

CareManagement

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Gary S. Wolfe

Health Care 2024

As we look ahead in 2024, we can reflect on what occurred in 2023 and what health care in 2024 will look like. For the last few years, health care has been in a dynamic state and under considerable stress. The demand has outstripped supply in most instances.

In 2023 some of the driving forces included price inflation, public health emergencies, expansion of nontraditional providers, the digital telehealth expansion, alternate payment methods, consolidation, health care worker shortages, and chat-based artificial intelligence (AI) systems in the health care arena. In the area of medical science, new developments included new weight-loss drugs, RSV vaccines, xenotransplants moving closer to reality, many new drugs including CRISPR gene-editing technology, and new information on long COVID. In 2023, we saw the first successful face and eye transplant. Although the public health emergency of COVID officially ended, we saw and continue to see the effects of the COVID pandemic on much of what we do. Case management was challenged in 2023 with labor shortages and increased demand for services. As health care grew in complexity, so did the demand for case managers.

As we look ahead in 2024, the driving forces for change in health care will continue to be inflation, labor shortages, rapidly evolving medical science, and the consumer demand for access, quality, and cost-effective care. I predict the following will dominate the health care landscape in 2024:

- **Value-based Care:** Consumers are demanding holistic,

Value-based care will increase the demand for case management services, and case managers will play a significant role in fostering patient-centered care through the case management process.

outcome-oriented care—not quantity over quality. Value-based care changes the paradigm of how care is delivered. The focus shifts to prevention, planning, and coordination. The number of people enrolled in value-based care programs will more than double in the next few years. This change will drive innovation and lead to better patient experiences. Value-based care will increase the demand for case management services.

- **Patient-centered Care:** Patient-centered care is a growing trend that prioritizes involving patients in their health care decisions. Patients want to be involved and not just told what to do. They want to know options, outcomes, risks, and costs. This will lead to improved patient satisfaction and better health outcomes. The case manager will play a significant role in fostering patient-centered care through the case management process.
- **Labor Shortages:** Labor shortages will continue in 2024 partly because of increased demand but also because of the aging registered nurse population who are retiring or leaving the workforce. New

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Catherine M. Mullahy

Make 2024 the Year You Build Recognition for Case Management

Catherine M. Mullahy, RN, BS, CRRN, CCM, FCM

The value of case management has been analyzed and confirmed in numerous studies by diverse entities. Still, I cannot help thinking that case management remains the undervalued, misunderstood, and uncelebrated stepchild of health care. I do not believe the annual Case Management Week does enough to raise public awareness regarding the case manager's role, nor do we as case managers put forth before health care providers and payors our significant contributions to patient outcomes and satisfaction, population health management, and cost containment. We can blame the complexities involved in case management and our busy schedules for not developing a communications and education strategy for patients, providers, and payors. That, however, does not alone solve the problem for what has kept case management on the sidelines. It is time that case manager leaders and their staff begin to build a clear brand identity that conveys case management's role and value propositions for all stakeholders.

Building the Brand With Effective Communication, Information, and Reinforcement

Just as when a manufacturer builds a product brand, we need to first create a clear, concise definition of what case management is. Unfortunately, there are many descriptions used to explain case management, none of which are complete nor encompass our value propositions.

Still, I cannot help thinking that case management remains the undervalued, misunderstood, and uncelebrated stepchild of health care.

Here are a few examples:

- “Case Management is a dynamic process that assesses, plans, implements, coordinates, monitors, and evaluates to improve outcomes, experiences, and value.” —Commission for Case Manager Certification (CCMC)
- “Case management serves as a means for achieving client wellness and autonomy through advocacy, communication, education, identification of service resources, and service facilitators.” —Case Management Society of America
- Medical case management refers to the planning and coordination of health care services appropriate to achieve the goal of medical rehabilitation.” —Vermont Government

On the Case Management Body of Knowledge website (<https://cmbody-ofknowledge.com>), the Definition of Case Management, reads, “There is no one standardized or nationally recognized or even widely accepted definition of case management.”

In fairness to organizations defining case management, their definitions are all followed by long explanations of what case management entails, but not necessarily in simple terms. Nor do they promote our primary value proposition(s). Doing so needs to be a top priority.

National CMSA President Dr. Colleen Murphy addressed several related topics at the recent Legacy Leaders Council Coffee Connect, a meeting of all past CMSA presidents. Among them were:

- What messages and overall themes should all case managers, regardless of setting or discipline, use to promote themselves and the profession?
- What are the barriers to effectively communicating the value of case management?

As a Legacy Leader invited to this event, I was pleased to see that these concerns are shared by other case management leaders and advocates. In addition to developing a standardized definition of case management, we need to better leverage various studies that objectively, and backed by data, convey the value of case management.

The Credibility Factor When Conveying Value

In the peer-reviewed, open access scientific journal, *The International Journal of Environmental Research and Public Health*, the article, “Results of Nurse Case Management in Primary Health Care: Bibliographic Review,” discusses the findings of various studies on case

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Case Management: One CMSA's Journey

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

Looking back on a career that spans a quarter of a century in nursing and two decades in case management, I am filled with a sense of profound gratitude and reflection. My journey through the realms of health care has been a tapestry woven with dedication, challenges, learning, and immense satisfaction; one that I would imagine is not very different to others.'

My foray into the world of health care began 25 years ago, stepping into the profession of nursing after 11 years in the business world. Those initial years were formative, filled with the raw realities of patient care, the dynamics of health and illness, and the very human qualities of vulnerability and resilience. Nursing taught me the value of compassion, the importance of meticulous care, and the unspoken language of empathy. Each patient encounter was a lesson in humanity, each day a deeper understanding of life's fragility and strength. These years were instrumental in shaping my approach to patient care, emphasizing empathy, attention to detail, and a relentless pursuit of excellence.

Twenty years ago, I transitioned



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of Altra Healthcare Consulting in CO) and ANA Illinois Practice Improvement Award (2020) for her work in this area.

Case management allowed me to broaden my impact, focusing not just on immediate care but on the continuum of health.

into the specialized field of case management through a rather unexpected personal journey, a twisty-turny road of personal necessity combined with professional curiosity. This shift was more than a career move; it was a step into a world where the complexities of health care systems, patient needs, and my previous business experience intersected. Case management allowed me to broaden my impact, focusing not just on immediate care but on the continuum of health. It was here that I learned the art of advocacy, the significance of personalized care plans, and the critical need for resource management. Case management is a balancing act—aligning patient needs with health care offerings, navigating through bureaucracies, and always keeping the patient's best interest at the core.

Becoming the president of CMSA has been an incredible honor. This role is not just a position of leadership but a platform to advocate for and advance the practice of case management. It represents an opportunity to influence policies, foster professional development, and champion the integral role of case managers in the health care continuum. As president, I have aimed to harness my experiences to drive innovation, inclusivity, and excellence in case management.

Some of CMSA's key accomplishments over the past 18 months have been:

- Welcomed over 1,100 new members to the CMSA community
- Published a position paper on "Communicating Your Value: The Case Manager's Guide" in collaboration with the Center for Case Management
- Held a successful CMSA Conference in Las Vegas with over 40 educational sessions and 1,000 attendees
- Celebrated National Case Management Week with webinars, networking events, social media contests, bonus education, and prizes! Over 2,000 case managers participated
- Published over 200 blogs and articles providing key information on timely trends and topics
- Held the second CMSA Virtual Hill Visits program with case managers from across the country
- Launched the CMSA International Special Interest Group
- Released new resources on anti-microbial resistance and hepatic encephalopathy
- Inducted the CMSA CM Fellow Class of 2023
- Strengthened partnerships with Aging Life Care Association (ALCA), American College of Physician Advisors (ACPA), Nurses on Board Coalition (NOBC), Case Management Institute (CMI), Utilization Review Accreditation

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Advocacy—Always and Everywhere

Nina Mottern, RN, BSN, CCM

The young man walked toward me with a pronounced limp, dragging his foot. As he neared the van where I was administering screening tests for sexually transmitted infections (STI) as part of a public health clinic, my first thought was about his ankle.

“What happened to you?” I asked, pointing to his foot.

The man hesitated, then explained that he’d fallen the night before. He couldn’t remember exactly what happened; he and his wife had been using drugs. I made no comment about what he disclosed regarding his drug use. As a CCM, I am an advocate—always and everywhere. Without judgment, I try my best to meet people where they are in their current life circumstances and to offer help that they want and need. It is an approach to person-centric practice that applies not only to CCM certificants but also to our colleagues in disability management, including those holding the certified disability management specialist (CDMS) designation.

Nina Mottern, RN, BSN, CCM,

is a Commissioner with CCMC, the first and largest nationally accredited organization that certifies more than 50,000 professional case managers and disability management specialists with its CCM® and CDMS® credentials. With more than 20 years in professional case management, Nina has served a variety of care settings, including public health, geriatric care management, and the Veterans Administration.



As a CCM, I am an advocate—always and everywhere. With judgment, I try my best to meet people where they are in their current life circumstances and to offer help that they want and need.

In that moment, beyond the STI testing he was seeking, I determined that the young man might want to know how he could receive free medical attention for his ankle. “If you can wait a little longer, the hospital’s mobile medical van will be here,” I told him.

He shook his head. “I’m not waiting around.”

His tense body language told me he suspected the suggestion to wait could be some kind of entrapment, and I needed to assure him it was safe. Equally important, the advocacy role compels us to uphold each person’s autonomy. Receiving services would have to be his decision.

“You don’t have to hang around if you don’t want to,” I told him. “You can go and come back around 2:00 pm.”

He left, and I tended to other people who had come to the STI testing clinic. But at 2:00 pm, I saw the young man approaching the clinic again and limping slowly toward the van.

Random Acts of Advocacy

By nature, I like to help people. Whenever I see an opportunity to provide information, assistance, or support, I’m going to take the risk of offering it. It’s simply the way I’m wired. Over my almost 50 years as a nurse and nearly 20 as a CCM, my

predisposition to assist people—emotionally, physically, and even spiritually—has defined advocacy for me.

In every care setting in which I have worked—including medical/surgical, primary care, geriatric case management, the Veterans Administration (VA), and public health—I strive to see people as individuals, with unique needs and circumstances, and without judgment or assumptions. Sometimes these interventions occur during my professional involvement with people, as in the case of the young man at the STI screening. Other times, they occur while I am in the community.

While out for a walk in my neighborhood one day, I met a man in his early 70s, who was out in his yard with a family member. He told me he had to leave his home because of numerous health issues, including Parkinson’s disease and a heart condition that made living independently impossible, even with support.

Given his age and health status, I asked if he had served in the military. “Yes, in Vietnam,” the man replied. Knowing the link between Parkinson’s and exposure to the herbicide known as Agent Orange used during the Vietnam War, I explained that his military service could possibly have contributed to his medical conditions. If so, the man could be eligible for

compensation and other benefits from the VA. He resisted at first; like many Vietnam-era veterans, he harbored some hurt feelings about the way people who had served in the military were treated at the time. I listened but reminded him that these benefits were for people like him who had served their country.

What happened next (which I have shared previously [Mottern & Franklin, 2023]) makes this one of my favorite examples of what I call “random acts of advocacy.” With their agreement, I assisted the man and his family in completing and submitting the required forms to apply for veterans’ benefits. After his military service was confirmed, he began receiving health services from a local VA hospital. Not only that, but he was also determined to be 100% eligible for compensation benefits due to his service-related disability.

He received a grant of more than \$150,000 to make his home safer and more accessible, including installation of an elevator and an exterior ramp. Along with many other supports, he also received a motorized scooter and a van conversion with a platform for his chair. Before receiving these benefits, the man had been paying thousands of dollars out-of-pocket each month for boutique medical care. Now, through the VA, his care was free.

Although this is a story I love to share, it’s not about me. Rather, it speaks to being in the right place at the right time when someone needed help. When we are open to being the conduit for that assistance, opportunities to provide information and promote self-advocacy often appear.

A Helping Profession

Given my nature, it’s no surprise that I pursued a career in health care. My initial decision wasn’t profound. Rather, I idolized my older sister and

her high school friends. When her friend Rosemary picked nursing as a career, that was it for me, too. Fifty-plus years later, I can attest that it is still a good fit for me.

I began my journey as a nursing assistant, then an LPN, while putting myself through nursing school at City College of New York and then Rockland Community College to become a registered nurse (RN). The nurses I worked with knew my career plans and mentored me, exposing me to procedures and patient care that were well beyond my responsibilities at the time. That early clinical experience helped shape me and today serves as a reminder of the importance of developing others. After becoming an RN, I worked in the medical/surgical field before moving from New York State to Pennsylvania with my husband. I transitioned to geriatrics, working in nursing homes, which fit my schedule as a parent with young children. This area of specialization, however, became my true passion. I found so much satisfaction serving clients who had much to share about their lives—and I always appreciated their stories.

With changes in my personal life (I divorced and later remarried), I changed care settings again. My husband, an internist, and I opened a private practice in 1994. Ours was a multigenerational practice, and we often served three generations of family members (and, with one family I recall, four generations). If a person needed an hour-long consultation, that’s what they received. When necessary, we made home visits for patients who had difficulty coming into the office due to their health issues, such as amyotrophic lateral sclerosis (ALS), as well as the inability to get to the office safely because of inclement weather or poor health.

Within the practice, I was the office manager and phlebotomist and

administered immunizations, allergy shots, pulmonary function tests, and ECGs. Looking back, I was also the case manager, even before I heard that term or knew what it meant. I provided care coordination, making sure each patient received the resources and referrals they needed. If they had difficulty making appointments themselves for any reason, I assisted them.

In 2004, my husband was recruited by the VA in the primary care program. I was hired as well and began my VA career as a geriatric care RN. A year later, a new position was created. Based on my previous experience, the role of geriatric care coordinator made perfect sense for me, and I welcomed the challenge. That was when I first became aware of the Commission for Case Manager Certification (CCMC) and the CCM certification. The VA supported certification, offering training and paying the fees. A group of designated case managers from Western New York State VA facilities met once a week by conference call, studying together and taking practice tests. In 2009, one year after I completed my bachelor’s degree, I became a CCM.

Becoming certified was an important milestone in my long career. It attested to my knowledge and skills gained over many years as a nurse, clinician, and patient advocate. Within Health and Human Services, we sometimes encounter people who have the title of “case manager,” but they do not have a clinical background; theirs is more of an administrative role. To earn the CCM is to demonstrate the requisite knowledge, skills, and experience to provide comprehensive case management services, including care coordination. As the Code of Professional Conduct for Case Managers, published by the Commission, states: “Board-Certified Case Managers (CCMs) believe that

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How Case Managers Help

Kathy Barrows, BSN, RN, CCM

The public often wonders just what a case manager does and how they help patients. Below are scenarios in which case managers worked their magic.

A case manager talked with a patient about new left calf pain he was experiencing. He had no injury to his left leg from the accident that began his health care journey. Since he was complaining of intense pain and had not had any pain previously, including no pain at the orthopedic surgeon's appointment earlier that day, the case manager was concerned. She was able to explain over the phone how the patient could do a simple physical test, which can demonstrate the presence of a blood clot in the lower leg. The patient did the test while the case manager waited, and when the patient reported the reaction of his leg to the test, the case manager advised the patient to have the leg evaluated right away. She explained that there was a possible blood clot.

The patient had the left leg checked at the emergency department after the call, and he was admitted to the hospital with large blood clots in both legs, requiring anticoagulation treatment as

well as a special procedure called a thrombectomy, done by an interventional radiologist to remove both large blood clots.

The blood clots extended from the abdomen all the way down both legs. The patient also had one small clot in each lung. He had immediate relief of pain to his legs after the thrombectomy.

The patient told the case manager that if she had not strongly encouraged him to have his leg evaluated, he would have put it off until the next day when he was scheduled for outpatient physical therapy. That delay would most likely have led to worse consequences. A case manager was covering a case for a colleague on a Friday evening before

The patient told the case manager that if she had not strongly encouraged him to have his leg evaluated, he would have put it off until the next day when he was scheduled for outpatient physical therapy. That delay would most likely have led to worse consequences.

a holiday. She received a voicemail from a patient saying he was in severe pain and the doctor could not treat him until he had an MRI, which would require approval from the patient's insurance company. Even though it was late on a Friday evening before Memorial Day, the case manager called the insurance provider regarding the patient's situation. She asked if expedited approval of the MRI could be made. The insurance representative

said they were closed on Saturday and Sunday, but had some staff coming in on Monday, Memorial Day. They could expedite the case then.

The case manager called the patient to let him know that the MRI had been marked for expedited review. He was appreciative of the help. The expedited approval was given that Monday, and the patient was able to have the expedited MRI on Wednesday after Memorial Day so that the doctor could move forward with treatment.

A patient's wife requested to have a leg prosthesis authorization so that her husband could receive the leg prosthesis in time to stand at his son's wedding. The patient's wife reported that the prosthetics company had submitted the authorization while the patient was at the office, but it was not showing as approved yet.

The case manager advised the insurance that there was a tight timeline to have the authorization approved. The prosthetics company needed to make the prosthesis, and then the prosthesis had to be fitted and adjusted in time for the son's wedding. The case manager discussed the case with both the clinical manager and medical director of the insurance company. There were a number of complicating issues, but the case manager was able to work with the management in the insurance company as well as the nurse doing the reviews to get the process moved along quickly.

The leg prosthesis was approved and was delivered to the patient in

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Kathy Barrows, BSN, RN, CCM, has worked as a complex case manager nurse for 32 years. She has co-presented a poster at the National CMSA meeting each year since 2012. Kathy won the Case Manager of the Year from SOV-CMSA this past October.

won the Case Manager of the Year from SOV-CMSA this past October.

OIG General Compliance Guidance, Part 1

Elizabeth E. Hogue, Esq.

This is the first in a series of articles that will identify and provide information about key provisions of the General Compliance Guidance. Stay tuned for more on this topic.

The Office of Inspector General (OIG) of the US Department of Health and Human Services (HHS) is the primary enforcer of fraud and abuse prohibitions. The OIG periodically publishes guidance to help providers in their compliance efforts.

Beginning in 1998, the OIG published compliance program guidance (CPG) for:

- Hospitals
- Home health agencies
- Clinical laboratories
- Third-party medical billing companies
- Durable medical equipment
- Hospices
- Medicare Advantage Plans
- Nursing facilities
- Physicians
- Ambulance suppliers
- Pharmaceutical manufacturers

The OIG has just published additional General Compliance Guidance that applies to all health care providers. The OIG also announced that it will publish new guidance specific to segments of the health care industry in

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Although the General Compliance Guidance is intended as a resource for providers, it is also clear that the Guidance provides a “window” into what the OIG considers to be effective Compliance Programs.

2024. After new specific guidance is published, the General Compliance Guidance will still be effective.

The OIG emphasizes in new General Compliance Guidance that both general and specific guidance do not constitute model compliance programs. Rather, both general and specific guidance are for use as resources by health care providers. The OIG’s Guidance is not intended to be one-size-fits-all, comprehensive, or all-inclusive of compliance considerations and fraud and abuse risks for every provider.

Instead, guidance is intended to provide voluntary compliance guidelines and tips and to identify risk areas that the OIG thinks providers should consider when developing and implementing new compliance programs or evaluating and updating existing programs.

Separate sections for small and large providers in the General Compliance Guidance may be of special interest to providers. It is helpful for the OIG to recognize that there

should be a difference in compliance programs as between large and small providers.

Although the General Compliance Guidance is intended as a resource for providers, it is also clear that the Guidance provides a “window” into what the OIG considers to be effective Compliance Programs. Providers must educate themselves about the Guidance and incorporate it into their Compliance Programs as appropriate.

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Enhancing Safety and Independence With Transfers: A Guide to Transfer Devices for Case Managers

John V. Rider, PhD, MS, OTR/L, MSCS

As case managers, the safety and well-being of our patients are of utmost importance. The need for effective patient transfer devices cannot be overstated in health care, where we frequently encounter individuals with varying degrees of mobility challenges and safety concerns. These devices, also known as patient transfer equipment or transfer aids, play a critical role in safely moving patients to and from wheelchairs, chairs, beds, cars, bathtubs, showers, and toilets and can be used collaboratively by health care professionals, care partners, and patients. Without transfer devices, patients with limited mobility or high fall risk may be unable to get out of bed, leave their homes, or participate in daily activities, leading to isolation and further physical and psychological deconditioning. Transfer devices can enhance the quality of life for patients by giving them the ability to be more mobile and access their environment to engage in meaningful activities with increased safety and independence. These devices can also reduce the risk of injury to care partners assisting with transfers. With falls being the leading cause of fatal and nonfatal injuries among older adults (Moreland et al., 2020), ensuring that patients are transferred safely and efficiently is paramount to reducing risks for both patients and care partners.

This article will delve into the most common patient transfer devices, examining the various types available and how they can increase safety and independence for patients with mobility challenges. We will explore different categories of transfer devices based on the level of assistance required, highlight transfer aids for specific needs, and provide insights into choosing the most appropriate devices.

Considerations in Choosing the Best Transfer Device for Each Patient

Patient transfer devices come in various forms, and the choice of the right device depends on the level of assistance a patient requires. While health care providers use many different assistance levels, for ease of understanding, this article will categorize these devices based on self-transfer, assisted transfer, and dependent transfer. However, it is important to recognize that many patients require different

levels of assistance for different activities, depending on energy levels, pain, time of day, and other symptoms that may affect strength and endurance. Furthermore, many transfer devices can be used across assistance levels by decreasing or increasing the care partner's assistance. Case managers must consider the patient's current and expected level of assistance when recommending appropriate patient transfer devices. Reviewing rehabilitation and therapy notes can provide insight into current and expected patient assistance levels. Occupational and physical therapists can assist with making appropriate recommendations based on clinical evaluations. Occupational therapists receive extensive training in assistive technology, and the rehabilitation care plan should include exploring necessary assistive technology and training patients and care partners on their appropriate use. If documentation is unclear or patients and care partners are unaware of what equipment they may need, coordinating with occupational and physical therapists is the best approach to ensure proper recommendations for assistive devices.

Self-Transfer Mobility Aids

Self-transfer mobility aids are designed for individuals needing minimal to no assistance transitioning between sitting and standing. Individuals in this category complete most transfers on their own or with supervision or contact-guard assistance. These transfer devices help make the transfer safer or compensate for minimal impairments and empower patients to maintain independence in their daily activities. They are often inexpensive and require minimal training.

Individuals who can transfer on their own or with minimal assistance may use mobility aids, such as canes or walkers, to increase their base of support and provide additional stability when transferring between surfaces and ambulating. Numerous devices can be easily installed on chairs, beds, and toilets to provide rails and arm support for safer standing,



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Case managers must consider the patient's current and expected level of assistance when recommending appropriate patient transfer devices.

sitting, and repositioning. Grab bars can be installed anywhere there is structural support to provide additional leverage when standing or sitting. These will be covered in more depth when discussing common transfer devices for the bedroom and bathroom.

Self-transfer aids can also support vehicle transfers. Patients must be able to transfer in and out of vehicles to attend medical appointments. While vehicle transfers should be addressed in rehabilitation, they are often left toward the end when preparing for discharge. They are sometimes overlooked due to more pressing therapy needs, leaving patients with questions for their case managers. Vehicle assistance straps include removable and permanent handles and straps from the top of the car door or inside to enhance stability when entering and exiting a car. They provide essential support to individuals who need extra balance during transfers or must use their arms to help pull themselves up or lower themselves down. Vehicle support handles provide a stable handle for leverage when getting in and out of a car. These simple devices are temporarily inserted in the door latch with no modifications and provide a stable surface to push up from when standing. They are easy to use and portable, making car transfers safer and more manageable for individuals with mobility impairments. Swivel seat cushions allow patients to rotate their seated positions easily. These devices eliminate the need to twist or lean while getting in and out of a car, promoting safer transfers and increasing independence, especially for patients with poor trunk control or lower body weakness. Lift chairs are household chairs with built-in power lifts and can provide extra assistance getting up and down but can be expensive. Portable chair lifts are less costly and can be placed on multiple surfaces to help patients rise to a standing position. Generally, self-transfer aids are not covered under insurance but can be purchased online and in-person from medical supply stores and online retailers. Aside from the lift chairs and portable chair lifts, self-transfer aids listed here are typically \$25 or less.

Assisted Transfer Devices

Assisted transfer devices are best suited for individuals who require physical assistance from care partners during transfers because they are unsafe or cannot move without help. Many of these devices are used in rehabilitation as

patients recover from injury and illness. Rehabilitation clinicians will often recommend these devices to patients and care partners if the patient is still using them at discharge or if significant progress is not expected. These devices work collaboratively with both the patient and care partner. They are designed to ease the physical strain on care partners and ensure the patient's safety during transfers. As with all transfer devices, they can be used during rehabilitation or as part of a home therapy program by grading the amount of care partner assistance to help patients build strength and improve balance.

Transfer belts, also known as gait belts, are placed around a patient's waist, providing care partners with a handle to grasp for assistance and support during short-distance transfers. They are particularly useful for patients who lack the strength or stability to stand and ambulate independently and have balance concerns. Different kinds are available that include handles and provide varying levels of support. They eliminate the need for a care partner to grab the patient's clothing, which may not be secure, or their arms, which may cause injury or prevent them from using them appropriately when transferring. Transfer belts provide more proximal control at the pelvis to assist with transfers and mobility and provide more stable contact points between the patient and the care partner. Transfer boards, sometimes called sliding boards, enable patients with limited upper or lower body strength to move between surfaces with minimal lifting or physical strain. The transfer board is placed between two surfaces, such as the bed and a wheelchair. Care partners support the patient's upper body and slide them across the board from one seat to another. These can be helpful for a range of diagnoses, from cerebrovascular accidents to knee replacements to spinal cord injuries, when patients cannot stand safely. They are also often used as a primary transfer device for individuals with paraplegia and those who cannot bear weight in their lower extremities, because the patient can slide across only using their upper body. Patients can learn to use transfer boards independently for self-transfers with training from occupational and physical therapists. Transfer boards come in different shapes and sizes to support all body types and transfers to different surfaces.

Pivot discs are helpful for individuals who can bear weight but have difficulty turning or changing positions. Pivot discs,

Generally, self-transfer aids are not covered under insurance but can be purchased online and in-person from medical supply stores and online retailers. Aside from the lift chairs and portable chair lifts, self-transfer aids listed here are typically \$25 or less.

sometimes called pivot aids, spin easily, facilitating the pivot needed to transfer from one surface to another. Patients stand directly on the pivot disc, and care partners help them turn and sit on the desired transfer surface. Patients must be able to stand and bear weight to use these devices. As with patients who can self-transfer, mobility aids such as canes and walkers are often necessary for standing and ambulating when patients need physical assistance with transfers. In rehabilitation, patients often use a mobility device, such as a cane, while the therapist uses a gait belt to provide additional physical assistance. If needed, care partners can also use this approach at home. Depending on the level of assistance and impairments, canes can have a single point of contact, three points of contact, or even four points of contact with the ground and multiple handle configurations. Patients often use canes incorrectly. Physical therapists should be consulted if the client is new to walking with a cane.

Many kinds of walkers exist, which can be overwhelming for patients, care partners, and even case managers. There are walkers designed for individuals with hemiplegia who can only use one arm, attachments for individuals who cannot bear weight on one arm because of a fracture, and walkers with large wheels, hand brakes, and seats to allow patients to sit and rest when ambulating. There are walkers with handles in the front or the back designed to improve upright standing posture. Multiple modifications and attachments exist to support independence and safety when using walkers for transfers and daily activities, and recommendations should be individualized to the patient's needs. When recommending a walker for the first time or any type beyond a basic four-point walker, a referral to physical and/or occupational therapy should be made if the patient is not already receiving therapy. Walkers and canes are typically covered under insurance as durable medical equipment, but they must be medically necessary as determined by a physician or provider. Walker accessories and attachments are generally not covered and must be purchased out-of-pocket. Canes typically cost anywhere from \$20 to \$40. Because there are so many kinds of walkers, from the basic silver folding walkers used in hospitals and nursing homes to rollators with seats and hand brakes to upright walkers, costs can vary when paying out-of-pocket, from \$40 to \$300. They can be purchased from medical supply stores, department stores with health care sections, and many places

online. Most are adjustable, but patients who are shorter or taller than average may need to consider height recommendations when purchasing equipment.

Dependent Transfer Aids

For patients with severe mobility impairments who rely entirely on care partners for transfers, special aids are required. These devices allow multiple care partners to work together when necessary to ensure safe and efficient patient transfers. Patient lifts are designed to move patients with little to no independent mobility or with medical precautions or contraindications. They provide a safe and comfortable experience while reducing the physical strain on care partners. Floor lifts are mobile devices that can be used by one care partner and can even be taken on vacations, supporting improved quality of life and meaningful activity engagement beyond basic activities of daily living. They are often called mechanical lifts and can be powered by an electrical motor (operated by a controller, requiring them to be plugged in or charged) or a hydraulic pump (requiring the caregiver to manually pump the lift when transferring a patient). While pumping the lift sounds strenuous, manual lifts require very little force. Floor lifts require a sling that wraps around the patient's back and attaches to the lift. Different slings are available based on patient size, material preferences, skin integrity, and whether the patient wants to be lifted in a seated or lying down position. Floor lifts have wheels to move the patient around their environment and be lowered onto another surface with minimal physical strain on the care partner. In addition to transferring patients, floor lifts can be used to help lift patients from the floor if they have fallen or reposition them when seated or lying down. When medically necessary, floor lifts can be covered by insurance. When purchased out-of-pocket, the simple manual/hydraulic floor lifts can be purchased for as low as \$300-\$400, with patient slings starting at \$50. Prices increase for higher weight limits on slings and lifts, foldable lifts, and when moving from hydraulic to electrical power options.

Ceiling lifts are permanent mechanical structures mounted on the ceiling to help the care partner raise, lower, tilt, or roll the patient. Ceiling lifts can be mounted on a rail system extending to rooms throughout the home, allowing the patient to move around the home while in a sling. Unlike

While it is exciting to recognize the available assistive technology to improve safety and independence among our patients, it is crucial to understand that patients often need training on how to use them properly.

floor lifts, ceiling lifts free up space on the floor, reducing the amount of equipment caregivers and patients have to maneuver around. However, they require permanent installation. They are often used for patients with no expected improvement, when structural home modifications are not feasible, such as multilevel homes, or when floor lifts cannot be maneuvered safely. Lastly, sit-to-stand lifts can help patients who can bear weight through their lower extremities but cannot stand independently to transition from seated to standing with minimal care partner assistance. Patients can quickly and easily be moved from seated to standing, and the care partner can push the lift, which has wheels, to another surface for a safe and efficient transfer. Care partners can use these different lifts to transfer a patient to or from the bed, a wheelchair, a commode or toilet seat, a shower chair, or a comfortable chair.

Transfer sheets, also called slide or glide sheets, reduce friction on the skin and allow one or more care partners to more easily reposition a patient without causing skin breakdown. Similar to floor lifts, ceiling lifts and sit-to-stand lifts can be covered by insurance when a medical necessity is demonstrated, and they are the only safe option to transfer the patient within the home. Alternative funding options, such as grants, are available for ceiling lifts, often with disease-specific national organizations. Sit-to-stand lifts typically start around \$500 out-of-pocket and increase depending on weight capacity and features.

As technology and manufacturing progress, innovative devices to assist with transfer and mobility safety continue to be developed. This article is not an exhaustive list. Instead, it is meant to provide a greater understanding of the types of devices currently available and how they can help patients safely do more of what is important to them. In addition to transfer devices, home modifications are often necessary to reduce fall risk and increase independence and safe access to the patient's home environment (Rider, 2020). It is also helpful to consider beneficial equipment in specific rooms where daily activities are challenging, such as the bedroom and the bathroom.

Beyond the equipment already discussed, multiple devices are available to assist patients when getting in and out of bed and positioning themselves appropriately. Bed rails are popular because they can prevent a patient from rolling out

of bed and can be used for additional upper extremity support when sitting up, standing up from the bed, or balancing when transferring. They can be securely attached to the bed frame or placed under the mattress and are height-adjustable. Grab bars can be mounted on the wall next to a bed, and assist poles can be installed from the floor to the ceiling near the head of the bed to serve a similar purpose. When patients struggle to pull themselves up in bed or get to a partially seated position to read, watch television, eat, drink, or take medications, overhead trapezes can be mounted over the bed, allowing patients to grab onto them and pull themselves up. Bed ladders or assistive straps may be a more straightforward option and can be attached to the foot of the bed, allowing patients to use their upper extremities to pull themselves up by each ladder rung or webbing. While most of these devices are not covered by insurance, they are available online and in medical supply stores. When medically necessary, overhead trapezes can be covered by insurance, but they require professional installation and are mounted to the wall or the headboard.

The bathroom is one of the most common areas for falls among older adults and is more likely to result in injuries than falls in other home areas (Stevens et al., 2014). When considering toileting and showering, a wide range of equipment is available to support patients in the bathroom. Grab bars are often the first recommendation and should be placed strategically to support the individual and their leverage needs. Grab bars must be installed over studs and may require professional installation to ensure they are safe. Zero-threshold showers can increase safety because patients don't have to step over a threshold to get in or out. However, bathroom remodels may not be financially feasible. Many states have nonprofits, such as Rebuilding Together, that offer home repairs and modifications to low-income seniors, veterans, and individuals with disabilities to increase safety and allow them to stay in their homes longer. Shower chairs come in all sizes and shapes, from stools to chairs with or without backrests or arm supports, and can provide varying levels of positioning needs for patients who need postural support or cannot stand long enough to shower due to poor endurance, pain, or impaired lower body strength. Shower chairs can also have wheels, allowing patients to transfer from the bed to a shower chair and then wheel into the shower. If a patient only

When appropriately recommended, a relatively inexpensive device purchased out-of-pocket or durable medical equipment covered by insurance can drastically improve a patient's life.

has a tub-shower combination, tub transfer benches are an excellent option for those who cannot lift their legs to step in and out. Tub transfer benches sit partially in and out of the tub, allowing the patient to sit on the bench and safely lift their legs into the shower. Patients can then scoot completely inside the shower. Some tub transfer benches even have sliding seats for patients who cannot scoot independently. Like shower chairs, tub transfer benches come in multiple sizes and designs for all bathtub configurations and patient needs. They can be made with hard or soft materials, varying extremity and back support, open bottoms for perineal care, and even swivel seats. Because shower chairs and tub transfer benches are typically not considered durable medical equipment by Medicare, they are generally not covered by insurance. However, some insurances may cover a shower chair or tub transfer bench for specific diagnoses and when medical necessity is demonstrated. When purchased out-of-pocket, they start around \$30 for a small shower chair and \$60 for a standard tub transfer bench. Prices increase for higher weight capacities and additional features, such as adjustable backs, moveable components, softer surface material, etc.

One of the most versatile transfer devices for toileting is commonly called the 3-in-1 commode because it can serve three functions. It can be used as a stand-alone toilet next to the bed for easy transfers, placed over the existing toilet to increase the height and provide arm rails for upper extremity support, or as a shower chair for someone who cannot stand long enough or safely when showering. Medicare considers 3-in-1s durable medical equipment, so they are often covered by insurance and start around \$35 when purchased out-of-pocket. Many toilet safety frames are available to provide increased stability and confidence when transferring on and off the toilet. Designs include free-standing frames or frames mounted directly to the toilet or the wall. Power-operated toilet lifts are also available and can be used without care partner assistance for patients who cannot stand on their own, promoting privacy and maintaining independence with toileting. These are generally not covered by insurance. Stand-alone toilet safety frames start around \$30.

Patient Training and the Case Manager

While it is exciting to recognize the available assistive technology to improve safety and independence among our

patients, it is crucial to understand that patients often need training on how to use them properly. Case managers may be the first to advocate for assistive technology and durable medical equipment for their patients. When making recommendations or educating patients on specific devices, case managers should consider whether the patient is currently receiving therapy. If they are not working with an occupational or physical therapist, a referral should be made to ensure the patient and care partner are trained in the proper use. Device abandonment or misuse may occur without training, increasing injury and fall risk. Self-transfer devices may not require training; however, assisted transfer and dependent transfer devices should be accompanied by skilled training. While occupational and physical therapists both receive comprehensive training in supporting patients with mobility impairments and disabilities, they often have areas of expertise or advanced training. For example, the effective and efficient use of canes, walkers, and ambulation aids is most commonly provided by physical therapists. However, devices for activities of daily living, such as going to the bathroom, bathing, cooking, and getting in and out of bed, are most commonly addressed by occupational therapists. Both professions have training in all forms of transfers and patient lifts and can collaborate on appropriate recommendations.

The realm of patient transfer devices is vast and continually evolving, offering a comprehensive range of options for the diverse needs of individuals with mobility challenges. From self-transfer aids supporting patient independence to assisted transfer devices keeping patients and care partners safe and injury-free to specialized devices for individuals reliant on care partner support, the assistive device landscape is rich with solutions. The benefits of these devices extend beyond their immediate utility, significantly reducing fall and injury risks, promoting independence with daily activities, and helping individuals stay in their homes longer. When appropriately recommended, a relatively inexpensive device purchased out-of-pocket or durable medical equipment covered by insurance can drastically improve a patient's life. Whether through the simplicity of vehicle assistance straps or the advanced features of ceiling lifts, each device plays a crucial role in addressing specific transfer and mobility needs. Case managers should be aware that care partners

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New Challenges in Hospice Care

Michael J. Demoratz, PhD, LCSW, CCM

Hospice care has always had its marketing challenges—marketing a service where the goal of care is that the recipient of the service dies a peaceful, orchestrated, good death is not very inviting. Over the next few pages, we will discuss the current challenges that hospice programs face on a regular basis, including:

- Language use around end-of-life care
- Palliative care options
- Available curative options adding 6 months of life expectancy
- Cost of custodial care
- Opioid crisis impact on choosing hospice
- POLST—Physician Orders for life-sustaining treatment
- Physician aid in dying (PAD) /Assisted Suicide
- VSED—Voluntarily stopping eating and drinking
- Assisted slumber

The Modern Hospice Movement

The modern hospice movement began in 1967 with the founding of St Christopher’s Hospice in England by Dame Cicely Saunders; 7 years later the Connecticut Hospice was founded in Branford, Connecticut. Hospice has at its core the mission to do no harm and to make a difference in the quality of life as someone is dying. As we approach the 50th anniversary of the founding of the first US Hospice Program, we reflect on the status of hospice care in the US and the continuing challenges to use hospice as the way to “orchestrate a good death for our patients.” Currently there are more than 5500 Medicare-certified hospice programs in the US.

History of the Hospice Medicare Benefit

In 1982, Congress included a provision to create a Medicare hospice benefit. In 1983, Initial Medicare Hospice Regulations were published in the Federal Register. Regulations established the four levels of care and outlined the cost components of the routine home care rate. Finally, the government offered support to these vulnerable patients and their families desperately seeking a new way of caring for the dying in this country. Over the years, the Medicare Hospice benefit has expanded—no longer are the benefit periods limited to 4—now a patient who meets criteria can

have two 90-day benefit periods and then unlimited 60-day benefit periods.

One early challenge for hospice programs was getting primary care physicians to state that a patient was certified by them as “terminal,” meaning probably living 6 months or less. Physicians would often say—“We can’t do nothing” even after hospice programs could show that quite a bit of something was being provided to their patients.

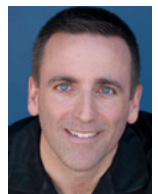
This is still a challenge today as patients are offered treatment that is curative (ie, immunotherapy cancer treatments) in nature and inconsistent with hospice goals of care. Some of these are offered as rescue medications. Patients at end of life will accept any “life preserver” even if the potential for cure is remote and may only add a few months to life expectancy. Patient referral to hospice is often delayed because treatment options are still being offered.

Length of Stay on Hospice

The National Hospice and Palliative Care Organization (NHPCO) annual report indicates that among Medicare beneficiaries, 47.3% received hospice care for 1 day or more in 2021. A quarter (25%) of beneficiaries received care for 5 days or less, which is considered too short a period for patients to fully benefit from the person-centered care available from hospice (NHPCO, 2024).

Language plays a large part in patient and family communication with the clinical team. Hospice is often seen as giving up the “fight”. Hospice is frequently restated and offered as comfort care, supportive care, or palliative care when the patient is no longer improving or may, in fact, be close to the end of life and still wish to pursue treatment available. Palliative care has some legitimacy in practice today. Palliative care programs are structured more-or-less like

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Families should be reminded that hospice is reimbursed on a per-diem basis, and there is no incentive to hasten death. Hospice is about quality of life and symptom management until one dies.

skilled home health where comfort care or supportive care is generally closer to hospice and may even involve signing consents for hospice care. Families may request that the word hospice not be used in front of the patient. Many programs will honor this request and continue euphemistically calling it the less-emotionally charged *comfort or supportive care*.

Palliative Care

Palliative care is frequently offered to patients as an alternative to hospice when the patient and family wish to have the options for aggressive treatment still available to them. Palliative care consults are offered with admission to a palliative care program when patients are not “ready” for hospice. Confusing the patients and families more is when patients ask, “What is palliative care”? The answer is often described as “hospice light” or similar to hospice without being told they will not have access to the significant basket of services offered by the Medicare Hospice benefit. Sadly, families who delay hospice admission often say, “I wish I knew about hospice sooner.”

Palliative care as defined by the Center to Advance Palliative Care (CAPC) is (CAPC 2024):

specialized medical care for people living with a serious illness. This type of care is focused on providing relief from the symptoms and stress of the illness. The goal is to improve quality of life for both the patient and the family.

Palliative care is provided by a specially trained team of doctors, nurses, and other specialists who work together with a patient’s other doctors to provide an extra layer of support. Palliative care is based on the needs of the patient, not on the patient’s prognosis. It is appropriate at any age and at any stage in a serious illness, and it can be provided along with curative treatment.

Further confusing patients and their families is that many palliative care programs are often attached to hospice programs—the names of many hospice companies include the word palliative. Because the reimbursement for palliative care is limited or nonexistent, patients will be offered palliative care at no cost—essentially free. This is done with the hope, plan, or expectation (on the part of the hospice program) that

the patient will transition to hospice at some point in time.

Stand-alone palliative care programs are often offered as an insurance or health plan benefit. The goals of care are generally hospice admission, when appropriate, in addition to a reduction in emergency room visits—with the risk of intensive-care admission and aggressive treatment that, when pressed, patients and families don’t want either.

Many of the dual-purpose programs find that patients will remain on the palliative care service until the symptom burden becomes too great and hospice becomes the only option for a patient who often is actively dying. Hospice is emergently called in, and the patient is admitted to the hospice program only to quickly succumb to their condition, thereby reinforcing for the consumer that hospice is more-or-less about the dying process at the very end. Some families will state that hospice just wants you to die quickly. Families should be reminded that hospice is reimbursed on a per-diem basis, and there is no incentive to hasten death. Hospice is about quality of life and symptom management until one dies.

Cost of Custodial Care (Caregivers, Private Pay Settings)

Cost of care is often an issue in managing the end-of-life process. Medicare and most insurance plans cover the cost of the hospice program services. What is not covered falls under custodial care or nonskilled care that is provided by caregivers who are either paid or are family members. Bathing aides are covered by hospice programs, but this service is solely about bathing and changing bed linens. Hourly cost of custodial care can be as much as \$40 per hour in some localities—high cost of living in some cities pushes this amount to \$50 per hour. Patients and families will bristle at the cost of having a person just sitting in the home waiting to be needed. The amount of care can be upwards of 24 hours per day for patient safety, meal preparation, and incontinence care. As the cost of caregiving has arisen, so too has the number of family members taking on the role of caregiver. Families will pool resources to allow for one or two family members to take on this role, greatly saving limited resources. Some states have offset some of the cost of caregiving in the home and will pay family directly to arrange for caregiving. It is never the full amount that one needs to manage a total care

**Language plays a large part in patient and family communication with the clinical team.
Hospice is often seen as giving up the “fight”.**

patient in the home, which is why having a family member taking on this role is the best option for some families.

Hospice can be provided in several settings: group homes, assisted living, and skilled nursing facilities. The challenge for hospice programs is that although hospice care is paid for by Medicare and private insurance, the setting of care is privately paid unless patients financially qualify for state assistance in some settings.

The cost of care and the physical and financial burden may facilitate more people interested in the option of physician aid in dying when they cannot cover the cost of caregiving.

Physician Orders for Life-Sustaining Treatment (POLST), MOST, POST, MOLST and Others

These treatments come under the auspices of the national POLST paradigm and may have slightly different acronyms but overall offer the same benefits to the clinical team, patient, and family. The overarching goal is to memorialize a rich conversation with the patient and family by the clinician, creating a document with actionable clinician orders that travels with the patient from setting to setting. These documents primarily address goals of care and cover three areas:

1. Code status
2. Intensity of care desired
 - Full treatment that includes all aggressive/curative care
 - Selective treatment like antibiotics
 - Comfort-focused care like hospice

3. Artificial nutrition and/or hydration

The document essentially can be seen as the palliative care consult. After completion and clinician signature, it shows all who encounter this patient that they have certain goals of care and they have been presented with all the options. The document basically says “yes, no, or maybe” when thinking about desired care. It should be completed even if the patient selects the default/conservative response since it shows that the patient at least reviewed the choices in the document.

Opiate Crisis

Patients will continue to be concerned about addiction. Consistently over the years, patient naïve to opioids will emphatically state that they don't want to be addicted. The current opioid crisis is not helping to counter this patient

choice. It involves news and discussion of Fentanyl®, which is one of many effective pain medications used in the management of hospice and palliative care patients. Hearing about addiction potential in the news may cause hesitation in the use of this and other opioid drugs, leaving us with patients in pain who would otherwise be well managed.

Physician Aid in Dying (PAD), Physician-Assisted Suicide, Death With Dignity

Currently nine states offer physician aid in dying. The link that follows includes states that do or don't allow it or have pending legislation deathwithdignity.org/states/ about the issue. Case managers should review their state's position as well as that of nearby states to become more familiar with the legislation.

The process typically follows this process:

- Patient has been diagnosed or certified with a terminal or life-threatening illness with 6 months or less life expectancy
- Patient requests from two physicians dying assistance (generally this request is made twice in two weeks)
- Physicians document the request, confirm eligibility, make an offer for the patient to be referred to hospice
- A one-week waiting period is allotted for the second physician request
- One physician will certify the request and write the order for the end-of-life prescription
- Patient can then take the medication whenever they wish

Some patients will take the drug immediately once available; others will consider that they can control the timing when it meets their timeframe (scheduling for family participation, etc). Still others may never take the medication but instead are comforted by the fact that they have the option to take it if they feel that they need to do so. If a patient does take the prescription to end their life, the death certificate will not state it was suicide; instead it will be the underlying disease or condition like cancer or emphysema that is written as a cause of death.

Dignity

Dignity, when associated with the word suffering, is often a triggering word for many who yearn for death to be dignified. It is important to also recognize that this is a relative term as well—the patient determines what is dignified. The only way to achieve dignity is to allow the patient to take

The overarching goal [of POLST] is to memorialize a rich conversation with the patient and family by the clinician, creating a document with actionable clinician orders that travels with the patient from setting to setting. These documents primarily address goals of care.

control of this process and determine when death should occur. Alternative language may need to be considered: the ultimate goal is an “orchestrated good death.”

Voluntarily Stopping Eating and Drinking (VSED)

What if a patient has religious or emotional convictions against suicide even with the assurance that the cause of death will not be suicide. This is an option that some religious/faith communities find acceptable within their belief system. This option is referred to as VSED. Patients generally choose this option when they are told that death may occur in days or weeks, and they don't want to prolong the process and suffering. Basically, such a patient stops eating and drinking. We know, however, that bodies can go quite a while without eating—generally not more than a week, and 10 days without drinking fluids. It is a conscious option selected by the patient and begun when they desire. Family may hesitate to accept this option, because they may feel the patient is starving. It is important to note that most patients stop eating and drinking at some point and do not experience the pain or other feelings associated with starving. Again, hospice admission and clinical support of the process is appropriate and supportive of the goals of care expressed by the patient.

Assisted Slumber

Another option is used frequently but does not have a formal term—that is *assisted slumber*. Some might refer to this as conscious sedation or palliative sedation, which is often issued when patients have intractable bone pain. It is utilized when all efforts to control pain and suffering are ineffective. Patients are intentionally provided enough pain medication that makes the patient no longer aware; they are sedated and will not allow to be awakened because the pain intensity would still be an underlying symptom burden.

Assisted slumber was mentioned here as an end-of-life option discussed in the text *Dying 101: A Candid Conversation on Terminal illness*. Assisted slumber is a request made to a physician at some point in the end stages of a medical process in which the patient states they wish to be provided enough medication to be sedated and essentially sleep the remaining time they are alive. These patients are often on hospice and provided medications for comfort only at amounts that will sedate but not end their life. Patients

are given medication for pain, agitation, and shortness of breath, as well as any other distressing symptom. This option is explained to family as a kind and merciful death for the patient that avoids prolonged suffering. It will place family on notice that death may be near.

Case Managers and End-of-Life Care

Case managers working in end-of-life care will find many choices to offer a patient as their disease process progresses. The autonomy and ability of the patient to make choices as their needs change is crucial for case managers to uphold. But when does a case manager discuss these options? Who brings this up or raises the issue? Some family feel that there should be an obligation for someone on the care team to discuss physician aid in dying. Physicians are not always the best at presenting this option, and many refuse, citing their own ethical positions of “do no harm.” Hospice companies have taken differing positions on the issue. Some will present the choice to everyone; some will state they educate but do not participate; some will educate and participate; and some will refer out for education and not allow staff to participate.

How case managers present this information can create an emotional minefield. For example, patients are often unaware of the law in California that allows physician-aided dying and surprised it has been in existence almost six years. The numbers of patients choosing this option is small—it could be lack of awareness or lack of desire for the process.

The concept of fidelity is key in the relationship with our dying patients. Case managers must be trusted to provide the information, education, and emotional support every step of the way. Trust and fidelity are expected all along the continuum of health care. A lack of trust in these patients and their family members can only cause harm and discomfort when trust is not in the forefront of our work. Veracity or truthfulness is also key to the case management process. If another team member would be better in presenting information, they should be brought into the conversation. Time is limited for patients facing an end-of-life process. Although the truth may be painful, it is often necessary to ensure patient autonomy.

Case managers should do their own inner work too. One suggestion might be to complete an advanced health care directive for yourself and your loved ones. In a small way,

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The Value of Case Management: Does Your Mother Know What You're Doing?

Nancy Skinner, RN, CCM, CMGT-BC, ACM-RN, CMCM, FCM

Case managers have been called the linchpins of health care reform and have become integral to the advancement of the National Quality Strategy, which seeks to “achieve optimal health and well-being for all individuals” (CMS, 2023). We have been told we are at the point of health care’s future and named the glue that holds health care together. We have been called the GPS of health care; guiding our patients as they navigate the turbulent waters of a disease or health management journey. We are and have consistently been patient advocates who seek to foster the careful shepherding of health care dollars. Yet, we remain the best-kept secret in health care.

Best-Kept Secret in Health Care

Rarely do patients, families, or caregivers seek the interventions and support offered by a case management professional. Instead, case managers reach out to them in acute or post-acute care environments, identify them based on a catastrophic or chronic diagnosis, or recognize them after a devastating occurrence has compromised the patient’s ability to effectively manage their own health care needs. Case managers have often been called the “fire department” of health care delivery. We arrive when it is time to prevent or extinguish a negative outcome or an untoward event. But unlike actual fire departments, the person at risk rarely reaches out directly to the case manager. Instead, the case manager generally identifies them and contacts the patient to offer support.

Today we must begin to change that paradigm. It is now time for the value of case management support and advocacy to be recognized not only by payors and providers but also by the patients, families, and caregivers we serve. It is time not only for case managers to realize the definition, roles, and

functions of a professional practice of case management, but also for our mothers, families, neighbors, and communities to realize the benefits and the support that case managers are able to provide.

The History of Case Management and the Organizations Who Pushed Change

But before the journey to achieve a greater understanding of the value of that patient/case manager partnership, it is important to consider the beginnings or early stages of the practice of case management and the ultimate evolution to the professional practice of case management experienced today. Although case management interventions can be traced back to the public health nurses and social workers who coordinated services for families in tenements through a variety of charity organizations in the early 1900s, the benefits of case coordination began to be fully realized as a variety of practitioners assisted soldiers injured in World War II to achieve their highest level of function and well-being. During this time, insurance companies also began to use nurses, social workers, and rehabilitation professionals to coordinate care for individuals who experienced a work-related injury (CMSA 2002). Through the 1960s and 1970s, community-based case management sought to address the needs of older Americans with a focus on maintaining the patient in the home rather than a nursing home or long-term care facility.

In the 1980s, there was a shift from community case management to hospital-based utilization management and discharge planning. This shift was most closely associated with changes in payment structures with fee-for-service payments moving to case-based payments or diagnosis-related groups (DRGs). Acute care case managers were focused on the development of efficient and effective discharge pathways that balanced the patient’s continuing care needs with the necessity of advancing the financial viability of the acute care facility. Length-of-stay was no longer associated with the patient’s desire to remain hospitalized but rather based on the patient’s severity of illness and the intensity of services required to address the identified illness or injury.

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**Case managers have often been called the “fire department” of health care delivery.
We arrive when it is time to prevent or extinguish a negative outcome or an untoward event.**

The role case managers played became essential not only in acute and post-acute environments but also in payor environments that realized the benefit of care coordination and the economic value achieved when medically necessary care was provided in a timely manner and negative outcomes were minimized or avoided.

As case management became an important aspect of health care practices and delivery, a mandate arose to develop not only a definition of case management but also Standards of Practice to guide case managers as they embraced a professional practice of case management. In 1995, the Case Management Society of America (CMSA) published an initial set of Standards that defined case management as “a collaborative process which assesses, plans, implements, coordinates, monitors, and evaluates options and services required to meet an individual’s health needs through communication and available resources to promote quality cost-effective care” (CMSA, 1995). This definition was also adopted by the Commission for Case Manager Certification (CCMC), which offered their initial case manager certification exam in 1993.

In the years following publication of the Standards of Practice as presented by CMSA, numerous factors impacted not only health care delivery in America but also the manner in which those services were funded. In 2001, the Institute of Medicine (IOM) published a call to action entitled, *Crossing the Quality Chasm: A New Health System for the 21st Century* (IOM, 2001). Calling for a fundamental change in how health care is delivered, the report sought to close the quality gap between what is known to be good health care and the health care that many patients were receiving. The publication recommended specific quality initiatives that were focused on patient safety, care effectiveness, patient-centeredness, timeliness, care efficiency, and equity. Strategies to advance the quality of these six dimensions of health care performance were later incorporated into legislative actions that advanced the need for care coordination throughout the care continuum.

Another initiative that ultimately influenced the professional practice of case management was the Triple Aim, which was introduced in 2007 by the Institute for Health care Improvement (IHI). IHI sought to assist health care organizations to improve the patient’s experience in receiving

care including quality, access, satisfaction, and reliability while lowering or reducing the per capita cost of care. The final component of the Triple Aim focused on improving the health of populations by supporting proven interventions to address behavioral, social, and environmental determinants of health (Berwick, 2008). These three aims served as the foundation of the National Quality Strategy with the goal of improving the delivery of health care services, patient health outcomes, and population health.

The National Quality Strategy also listed several priorities that have influenced the delivery of case management services (AHRQ, 2017):

- Patient safety: Making care safer by reducing harm caused in the delivery of care, including reducing or preventing hospital admissions and readmissions
- Person- and family-centered care: Ensuring patients, families, and caregivers become engaged as partners in their care with a focus on enabling them to navigate, coordinate, and manage their care appropriately and effectively
- Effective communication and care coordination: Promoting effective communication and coordination of care, including improving the quality of care transitions and communications through and across all settings of care

The practice of case management was also impacted by several of the quality improvement initiatives that were implemented following the enactment of the Affordable Care Act (ACA) in 2010. Building on key priorities of the National Quality Strategy, the ACA prompted further development of value-based purchasing policies with a focus on the delivery of quality care rather than quantity of provided services. Key aspects of value-based care and reimbursement for that care included a focus on the patient’s experience of care, care coordination across each transition of care, patient safety, and readmission reduction. Individual elements of this broad quality initiative fell within the scope of practice for the case management or transition-of-care professional (CMS, 2023).

While the Centers for Medicare & Medicaid Services (CMS) focused on the provision of and reimbursement for quality in the delivery of care, many private insurers adopted enhanced quality measures that reflected the efforts CMS promoted. The promotion of quality in managed care organizations had a foundation in the creation and the implementation of performance improvement measures in 1993.

Today we must begin to change that paradigm [of case management]. It is now time for the value of case management support and advocacy to be recognized not only by payors and providers but also by the patients, families, and caregivers we serve.

Developed by the National Committee for Quality Assurance (NCQA), the Healthcare Effectiveness Data and Information Set (HEDIS) measured key performance metrics identified by six domains of care. The domains that minimally fell within the scope of care coordination and case management include (NCQA, 2024):

- Effectiveness of Care—disease management, medication management, and care coordination
- Risk Adjusted Utilization—all-cause readmission, emergency department utilization, and hospitalization for a potentially preventable complication

Ensuring Quality and Appropriateness of Care: A Case Manager's Role

These organizations' programs and reports focus on enhancing the quality and appropriateness of care across each transition of care prompted an enhanced need for case managers in all practice settings. Case managers played a vital role in reviewing the medical necessity of care, providing care coordination as the patient moved through the care continuum, identifying appropriate supportive services to meet the patient's continuing care needs, and advancing patient education throughout the patient's journey. To assist case managers to perform these vital roles and functions, educational programs were developed not only through formal education offered by colleges and universities but also through educational programs and conferences presented by professional associations, certification bodies, and employer groups.

To align with this changing landscape of health care delivery and funding and to support the enhanced role of the case manager, previously accepted definitions of case management were revised, and multiple new definitions were presented to reflect the evolving roles of the case manager. In 2022, CMSA published revised Standards of Practice for Case Management that included the following definition: "Case management is a collaborative process of assessment, planning, facilitation, care coordination, evaluation, and advocacy for options and services to meet an individual's and family's comprehensive health needs through communication and available resources to promote patient safety, quality of care, and cost-effective outcomes" (CMSA, 2022).

Another definition of case management was developed by CCMC in collaboration with the American Case Management

Association (ACMA) and published in 2022. That definition is: "Case management is a dynamic process that assesses, plans, implements, coordinates, monitors, and evaluates to improve outcomes, experiences, and value. The practice of case management is professional and collaborative, occurring in a variety of settings where medical care, mental health care, and social supports are delivered. Services are facilitated by diverse disciplines in conjunction with the care recipient and their support system. In pursuit of health equity, priorities include identifying needs, ensuring appropriate access to resources/services, addressing social determinants of health, and facilitating safe care transitions. Professional case managers help navigate complex systems to achieve mutual goals, advocate for those they serve, and recognize personal dignity, autonomy, and the right to self-determination" (CCMC, 2022).

In addition to these definitions, other descriptions of case management were developed with as many as 22 definitions identified in the literature (Giardino, 2023). These definitions appear to be more focused on the functions rather than the purpose and goals of case management and few are directed to the patients, families and caregivers who might benefit from case management interventions. It is therefore easy to understand why the patients we serve have little grasp of the value case management can bring to their health care journey.

Definitions and Standards

To advance a greater patient understanding of the practice of case management, the Case Management Leadership Coalition developed a consumer-friendly definition of case management in 2005. That definition was "Case managers work with people to get the health care and other community services they need, when they need them, and for the best value" (Mullahy, 2017). This definition was the single consumer-focused description of case management until CMSA published the Revised Standards of Practice for Case Management in 2022. These Standards included the following definition that can be utilized to inform patients and the public regarding the role of the case manager: "Case managers are health care professionals who serve as patient advocates to support, guide and coordinate care for patients, families, and caregivers as they navigate their health and

“Case managers are health care professionals who serve as patient advocates to support, guide and coordinate care for patients, families, and caregivers as they navigate their health and wellness journeys.”

wellness journeys” (CMSA, 2022).

Although these two consumer-focused definitions serve as an initial step in educating the public regarding the case manager’s role, they may not offer sufficient information to describe the benefits of partnering with a professional case manager. There may also be confusion regarding who is a case manager and which interventions and/or support the case manager might offer.

Since patients and their families often seek information through internet searches, a comprehensive search for patient-focused information regarding the patient/case manager partnership was performed. Only one consumer-friendly definition of case management was identified, and that definition was the consumer-focused definition presented by CMSA. Any additional information realized during that search appeared to be more focused on educating other health care professionals regarding the role case managers perform. Without clear consumer-targeted descriptions of the many roles case managers perform as well as information regarding the potential benefits that can be achieved due to that collaborative partnership, case management will remain the best kept secret in health care.

No Definitions for Patients

A patient’s understanding of a professional practice of case management could be enhanced with information regarding case management and care coordination available from the CMS website, www.cms.gov. However, no patient-directed information associated with case management could be identified on that site. That site does present consumer-directed education on Chronic Care Management (CCM). CMS defines CCM as “a critical primary care service that contributes to better patient health and care” (CMS, 2023). While a case manager might function to coordinator care for patients with multiple chronic diseases as a component of this program, no mention of their expertise or involvement is detailed within that website.

Patients might also reach out to acute care or post-acute care facilities or payor websites to gain further information regarding case management, but those resources do not consistently detail a description of or access to case management services for the populations serviced. And still, case management continues to be the best kept secret in health care.

There are several avenues case managers can use to advance a patient’s understanding of the value case management provides as the patient moves through and across each care transition, seeks to attain their desired health-related goals, and strives to become an active member of their health care delivery team.

Initially, case managers may want to evaluate any challenges associated with the ability to serve as a patient advocate: to advance the delivery of quality and appropriateness of health care services, support safe care transitions, and consistently foster the careful shepherding of health care dollars. That evaluation might begin with a review of the quality metrics. One set of quality measures focuses on the patient experience of care. This important measure of quality is defined as “the sum of all interactions, shaped by an organization’s culture, that influence patient perceptions, across the continuum of care” (Wolf, 2014). A key metric of patient experience is the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS). This publicly reported survey offers a patient’s perspective of the quality of clinical care and care coordination provided during an acute care hospitalization. Developed and maintained by CMS, the survey asks two questions that might fall within the scope of a case management practice. One question asks the patient if they were “given information about their recovery at home.” Nationally, 86% of patient responded “yes”. The second question asked the patient if “they understood their care when they left the hospital. The national average of patients who strongly agreed with that question was 51% (CMS, 2023).

Case managers might wish to consider this metric (understanding their care) as the patient transitions to the next level of care. While it may not truly reflect the efficacy or effectiveness of provided case management services, it may potentially serve as a method to identify any gaps in patient education that may compromise the patient’s ability to follow discharge instructions. It may also offer an opportunity to collaborate with community or payor case managers to identify a continuum of case management services in each setting of care. When case managers in unique and diverse practice settings work collaboratively to communicate the patient’s continuing care needs, the patient may realize a greater continuity of care.

A key metric of patient experience is the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) ... a public report that offers a patient's perspective of the quality of clinical care and care coordination provided during an acute care hospitalization.

Educational Strategy for Health Literacy Through Ask Me 3

Case managers might also wish to adopt an educational strategy that was developed by health literacy experts to assist patients to become more active participants in their continuing care plan. This strategy, entitled Ask Me 3,[®] encourages the patient, family, or caregiver to ask three specific questions with a goal of gaining a better understanding of their disease, illness or injury and the steps necessary to achieve wellness or effectively managed their illness.

These three questions are (IHI, 2012):

- What is my main health problem?
- What do I need to do?
- Why is it important for me to do this?

Communicating the patient's responses to these questions to all members of the health care team including case management professionals who represent diverse practice settings can advance the delivery of quality of care while ensuring patients receive consistent support throughout their illness or injury journey.

As more and more initiatives are developed to enhance the quality of care provided to our patients, it is vital that case management services truly become an essential element of the care delivery. It is my sincere hope that one day every patient will not only have access to a case manager but will also realize the benefits of working in partnership with a case manager. Our job is not done until patients, families, and caregivers ask, "Who is my case manager and when will they be available to guide me in my health care journey?"

To realize that hope, case managers and their professional associations, organizations, and certification bodies need to act now. Case managers might wish to share a clear picture of their role with family and friends.

- Offer a presentation to a church or community group.
- Focus the presentation on the role of the case manager in a manner the audience can fully understand and appreciate.
- Share a patient-focused definition of case management on social media.
- Offer a consumer-friendly definition of case management to the Academy of Certified Case Managers' (ACCM) Facebook page.
- Write an article for a local newspaper or magazine regarding case management.

- Review any patient-directed information regarding the role of the case manager that is available on your employer's website.
- Offer to join a committee to develop patient-targeted information about case management.

Professional organizations and associations might wish to dedicate a portion of their website to educate patients, families, and caregivers regarding what case managers do and why they do it. That patient education portal could provide definitions of case management that are developed to be easily understood by the patients we serve. The portal could also demonstrate the importance of case management by "telling patient stories" that demonstrate how a case manager has assisted a patient to achieve their desired health care goals. The portal might also offer a prepared article that a case manager could forward to a local newspaper to further highlight the value of our role. The portal might include a presentation that a case manager could use in their community to provide further information regarding the role of the case manager. A portal might also offer information regarding the multiple practice settings in which case managers function and the value case management brings to clients within those settings. And the portal might allow patients to offer their own personal stories regarding their individual experience working in partnership with a case manager.

It is well past time for case management to be fully appreciated not only by our professional colleagues but most importantly by the patients. When we take the time to accurately define and describe the role of the case manager, we will be able to unequivocally say, "My Mother knows what I am doing!" **CM**

[References continued on page 35](#)

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PharmaFacts for Case Managers



CASGEVY (exagamglogene autotemcel), suspension for intravenous infusion

INDICATIONS AND USAGE

CASGEVY is indicated for the treatment of sickle cell disease (SCD) in patients 12 years and older with recurrent vaso-occlusive crises (VOCs).

DOSAGE AND ADMINISTRATION

For autologous use only. For one-time, single dose intravenous use only.

Dose

The minimum recommended dose of CASGEVY is 3×10^6 CD34+ cells/kg.

CASGEVY is provided as a single dose for infusion containing a suspension of CD34+ cells in one or more vials. See the Lot Information Sheet provided with the product shipment for additional information pertaining to the number of vials required to achieve the patient-specific dose. Administer all vials.

Preparation before CASGEVY infusion

Confirm that hematopoietic stem cell (HSC) transplantation is appropriate for the patient before mobilization, apheresis and myeloablative conditioning are initiated.

Screen patients for HIV-1, HIV-2, HBV, HCV, and any other infectious agents in accordance with local guidelines before collection of cells for manufacturing. CASGEVY should not be used in patients with active HIV-1, HIV-2, HBV or HCV.

Prior to apheresis it is recommended that patients be transfused with a goal to maintain hemoglobin S (HbS) levels $< 30\%$ of total hemoglobin (Hb) while keeping total Hb concentration ≤ 11 g/dL.

Discontinue disease modifying therapies for sickle cell disease (e.g., hydroxyurea, crizanlizumab, voxelotor) 8 weeks before the planned start of mobilization and conditioning.

Mobilization and Apheresis

Patients are required to undergo CD34+ HSC mobilization followed by apheresis to isolate the CD34+ cells needed for CASGEVY manufacturing.

Plerixafor was used for mobilization. Granulocyte-Colony

Stimulating Factor (G-CSF) should not be administered for mobilization in patients with sickle cell disease.

Refer to the prescribing information for the mobilization agent prior to treatment.

Administration

CASGEVY is for autologous use only. Before infusion, confirm that the patient's identity matches the unique patient identifiers on the CASGEVY vial(s). Do not infuse CASGEVY if the information on the patient-specific label does not match the intended patient.

A patient's dose may consist of multiple vials. All vials must be administered. Use the Lot Information Sheet to confirm the total number of vials to be administered. The entire volume of each vial provided should be infused. If more than one vial is provided, administer each vial completely before proceeding to thaw and infuse the next vial.

DOSAGE FORMS AND STRENGTHS

CASGEVY is a cell suspension for intravenous infusion.

A single dose of CASGEVY is composed of one or more vials. Each vial contains 4 to 13×10^6 CD34+ cells/mL suspended in 1.5 to 20 mL cryopreservative medium [see How Supplied/Storage and Handling (16)]. The minimum recommended dose of CASGEVY is 3×10^6 CD34+ cells per kg of body weight.

See the Lot Information Sheet for actual strength and dose. The Lot Information Sheet is included inside the lid of the liquid nitrogen dry shipper used to transport CASGEVY.

CONTRAINDICATIONS.

None.

WARNINGS AND PRECAUTIONS

Potential Neutrophil Engraftment Failure

Neutrophil engraftment failure is a potential risk in HSC transplant, defined as not achieving neutrophil engraftment after CASGEVY infusion and requiring use of unmodified rescue CD34+ cells. In the clinical trial, all treated patients achieved neutrophil engraftment and no patients received rescue CD34+ cells.

Monitor absolute neutrophil counts (ANC) and manage infections according to standard guidelines and medical judge-



ment. In the event of neutrophil engraftment failure, patients should be infused with rescue CD34+ cells

Prolonged Time to Platelet Engraftment

Longer median platelet engraftment times were observed with CASGEVY treatment compared to allogeneic HSC transplant. There is an increased risk of bleeding until platelet engraftment is achieved. In the clinical trial, there was no association observed between incidence of serious bleeding and time to platelet engraftment.

Monitor patients for bleeding according to standard guidelines and medical judgement. Conduct frequent platelet counts until platelet engraftment and platelet recovery are achieved. Perform blood cell count determination and other appropriate testing whenever clinical symptoms suggestive of bleeding arise

Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis can occur due to dimethyl sulfoxide (DMSO) or dextran 40 in the cryopreservative solution. Monitor patients for hypersensitivity reactions during and after infusion.

Off-Target Genome Editing Risk

Although off-target genome editing was not observed in the edited CD34+ cells evaluated from healthy donors and patients, the risk of unintended, off-target editing in an individual's CD34+ cells cannot be ruled out due to genetic variants. The clinical significance of potential off-target editing is unknown.

ADVERSE REACTIONS

The most common Grade 3 or 4 non-laboratory adverse reactions (occurring in $\geq 25\%$) were mucositis, febrile neutropenia, and decreased appetite.

The most common Grade 3 or 4 laboratory abnormalities (occurring in $\geq 50\%$) were neutropenia, thrombocytopenia, leukopenia, anemia, and lymphopenia.

The following serious adverse reactions are discussed in greater detail in other sections of the label:

- Potential Neutrophil Engraftment Failure
- Prolonged Time to Platelet Engraftment
- Hypersensitivity Reactions

DRUG INTERACTIONS

No formal drug interaction studies have been performed. CASGEVY is not expected to interact with the hepatic cytochrome P-450 family of enzymes or drug transporters.

Use of Granulocyte-Colony Stimulating Factor (G-CSF)

Granulocyte-Colony Stimulating Factor (G-CSF) must not be used for CD34+ HSC mobilization of patients with sickle cell disease.

Use of Hydroxyurea

Discontinue the use of hydroxyurea at least 8 weeks prior to

start of each mobilization cycle and conditioning. There is no experience of the use of hydroxyurea after CASGEVY infusion.

Use of Voxelotor and Crizanlizumab

Discontinue the use of voxelotor and crizanlizumab at least 8 weeks prior to start of mobilization and conditioning, as their interaction potential with mobilization and myeloablative conditioning agents is not known.

Use of Iron Chelators

Discontinue the use of iron chelators at least 7 days prior to initiation of myeloablative conditioning, due to potential interaction with the conditioning agent. Some iron chelators are myelosuppressive. If iron chelation is required, avoid the use of non-myelosuppressive iron chelators for at least 3 months and use of myelosuppressive iron chelators for at least 6 months after CASGEVY infusion. Phlebotomy can be used instead of iron chelation, when appropriate.

Live Vaccines

The safety of immunization with live viral vaccines during or following CASGEVY treatment has not been studied.

USE IN SPECIFIC POPULATIONS

Consider the risks of mobilization and myeloablative conditioning agents in patients with reproductive potential and patients that are pregnant or breast-feeding.

Pregnancy

Risk Summary

There are no clinical data from the use of exagamglogene autotemcel in pregnant women. No animal reproductive and developmental toxicity studies have been conducted with exagamglogene autotemcel to assess whether it can cause fetal harm when administered to a pregnant woman. CASGEVY must not be administered during pregnancy because of the risks associated with myeloablative conditioning. Pregnancy after CASGEVY infusion should be discussed with the treating physician.

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

Lactation

Risk Summary

There are no data on the presence of exagamglogene autotemcel in human or animal milk, the effects on the breastfed child, or the effects on milk production. Because of the potential risks associated with myeloablative conditioning, breastfeeding should be discontinued during conditioning. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for CASGEVY and any potential adverse effects on the breastfed child from CASGEVY or from the underlying maternal condition. Breastfeeding after CASGEVY infusion should be discussed with the treating physician.



Females and Males of Reproductive Potential

Pregnancy Testing

A negative serum pregnancy test must be confirmed prior to the start of each mobilization cycle and re-confirmed prior to myeloablative conditioning.

Contraception

There are insufficient exposure data to provide a precise recommendation on duration of contraception following treatment with CASGEVY. Women of childbearing potential and men capable of fathering a child must use effective method of contraception from start of mobilization through at least 6 months after administration of CASGEVY.

Infertility

There are no data on the effects of exagamglogene autotemcel on human fertility. Effects on male and female fertility have not been evaluated in animal studies. Infertility has been observed with myeloablative conditioning therefore, advise patients of fertility preservation options before treatment, if appropriate.

Pediatric Use

The safety and efficacy of CASGEVY has been established in pediatric patients with SCD aged 12 years and older. Use of CASGEVY is supported by data in 12 patients aged 12 to less than 18 years in Trial 1. The efficacy and safety profile was generally consistent among pediatric patients aged 12 years and older and adult patients. [see *Adverse Reactions (6.1) and Clinical Studies (14.1)*].

The median (min, max) time to platelet engraftment was 45 (23, 81) days in pediatric patients aged 12 years and older and 32 (23, 126) days in adult patients. The median (min, max) time to neutrophil engraftment was 28 (24, 40) days in pediatric patients aged 12 years and older and 26 (15, 38) days in adult patients.

The safety and efficacy of CASGEVY in pediatric patients aged less than 12 years has not been established.

Geriatric Use

CASGEVY has not been studied in patients > 65 years of age. HSC transplantation must be appropriate for a patient to be treated with CASGEVY.

Patients with Renal Impairment

CASGEVY has not been studied in patients with renal impairment, defined as estimated glomerular filtration rate < 60 mL/min/1.73 m². Patients should be assessed for renal impairment to ensure HSC transplantation is appropriate.

Patients with Hepatic Impairment

CASGEVY has not been studied in patients with hepatic impairment. Patients should be assessed for hepatic impairment to ensure HSC transplantation is appropriate.

Patients Seropositive for Human Immunodeficiency Virus

(HIV), Hepatitis B Virus (HBV) or Hepatitis C Virus (HCV)

CASGEVY has not been studied in patients with HIV-1, HIV-2, HBV or HCV. Perform screening for HIV-1, HIV-2, HBV and HCV and any other infectious agents in accordance with local guidelines before collection of cells for manufacturing. CASGEVY should not be used in patients with active HIV-1, HIV-2, HBV or HCV.

Patients with Prior HSC Transplant

CASGEVY has not been studied in patients who have received a prior allogeneic or autologous HSC transplant. Treatment with CASGEVY is not recommended in these patients.

CLINICAL STUDIES

Sickle Cell Disease

Trial 1 (NCT03745287) is an ongoing single-arm, multi-center trial evaluating the safety and efficacy of a single dose of CASGEVY in adult and adolescent patients with sickle cell disease. Eligible patients underwent mobilization and apheresis to collect CD34+ stem cells for CASGEVY manufacture, followed by myeloablative conditioning and infusion of CASGEVY. Patients were then followed in Trial 1 for 24 months after CASGEVY infusion. Patients who complete or discontinue from Trial 1 are encouraged to enroll in Trial 2 (NCT04208529), an ongoing long-term follow-up trial for additional follow up for a total of years after CASGEVY infusion.

Patients were eligible for the trial if they had a history of at least 2 protocol-defined severe vaso-occlusive crisis (VOC) events during each of the 2 years prior to screening. In this trial severe VOC is defined as an occurrence of at least one of the following events:

- Acute pain event requiring a visit to a medical facility and administration of pain medications (opioids or intravenous [IV] non-steroidal anti-inflammatory drugs [NSAIDs]) or RBC transfusions
- Acute chest syndrome
- Priapism lasting > 2 hours and requiring a visit to a medical facility
- Splenic sequestration.

Patients were excluded if they had advanced liver disease, history of untreated Moyamoya disease, or presence of Moyamoya disease that in the opinion of the investigator put the patient at risk of bleeding. Patients aged 12 to 16 years were required to have normal transcranial doppler (TCD), and patients aged 12 to 18 years were excluded if they had any history of abnormal TCD in the middle cerebral artery and the internal carotid artery. Patients with an available 10/10 human leukocyte antigen matched related hematopoietic stem cell donor were excluded. Patients with more than 10 unplanned hospitalizations or emergency department visits related to chronic pain rather than SCD-related acute pain crises in the



year before screening were excluded.

At the time of the interim analysis, a total of 63 patients enrolled in the trial, of which 58 (92%) patients started mobilization. A total of 44 (76%) patients received CASGEVY infusion and formed the full analysis set (FAS). Thirty-one patients from the FAS (70%) had adequate follow-up to allow evaluation of the primary efficacy endpoint and formed the primary efficacy set (PES). The key demographics and baseline characteristics for all patients administered CASGEVY in Trial 1 are shown in Table 5 below. The baseline characteristics and demographics are consistent between the PES and the FAS.

DEMOGRAPHICS AND BASELINE CHARACTERISTICS OF PATIENTS TREATED WITH CASGEVY AT THE INTERIM ANALYSIS IN TRIAL 1

Demographics and disease characteristics	Full Analysis Set (FAS) * (N=44)	Primary Efficacy Set (PES) *,† (N=31)
Age, n (%)		
Adults (≥ 18 and ≤ 35 years)	32 (73%)	24 (77%)
Adolescents (≥ 12 and < 18 years)	12 (27%)	7 (23%)
All ages (≥ 12 and ≤ 35 years)	20 (12, 34)	21 (12, 34)
Sex, n (%)		
Female	20 (45%)	14 (45%)
Male	24 (55%)	17 (55%)
Race, n (%)		
Black or African American	38 (86%)	27 (87%)
White	3 (7%)	1 (3%)
Other	3 (7%)	3 (10%)
Genotype, n (%)		
β ^S /β ^S	40 (91%)	30 (97%)
β ^S /β ⁰	3 (7%)	1 (3%)
β ^S /β ⁺	1 (2%)	0
Annualized rate of severe VOCs in the 2 years prior to enrollment (events/year) Median (min, max)	3.5 (2.0, 18.5)	3.5 (2.0, 18.5)
Annualized rate of hospitalizations due to severe VOCs in the 2 years prior to enrollment (events/year) Median (min, max)	2.5 (0.5, 9.5)	2.0 (0.5, 8.5)

* Interim analysis conducted based on June 2023 data cut-off date.

† The primary efficacy set (PES), is a subset of the full analysis set (FAS). The PES was defined as all patients who had been followed for at least 16 months after CASGEVY infusion. Patients who had less than 16 months follow-up due to death or discontinuation due to CASGEVY-related adverse events, or continuously received RBC transfusions for more than 10 months after CASGEVY were also included in this set. An additional patient who had less than 16 months of follow-up but was otherwise determined to be a non-responder for the primary efficacy endpoint, was also included in PES.

Mobilization and Apheresis

Patients underwent RBC exchange or simple transfusions for a minimum of 8 weeks before the planned start of mobilization and continued receiving transfusions or RBC exchanges until the initiation of myeloablative conditioning. Hemoglobin S (HbS) levels were maintained at < 30% of total Hb while keeping total Hb concentration ≤ 11 g/dL.

To mobilize stem cells for apheresis, patients in Trial 1 were administered plerixafor at a planned dose of 0.24 mg/kg via subcutaneous injection approximately 2 to 3 hours prior to each planned apheresis. Apheresis was carried out for up to 3 consecutive days to achieve the target collection of cells for manufacture and for the unmodified rescue CD34+ cells. The mean (SD) and median (min, max) number of mobilization and apheresis cycles required for the manufacture of CASGEVY and for the back-up collection of rescue CD34+ cells were 2.3 (1.41) and 2 (1, 6), respectively. Six (10%) patients were unable to receive CASGEVY therapy due to not achieving the minimum dose.

Pre-treatment Conditioning

All patients received full myeloablative conditioning with busulfan prior to treatment with CASGEVY. Busulfan was administered for 4 consecutive days intravenously (IV) via a central venous catheter at a planned starting dose of 3.2 mg/kg/day once daily (qd) or 0.8 mg/kg every 6 hours (q6h). Busulfan plasma levels were measured by serial blood sampling and the dose adjusted to maintain exposure in the target range.

For the once daily dosing, four-day target cumulative busulfan exposure was 82 mg*h/L (range 74 to 90 mg*h/L), corresponding to AUC_{0-24h} of 5000 μM*min (range: 4500 to 5500 μM*min). For the every 6 hours dosing, the four-day target cumulative busulfan exposure was 74 mg*h/L (range 59 to 89 mg*h/L), corresponding to AUC_{0-6h} of 1125 μM*min (range: 900 to 1350 μM*min).

All patients received anti-seizure prophylaxis with agents other than phenytoin prior to initiating busulfan conditioning. Phenytoin was not used for anti-seizure prophylaxis because of its induction of cytochrome P-450 and resultant increased clearance of busulfan.

Prophylaxis for hepatic veno-occlusive disease (VOD)/ hepatic sinusoidal obstruction syndrome was administered, per regional and institutional guidelines.

CASGEVY Administration

Patients were administered CASGEVY with a median (min, max) dose of 4.0 (2.9, 14.4) × 10⁶ cells/kg as an IV infusion. All patients were administered an antihistamine and an antipyretic prior to CASGEVY infusion.

After CASGEVY Administration

G-CSF was not recommended within the first 21 days after CASGEVY infusion.



As CASGEVY is an autologous therapy, immunosuppressive agents were not required after initial myeloablative conditioning.

Efficacy Results

An interim analysis (IA) was conducted with 31 patients eligible for the primary efficacy analysis, i.e., the primary efficacy set (PES). The median (min, max) total duration of follow up was 19.3 (0.8, 48.1) months from the time of CASGEVY infusion in FAS. There were no cases of graft failure or graft rejection.

The primary efficacy outcome was the proportion of VF12 responders, defined as patients who did not experience any protocol-defined severe VOCs for at least 12 consecutive months within the first 24 months after CASGEVY infusion in Trial 1. The proportion of patients who did not require hospitalization due to severe VOCs for at least 12 consecutive months within the 24-month evaluation period (HF12) was also assessed. The evaluation of VF12 and HF12 began 60 days after the last RBC transfusion for post-transplant support or SCD management. The median (min, max) time to the last RBC transfusion was 19 (11, 52) days following CASGEVY infusion for patients in the primary efficacy set.

The interim analysis occurred at the time when the alpha spending was approximately 0.02 for a one-sided test, when 31 patients were evaluable for VF12 responder status. The VF12 response rate was 29/31 (93.5%, 98% one-sided CI: 77.9%, 100.0%). The 29 VF12 responders did not experience protocol defined severe VOCs during the evaluation period with a median duration of 22.2 months at the time of the interim analysis. One VF12 responder, after initially achieving a VF12 response, experienced an acute pain episode meeting the definition of a severe VOC at Month 22.8 requiring a 5-day hospitalization; this patient was reported to have a parvovirus B19 infection at the time. Of the 31 patients evaluable for VF12 response, one patient was not evaluable for HF12 response; the remaining 30 patients (100% [98% one-sided CI: 87.8%, 100.0%]) achieved the endpoint of HF12.

HOW SUPPLIED/STORAGE AND HANDLING


CASGEVY is supplied in one or more vials containing a frozen suspension of genome edited autologous CD34+ cells in a cryo-preserved medium containing 5% DMSO and dextran 40.

CASGEVY is stored in the vapor phase of liquid nitrogen and is shipped from the manufacturing facility to the treatment center storage facility in a cryoshipper. CASGEVY is supplied in vial(s) packaged in carton(s). One carton contains a single lot of CASGEVY consisting of 1 to 9 vials. A single dose of CASGEVY may consist of multiple CASGEVY lots, and therefore may consist of multiple cartons. A Lot Information Sheet listing the total dose of CASGEVY is affixed inside the shipper.

For full prescribing information, see Product Insert.

CASGEVY is manufactured by Vertex Pharmaceuticals Incorporated.

Other New Drug Approvals:

- Zelsuvmi (berdazimer sodium) is a nitric oxide-releasing agent indicated for the topical treatment of molluscum contagiosum (MC) in adults and pediatric patients 1 year of age and older.
- Wainua (eplontersen) is a transthyretin-directed antisense oligonucleotide indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.
- Alyglo (immune globulin intravenous, human-stwk) is a 10% immune globulin liquid for intravenous injection indicated for the treatment of primary humoral immunodeficiency (PI) in adults.
- Iwilfin (eflornithine) is an ornithine decarboxylase inhibitor used to reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma (HRNB).
- Lyfgenia (lovotibeglogene autotemcel) is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of patients 12 years of age or older with sickle cell disease and a history of vaso-occlusive events.
- Avzivi is a vascular endothelial growth factor inhibitor biosimilar to Avastin used for the treatment of colorectal cancer, non-small cell lung cancer, glioblastoma, renal cell carcinoma, cervical cancer, and epithelial ovarian, fallopian tube, or primary peritoneal cancer.
- Truqap (capivasertib) is an AKT inhibitor used in combination with fulvestrant for the treatment of advanced hormone receptor-positive breast cancer. 

ACCM has partnered with Pfizer to bring our members special access to ArchiTools, a centralized resource to help case managers deliver value-driven health care with interactive training modules, downloadable tools, annotated and detailed article reprints, and more.

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Building Improved Healthcare

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.

AIDS. 2023 Dec 29.

[The association of changes in depression severity after the onset of the COVID-19 pandemic and viral nonsuppression among people with HIV](#)

Tarfa Verinumbé, Catherine R Lesko, Richard D Moore, Anthony T Fojo, Jeanne Keruly, LaQuita N Snow, Heidi Hutton, Geetanjali Chander, Jarratt D Pytell, Oluwaseun Falade-Nwulia

OBJECTIVE: This study sought to characterize changes in depressive symptom severity during the COVID-19 pandemic and the association of these changes with HIV viral nonsuppression among people with HIV (PWH).

DESIGN: A clinical cohort study.

METHODS: We included PWH in the Johns Hopkins HIV Clinical Cohort who completed the Patient Health Questionnaire 8 (PHQ-8) pre-pandemic (1 March 2018 to 28 February 2020) and during the COVID-era (1 September 2020 to 28 February 2022). PWH were classified according to depression severity categories pre-pandemic and during the COVID-era as: consistently depressed (pre-pandemic PHQ-8 >4 and no change in severity category); consistently nondepressed (pre-pandemic PHQ-8 ≤4 and no change in severity category); worsened (changed to a higher severity category) and; improved (change to a lower severity category). The association between changes in depressive symptom severity and viral non-suppression (HIV RNA >200 copies/ml on the earliest viral load measured 7 days before to 12 months after the COVID-era PHQ-8 survey) was assessed using multivariable logistic regression.

RESULTS: Of 793 PWH, mean age was 56 (SD 10) years, 60% were male individuals and 88% were Black. After the onset of the pandemic, 60% were consistently nondepressed, 9% were consistently depressed, 15% worsened and 16% improved. PWH who worsened had 2.47 times the odds of viral nonsuppression (95% CI: 1.09-5.55) compared with the nondepressed group. Associations among other groups were not statistically significant.

CONCLUSION: Worsening depression during the COVID era was associated with HIV viral nonsuppression. Strategies to monitor and address depression among PWH may contribute to reduced risk of viral nonsuppression.

Eur J Heart Fail. 2023 Dec 20.

[Effect of paced heart rate on quality of life and natriuretic peptides for stage B or C heart failure with preserved ejection fraction: a secondary analysis of the myPACE trial](#)

de la Espriella R, Wahlber KJ, Infeld M, Palau P, Núñez E, Sanchis J, Meyer M, Núñez J

AIM: Emerging evidence suggests a beneficial effect of higher heart rates in some patients with heart failure with preserved ejection fraction (HFpEF). This study aimed to evaluate the impact of higher backup pacing rates in HFpEF patients with preexisting pacemaker systems that limit pacemaker-mediated dyssynchrony across left ventricular (LV) volumes and LV ejection fraction (LVEF).

METHODS AND RESULTS: This is a post-hoc analysis of the myPACE clinical trial that evaluated the effects of personalized accelerated pacing setting (myPACE) versus standard of care on changes in Minnesota Living with Heart Failure Questionnaire (MLHFQ) score, N-terminal pro-brain natriuretic peptide (NT-proBNP), pacemaker-detected activity levels, and atrial fibrillation (AF) burden in patients with HFpEF with preexisting pacemakers. Between-treatment comparisons were performed using linear regression models adjusting for the baseline value of the exposure (ANCOVA design). This study included 93 patients with pre-trial transthoracic echocardiograms available (usual care n = 49; myPACE n = 44). NT-proBNP levels and MLHFQ scores improved in a higher magnitude in the myPACE group at lower indexed LV end-diastolic volumes (iLVEDV) (NT-proBNP-iLVEDV interaction p = 0.006; MLHFQ-iLVEDV interaction p = 0.068). In addition, personalized accelerated pacing led to improved changes in activity levels and NT-proBNP, especially at higher LVEF (activity levels-LVEF interaction p = 0.009; NT-proBNP-LVEF interaction p = 0.058). No evidence of heterogeneity was found across LV volumes or LVEF for pacemaker-detected AF burden.

CONCLUSIONS: In the post-hoc analysis of the myPACE trial, we observed that the benefits of a personalized accelerated backup pacing on MLHFQ score, NT-proBNP, and pacemaker-detected activity levels appear to be more pronounced in patients with smaller iLVEDV and higher LVEF.

Clin Infect Dis. 2023 Dec 26:ciad782.

[Polypharmacy is associated with slow gait speed and recurrent falls in older people with HIV](#)

Kosana P, Wu K, Tassiopoulos K, Letendre S, Ma Q, Paul R, Ellis R, Erlandson KM, Farhadian SF.

BACKGROUND: Older people with HIV (PWH) are prone to using multiple medications due to higher rates of medical comorbidities and the use of antiretroviral therapy (ART). We assessed the prevalence and clinical impact of polypharmacy among PWH.

METHODS: We leveraged clinical data from the AIDS Clinical Trials Group (ACTG) A5322 (HAILO) cohort of PWH aged 40 or older with plasma HIV RNA levels below 200 copies/ μ L. We assessed the relationship between polypharmacy (defined as the use of 5 or more prescription medications, excluding ART) and hyperpolypharmacy (defined as the use of 10 or more prescription medications) with slow gait speed (less than 1 meter/second) and falls, including recurrent falls.

RESULTS: Excluding ART, 24% of study participants had polypharmacy and 4% had hyperpolypharmacy. Polypharmacy was more common in women (30%) than men (23%). Participants with polypharmacy had a higher risk of slow gait speed (Odds ratio (OR) = 1.78 [95% CI=1.27, 2.50]) and increased risk of recurrent falls (OR= 2.12 [95% CI=1.06, 4.23]). The risk for recurrent falls was further increased in those with hyperpolypharmacy compared to those without polypharmacy (OR = 3.46 [95% CI=1.32, 9.12]).

CONCLUSIONS: In this large, mixed-sex cohort of PWH AGED over 40, polypharmacy was associated with slow gait speed and recurrent falls, even after accounting for medical comorbidities, alcohol use, substance use, and other factors. These results highlight the need for increased focus on identifying and managing polypharmacy and hyperpolypharmacy in PWH.

J Med Virol. 2023 Dec;95(12):e29310.

[Outpatient randomized controlled trials to reduce COVID-19 hospitalization: systematic review and meta-analysis](#)

Sullivan DJ, Focosi D, Hanley DF, Cruciani M, Franchini M, Ou J, Casadevall A, Paneth N

ABSTRACT: This COVID-19 outpatient randomized controlled trials (RCTs) systematic review compares hospitalization outcomes amongst four treatment classes over pandemic period, geography, variants, and vaccine status. Outpatient RCTs with hospitalization endpoint were identified in Pubmed searches through May 2023, excluding RCTs <30 participants (PROSPERO-CRD42022369181). Risk of bias was extracted from COVID-19-NMA, with odds ratio

utilized for pooled comparison. Searches identified 281 studies with 61 published RCTs for 33 diverse interventions analyzed. RCTs were largely unvaccinated cohorts with at least one COVID-19 hospitalization risk factor. Grouping by class, monoclonal antibodies (mAbs) (OR = 0.31 [95% CI = 0.24-0.40]) had highest hospital reduction efficacy, followed by COVID-19 convalescent plasma (CCP) (OR = 0.69 [95% CI = 0.53-0.90]), small molecule antivirals (OR = 0.78 [95% CI = 0.48-1.33]), and repurposed drugs (OR = 0.82 [95% CI: 0.72-0.93]). Earlier in disease onset interventions performed better than later. This meta-analysis allows approximate head-to-head comparisons of diverse outpatient interventions. Omicron sublineages (XBB and BQ.1.1) are resistant to mAbs Despite trial heterogeneity, this pooled comparison by intervention class indicated oral antivirals are the preferred outpatient treatment where available, but intravenous interventions from convalescent plasma to remdesivir are also effective and necessary in constrained medical resour

J Thorac Cardiovasc Surg. 2023 Dec 26:S0022-5223(23)01207-2.

[Comparing 3-year survival and readmissions between HeartMate 3 and heart transplant as primary treatment for advanced heart failure](#)

Kirschner M, Topkara VK, Sun J, Kurlansky P, Kaku Y, Naka Y, Yuzefpolskaya M, Colombo PC, Sayer G, Uriel N, Takeda J

OBJECTIVE: Our objective was to compare 3-year survival and readmissions of patients who received HeartMate 3 (HM3) left ventricular assist device (LVAD) or orthotopic heart transplantation (OHT) as primary treatment for advanced heart failure.

METHODS: We retrospectively analyzed 381 adult patients who received HM3 LVAD or were listed for OHT between January 2014 and March 2021 at our center. To minimize crossover bias, OHT patients with prior LVAD were excluded and HM3 patients were censored at time of transplant. Cohorts were propensity score-matched (PSM) to reduce confounding variables. Primary outcome was 3-year survival. Secondary outcome was mean cumulative, all-cause, unplanned readmission.

RESULTS: Cohorts consisted of 185 (49%) HM3 patients and 196 (51%) OHT patients, with 104 PSM patients in each group. After PSM, there was no statistical difference in 3-year survival (HM3 83.7% vs. OHT 87.0%, P = 0.91; RR = 1.00, 95% CI = 0.45-2.20). In unmatched cohorts, patients ages 18-49 had comparable survival with HM3 as with OHT (96.9% vs 95.9%, N = 91, P = 1.00; RR = 0.92, 95% CI = [0.09-9.78]); patients ages 50+ had similar with HM3, despite an 8.9% difference (75.0% vs 83.9%, N = 290, P = 0.60; RR = 1.51, 95% CI = [0.85-2.68]). Mean cumulative readmissions at 3-years was higher in the HM3 cohort (3.89 vs. 2.05, P < 0.001).

CONCLUSION: This exploratory analysis suggests that for

similar patients HM3 may provide comparable 3-year survival to OHT as a primary treatment for heart failure, but may result in more readmissions.

Am J Respir Crit Care Med. 2024 Jan 1;209(1):59-69.

[Early evidence of chronic obstructive pulmonary disease obscured by race-specific prediction equations](#)

EA Regan, Lowe ME, Make BJ, et al.

RATIONALE: The identification of early chronic obstructive pulmonary disease (COPD) is essential to appropriately counsel patients regarding smoking cessation, provide symptomatic treatment, and eventually develop disease-modifying treatments. Disease severity in COPD is defined using race-specific spirometry equations. These may disadvantage non-White individuals in diagnosis and care.

OBJECTIVES: Determine the impact of race-specific equations on African American (AA) versus non-Hispanic White individuals.

METHODS: Cross-sectional analyses of the COPDGene (Genetic Epidemiology of Chronic Obstructive Pulmonary Disease) cohort were conducted, comparing non-Hispanic White ($n = 6,766$) and AA ($n = 3,366$) participants for COPD manifestations.

MEASUREMENTS AND MAIN RESULTS: Spirometric classifications using race-specific, multiethnic, and “race-reversed” prediction equations (NHANES [National Health and Nutrition Examination Survey] and Global Lung Function Initiative “Other” and “Global”) were compared, as were respiratory symptoms, 6-minute-walk distance, computed tomography imaging, respiratory exacerbations, and St. George’s Respiratory Questionnaire. Application of different prediction equations to the cohort resulted in different classifications by stage, with NHANES and Global Lung Function Initiative race-specific equations being minimally different, but race-reversed equations moving AA participants to more severe stages and especially between the Global Initiative for Chronic Obstructive Lung Disease (GOLD) stage 0 and preserved ratio impaired spirometry groups. Classification using the established NHANES race-specific equations demonstrated that for each of GOLD stages 1-4, AA participants were younger, had fewer pack-years and more current smoking, but had more exacerbations, shorter 6-minute-walk distance, greater dyspnea, and worse BODE (body mass index, airway obstruction, dyspnea, and exercise capacity) scores and St. George’s Respiratory Questionnaire scores. Differences were greatest in GOLD stages 1 and 2. Race-reversed equations reclassified 774 AA participants (43%) from GOLD stage 0 to preserved ratio impaired spirometry.

CONCLUSIONS: Race-specific equations underestimated disease severity among AA participants. These effects were particularly evident in early disease and may result in late detection of COPD.

Am J Kidney Dis. 2023 Dec 29;S0272-6386(23)01000-4.

[Infections following kidney transplantation after exposure to immunosuppression for treatment of glomerulonephritis](#)

Massicotte-Azarniouch D, Detwiler RK, Hu Y, Falk RJ, Saha MK, van Duin K, Hogan SL, Derebail VK

RATIONALE & OBJECTIVE: Kidney transplant patients with glomerulonephritis (GN) as their native disease commonly have received pre-transplant immunosuppression (PTI). This may contribute to the immunosuppression burden potentially increasing the risk for infections following transplantation.

STUDY DESIGN: Single-center, retrospective cohort study.

SETTING & PARTICIPANTS: Recipients of a kidney transplant from January 2005 until May 2020 at a tertiary care university teaching hospital.

EXPOSURE: Patients with GN as their native kidney disease who received PTI for treatment of GN ($n=184$) were compared to non-diabetic recipients of kidney transplants who did not receive PTI ($n=579$).

OUTCOMES: First occurrence after transplantation of an infection outcome, either viral (BK or CMV infection) or bacterial.

ANALYTICAL APPROACH: Cox regression analysis adjusted for age at transplant, sex, race, donor type, year of transplant surgery, dialysis vintage, receipt of T-cell depleting induction, and CMV transplant status.

RESULTS: Over a median follow-up of 5.7 years, patients with GN PTI were neither at an increased risk for developing any first viral infection compared to controls, aHR (95%CI) 0.69 (0.52-0.91), nor for specific viral infections (BK infection 19.6% vs 26.3%, aHR 0.72 [0.50-1.05]; CMV infection 24.5% vs 29.0%, aHR 0.76 [0.54-1.07], respectively). There was also no increased risk of developing a first bacterial infection (54.5% vs 57.5%, aHR 0.90 [0.71-1.13]). These findings of no increased risk for infection were independent of the type of PTI used (cyclophosphamide, rituximab, mycophenolate mofetil, or calcineurin inhibitor) and the type of T-cell depleting induction therapy (alemtuzumab or anti-thymocyte globulin) administered.

LIMITATIONS: Single-center study, no data on methylprednisone use for PTI, unmeasured confounding
CONCLUSION: Use of PTI for the treatment of GN was neither associated with an increased risk of viral (BK or CMV) nor of bacterial infection following transplantation. Additional surveillance for infection following transplantation for patients who received PTI may not be necessary.

J Hypertens. 2024 Feb 1;42(2):197-204.

[Exercise training reduces arterial stiffness in women with high blood pressure: a systematic review and meta-analysis](#)

Zaman S, Selva Raj I, Wei A, Yang Hong, Lindner R, Denham J

ABSTRACT: The acute and long-term benefits of exercise on cardiovascular health are well established, yet the optimal mode of exercise training that improves arterial stiffness in women with high blood pressure remains unclear. The aim of this systematic review and meta-analysis was to assess the influence of aerobic and resistance training on arterial stiffness in women with high blood pressure. After an extensive search of four online databases, six randomized controlled trials met the inclusion criteria and were included in meta-analyses. Data were extracted from six studies examining the influence of exercise on arterial stiffness assessed by pulse wave velocity (PWV) and were expressed as standardized mean difference (SMD). Whereas aerobic exercise significantly reduced arterial PWV in women with high blood pressure after long-term training [SMD -1.87, 95% confidence interval (CI) -2.34 to -1.40], resistance training had a more modest effect that was borderline statistically significant (SMD -0.31, 95% CI -0.65 to 0.03). These findings suggest regular long-term aerobic exercise training (i.e. 12-20 week interventions) reduces arterial stiffness in women with high blood pressure. Although not statistically significant, the modest number of included trials and lack of publication bias encourages further assessments on the efficacy of resistance exercise for improving arterial stiffness in women with high blood pressure. Given the unique benefits of aerobic and resistance training, particularly for postmenopausal women (e.g. bone health and muscular strength), both modes of training should be encouraged for women with high blood pressure to enhance arterial function and support favorable cardiovascular outcomes.

Anticancer Res. 2024 Jan;44(1):133-137.

[Metformin in conjunction with stereotactic radiotherapy for early-stage non-small cell lung cancer: long-term results of a prospective phase II clinical trial](#)

Tate MK, Hernandez M, Chang JY, Lin. SH, Liao Z, Koshy SM, Skinner HD, Chun SG

BACKGROUND/AIM: Non-small cell lung cancer (NSCLC) is increasingly detected in early stages and there is interest in improving outcomes with stereotactic body radiotherapy (SBRT). As metformin affects NSCLC signaling pathways, it might alter the metabolism of NSCLC treated with SBRT. This study investigated the

long-term outcomes of a phase II clinical trial evaluating metformin in conjunction with SBRT for early-stage NSCLC.

PATIENTS AND METHODS: The trial evaluated patients with American Joint Commission on Cancer (AJCC) 7th edition Stage I-II, cT1-T2N0M0 NSCLC who were randomized 6:1 to receive metformin versus placebo in conjunction with SBRT. The outcomes analyzed included local failure (LF), progression-free survival (PFS), overall survival (OS), and Common Terminology Criteria for Adverse Events (CTCAE) version 4 toxicities.

RESULTS: There were 14 patients randomized to the metformin arm and one to the placebo. Median follow-up was four years. In the metformin group, the median PFS was 4.65 years [95% confidence interval (CI)=0.31-5.93] and median survival was 4.97 years (95%CI=3.05-4.61). Five year PFS was 27.8% (95%CI=5.3-57.3%) and OS was 46.0% (95%CI=16.0-71.9%). The one patient randomized to placebo was alive and without progression at five years. There were no LFs in the primary SBRT treatment volumes and no CTCAE version 4 Grade ≥ 3 adverse events.

CONCLUSION: Outcomes of SBRT and metformin for early-stage NSCLC were similar to historic controls. These findings along with the results of the NRG-LU001 and OCOG randomized trials do not support the therapeutic use of metformin for NSCLC.

Dig Dis Sci. 2024 Jan 3.

[Development and evaluation of a patient cirrhosis knowledge assessment](#)

Bloom PP, Che K, Hyde A, Johnson E, Miguel-Cruz A, Carbonneau M, Hazra D, Tandon D

BACKGROUND AND AIMS: Self-management skills improve outcomes for patients with cirrhosis. While education programs exist to teach these skills, there are limited patient assessments to evaluate their efficacy. We aimed to develop and evaluate cirrhosis knowledge assessments for patients with compensated and decompensated cirrhosis.

METHODS: Across two institutions, a 4-stage process was undertaken: first, we developed a comprehensive set of questions regarding cirrhosis self-management. Second, the questions underwent critical review by patients and hepatology providers. Third, patients with cirrhosis answered these questions before and after a written educational tool. Questions were updated based on results. Fourth, patients answered the updated questions before and after a video educational tool. Binomial test or paired sample t-test was used to compare pre- and post-tests depending on question type.

RESULTS: In phase 3, 134 patients completed pre- and post-tests. 44% were decompensated, 81% were diagnosed with cirrhosis at least 3 years, and 52% were 60-75 years. 95% of single-answer

questions were answered correctly by at least 70% of patients in the pre-test. None of the answers improved significantly with education. After phase 3, 6 questions were removed and 6 questions were edited to increase challenge. In phase 4, 96 patients (42 compensated, 54 decompensated) completed pre- and post-tests. In the compensated assessment, 3 questions improved after education and the summative score increased (7.9 to 9.0, $P < 0.001$). In the decompensated assessment, 4 questions improved after education and the summative score increased (7.0 to 7.7, $P = 0.004$).

CONCLUSION: Through a rigorous process, we created and evaluated cirrhosis knowledge assessments for patients with compensated and decompensated cirrhosis. Further validation is required and then these assessments can be used to improve patient education.

Make 2024 the Year You Build Recognition for Case Management

continued from page 3

management's effect in the management of patient care. Several hundred articles, published between 2014 and 2020, focused on the role of nurse case managers, case management applied in chronic disease cases, and the efficiency of nurse case managers' interventions in terms of cost savings, reductions in complications, etc.

Their findings validated the value of nurse case managers in addressing patients with chronic diseases; reducing emergency department (ED) visits, hospital admissions, and readmissions; and reducing direct/indirect costs to health systems. Most importantly, the findings noted the role of nurse case managers in improving patient outcomes. The article summarized the studies with this sentence, "Case management is effective and efficient in most of the literature consulted, reducing health care costs and improving the quality of care."

Communicating Case Management and Its Value to Key Markets

In this issue of *CareManagement*, Nancy Skinner's article titled, "The Value of Case Management: Does Your Mother

Know What You're Doing?" presents the need for case managers to better communicate our role and its value to patients, families, and caregivers. She discusses the many definitions of case management and points out they are not consumer-friendly and fail to convey case management's benefits and value. Helping consumers understand what case management is and how they can benefit from it is paramount to it gaining the recognition it deserves with them, other professionals, and payors. The most recent version of the CMSA Standards of Practice (2022) included a consumer definition for the first time: "...case managers are health care professionals who serve as patient advocates to support, guide, and coordinate care for patients, families, and caregivers as they navigate their health and wellness journeys..."

To build case management's brand recognition, we must be proactive in creating a clear and concise definition of case management and communicate its evidence-based value in improving patient outcomes and reducing health care costs. We must use all communications tools available—from, broadcast, mass media, and news releases reporting on studies citing case management's value to holding consumer-focused programs with

Am J Clin Nutr. 2023 Dec 29;S0002-9165(23)66356-7.

Post hoc analysis of food costs associated with dietary approaches to stop hypertension (DASH) diet, whole food, plant-based diet, and typical baseline diet of individuals with insulin-treated type 2 diabetes mellitus in a non-randomized crossover trial w

Campbell EK, Taillie L, Blanchard LM, Wixom N, Harrington DK, Peterson DR, Wittlin SR, Campbell TM

BACKGROUND: Americans consume diets that fall short of dietary recommendations, and the cost of healthier diets is often

Continued on page 35

area hospitals or physician groups. We can further capitalize on National Case Managers Week by celebrating our case manager heroes on social media platforms and in local news media. During the most recent Legacy Leaders meeting, several recommendations were made, including retaining a public relations professional to expand our visibility and sharpen our message.

Case Managers—The Best Brand Ambassadors for Case Management

Each of us can help advance case management. We are case management's best brand ambassadors. Step up and be a credible brand ambassador whenever you are interacting with a patient, family member, other health care professionals or hospital leaders, as well as nurses and social workers who may be considering becoming a case manager. Know and communicate your value. Individually and collectively, we can make a difference in building greater recognition for case management.

We can and must do this on behalf of those recipients of our interven-

Catherine M. Mullahy

tion...one patient at a time!

Catherine M. Mullahy, RN, BS, CRRN,

Health Care 2024 *continued from page 2*

approaches will be introduced, some of which might include virtual assistants, virtual reality therapy, wearable health technology, and a rise in telemedicine 2.0. All these programs focus on labor-saving activities. Case management must be creative in using technology and other resources in facilitating the case management process in 2024.

- **Artificial Intelligence:** AI simulates human intelligence and performs complex automated tasks. Some of the areas AI will be involved in include machine learning, robotic process automation including utilization management, procedures that personalize treatment plans, prediction of disease and illness, interpretation of tests, improved decision making, optimized health outcomes, support of population health management, monitoring of patients, and development of new drugs and procedures. The AI opportunities seem unlimited. AI will change the health care landscape. With AI comes risk, so safeguards will have to be developed.
- **Drug Costs:** As usual in January drug manufacturers raised drug prices. That happened with over 600 drugs, but the increases were not as high as they were during previous trends. The bottom-line drugs are costly, and although in recent

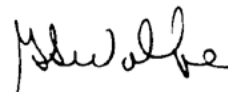
years we have seen some attempts to control prices like capping the out-of-pocket cost for insulin, drug prices continue to escalate. Some patients adjust the dose or delay taking their medication to make the medication go farther. We will see a feeble attempt by Congress to address drug costs but probably will see little action until after the 2024 presidential election, which, in reality, probably means in the 2025 Congress. There will be a focus on addressing the complexities of drug pricing while ensuring access to necessary medications.

- **Health Equity:** We will see greater emphasis on understanding the social determinants of health for achieving health equity. All people should have the same opportunities to achieve their full health potential regardless of social, economic, or environmental circumstances. The case manager is in the forefront of accessing social determinants of health and improving patients' outcomes.
- **Convergence of Mental and Physical Health Care Delivery:** In the history of medicine, physical health and mental health have been relatively separate. COVID certainly changed that concept. Although in recent years we have seen convergence of mental and physical health, we will see it accelerate in 2024. We will see more frontline health care providers,

like primary care offices, screening for ways to identify mental health issues that may impact treatment and recovery of physical ailments. The case manager is a principal person in screening for mental health issues.

- **Cybersecurity in Health Care:** Cybersecurity is an increasing problem. With the increased capabilities and use of technology, the risk has become greater. We will see a significant focus of enhancing cybersecurity measures to protect patient data from cyber threats, ensuring trust and reliability in health care systems. Case managers use technology extensively and must understand the security safeguards.

In 2024, we will see transformative efforts undertaken in reshaping health care. Most trends I have listed above will place an increased demand on case managers. We will continue to be patients' advocates and utilize the case management process to grow and develop in 2024. Work hard and take care of yourself—2024 will be quite a ride!



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Enhancing Safety and Independence With Transfers: A Guide to Transfer Devices for Case Managers

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also require specific training in the proper use of transfer devices to protect themselves and the patient and consider these needs when coordinating care and discharge planning. As technology advances, the development of novel devices ensures a continually expanding toolkit for case managers to consider, emphasizing the importance of tailoring solutions to individual patient and care partner needs and collaborating with the health care team, including occupational and physical therapists. Integrating these transfer devices into comprehensive care strategies, alongside potential home modifications, not only fosters a safer environment but empowers patients to navigate their daily lives with increased confidence and independence. **CE1**

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New Challenges in Hospice Care *continued from page 17*

this can show you what your patients and their families are experiencing.

Conversation is listening and gently sharing/educating your patients and their families while understanding that their pain and concern is key to developing rapport and trust. Case managers have an obligation to uphold these ethical constructs of autonomy, fidelity, and veracity. Good end-of-life health care demands it. **CE II**

Additional information can be found on these websites:

- www.capc.org Center to Advance Palliative Care
- www.polst.org National POLST Paradigm
- www.coalitionccc.org Coalition for Compassionate Care of California
- www.nhcpo.org National Hospice and Palliative Care Organization
- www.theconversationproject.org Conversation Project
- <https://youtube.com/@dying101> Free deeper-dive videos on end-of-life care topics
- <https://deathwithdignity.org/states/>

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The Value of Case Management: Does Your Mother Know What You're Doing? *continued from page 22*

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How Case Managers Help *continued from page 7*

time for him to get help walking with the prosthesis before the wedding. He let the case manager know that he was able to stand for the entire wedding of his son and even dance with his new daughter-in-law. He said he and his wife will always remember everything she did for them. **CM**

"This work has been previously published by CMSA Chicago 2023 in "Case Management: Creating Connections...Shaping Solutions – 5th Edition" and reprinted with permission by Eric Bergman and Colleen Morley, Editors and the author, Kathy Barrows



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cited as a barrier to dietary change. We conducted a non-randomized crossover trial with meals provided utilizing two diets: Dietary Approaches to Stop Hypertension (DASH) and whole food, plant-based (WFPB), and thus had intake data from baseline and both intervention diets.

OBJECTIVE: Using actual diet records, describe **FOOD** costs of baseline diets of individuals with type 2 diabetes (T2DM) as well as therapeutic DASH and WFPB diets.

METHODS: 3-day food records were collected and analyzed for each 7-day diet phase: baseline, DASH, and WFPB. Nutrient content was analyzed using Nutrient Data System for Research (NDSR) and cost was determined using Fillet, an application to manage menu pricing. Food costs were calculated for each diet as consumed and adjusted to a standardized 1800 kcal/day. Ingredient only costs of food away from home (FAFH) were approximated and analyzed. Costs were analyzed using linear mixed effect models as a function of diet.

RESULTS: Fifteen subjects enrolled; 12 completed all dietary phases. The baseline, DASH, and WFPB diets, as consumed, cost \$15.72/day (95% CI; \$13.91, \$17.73), \$12.74/day (\$11.23, \$14.25), and \$9.78/day (\$7.97, \$11.59), respectively. When adjusted to an 1800 kcal/day intake, the baseline, DASH, and WFPB diets cost \$15.69/day (\$13.87, \$17.52), \$14.92/day (\$13.59, \$16.26), and \$11.96/day (\$10.14, \$13.78), respectively. When approximated ingredient only costs of FAFH were analyzed, as consumed baseline (\$11.01 (\$9.53, \$12.49)) and DASH diets (\$11.81 (10.44, \$13.18)) had similar costs; WFPB diet (\$8.83 (\$7.35, \$10.31)) cost the least.

CONCLUSIONS: In this short-term study with meals provided, the food costs of plant-predominant diets offering substantial metabolic health benefits were less than or similar to baseline food costs of adults with insulin-treated T2DM. Longer-term data without meal provision are needed for more generalizable results. **■**

Advocacy—Always and Everywhere

continued from page 6

case management is a means for improving client health, wellness and autonomy through advocacy, communication, education, identification of service resources, and service facilitation” (CCMC, Code, 2018, p. 3). At the heart of what we do is advocacy.

Where Advocacy Meets Empathy

One of the most impactful influences of my role as an advocate is being a recipient of assistance. We all need help and support at times, and these incidents remind us that no one has all the answers. We need each other to navigate complex problems and systems. In my own life, I have experienced a profound need for help when I was pregnant with my first child. My request for maternity leave was rescinded and my husband was unsuccessfully seeking employment

following graduate school. We had very little money, no health insurance—and a baby on the way.

Someone reached out to me and said, “You need to go to social services.” I’ll admit it—I felt embarrassed at first because I had never imagined needing to be on Medicaid and relying on food stamps. It seemed I had no other choice. At social services, I met with a social worker who changed my perspective. “You’re in a rough spot right now. This assistance is intended for times like these.”

I’ll never forget what it was like to be seen through that social worker’s eyes—a powerful experience of empathy that has stayed with me for more than four decades. I recall this encounter every time I meet someone who needs my help. In my current role in public health, providing services in the community, I remember well what it felt like to encounter compassion, not judgment.

I am reminded of this fundamental truth about advocacy every time I go into the offices of the health department. I enter the building through a set of glass doors into a large lobby. On one side of the elevator is the Department of Public Health, for which I now work. On the other side is the Department of Social Services where, so many years ago, I had applied for aid. Forty-seven years and 30 feet separate those two experiences that have become like bookends in my life: needing help and giving help. It is a perspective I would not trade for anything. **CM**

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Case Management: One CMSA’s Journey

continued from page 4

- Commission (URAC), and National Quality Forum (NQF) and welcomed new collaborations with America Association of Nurse Life Care Planners (AANLCP), National Adult Day Services Association (NADSA), and Society for Social Work Leadership in Health Care (SSWLHC)
- Made over 150 online courses available free to members
 - Launched new committees for affiliate and academia collaboration; public information; future trends; and diversity, equity, inclusion, and belonging (DEIB)
 - Unveiled the newly updated Opioid Use Disorder Case Management Guide
 - Held two in-person CMSA Boot Camp sessions and five virtual Integrated Case Management (ICM)

programs based on recently published ICM manual

- Provided continuing education credits for CCM, CCM Ethics, RN, social work, CDMS, CDMS Ethics, certified professional in healthcare quality (CPHQ), certified rehabilitation counselor (CRC) and CRC Ethics
- Provided value through partnerships with leading industry vendors
- Engaged with over 30,000 case managers through education, information, celebration, collaboration, and networking

Now, as I enter the last 6 months in my role as president of CMSA, I continue to dedicate my energies to elevating the profession, ensuring that case managers are recognized as key contributors to holistic patient care (no longer the “best kept secret in health care”); a vision that is rooted in real-world experiences and elevated by aspirations for a future in which case management is recognized as a

cornerstone of effective health care.

If you are a member of CMSA, thank you! You are an integral part of our community. If you have not yet joined CMSA, please consider it. It was the absolute best decision I made to support my case management practice/career. I hope to see you at the CMSA National Conference in Providence, Rhode Island, June 4-7, 2024. Together, we can look forward to a future where our profession is not just acknowledged but celebrated for its integral role in health care. **CM**

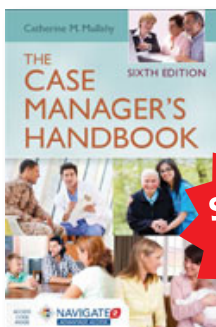
The Case Management Society of America (CMSA) facilitates the growth and development of professional case managers across the full health care continuum, promoting high quality, ethical practice benefitting patients and their families. We strive for improved health outcomes by providing evidence-based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



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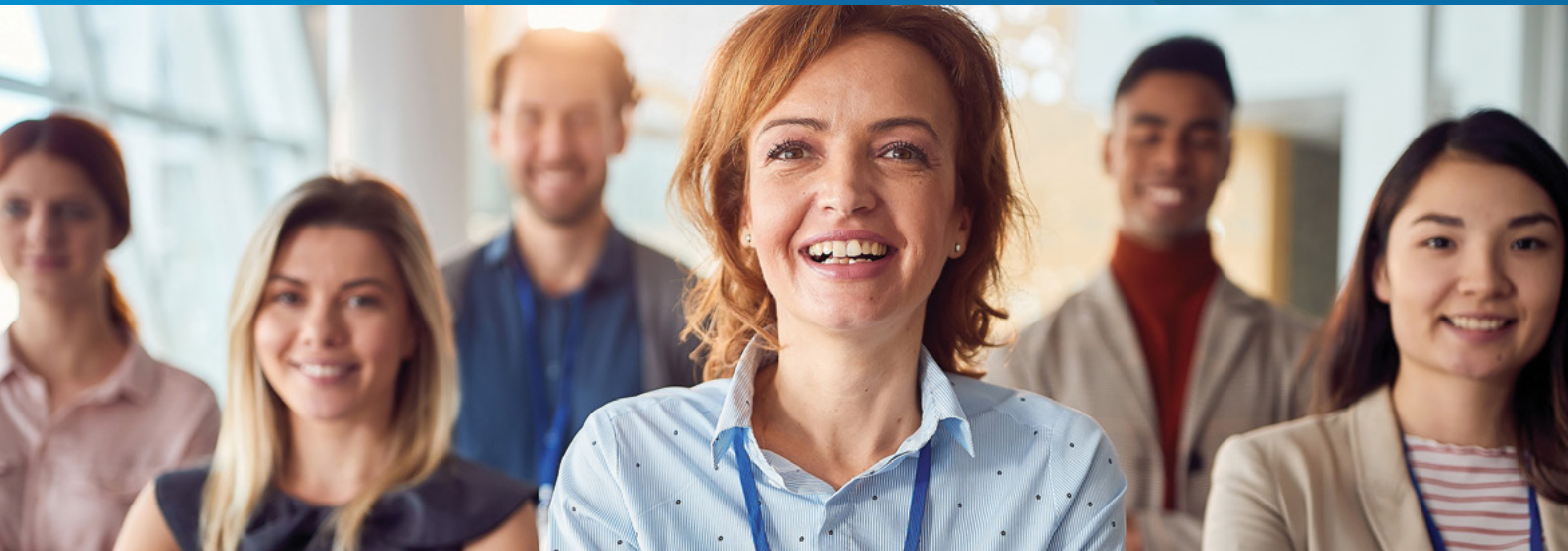
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