CareManagement

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

Vol. 30, No. 3 June/July

INSIDE THIS ISSUE

CONTINUING EDUCATION ARTICLES:

8 Beyond Words: Navigating Pain in Dementia CE1

By John V. Rider, PhD, MS, OTR/L, MSCS, ATP, and Jessica M. Galilo, OTD-S

Those with dementia who have difficulty communicating verbally may have difficulty expressing pain they are experiencing. Evidence suggests that 60% to 80% of patients in skilled nursing facilities experience daily pain. This article suggests ways in which case managers can recognize symptoms of pain even in those unable to communicate effectively with caregivers. It answers the question: What clues are available to determine pain in dementia patients?

14 Loneliness is Deadly CE2

By Judith R. Sands, BSN, MSL, RN, CPHRM, ARM, CCM, CPHQ

Chronic loneliness and social isolation, which affect all age groups, increase the risk of developing dementia, heart disease, and stroke. Although loneliness and social isolation are related, loneliness is a subjective internal state that results from perceived isolation or unmet needs. How can the case manager help patients who are lonely? This article explores some of the assessment skills needed to identify loneliness and suggestions for how to help patients/clients who may be experiencing loneliness and social isolation.

19 Understanding Clinical Trials: Part 2 CE3

By Gary Wolfe, RN, CCM, FCM

Part 2 of the series about clinical trials (see the April/May issue for Part 1) focuses on the nuts and bolts of clinical trials, the different types and how they work, and where case managers fit in by working with patients to find clinical trials, explaining how specific types of clinical trials work, and discussing the pros and cons of joining a clinical trial so patients can make informed decisions.

CE Exam CE

Members: Take exam online or print and mail.

Nonmembers: Join ACCM to earn CE credits.

SPECIAL SECTIONS:

25 PharmaFacts for Case Managers

Approvals, warnings and the latest information on clinical trials—timely drug information case managers can use..

30 LitScan for Case Managers

The latest in medical literature and report abstracts for case managers.

DEPARTMENTS:

2 From the Editor-in-Chief
Loneliness: Implications for Case Managers

3 From the Executive Editor
Case Managers: Own Your Vital Role in Social Determinants of Health

4 News from CCMC and CDMS
Managing An Aging Workforce: Creativity and Flexibility Lead to More Opportunities

5 News from CCMC
You Are Invited: The Commission's Role & Function Study

6 Case Manager Insights
Networking and the Benefits of LinkedIn

7 News from CMSA
The Future of Health Care Powered by Case Management

37 How to Contact Us

37 FAQs

38 Membership Application

Gary S. Wolfe

Loneliness: Implications for Case Managers

Everyone has felt loneliness at some time in their life, but the feeling was fleeting or transient. When loneliness becomes a chronic issue, problems arise including implications for health. There is an epidemic of loneliness in the United States, and the situation is worsening. The American Psychological Association defines loneliness as the "affective and cognitive discomfort of uneasiness from being or perceiving oneself to be alone or otherwise solitary." Loneliness is an unpleasant emotional response to perceived isolation. Our need to connect is innate, but many feel alone. Even people surrounded by others may or can experience a deep and pervasive loneliness. The US Surgeon General released a report, *Our Epidemic of Loneliness and Isolation: The US Surgeon General's Advisory on the Healing Effects of Social Connection and Community,* in 2023. In the same year, The World Health Organization declared loneliness a "global public health concern" and launched a commission to study the problem. Loneliness is of interest to case managers because loneliness has a significant impact on physical and mental health.

There are several factors driving this public health crisis. Americans are becoming less socially connected over time. Decreased individual social participation, demographics, decreased community involvement, and increased use of technology over time suggest a decline in social connection. Trust in each other and major institutions is near historic lows. This lack of trust has created high levels of polarization—all contributing to loneliness and lack of social connections.

Who are lonely? Loneliness is not confined to any one demographic. In a national survey conducted in 2021 by Harvard Graduate School of Education found 36% of all respondents reported serious loneliness, which included 61% of young people aged 18 to 25 and 51% of mothers with young children. In the same study, some 43% of young adults reported increases in loneliness since the outbreak of the COVID pandemic. The National Academies of Sciences, Engineering, and Medicine noted in a 2020 study that one-third of all adults over the age of 45 were lonely. Other experts have estimated that 40% to 69% of people in the United States feel lonely. A 2022 study found that when people were asked how close they felt to others emotionally, only 39% of adults in the United States said that they felt very connected to others.

The symptoms of loneliness can be somewhat vague and transient but may include the following:

- Decreased energy
- Feeling goofy or inability to focus
- Insomnia, interrupted sleep, or other sleep issues
- Decreased appetite
- Feeling of self-doubt, hopelessness, or worthlessness
- Body aches and pains
- Substance misuse
- Increased desire to binge-watch shows or movies
- Increased shopping
- Tendency to get sick often
- Anxiousness or restlessness
- Wishing you had more friends

continues on page 35

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

Vol. 30, No. 3, June/July 2024. CareManagement (ISSN #1531-037X) is published electronically six times a year, February, April, June, August, October, and December, and its contents are copyrighted by Academy of Certified Case Managers, 2740 SW Martin Downs Blvd. #330, Palm City, FL 34990; Tel: 203-454-1333; Fax: 203-547-7273.

Subscription rates: $130 per year for ACCM members; $150 for institutions.

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

Catherine M. Mullahy

Case Managers: Own Your Vital Role in Social Determinants of Health

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

Social determinants of health (SDOH) have become a critical tool in today's provision of health care. From individuals' quality health care access, economic stability, job opportunities, and education, to their access to healthy foods, clean water, a stable living environment, and social/community resources, these nonmedical factors have a tremendous impact on one's overall health, contributing to an estimated 50% of all health outcomes. There has been great progress in leveraging SDOH within organizations like the Robert Wood Johnson Foundation (RWJF), which is driving successful programs including those involving reproductive care, food security, home ownership, and community resilience. Like RWJF, case managers are also playing a vital role in the application of SDOH. That is why it is so important that case managers take ownership of this role in the best possible ways.

These initiatives will rely heavily on the application of various technologies, telemedicine platforms, and data captured through advanced algorithms and wearable technologies.

A Natural Role for Case Managers

SDOH are included in the Case Management Society of America (CMSA) Standards of Practice (CMSA, 2022). Case managers are the links between patients and the broader health care systems. They go between patients and their families and the clinical team, other health care providers, social services, and community services. Case managers assess our patients and track their progress and medical outcomes. Case managers advocate for their patients' needs, while educating patients and their families regarding prevention wellness, stress management, their specific medical condition(s), and the influence of SDOH on their health. Through their patient interviews and use of various screening tools, case managers identify those SDOH that will most affect their patients and then work to find and coordinate appropriate solutions.

Participating in SDOH initiatives, however, is not without its challenges. Case managers must navigate a complex health care system, while being mindful of changing regulatory requirements. They must be culturally sensitive to our nation's multicultural society. This may require using translators to ensure that each patient's voice is being heard and their expectations met. Then, of course, there are the medically complex individuals who bring their own set of challenges. For patients suffering from a mental health disorder, the challenges are further intensified.

Obstacles Case Managers Face With SDOH

On January 17, 2024, the US Centers for Medicare & Medicaid (CMS) released its "Interoperability and Prior Authorization Final Rule," which emphasized the need to improve health information exchange to achieve appropriate, required access to health records for patients, health care providers, and payers. New regulations are also underway at the state level, specifically related to artificial intelligence (AI) and its applications in prior authorization reforms and how peer-to-peer reviews are performed. These initiatives will rely heavily on the application of various technologies including telemedicine platforms and data captured through advanced algorithms and wearable technologies. Case managers should understand what is required to meet new regulations in addition to complying with legislation such as the Health Insurance Portability and Accountability Act (HIPAA), the Affordable Care Act (ACA), and other applicable legislation.

There are sound strategies that case managers can apply to manage the challenges associated with SDOH. Previously, data collected and related documentation compiled for SDOH purposes were used in several ways (eg, intake forms focused on perceived barriers, professionals' notes). Structure was generally lacking. A more structured approach, backed by digital tools

continues on page 34

Managing An Aging Workforce: Creativity and Flexibility Lead to More Opportunities

By Patty Nunez, MA, CRC, CDMS, CCM

Disability management professionals need to ensure that workplace programs and policies are aligned with the needs of workers at every age. Practices such as return-to-work and stay-at-work programs, especially accommodations and job reassignments, can keep highly valued, experienced employees in the workplace.

Several years ago, a long-time director in a medical management department needed to take a six-month leave of absence as he underwent treatment for a serious medical condition. This left a gap at the leadership level, which the employer could have filled by reassigning tasks to two other directors. Instead, the employer decided to expand the roles of three people to enhance their knowledge and advance their career development—while also preserving the position of a valued employee who was off work for medical treatment.

Two other directors on the team were offered the opportunity to switch roles during the six-month period. They eagerly agreed, and each began working in new positions. The third director role left vacant was offered to me on an interim basis. At the time, I was a manager on the case management team and accepted this director role opportunity to expand my knowledge and experience.

Six months later, the director returned to work and resumed his role in a well-run department. I went back to my regular job but with expanded knowledge and new expertise that led me to be promoted into another directorship role within a month. As for the other two directors, their jobs were redefined to reflect their expanded skill sets. Everyone benefited.

This is an example of what can happen when an employer is creative and farsighted in managing absences by creating new opportunities. Equally important, it offers insights into the importance of flexibility to accommodate the needs of highly valued, experienced employees who face illness or injury. This issue is particularly timely as the population ages.

What to Consider as the Workforce Ages

Employers today are facing greater challenges in supporting employees who may be near or beyond traditional retirement age but want to keep working. According to Pew Research, 20% of Americans 65 and older are employed, about double the number from 35 years ago. An aging workforce will increase the prevalence of conditions and disabilities, as almost 95% of adults aged 60 or older have at least one chronic health condition, and 78.7% of those adults have two or more conditions.

As people live longer and stay in the workforce for an extended time, it is inevitable that more mature workers will face conditions that require some type of accommodation. For example, cancer affects more people as they age. This calls for advocacy on employees' behalf, in our roles as Certified Case Managers (CCM) and Certified Disability Management Specialists (CDMS).

Case managers have a central role in ensuring that proper accommodations are given to people in all scenarios. Accommodation should be included in the care plan, as the person transitions from treatment to recuperation and return to work (provided that is the individual's goal).

Disability management professionals need to ensure that workplace

continues on page 34

Patty Nunez, MA, CRC, CDMS, CCM, *is the incoming chair (2024-2025) of the Commission for Case Manager Certification (CCMC), the first and largest nationally accredited organization that certifies more than 50,000 professional case managers and disability management specialists. The Commission oversees the process of case manager certification with its CCM® credential and disability management specialist certification with its CDMS® credential. Patty recently retired as a director within the Claim Vendor Management office of CAN.*

You Are Invited: The Commission's Role & Function Study

By MaryBeth Kurland, MPA, CAE, ICE-CCP

Every five years, the Commission for Case Manager Certification conducts a Role & Function Study, the Commission's most comprehensive and rigorous field research. And it starts with you—the case manager.

A job task analysis survey is being distributed to an extensive list of case management professionals, with questions that examine the work performed by case managers, as well as the knowledge and skills needed to perform this work. Case managers are also asked questions about their backgrounds and where they practice, along with other related queries.

The response period begins June 3 and lasts until June 21. The Commission is asking all case managers, both professional and board-certified, to take the time to complete it. The more case managers who respond, the more robust the data gathered in this field research.

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

A job task analysis survey is being distributed to an extensive list of case management professionals, with questions that examine the work performed by case managers, as well as the knowledge and skills needed to perform this work.

Results from the Role & Function Study form the basis of the Board-Certified Case Manager (CCM®) examination and help ensure that what is covered on the certification examination relates directly back to current professional practice. Analysis of survey results helps determine the most important knowledge areas and job tasks in case management practice, as well as the selection and weight of the knowledge tested on the certification exam.

In addition to the case management survey, the Role & Function Study also involves the collaboration of researchers, subject matter experts, test developers, and psychometricians. (Read more about the Role & Function process, in a blog about our 2019 study.)

Please help the Commission conduct a robust and accurate Role & Function Study by participating in the field survey. Invitations will be sent via email, or you may access the survey through social media posts and the Commission's website. The time you take to answer the questions is a direct investment in the value and recognition of the CCM credential, case management practice, and ultimately your own professionalism. CM

Networking and the Benefits of LinkedIn

By Marianne DiMola

The definition of networking is "the action or process of interacting with others to exchange information and develop professional or social contacts; the skills of networking…."

Unfortunately, networking is not something everybody likes to do. Well, if you don't like walking into a room, introducing yourself, and shaking hands, let me introduce you to LinkedIn—the largest professional networking platform available today.

Why is networking important? Having connections—people you can reach out to when you need information, additional resources to help with something that is critical, and network outside your own company—is beneficial. If we continue to network just within our own business, our information is always limited. If you happen to be looking for a job, networking outside your company is even more important.

I see LinkedIn as the largest networking room available, and it's open 24/7. That means whenever you are interested or available in networking, LinkedIn is there, and everyone has a name tag on. Not only that, but they also have additional information, so if you want to connect with that person, you may have worked at the same company in the past or gone to the same school or have a similar volunteer interest. There are so many different ways to look at a commonality and ask for someone to connect with you. That said, are you on LinkedIn? Are you present? Is your profile the best it can be? If not, read on.

Having connections—people you can reach out to when you need information, additional resources to help with something that is critical, and network outside your own company—is beneficial.

Your profile should have a header and a profile picture. Some people are camera shy, so if that's the case, you don't have to put a picture up of you, but make sure you have something up there—a picture of a pet or something related to the medical field or case management. The header can be your company logo, or you can even type in "case manager" and then hit on images and you'll find so many different things that you can use. You can also use a part of case management that excites you. You can look up images showing passion, utilization, discharge planning, health equity, and more. By doing this, you automatically create a warmer profile. A profile that says I'm in the room, I am present, and I want to connect.

The "About" section should be about your professional experience, expertise, and if you like you can add your professional passion. It is okay for this section to speak a little more about yourself within your profession. You can also put in what you hope your next career step will be or overall career goals. This is also a great space to add any organization you are involved with, publications you have written, or presentations you have done.

Remember to add your education, certifications, publications, and volunteer roles you have in the designated areas.

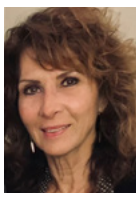
Ask for recommendations! Displaying public acknowledgement for your expertise gives you a boost! Give recommendations! Giving a recommendation is the best "thank you" you can offer!

Trying to get a job? Then share your expertise, make comments on posts about case management, reshare with your thoughts. Trying to create professional branding? Post a few times a week, add your thought to other posts. Thank people for sharing your post.

If you belong to an organization, follow the organization. Reshare their posts, like them, make comments. It's a wonderful way to let others know what your affiliations are and to get others to join you.

Thanks for taking the time to read this Insights column. I hope it was helpful. If so, please connect with me on LinkedIn and let me know. Happy networking! CM

Marianne DiMola *is president of Global Care Management and a subject matter expert in case management, utilization, quality, and appeals and denials.*



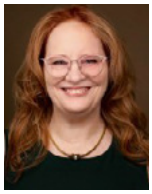
The Future of Health Care Powered by Case Management

By Dr. Colleen Morley-Grabowski, DNP ,RN, CCM, CMAC, CMCN, CMGT-BC, ACM, RN, IQCI, FCM, FAACM

The title of this article was the theme of the recently completed CMSA National Conference in Providence, RI, on June 4–7, 2024. It's an interesting concept and one that we, as case managers, should be embracing. We are, after all (among other hats), the communication hub, the patient advocate, the coordinators of care along the continuum, and the masters of the social determinants of health well before it became a "buzzword."

In the ever-evolving landscape of health care, one thing remains constant: the central focus on providing optimal care for patients. As the complexities of health care systems continue to grow, the role of professional case management emerges as a vital force driving the future of health care. Let's look at the multifaceted realm of case management, exploring its evolution, integration with technology, impact on patient-centered care, coordination across the continuum of care, and cost-efficiency, as well as the role of education and empowerment in shaping the future of health care.

Dr. Colleen Morley-Grabowski, DNP ,RN, CCM, CMAC, CMCN, CMGT-BC, ACM, RN, IQCI, FCM, FAACM



By tailoring health care services to individual patient needs, preferences, and values, case managers foster a collaborative and personalized approach to care.

Case management has undergone a remarkable evolution from its early days as a service coordination tool to its status as a comprehensive approach to health care delivery. Originally developed to ensure that patients received appropriate services and resources (circa 1830), case management has evolved into a dynamic process encompassing assessment, planning, coordination, implementation, and evaluation of health care services. Today, professional case managers work collaboratively with patients, families, health care providers, and community resources to address the holistic needs of individuals across various health care settings.

The future of health care is intricately linked to technological advancements, and case management is no exception. The integration of electronic health records (EHRs), telehealth platforms, data analytics, and artificial intelligence (AI) into case management processes holds immense potential for improving health care outcomes. EHRs facilitate seamless information sharing among health care providers, enabling case managers to access comprehensive patient data in real time. Telehealth platforms expand access to care, particularly in remote or underserved areas, whereas data analytics and AI offer insights into population health trends, enable predictive modeling, and help to create individual personalized treatment recommendations.

At the heart of modern health care lies the concept of patient-centered care, and case management plays a pivotal role in its implementation. By tailoring health care services to individual patient needs, preferences, and values, case managers foster a collaborative and personalized approach to care. This means actively involving patients in decision-making, respecting their autonomy, and addressing their physical, emotional, social, and spiritual needs. Patient-centered case management not only improves patient satisfaction but also enhances treatment adherence, reduces health care disparities, and ultimately leads to better health outcomes.

Health care delivery is no longer confined to the walls of a hospital; instead, it spans a continuum of care that encompasses primary care, specialty services, postacute care, and community-based resources. Case managers serve as navigators, facilitating smooth transitions between different health care settings and ensuring continuity of care. This involves coordinating appointments, facilitating communication among health care providers, addressing barriers to care, and providing support during care transitions. By promoting

continues on page 35

CE1 Approved for 1 hour of CCM, CDMS, and nursing education ethics credit
Exam expires on December 17, 2024
CCM PACE™ Pre-Approved Continuing Education

Beyond Words: Navigating Pain in Dementia

By John V. Rider, PhD, MS, OTR/L, MSCS, ATP, and Jessica Elyza M. Galilo, OTD-S

The World Health Organization (WHO 2023) has reported that more than 55 million people worldwide live with dementia, with nearly 10 million new cases each year. As life expectancy continues to increase, so will the prevalence of more age-related disorders that negatively impact cognition and language, such as dementia. Dementia is not a specific disease; it comprises a multifactorial process associated with cognitive decline and impaired functioning (Cipriani et al., 2020). More specifically, dementia is characterized by a decline in memory, language, problem-solving, communication, and other areas of cognition that affect an individual's ability to perform everyday activities and social functioning, requiring assistance from care partners (Cipriani et al., 2020). While dementia affects each person differently, depending on the underlying cause and comorbid health conditions, a significant concern among individuals living with dementia is pain.

A Deeper Understanding of Pain

According to the International Association for the Study of Pain (IASP; Raja et al., 2020), pain is defined as a sensory and emotional experience characterized as "unpleasant" and can be associated with actual or potential tissue damage. The perception of pain is influenced by biological, psychological, and social factors, making it a deeply personal experience (Raja et al., 2020). There are predominately three types of pain: nociceptive, neuropathic, and nociplastic pain. Nociceptive pain is associated with nociceptors, or sensory endings on nerves, with a protective purpose of providing a warning system following tissue injury or potential damage (IASP, n.d.). Neuropathic pain occurs with injury or disease of nerve tissue (eg, shingles, diabetic neuropathy) (IASP, n.d.). Medication to treat this type of pain aims to reduce nerve excitability, decreasing one's subjective pain experience. Pain under this category can feel like pins and needles, electric shocks, numbness, hypersensitivity, and hot or cold sensations. Nociplastic pain, often the least understood type of pain, reflects changes in how the nervous and immune systems function, as pain results from altered nociception, even in the absence of tissue damage and nerve disease or lesions (IASP, n.d.). This type of pain is associated with chronic conditions such as fibromyalgia or chronic low back pain. This specific type of pain may especially benefit from nonpharmacological interventions, such as lifestyle changes and psychosocial strategies, in addition to the use of medications. A deeper understanding of the types of pain can improve appropriate assessment and treatment approaches, including consistent documentation between the interprofessional team. This article aims to review the prevalence and impact of pain among individuals with dementia, highlighting assessment methods and advocating for improved recognition and management across health care settings.

Prevalence and Impact of Pain in Dementia

Unfortunately, pain is prevalent, difficult to assess, and has significant detrimental consequences on functional independence and quality of life for individuals living with dementia (Achterberg et al., 2020). Evidence suggests that more than half of individuals with dementia experience daily pain (Barry et al., 2016), and around 60%–80% of residents in nursing homes with dementia regularly experience pain (Corbett et al., 2012; Williams et al., 2005), demonstrating the importance of pain recognition among this population. While not all clients experiencing pain have persistent or chronic pain, those who do are more likely to have an accelerated decline in memory, leading to increased care partner assistance (Rajkumar et al., 2017). Evidence also suggests that patients with more severe dementia experience more pain than those with less severe dementia (van Kooten et al., 2017). Furthermore, the impact of pain extends beyond the individual living with pain to the quality of life of care partners and the need for additional health care services.

John V. Rider, PhD, MS, OTR/L, MSCS, is associate professor, School of Occupational Therapy, College of Health and Human Services at Touro University, Nevada, an occupational therapist, home safety specialist, and a medical expert for litigation.

Jessica Elyza M. Galilo, BA, OTD-S, is an occupational therapy doctoral student at Touro University Nevada interested in supporting older adults living with chronic pain and chronic diseases to maximize their functional independence and quality of life.

Unfortunately, pain is prevalent, difficult to assess, and has significant detrimental consequences on functional independence and quality of life for individuals living with dementia.

Evidence suggests that pain left untreated can result in limited mobility, increased physiologic stress, and increased behavioral and psychological symptoms (eg, agitation, aggression) that can lead to a higher risk of mortality, institutionalization, and/or prescriptions of unnecessary medications (Herr et al., 2011; Lichtner et al., 2014). Additional downstream consequences include psychological risks, such as depression, poorer quality of life, sleep disturbances, diminished social participation, further cognitive decline, and increased health care and utilization costs (Herr et al., 2006). All interprofessional team members must be aware of how significant pain is among this population and ensure that pain levels are assessed and addressed across all health care settings. The interprofessional team can include physicians, physician assistants, nurse practitioners, nurses, rehabilitation therapists (occupational, physical, and speech-language pathologists), case managers, social workers, family members, care partners, support staff, and most importantly, the client. Communication and collaboration within the interprofessional team will facilitate the best client outcomes. Case managers can play a prominent role by advocating for appropriate pain assessment and management throughout the continuum of care.

Recognition of Pain in Dementia

Although most health care clinicians and case managers recognize that pain has severe consequences on function and quality of life, it is still commonly overlooked among individuals with dementia or cognitive impairments. Studies indicate that pain is inadequately treated in patients with cognitive impairments (Achterberg et al., 2019; Lukas et al., 2012). Individuals with dementia (now commonly referred to as major neurocognitive disorders in the 5th edition of the *Diagnostic and Statistical Manual of Mental Disorders, DSM-5*) and cognitive impairments are at a high risk of untreated pain because their ability to recognize, evaluate, and verbally communicate their pain gradually decreases throughout the progression of their disease (Gibson & Lautenbacher, 2017; Hadjistavropoulos et al., 2014; IASP, 2021). Because individuals with cognitive impairment report pain less often, less spontaneously, and at a lower intensity than those without cognitive impairment, their pain is more commonly underdetected and undertreated (Zwakhalen et al., 2006). Verbal expression of pain is the most common way of expressing self-reported pain; however, the more severe the dementia and subsequent cognitive impairment, the less capable the individuals are of verbally expressing their pain sensation (Williams et al., 2005). Because individuals with dementia may not be able to express their pain accurately through verbal methods, multiple assessment approaches based on the stage of dementia and severity of cognitive impairment should be used to evaluate pain to ensure accurate detection.

Challenges in Pain Assessment

It is important to remember that pain is always a personal experience, and therefore, the gold standard of pain assessment is self-reporting. Pain self-reports can be provided in standardized (ie, standardized and validated pain assessment tool or questionnaire) or unstandardized forms (ie, client description of their pain experience). Pain questionnaires can take anywhere from a few minutes to 15 minutes, depending on the length of the questionnaire and the client's cognitive abilities. These can be administered verbally by the clinician or filled out by the client. However, for individuals living with dementia, as cognitive and language abilities decline, an observer tool should also be used along with self-report questionnaires when individuals may not be able to express their pain to clinicians fully, and self-reporting, or the lack thereof, may be unreliable. For example, individuals with significant cognitive or language impairments may be experiencing pain but be unable to express it to their health care providers or care partners. Routine neuropsychological screening of cognitive status should be performed by occupational therapists, speech-language pathologists, or neuropsychologists to identify when self-reporting may be unreliable. Case managers and interprofessional team members should review cognitive assessment results and request an updated cognitive evaluation when cognitive changes are observed, or cognitive status is unknown. Observing and documenting pain behaviors is one way to identify when clients may be experiencing pain and ensure clinicians initiate appropriate pain management. Clinicians commonly use the following list of behavioral pain indicators as a guide when working with and observing individuals with limited ability to self-report

While it is often easy to estimate the time required to complete a standardized self-report questionnaire based on the number of questions, it is more difficult to identify how long a pain assessment may require for someone with dementia and limited communication.

pain. The interprofessional team should document these behavioral pain indicators to ensure pain is recognized and appropriately managed. For example, an individual who begins resisting care, withdrawing, demonstrating guarded movements, and grunting may be experiencing pain, especially when these behaviors are not typical for them, and these behaviors should be documented in their medical record and discussed with their care team.

Behavioral Pain Indicators*

Facial expressions (eg, frowning, grimacing, wrinkling the forehead, rapid blinking, tightly closed eyes)

- Verbalizations or vocalizations (eg, moaning, sighing, groaning, grunting, chanting, calling out, noisy breathing, asking for help)
- Body movements (rigid or tense posture, guarding, fidgeting, pacing, rocking, restricting movement, gait, balance, or mobility changes)
- Changes in interpersonal interactions (eg, aggression, combativeness, resisting care, decreasing social interactions, inappropriate social interactions, disruptive behavior, withdrawing, verbally abusing others
- Changes in activity patterns or routines (eg, refusing food, appetite changes, increasing rest periods, changing sleep patterns, sudden cessation of everyday routines, increased wandering)
- Mental status changes (eg, crying, increased confusion, irritability, distress, changes in attentiveness)
- Physiological changes (eg, heart rate, blood pressure, sweating)

**Adapted from the AGS Panel on Persistent Pain in Older Persons* (2002)

Collaboration and Communication in Pain Assessment

Reports of pain should always be taken seriously, even among those with cognitive impairments. For example, further evaluation is necessary when an individual living with dementia reports pain despite demonstrating overt behavioral pain indicators. Further evaluation is also necessary when an individual demonstrates behavioral pain indicators but may not verbally report pain. Pain expression can take the form of overt behavioral pain indicators and less obvious forms, such as subtle behavioral changes. Some forms of dementia result in muted facial expressions and quiet or withdrawn behavior, making it more challenging to interpret typical behavioral pain indicators (Herr et al., 2006). Collaboration with those familiar with the individual is essential to understand baseline behaviors and usual routines. Information from care partners, staff, roommates, and the interprofessional team can aid in recognizing small and large behavioral changes that may indicate a new onset of pain. Consistent communication and an understanding of the role of each interprofessional team member will facilitate the best client outcomes across the continuum of care.

Evaluations and observations for pain behaviors should be done during functional activities, such as when the individual is transferring, ambulating, repositioning in bed or a chair, or completing self-care, and when at rest, for a comprehensive clinical picture of their pain experience and how it might impact and be impacted by daily activities or change throughout the day. For individuals receiving therapy, rehabilitation clinicians, such as occupational and physical therapists, are often the health care clinicians who observe individuals with dementia during functional activities and may be the first to notice pain behavior indicators. Rehabilitation clinicians can provide helpful insight into the individual's pain experience. Identifying whether the client is in the early, middle, or late stages of dementia will allow the interprofessional team to determine the most appropriate assessment tools and tailor the care plan and pain management interventions to best suit each individual's needs. Emphasizing person and family-centered care allows the family and client to be active members in their care.

While it is often easy to estimate the time required to complete a standardized self-report questionnaire based on the number of questions, it is more difficult to identify how long a pain assessment may require for someone with dementia and limited communication. In the middle and late stages of dementia, pain assessment involves a medical chart review, conversations with individuals who interact with the client regularly, and observations for pain behaviors in a variety of activities, from low to high levels of functional activities specific to the client. This may require 15 to 60 minutes to obtain a comprehensive clinical picture. However, the more

Behavioral pain indicators can include facial expressions conveying discomfort, verbalizations or vocalizations, tense body movements, interpersonal interaction changes, activity patterns or routine changes, mental status changes, and physiological changes, such as elevated blood pressure or sweating.

information available about the client and their pain behaviors, the better the understanding of their pain experience. If the individual receives any form of rehabilitation, the pain assessment can be done during therapy, as the client will already be engaging in functional activities and demonstrating various movements. Additionally, staff and other health care professionals can observe for pain behaviors when interacting with the client, allowing pain assessment to occur more often. It can be helpful to have those working with the client most often keep a record of pain behavior indicators for review by the interprofessional team. Gathering information about the client from as many sources as possible can help clinicians understand the frequency and intensity of the client's pain and what may increase or decrease it.

Assessing Pain in the Early Stages of Dementia

During the early stages of dementia, it may be suitable for individuals with sufficient cognitive and communication skills to express pain verbally or visually. However, health care clinicians should also be attentive to behavioral pain indicators whenever working with an individual living with dementia. To ensure a thorough understanding and accurate documentation of pain, clinicians should use simple pain scales that offer verbal and visual content, speak clearly and repeat questions and instructions as necessary, allow for an extended time for responses, use an individualized approach based on the client's specific neuropsychological deficits, ask the client to describe their pain, and recognize the impact of the environment and try to reduce distractions when assessing pain. For example, eliminating unnecessary external stimuli can improve communication if a client is easily distracted. Pain assessments should gather information about pain sensations, and the impact pain has on the individual's life, including what has been helpful with past pain management. Care partners, family members, and staff should be educated on behavioral pain indicators in the early stages of dementia to maximize the quality of life for these individuals through early pain recognition and intervention.

Assessing Pain in the Middle and Late Stages of Dementia

As dementia progresses, self-reported pain may not be feasible. Therefore, observable behavioral pain indicators should be the primary means of identifying pain (Achterberg et al., 2019). Behavioral pain indicators can include facial expressions conveying discomfort, verbalizations or vocalizations, tense body movements, interpersonal interaction changes, activity patterns or routines, mental status changes, and physiological changes, such as elevated blood pressure or sweating. In the later stages of dementia, the interprofessional team must obtain a history from family members and care partners to help recognize altered behavior that may be in response to pain. Among behavioral pain indicators, three domains have been widely accepted as mirroring pain-related states when using observer rating scales and should be documented and reported to the entire team (Achterberg et al., 2019). These domains include facial responses, such as frowning or grimacing; vocalizations, including loud or repetitive verbal utterances; and body movement or body posture, such as trying to reposition constantly, rubbing a specific area, or holding a body part tightly. The onset of any such behavior suggests the presence of pain. Health care clinicians should also pay attention to what may provoke the behavior. For example, did the individual demonstrate behavioral pain indicators when moving from seated to standing? Did it occur when trying to swallow, when they had to move their arm, or when someone touched them? Identifying potential causes of pain can help to prevent future injury and improve pain management approaches.

While most health care clinicians use client self-reporting, numerical rating scales, and observed behavioral pain indicators, there are standardized pain assessments designed for individuals with impaired cognition or dementia. Many of these assessments are available online and free to use. However, when considering their clinical utility, it is worth noting that most of them utilize known behavioral pain indicators, such as those listed earlier in this article. Many assessments include standardized behavioral pain indicators that allow clinicians to measure the frequency and intensity of behaviors and track them over time using checklists, Likert scales, and various ways of scoring the behaviors. They can be very helpful as they ensure that the clinician does not overlook any behaviors that may indicate the individual is experiencing pain. While there is not one assessment that is considered the best for individuals experiencing a

neurocognitive disorder, many of them can be helpful and advocate for improved practices in identifying and treating pain among individuals with dementia. The selection of standardized assessments should be based on the client's situation and the clinician's clinical reasoning. While there are many standardized pain assessments, the following assessments are designed for individuals with impaired cognition or dementia, available online, and free to use: Abbey Pain Scale (APS), Checklist of Nonverbal Pain Indicators (CNPI), Critical Care Pain Observation Tool (CPOT), Disability Distress Assessment Tool (Dis DAT), Discomfort Scale for Dementia of the Alzheimer's Type (DS-DAT), and the Pain Assessment in Advanced Dementia Scale (PAINAD).

Links to pain assessments:

Abbey Pain Scale: https://www.apsoc.org.au/PDF/Publications/APS_Pain-in-RACF-2_Abbey_Pain_Scale.pdf

Checklist of Nonverbal Pain Indicators: https://health.maryland.gov/ohcq/AMDC/docs/Checklist%20of%20Nonverbal%20Pain%20Indicators(CNPI)-2012.pdf

Critical Care Pain Observation Tool: https://blog.summit-education.com/wp-content/uploads/CPOT.pdf

Disability Distress Assessment Tool: http://www.wamhinpc.org.uk/sites/default/files/Dis%20DAT_Tool.pdf

Discomfort Scale for Dementia of the Alzheimer's Type: https://www.hhs.texas.gov/sites/default/files/documents/doing-business-with-hhs/provider-portal/QMP/dementiapainscale.pdf

Pain Assessment in Advanced Dementia Scale: https://pami.emergency.med.jax.ufl.edu/wordpress/files/2019/10/Pain-Assessment-in-Advanced-Dementia.pdf

Multidimensional Pain Assessment

Pain has been referred to as the "fifth vital sign," originally intended to elevate awareness of pain treatment among health care clinicians. However, pain screening is often reduced to a quick, unidimensional numerical rating (eg, "On a scale from 0-10, how would you rate your pain?") with little impact on the care plan. Significant evidence has demonstrated that measuring pain intensity using unidimensional tools has not improved pain outcomes, despite a push to assess pain in all clinical encounters (Scher et al., 2018). Instead, whenever possible, the interprofessional team should utilize multidimensional pain assessments to comprehensively measure all aspects of the pain experience, such as the psychosocial impact of pain and the effect it has on daily functioning to establish realistic goals aligned with the client's needs (Arnstein & Herr, 2017). Many multidimensional assessments cover the biopsychosocial aspects of the pain experience and can be used when self-reporting is feasible, such as in the early stages of dementia. However, for individuals with dementia in the later stages, multidimensional assessments include standardized and nonstandardized assessments, including skilled observations. Documentation from the interprofessional team should also include the client's response to their current care plan and provide justification for why they can benefit from continued care, recommended interventions, and plans for discharge or alternate placement. Ensuring that pain is always assessed beyond a unidimensional numerical rating scale and documented in the medical record allows other clinicians and insurance companies to obtain a clearer picture that will allow case managers to connect people to the health care and community services they need. Being aware of community resources and providers specializing in pain management services for individuals with cognitive and communication impairments can help case managers make appropriate referrals and provide clients and care partners with supportive resources. By asking appropriate questions and requesting pain assessments and updated documentation, case managers can advocate for individuals who may not have a voice to express the pain they are experiencing or request the help they need.

Conclusion

As case managers, it is imperative to recognize the significant impact of pain on individuals living with dementia. The prevalence of pain in this population and its assessment and management challenges underscore the importance of an interprofessional approach. Collaborating with interprofessional teams, advocating for appropriate pain assessment tools, and ensuring comprehensive pain management strategies are integral to improving the quality of life for individuals with dementia. By prioritizing thorough pain assessment and effective management, case managers play a vital role in promoting holistic care and enhancing the well-being of their clients living with dementia who may be experiencing pain yet unable to voice their concerns. CE1

Collaborating with interprofessional teams, advocating for appropriate pain assessment tools, and ensuring comprehensive pain management strategies are integral to improving the quality of life for individuals with dementia.

References

Achterberg, W., Lautenbacher, S., Husebo, B., Erdal, A., & Herr, K. (2019). Pain in dementia. *Pain Reports, 5(*1), e803. https://doi.org/10.1097/pr9.0000000000000803

AGS Panel on Persistent Pain in Older Persons. (2002). The management of persistent pain in older persons. *Journal of the American Geriatrics Society*, *50*(Suppl. 6), 205-224. https://doi.org/10.1046/j.1532-5415.50.6s.1.x

Arnstein, P., Herr, K. A., & Butcher, H. K. (2017). Evidence-based practice guideline: Persistent pain management in older adults. *Journal of Gerontological Nursing*, *43*(7), 20–31. https://doi.org/10.3928/00989134-20170419-01

Barry, H. E., Parsons C., Passmore A. P., & Hughes, C. M. (2016). Exploring the prevalence of and factors associated with pain: A cross-sectional study of community-dwelling people with dementia. *Health & Social Care in the Community*, 24(3), 270-282. https://doi.org/10.1111/hsc.12204

Cipriani, G., Danti, S., Picchi, L., Nuti, A., & Fiorino, M. D. (2020). Daily functioning and dementia. *Dementia & Neuropsychologia*, *14*(2), 93–102. https://doi.org/10.1590/1980-57642020dn14-020001

Corbett, A., Husebo, B., Malcangio M., Staniland, A., Cohen-Mansfield., J., Aarsland, D., & Ballard, C. (2012). Assessment and treatment of pain in people with dementia. *Nature Reviews Neurology, 8*(5), 264-274. https://doi.org/10.1038/nrneurol.2012.53

Gibson, S. J., & Lautenbacher S. (2017). Pain perception and report in persons with dementia. In: Lautenbacher, S. , & Gibson, S. J. (Eds.), *Pain in dementia*. (pp. 43-54). Wolters Kluwer and IASP Press.

Hadjistavropoulos, T., Herr, K., Prkachin, K. M., Craig, K. D., Gibson, S. J., Lukas, A., & Smith, J. H. (2014). Pain assessment in elderly adults with dementia. *The Lancet Neurology, 13*(12), 1216-1227. https://doi.org/10.1016/s1474-4422(14)70103-6

Herr, K., Bjoro, K., & Decker, S. (2006). Tools for assessment of pain in nonverbal older adults with dementia: A state-of-the-science review. *Journal of Pain and Symptom Management, 31*(2), 170-192. https://doi.org/10.1016/j.jpainsymman.2005.07.001

Herr, K., Coyne., P. J., McCaffery, M., Manworren, R., & Merkel, S. (2011). Pain assessment in the patient unable to self-report: Position statement with clinical practice recommendations. *Pain Management Nursing, 12*(4), 230-250. https://doi.org/10.1016/j.pmn.2011.10.002

International Association for the Study of Pain. (n.d.). *Terminology. https://www.iasp-pain.org/resources/terminology/*

International Association for the Study of Pain. (2021). *Pain Assessment in Dementia* [Fact sheet]. https://www.iasp-pain.org/resources/fact-sheets/pain-assessment-in-dementia/

Lichtner, V., Dowding, D., Esterhuizen, P., Closs, S. J., Long, A. F., Corbett, A., & Briggs, M. (2014). Pain assessment for people with dementia: A systematic review of systematic revies of pain assessment tools. *BMC Geriatrics, 14*(138). https://doi.org/10.1186/1471-2318-14-138

Lukas, A., Schuler, M., Fischer, T. W., Gibson, S. J., Savvas, S. M., Nikolaus, T., & Denkinger, M. (2012). Pain and dementia: A diagnostic challenge. *Zeitschrift fur Gerontologie und Geriatrie, 45*(1), 45-49. https://doi.org/10.1007/s00391-011-0272-4

Raja, S. N., Carr, D. B., Cohen, M., Finnerup, N. B., Flor, H., Gibson, S., … Vader, K. (2020). The revised IASP definition of pain: Concepts, challenges, and compromises. *Pain, 161*(9), 1976-1982. https://doi.org/10.1097%2Fj.pain.0000000000001939

Rajkumar, A. P., Ballard, C., Fossey, J., Orrell, M., Moniz-Cook, E., Woods, R. T., … Corbett, A. (2017). Epidemiology of pain in people with dementia living in care homes: Longitudinal course, prevalence, and treatment implications. *Journal of the American Medical Directors Association, 18*(5), 453.e1-453.e6. https://doi.org/10.1016/j.jamda.2017.01.024

Scher, C., Meador, L., Van Cleave, J. H., & Reid, M. C. (2018). Moving beyond pain as the fifth vital sign and patient satisfaction scores to improve pain care in the 21st century. *Pain management nursing : official journal of the American Society of Pain Management Nurses*, *19*(2), 125–129. https://doi.org/10.1016/j.pmn.2017.10.010

van Kooten, J., Smalbrugge, M., van der Wouden, J. C., Stek, M. L., & Hertogh, C. M. P. M. (2017). Evaluation of a pain assessment procedure in long-term care residents with pain and dementia. *Journal of Pain and Symptom Management, 54*(5), 727-731. https://doi.org/10.1016/j.jpainsymman.2017.07.020

Williams, C. S., Zimmerman, S., Sloane, P. D., & Reed, P. S. (2005). Characteristics associated with pain in long-term care residents with dementia. *The Gerontologist, 45*(Suppl. 1), 68-73. https://doi.org/10.1093/geront/45.suppl_1.68

World Health Organization (2023). *Dementia* [Fact sheet]. https://www.who.int/news-room/fact-sheets/detail/dementia

Zwakhalen, S. M., Hamers, J. P., Abu-Saad, H. H., & Berger, M. P. (2006). Pain in elderly people with severe dementia: A systematic review of behavioural pain assessment tools. *BMC Geriatrics, 6(*3). https://doi.org/10.1186/1471-2318-6-3

CE2 Approved for 1 hour of CCM, CDMS, and nursing education credit
Exam expires on December 17, 2024

Loneliness is Deadly

By Judith R. Sands, RN, MSL, BSN, CPHRM, ARM, CCM, CPHQ

The US Surgeon General's (OSG's) 2023 Advisory *Our Epidemic of Loneliness and Isolation* validated what many health care professionals suspected. This groundbreaking report quantified the very significant negative health and well-being outcomes for those with limited social connections. The lack of social connections and interactions with other individuals increases the risk of premature death as much as smoking 15 cigarettes a day (OSG 2023). The impact of poor or insufficient social connections has been noted to have "a 29% increased rate of heart disease and a 32% increased risk of stroke" (OSG 2023, p. 8). "Chronic loneliness and social isolation can increase the risk of developing dementia by approximately 50% in older adults, even after controlling for demographics and health status" (OSG 2023, p. 28). "Social isolation and loneliness are related, but they are not the same. Social isolation is objectively having few social relationships, social roles, group memberships, and infrequent social interaction. On the other hand, loneliness is a subjective internal state. It's the distressing experience that results from perceived isolation or unmet need between an individual's preferred and actual experience" (OSG 2023, p. 8). You don't have to be alone to feel lonely. The American Psychological Association (APA) defines loneliness as the "affective and cognitive discomfort or uneasiness from being or perceiving oneself to be alone or otherwise solitary" (APA 2018, 04, 19). Loneliness and social isolation, living alone, and the self-perception of being a burden to others have a very strong association with self-harm and suicide. "Loneliness and social isolation among children and adolescents increase the risk of depression and anxiety" (OSG 2023, p. 29). Given the significant physical systemic implications of insufficient social connections, the individual is at risk for increased levels of anxiety, depression, and dementia. The lack of social connections and a sense of not belonging negatively impact wellness. Loneliness is deadly!

The Importance of Social Connections

Social connections are dynamic. The number, quality, and type of social connections change during our lifespan. In adulthood, the social circle tends to dwindle because of illness of self or others, death of loved ones and friends, relocation, other life events, and changes in the community and society that impact one's ability to retain and make meaningful social connections. Competing demands between work, must-do appointments, and other obligations decrease the time available to nurture relationships. Some individuals have robust family and work/school social networks that keep them engaged. Others may have smaller family and work/school networks and they have little true engagement, belonging, or connection outside of the work/school setting.

The traditional community places of social engagement have become less important or accessible over time to Americans. Religious/faith-based groups, clubs, veterans' groups, and labor unions, which in the past were strong sources of social connection and belonging, have seen large declines in attendance (Office of the Surgeon General (OSG), 2023, p. 16). Households are smaller, there are more single households, and financial pressures are resulting in limiting the individual's ability to nurture social connections. Those who previously participated in volunteering or took part in in-person events may no longer be engaging in such activities and have not found new ways to maintain social connections and mentally stimulating activities.

In 1943, Maslow's hierarchy of needs noted the importance of love and belonging as being the third category of human needs, following physiological and safety needs. The importance of human connections/affiliations, love, and relationships are critical factors in human motivation and psychological importance. The significance of human connections cannot be underplayed, and the pandemic highlighted the adverse impact of physical isolation on individuals of varying ages.

Judith R. Sands, RN, MSL, BSN, CPHRM, ARM, CCM, CPHQ, *is an independent health care clinical consultant, educational content developer, and author. Judith is a nurse with a graduate degree in leadership with over 30 years of progressive leadership and consultative experience working in academia, hospitals, managed care, specialty networks, and health information technology organizations. She has presented at annual national professional and regional conferences and published* Home Hospice Navigation: The Caregiver's Guide *and numerous articles in the areas of case, risk, and quality management.*

The lack of social connections and interactions with other individuals increases the risk of premature death as much as smoking 15 cigarettes a day (OSG 2023).

True Connections

Social relationships are the basis of true connections between individuals. Often, they are based on shared values, interests, social relations, and religion. The common threads that result in dialogue and expression of ideas and thoughts. Typically, there is mutual respect, engagement, and acknowledgment of their value to the relationship between the individuals.

As individuals advance in age, it becomes harder to maintain and develop new relationships and friendships. It is a thoughtful, time-consuming process, and it has been "estimated that it takes between 40-60 hours together for an acquaintance to become a casual friend." Moving from casual friends to friends takes "an additional 140 to 160 hours together" (Ansberry, 2024). For those already suffering from isolation and loneliness, the expenditure of such a commitment of time is overwhelming, potentially furthering negative thoughts and anxiety.

Who Is Lonely?

The impact of loneliness can be viewed through the social determinant of health (SDOH) lens. The broad features of societal and environmental factors coupled with the individual's socioeconomic characteristics, physiological and psychological health, and safety status are all aspects impacting the individual's social engagement. Access to safe and permanent housing, threats of violence, reliable transportation, and overall health and mobility status are key influences in the individual's ability to feel comfortable leaving their residence to engage with others. Financial stability is a major barrier for some; if they must choose between purchasing their medication or eating, they are less likely to be able to or feel comfortable engaging with others.

Depending on the community, language and literacy may also be roadblocks to engagement. Other at-risk individuals include those from ethnic and racial minorities, LGBQT+, rural residents, victims of violence, especially victims of domestic violence, those with ties to the correctional health system and others experiencing discrimination and marginalization may also suffer from mental health issues, and substance use all further compounding the negative health impacts of social disconnection (Office of the Surgeon General (OSG), 2023, p. 19). Individuals with a history of mental health issues are especially vulnerable to isolation, loneliness, and depression. It is well-documented that depression is a silent killer. Given the nature of their condition, they are more reticent to engage with others and glean the benefits of physical activity.

Studies indicate the highest prevalence of loneliness and isolation is among those with poor physical or mental health, disabilities, financial insecurity, those living alone, single parents, and the younger and older populations (Office of the Surgeon General (OSG), 2023, p. 19). "Seniors" suffer the highest rates of social isolation. Yet, loneliness is experienced by individuals of all ages. "The rate of loneliness among young adults has increased every year between 1976 and 2019" (Office of the Surgeon General (OSG), 2023, p. 19).

The Surgeon General's Advisory noted multiple studies that indicated that about half of American adults felt less connected, more isolated, and lonely yet did not recognize it as a health issue (Office of the Surgeon General (OSG), 2023, p. 9). Yet, the highest level of prevalence is among those 18 to 24 years of age. Young people report feeling lonelier; the negative impacts of social media, especially bullying, are having devastating effects on the mental health and well-being of young Americans. Despite the phone being a tool for connection, it also reveals when someone is excluded or ostracized by their peers. Technology addictions result in individuals missing out on peer relationships that are vital for development and well-being. Nobody truly wants to be alone.

Determining Loneliness

Loneliness is subjective. Most individuals will not openly share that they have lost social connections. Social disconnection may occur gradually as a person's or spouse's health status changes or a spouse dies. Friends may relocate, become incapacitated, or die, and relationships end. Working alone and retirement are additional contributing factors to loneliness. This results in a decrease in the size of the individual's social circle. The individual's physical decline further compounds the sense of alienation and loneliness. Besides a decrease in mobility and balance issues, the loss of hearing is another key factor that impacts an individual's ability to stay connected and actively continue to participate in social

engagement. Too often individuals do not want to recognize that they are experiencing a decline in hearing. They may have no issues with wearing glasses or utilizing a mobility device, yet the topic of "hearing" may be taboo to them.

Hearing and Loneliness

Extensive data supports the importance of good hearing in warding off dementia and keeping individuals engaged. The ability to hear and comprehend conversation significantly impacts communication between individuals. Some seniors have purchased hearing aids at the demand of family members and friends who complained about communication challenges. Yet, the devices may go unused for a variety of reasons. Determine if the individual has hearing aids, how and when they are used, and if there are barriers (ie, ability to obtain batteries, devices needing adjustment or repair). The cost of a hearing test is covered by most insurance programs and should not be a deterrent. Yet, the cost of hearing aids is another matter. Some Medicare Advantage plans will cover the devices whereas traditional Medicare and insurance plans do not. The cost can reach $8,000 for a pair of hearing aids. The client needs to recognize that there is an adjustment period and extra visits to the audiologist will be needed. Many of the newer models can be adjusted for different types of background noise. Many venues provide the capability for individuals with hearing aids to connect to their audio system thus enhancing the acoustic experience. Hearing aids can be Bluetooth connected to smart TVs and closed captioning can be enabled to improve the individual's listening and comprehension experience.

The Role of Technology and Social Connections

The digital age has provided many advantages that earlier generations did not have. Smartphones, computers, laptops, tablets, and gaming devices provide a mechanism to communicate, research, entertain, and work. Despite these devices providing instant information and access, there is the downside of overengagement. It is the disconnection from direct human interactions and physical activities. Individuals with disabilities, lower incomes, and in rural communities may not have electronic devices or reliable access and support, contributing to further social disengagement. Cyberbullying, fear of technology, and privacy concerns are other factors that prevent them from taking advantage of what technology can offer them.

The downside of technology has resulted in individuals overengaging and connecting with their devices at the expense of direct communication with others. Face-to-face communication is the most important form of connection. Both parties can take visual and auditory cues in this form of communication. Micro-expressions provide insights into true feelings. The use of audiovisual applications is the next best thing to being there. There is still the opportunity to hear the change in voice inflection and the ability to glean some micro-expressions.

Electronic communication via email or text removes both the visual and audio cues from the interaction. Too often written communication does not adequately or accurately reflect what the writer is trying to convey. Miscommunications are more common for frequently utilizing these tools. For those who are already isolated, socially disconnected, and not adept at this form of messaging, this can lead to unintended communication consequences.

The phone is still a wonderful way for individuals to connect with others. It is a low-cost option, and although it lacks the visual component, it is a trusted mechanism of communication for seniors. A UK-based eight-week phone therapy study conducted during the pandemic revealed that phone therapy is a valuable tool to combat loneliness and depression, especially for seniors with multiple chronic conditions.

Impact of Premature Death

The impact of loneliness "results in a decline of well-being and has an adverse effect on physical health, possibly through immunologic impairment or neuroendocrine changes. Loneliness is thus, among the latent causes of hospitalization and of placement in nursing homes" (Tiwari, 2013, p. 320). The clinical studies all point to the fact that loneliness has been linked to the progression of numerous chronic illnesses, including dementia and Parkinson's disease.

Given that loneliness is a psychological predictor of health issues, cognitive decline, and early mortality, social disconnection is a critical public health concern. Finding a purpose can lower risk of loneliness in older adults. Substance misuse, self-harm, and suicide are other risks that contribute to premature death. Case managers are positioned to engage with clients and intervene to alter the course of the individual's loneliness journey and improve their life-sustaining social connections.

International Public Health Approaches

On February 12, 2021, the Prime Minister of Japan appointed a minister to address the "loneliness problem," which has been growing and compounded by the spread of COVID-19 along with the increasing rate of suicides. The UK appointed a designated loneliness minister in 2018 to address the issue of isolation within its senior population. Other at-risk groups being addressed are the youth and the unemployed. Both countries have agreed to collaborate and share findings with the global community (Joint message from the UK and Japanese Loneliness Ministers, 2021).

Besides a decrease in mobility and balance issues, the loss of hearing is another key factor that impacts an individual's ability to stay connected and actively continue to participate in social engagement.

Case Management Strategies to Positively Impact Clients' Health

The setting and roles of case managers differ, yet each one of us can positively impact those we work with. It is important to recognize that loneliness and social isolation impact clients of every age and demographic. Poor and insufficient social connections compound chronic medical and psychological conditions and contribute to significant long-term health issues. Design strategies internally and with other disciplines and public health influencers to overcome loneliness to improve public health.

Clients need to be reminded that they are not the only ones experiencing loneliness, and there is help available! Social connections heal and are life-sustaining. Work your case management magic to positively impact clients' outcomes. Loneliness, social isolation, and disconnection are serious public health issues for individuals of all ages, and case managers can make a difference to a client's outcome.

- Explore if/how the issue of social isolation is addressed for the clients served. Is this a component of the biopsychosocial assessment along with alcohol and substance misuse?
- Provide resources that connect the individual with appropriate engagement.
  - For seniors: Suggest senior daycare or activity centers, clubs, adult education/enrichment programs (often offered through the County educational system or community college/universities).
  - For youth: Suggest clubs, sports programs, youth groups, scouts, Boys & Girls clubs, county recreational centers.
- Listen closely for the verbiage expressed by lonely clients; it may include the sentiments of "I am isolated, invisible, insignificant; no one will know if I am not here tomorrow" indicating that they are socially disconnected or lack social connections.
- Determine if the individual has thoughts of self-harm or suicide or would benefit from therapy or medication. Discuss status with the provider and consider a mental health referral. Reinforce that they are important members of the community, they are valued, and they would be missed.
- Cultivate a culture of connection by regularly practicing the values of kindness and respect.
- Employ a comprehensive case management assessment that utilizes open-ended questions—relating to the social determinants of health and thoroughly explores the client's social connections and engagement.
- Ask the client to name the individuals with whom they have a connection, and explore the status of the relationship. Consider if the other party is truly in contact with the client and if they can address the loneliness experienced by the client.
- Determine if the client has an individual to escort them home and check on them. Consider if the individual has someone to check on them in person.
- Work with the client on acknowledging that they are not as social as they used to be. Explore what they view as something that is "meaningful" that they might want to engage in. What will bring you joy? Then explore a way to connect.
- Encourage the client to adopt a routine.
- Suggest pet watching, volunteering at an animal shelter, or exploring getting a pet—potential source of exercise and a mechanism to focus on something beyond themselves
- Encourage volunteering within the scope of their abilities. Helping others has a tremendous positive effect on the volunteer. Determine how engaged the client is with the smartphone; is it a substitute for true connections with others? Yet, it is so much better than having a client sit at home alone with no social stimulation.
- Consider the client's ability to hear; make recommendations accordingly.
- Encourage gratitude writing, tailored to the individual; it may be recording one positive or nice thing that happened each day and expanding the list over time. Have the client look at the list when feeling lonely or sad. It may be as simple as "I got a call from a friend today" or "The sun was shining, and I saw birds."
- Connect individuals to resources that are age- and interest-appropriate.
- Read and discuss with colleagues the Surgeon General's Advisory (OSG, 2023) to gain a fuller understanding of the impact. Explore additional actions relevant to your practice and those that should be addressed in your community.

Listen closely for the verbiage expressed by lonely clients; it may include the sentiments of "I am isolated, invisible, insignificant; no one will know if I am not here tomorrow" indicating that they are socially disconnected or lack social connections.

Case Manager Self-Care

Case managers are stressed in their roles beyond any other time in the history of case management. Self-care and social engagement are vital to the individual case manager's well-being. Just as the case manager's role assesses the client's level of loneliness and the strength of social connections, the case manager must perform a similar self-evaluation and implement strategies for their social engagement, continued health, and well-being.

- Discuss the loneliness issue with peers; you may be surprised to find out that you are not alone.
- Explore engagement opportunities that are easy for you to access (clubs, gyms, libraries, religious groups, educational offerings/adult continuing education, community centers, and volunteer opportunities).
- Get physical–exercise and get outdoors, spend time with nature.
- Take advantage of the free WELL-B Essentials (a 5-hour module of the Web-based Duke Center for the Advancement of Well-being Science.
- Get together with someone you have not been in touch with for a while.
- Explore repairing a fractured relationship.
- Do something to brighten the day for someone else; the benefits are remarkable.
- Take a break from electronics.
- Take up gratitude writing, focusing on the positives of the day, no matter how small they may be.
- Step out of your comfort zone and be proactive in strengthening your social connections.

Wrap-Up

Loneliness and social disconnection are growing public health concerns that do not discriminate. The consequences on physical and mental well-being represent profound implications for the individual, society, and the health care system. There is no pill for loneliness, and social connections are truly life sustaining. Case management leaders and case managers can positively affect a client's journey by first recognizing that loneliness and the loss of social connections are growing public health issues that negatively impact clients' health and outcomes. Acknowledging the clinical research and the recently published Surgeon General's Advisory are starting points that should lead to the review of internal client assessment processes and consideration of engagement referrals to assist in facilitating connections. Social connections heal and improve outcomes! CE II

References

Adib, B. M., & Sabharwal, J. K. (2023, March 3). Experience of loneliness on well-being among young individuals: A systematic scoping review. *Current Psychology*, pp. 1-21. doi:10.1007/s12144-023-04445-z

American Psychological Association. (2018). Loneliness. In *APA Dictionary of Psychology*. APA https://dictionary.apa.org/loneliness?s2=P1382021636_1683417608206677824

Ansberry, C. (2024, January 2). It takes at least 200 hours to make a close friendship, and more to maintain it. *The Wall Street Journal*. https://www.wsj.com/health/wellness/how-much-time-close-friend-a63350c3

Joint message from the UK and Japanese Loneliness Ministers. (2021, June 17). GOV.UK. https://www.gov.uk/government/news/joint-message-from-the-uk-and-japanese-loneliness-ministers

Office of the Surgeon General (OSG). (2023, May). Our epidemic of loneliness and isolation: *the US Surgeon General's Advisory on the Healing Effects of Social Connection and Community.* US Department of Health and Human Services. https://www.hhs.gov/sites/default/files/surgeon-general-social-connection-advisory.pdf

Our Epidemic of Loneliness and Isolation 2023 The U.S. Surgeon Genral's Advisory on the Healing Effects of Scocial Connection and Community. (2003, November). Retrieved from Health and Human Services: https://www.hhs.gov/sites/default/files/surgeon-general-social-connection-advisory.pdf

Tiwari, S. C. (2013, Oct-Dec). Loneliness: A disease? *Indian Journal of Psychiatry*, 55(4), 320-322. doi:10.4103/0019-5545.120536

CE3 Approved for 1 hour of CCM, CDMS, and nursing education credit
Exam expires on December 17, 2024

Understanding Clinical Trials (Part 2)

By Gary Wolfe, RN, CCM, FCM

Part 2 of a 2-part series topic.

In the April/May issue of *CareManagement*, I discussed the history, the why, and the who of clinical trials. In this issue, I will discuss the nuts and bolts of clinical trials, the types, how they work, and how case managers fit in. Let's get started.

Types of Clinical Trials

Clinical trials come in two main varieties:

- **Observational:** This type of clinical trial monitors conditions and health over time. The patients in these trials may be receiving treatment, but they are not assigned to specific interventions. The data collected from these studies advances researchers' understanding of a condition and its treatments.
- **Interventional:** These are what most people think of when they think of clinical trials—the studies that assign interventions such as drugs or experimental treatments to patients with an illness or condition.

There are two types of interventional studies: controlled (or comparative) studies and open-label studies. Controlled studies assign the intervention to one group and a placebo to the other group. A placebo patient receives the same protocol as the other patients, whether that is a pill, an injection, or an infusion, but without the active ingredient that the trial is studying. Often, studies that are controlled are randomized as well. Randomized controlled trials (RCTs) randomly allocate patients in trials. Often, the researchers use a computer program to randomize participants into distinct groups. This kind of randomization ensures that the research team's opinions do not affect who gets which treatment. This method, thereby, decreases bias as much as possible. RCTs are often considered the gold standard of medical intervention studies.

Open-label studies, on the other hand, are transparent (or "open") regarding which patients are receiving the active drug and which are receiving a placebo. Critics of this type of trial argue that excessive bias is built into the study's design.

Often, researchers distinguish between efficacy trials and effectiveness trials. Efficacy trials are explanatory trials meant to discover whether an intervention yields the expected results under ideal circumstances. Effectiveness trials are pragmatic trials that measure an intervention's degree of positive effect in real-world circumstances. The study's design and hypotheses are based on routine clinical practice conditions. Scientists can also assign clinical trials to the following study categories:

- **Treatment Trials:** These trials test medicine or treatment protocols on patients with a specific illness.
- **Prevention Trials:** These trials test such preventive measures as vaccines or interventions that may lower the risk for developing a specific condition or illness. Prevention trials may be broken down into action or agent studies. In action trials, the participant "does" something to prevent a disease; in agent trials, the participant "takes" something to prevent a disease.
- **Screening Trials:** These trials test ways of detecting an illness or condition, especially in its preliminary stages.
- **Palliative Trials:** These trials look for protocols or approaches to improve the comfort or quality of life of someone living with an illness or condition.
- **Genetic Trials:** These trials look for the inherited risk of a condition or illness.

The literature on clinical research describes several types of studies that have published results:

- **Case Series:** Also called clinical series, these observational studies track patients who have the designated condition or illness. Often considered half of a case-control study, case series alone have no control group. (The members of a control group are not afflicted with the condition or illness under study.) The patients in case series studies often receive the same intervention. Case series studies usually describe these patients, what treatments have been performed, and what their outcomes look like without much comparison between them, or conclusions being drawn in the study report.
- **Cohort Studies:** In contrast with case series, cohort studies have a defined group of people (a cohort) who are followed over time (for their designated illness or condition and

***Gary Wolfe, RN, CCM, FCM, i**s Editor-in-Chief of* CareManagement *journal.*

Interventional: **These are what most people think of when they think of clinical trials—the studies that assign interventions such as drugs or experimental treatments to patients with an illness or condition.**

their treatment) and compared to each other. For example, a cohort study design could look at two groups of patients, both with the same illness but receiving two different treatments to see if one works better than the other. Researchers say that it is often difficult to determine the difference between case series and cohort studies because they are often designed so similarly, and some publication authors do not categorize their studies as either type.

Another way to designate a type of clinical trial is whether it is a multicenter or single-center trial. Multicenter or multisite trials are the same trial offered at more than one clinic or medical center. Large trials, particularly those in Phase III, offer more flexibility for patients and ability for the study to garner more participants and variability when they are offered in more than one location. Further, some studies compare several treatments at once. Called multiarm multistage (MAMS) trials, there may be three or more treatment groups testing different interventions, and they may shut one treatment arm down if the early results do not show a treatment is working, or it has more side effects.

Medical device clinical trials are unique because they are smaller in scale overall and require fewer phases. Medical device studies are more difficult to randomize, and control. Many are dependent on physician's technique and device modifications usually happen during the trial. It may be impossible or unethical to use a placebo in a medical device study.

Not all medical devices require a clinical trial for release. There are three different classes of medical devices: I, II, and III. The class types escalate with the risk to the patient of the device.

- Class I are low to moderate risk, comprising 47% of devices, and include things such as bandages, gloves, bedpans, and manual stethoscopes.
- Class II are moderate to elevated risk for the patient, comprising 43% of devices, and can include things such as single-use scalpels or pregnancy test kits.
- Class III medical devices are the highest risk to the patient and are usually implanted or support life. Examples of these are breast implants or pacemakers.

There are two types of medical device clinical trials:

- **Early Feasibility or Feasibility Study (EFS):** This small study is designed to get insights into a novel medical technology during development before a larger clinical trial. These studies are optional but involve the FDA early to streamline clinical testing later. In a traditional feasibility study, formal endpoints (also called possible outcomes) are determined and inform future testing.
- **Pivotal Study:** This is an FDA term and is not exclusive to medical device studies. For medical devices, however, the process is sped up considerably, so the pivotal study comes much earlier than it would be required for a drug or vaccine study. The pivotal study is the large, human study that directly precedes a marketing application.

Designing Clinical Trials

Researchers design a clinical trial to follow a specific study plan or protocol. This helps them answer specific research questions about their studies' intervention. A well-designed study plan helps secure funding, ethics approvals, regulatory approvals, and any needed development approvals. Professionals recommend getting statisticians involved in the planning process to help with design: choosing an appropriate outcome, sample size, randomization methods, analysis plan, data collection tools, and interim data reports. Good protocol plans have the following:

- A simple method targeted to the patient group, delineating the selection criteria, number of participants needed, study length, and drug administration and dosage (where applicable)
- A research question and objectives that are clinically relevant and not addressed already
- Justified data requirements
- The most reasonable choice of controls (where applicable)
- Allocation concealment (where applicable)
- Blinding procedures for the intervention and the outcome assessments (where applicable)
- An explanation of how research bias will be confined

For drug trials, the sponsors (or the development company) must apply for an investigational new drug (IND). This application includes the data detailing the effects of the animal trials, the manufacturing information, the study plan, prior human research data, and the principal investigator credentials. The FDA helps for free when drug companies ask for help during any part of the drug development process. This can include before the IND is submitted and during some of the clinical trials phases.

Efficacy trials are explanatory trials meant to discover whether an intervention yields the expected results under ideal circumstances. Effectiveness trials are pragmatic trials that measure an intervention's degree of positive effect in real-world circumstances.

The FDA has a review team, consisting of scientific specialists who are responsible for distinct parts of the review, for each IND application they receive. This process is meant to protect clinical trial participants from excessive risks. These teams include the following:

- **Project Manager:** This is the FDA's main internal application coordinator and the main point for contact for the applicant (or sponsor).
- **Medical Officer:** This team member reviews all the study's clinical data during all study intervals.
- **Statistician:** The statistician on the team is responsible for reviewing the study design and data and working with the medical officer to ensure the protocol is safe and efficacious.
- **Pharmacologist:** This member reviews any preclinical study data.
- **Pharmacokineticist:** The pharmacokineticist is responsible for regular review of the data on the drug's effect in the body, including whether the dosages and administration schedules are appropriate.
- **Chemist:** This is the person responsible for understanding the drug's chemical composition, how it was made, its stability, whether there is good quality control during manufacture, and whether there are any impurities present.
- **Microbiologist:** If the drug is an antimicrobial, this person reviews the data submitted to see the microbial response.

For IND submissions, the FDA has 30 days to respond. They either approve the application or put a hold on or completely stop the investigation. Although rare, a clinical hold could be because of exceptional risk, unqualified investigators, misleading participant marketing, or lack of information about risks. In these cases, the FDA will respond with comments about what they need to continue their review. The investigators are responsible for communicating any protocol changes, significant side effects, and reporting to the review team. This process continues through the trial and until its end unless a marketing application is filed. Two large controlled trials worth of data must be submitted with a marketing application. For medical devices, researchers would request an investigational device exemption (IDE) for their application, as an IND is not obligatory. An IDE is used so that clinical data can be gathered on a medical device without the same procedural requirements that drugs, vaccines, or cancer protocols must go through.

What Is a Clinical Trial Phase?

Clinical trials are conducted in a series of steps called phases. Each phase has a different purpose and helps researchers answer different questions. (National Institutes of Health n.d.)

- **Phase I Trials:** Researchers test a drug or treatment in a small group of people (20–80) for the first time. The purpose is to study the drug or treatment to learn about safety and identify side effects.
- **Phase II Trials:** The new drug or treatment is given to a larger group of people (100–300) to determine its effectiveness and to further study its safety.
- **Phase III Trials:** The new drug or treatment is given to large groups of people (1000–3000 or more) to confirm its effectiveness, monitor side effects, compare it with standard or similar treatments, and collect information that will allow the new drug or treatment to be used safely.
- **Phase IV Trials:** After a drug is approved by the FDA and made available to the public, researchers track its safety in the general population, seeking more information about a drug or treatment's benefits, and optimal use.

Study Recruitment

Recruitment and retention of patients in a clinical trial is key to the trial success. In agreeing to be a study site or investigator, it is important to have a recruitment strategy that will devote the resources for the recruitment plan to be successful. Clinical trials are usually conducted in settings where the disease or procedure is regularly performed so there is a potential pool of study patients. Recruitment is a multistep process. Recruitment may start with a review of medical records, posting of an information flier, and talking to providers treating patients. A recruitment strategy should identify the potential candidates and then identify how they seek and find information. This will provide an avenue into successful recruitment.

Recruitment in a clinical trial includes the following steps:

1. Identifying or sourcing potential participants who may be eligible
2. Discussing all aspects of the trial with them, ensuring comprehension and voluntariness, and subsequently obtaining informed consent for participation

A cohort study design could look at two groups of patients, both with the same illness but receiving two different treatments to see if one works better than the other.

3. Conducting a physical examination and screening procedures as mentioned in the protocol
4. Enrolling the participant based on the eligibility criteria.

Once a potential patient or study subject is identified, the protocol is explained. The patient may want some time to think about their decision and even take the protocol home to review. When the patient returns, they may have questions before they commit to participating in the clinical trial. Some of the reasons patients don't participate in a clinical trial include (Chaudhariet et al 2020):

- Intricacy of study protocol
- Sociocultural issues
- Negative publicity by media
- Inconvenient study schedules
- Geographical distance
- Concerns about getting a placebo
- Concerns about investigational product
- Discouragement by treating physician
- Lack of awareness of clinical trials
- Fear of adverse event

Successful recruitment includes a discussion of all aspects of the clinical trial in language the patient can understand and overcoming any perceived barriers. Retention in clinical trials is important because of the amount of time and expense in recruiting new patients.

Adherence to the study protocol is very important. Tasks and procedures are done at certain times and intervals along with monitoring, particularly for adverse events.

There are many unique terms used in clinical trials which the case manager should be familiar with, or have a good understanding of, the process and be able to explain to patients. Here are some of the common terms:

- **Adverse Event:** Any medical occurrence that happens during a clinical trial or within a certain period after the trial has ended. An adverse event may or may not be caused by or related to the treatment being studied.
- **Blinding:** A type of trial design in which one or more parties involved with the trial, such as the research team or patient, do not know which treatments have been assigned to which participants. Single- or double-blind studies, which also may be called single- or double- masked studies are those in which the participants do not know which medicine is being used, so they can describe what happens without bias. In single-blinded studies, the patient is not told what is being given, but the research team knows. In a double-blinded study, neither the patient nor the research team are told what intervention is being administered to which patients.
- **Control:** The control or "standard" treatment is compared against the investigational treatment. It is intended to show that an approved treatment in the trial works, and the investigational treatment is compared against it.
- **Crossover Trial:** A clinical trial in which groups of patients are administered two or more interventions in a specific order.
- **Eligibility Criteria:** There are inclusion and exclusion criteria. Inclusion criteria are the criteria that allow a patient to join a study. Exclusion criteria are the criteria that do not allow a patient to join a study.
- **Good Clinical Practice:** A standard for the design, conduct, performance, monitoring, auditing, recording, analyzing, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and the rights, integrity, and confidentiality of trial participants are protected.
- **Informed Consent:** Informed consent is used by researchers to explain a clinical trial to potential patients. The purpose is to protect the patient. This information is provided in a written document called the informed consent form, which is designed to be clear and easy to understand. The informed consent is not a contract, and the patient can withdraw from the trial at any time.
- **Institutional Review Board (IRB):** The IRB is an independent body of medical, scientific, and nonmedical members whose responsibility is to ensure protection of the rights, safety, and well-being of human subjects involved in a trial by reviewing, approving, providing continuing review of trials, protocols, and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial participants.
- **Placebo:** Placebos are inactive substances. In a clinical trial, a placebo, made to look just like the investigational treatment, is sometimes used to compare against the actual investigational treatment to evaluate effectiveness.
- **Principal Investigator:** The person who is responsible for the scientific and technical operations of the clinical trial.

An investigational new drug (IND) application includes the data detailing the effects of the animal trials, the manufacturing information, the study plan, prior human research data, and the principal investigator credentials.

There may be subinvestigators who hold delegated authority for the conduct of a trial at a specific trial site.

- **Protocol:** The protocol is the written study plan on which the clinical trial is based. The protocol is very specific about who can participate in the trial; the schedule of events, procedures, medications and dosages; the outcomes of the study; and the length of the study.
- **Protocol Amendments:** An amendment is a written description of a change in the protocol.
- **Protocol Deviation:** Protocol deviations are failures to conduct a study as described in the protocol. The failure can be accidental or due to negligence and in either case, the deviation must be documented. Examples of protocol deviations may include failure to obtain/maintain approval for research, failure to obtain informed consent when required, failure to file adverse event reports, performance of an unapproved study procedure, using an unapproved site, and/or failure to adhere to an approved protocol.
- **Randomization:** A strategy in which participants are randomly assigned to study arms of the clinical trial, and this may be done by a computer.
- **Recruitment Plan:** A written plan outlining how, when, and where people will be recruited for the clinical trial.
- **Safety Monitoring Plan:** The plan that oversees the clinical trial.
- **Serious Adverse Event (SAE):** Any adverse event that is life-threatening, requires hospitalization or extended hospital stay, results in ongoing or significant incapacity, causes congenital anomalies or birth defects, or results in death.
- **Source Document:** Original documents, data, and reports including hospital records, clinical and office charts, laboratory notes, memoranda, participant diaries, recorded data from automated instruments, x-rays, etc, that are used in a clinical trial.
- **Sponsor:** The sponsor is the organization or person who is responsible for oversight of the entire clinical trial.
- **Stopping Rules:** Established safety criteria that would either pause or halt a clinical trial due to reasons including but not limited to futility risk(s) to participants.
- **Subject:** In clinical trial language, subject is just another name for patient, client, volunteer, or a person participating in the study.
- **Unmasking/Unblinding:** This is a procedure in which one or more of the parties (researchers or patients) to the trial are made aware of the treatment assignments.

Institutional Review Board

All clinical trials must be reviewed and approved by Institutional Review Boards (IRB). All IRBs are regulated by the US Food and Drug Administration (FDA). IRBs must be registered with the FDA and entered in an internet-based list maintained by the US Department of Health and Human Services. The purpose of an IRB is to make sure that all the appropriate steps are taken to protect the rights and welfare of all study participants enrolled in research. An IRB regulates a clinical trial through approving, disapproving, or requesting changes to a clinical trial. An IRB must be composed of at least five members reflecting diversity in race, gender, cultural background, and profession that include scientists, doctors, and lay people. At least one member of the IRB must have expertise with the research being reviewed and at least one member must be of the greater community. All trials must be reviewed and approved before the trial begins. The IRB review process includes among other considerations inclusion and exclusion criteria, how and when recruitment for the clinical trial will occur, how much money participants will receive to make sure they are not coerced or do not have undue influence upon someone's decision to participate, adequacy of the informed consent including appropriate reading level and understandability to study participants, quality and integrity of data collected. Clinical trials are reviewed by the IRB before the start of a clinical trial and periodically during a clinical trial. The institutional review board is an important component of the clinical trial process.

Who Pays for A Clinical Trial?

The costs of a clinical trial are paid for by the sponsor, which could be a pharmaceutical manufacturer or other product manufacturer, a government agency, a health care organization, or an individual. It really depends on who the sponsor is. The clinical trial sponsor will pay for physician visits, office/clinic visits, hospitalizations, treatments, investigational product/drug, laboratory tests, x-rays, or other imaging tests. The patient should not pay for any part of the clinical trial. In addition, the patient may be reimbursed for travel and any other approved expenses. The patient's health plan will

The National Institutes of Health maintains a searchable registry and results database, www.clinicaltrials.gov, of clinical trials being conducted in the United States and worldwide.

still be responsible for routine care not associated with the clinical trial during the clinical trial period. Cost, payment, and reimbursement to the patient will be detailed in the informed consent.

Role of the Case Manager

The case manager plays an important role in clinical trials. It may be the case manager who first introduces the idea of participating in a clinical trial to the health care team and patient and family. The case manager knows the health condition of the patient as well as the wishes and desires of the patient. The introduction of a clinical trial may start when the case manager is reviewing treatment options with the patient. In some cases, the patient may introduce the idea of a clinical trial or ask questions about clinical trial participation. Below is a list of questions the patient should have knowledge about when considering a clinical trial:

- What is the purpose of the study?
- Who will be enrolled in the study?
- What will the experimental treatment consist of?
- What Phase is the clinical trial?
- What kind of treatment and tests will be involved?
- How long will the trial last?
- Will hospitalization be required?
- Who will pay for the clinical trial?
- Will the patient receive any compensation or reimbursement?
- Will the patient know the results of the clinical trial?

The case manager plays an important role in clinical trial recruitment but also in supporting the patient/family during the clinical trial. Supporting the patient, educating the patient, and helping make sure the patient is adherent to the clinical trial procedures is part of the case manager's role. The case manager works closely with the research team to keep them informed about patient insights and concerns.

Finding a Clinical Trial

Once a patient or the health care team has expressed interest in participating in a clinical trial, the case manager can facilitate locating a trial. The National Institutes of Health maintains a searchable registry and results database, www.clinicaltrials.gov, of clinical trials being conducted in the United States and worldwide. The registry lists the trial purpose, who may participate, and location of the trial. Check out pharmaceutical companies that are seeking out specific disease associations. Another way of finding a clinical trial is asking local physicians and organizations if they are conducting any clinical trials. Patients or the health care team can use ResearchMatch, www.researchmatch.org, which maintains a registry of people interested in participating in research. A potential research participant completes a profile listing interests and then receives notifications about potential research of interest. Researchers also use ResearchMatch to list their research.

Clinical trials are a valuable resource for patients who have exhausted current treatment options or wish to further medical science and treatment. Benefits of participating in a clinical trial include helping scientists better understand a disease and advancing treatment, gaining a more active role in their health, and having greater access to potential new treatments before they are widely available. Along with benefits come risks including the investigational product not working, inconvenience, receiving a placebo, and undergoing tests and procedures that may be harmful. The case manager can help educate the patient interested in a clinical trial about these benefits and risks. CM

References

National Institutes of Health, NIH Clinical Research Trials and You (n.d.). https://www.nih.gov/health-information/nih-clinical-research-trials-you. Accessed February 6, 2024.

Chaudhari, N., Ravi, R., Gogtay, N.J., & Thatte, U.M. (2020). Recruitment and retention of the participants in clinical trials: Challenges and solutions. *Perspectives in Clinical Research*, 11, 64–69.

PharmaFacts for Case Managers

BEQVEZTM (fidanacogene elaparvovec-dzkt) injection, for intravenous infusion

INDICATIONS AND USAGE

BEQVEZ is an adeno-associated virus, vector-based gene therapy indicated for the treatment of adults with moderate to severe hemophilia B (congenital factor IX deficiency) who:

- Currently use factor IX prophylaxis therapy, or
- Have current or historical life-threatening hemorrhage, or
- Have repeated, serious spontaneous bleeding episodes, and,
- Do not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test.

Select patients for therapy based on an FDA-approved companion diagnostic for BEQVEZ.

DOSAGE AND ADMINISTRATION

For one-time single-dose intravenous infusion only.

Initiate and administer BEQVEZ in hospitals and other clinical centers under the supervision of a physician experienced in the treatment of hemophilia.

For Patient Selection

Perform testing for preexisting neutralizing antibodies to AAVRh74var using the FDA-approved companion diagnostic. DO NOT administer BEQVEZ to patients with a positive test for antibodies to AAVRh74var.

Information on FDA-approved tests for the detection of AAVRh74var preexisting neutralizing antibodies is available at http://www.fda.gov/companiondiagnostics.

- Perform factor IX (FIX) inhibitor testing prior to infusion. DO NOT administer BEQVEZ to patients with a positive test (≥0.6 Bethesda Units [BU]) or a prior history for factor IX inhibitor.
- Perform HIV testing prior to infusion. DO NOT administer BEQVEZ to patients with either CD4+ cell count <200 mm^3 or viral load ≥20 copies/mL in case of serological evidence of HIV-1 or HIV-2 infection.
- DO NOT administer BEQVEZ to patients with hypersensitivity to factor IX replacement product.
- Perform liver health assessments, which include:
  - Liver function tests (alanine transaminase [ALT], aspartate transaminase [AST], alkaline phosphatase [ALP], bilirubin, albumin).
  - Laboratory tests for active hepatitis B or C.
  - Elastography and/or ultrasound and other laboratory assessments for liver fibrosis.
  - DO NOT administer BEQVEZ to patients with current liver-related coagulopathy, hypoalbuminemia, persistent jaundice, or cirrhosis), portal hypertension, splenomegaly, hepatic encephalopathy, hepatic fibrosis, or active viral hepatitis.
  - In case of radiological liver abnormalities and/or sustained liver enzyme elevations, consider a consultation with hepatologist to assess eligibility for BEQVEZ.

Dose

The recommended dose of BEQVEZ is a single-dose intravenous infusion of 5×10^{11} vector genomes per kg (vg/kg) of body weight.

Dose weight in kilograms (kg) divided by 20 = dose in mL

Administration

Administer BEQVEZ in a setting where personnel and equipment are immediately available to treat infusion-related reactions,

General Precautions After Handling or Administering BEQVEZ

BEQVEZ may be transmitted to persons other than the patient receiving the treatment through patient excretions and secretions [see Clinical Pharmacology (12.3)]. Temporary vector shedding of intravenously administered AAV-based gene therapies occurs primarily through urine and feces, and to some extent saliva, mucus, and semen.

To minimize the risk of transmission to other persons, instruct patients regarding proper hand hygiene when coming into direct contact with patient secretions or excretions.

Follow these precautions for 6 months after BEQVEZ infusion, especially in the case of pregnancy or immunodeficiency of close contacts.

Monitoring Postadministration

Conduct the following laboratory tests after administration of BEQVEZ:

- Perform ALT/AST as in Table 1 to monitor for liver enzyme elevation, which may indicate immune-mediated hepatotoxicity. Liver enzyme elevation may result in decrease in factor IX activity. Perform factor IX activity testing as shown in Table 1.
- In patients with elevated transaminases and/or decline in factor IX activity, continue monitoring transaminases and factor IX activity until transaminases return to baseline and/or factor IX activity has plateaued.
- Consider implementing a course of corticosteroids as outlined in Table 1 for any of the following:
  - Single increase in either ALT or AST of ≥1.5-fold from baseline after screening and prior to infusion even if within the normal range.
  - Consecutive increases in transaminases (ALT or AST or both) on 2 subsequent blood tests even if within the normal range.
  - Factor IX activity decrease
    - » In the absence of alternative etiology, a decrease that could trigger the risk of bleeding.
    - » A decrease in factor IX activity on 2 consecutive blood tests especially if occurring during the first 4 months post-infusion.
- The recommended starting dose of oral corticosteroids is 60 to 100 mg once a day. Start to taper prednisolone/prednisone when the ALT and/or AST have declined for at least 2 consecutive lab draws and/or the levels have begun to normalize and any decline in factor IX activity has plateaued.
- Monitor for and manage adverse reactions secondary to corticosteroid use. Refer to the corticosteroid prescribing information for risks and required precautions.

If there is persistent transaminase elevation while on oral corticosteroids treatment alone, consult with a hepatologist as required to discuss use of combined oral and intravenous corticosteroids (methylprednisolone).

- Monitor factor IX activity.
  - Monitor factor IX activity levels according to Table 1 to confirm adequate endogenous FIX activity levels to support discontinuation of preinfusion FIX prophylaxis therapy. In the clinical studies, a prophylactic dose of factor IX replacement was given prior to BEQVEZ infusion and following that, patients discontinued prophylaxis. Exogenous factor IX or other hemostatic products may also be required in case of surgery, invasive procedures, trauma, or bleeds in the event that BEQVEZ-derived factor IX activity is deemed insufficient for adequate hemostasis in such situations.
  - The use of different assays may impact test results; therefore, use the same assay and reagents to monitor patients over time, if feasible.

TABLE 1 RECOMMENDED TREATMENT REGIMEN FOR ORAL CORTICOSTEROIDS

Schedule (oral corticosteroid treatment regimen)	**Prednisolone/Prednisone** (mg/day)
Week 1	~60 to 100*
Week 2	60**
Week 3	40
Week 4	30
Week 5	30
Week 6	20***
Week 7	15
Week 8	10

**Based on body weight.*

***See the following paragraph.*

****Maintain at 20 mg/day until transaminases return to baseline, then reduce by 5 mg/day until 10 mg/day are achieved and* then reduce by 2.5 mg/week to 5 mg daily.

  - Use of exogenous FIX concentrates before and after BEQVEZ administration may impede assessment of endogenous, BEQVEZ-derived factor IX activity.
- Monitor patients for factor IX inhibitors (neutralizing antibodies to factor IX). Test for factor IX inhibitors especially if bleeding is not controlled, or plasma factor IX activity levels decrease.

Perform regular liver ultrasound (eg, annually) and alpha-fetoprotein (AFP) testing in patients with risk factors of hepatocellular carcinoma (eg, hepatitis B or C, nonalcoholic fatty liver disease, chronic alcohol consumption, nonalcoholic steatohepatitis, advanced age).

DOSAGE FORMS AND STRENGTHS

BEQVEZ is supplied as a clear to slightly opalescent, colorless to slightly brown suspension for intravenous infusion with each mL containing 1×10^{13} vector genomes (vg).

Each vial of BEQVEZ contains 1 mL of extractable volume. The total number of vials will be customized to meet dosing requirements for individual patients based on their weight. Vial contents are to be diluted prior to infusion.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Hepatotoxicity

Intravenous administration of a liver-directed AAV vector could potentially lead to liver transaminase elevations. Transaminase elevations, particularly when observed in the first 4 months after BEQVEZ administration, is presumed to occur due to

immune-mediated injury of transduced hepatocytes and may reduce the therapeutic efficacy of the AAV vector-based gene therapy.

In clinical studies with BEQVEZ, transaminase elevations (defined as ≥1.5 x baseline) occurred in 29 of 45 and 7 of 15 patients in study 1 and study 2, respectively. Twenty-eight (62%) patients in clinical study 1 received corticosteroids for transaminase elevation and/or decline in factor IX activity. The mean time to corticosteroid initiation was 45 days. The mean duration of corticosteroid treatment was 113 days (range: 41 to 276 days).

Three (20%) patients in clinical study 2 received corticosteroids for transaminase elevation and/or decline in factor IX activity with time to initiation and duration of corticosteroid use within the range seen in clinical study 1.

Monitor ALT, AST, and factor IX activity levels once or twice weekly for at least 4 months, and institute corticosteroid treatment in response to transaminase elevation and/or decrease in FIX activity, as required [see Dosage and Administration (2.3)]. Monitor for and manage adverse reactions secondary to corticosteroid therapy.

For the first year following administration of BEQVEZ, advise patients to limit alcohol consumption, as alcohol may impact liver enzyme elevation and potentially reduce factor IX activity over time.

Infusion Reactions

Infusion reactions, including hypersensitivity reactions and anaphylaxis, may occur. Symptoms of hypersensitivity may include but are not limited to hypotension, pyrexia, palpitation, nausea, vomiting, chills or headache. Closely monitor patients for clinical signs and symptoms of infusion reactions throughout the infusion period and for at least 3 hours after end of infusion. In the event of an infusion reaction during administration, the infusion may be slowed or stopped. If the infusion is stopped, restart at a slower rate when the infusion reaction has resolved. Consider treatment with an antihistamine, corticosteroid or other measures for management of an infusion reaction.

Malignancy

The integration of liver-targeting AAV vector DNA into the genome may carry the theoretical risk of hepatocellular carcinoma development. Integration of AAV vector DNA into the host cell DNA in other tissues may also occur.

Monitor patients with risk factors for hepatocellular carcinoma (e.g., hepatitis B or C, non-alcoholic fatty liver disease, chronic alcohol consumption, non-alcoholic steatohepatitis, advanced age) with regular liver ultrasound (e.g., annually) and alpha-fetoprotein testing for 5 years following BEQVEZ.

In the event that a malignancy occurs, contact Pfizer Inc. at 1-800-438-1985 to obtain instructions on collecting patient samples for testing.

Monitoring Laboratory Tests

Factor IX Assays

When using an *in vitro* activated partial thromboplastin time (aPTT)-based one-stage clotting assay (OSA) for determining factor IX activity, plasma factor IX activity results can be affected by both the type of aPTT reagent, and the reference standard used in the assay. Higher inter-laboratory and inter-reagent variability in OSA results is observed at the lower factor IX activity levels (0.025 IU/mL). This is important to consider particularly when changing the laboratory and/or reagents used in the assay. It is recommended where possible to use the same laboratory (applicable to both, chromogenic or one-stage assays) for factor IX activity monitoring over time, particularly during the timeframe for corticosteroid treatment decision making, to minimize the impact of inter-laboratory variability.

In clinical study 1 with BEQVEZ, silica-based OSA returned consistently higher values of factor IX activity compared to ellagic acid-based OSA and chromogenic substrate assay (CSA). Generally, values of the ellagic acid-based OSA aligned with values of CSA.

Based on clinical trials (central laboratory), the approximate conversion factor between a silica-based OSA and ellagic acid-based OSA/CSA is 2. For example, a factor IX activity level of 10 IU/dL using CSA calculates approximately to a level of 20 IU/dL using silica-based OSA. At low factor IX activity levels (0.05 IU/mL) the conversion factor is approximately 2.5.

Factor IX Inhibitors

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

ADVERSE REACTIONS

The most common adverse reaction (incidence ≥5%) reported in clinical studies was an increase in transaminases.

DRUG INTERACTIONS

No interaction studies have been performed.

The use of BEQVEZ in patients receiving hepatotoxic medication or using hepatotoxic substances is limited. Use of hepatotoxic medications or substances may reduce the efficacy of BEQVEZ, and the risk of serious hepatic reactions may increase following administration.

Prior to BEQVEZ administration, review the patient's existing medications to determine if they should be modified to prevent anticipated interactions described in this section.

Monitor concomitant medications after BEQVEZ administration and evaluate the need to change concomitant medications based on patient's hepatic status and risk.

Vaccinations
Prior to BEQVEZ infusion, ensure patients are up to date on their vaccinations. If concomitant corticosteroid administration is needed following BEQVEZ infusion, delay administration of live vaccines until the patient has been weaned off corticosteroids

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary
BEQVEZ is not intended for administration in women. There are no data from the use of BEQVEZ in pregnant women. No animal reproductive studies have been conducted with BEQVEZ.

In the US general population, the estimated background risk of major birth defect and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Lactation

Risk Summary
There is no information regarding the presence of BEQVEZ in human milk, the effect on the breastfed infant, and the effects on milk production.

BEQVEZ is not intended for administration in women.

Females and Males of Reproductive Potential
No studies in animals or clinical studies have been performed to evaluate the potential effects of BEQVEZ on fertility in humans.

Contraception

Males
Vector DNA was shed in semen but declined to undetectable levels in semen within a mean of 1 to 4 months after infusion. Male patients should refrain from donating sperm, be abstinent or use a male condom for up to 6 months after receiving BEQVEZ.

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

Geriatric Use
The clinical study did not have any patient ≥65 years of age. The safety and efficacy of BEQVEZ have not been established in geriatric patients.

Hepatic Impairment
BEQVEZ has not been studied in patients with hepatic impairment.

Renal Impairment
BEQVEZ has not been studied in patients with renal impairment.

Human Immunodeficiency Virus (HIV) Positive Patients
Clinical studies of BEQVEZ included a limited number of HIV patients, which precludes a determination of whether the efficacy and safety data differ when compared to patients without HIV infection.

Factor IX Inhibitors
The safety and effectiveness of BEQVEZ in patients with prior or active factor IX inhibitors have not been established [see Clinical Pharmacology (12.6)]. Patients with history of or active factor IX inhibitors should not take BEQVEZ.

After administration of BEQVEZ, patients should be monitored for the development of factor IX inhibitors by appropriate clinical observations and laboratory tests.

CLINICAL STUDIES
The efficacy of BEQVEZ was evaluated in clinical study 1 (NCT03861273), which is an ongoing, prospective, open-label, single-arm, multi-national study. The study enrolled 45 adult male patients with moderately severe to severe hemophilia B (factor IX activity ≤2 IU/dL). All patients completed a prospective lead-in study of at least six months for baseline data collection while they received routine factor IX prophylaxis in the usual care setting before entering clinical study 1. Enrolled patients then received a single intravenous infusion of BEQVEZ at a dose of 5×10^{11} vg/kg of body weight and entered a follow-up (FU) period of 6 years. Of the 45 patients, 41 completed at least 15 months of FU. The median FU of the 45 treated patients was 2.0 years (range: 0.4 to 3.2 years) from the time of infusion.

Only patients who were negative for preexisting neutralizing antibodies to AAVRh74var capsid were eligible. Other key exclusion criteria included history of or current inhibitor to factor IX (≥0.6 Bethesda units), active hepatitis B or C infection, HIV infection with CD4 cell count ≤200 mm3 or viral load >20 copies/mL, hypersensitivity to factor IX product, ALT/AST/ALP >2 times ULN, bilirubin >1.5 times ULN, unstable liver or biliary disease, and significant liver fibrosis.

Enrolled patients were 73% White, 16% Asian, and 2.2% Black. The median age was 29 years (range: 18 to 62 years). A total of 13 (29%) and 15 (33%) patients had a history of hepatitis B and C, respectively. One (2%) patient was HIV positive.

The main efficacy outcome was a noninferiority (NI) test of annualized bleeding rate (ABR) during the efficacy evaluation period (EEP), Week 12 (Day 82) to data cutoff following BEQVEZ treatment, compared with baseline ABR during the lead-in period. The ABR included treated and untreated bleeds, excluding procedural bleeds. The NI margin on the difference between the mean EEP ABR and the mean baseline ABR was 3.0 bleeds/year.

Table 2 summarizes the efficacy results. The model derived mean ABR was 4.5 bleeds/year (95% CI: 1.9, 7.2) during the baseline period and 2.5 bleeds/year (95% CI: 1.0, 3.9) during post-BEQVEZ EEP, resulting in a difference between the mean post-BEQVEZ EEP ABR and the baseline ABR of -2.1 bleeds/year (95% CI: -4.8, 0.7). The upper bound of the 95% CI in the difference was less than 3.0 bleeds/year, meeting the NI study

TABLE 2 **SUMMARY OF ANNUALIZED BLEEDING RATE AND BLEEDING EVENTS (N=45)**

	Baseline (Prospective Lead-in Period)	Post-BEQVEZ Efficacy Evaluation Period[a]
Median (range) of follow-up time (years)	1.2 (0.6, 2.4)	1.8 (0.2, 3.0)
Total follow-up time (person-years)	59	83
Median (min, max) ABR (bleeds/year)[b]	1.3 (0.0, 53.9)[c]	0.0 (0.0, 19.0)
Model derived mean ABR [bleeds/year] (95%)[b,d]	4.5 (1.9, 7.2)	2.5 (1.0, 3.9)
n (%) of patients without any bleeds	13 (29%)	27 (60%)
Total number of observed bleeds	225	98
Number of observed spontaneous bleeds (proportion of total bleeds)	157 (70%)	60 (61%)
Number of observed joint bleeds (proportion of total bleeds)	184 (82%)	71 (72%)

ABR = annualized bleeding rate for all bleeds (treated and untreated with factor IX, excluding procedural bleeds). CI = confidence interval.

a. Post-BEQVEZ efficacy evaluation period is from Week 12 (Day 82) to data cutoff.

b. A total of 7 participants (16%) had used factor IX replacement products during the efficacy evaluation period for extended prophylaxis that confounded the treatment effect of BEQVEZ, with a median start time at 0.8 (range: 0.4 to 1.1) years. An ABR of 20 bleeds/year was imputed for the confounded periods.

c. The results presented in this table included data on a participant with a baseline ABR of 53.9 bleeds/year, which disproportionately influenced the baseline ABR estimate. A posthoc sensitivity analysis, excluding this participant, still met the non-inferiority study success criterion.

d. Model-based ABR estimates from a repeated measures generalized linear model with negative binomial distribution and identity link function.

success criterion. Six out of 45 patients (13%) resumed routine factor IX prophylaxis after BEQVEZ treatment, starting from 0.4 years to 1.7 years after BEQVEZ infusion. An additional patient had intermittent exogenous factor IX use and had a higher ABR post BEQVEZ (5.0 bleeds/year) compared to baseline (1.2 bleeds/year) with a factor IX activity <5% (SynthASil assay) starting at 0.4 years.

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

BEQVEZ is supplied as a clear to slightly opalescent, colorless to slightly brown suspension with each mL containing 1×10^{13} vg.

BEQVEZ is shipped frozen (−100 °C to −60 °C [−148 °F to −76 °F]) in plastic vials with an elastomeric stopper and plastic snap fit cap with an extractable volume of 1 mL.

BEQVEZ is provided as a customized kit containing the number of vials (NDC 0069-0422-01) required to meet dosing requirements for each patient. The customized kit is accompanied with patient's specific identifier number (Pfizer Patient Identifier) on the outer carton.

Storage and Handling

BEQVEZ is shipped and delivered frozen between −100 °C to −60 °C (−148 °F to −76 °F) in clear vials. Upon receipt, immediately place in a freezer between −90 °C to −60 °C (−130 °F to −76 °F).

Store in the original package to avoid direct sunlight and ultraviolet light exposure.

Store upright in the original package. If cartons or individual vials are tipped over or inverted during storage and handling, place the carton or individual vials back in the upright orientation immediately.

Frozen vials in the inner carton will take up to 1 hour to thaw at room temperature (up to 30 °C [86 °F]). Vials may be gently swirled but not shaken or inverted. The total time at room temperature between removing vials from frozen storage until the beginning of dose preparation should be no more than 3 hours. Once thawed, the medicinal product should not be re-frozen and may be stored refrigerated at 2 °C to 8 °C (36 °F to 46 °F) in the inner carton up to 24 hours.

Following dilution in 0.9% sodium chloride with 0.25% HSA, chemical and physical in-use stability has been demonstrated for 24 hours at 2 °C to 30 °C (36 °F to 86 °F).

For full prescribing information, please see Product Insert.

BEQVEZ is manufactured by Pfizer, Inc.

LitScan for Case Managers

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

Br J Anaesth. 2024 Apr 26:S0007-0912(24)00181-8. doi: 10.1016/j.bja.2024.03.025. Online ahead of print.

Reducing Airborne Transmissible Diseases in Perioperative Environments

Bowdle A, Brosseau LM , Tellier R, MacIntyre CR, Edwards M, Jelacic S

The COVID-19 pandemic has transformed our understanding of aerosol transmissible disease and the measures required to minimise transmission. Anaesthesia providers are often in close proximity to patients and other hospital staff for prolonged periods while working in operating and procedure rooms. Although enhanced ventilation provides some protection from aerosol transmissible disease in these work areas, close proximity and long duration of exposure have the opposite effect. Surgical masks provide only minimal additional protection. Surgical patients are also at risk from viral and bacterial aerosols. Despite having recently experienced the most significant pandemic in 100 yr, we continue to lack adequate understanding of the true risks encountered from aerosol transmissible diseases in the operating room, and the best course of action to protect patients and healthcare workers from them in the future. Nevertheless, hospitals can take specific actions now by providing respirators for routine use, encouraging staff to utilise respirators routinely, establishing triggers for situations that require respirator use, educating staff concerning the prevention of aerosol transmissible diseases, and providing portable air purifiers for perioperative spaces with low levels of ventilation.

Am Heart J. 2024 Apr 27:S0002-8703(24)00104-2. doi: 10.1016/j.ahj.2024.04.017. Online ahead of print.

Association Between Atrial Fibrillation and Heart Failure Patient Reported Outcomes Across the Ejection Fraction Spectrum

Elkholey K, Esraa Shehata Z, Mustafina I, Fudim M, Stavrakis S

BACKGROUND: Atrial fibrillation (AF) is common in patients with heart failure (HF) and is associated with worse clinical outcomes. We evaluated the relationship between AF and longitudinal changes in health-related quality of life (HRQoL) measured by Kansas City Cardiomyopathy Questionnaire (KCCQ) in both HF with preserved (HFpEF) and reduced ejection fraction (HFrEF).

METHODS: This is a post-hoc analysis of the TOPCAT and HF-ACTION trials. The effect of AF on KCCQ overall summary scores (OSS), in both trials, was examined using a mixed effects regression model. Patients were divided into 3 groups according to AF status at baseline: patients with a history of AF but no AF detected on ECG at enrollment (Hx AF group), patients with history of AF and AF detected on ECG at enrollment (ECG AF group) and patients with post-randomization new-onset AF (New AF group).

RESULTS: In TOPCAT, among 1710 patients with KCCQ data available, AF was associated with a significantly lower KCCQ-OSS (-3.98; 95% CI -7.21: -0.74) at 48 months, with a significant AF status by time interaction (p=0.03). In HF-ACTION, among 1814 patients with available KCCQ data, AF was associated with a significantly lower KCCQ-OSS (-3.67; 95% CI -6.21: -1.41) at 24 months but there was no significant AF status by time interaction. In both trials, the type of AF was not associated with significant changes in KCCQ-OSS score.

CONCLUSION: In patients with both HFpEF and HFrEF, AF was independently associated with worse HRQoL measured by KCCQ.

Circ Cardiovasc Qual Outcomes. 2024 Apr 29:e010800. doi: 10.1161/CIRCOUTCOMES.123.010800. Online ahead of print.

Association Between Coronary Assessment in Heart Failure and Clinical Outcomes Within a Safety-Net Setting Using a Target Trial Emulation Observational Design

Matthew S Durstenfeld, MS, Thakkar A, Ma Y, Zier LS, Davis JD, Hsue PY

BACKGROUND: Ischemic cardiomyopathy is the leading cause of heart failure (HF). Most patients do not undergo coronary assessment after HF diagnosis. There are no randomized clinical trials of coronary assessment after HF diagnosis.

METHODS: Using an electronic health record cohort of all individuals with HF within the San Francisco Health Network

from 2001 to 2019, we identified factors associated with coronary assessment. Then, we studied the association of coronary assessment within 30 days of HF diagnosis with all-cause mortality and a composite of mortality and emergent angiography using a target trial emulation observational comparative-effectiveness approach. Target trial emulation is an approach to causal inference based on creating a hypothetical randomized clinical trial protocol and using observational data to emulate the protocol. We used propensity scores for covariate adjustment. We used national death records to improve the ascertainment of mortality and included falsification end points for the cause of death.

RESULTS: Among 14 829 individuals with HF (median, 62 years old; 5855 [40%] women), 3987 (26.9%) ever completed coronary assessment, with 2467/13 301 (18.5%) with unknown coronary artery disease status at HF diagnosis assessed. Women, older individuals, and people without stable housing were less likely to complete coronary assessment. Among 5972 eligible persons of whom 627 underwent early elective coronary assessment, coronary assessment was associated with lower mortality (hazard ratio, 0.84 [95% CI, 0.72-0.97]; P=0.025), reduced risk of the composite outcome (hazard ratio, 0.86 [95% CI, 0.73-1.00]), higher rates of revascularization (odds ratio, 7.6 [95% CI, 5.4-10.6]), and higher use of medical therapy (odds ratio, 2.5 [95% CI, 1.7-3.6]), but not the falsification end points.

CONCLUSIONS: In a safety-net population, disparities in coronary assessment after HF diagnosis are not fully explained by coronary artery disease risk factors. Early coronary assessment is associated with improved HF outcomes possibly related to higher rates of revascularization and guideline-directed medical therapy but with low certainty that this finding is not attributable to unmeasured confounding.

AIDS. 2024 Apr 25. doi: 10.1097/QAD.0000000000003917. Online ahead of print.

Risk Score Prediction for Bacteriologically Confirmed Tuberculosis Among HIV-Infected Adults on Antiretroviral Therapy in Ethiopia: Prognostic Model Development

Derseh NM, Chanie Agimas M, Kidie Tesfie T.

OBJECTIVE: This study was aimed at developing a risk score prediction model for bacteriologically confirmed TB among HIV-infected adults receiving antiretroviral therapy in Ethiopia.

METHODS: An institutional-based retrospective follow-up study was conducted among 569 HIV-infected adults on ART. We used demographic and clinical prognostic factors to develop a risk prediction model. Model performance was evaluated by discrimination and calibration using the area under the receiver operating characteristic (AUROC) curve and calibration plot. Bootstrapping was used for internal validation. A decision curve analysis was used to evaluate the clinical utility.

RESULTS: Opportunistic infection, functional status, anemia, isoniazid preventive therapy, and WHO clinical stages were used to develop risk prediction. The AUROC curve of the original model was 87.53% (95% CI: 83.88-91.25) and the calibration plot (p-value = 0.51). After internal validation, the AUROC curve of 86.61% (95% CI: 82.92-90.29%) was comparable with the original model, with an optimism coefficient of 0.0096 and good calibration (p-value = 0.10). Our model revealed excellent sensitivity (92.65%) and negative predictive value (NPV) (98.60%) with very good specificity (70.06%) and accuracy (72.76%). After validation, accuracy (74.85%) and specificity (76.27%) were improved, but sensitivity (86.76%) and NPV (97.66%) were relatively reduced. The risk prediction model had a net benefit up to 7.5 threshold probabilities.

CONCLUSION: This prognostic model had very good performance. Moreover, it had very good sensitivity and excellent NPV. The model could help clinicians use risk estimation and stratification for early diagnosis and treatment to improve patient outcomes and quality of life.

J Infect Dis. 2024 May 2:jiae195. doi: 10.1093/infdis/jiae195. Online ahead of print.

Food Is Medicine for HIV: Improved Health and Hospitalizations in the Changing Health Through Food Support (CHEFS-HIV) Pragmatic Randomized Trial

Palar K, Sheira LA, Frongillo EA, et al.

BACKGROUND: Policy support for "Food is Medicine"-medically tailored meals or groceries to improve health-is rapidly growing. No randomized trials have heretofore investigated the benefits of medically tailored food programs for people living with HIV (PLHIV).

METHODS: The CHEFS-HIV pragmatic randomized trial included PLHIV who were clients of Project Open Hand (POH), a San Francisco-based nonprofit food organization. The intervention arm (n = 93) received comprehensive medically tailored meals, groceries, and nutritional education. Control participants (n = 98) received less intensive (POH "standard of care") food services. Health, nutrition, and behavioral outcomes were assessed at baseline and 6 months later. Primary outcomes measured were viral non-suppression and health related quality of life. Mixed models estimated treatment effects as differences-in-differences between arms.

RESULTS: The intervention arm had lower odds of hospitalization (odds ratio [OR] = 0.11), food insecurity (OR = 0.23), depressive symptoms (OR = 0.32), antiretroviral therapy adherence <90%

(OR = 0.18), and unprotected sex (OR = 0.18), and less fatty food consumption (β= -0.170 servings/day) over 6 months, compared to the control arm. There was no difference between study arms in viral non-suppression and health-related quality of life over 6 months.

CONCLUSIONS: A "Food-is-Medicine" intervention reduced hospitalizations and improved mental and physical health among PLHIV, despite no impact on viral suppression.

Ann Thorac Surg. 2024 May;117(5):1035-1043. doi: 10.1016/j.athoracsur.2023.02.063. Epub 2023 Apr 23.

An Analysis of 186 Transplants for Pediatric or Congenital Heart Disease: Impact of Pretransplant VAD

Bleiweis MS, Stukov Y, Sharaf OM, et al.

BACKGROUND: We reviewed our management strategy and outcome data for all 181 patients with pediatric or congenital heart disease who received 186 heart transplants from January 1, 2011, to March 1, 2022, and evaluated the impact of pretransplant ventricular assist device (VAD).

METHODS: Continuous variables are presented as mean (SD); median [interquartile range] (range). Categorical variables are presented as number (percentage). Univariable associations with long-term mortality were assessed with Cox proportional hazards models. Impact of pretransplant VAD on survival was estimated with multivariable models.

RESULTS: Pretransplant VAD was present in 53 of 186 transplants (28.5%). Patients with VAD were younger (years): 4.8 (5.6); 1 [0.5-8] (0.1-18) vs 12.1 (12.7); 10 [0.7-17] (0.1-58); P = .0001. Patients with VAD had a higher number of prior cardiac operations: 3.0 (2.3); 2 [1-4] (1-12) vs 1.8 (1.9); 2 [0-3] (0-8); P = .0003. Patients with VAD were also more likely to receive an ABO-incompatible transplant: 10 of 53 (18.9%) vs 9 of 133 (6.8%); P = .028. Univariable associations with long-term mortality included: In multivariable analysis, pretransplant VAD did not impact survival while controlling for each one of the factors shown in univariable analysis to be associated with long-term mortality. Kaplan-Meier 5-year survival (95% CI) was 85.8% (80.0%-92.1%) for all patients, 84.3% (77.2%-92.0%) without pretransplant VAD, and 91.1% (83.1%-99.9%) with pretransplant VAD.

CONCLUSIONS: Our single-institution analysis of 181 patients receiving 186 heart transplants for pediatric or congenital heart disease over 11.25 years reveals similar survival in patients with (n = 51) and without (n = 130) pretransplant VAD. The presence of a pretransplant VAD is not a risk factor for mortality after transplantation for pediatric or congenital heart disease.

Hypertension. 2024 May 1. doi: 10.1161/HYPERTENSIONAHA.124.22698. Online ahead of print.

Hypertension Impacts the Oscillatory Dynamics Serving the Encoding Phase of Verbal Working Memory

Arif Y, Killanin AD, Zhu J, et al.

BACKGROUND: Chronic hypertension is known to be a major contributor to cognitive decline, with executive function and working memory being among the domains most commonly affected. Despite the growing literature on such dysfunction in patients with hypertension, the underlying neural processes are poorly understood.

METHODS: In this cross-sectional study, we examine these neural processes by having participants with controlled hypertension, uncontrolled hypertension, and healthy controls perform a verbal working memory task during magnetoencephalography. Neural oscillations associated with the encoding and maintenance components of the working memory task were imaged and statistically evaluated among the 3 groups.

RESULTS: Differences related to hypertension emerged during the encoding phase, where the hypertension groups exhibited weaker α-β oscillatory responses compared with controls in the left parietal cortices, whereas such oscillatory activity differed between the 2 hypertension groups in the right prefrontal regions. Importantly, these neural responses in the prefrontal and parietal cortices during encoding were also significantly associated with behavioral performance across all participants.

CONCLUSIONS: Overall, our data suggest that hypertension is associated with neurophysiological abnormalities during working memory encoding, whereas the neural processes serving maintenance seem to be preserved. The right hemispheric neural responses likely reflected compensatory processing, which patients with controlled hypertension may use to achieve verbal working memory function at the level of controls, as opposed to the uncontrolled hypertension group where diminished resources may have limited such additional recruitment.

J Allergy Clin Immunol. 2024 Apr 24:S0091-6749(24)00406-8. doi: 10.1016/j.jaci.2024.04.008. Online ahead of print.

Alzheimer's Incidence and Prevalence With and Without Asthma: A Medicare Cohort Study

Bartels CM, Chen Y, W Ryan Powell WR, et al.

BACKGROUND: International data suggest that asthma, like other inflammatory diseases, might increase Alzheimer's disease (AD) risk.

OBJECTIVE: To explore risk pathways and future mitigation strategies by comparing diagnostic claims-based AD incidence and

prevalence among US patients with asthma to non-asthma patients.

Methods: This cohort study included a national Medicare 20% random sample 2013-2015. Adult patients with >12 months continuous Medicare with asthma were compared to non-asthma subjects overall and as matched. Asthma was defined by one inpatient or two outpatient codes for asthma. The main outcomes were two-year incident or prevalent AD defined as any codes for ICD-9 331.0 or ICD-10 G30.0, G30.1, G30.8, G30.9.

RESULTS: Among 5,460,732 total beneficiaries, 678,730 patients were identified with baseline asthma and more often identified as Black or Hispanic, were Medicaid eligible, or resided in a highly disadvantaged neighborhood than those without asthma. Two-year incidence of AD was 1.4% with asthma vs 1.1% without; prevalence was 7.8% vs 5.4% (both p=<0.001). Per 100,000 patients over two years, 303 more incident AD diagnoses occurred in asthma, with 2,425 more prevalent cases (p<0.001). Multivariable models showed asthma had greater odds of two-year AD incidence [AOR 1.33 (1.29-1.36); matched 1.2 (1.17-1.24)] and prevalence [AOR 1.48 (1.47-1.50); matched 1.25 (1.22-1.27)).

CONCLUSION: Asthma was associated with 20-33% increased two-year incidence and 25-48% increased prevalence of claims-based Alzheimer's disease in this nationally representative US sample. Future research should investigate risk pathways of underlying comorbidities and social determinants, as well as whether there are potential asthma treatments that may preserve brain health.

Pediatr Pulmonol. 2024 May;59(5):1313-1320. doi: 10.1002/ppul.26908. Epub 2024 Feb 14.

Acute Exposure to Pollen and Airway Inflammation in Adolescents

Nassikas NJ, Luttmann-Gibson H, Rifas-Shiman SL, Oken E, Gold DR, Rice MB

INTRODUCTION: Pollen exposure is known to exacerbate allergic asthma and allergic rhinitis symptoms, yet few studies have investigated if exposure to pollen affects lung function or airway inflammation in healthy children.

METHODS: We evaluated the extent to which higher pollen exposure was associated with differences in airway inflammation and lung function among 490 early adolescent participants (mean age of 12.9 years) in Project Viva, a prebirth cohort based in Massachusetts. We obtained regional daily total pollen counts, including tree, grass, and weed pollen, from a Rotorod pollen counter. We evaluated associations of 3- and 7-day moving averages of pollen with fractional exhaled nitric oxide (FeNO) and lung function using linear regression models and evaluated the linearity of associations with penalized splines. We tested if associations of pollen with FeNO and lung function were modified by current asthma diagnosis, history of allergic rhinitis, aeroallergen sensitivity, temperature, precipitation, and air pollution.

RESULTS: Three- and 7-day median pollen concentrations were 19.0 grains/m3 (IQR: 73.4) and 20.9 grains/m3 (IQR: 89.7). In main models, higher concentrations of total pollen over the preceding 3 and 7 days were associated with a 4.6% (95% CI: 0.1,9.2) and 7.4% (95% CI: 0.9,14.3) higher FeNO per IQR of pollen, respectively. We did not find associations of pollen with lung function in main models. Asthma, allergic rhinitis, precipitation, and air pollution (nitrogen dioxide and ozone) modified associations of pollen with lung function (Pinteraction < 0.1), while temperature, sex, and aeroallergen sensitization did not.

CONCLUSION: Short-term exposure to pollen was associated with higher FeNO in early adolescents, even in the absence of allergic sensitization and asthma.

Am J Kidney Dis. 2024 May;83(5):677-683. doi: 10.1053/j.ajkd.2023.09.019. Epub 2023 Nov 20.

Engineering Equity into the Promise of Xenotransplantation

Reese PP, Powe NR, Lo B

Two of the greatest challenges facing kidney transplantation are the lack of donated organs and inequities in who receives a transplant. Xenotransplantation holds promise as a treatment approach that could solve the supply problem. Major advances in gene-editing procedures have enabled several companies to raise genetically engineered pigs for organ donation. These porcine organs lack antigens and have other modifications that should reduce the probability of immunological rejection when transplanted into humans. The US Food and Drug Administration and transplantation leaders are starting to chart a path to test xenotransplants in clinical trials and later integrate them into routine clinical care. Here we provide a framework that industry, regulatory authorities, payers, transplantation professionals, and patient groups can implement to promote equity during every stage in this process. We also call for immediate action. Companies developing xenotransplant technology should assemble patient advocacy boards to bring the concerns of individuals with end-stage kidney disease to the forefront. For trials, xenotransplantation companies should partner with transplant programs with substantial patient populations of racial and ethnic minority groups and that have reciprocal relationships with those communities. Those companies and transplant programs should reach out now to those communities to inform them about xenotransplantation and try to address their concerns. These actions have the potential to make these communities full partners in the promise of xenotransplantation.

Managing An Aging Workforce: Creativity and Flexibility Lead to More Opportunities
continued from page 4

programs and policies are aligned with the needs of workers at every age. Practices such as return-to-work and stay-at-work programs, especially accommodations and job reassignments, can keep highly valued, experienced employees in the workplace.

Older workers may need accommodations and job assignments that allow them to contribute their knowledge and expertise, but in less physically demanding jobs or with greater flexibility in their work schedules. In addition, roles can be created as permanent accommodations. In health care, this may mean reassigning a nurse from a role that requires being on the hospital floor 40 hours a week to another position, such as in the training department.

The aging of the workforce raises the stakes for advocacy. With a person-centered approach, CCM and CDMS certificants alike consider the needs and abilities of the individual to help them pursue their goals. When those goals include remaining productive, flexibility and creativity in developing roles and reassigning responsibilities can help older employees contribute their knowledge and skills well beyond retirement age. CM

Readers:

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

Authors:

Consider contributing an article to *CareManagement*. Please send manuscripts or inquiries to: cmullahy@academyccm.org.

Case Managers: Own Your Vital Role in Social Determinants of Health
continued from page 3

to capture, analyze, and apply SDOH findings, enables case managers to better meet their clients' needs and promote improved health outcomes.

The Vanderbilt University Medical Center (VUMC), an academic medical center serving over two million patients nationwide in primary care, specialty care, inpatient and outpatient settings, conducted a mixed method study. Participants included physicians, advanced practice providers, outpatient nurses, social workers, case managers, pharmacists, and administrators in internal primary care and hospital medicine. The study demonstrated that a structured approach when considering and implementing SDOH screenings is important when case managers refer patients to health systems, social services, and community resources, and partner and collaborate with other providers.

Case managers have an opportunity to strengthen the application of SDOH. By taking a strategic approach to their role in SDOH programs, they can help eliminate the silos in health care and replace them with collaborative relationships. Collaborations help facilitate improved information exchanges, advance treatment plans, and promote a whole-person health approach. Case managers can ensure their greatest contribution in SDOH initiatives by applying best practices.

Best Practices

To ensure the best application of SDOH, case managers should strive to conduct thorough assessments of their patients' needs and strengths (ie, income, education, housing social support, culture, and health behaviors) and rely on a structured approach to SDOH, collaborate and coordinate with other members of each patient's clinical team (ie, exchange information, provide updates, schedule meetings with other clinicians to discuss a patient's needs directly), continuously monitor and assess the results and outcomes of SDOH patient assessments (eg, analyze data on the patient's health, new symptoms, mental state), benchmark these findings against the starting baseline, and make adjustments to the care plan when needed.

As an essential member of a patient's care team, case managers have a valuable vantage point in their close contact with their patients to offer both advocacy on their behalf and compassion. They are also the hub in the wheel of a complex health care system that relies on professionals who have a broad understanding and ability to access all of the essential resources their patients need within the context of SDOH.

In an increasingly complex system, it is often the most basic elements included in SDOH that can present as major barriers for our patients. In our role as case managers, we need to prioritize the assessment of these factors and, of course, identify, and resolve those that are jeopardizing the best outcomes for those most at risk.

We can and need to make a difference … one patient at a time.

Warm regards and best wishes for a wonderful summer!

Catherine

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

The Future of Health Care Powered by Case Management
continued from page 7

collaboration and integration across the continuum of care, case managers optimize health care delivery and improve patient outcomes.

In an era of escalating health care costs and finite resources, cost efficiency, and resource optimization are critical imperatives. Case management contributes to this goal by preventing unnecessary hospital readmissions, avoiding duplicate tests and procedures, and optimizing resource utilization. By identifying high-risk patients, providing proactive interventions, and promoting preventive care, case managers help reduce health care expenditures while improving the quality of care. Additionally, by leveraging community resources and social support networks, case managers address the social determinants of health, further enhancing cost-effectiveness and resource allocation.

A fundamental aspect of case management involves educating and empowering patients to actively participate in their health care journey. This education encompasses understanding diagnosis and treatment options, managing chronic conditions, navigating the health care system, and advocating for their own health needs. By providing patients with the knowledge, skills, and support they need to make informed decisions, case managers empower them to take control of their health and well-being. This not only improves health outcomes but also fosters a sense of ownership and self-efficacy among patients, leading to greater satisfaction and engagement in their care.

The future of health care is intricately intertwined with the evolution and integration of case management. As health care systems continue to evolve and adapt to changing needs and technologies, the role of case managers becomes increasingly pivotal. By embracing the principles of patient-centered care, leveraging technology, promoting coordination across the continuum of care, optimizing resource utilization, and empowering patients through education and support, professional case management has the potential to transform health care delivery and improve outcomes for individuals and communities alike. As we look ahead to the future of health care, one thing is clear: case management will continue to play a central role in shaping a more efficient, effective, and patient-centered health care system.

It's time to no longer be "the best kept secret in health care." CM

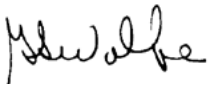
Loneliness: Implications for Case Managers *continued from page 2*

- Feeling that no one understands you
- Feeling alone
- Not wanting to socialize
- Feeling off physically
- Spending more time on social media
- Declining healthy habits

Loneliness and the lack of social connection poses a significant risk for individual health and longevity. Loneliness and social isolation increase the risk of premature death by 26% and 29%, respectively. Put another way, lack of social connection can increase the risk of premature death as much as smoking 15 cigarettes a day. People experiencing loneliness and insufficient social connections have a 29% increased risk of heart disease and a 32% increased risk of stroke. Loneliness is associated with a significantly increased risk for early death from all causes. It is also associated with increased risk of anxiety, depression, and dementia. Research has also shown an increased susceptibility to viruses and respiratory illness. Social isolation is the strongest and most reliable predictor of suicidal ideation, attempts, and lethal suicidal behavior, varying in groups based on age, gender, nationality, and clinical severity. Loneliness is the strongest protective factor against self-harm and suicide among people with and without serious underlying mental health challenges.

The case manager plays an important role in assessing and supporting patients with loneliness. Because loneliness is so prevalent, the case manager should include loneliness in their assessments. In many situations, this will be just a few questions, but in some, it will lead to an in-depth assessment of the patient's loneliness. Providing intervention can improve the patient outcomes. Improving outcomes is a goal all case managers seek. To systemically address the loneliness problem, we must train health care workers, assess and support patients, and expand public health surveillance and intervention.

Loneliness is known to be related to poor health outcomes. We can overcome the loneliness crisis by being engaged in a meaningful way with others. People need good social support, good relationships with others, a strong family life, and balance in daily time spent well. The case manager can address the loneliness crisis through their patient assessment and make a significant difference in patient outcomes.



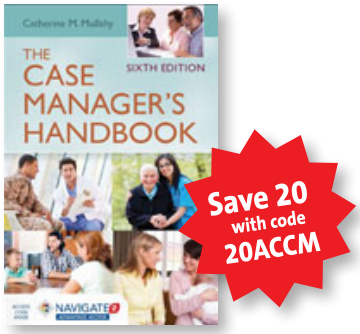
Gary S. Wolfe, RN, CCM, FCM,
Editor-in-Chief
gwolfe@academyccm.org

ACCM: Improving Case Management Practice through Education

Case Managers: There's no better time to advance your career than now!

Whether you're an experienced Certified Case Manager (CCM), a new case manager looking to earn your CCM credential, or a case manager thinking about starting your own case management practice, Catherine M. Mullahy, RN, BS, CRRN, CCM and Jeanne Boling, MSN, CRRN, CDMS, CCM can help. Their award-winning case management education and training resources incorporate their decades of experience, leadership and success in case management. These CMSA Lifetime Achievement Award Winners and veterans who helped develop case management standards and codes of conducts have created "Best in Class" tools to address your career needs and goals.

Here are just some of Mullahy & Associates' career-advancing resources:



THE CASE MANAGER'S HANDBOOK, 6TH EDITION

- The definitive resource in case management
- A trusted study guide for CCM preparation
- A comprehensive compendium of best practice fundamentals, latest developments, strategies for managing various cases, legal and ethical issues, and much more
- Used in nursing schools/university curriculum across the globe

ORDER NOW!

BEST IN CLASS CASE MANAGEMENT ONLINE COURSE, 2.0 EDITION

- Your gateway to certification and leading-edge practice
- 14 Interactive, Multi-Media Modules which together define case management and the duties of a case manager
- Ideal for beginners, intermediate and advanced level learners
- Aligned with the CCMC Knowledge Domains
- Study at your own pace, 24/7, with easy to access online content
- Robust platform complete with sample questions, helpful study tips, case management videos and more

ORDER NOW!

GOLD ENTREPRENEUR PACKAGE FOR INDEPENDENT CASE MANAGERS

- Designed to help you build a successful case management business
- Includes marketing brochures, administrative & practice management tools, templates and access to an online forms library
- Complete with a copy of The Case Manager's Handbook, Sixth Edition and Direct-to-Consumer Case Management Guide provided
- Provides mentorng access with experienced industry leaders

ORDER NOW!

To learn more about these career-advancing resources and others click here, or call: 631-673-0406.

M&A
MULLAHY AND ASSOCIATES

REFER A COLLEAGUE TO ACCM

Help your colleagues maintain their certification by referring them to ACCM for their continuing education needs. They can join ACCM at www.academyCCM.org/join or by mailing or faxing the Membership Application on the next page to ACCM.

Why join ACCM? Here are the answers to the most commonly asked questions about ACCM Membership:

Q: Does membership in ACCM afford me enough CE credits to maintain my CCM certification?

A: If you submit all of the CE home study programs offered in *CareManagement*, you will accumulate 90 CE credits every 5 years.

Q: Does membership in ACCM afford me enough ethics CE credits to maintain my CCM certification?

A: If you submit all of the CE home study programs for ethics credits offered in *CareManagement*, you will accumulate at least 10 ethics CE credits every 5 years.

Q: Are CE exams available online?

A: Yes, ACCM members may mail exams or take them online. When taking the exam online, you must print your certificate after successfully completing the test. ***This is a members only benefit.*** If mailing the exam is preferred, print the exam from the PDF of the issue, complete it, and mail to the address on the exam form.

Q: Where can I get my membership certificate?

A: Print your membership certificate instantly from the website or click here. Your membership is good for 1 year based on the time you join or renew.

Q: How long does it take to process CE exams?

A: Online exams are processed instantly. Mailed exams are normally processed within 4 to 6 weeks.

Q: Do CE programs expire?

A: Continuing education programs expire approximately 6 months from date of issue. Continuing education programs that offer ethics CE credit expire in 1 year.

Q: Is your Website secure for dues payment?

A: ACCM uses the services of PayPal, the nation's premier payment processing organization. No financial information is ever transmitted to ACCM.

application on next page

CareManagement

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

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

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

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

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

Copy Editor: Jennifer Maybin
e-mail: jmaybin@academyccm.org

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

ACCM
ACADEMY OF CERTIFIED CASE MANAGERS

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

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

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

Vol. 30, No. 3, June/July 2024.
CareManagement (ISSN #1531-037X) is published electronically six times a year, February, April, June, August, October, and December, and its contents are copyrighted by Academy of Certified Case Managers, Inc., 2740 SW Martin Downs Blvd. #330, Palm City, FL 34990;
Tel: 203-454-1333; Fax: 203-547-7273.

ACCM
ACADEMY OF CERTIFIED CASE MANAGERS

Membership Application

Do not use this application after December 31, 2024

Join or renew ACCM online at www.academyCCM.org

❑ I wish to become a member. Date _____

First Name Middle Name Last Name

Home Address

City State Zip

Telephone Fax e-mail (required)

Certification ID #_____ *(ACCM mailings will be sent to home address)*

Practice Setting:

Which best describes your practice setting?

❑ Independent/Case Management Company
❑ Rehabilitation Facility
❑ Medical Group/IPA
❑ Hospice
❑ Consultant
❑ HMO/PPO/MCO/InsuranceCompany/TPA
❑ Hospital
❑ Home Care/Infusion
❑ Academic Institution
❑ VA
❑ DOD/Military
❑ Other: _____

JOIN ACCM TODAY!

❑ 1 year: $130 (year begins at time of joining)

❑ Check or money order enclosed made payable to: **Academy of Certified Case Managers.**
Mail check along with a copy of application to:
Academy of Certified Case Managers, 2740 SW Martin Downs Blvd. #330, Palm City, FL 34990.

❑ Mastercard ❑ Visa ❑ American Express If using a credit card you may fax application to: 203-547-7273

Card # _____ Exp. Date: _____ Security Code:_____

Person's Name on Credit Card:_____ Signature: _____

Credit Card Billing Address:_____

City: _____ State:_____ Zip: _____

For office use only:_____ **Membership #**_____ **Membership expiration** _____

HEALTH CARE CASE MANAGEMENT

GET CERTIFIED.

STAY CERTIFIED.

DEVELOP OTHERS.

*The CCM is the oldest, **largest and most widely recognized** case manager credential.*

Ready to demonstrate your value?

When you become a CCM®, you join the top tier of the nation's case managers. It's a commitment to professional excellence, elevating your career and influencing others.

Those three letters behind your name signal the best in health care case management.

Employers recognize proven expertise. Among employers of board-certified case managers:

- 44% require certification
- 58% help pay for the exam
- 43% help pay for recertification

Join the ranks of more than 50,000 case managers holding the ***only*** cross-setting, cross-discipline case manager credential for health care and related fields that's accredited by the National Commission for Certifying Agencies.

You're on your way to great things.

GET CERTIFIED. STAY CERTIFIED. DEVELOP OTHERS.

CCMC®

Commission for Case Manager Certification | 1120 Route 73, Ste. 200 | Mount Laurel, NJ 08054
ccmchq@ccmcertification.org | www.ccmcertification.org | 856-380-6836

H2R.072022.CMBOK