops, treat appropriately, and discontinue Tzield.

Lymphopenia

In clinical trials, 78% of Tzield-treated patients developed lymphopenia compared to 11% of control-treated patients. For most Tzield-treated patients who experienced lymphopenia, lymphocyte levels began to recover after the fifth day of treatment and returned to pretreatment values within two weeks after treatment completion and without dose interruption. Severe lymphopenia (<500 cells per mcL) lasting 1 week or longer occurred in 0.9% of Tzield-treated patients, and 0.5% of Tzield-treated patients permanently discontinued Tzield because of lymphopenia.

Monitor white blood cell counts during the treatment period. If prolonged severe lymphopenia (<500 cells per mcL lasting 1 week or longer) develops, discontinue Tzield.

Hypersensitivity Reactions

Acute hypersensitivity reactions including serum sickness, angioedema, urticaria, rash, vomiting and bronchospasm occurred in Tzield-treated patients. If severe hypersensitivity reactions occur, discontinue use of Tzield and treat promptly.

Vaccinations

The safety of immunization with live-attenuated vaccines in Tzield-treated patients has not been studied. Additionally, Tzield may interfere with the immune response to vaccination and decrease vaccine efficacy.
- Administer all age-appropriate vaccinations prior to starting Tzield.
- Inactivated or mRNA vaccinations are not recommended within the 2 weeks prior to Tzield treatment, during treatment, or 6 weeks after completion of treatment.
- Live-attenuated vaccinations are not recommended within the 8 weeks prior to Tzield treatment, during treatment, or up to 52 weeks after treatment.

ADVERSE REACTIONS
- Cytokine Release Syndrome
- Serious Infections
- Lymphopenia
- Hypersensitivity Reactions

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Available case reports from clinical trials with Tzield are insufficient to identify a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. Although there are no data on teplizumab-mzwv, monoclonal antibodies can be actively transported across the placenta, and Tzield may cause immunosuppression in the utero-exposed infant. To minimize exposure to a fetus, avoid use of Tzield during pregnancy and at least 30 days (6 half-lives) prior to planned pregnancy.

Tzield is not active in rodents. In animal reproduction studies, mice were given a surrogate anti-mouse CD3 antibody subcutaneously during organogenesis through lactation. Pups born to dams administered the murine surrogate antibody during pregnancy showed a reduction in the adaptive immune response consistent with the expected pharmacology.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2%-4% and 15%-20%, respectively.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Transport of endogenous IgG antibodies across the placenta increases as pregnancy progresses and peaks during the third trimester. Because teplizumab-mzwv may interfere with immune response to infections, risks and benefits should be considered prior to administering live vaccines to infants exposed to teplizumab-mzwv in utero. There are insufficient data regarding infant serum levels of teplizumab-mzwv at birth and the duration of persistence of teplizumab-mzwv in infant serum after birth to identify a specific timeframe to delay live virus immunizations in infants exposed in utero.

Lactation

Risk Summary

There are no data on the presence of teplizumab-mzwv in either human or animal milk, the effects on the breastfed child, or the effects on milk production. Endogenous maternal IgG and monoclonal antibodies are transferred into human milk. The effects of local gastrointestinal exposure and limited systemic exposure in the breastfed infant to teplizumab-mzwv are unknown.

Although the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Tzield and any potential adverse effects on the breastfed child from Tzield or from the underlying maternal condition, a lactating woman may interrupt breastfeeding and pump and discard breast milk during treatment and for 20 days after Tzield administration to minimize drug exposure to a breastfed child.

Pediatric Use

The safety and effectiveness of Tzield to delay the onset of Stage 3 type 1 diabetes have been established in pediatric patients 8 years of age and older with Stage 2 type 1 diabetes. Use of Tzield for this indication is supported by evidence from an adequate and well-controlled study (Study TN-10) in adults and pediatric patients 8 years of age and older (including 29 pediatric patients). Adverse reactions observed in pediatric patients 8 years of age and older who received Tzield were consistent with those reported in adult patients.

The safety and effectiveness of Tzield have not been established in pediatric patients younger than 8 years of age.

Geriatric Use

Stage 2 type 1 diabetes is largely a condition that occurs in pediatric and younger adult patients. Clinical studies of Tzield to delay the onset of Stage 3 T1D did not include patients 65 years of age and older.

CLINICAL STUDIES

The effectiveness of Tzield was investigated in a randomized, double-blind, event-driven, placebo-controlled study (Study TN-10; NCT01030861) in 76 patients, 8 to 49 years of age with Stage 2 type 1 diabetes. Stage 2 type 1 diabetes was defined as having both of the following:

1. Two or more of the following pancreatic islet autoantibodies:
   - —Glutamic acid decarboxylase 65 (GAD) autoantibodies
   - —Insulin autoantibody (IAA)
   - —Insulinoma-associated antigen 2 autoantibody (IA-2A)
   - —Zinc transporter 8 autoantibody (ZnT8A)
   - —Islet cell autoantibody (ICA)
2. Dysglycemia on oral glucose tolerance testing

In this study, patients were randomized to receive Tzield or placebo once daily by intravenous infusion for 14 days. Patients in the Tzield group had a total drug exposure that was comparable to the total drug exposure achieved with the recommended total Tzield dosage. The primary efficacy endpoint in this study was the time from randomization to development of Stage 3 type 1 diabetes diagnosis.

Baseline Patient Characteristics

In this study, 45% were female; 97% White, 1% Asian, and 1% reported multiracial background; 3% were Hispanic or Latino ethnicity; and 95% were from the United States. The median age was 14 years (72% were <18 years old).

Efficacy Results

In Study TN-10, Stage 3 type 1 diabetes was diagnosed in 20 (45%) of the Tzield-treated patients and in 23 (72%) of the placebo-treated patients. A Cox proportional hazards model, stratified by age and oral glucose tolerance test status at randomization, demonstrated that the median time from randomization to Stage 3 type 1 diabetes diagnosis was 50 months in the Tzield group and 25 months in the placebo group, for a difference of 25 months. With a median follow-up time of 51 months, therapy with Tzield resulted in a statistically significant delay in the development of Stage 3 type 1 diabetes, hazard ratio 0.41 (95% CI: 0.22 to 0.78; p=0.0066).

Study TN-10 was not designed to assess whether there were differences in the effectiveness between subgroups based on demographic characteristics or baseline disease characteristics.

HOW SUPPLIED / STORAGE AND HANDLING

Tzield (teplizumab-mzwv) injection is a clear and colorless solution (2 mg/2 mL [1 mg/mL]) supplied in a single-dose vial.

Refrigerate Tzield vials at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Store upright. Do not freeze or shake the vials.

If not used immediately, store the diluted solution at room temperature (15°C to 30°C [59°F to 86°F]) and complete infusion within 4 hours of the start of preparation. Discard the diluted solution if not administered within 4 hours of preparation.

Cost: $13,850 per vial; $194,000 for a full 14-day course of treatment.

For full prescribing information, please see Product Insert.

Tzield is manufactured by Provention Bio Inc.

Hemgenix® (etranacogene dezaparvovec-drlb) suspension, for intravenous infusion

INDICATIONS AND USAGE

Hemgenix is an adeno-associated virus vector-based gene therapy indicated for treatment of adults with Hemophilia B (congenital Factor IX deficiency) who:

- Currently use Factor IX prophylaxis therapy, or
- Have current or historical life-threatening hemorrhage, or
- Have repeated, serious spontaneous bleeding episodes.

DOSAGE AND ADMINISTRATION

For single-use intravenous infusion only

For patient selection:

Perform Factor IX inhibitor titer testing.

- In case of a positive test result for human Factor IX inhibitors, perform a re-test within approximately 2 weeks. If both the initial test and re-test results are positive, do not administer Hemgenix to this patient.
- Perform liver health assessments, including:
  - —Enzyme testing (alanine aminotransferase [ALT], aspartate aminotransferase [AST], alkaline phosphatase

[ALP] and total bilirubin),

—Hepatic ultrasound and elastography.

In case of radiological liver abnormalities and/or sustained liver enzyme elevations, consider a consultation with hepatologist to assess eligibility for Hemgenix.

Dose

The recommended dose of Hemgenix is 2 x 10^{13} genome copies (gc) per kilogram (kg) of body weight (or 2 mL/kg body weight) administered as an intravenous infusion after dilution with 0.9% sodium chloride solution (normal saline).

Calculate the dose as follows:

Hemgenix dose (in mL) = patient body weight (in kilogram) x 2

The multiplication factor 2 represents the per kilogram dose (2×10^{13} gc/kg) divided by the amount of genome copies per mL of the Hemgenix solution (1×10^{13} cg/mL).

Number of Hemgenix vials needed = Hemgenix dose (in mL) divided by 10 (round up to next whole number of vials).

The division factor 10 represents the extractable volume of Hemgenix from each vial (10 mL).

The total volume of the patient's Hemgenix dose to be diluted may be less than the total volume of vials needed.

DOSAGE FORMS AND STRENGTHS

Hemgenix is a clear and colorless suspension for intravenous infusion.

Hemgenix is provided in a kit containing 10 to 48 vials. Each kit constitutes a dosage unit based on the patient's body weight.

Hemgenix has a nominal concentration of 1 x 10^{13} gc/mL, and each vial contains an extractable volume of not less than 10 mL.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Infusion Reactions

Infusion reactions, including hypersensitivity reactions and anaphylaxis, may occur. Symptoms may include chest tightness, headaches, abdominal pain, lightheadedness, flu-like symptoms, shivering, flushing, rash, and hypertension. Closely monitor patients for signs or symptoms of an infusion reaction throughout the infusion period and for at least 3 hours after end of infusion. Do not infuse the product faster than 500 mL/hour.

In the event of an infusion reaction during administration, the infusion may be slowed or stopped. If the infusion is stopped, restart at a slower rate when the infusion reaction has resolved. Consider treatment with a corticosteroid or antihistamine for management of an infusion reaction.

Hepatotoxicity

Intravenous administration of a liver-directed AAV vector could potentially lead to liver transaminase elevations (transaminitis). Transaminitis, particularly when observed in the first 3 months after Hemgenix administration, is presumed to occur due to immune-mediated injury of transduced hepatocytes and may reduce the therapeutic efficacy of the AAV-vector based gene therapy.

In clinical studies with Hemgenix, most subjects had asymptomatic and predominantly mild elevations in transaminases. Elevated ALT levels occurred most often in the first 4 months after Hemgenix administration. There were some subjects who had a late onset of elevated ALT levels between Months 6–24 (range = 42 IU/L-193 IU/L); however, all of these ALT values were <2x ULN with the exception of one subject. Three additional subjects had AST elevations with onset and resolution between Months 6 and 12 (range = 41 IU/L – 96 IU/L).

In one subject, an ALT elevation >5x ULN occurred 24 days after Hemgenix administration and resolved by 51 days post-Hemgenix administration. There was one subject who had an AST elevation > 5x ULN that occurred 11 months post-Hemgenix administration and resolved to <2x ULN eight days later. The majority of the elevated ALT values returned to baseline, although 9 subjects' ALT values never resolved to normal (range at 2-year follow up = 48 IU/L – 193 IU/L).

Closely monitor transaminase levels once per week for 3 months after Hemgenix administration to mitigate the risk of potential hepatotoxicity. Continue to monitor transaminases in all patients who developed liver enzyme elevations until liver enzymes return to baseline. In case of increased ALT levels above the upper limit of normal or double baseline levels, consider implementing a course of corticosteroid, along with human Factor IX activity monitoring.

Immune-mediated neutralization of the AAV5 vector capsid

In AAV-vector based gene therapies, preexisting neutralizing anti-AAV antibodies may impede transgene expression at desired therapeutic levels. Following treatment with Hemgenix, all subjects developed neutralizing anti-AAV antibodies. Currently, there is no validated neutralizing anti-AAV5 antibody assay.

In the clinical studies with Hemgenix, an unvalidated clinical trial assay was utilized to assess preexisting neutralizing anti-AAV5 antibodies. The subject sub-group with detectable preexisting neutralizing anti-AAV5 antibodies up to titers of 1:678 showed mean Factor IX activity that was numerically lower compared to that subject sub-group without detectable preexisting neutralizing anti-AAV5 antibodies. Subjects, with and without preexisting neutralizing anti-AAV5 antibodies, demonstrated hemostatic protection. In one subject with a preexisting neutralizing anti-AAV5 antibody titer of 1:3212, no human Factor IX expression was observed, and restart of the exogenous Factor IX prophylaxis was needed for bleeding events.

Anti-AAV5 Antibody Study
Patients who intend to receive treatment with Hemgenix are encouraged to enroll in a study to measure pre-existing anti-AAV5 neutralizing antibodies by calling CSL Behring at 1-800-504-5434. The study evaluates the effect of pre-existing anti-AAV5 neutralizing antibodies on the risk of bleeding.

Hepatocellular carcinogenicity
The integration of liver-targeting AAV vector DNA into the genome may carry the theoretical risk of hepatocellular carcinoma development.

Hemgenix is composed of a non-replicating AAV5 vector whose DNA persists largely in episomal form. Random integration of Hemgenix vector DNA to the human DNA at low frequency is possible. No Hemgenix-associated clonal expansion or carcinogenicity was observed in clinical studies. One subject with preexisting risk factors for developing hepatic cancer developed a hepatocellular carcinoma, which was assessed as not likely related to Hemgenix treatment based on vector integration site analyses and whole genome sequencing.
Patients with preexisting risk factors for hepatocellular carcinoma (e.g., patients with cirrhosis, advanced hepatic fibrosis, hepatitis C or B, non-alcoholic fatty liver disease [NAFLD], chronic alcohol consumption, non-alcoholic steatohepatitis [NASH], and advanced age) should receive abdominal ultrasound screenings and be monitored regularly (e.g., annually) for alpha-fetoprotein (AFP) elevations in the 5 years following administration.

Monitoring Laboratory Tests
After Hemgenix administration, regularly monitor patient's Factor IX activity levels.

When using an in vitro activated partial thromboplastin time (aPTT)-based one-stage clotting assay (OSA) for determining Factor IX activity, plasma Factor IX activity results can be affected by both the type of aPTT reagent and the reference standard used in the assay. This is important to consider, particularly when changing the laboratory and/or reagents used in the assay. Therefore, the same assay and reagents are recommended to be used to monitor Factor IX activity over time.

The results of Factor IX activity tests are lower if measured with chromogenic substrate assay (CSA) compared to OSA.

In the clinical efficacy study with Hemgenix, the post-dose Factor IX activity measured with CSA returned lower values with the mean CSA to OSA Factor IX activity ratio ranging from 0.41 to 0.55.

Monitor patients through appropriate clinical observations and laboratory tests for the development of inhibitors to Factor IX after Hemgenix administration. Perform an assay that detects Factor IX inhibitors if bleeding is not controlled or if plasma Factor IX activity levels decrease.

ADVERSE REACTIONS
The most common adverse reactions (incidence ≥5%) reported in clinical studies were ALT elevations, headache, blood creatine kinase elevations, flu-like symptoms, infusion-related reactions, fatigue, malaise, and AST elevations.

USE IN SPECIFIC POPULATIONS
Pregnancy
Risk Summary
Hemgenix is not intended for administration in women. No adverse effects on mating rate and fertility indices or fetal weights were observed in healthy naive female mice mated with healthy male mice that were intravenously administered a predecessor of Hemgenix product 6 days prior to mating. Vector DNA was not detected in the uterus, placenta, or fetus. In the United States 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.

Lactation
Risk Summary
Hemgenix is not intended for administration in women.

Females and Males of Reproductive Potential
Risk Summary
No clinical studies have been performed to evaluate the effects of Hemgenix on fertility in humans. Twenty days after intravenous administration of a predecessor of Hemgenix product in healthy male mice, vector DNA was detected in all reproductive tissues examined (epididymis, seminal vesicles, testes, and sperm). However, no differences were observed in mating rates and fertility indices in healthy naive female mice following mating with the dosed males.

Pediatric Use
The safety and efficacy of Hemgenix in pediatric patients have not been established.

Geriatric Use
The clinical studies included a total of 6 geriatric subjects with Hemophilia B, aged 68 to 75 years at time of enrollment. No meaningful differences in the safety and efficacy profile were observed in these subjects compared to subjects aged 18 to 65 years, and no dose adjustment was made.

Hepatic Impairment
Limited clinical data in subjects with liver impairment indicate numerically lower FIX activity as compared to subjects without hepatic impairment. In the clinical studies, no dose adjustment was made in subjects with hepatic pathologies. The safety and efficacy in subjects with advanced hepatic impairment, including cirrhosis, advanced liver fibrosis, or uncontrolled Hepatitis B and C, have not been studied.

continues on page 35

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.

Clin Infect Dis. 2022 Oct 31;ciac851.doi: 10.1093/cid/ciac851. Online ahead of print.

Higher levels of cerebrospinal fluid and plasma neurofilament light in human immunodeficiency virus-associated distal sensory polyneuropathy

Ellis RJ, Chenna A, Lie Y, et al.

BACKGROUND: Neurofilament light chain (NFL) concentrations, reflecting axonal damage, are seen in several polyneuropathies, but have not been studied in HIV distal sensory polyneuropathy (DSP). We evaluated NFL in CSF and plasma in relation to DSP in people with HIV (PWH) from two independent cohorts, and in people without HIV (PWoH).

METHODS: Cohort 1 consisted of PWH from the CHARTER Study. Cohort 2 consisted of PWH and PWoH from the HIV Neurobehavioral Research Center (HNRC). We evaluated DSP signs and symptoms in both cohorts. Immunoassays measured NFL in CSF for all and for plasma as well in Cohort 2.

RESULTS: Cohort 1 consisted of 111 PWH, mean ± SD age 56.8 ± 8.32 years, 15.3% female, 38.7% black, 49.6% white, current CD4+ T-cells (median, IQR) 532/μL (295, 785), 83.5% with plasma HIV RNA ≤ 50 copies/mL. Cohort 2 consisted of 233 PWH of similar demographics to PWH in Cohort 1, but also 51 PWoH, together age 58.4 ± 6.68 years, 41.2% female, 18.0% black, Hispanic, non-Hispanic white 52.0%, 6.00% white. In both cohorts of PWH, CSF and plasma NFL were significantly higher in both PWH with DSP signs. Findings were similar, albeit not significant, for PWoH. The observed relationships were not explained by confounds.

CONCLUSIONS: Both plasma and CSF NFL were elevated in PWH and PWoH with DSP. The convergence of our findings with others demonstrates that NFL is a reliable biomarker reflecting peripheral nerve injury. Biomarkers such as NFL might provide, validate, and optimize clinical trials of neuroregenerative strategies in HIV DSP.

Clin Infect Dis. 2022 Nov 9;ciac793.doi: 10.1093/cid/ciac793. Online ahead of print.

Maternal antibody response and transplacental transfer following SARS-CoV-2 infection or vaccination in pregnancy

Otero S, Miller ES, Sunderrai A, et al.

BACKGROUND: Pregnant persons are at increased risk of severe COVID-19 and adverse obstetric outcomes. Understanding maternal antibody response, duration, and transplacental transfer after SARS-CoV-2 infection and COVID-19 vaccination is important to inform public health recommendations.

METHODS: This prospective observational cohort study included 351 pregnant people who had SARS-CoV-2 infection or COVID-19 vaccination during pregnancy. IgG and IgM to SARS-CoV-2 S1 receptor binding domain were measured in maternal and cord blood. Antibody levels and transplacental transfer ratios were compared across 1) disease severity for those with SARS-CoV-2 infection and 2) infection versus vaccination.

RESULTS: There were 252 individuals with SARS-CoV-2 infection and 99 who received COVID-19 vaccination during pregnancy. Birthing people with more severe SARS-CoV-2 infection had higher maternal and cord blood IgG levels ($p = 0.0001$, $p = 0.0001$). Median IgG transfer ratio was 0.87-1.2. Maternal and cord blood IgG were higher after vaccination than infection ($p = 0.001$, $p = 0.001$). Transfer ratio was higher after 90 days in the vaccinated group ($p < 0.001$). Modeling showed higher amplitude and half-life of maternal IgG following vaccination ($p < 0.0001$). There were no significant differences by fetal sex.

CONCLUSIONS: COVID-19 vaccination in pregnancy leads to higher and longer lasting maternal IgG levels, higher cord blood IgG, and higher transfer ratio after 90 days compared to SARS-CoV-2 infection. Greater infection severity leads to higher maternal and cord blood antibodies. Maternal IgG decreases over time following both vaccination and infection, reinforcing the importance of vaccination, even after infection, and vaccine boosters for pregnant patients.

Am J Cardiol. 2022 Nov 4;186:30-35. doi: 10.1016/j.amjcard.2022.10.017. Online ahead of print.

Cachexia is associated with adverse outcomes in patients admitted with heart failure

Mohamad Alahmad MA, Acharya P, Gibson CA, et al.

Cachexia is often seen in patients with heart failure (HF). This study aimed to examine the association between cachexia and clinical outcomes in patients hospitalized for HF. We extracted all adult cases with a primary diagnosis of HF that were discharged between January and November, identified in the Nationwide Readmissions Database for 2016 through 2019. Exclusion criteria included cases with missing data or a diagnosis of acquired immunodeficiency syndrome, advanced liver disease, end-stage renal disease, chronic lung disease, or malignancy. Appropriate weighting was used to obtain national estimates. Primary outcomes were inpatient mortality, length of stay, and 30-day readmission in patients with HF with cachexia compared with patients with no cachexia. Multivariable logistic regression was used to estimate the association between cachexia and clinical outcomes. Survey procedures were applied using Statistical Analysis Software 9.4. The final analysis included 2,360,307 HF-related hospitalizations. Cachexia was present in about 7% of the study population. A greater percentage of patients with cachexia were female and older than patients without cachexia (52% vs 47% female, the mean age of 77 vs 72 years, respectively). However, after adjusting for demographics and co-morbidities, including coronary artery disease and atrial fibrillation, patients with cardiac cachexia had higher inpatient mortality (odds ratio 3.01, 95% confidence interval 2.88 to 3.15, p <0.001), prolonged hospital stays (9 vs 5 days, p <0.0001), and greater all-cause 30-day readmissions (23% vs 21%, p <0.0001). HF-related cachexia is associated with increased inpatient mortality, greater resource use, and additional healthcare costs.

MMWR Morb Mortal Wkly Rep. 2022 Nov 4;71(44):1412-1417. doi: 10.15585/mmwr.mm7144e1.

Severe monkeypox in hospitalized patients—United States, August 10–October 10, 2022

Miller MJ, Cash-Goldwasser S, Marx GE, et al.

As of October 21, 2022, a total of 27,884 monkeypox cases (confirmed and probable) have been reported in the United States. Gay, bisexual, and other men who have sex with men have constituted a majority of cases, and persons with HIV infection and those from racial and ethnic minority groups have been disproportionately affected (1,2). During previous monkeypox outbreaks, severe manifestations of disease and poor outcomes have been reported among persons with HIV infection, particularly those with AIDS (3-5). This report summarizes findings from CDC clinical consultations provided for 57 patients aged ≥18 years who were hospitalized with severe manifestations of monkeypox during August 10-October 10, 2022, and highlights three clinically representative cases. Overall, 47 (82%) patients had HIV infection, four (9%) of whom were receiving antiretroviral therapy (ART) before monkeypox diagnosis. Most patients were male (95%) and 68% were non-Hispanic Black (Black). Overall, 17 (30%) patients received intensive care unit (ICU)-level care, and 12 (21%) have died. As of this report, monkeypox was a cause of death or contributing factor in five of these deaths; six deaths remain under investigation to determine whether monkeypox was a causal or contributing factor; and in one death, monkeypox was not a cause or contributing factor. Health care providers and public health professionals should be aware that severe morbidity and mortality associated with monkeypox have been observed during the current outbreak in the United States (6,7), particularly among highly immunocompromised persons. Providers should test all sexually active patients with suspected monkeypox for HIV at the time of monkeypox testing unless a patient is already known to have HIV infection. Providers should consider early commencement and extended duration of monkeypox-directed therapy in highly immunocompromised patients with suspected or laboratory-diagnosed monkeypox. Engaging all persons with HIV in sustained care remains a critical public health priority.

J Am Coll Cardiol. 2022 Nov 8;80(19):1775-1784. doi: 10.1016/j.jacc.2022.08.745. Epub 2022 Aug 27.

Estimated long-term benefit of dapagliflozin in patients with heart failure

Vaduganathan M, Claggett BL, Jhund P, et al.

BACKGROUND: Recent guidelines support consideration of sodium-glucose cotransporter-2 inhibitors in the long-term management of heart failure (HF) with mildly reduced or preserved ejection fraction. Patients and clinicians may be interested in the expected lifetime benefits of sodium-glucose cotransporter-2 inhibitors in this population.

OBJECTIVES: This study aimed to estimate event-free survival gains from long-term use of dapagliflozin in patients with HF with mildly reduced or preserved ejection fraction overall and in clinically relevant subgroups.

METHODS: In this prespecified analysis of DELIVER (Dapagliflozin Evaluation to Improve the Lives of Patients With Preserved Ejection Fraction Heart Failure), we applied validated nonparametric age-based methods to extrapolate potential gains in

survival free from the primary endpoint (cardiovascular death or worsening HF event) from long-term use of dapagliflozin. Eligible participants had symptomatic HF, left ventricular ejection fraction >40%, elevated natriuretic peptide levels, and structural heart disease. For every year between the ages of 55 and 85 years, we estimated event-free survival using age at randomization rather than time from randomization as the time horizon. Residual lifespan free from a primary endpoint was estimated based on area under the survival curve in each arm.

RESULTS: Among 6,263 participants, mean survival free from the primary endpoint for a 65-year-old participant was 12.1 years (95% CI: 11.0-13.2 years) with dapagliflozin and 9.7 years (95% CI: 8.8-10.7 years) with placebo, representing a 2.3-year (95% CI: 0.9-3.8 years) event-free survival gain (P = 0.002). Treatment gains in survival free from the primary endpoint ranged from 2.0 years (95% CI: -0.6 to 4.6 years) in a 55-year-old to 1.2 years (95% CI: -0.1 to 2.4 years) in a 75-year-old patient. Mean event-free survival was greater with dapagliflozin than with placebo across all 14 subgroups.

CONCLUSIONS: Treatment with dapagliflozin is projected to extend event-free survival by up to 2.0 to 2.5 years among middle-aged and older individuals with HF with mildly reduced or preserved ejection fraction. (DELIVER [Dapagliflozin Evaluation to Improve the Lives of Patients With Preserved Ejection Fraction Heart Failure]; NCT03619213).

Clin Transplant. 2022 Nov 8;e14842. doi: 10.1111/ctr.14842. Online ahead of print.

Retrospective analysis of the impact of pre-transplant implantable cardioverter-defibrillator status on long-term prognosis in heart transplant patients

Dean M, Zoni CR, Copeland LA, et al.

BACKGROUND: Sudden cardiac death (SCD) post-heart transplantation affects 8%-35% of patients; however, the risk profile remains to be completely elucidated. While pre-transplant ICDs are typically removed during transplantation, no information exists to suggest if this pre-transplant risk stratification is also associated with post-transplant outcomes. The objective of this study was to assess the impact of pre-transplant ICD status on long-term prognosis post-heart transplant.

METHODS: The United Network for Organ Sharing registry was queried for all adult heart transplant recipients from 2010 to 2018. Patients were categorized as with versus without ICD prior to heart transplantation. Survival was compared using Kaplan-Meier analysis. Proportional hazards regression analysis assessed the impact of ICDs adjusting for clinical and demographic covariates.

RESULTS: Of 19 026 patients included, 78.6% (n = 14 960) had received an ICD at time of registration. Patients with an ICD were older [54.9 (±11.6) years vs. 48.6 (±15.3) years, p < .001], less likely to be female [25.7% (n = 3842) vs. 31.2% (n = 1269), p < .001], and more commonly diabetic [29.3% (n = 4376) vs 23.5% (n = 954), p < .001]. Kaplan-Meier analysis showed no difference in unadjusted survival trajectory by ICD status (chi-square = .48, p = .49). Survival was unrelated to ICD status in the multivariable model (HR = .98; 95% CI .90-1.07).

CONCLUSIONS: Patients receiving an ICD pre-transplant had a higher prevalence of risk factors for SCD than non-ICD patients, yet ICD status prior to heart transplantation was not associated with a change in long-term prognosis post-heart transplantation.

BMC Cancer. 2022 Nov 8;22(1):1152.doi: 10.1186/s12885-022-10215-0.

Body mass index and incidence of lung cancer in the HUNT study: using observational and Mendelian randomization approaches

Jiang L, Sun Y-Q, Brumpton BM, et al.

BACKGROUND: Traditional observational studies have shown an inverse association between body mass index (BMI) and lung cancer risk. Mendelian randomization (MR) analysis using genetic variants as instruments for BMI may clarify the nature of the association.

AIMS: We studied the causal association between BMI and lung cancer incidence using observational and MR approaches.

METHODS: We followed up 62,453 cancer-free Norwegian adults from 1995-97 (HUNT2) until 2017. BMI at baseline in HUNT2 was classified as < 25.0, 25.0-29.9 and ≥ 30.0 kg/m^2. BMI change over ten years between HUNT1 (1984-86) and HUNT2 was calculated and classified into quartiles. Seventy-five genetic variants were included as instruments for BMI (among which 14 also associated with smoking behavior). Incident lung cancer cases were ascertained from the Cancer Registry of Norway. Cox regression models were used to estimate hazard ratios (HRs) with 95% confidence intervals (CIs). Multivariable MR was used to examine the effect of BMI after genetically controlling for smoking.

RESULTS: During a median follow-up of 21.1 years, 1009 participants developed lung cancer including 327 with lung adenocarcinoma. The HRs and 95% CIs for incidence of adenocarcinoma were 0.73 (0.58-0.92) for BMI 25.0-29.9 kg/m^2 and 0.53 (0.37-0.76) for BMI ≥ 30 kg/m^2 compared with BMI < 25.0 kg/m^2 in HUNT2 (P for trend < 0.001). However, there was little evidence of a dose-response relationship between the BMI change from HUNT1 to HUNT2 in quartiles and the

incidence of adenocarcinoma (P for trend = 0.08). Furthermore, multivariable MR approach suggested a positive association between genetically determined 1 kg/m^2 increase in BMI and the incidence of adenocarcinoma (HR 1.25, 95% CI 1.02-1.53). No associations were found with other lung cancer histologic types.

CONCLUSIONS: Our study suggests that the inverse association between baseline BMI and lung adenocarcinoma in observational analysis may not be causal. More MR studies are needed to confirm our finding of a positive association between BMI and lung adenocarcinoma.

Ann Surg Oncol. 2022 Nov 9.doi: 10.1245/s10434-022-12696-6. Online ahead of print.

Health-related quality of life following simultaneous resection for synchronous colorectal cancer liver metastases

Griffiths CD, Karanicolas P, Gallinger S, et al.

INTRODUCTION: Up to 25% of colorectal cancer patients present with synchronous liver metastases that can be treated with two operations or a single 'simultaneous' operation. Morbidity and mortality appear similar between approaches, however changes in health-related quality-of-life following simultaneous resection are not well reported.

METHODS: A prospective, feasibility trial for simultaneous resection of synchronous colorectal liver metastases was conducted. Patients completed the European Organization for Research and Treatment of Cancer QLQ-C30 and LMC21 at baseline (preoperatively), and 4 and 12 weeks postoperatively. Week 4 and 12 scores were compared with baseline using t-tests. Minimally important clinical differences were considered as a 10-point difference from baseline.

RESULTS: C30 and QLQ-LMC21 were completed at baseline, 4 weeks, and 12 weeks by 39 (95%), 35 (85%) and 34 (83%) patients, and 39 (95%), 33 (80%) and 33 (80%) patients, respectively; 79% and 75% had at least one MICD according to QLQ-C30 at 4 and 12 weeks. At 4 weeks, physical functioning (mean difference (MD) - 11.9%, p = 0.002), role functioning (MD - 23.6, p = 0.007), and pain (MD + 19.7, p = 0.017) had significant worsening from baseline. At 12 weeks postoperatively, role functioning (MD - 19.7, p = 0.011) and fatigue (MD + 14.3, p = 0.03) were the only domains that remained significantly worse. By 12 weeks, pain and physical functioning had returned to baseline. There were no major demographic differences among those with and without an MICD at 12 weeks.

CONCLUSIONS: Simultaneous resection of colorectal liver metastases led to clinically significant worsening fatigue and role functioning that persisted at 12 weeks post-surgery.

Breast Cancer Res Treat. 2022 Dec;196(3):517-525.doi: 10.1007/s10549-022-06761-7. Epub 2022 Oct 15.

High-risk lesions in the breast diagnosed by MRI-guided core biopsy: upgrade rates and features associated with malignancy

Cha E, Ambinder EB, Oluyemi ET, et al.

PURPOSE: This study assessed the upgrade rates of high-risk lesions (HRLs) in the breast diagnosed by MRI-guided core biopsy and evaluated imaging and clinical features associated with upgrade to malignancy.

METHODS: This IRB-approved, retrospective study included MRI-guided breast biopsy exams yielding HRLs from August 1, 2011, to August 31, 2020. HRLs included atypical ductal hyperplasia (ADH), lobular carcinoma in situ (LCIS), atypical lobular hyperplasia (ALH), radial scar, and papilloma. Only lesions that underwent excision or at least 2 years of MRI imaging follow-up were included. For each HRL, patient history, imaging features, and outcomes were recorded.

RESULTS: Seventy-two lesions in 65 patients were included in the study, with 8/72 (11.1%) of the lesions upgraded to malignancy. Upgrade rates were 16.7% (2/12) for ADH, 100% (1/1) for pleomorphic LCIS, 40% (2/5) for other LCIS, 0% (0/19) for ALH, 0% (0/18) for papilloma, and 0% (0/7) for radial scar/complex sclerosing lesion. Additionally, two cases of marked ADH bordering on DCIS and one case of marked ALH bordering on LCIS, were upgraded. Lesions were more likely to be upgraded if they presented as T2 hypointense (versus isotense, OR 6.46, 95% CI 1.27-32.92) or as linear or segmental non-mass enhancement (NME, versus focal or regional, p = 0.008).

CONCLUSION: Our data support the recommendation that ADH and LCIS on MRI-guided biopsy warrant surgical excision due to high upgrade rates. HRLs that present as T2 hypointense, or as linear or segmental NME, should be viewed with suspicion as these were associated with higher upgrade rates to malignancy.

Gynecol Oncol. 2022 Nov 4;S0090-8258(22)01890-X. doi: 10.1016/j.ygyno.2022.10.013. Online ahead of print.

Cost-effectiveness of management strategies for patients with recurrent ovarian cancer and inoperable malignant bowel obstruction

Peters PN, Moyett JM, Davidson BA, et al.

OBJECTIVES: Patients with recurrent platinum-resistant ovarian cancer often present with inoperable malignant bowel obstruction (MBO) from a large burden of abdominal disease. Interventions such

continues on page 38

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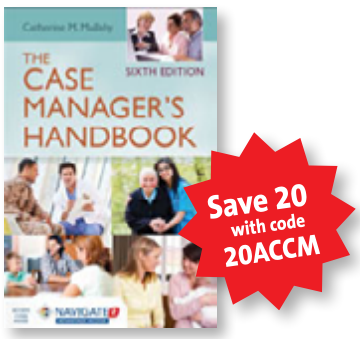

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Reducing Hospital Length of Stay by Expediting Precertification *continued from page 13*

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What About Gifts to Patients During the Holiday Season? *continued from page 5*

expressed a willingness to periodically review these limits and adjust them based on inflation.

Consequently, effective on December 7, 2016, the OIG increased the limits of items and services of nominal value that may be given by providers and suppliers to beneficiaries to a retail value of no more than $15 per item or $75 in the aggregate per patient on an annual basis.

Providers may not, however, give cash or cash equivalents. Cash equivalents include gift cards and gift certificates.

However, in view of some patients' needs for basic items such as food, prescribed medications, and payment of utility bills, these amounts may still seem paltry to many providers. According to the OIG, providers who see that patients need items worth more than these limits should establish relationships with charitable organizations that can provide items and/or services that are not subject to these limits.

It is important to note, however, that relationships between providers and charitable organizations must be independent and charitable organizations must be bona fide. The OIG has rescinded advisory opinions because these requirements were not met. On November 28, 2017, for example, the OIG rescinded Advisory Opinion 06-04 on the basis that the relationship with a charitable organization was not independent.

The notice rescinding the Advisory Opinion says that the OIG is mindful of the importance of helping financially needy beneficiaries of Federal programs receive assistance. The OIG also acknowledged that independent charities can play an important role in advancing this goal. If, however, charities act as a conduit for providers to induce patients to use providers' services, federal health care programs may be at risk.

In other words, work together to meet the needs of patients, but charitable organizations must maintain independence! CM

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Renal Impairment

Limited clinical data are available in subjects with mild and moderate renal impairment. In the clinical studies, no dose adjustment was made in these subjects. The safety and efficacy in subjects with severe renal impairment and end-stage renal disease have not been studied

CLINICAL STUDIES

The efficacy of Hemgenix was evaluated in a prospective, open-label, single-dose, single-arm, multinational study (N = 54). The study enrolled adult male subjects aged 19 to 75 years, with severe or moderately severe Hemophilia B, who received a single intravenous dose of 2×10^{13} gc/kg body weight of Hemgenix and entered a follow-up period of 5 years. The study is ongoing.

The 54 subjects prospectively completed a lead-in period of at least six months with the intent to receive standard of care routine Factor IX prophylaxis. These 54 subjects then received the indicated single intravenous dose of Hemgenix. Subjects were then followed up monthly until Month 12, and then at 6-month intervals until Year 5. For the efficacy evaluation, data up to 18 months post-treatment were used. Of the 54 subjects, 53 subjects completed at least 18 months of follow-up in the ongoing study. One subject with numerous cardiovascular and urologic risk factors, aged 75 years at screening, died of urosepsis and cardiogenic shock at Month 15 post-dose (at age 77 years) unrelated to treatment. Another subject received around 10% of the intended dose of Hemgenix due to an infusion-related hypersensitivity reaction.

The main efficacy outcome was a non-inferiority test of annualized bleeding rate (ABR) during Months 7 to 18 after Hemgenix treatment compared with ABR during the lead-in period. All bleeding episodes, regardless of investigator assessment, were counted. Subjects were allowed to continue prophylaxis during Months 0 to 6. The estimated mean ABR during Months 7 to 18 after Hemgenix treatment was 1.9 bleeds/year with a 95% confidence interval (CI) of (1.0, 3.4), compared with an estimated mean ABR of 4.1 [95% CI: 3.2, 5.4] during the lead-in period. The ABR ratio (Months 7 to 18 post-treatment/ lead- in) was 0.46 [95% CI: 0.26, 0.81], demonstrating non-inferiority of ABR during Months 7 to 18 compared to the lead-in period.

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

Hemgenix is supplied as sterile, preservative-free, clear, and colorless suspension. Hemgenix has a nominal concentration of 1 × 1013 gc/mL.

Hemgenix is provided as a customized kit to meet dosing requirements for each patient, with each kit containing 10 (ten) to 48 (forty-eight) single-use vials (NDC 0053-0099-01), each with an extractable volume of no less than 10 mL of Hemgenix. The total number of vials in each kit corresponds to the dosing requirement for the individual patient depending on the patient`s body weight. The customized kit is accompanied with patient's specific identifier number (Lot) on the outer carton. Each Hemgenix kit may contain different drug product lots.

Storage and Handling

- Hemgenix is shipped at 2°C to 8°C (36°F to 46°F).
- Upon receipt, store Hemgenix vials in a refrigerator at 2°C to 8°C (36°F to 46°F).
- Store Hemgenix in the original carton until use.
- Protect Hemgenix from light until time of dilution and administration.
- Do NOT FREEZE.

After dilution

- Once diluted, store Hemgenix in the infusion bag protected from light.
- Store diluted Hemgenix in the infusion bag at 15°C to 25°C (59°F to 77°F).

Infuse the diluted product within 24 hours after the dose preparation

Cost: $3.5 million for a course of treatment

For full prescribing information, please see Product Insert.

Hemgenix is distributed by CSL Behring LLC.

CE2

Fentanyl: The Silent Opioid Epidemic

continued from page 18

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What "Quiet Quitting" Really Means—and 6 Ways to Respond *continued from page 7*

in the pandemic, I sent each of my team members gratitude journals. In normal circumstances, I probably would not have done something so personal, but this small gift was well received by our team members who had been thrust into the uncharted territory of dealing with so many unknowns while supporting tens of thousands of our certificants.

4. **Ask, care, remember.** The irony of the remote work environment is that the more physically distant we are, the more personal our connections often became. Zoom calls give us windows into the homes of colleagues, clients, and others. Conversations about what's going on in people's lives go beyond small talk and into genuine sharing. To do this effectively, we need to ask questions, show genuine care and concern, and remember what's going on with each individual. The key is the follow-up query or comment, whether about a loved one with an ongoing health issue or a wedding or other celebration that was delayed during the pandemic.
5. **Have an honest conversation about burnout.** At times, discussing "what's going on" will reveal that a colleague or direct report is feeling burned out. This is time for an honest conversation about what that person really needs. The solution may be as simple as taking off a few days or getting help with a large project. In other situations, though, the problem may be job dissatisfaction that necessitates a change. One professional I know felt so burned out in her position that she could no longer perform that job. She was happy with her employer, so the solution was to find a new position in which she could thrive.
6. **Know what programs and benefits are available.** As leaders, we need to know what programs and benefits are available to employees, for example, an Employee Assistance Program (EAP) or Family and Medical Leave Act (FMLA). By providing even basic information about these programs and how to access them we can encourage others to get the help they need. We can't rely on human resources to do it all—they are experiencing burnout too. We can all be advocates for better mental and physical health and wellness by encouraging direct reports and colleagues to find the help and support that is available to them.

Regardless of the name or label we assign to it, the quiet quitting phenomenon is not new, nor is it likely to go away any time soon. As leaders, we can respond by listening, showing compassion and empathy, and helping others explore and express the help they need. CM

Becoming an FCM–A Fellow in Case Management *continued from page 2*

your significant contribution to case management. Applicants should capture their education, certifications, experience, leadership achievements, innovations, mentorship, community service, special recognitions, and research as well as the impact of their contributions.

Qualification criteria for becoming a Fellow include:

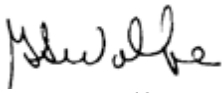
- Hold a case management certification from a nationally recognized certifying body.
- Current member of CMSA for most recent 5 years.
- Minimum of 10 years in the professional practice of case management.
- Possess a professional licensure or hold an advanced health and human services degree.
- Make a significant contribution to the professional practice of case management through leadership, innovation, and/or scholarship.

All applications meeting the criteria are reviewed by the Case Management Fellow Selection Committee, and a scoring rubric is used to decide who will be selected as a Fellow. The bar is high because Fellows are the leaders who make a real difference in the professional practice of case management. There are many great case managers and leaders, but becoming a Fellow is the next level of recognition. Becoming a Fellow is the highest recognition for case managers in the professional practice of case management.

The application cycle for the Case Management Fellow Class of 2023 is open until January 13, 2023.

Apply on line at www.cmsa.org.

Earning the designation of Case Management Fellow attests to your expertise and leadership in the professional practice of case management. This impressive credential positions you as a recognized leader. If you think you have made a significant contribution to the professional practice of casemanagement, please apply. If you are growing in your career, use the criteria for becoming a Fellow to guide you so at some point you too might become a Fellow.



Gary S. Wolfe, RN, CCM, FCM,
Editor-in-Chief
gwolfe@academyccm.org

ACCM: Improving Case Management Practice through Education

Medical Cannabis and Workers' Compensation: Ethical Considerations for the Care Manager *continued from page 23*

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Jeff *continued from page 8*

to address their socioeconomic issues to the best of our ability with the time we had. The types of innovative solutions that make me passionate about case management are identifying a problem, brainstorming solutions, and implementing, assessing, and driving change for better patient outcomes.

About 3 months into the contract with the hospital, I received that referral for Jeff. A few months after coming into our housing and starting treatment, Jeff declined and returned to the hospital, where he was admitted for over a month. He called me while in the hospital and let me know he now had a permanent feeding tube and wanted to return to our housing if we would let him. Jeff said they taught him how to take care of all his feeding supplies himself and while he had the option to go to long-term care or hospice, he felt at home in our housing surrounded by the staff and other residents and wished to return.

We agreed for him to return when he was medically stable, and the hospital agreed to renew his housing contract with us. Jeff had lost a lot of weight and become very frail. Once he returned, it was only a few weeks until he called me into his room one day. He said he was ready to go back to the hospital. Jeff called me a few days after that from the hospital and we spoke for a few minutes. He thanked me for everything we had done for him and without saying so, we both knew it would be the last time we spoke.

There are so many reasons case managers do what they do. We all have that patient or story we look back to that keeps us going and motivates us, and this is one of mine. CM

Complex Patients with Complex Discharge Needs: The Continuing Challenge *continued from page 3*

be part of the solution or lead the process that will solve these problems?

In the early days of case management (before it even had that name), we conducted what might be termed rudimentary research to find solutions to improve care for the small number of patients with the most complex and costly medical conditions. This effort resulted in the evolution of case management, but we now need to revisit and revise our process. Although we know that case management is not a one-size-fits all, what process is or could be the most successful one?

I challenge you and all case management leaders to consider that question as we embark on a new year and perhaps a new and improved chapter in the continuing legacy of case management.

On behalf of all of us at *CareManagement*, we thank you for your loyalty as readers and contributors and wish you a happy holiday season and a happy, healthy New Year!!

As we conclude this year and look forward to the next, we hope you'll renew your efforts and continue to make a difference…one patient at a time!
–Catherine

Catherine M. Mullahy, RN, BS, CRRN, CCM, FCM, Executive Editor
cmullahy@academyccm.org

Not Just One Week A Year!
Case Management Appreciation
continued from page 6

As the oldest professional organization for the practice of case management, CMSA has long supported the case management community across the continuum in a myriad of ways and celebrates the profession every day. From developing and providing relevant, timely education, critical policy information, and the ability to connect with the wider case management community, CMSA is the one stop for professional case managers and those who support them in their goal of providing excellent patient-centered care.

Please make plans to join us June 27–30, 2023, at the Mandalay Bay in Las Vegas for the 2023 CMSA annual conference. This year's theme is "Discovering Solutions. Driving Change," which perfectly describes the value of attending the conference and the everyday role of the case manager.

CMSA honors case managers in all settings and disciplines by providing best-in-class education to elevate the profession. The celebration of case management and the case management community continues with valuable education, networking, and continued recognition through awards and designations such as Case Manager of the Year, Award of Service Excellence, and Case Management Fellow program.

We hope you'll join us in celebrating case management and we know how much you are appreciated as a member of the case management community! CM

The Case Management Society of America (CMSA) facilitates the growth and development of professional case managers across the full health care continuum, promoting high quality, ethical practice benefitting patients and their families. We strive for improved health outcomes by providing evidence-based resources, impacting health care policy and sustaining the CMSA-developed Standards of Practice for Case Management. www.cmsa.org

LITSCAN FOR CASE MANAGERS

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as total parenteral nutrition (TPN) and chemotherapy may be used in this setting. We aim to describe the relative cost-effectiveness of these interventions to inform clinical decision making.

METHODS: Four strategies for management of platinum-resistant recurrent ovarian cancer with inoperable MBO were compared from a societal perspective using a Monte Carlo simulation: (1) hospice, (2) TPN, (3) chemotherapy, and (4) TPN + chemotherapy. Survival, hospitalization rates, end-of-life (EOL) setting, and MBO-related utilities were obtained from literature review: hospice (survival 38 days, 6% hospitalization), chemotherapy (42 days, 29%), TPN (55 days, 25%), TPN + chemotherapy (74 days, 47%). Outcomes were the average cost per strategy and incremental cost-effectiveness ratios (ICERs) in US dollars per quality-adjusted life year (QALY) gained.

RESULTS: In the base case scenario, TPN + chemotherapy was the most costly strategy (mean; 95% CI) ($49,741; $49,329-$50,162) and provided the highest QALYs (0.089; 0.089-0.090). The lowest cost strategy was hospice ($14,591; $14,527-$14,654). The TPN alone and chemotherapy alone strategies were dominated by a combination of hospice and TPN + chemotherapy. The ICER of TPN + chemotherapy was $918,538/QALY compared to hospice. With a societal willingness to pay threshold of $150,000/QALY, hospice was the strategy of choice in 71.6% of cases, chemotherapy alone in 28.4%, and TPN-containing strategies in 0%.

CONCLUSIONS: TPN with or without chemotherapy is not cost-effective in management of inoperable malignant bowel obstruction and platinum-resistant ovarian cancer.

Am J Epidemiol. 2022 Nov 7;kwac195. doi: 10.1093/aje/kwac195. Online ahead of print.

Peripheral neuropathy and vision and hearing impairment in US adults with and without diabetes

Hicks CW, Wang D, Lin FR, et al.

We aimed to assess the associations of peripheral neuropathy (PN) with vision and hearing impairment among adults aged ≥40 years who attended the lower extremity disease exam for the National Health and Nutrition Examination Survey (NHANES) 1999-2004. Overall, 11.8±0.5% of adults had diabetes, 13.2±0.5% had PN (26.6±1.4% with diabetes, 11.4±0.5% without diabetes), 1.6±0.1% had vision impairment, and 15.4± 1.1% had hearing impairment. The prevalence of vision impairment was 3.89% (95%CI 2.99-5.05) among adults with PN and 1.29% (95%CI 1.04-1.60) among adults without PN (P<0.001). After adjustment, PN was associated with vision impairment overall (OR 1.48, 95%CI 1.03-2.13) and among adults without diabetes (OR 1.80, 95%CI 1.17-2.77), but not among adults with diabetes (P-for-interaction=0.018). The prevalence of hearing impairment was 26.5% (95%CI 20.4-33.7) among adults with PN and 14.2% (95%CI 12.4-16.3) among adults without PN (P<0.001). The association of PN with any hearing impairment was not significant after adjustment (OR 1.24, 95%CI 0.86-1.77). However, the association of PN with moderate/severe hearing impairment was significant overall (OR 2.55, 95%CI 1.40-4.64) and among adults without diabetes (OR 3.26, 95%CI 1.80-5.91). Overall, these findings suggest an association between peripheral and audiovisual sensory impairment that is unrelated to diabetes.

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application on next page

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Editor-in-Chief/Executive Vice President:
GARY S. WOLFE, RN, CCM, FCM
541-505-6380
email: gwolfe@academyccm.org

Executive Editor: Catherine M. Mullahy, RN, BS, CRRN, CCM, FCM, 631-673-0406
email: cmullahy@academyccm.org

Publisher/President: Howard Mason, RPH, MS, 203-454-1333, ext. 1;
e-mail: hmason@academyccm.org

Art Director: Laura D. Campbell
e-mail: lcampbell@academyccm.org

Copy Editor: Esther Tazartes
e-mail: justice@dslextreme.com

Subscriptions: 203-454-1333
Website: academyCCM.org

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Executive Vice President:
Gary S. Wolfe, RN, CCM, FCM
541-505-6380
email: gwolfe@academyccm.org

Member Services:
203-454-1333, ext. 3
e-mail: hmason@academyccm.org

Phone: 203-454-1333; fax: 203-547-7273
Website: academyCCM.org

Vol. 28, No. 6, December 2022/January 2023. *CareManagement* (ISSN #1531-037X) is published electronically six times a year, February, April, June, August, October, and December, and its contents are copyrighted by Academy of Certified Case Managers, Inc., 2740 SW Martin Downs Blvd. #330, Palm City, FL 34990;
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