CareManagement

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

Vol. 29, No. 5 October/November 2023

INSIDE THIS ISSUE

CONTINUING EDUCATION ARTICLES:

SPECIAL SECTIONS:

DEPARTMENTS:

Gary S. Wolfe

Celebrating National Case Management Week

National Case Management Week, October 8–14, is just concluding. The theme, Keeping the Person at the Heart of Collaborative Care, demonstrates the foundation of case management—the patient. Case management focuses on patient-centered care, bringing the diverse components of health care—provider, facilities, programs, families—together to achieve the best outcomes for a specific situation for a person. Yes, we should celebrate case managers because it is case managers that bring together all the components to make health care "work" for each patient. It is a time to be proud and to recognize case management work.

With the growing complexity of health care delivery, case managers are needed and the demand for them continues to accelerate. Unfortunately, health care is fragmented, disoriented, and confusing to many. Because of the recent COVID-19 pandemic, the way that health care is delivered has probably changed forever. The increase in knowledge about disease and treatment continues to grow. Technology now allows us to do things that were only dreams and in our imagination a few years ago. All of these things point out the continued and growing demand for case managers.

What we do as case managers makes a significant difference and helps patients move across the health care continuum successfully. The core of case management at this year's National Case Management Week was the theme of collaboration. If other health care workers were collaborating, case managers would not be needed but these others aren't. As health care delivery continues to grow in complexity, the need for collaboration will also continue to grow, increasing the demand for case managers.

The demands on a case manager are rigorous. In the end, you, the case manager, rise to the occasion with a smile on your face! Although at times you wonder, you know you DO make a difference every single day.

I recognize the work a case manager does is demanding and challenging. I know that with increasing caseloads, sometimes you wonder, when will it stop? Did I get everything done today? Why aren't there more resources available when I need them? The demands on a case manager are rigorous. In the end, you, the case manager, rise to the occasion with a smile on your face! Although at times you wonder, you know you DO make a difference every single day. To you, what may be routine probably has a big, positive impact on the patient. You may or may not hear a lot of thank yous from patients, managers, or co-workers. Instead, it may just be a beautiful smile just when you need it! It may be a lovely card sometime after that patient was discharged from your services. You know, the patient knows, and your employer knows, you make a difference. You are providing the core services of collaborative care, and you do it well!

continues on page 34

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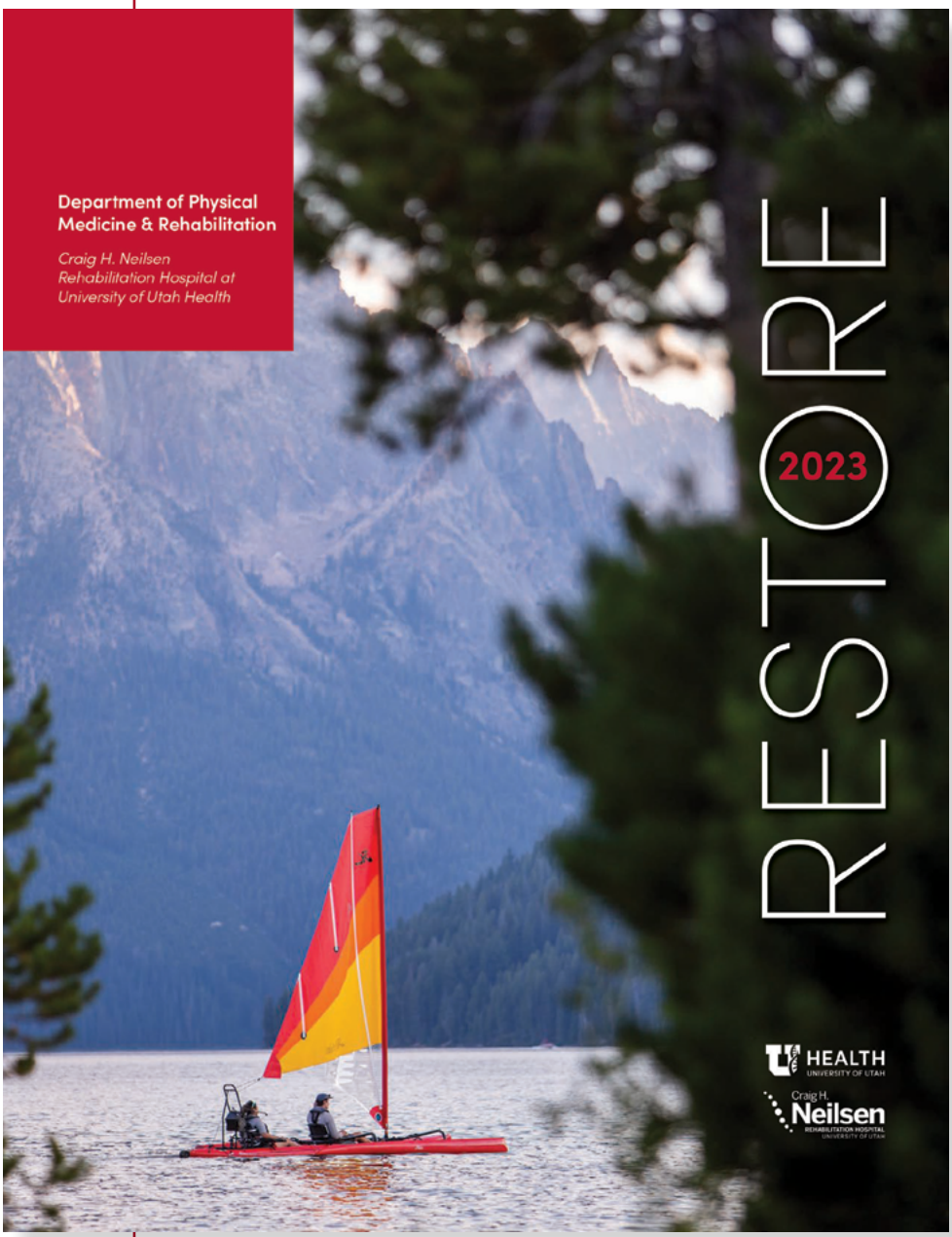
WHEN INSPIRED PATIENTS MEET INNOVATIVE CARE, AMAZING STORIES ARE WRITTEN.



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Catherine M. Mullahy

Professional Development, Interprofessional Collaboration, and Case Management Recognition

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

As we recognize and celebrate National Case Management Week this month, we should also examine the elements of professional development and interprofessional collaboration that will result in the kind of recognition that case managers deserve. Perhaps "deserve" is not really accurate or warranted because case managers, as accountable professionals, have a heightened responsibility to pursue excellence on behalf of their patients. "Keeping the patient at the heart of collaborative care" is the theme for this designated week, and of course, should be a continuous mission and one that shines a spotlight on the work that we do.

With the many distractions, increased workloads, and continuing staff shortages, it's more than a little challenging to accomplish everything expected of case managers and meet the expectations of our patients, their families, our colleagues, and other members of the health care team. Do we merely pay lip service to such an ideal goal, or do we need to take constructive steps to ensure that it becomes a reality?

In this issue of *CareManagement*, there are several articles that will provide you with actionable concepts, motivation, and "food for thought." I have been a member of the National Transition of Care Coalition (NTOCC) Pharmacy Advisory Task Force since 2021. Case managers across the care continuum have long recognized that a lack of proper medication use and appropriate medication management, especially across transitions of care, can result in readmissions. In the article, "All Hands on Deck: An Interprofessional Collaboration Model for Successful Transitions of Care," Sierra Weathers, MSN, APRN, and her colleagues illustrate how this model of care can be implemented with the inclusion of the pharmacist as an active participant in the TOC Care Management Team. The article provides a wonderful overview of a successful program at an academic medical center that includes an RN care manager, social worker care manager, care management navigator, and the pharmacist! As this successful model illustrates so well, it's not just one member of the team who is more important than the next, but rather, each one is essential to the overall success. Keeping the patient at the center of their involvement is key. The Ten Principles that were established by the task force, as well as the delineation of the role of the TOC pharmacist might serve as inspiration for you or your team.

Education for case managers is not a mandate; yet, it needs to be more than an obligatory process to maintain the continuing education requirements of a professional license and certification.

Education for case managers is not a mandate; yet, it needs to be more than an obligatory process to maintain the continuing education requirements of a professional license and certification. Far too many professionals, however, have unrealistic expectations concerning just who is responsible for the maintenance of licenses and certification. The author, Rebecca Perez, RN, MSN, CCM, FCM, a newly appointed member of our Editorial Advisory Board, affirms in her article "Professional Growth and Development: The Path to Excellence" that the individual professional is responsible for that and further asserts that they must become lifelong learners (ie, participate in more than what is required). While continuing education certainly benefits the individual case manager, more importantly, it ultimately benefits our patients, and isn't that what we want? Perez provides a professional growth or development plan. As you read through her article, you will recognize many of the components of the case management process. Why not take steps to prioritize your education and professional development…for you and on behalf of those who will be the beneficiaries of your intervention?

In her article "The Intersection of Ethics and Technology: Evaluating the Ethical Implications of Digital Mental Health Apps," Chikita Mann, RN, MSN, CCM, PGAP, a frequent

continues on page 35

Speaking With One Voice: 3 Case Management Organizations Celebrate Case Managers

By MaryBeth Kurland, MPA, CAE, ICE-CCP

For more than 20 years, National Case Management Week has been observed during the second week of October. This year, the celebration—October 8 to 14—made case management history. The 3 leading organizations in case management—Commission for Case Manager Certification (CCMC), Case Management Society of America (CMSA), and American Case Management Association (ACMA)—joined together to speak with 1 voice to recognize the contributions of case managers.

In the past, each organization observed National Case Management Week separately. This year, however, CCMC, CMSA, and ACMA came together for the greater good of the profession with an aligned theme: *Keeping the Person at the Heart of Collaborative Care,* as outlined in their joint statement.

Each organization brought unique expertise, resources, and perspectives to the group to support the creation of a stronger collective voice for case managers, enabling them to advocate for improved care, professional standards, and policy changes. Additionally, to further elevate the contribution of case managers across health and human services, CCMC, CMSA, and ACMA held activities and events during National Case Management Week, including professional development opportunities such as CCMC's Virtual Symposium. Through these offerings, case managers will be able to build on their skills and strengthen their resilience to serve with compassion.

Across the spectrum of health and human services, professional case managers are on the front lines of ensuring quality, safety, cost consciousness, and other goals of value-based care delivery.

Case managers are change agents, skilled professionals, and lifelong learners. Through their advocacy, case managers connect millions of people to the clinical and community resources they need. They accomplish this through such actions as:

- **Providing collaborative care—**This approach puts the individual at the center of decision-making. By focusing on each person's unique needs, preferences, and goals, collaborative care promotes the individual's engagement, improved health outcomes, and satisfaction.
- **Improving the health care system—**As change agents within the health care system, case managers drive improvements, navigate challenges, and empower people to take an active role in their own health care journey. They rely on their highly valued skills of communication and collaboration to drive the best possible outcomes in support of individuals and their goals.

Helping people navigate across the care continuum—across different health care settings—including hospitals, clinics, rehabilitation centers, and home care—case managers help ensure smooth transitions and prevent gaps or delays in care.

Increasingly, the value of professional case managers is being recognized across health care and human services. However, more can be done to elevate this profession. For example, a recent study by J.D. Power found that among patients reporting the worst health status, only 17% were assigned a case manager to help guide care and communicate as a patient advocate with the rest of the health team. This is a missed opportunity, particularly for individuals with complex health conditions who are treated by multiple providers. When care delivery is fragmented, it can lead to poor outcomes, particularly among those who would most benefit from care coordination, which is a cornerstone of case management.

Across the spectrum of health and human services, professional case managers are on the front lines of ensuring quality, safety, cost

continues on page 34

MaryBeth Kurland, MPA, CAE, ICE-CCP, *is 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.*

Celebrate National Case Management Week: Keeping the Person at the Heart of Collaborative Care

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

This year, the Case Management Society of America (CMSA), the Commission for Case Manager Certification (CCMC), and the American Case Management Association (ACMA) collaborated and joined together to shine a spotlight on the important role that case managers play on the health care team. Together, these esteemed organizations leveraged their collective impact to raise awareness about the importance of case management.

National Case Management Week, held annually during the second week of October, is a week of appreciation, recognition, and celebration as we honor case managers, the dedicated professionals who make a difference in the lives of countless individuals and families. National Case Management Week is a time to reflect on the impact that case managers have on our health care systems, social services, and beyond.

The time of being "the best kept secret in all of health care" needs to end! I encourage YOU to step up and tell the world how case management matters!

The care continuum encompasses the entire journey of an individual's health and well-being from prevention and early intervention to acute care, rehabilitation, and beyond. It's a complex web of services and interventions that often require seamless coordination to ensure the best outcomes. This is where YOU, as case managers, step in, bridging gaps, reducing fragmentation, and paving the way for comprehensive, patient-centered care.

YOU are the compasses that guide individuals through complex health care systems, ensuring they receive the best care possible. YOU are the advocates who work tirelessly to address medical, emotional, and practical needs. From work in hospitals to social service agencies, YOU empower patients to make informed decisions and navigate their journeys to recovery and well-being.

National Case Management Week serves as a reminder to recognize and celebrate the vital work of YOU, case managers across the care continuum. It reminds us that every small step taken by a case manager has a profound impact on the lives of those they serve. Whether it's assisting patients in coordinating appointments, connecting them with community resources, or providing emotional support, you are the lighthouses that illuminate the path forward. YOUR tireless dedication, compassionate guidance, and unwavering commitment to improving lives deserve our utmost appreciation. As the recognition of National Case Management Week honors professional case managers across disciplines, settings, and the continuum of care, let's also advocate for our continued professional development, adequate resources, and recognition as integral members of the health care and social services ecosystem on a daily basis.

During National Case Management Week, case managers across the globe participated in educational events, networking sessions, recognition ceremonies, and activities to both recognize the important work being done and to reward our vital case managers with prizes and fun!

The time of being "the best kept secret in all of health care" needs to end! I encourage YOU to step up and tell the world how case management matters! CM

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

Always a Nurse, Forever a Case Manager

Wendy Jaffe, RN, MSN, CCM

Having retired from a more-than-40-year career in nursing of which the last 25 years were as a case manager, I looked forward to doing the things I've always wanted to do but did not have the time since I worked full time and overtime.

But as the saying goes, once a nurse always a nurse; it's in our blood. I was called on to help my neighbor who was 76 years old and facing major surgery: open heart. She had very little family and I felt compelled to help her in any way I could. I knew I had helped many patients that I didn't know personally, and here was my neighbor who needed my help.

My background as a case manager was an asset when I had to navigate the health care system to ensure my neighbor received the care she needed.

My journey began when I asked her how she was getting to the hospital for her surgery, and she replied, "taking a cab." I immediately told her I would take her and be there for her as she went through the preoperative process. I made sure her wishes were known to the surgical team, interpreted the medical lingo for her so she understood, and had them go over the surgical procedure until she was comfortable. I was there by her side to guide her through the myriad health care professionals asking her all their questions, and I helped explain to her in language she would understand what was going to happen.

I picked her up from the rehab and when we got home, I asked for her discharge papers and to my dismay, she told me no one had come by to give them to her. I immediately called the facility, left messages to call us, and unfortunately we received no return call.

I felt she relaxed, knowing she was in good hands, and that I would be there to help when needed.

I coordinated her discharge with the hospital social worker and found several 5-star rehab facilities by searching on Medicare.gov. We reviewed all the rehab facilities, and together my neighbor and I selected one near her home and one where her friends could visit. My neighbor had lived alone for over 30 years; she feared having to share her room with a stranger. What a surprise it was when I found out the rehab only had private rooms and the fear of having to share her room was alleviated. My neighbor asked me to attend her multidisciplinary team discharge meeting to discuss what we felt she would need at home since she lived alone. Home health care was essential, and together we decided on Advocate Home Health, which was in her network and associated with the hospital and facility so there would be continuity of care.

I picked her up from the rehab and when we got home, I asked for her discharge papers and to my dismay, she told me no one had come by to give them to her. I immediately called the facility, left messages to call us, and unfortunately we received no return call. I then called the home health agency, and the intake nurse was exceptional and contacted the rehab facility, received all the orders for discharge, and called in my neighbor's medications to her local pharmacy where I went to pick them up. We called the oxygen company right away and when they came out the technician and I helped to explain the oxygen setup for her. I then assisted with her medication setup, explaining all the new prescriptions she was on and provided her with the information on the importance of these medications and when to take them.

Since she was not allowed to drive yet, I took her to her postoperative visit with her cardiologist who, as an extremely busy surgeon, breezed in and breezed out, offering minimal help for her postoperative care. The nurse practitioner then came in and was very helpful and spent a lot of time explaining the postoperative course of treatment. Together, she, my neighbor, and

continues on page 34

Wendy Jaffe, RN, MSN, CCM, *has worked in a variety of settings and has spent the last 25 years in case management. She currently works part time for Brightstar Care Agency in Chicago.*

CMS Issues Memo to Hospitals About Requirement to Provide Information to Post-Acute Providers

Elizabeth E. Hogue, Esq.

On June 6, 2023, the Centers for Medicare & Medicaid Services (CMS) issued a memo to hospitals to remind them of their obligation to provide all necessary information to postacute providers (PACs) as part of the discharge process. "When a patient is discharged from a hospital, it is important to provide their postacute provider and caregivers, as applicable, with the appropriate patient information related to a patient's treatment and condition in order to decrease the risk of readmission or an adverse event," CMS said in the memo.

CMS is especially concerned about missing or inaccurate information related to:

- Patients with serious mental illness, complex behavioral needs, and/or substance use disorder, especially information about patients' underlying diagnoses and specific treatments that were implemented to help manage patients' conditions while in the hospital, but discontinued before discharge
- Medications, including an incomplete comprehensive list of all medications prescribed to patients during and before their hospital admissions. Common omissions also include diagnoses or problem lists, clinical indications, lab results, and/or clear orders for medications postdischarge, especially psychotropic medications, and narcotics
- Skin tears, pressure ulcers, bruising, and lacerations, such as surgical sites, skin conditions noted on admission, and/or acquired during hospitalizations, including orders or instructions for cultures, treatments, and dressings
- Durable medical equipment (DME), such as Trilogy, CPAP/BiPap, or high-flow oxygen used for respiratory treatments and skin healing equipment, such as mattresses, wound vacuum machines for treatment of a variety of wounds
- Patients' preferences and goals for care, such as choices for treatment and advance directives for end-of-life care
- Communications about patients' needs at home or how their home environment may impact their ability to maintain their health and safety after discharge.

CMS says that failure to provide complete, accurate information on discharge may put patients' health at risk. The health and safety of other residents and staff may also be at risk.

CMS says that failure to provide complete, accurate information on discharge may put patients' health at risk. The health and safety of other residents and staff may also be at risk. Incomplete and/or inaccurate information may also cause avoidable readmissions, complications, and other adverse events. Patients may also receive treatments that are unnecessary or inconsistent with their wishes.

CMS reminds state survey agencies, accrediting organizations, and hospitals in the memo that regulations of the Medicare Program require hospitals to "have an effective discharge planning process that focuses on the patient's goals and treatment preferences and includes the patient and his or her caregivers/support person(s) as active partners in the discharge planning for post-discharge care."

In addition, says CMS, "The hospital must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, postdischarge goals of care, and treatment preferences, at the time of discharge, to the appropriate postacute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care."

CMS concluded the memo by acknowledging that hospitals have discretion to develop their own policies and procedures to meet the above requirements. However, CMS makes the following recommendations to hospitals regarding discharge planning:

- Collaborate with PAC providers by, for example, agreement on standardized processes

continues on page 34

US Supreme Court Says Government Can Dismiss Whistleblower Lawsuits

Elizabeth E. Hogue, Esq.

Texas Children's Hospital has been cited by the US Department of Labor Occupational Safety and Health Administration (OSHA) for failing to protect employees from being physically assaulted by aggressive patients. In 2022, the hospital recorded 15 incidents in which aggressive patients attacked employees. The citation references an incident from November 10, 2022, for example, in which an aggressive patient "pulled a security officer to the ground by the hair and kicked them repeatedly in the chest and abdomen." The officer lost consciousness and was taken to the emergency department and hospitalized.

After an investigation, OSHA concluded that the hospital had inadequate policies and procedures to protect its employees from physical assault by patients. Nurses and aides were among the workers exposed to physical threats and assault. This citation involving violence follows another issued by OSHA against a homecare agency.

OSHA issued a $98,000 fine for an alleged willful violation of applicable requirements related to exposure to workplace violence, including physical and sexual assault. The citation was based on an investigation that began after a staff member was assaulted by a homecare client. In this case, a staff member who previously took care of the client had warned the agency about sexual assaults by the client. OSHA concluded that the agency failed to protect its staff from life-threatening hazards of workplace violence. According to OSHA, the agency also failed to provide an effective workplace violence prevention program.

The highest obligation of all homecare providers is to protect their employees. Possible action by OSHA provides a "road map" for providers to follow as they continue to work to address the issue of violence against staff.

Specifically, OSHA took issue with 2 types of conduct by the agency:

- Staff members were exposed to physical assault.
- There was no system in place for staff to use to report threats and instances of violence to the agency.

Contributing to the highest obligations of all homecare providers is to protect their employees. Possible action by OSHA described above provides a "road map" for providers to follow as they continue to work to address the issue of violence against staff. Violence is not part of the job description! CM

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

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The Intersection of Ethics and Technology: Evaluating the Ethical Implications of Digital Mental Health Apps

Chikita Mann, RN, MSN, CCM, PGAP Provider

Mental health disorders have been cited as a leading cause of disability worldwide. In the United States alone, there was a documented estimate of 57.8 million adults with mental illness in 2021. But only half of these individuals actively seek or have the financial means to obtain treatment. (NIMH 2023) Because of the COVID-19 pandemic, the World Health Organization (WHO) created a declaration—the Public Health Emergency of International Concern (PHEIC)—which highlighted the need for better access to mental health services. (Molfenter et al 2021) And there is a profound lack of available behavioral health clinicians to keep up with the demand for services. (Muench & Fraze 2022)

Amid the COVID-19 pandemic, when social distancing measures and lockdowns profoundly affected people's lives, digital mental health apps emerged as a lifeline for individuals seeking support and guidance during these unprecedented times. Out of more than 5 million mobile phone applications available through iTunes and Google Play, there are currently over 10,000 mental health apps. (Caron 2022) Most of digital health technology rests under the umbrella of the 5 largest technology companies—Apple, Google, Facebook, Amazon, and Microsoft. These technological solutions have provided a means of remotely accessing mental health resources, offering a semblance of connection and assistance when traditional in-person services were limited or inaccessible. (Storeng et al 2021)

However, as we navigate the intersection of ethics and technology, it becomes crucial to explore the ethical implications embedded within the realm of digital mental health apps. This article examines how these apps, propelled by the demands of the pandemic, have revolutionized mental health care delivery and also delves into the ethical considerations that arise when leveraging technology to address individuals' mental well-being. By evaluating these implications, we can better understand how these apps can be ethically developed, implemented, and regulated to ensure their positive impact on mental health while upholding the principles of autonomy, informed consent, privacy, and equality (justice).

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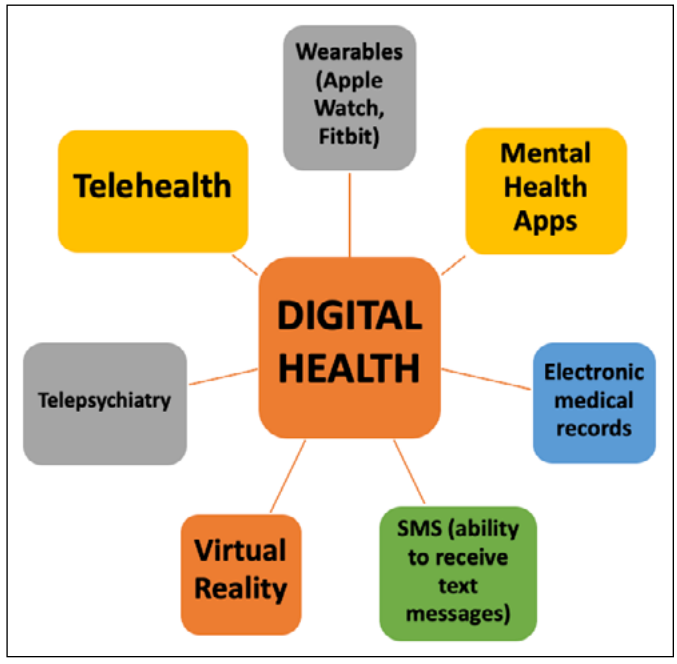
Technology and Mental Health

Let's explore the beginning of the intersection of technology and mental health to gain a better understanding of the ethics associated with this unique collaboration. In the early stages, technology was primarily used to gather and analyze data, aiding in the diagnosis and treatment of mental health

Figure 1 **DIGITAL HEALTH PLATFORMS**



From mobile applications that offer meditation and stress management techniques to virtual reality therapy for phobias and anxiety disorders, technology has created new avenues for individuals to access mental health resources conveniently.

conditions. This is shown in technology's relationship with the Diagnostic and Statistical Manual of Mental Disorders (DSM). The DSM is a widely used classification system that helps clinicians diagnose and treat mental health conditions. With the advent of technology, the DSM (now in version 5) has become more accessible and easier to navigate. Digital versions of the DSM-5 allow for quick searches, cross-referencing, and updates, making it more efficient for mental health professionals to use in their practice. Additionally, technology has facilitated the development of digital assessment tools and screening measures that align with the DSM criteria, aiding in the diagnostic process (Figure 1).

With advancements in artificial intelligence (AI) and digital platforms, technology now plays a more active role in providing mental health support. From mobile applications that offer meditation and stress management techniques to virtual reality therapy for phobias and anxiety disorders, technology has created new avenues for individuals to access mental health resources conveniently. It continues to be an exciting and promising field, with ongoing research and development aimed at improving the effectiveness and accessibility of mental health services through technology.

Telepsychiatry

Telepsychiatry, in its early stages, emerged as a response to the need for mental health services in underserved areas and for individuals with limited access to traditional in-person care. It was primarily used to bridge the geographical gap between patients and psychiatrists, allowing remote consultations through videoconferencing or telephone calls. This approach aimed to increase the availability and accessibility of mental health care, particularly in rural or remote regions where mental health professionals were scarce. Telepsychiatry also proved beneficial for individuals with mobility limitations or those who faced barriers to seeking in-person treatment. Videoconferencing, compliant with HIPAA privacy rules, has become routine with psychiatrists internationally. (Achtyes et al 2023) By leveraging technology, telepsychiatry provided a means for psychiatrists to conduct assessments, provide therapy, and prescribe medications remotely, ensuring that individuals could receive the care they needed regardless of their location or circumstances.

Even though great strides have been made in psychiatric care due to technology, we would be remiss in not discussing the challenges encountered in telepsychiatry. One of the primary concerns is ensuring the privacy and security of patient information. Transmitting sensitive mental health data over digital platforms requires robust encryption and secure communication channels to protect patient confidentiality. Additionally, establishing a therapeutic rapport and maintaining therapeutic boundaries can be more challenging in a remote setting. Nonverbal cues and subtle nuances may be missed, potentially impacting the accuracy of assessments and treatment plans. Moreover, technical issues such as poor internet connection or audiovisual glitches can disrupt the flow of the session and hinder effective communication. Lastly, there may be limitations in conducting physical examinations or administering certain treatments remotely, which can impact the comprehensive care that can be provided.

Digital Mental Health Firms

The advent of digital mental health firms has brought about significant changes in the way mental health services are accessed and delivered. It is projected that online therapy services will grow at a rate of 28.42% annually through the year 2027. These for-profit firms leverage technology to provide convenient and accessible platforms for individuals seeking mental health support. These firms are primarily consumer driven with advertising mainly through social media and internet ads. (Achtyes et al 2023) These firms' success capitalizes on the premise that clients should be active participants in their health care. Through mobile applications and online platforms, users can access a range of services including therapy sessions, self-help resources, and mental health assessments. Some even offer membership plans. The availability of these digital platforms has expanded access to mental health care, particularly for those who may face barriers such as geographical limitations or stigmatization. (Achtyes et al 2023)

Artificial Intelligence

The integration of AI in the field of mental health marks an exciting development in recent years. At its inception, AI was primarily used to assist in data analysis and research, providing valuable insights into mental health trends and patterns. However, as technology advanced, AI began to play a more

active role in supporting individuals' mental well-being. AI-powered chatbots and virtual assistants now offer personalized and accessible mental health support, providing users with a safe space to express their thoughts and emotions. These AI systems can offer coping strategies, provide psychoeducation, and even detect early signs of mental health issues. While AI in mental health is still in its early stages, it holds great potential to enhance the accessibility and effectiveness of mental health care, reaching individuals who may not have had access to traditional services. (Fiske et al 2019, Ray et al 2022).

However, there are some disadvantages of AI. Mental health has been built on the use of soft skills, such as observing emotions and behaviors and building rapport. AI obviously does not possess these skills. AI is also unable to convey empathy and compassion. Lacking are regulatory standards that govern the use of AI in mental health, which poses privacy and security concerns for the provider and the client. (Ray et al 2022)

Ethical Implications

For the board-certified case manager, the first resource that provides a guide for ethical standards is the Code of Professional Conduct for Case Managers and Certified Disability Management Specialist (CDMS) regularly (CCMC®, 2015) (Figure 2).

Figure 2 **PRINCIPLES OF THE CODE OF PROFESSIONAL CONDUCT FOR CASE MANAGERS**

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

Distributive Justice (or Equity)

To fully address the ethical principle of distributive justice, one must take into consideration digital inclusion and digital divide.

Digital Inclusion

Digital inclusion in health care refers to ensuring equal access and utilization of digital technologies and resources in health care services. It is now being deemed as a super social determinant of health because of the impact it has on the other social determinants of health. (Sieck et al 2021) It emphasizes the ethical principle of justice by promoting fairness and equal treatment in health care delivery. By providing access to digital tools, such as telehealth platforms, electronic health records, mobile health applications, and online patient portals, individuals from diverse backgrounds can participate more actively in their own health care (Figure 3). Digital inclusion in health care enables patients to schedule appointments, access medical information, communicate with health care providers, receive remote consultations, and manage chronic conditions from the comfort of their homes. It also empowers health care providers to deliver more efficient and personalized care. With health care transitioning to a "digital first" stance, digital inclusion is becoming increasingly interwoven with health care equity. (Rodriguez et al 2022, Sieck et al 2021)

Figure 3 **COMPONENTS OF DIGITAL INCLUSION (JAUREGUI 2022)**

1. Affordable internet access
2. Devices enabled to access the internet that is tailored to the user
3. Digital literacy training
4. Supreme technical support
5. Online content and applications that encourage self-sufficiency, collaboration, and participation

There have been different efforts related to increasing digital inclusion. President Biden signed a $1.7 trillion bill (Bipartisan Year-End Omnibus) that includes the creation of a Digital Health Equity Program. The National Digital Inclusion Alliance (NDIA) was created to be an entity that advocates for local, state, and federal agencies to prioritize digital equity. They help digital inclusion programs broaden their efforts and reach those who are greatly affected by digital divide. (National Digital Inclusion Alliance)

Unfortunately, allocated resources to improve digital inclusion have not been fully implemented. The

AI-powered chatbots and virtual assistants now offer personalized and accessible mental health support, providing users with a safe space to express their thoughts and emotions.

COVID-related Emergency Broadband Benefit, which helps with internet and device acquirement, has not been fully utilized. (Sieck et al 2021) Individuals with intellectual and learning disabilities are still unable to adequately use digital health for their health care needs. (Fitzpatrick & Trninic 2022) Health care organizations have not fully invested in efforts to expand digital inclusion. (Rodriguez et al 2022) By prioritizing digital inclusion in health care, we can enhance the quality of health care services, reduce disparities, and ensure that everyone has equal opportunities to benefit from the advancements in digital health technologies.

Digital Redlining

Digital redlining refers to the discriminatory practice of excluding certain communities or individuals, often based on socioeconomic factors, from equitable access to digital resources and opportunities. Similar to traditional redlining, which involved denying services or resources to specific neighborhoods or communities based on racial or ethnic discrimination, digital redlining perpetuates systemic inequalities in the digital realm. It manifests through limited internet access, inadequate infrastructure, lack of digital literacy programs, and unequal distribution of technological resources, which further marginalizes already disadvantaged populations. This exclusionary practice reinforces and deepens existing socioeconomic disparities, hindering equal participation and access to the benefits of the digital age. (McCall et al 2022)

As technology increasingly becomes a primary gateway to health care services and information, marginalized communities are often left behind because of the unequal distribution of digital resources. Digital redlining exacerbates existing health disparities by limiting access to online health platforms, telehealth services, and health information databases for underserved populations. This exclusionary practice reinforces the systemic barriers faced by marginalized communities, such as limited internet connectivity, low digital literacy, and socioeconomic constraints. As a result, individuals from these communities face hurdles in accessing critical health resources, leading to unequal health outcomes and exacerbating health disparities. Digital redlining is compounded by other factors, such as lack of access to internet-capable devices and high prices for broadband services. (Rodriguez et al 2022, Sieck et al 2021)

As a result, individuals who are already facing barriers to health care access encounter further hurdles in accessing digital health services, telemedicine, health information, and digital tools for self-care and prevention. Addressing digital redlining is crucial to bridging the digital divide in health care and ensuring that all individuals, regardless of their socioeconomic status or geographic location, have equal opportunities to benefit from the advancements in digital health technologies and resources.

Autonomy and Informed Consent, Privacy, and Beneficence

Ethical principles associated with digital literacy in health care include autonomy and informed consent, privacy, and beneficence. To fully understand this, digital literacy in health care must be explored.

Digital Literacy

Digital literacy in health care plays a crucial role in empowering individuals to navigate the complex landscape of health information technology. It encompasses the knowledge, skills, and attitudes needed to effectively access, evaluate, and utilize digital health resources. For patients, digital literacy enables them to access online health information, engage in telehealth services, and effectively use health-related apps and wearable devices. It allows patients to take an active role in managing their health, making informed decisions, and participating in shared decision-making with health care providers. Health care professionals with digital literacy can efficiently use electronic health records, access evidence-based resources, and leverage digital tools for communication, collaboration, and remote monitoring. It enhances their ability to provide quality care, stay updated with medical advancements, and engage in continuous professional development. In health care administration, digital literacy is essential for managing electronic systems, ensuring data security and privacy, and implementing efficient workflows. It enables administrators to leverage technology for streamlining processes, improving patient outcomes, and making data-driven decisions.

Autonomy and Informed Consent

Autonomy is upheld when individuals have the necessary digital literacy to actively participate in their health care decisions and engage with their health data. Autonomy and

Digital redlining refers to the discriminatory practice of excluding certain communities or individuals, often based on socioeconomic factors, from equitable access to digital resources and opportunities.

informed consent are crucial ethical considerations in the realm of digital mental health. Autonomy refers to an individual's right to make decisions about their own well-being, including their mental health. Informed consent, on the other hand, involves providing individuals with comprehensive information about the nature, risks, benefits, and alternatives of a particular intervention or treatment, allowing them to make an informed decision.

In the context of digital mental health, autonomy and informed consent become particularly important due to the unique nature of these apps. Users must have the freedom to choose whether to engage with these technologies and to understand the potential implications. They should be fully informed about the purpose, features, and limitations of the app, as well as any potential risks to their privacy and data security. Digital mental health apps should prioritize transparency and ensure that users have access to clear and understandable information about the app's data collection practices, how their information will be used, and any potential third-party involvement. Users should also be able to provide or withdraw consent for data sharing or participation in research. (Kopka et al 2023)

Respecting autonomy and informed consent in the digital mental health space involves empowering users to make informed decisions about their own mental health care. It also requires developers and providers to design apps that prioritize user privacy and data security and adhere to ethical guidelines. By upholding these principles, the intersection of autonomy, informed consent, and digital mental health can promote user agency and foster a trusting and ethical relationship between users and these technologies.

Privacy

Privacy is safeguarded when individuals possess the skills to protect their personal health information and understand the implications of sharing data online. Digital mental health apps collect and store sensitive personal information. Users often share personal details, symptoms, and even thoughts and feelings through these apps, which raises concerns about data privacy and confidentiality. Additionally, users should be informed about how their data will be used, who will have access to it, and the steps taken to ensure its protection. Transparency and obtaining informed consent are essential to uphold the principle of privacy in the context of digital mental health apps. However, health care providers must exercise caution and adhere to the Privacy Rule's provisions to strike a balance between sharing necessary information to facilitate coordinated care while respecting individuals' privacy rights and maintaining the confidentiality of their mental health information.

Beneficence

The ethical principle of beneficence, which emphasizes the promotion of well-being and the provision of benefits to individuals, is both influenced and impacted by the use of digital mental health apps. On one hand, these apps have the potential to enhance access to mental health resources, providing convenient and immediate support to individuals in need. They can offer a wide range of tools, such as self-help techniques, mindfulness exercises, and therapy modules, which can empower users to manage their mental health effectively.

However, the ethical implications arise when considering the quality and effectiveness of these apps. It is crucial to ensure that digital mental health apps are evidence-based, reliable, and developed by qualified professionals. The principle of beneficence requires that these apps genuinely benefit users and contribute to their well-being. Therefore, developers and providers of these apps must prioritize user safety, privacy, and the delivery of accurate information and interventions. Additionally, the principle of beneficence also calls for the consideration of potential harms and risks associated with digital mental health apps. Potential harms include self-diagnosis and self-medication. Self-medication is increasing at an alarming rate due to nonsanctioned internet pharmacies that sell fraudulent medications. (Achtyes et al 2023) Other issues such as data security, potential algorithmic biases, and the potential for overreliance on technology, may undermine the therapeutic relationship and the importance of human interaction in mental health care.

Special Ethical Concerns Associated With AI and Mental Health App Developers

Privacy

Mental health app developers have a responsibility to ensure that the personal and sensitive information shared by users on their platforms is protected and kept confidential. This includes implementing robust data security measures to prevent unauthorized access or breaches. Mental health app

As technology increasingly becomes a primary gateway to health care services and information, marginalized communities are often left behind because of the unequal distribution of digital resources.

developers should also be transparent about how user data is collected, stored, and used, obtaining informed consent from users regarding data-sharing practices. Respecting user privacy means providing clear and easily understandable privacy policies, allowing users to have control over their data, and ensuring that data are used only for the intended purposes.

Another facet of privacy as it relates to mental health app developers is the privacy policy. Providing easy-to-read privacy policies is crucial for mental health app developers for several reasons. This includes the policy being available in the client's primary language in case their primary language is not English. First, it ensures transparency and builds trust between the app users and developers. Clear and concise privacy policies help users understand how their personal information will be collected, stored, and used within the app. Second, easy-to-read privacy policies empower users to make informed choices about their data privacy. By presenting information in a user-friendly manner, developers enable individuals to understand the potential risks and benefits associated with using the app. Third, accessible privacy policies contribute to user autonomy and control over their personal information. When users can easily comprehend the privacy practices of an app, they are better equipped to exercise their rights, such as opting out of certain data collection or requesting the deletion of their data. (Achtypes et al 2023)

Algorithmic Biases

Algorithmic biases pose a significant concern within the realm of digital mental health apps, potentially exacerbating existing disparities in mental health care. These biases arise when algorithms used in these apps favor certain demographic groups or perpetuate stereotypes, leading to unequal treatment and outcomes. For instance, if an algorithm is trained on a dataset primarily composed of individuals from a specific race or socioeconomic background, it may not accurately capture the diverse experiences and needs of other groups. This can result in inadequate or biased recommendations, diagnoses, or treatment suggestions, further widening the gap in access to appropriate mental health care. It is crucial for developers and providers of digital mental health apps to be aware of algorithmic biases and actively address them by employing diverse and representative datasets, conducting regular audits, and incorporating fairness and equity considerations into the design and implementation of their algorithms.

Case Management Considerations

Board-certified case managers would normally not prescribe mental health treatment, but we are able to advocate for appropriate, safe, and ethical treatment. We are likely able to assist with coordinating care with a mental health provider. Bearing this in mind, here are some steps to consider with this unique type of care.

Best Practices:

1. Exercise caution and adhere to the Privacy Rule's provisions to strike a balance between sharing necessary information to facilitate coordinated care while respecting individuals' privacy rights and maintaining the confidentiality of their mental health information.
2. Assess the client's digital literacy. A common tool for this is the eHealth Literacy Scale. This scale measures an individual's ability to seek, find, evaluate, and apply electronic health (eHealth) information for their own health needs. (Faux-Nightingale et al 2022)
3. If you are arranging care via telepsychiatry, research the provider. What are their credentials? What measures do they take to protect their client's privacy and data safety?
4. Assess the client's understanding of how their privacy should be protected. Did they notice if the provider has a privacy policy in place? What does this mean to them?
5. Ascertain if the client understands the need to be in a private environment when utilizing telepsychiatry. Ask them where they have their sessions. Even at home, they should be in room that provides privacy and the freedom to disclose appropriately with the provider.
6. If the client is in a rural area, ask about their internet coverage. Some clients are unable to participate with telepsychiatry or use a digital mental health app due to lack of internet coverage. This could affect where they are able to conduct their sessions. This may also be an issue to address with the treating provider if they provided a referral for mental health services.
7. If the client has chosen to utilize a digital mental health app, have them show you which app they are using and how they are using it. Perform research on the app to be able to assist them with using it correctly. What devices are they using for telepsychiatry and/or accessing a mental health app?

8. Consult with the client's treating provider to determine if they have diagnosed the client with a mental health condition or if they provided a referral for mental health treatment. The goal is to assess if the client self-diagnosed.
9. Perform medication reconciliation with the client's treating provider(s). Do they have a prescription for all medications (especially medications for a mental health diagnosis)? Could a current medication's side effect be anxiety or depression and the client chose to self-diagnose and seek treatment without a prescription using a mental health app? Have they notified their treating provider of this?
10. Inform the client that you will need to disclose to their treating physician their use of prescribed/nonprescribed mental health treatment, especially if they are taking medications.
11. Assess if there is a language barrier. If there is a language barrier, the client may not fully understand the concepts of privacy and confidentiality. The language barrier could also be a reason why mental health treatment is not being sought.
12. The board-certified case manager should assess their own digital literacy. Digital literacy skills enable health care professionals to effectively communicate and collaborate with colleagues, patients, and other stakeholders through various digital platforms, such as email, telemedicine, and electronic health records. This enhances coordination of care, facilitates remote consultations, and improves overall patient outcomes.

Conclusion

In conclusion, the intersection of digital mental health apps and ethics presents both opportunities and challenges. While these apps offer convenient and accessible resources for mental health support, it is crucial to prioritize ethical considerations. Regulatory frameworks and ethical guidelines can provide a structure for developers and practitioners to navigate this complex landscape. Addressing digital redlining requires a concerted effort to bridge the digital divide, promote digital literacy, and ensure equitable access to health information technology for all, ultimately fostering a more inclusive and just health care system. Safeguarding user privacy, ensuring informed consent, and maintaining data security are paramount. Additionally, addressing algorithmic bias, establishing therapeutic boundaries, and upholding professional accountability are essential for ethical use. Ultimately, by prioritizing user autonomy, promoting evidence-based practices, and empowering individuals, we can harness the potential of digital mental health apps while upholding ethical standards. CE1

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References continued on page 37

CE2 Approved for 1 hour of CCM, CDMS, and nursing education
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All Hands on Deck: An Interprofessional Collaboration Model for Successful Transitions of Care

Abby Arens, MSW, LCSW; Laurice Knox, MPH; Klodiana Myftari, PharmD, BCACP; Elizabeth Valvo, MSW, LCSW, ACM-SW; Sierra Weathers, MSN, APRN

Rush University Medical Center is an academic medical center that focuses on being an anchor hospital on the west side of Chicago. The Ambulatory Care Management department was formed in 2014 in response to the Affordable Care Act, and the mission is to ensure equitable, quality, and accessible care for all patients through care management and navigation support. We established a triad model that consists of nurses, social workers, and care management navigators to complete social determinants of health (SDoH) screenings, transitions of care, and appointment/treatment plan coordination. The model evolved to include pharmacists and became an extension of primary care. Over time, each role solidified their intervention specialty and integration within the care management model, which further led to the development of our Longitudinal Care Management and Social Work Crisis Interventions within the primary care clinic.

This ambulatory care management model largely addresses the needs of our patients during transitions of care, in between hospital visits, and while they are in the community. However, we should note that our team works very closely with our inpatient case management partners to ensure patients' discharge plans are appropriate and followed through even after discharge. This could include completing necessary diagnostic testing, ordering home health services, placing necessary durable medical equipment (DME), ordering labs, and/or requesting close follow-up with specialty practitioners.

When a patient is admitted or discharged from the hospital, this may be their first introduction to the care management model. Our model supports patients across the lifespan including transitions of care from the hospital setting to the community and home when patients are most at risk for readmissions and poor health outcomes. The data suggest that 1 in 5 Medicare beneficiaries are readmitted to the hospital within 30 days. (CMS 2022) The transition of care (TOC) is a pivotal time in one's health journey that is often prone to errors. Some of the errors that commonly occur during TOC are communication breakdowns among health care practitioners, a lack of patient education, and medication reconciliation errors. (The National Board of Medication Therapy Management 2023)

During TOC, our teams work to promote safety through close follow-up, assessment, medication reconciliation, symptom management, and care coordination. The objective of the TOC is to connect the patient back to their primary care practitioner and all appropriate clinicians, such as the pharmacist and specialist, as applicable, with the goal of coordinating care and reducing hospitalizations. We place high importance on educating patients about the necessity of seeing a primary care practitioner after hospitalization or emergency department use, chronic disease management, and medication compliance. All patients are offered a close follow-up appointment between 7 and 14 days after discharge to ensure that quality care and a safe discharge took place.

A TOC assessment consists of the nurse or social worker care manager (CM) reaching out to the patient during admission to establish rapport, contacting a patient within 48 hours of discharge to review the discharge plan, reconciling medication, and ensuring timely follow-up with a

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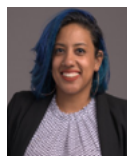

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"What makes me a great CM in the TOC role is my passion to serve, my integrity, and my commitment to patient advocacy. It is truly an honor to serve and care for patients at such a vulnerable time. It is a huge responsibility that I do not take lightly. Each encounter allows me the opportunity to be effective in the care I provide including engaging, educating, and connecting with the patient."
–Marlene Roman, RN Care Manager

practitioner. The CM ensures that the patient understands the reasons for admission to prevent, if possible, future admissions. The TOC assessment is sent to the primary care practitioner (and specialist, if applicable), and escalation occurs, if needed, for immediate attention and/or medication changes or discrepancies.

TOC settings can include:

- Inpatient discharge
  - Skilled nursing facility, long-term ambulatory care, rehabilitation
  - Behavioral health
  - Maternity
- Longitudinal settings
- Pediatric primary care to adult primary care
- Insurance plans

TOC patients are identified in several ways, including daily live admission-discharge-transfer (ADT) feeds from the patient's health plan, as well as the electronic medical record. The information includes notification for all patients that are established with a Rush primary care practitioner. The notifications alert the team to the patients' admissions and discharges from our hospital system and outside hospitals. Discharging diagnoses and chart review assist with appropriately assigning the correct discipline—RN or social worker—to lead the TOC activities.

In addition to the services we offer within care management, clarification of roles has been a successful approach in providing quality patient care throughout the journey.

RN Care Manager

A registered nurse (RN) care manager will most often lead a medically complex TOC. An integral role of the nurse care manager within the TOC process is to reduce unnecessary utilization while promoting in-network care.

A medically complex patient may be determined by the following:

- New diagnosis of chronic health condition
- Patient with chronic disease and enrolled in complex health programs (heart failure, hypertension, diabetes)
- High utilization due to medical conditions
- Comorbidities
- Polypharmacy
- Preventative health needs
- Multiple missed appointments

RNs who are most successful in this role are knowledgeable, bachelor-prepared nurses who work at the top of their license and implement evidence-based practice into their daily workflows. The nurse best suited for this role has several years of experience in the ambulatory and/or inpatient setting and a wide knowledge base, and possesses strong clinical assessment skills.

Such nurses are comfortable working with a diverse patient population including high-need, high-risk patients, and using their clinical judgment to identify and address barriers and/or needs. The TOC assessment requires frequent education, coaching, and counseling with patients to improve overall outcomes. Nurses in this role often go on to become certified in care management and/or other specific areas of nursing as well as to obtain higher degrees in the field of nursing.

When asked what makes you a great care manager or care management navigator for this role, one of our TOC RN care managers responded saying:

> *"What makes me a great CM in the TOC role is my passion to serve, my integrity, and my commitment to patient advocacy. It is truly an honor to serve and care for patients at such a vulnerable time. It is a huge responsibility that I do not take lightly. Each encounter allows me the opportunity to be effective in the care I provide including engaging, educating, and connecting with the patient."*
> *-Marlene Roman, RN Care Manager*

Social Work CM

A TOC that requires social work follow-up will often include patients with high-risk psychosocial, substance use, and/or behavioral health needs. Social work–led TOC is important because these clinicians have specialized knowledge of community resources, safety planning skills, psychosocial assessment, and motivational interviewing. Like the RN care manager, an integral role of the social work care manager within the TOC process is to provide education around behavioral health diagnosis and medications, assess for safety and create safety plans, and connect patients to community

A TOC that requires social work follow-up will often include patients with high-risk psychosocial, substance use, and/or behavioral health needs. Social work–led TOC is important because these clinicians have specialized knowledge of community resources, safety planning skills, psychosocial assessment, and motivational interviewing.

resources and back to their primary care practitioner.

Criteria for social work–led TOC often have the following:

- Multiple missed appointments
- Behavioral health diagnosis
- Behavioral health/psychiatric medications, or need of
- Need for connection to mental health resources
- New diagnosis of behavioral health condition
- High utilization due to behavioral health needs
- Suicidality
- Domestic violence
- Neglect/abuse/human trafficking
- Psychosocial barriers (housing, food insecurity, transportation barriers, etc.)
- Child and maternal health

In addition to the standard TOC process previously outlined, social work CMs follow up on behavioral health, substance use disorder, SDoH related needs, and child/maternal transitions of care. Connection to ongoing behavioral health or substance use practitioners is reviewed, safety plans are created or reinforced, psychosocial needs are reviewed and addressed, and transportation to follow-up appointments are confirmed or scheduled. If clinical decision dictates, a connection to longitudinal care management will be initiated.

Our social work CMs also follow up with maternity transitions of care. During those TOCs, the social work CM does a specialized assessment to review medications after discharge, verify that all discharge instructions are understood, postpartum depression signs and symptoms are assessed, safe sleep for the newborn is reviewed, and breast/formula feeding, car seat use, and support are available within the home for the patient and newborn. Additionally, close follow-up appointments are scheduled for the patient and newborn. Resources are provided such as the postpartum hotline, the local Fussy Baby Network (hotline for all questions about newborns), community parenting connections, and the Women, Infants, and Children (WIC) program.

CMs that are successful in this role typically have experience working in the health care field, especially community-based care management agencies, and are skilled in crisis intervention. These care managers are licensed social workers and/or licensed clinical social workers.

"A good social work CM will be patient centered in their decision-making, help the patient become more independent when managing their care, and will build a strong rapport and trust within the relationship so all needs of the patient can be identified and supported. Additionally, patience and continued communication are vital when helping patients to help them understand that many resources/systems can be complicated or time-consuming and a diagnosis or need does not define them as a person."
–Kleah Fernandez, LSW Care Manager

Care Management Navigator

To ensure the registered nurses and social workers are focusing on the TOCs that are best suited to their fields of expertise, the care management navigator (CMN) pulls, collates, and reviews the TOC/TCM lists daily. During this review, they identify and prepare patient names that were either discharged from the emergency department or inpatient unit for each of their team members, taking note to distribute work most evenly for the day. The CMN facilitates a short meeting with the team to discuss any patients who do not fall neatly into either role. The RNs and social workers review and share clinical input to determine which of them will make the outreach to the patient.

CMNs are nonlicensed professionals who are trained to complete initial health risk assessments for patients identified as low risk. The CMN will document the patient's responses and ensure the patient has appropriate follow-up to their primary care physician and specialty practitioners. In addition, the CMN may provide resources, according to a patient's response or identified SDoH needs. For example, if a patient indicates that due to transportation barriers, they are unable to travel to their primary care practitioner's office, the CMN will connect them to transportation resources or schedule a telehealth visit.

The combined goal is to prevent unnecessary hospital readmissions. Therefore, the person best suited for the TOC CMN role cares about the well-being of members of the community and is often the first level of support for a patient to connect back to their ambulatory practitioners. A CMN may have varied experiences in ambulatory clinics, pharmacies, or

health care call centers. In many instances, they are members of the same communities we serve, offering a spatial understanding that patients can relate to, which helps to establish trust. CMNs are savvy at scheduling, they have a solid understanding of the insurance benefits, and they are well-versed to navigate the health care system, and if appropriate, connect the patient to longitudinal care management.

Pharmacist

One of the main reasons for readmissions is a lack of proper medication use or medication adverse event. (El Morabet et al 2018). Many studies have shown that pharmacists' services that are implemented at the transitions of care result in a reduction in readmissions. (AHRQ 2022; Rafferty et al 2016) Data have shown that pharmacists can intervene and impede

TABLE 1 TRANSITION OF CARE PHARMACY SERVICES

1. ☑	We advocate that pharmacists have a crucial role and impact in improving transitions of care for patients, their identified family caregivers, and providers within the healthcare continuum.
2. ☑	We advocate for pharmacists to be an integral member of the interdisciplinary care team at each level of care transition and coordination
3. ☑	We acknowledge that while no one discipline is wholly responsible for care transition and coordination, we advocate that a larger involvement by pharmacists beyond medication reconciliation will help realize an improved standard of care, including Medication Management Services **and overall quality of care as well as patient satisfaction and safety
4. ☑	We believe that pharmacists are an integral part of quality health care delivery and thus play an essential role in helping to improve health care communication – a core element of quality transitions of care, between patients, their identified family caregivers, and providers.
5. ☑	We advocate that pharmacists practice Medication Management Services (**see definition), inclusive of: • Assessment of the patient to determine their clinical status Prioritize patient problems, medication related needs including medication access and barriers Assessment of social determinants of health that could interfere with patient access to medications and following the medication plan • Patient advocacy in support of their medication care plan to optimize therapies and achieve patient and caregiver specific outcomes • Active engagement and education for patients, identified family caregivers, providers, and other members of the interdisciplinary care team Coordinate and ensure that pertinent patient information is transferred between care settings • Ensuring medication continuity, immediate and sustained, medication access (i.e. insurance coverage, financial assistance, appropriate packaging, prior authorizations, compliance) • Follow-up care, including: Post-transition monitoring of the patient and identified family caregiver • Warm hand-off to next-level pharmacists between care settings • Accept accountability for the highest attainable quality of care in collaboration with the interdisciplinary care team to enhance clinical care and improve patient safety and satisfaction.
6. ☑	We support a financial reimbursement model for pharmacists which would recognize the unique and valuable role and expertise the pharmacist brings to each care transition through their assessment, management, monitoring, and advocacy to improve patient quality, safety and satisfaction.
7. ☑	We believe that patient contact and interaction (i.e., face to face, telephonic, or through virtual visits) are essential components necessary for pharmacists to provide quality medication management services that enhance transitions and care coordination.
8. ☑	We advocate for the concept that pharmacists in all practice settings (i.e., acute care, post- acute, outpatient, community-based, palliative & hospice care) are essential to the delivery of the Quadruple Aim, improving the patient experience of care, improving provider experience, improving the health of populations, and reducing the total cost of care.
9. ☑	We encourage interested pharmacists to consider specialization in transitions of care as an advanced practice initiative.
10. ☑	We conclude that the pharmacists' demonstration of their clinical expertise, commitment to a code of ethics, and dedicated interactions professionally and collegially with others warrants additional engagement of pharmacists in care transitions and acknowledgement of their crucial role on the interdisciplinary care team.

With permission.

risks of medication access issues and medication appropriateness and safety. (CMS 2022) Pharmacists are well-trained health care professionals, with 6 to 8 years of training that focuses not only on biomedical and pharmaceutical science but also on patient-centered care, cultural humility, and interprofessional collaborations. (Haines et al 2017) These facts led to the Joint Commission recommending that pharmacists be part of the medication reconciliation process and transitions of care. (JC 2022) Additionally, the Joint Commission recognized the importance of medication management services in all care settings. (JC 20222)

However, as highlighted previously, a successful transition of care requires a team-based approach. Interprofessional collaboration is key to the sustainability and success of our model. Just like with other professionals, we developed criteria for engaging the pharmacist in supporting the patient, the identified family caregiver, or the care management team during the TOC process. These criteria include:

- Polypharmacy, defined as 8 or more prescription medications
- Multiple medication changes during admission
- Questions about medications or side effects
- High-risk medications
- Support to CMs with medication access
- Medication management for chronic conditions

Besides the development of criteria, having principles that drive the role of the pharmacist in the team is essential to interdisciplinary collaborations. Therefore, the National Transitions of Care Coalitions (NTOCC), a national, interdisciplinary organization, created a task force that focused on developing the 10 principles of pharmacist services in the transition of care (Table 1). (NTOCC)

The first few principals advocate for pharmacists to be part of the team. (Box 1) This empowers any member of the care team to seek support from the pharmacists in their institution, or from the community pharmacist that would support patients once they are discharged. Pharmacist support could be as a consultant to the CMs or the pharmacist providing direct care to patients and family caregivers.

Pharmacists, as consultants, could empower team members with information that can help resolve medication-related issues or questions. Often pharmacists can recommend medication alternatives in cases when prior authorizations (PAs) are needed. Additionally, they can guide the team in the necessary documentation for successful PA. Another example of a pharmacist serving as a consultant is making sure that the monitoring plan for high-risk medications is well-designed and able to be completed.

Often, limited pharmacist resources result in pharmacists supporting TOCs regardless of their practice priorities and

continued on page 36

BOX 1

PRINCIPAL III & IV

III. We acknowledge that while no one discipline is wholly responsible for care transition and coordination, we advocate that a larger involvement by pharmacists beyond medication reconciliation will help realize an improved standard of care, including Medication Management Services *and overall quality of care as well as patient satisfaction and safety.

IV. We believe that pharmacists are an integral part of quality healthcare delivery and thus play an essential role in helping to improve healthcare communication–a core element of quality transitions of care, between patients, their identified family caregivers, and practitioners.

With permission. National Transitions of Care Coalitions (NTOCC).

Another principle (Box 2) provides a breakdown of services that pharmacists would be able to support as part of the medication management services. It is these services that highlight the importance and the unique skills of pharmacists. This principle focuses on pharmacist patient care services, where pharmacists work directly with the patients to ensure appropriate medication use and address any medication-related questions or side effects.

BOX 2

PRINCIPAL V

V. We advocate that pharmacists practice Medication Management Services inclusive of:

- Assessment of the patient to determine their clinical status
  - –Prioritization of patient problems, and medication-related needs including medication access and barriers
  - –Assessment of SDoH that could interfere with patient access to medications and following the medication plan
- Patient advocacy in support of the medication care plan to optimize therapies and achieve patient- and caregiver-specific outcomes
- Active engagement and education for patients, identified family caregivers, practitioners, and other members of the interdisciplinary care team
- Coordination of and assurance that pertinent patient information is transferred between care settings
- Assurance of medication continuity, immediate and sustained, medication access (ie, insurance coverage, financial assistance, appropriate packaging, PAs, compliance)
- Follow-up care including:
  - –Post-transition monitoring of the patient and identified family caregiver
  - –Warm hand-off to next-level pharmacist between care settings
  - –Accountability for the highest attainable quality of care in collaboration with the interdisciplinary care team to enhance clinical care and improve patient safety and satisfaction

With permission. National Transitions of Care Coalitions (NTOCC).

CE3 Approved for 1 hour of CCM, CDMS, and nursing education credit
Exam expires on April 15, 2024

Professional Growth and Development: The Path to Excellence

By Rebecca A. Perez, MSN, RN, CCM

Unlike other industries, health care is one that changes rapidly and frequently. Health care professionals must stay up-to-date and informed about changing clinical practices, reimbursement, quality measures, accreditation standards, and policy. Professional case managers (CMs) support patients and families through their health care journey with education, advocacy, and care coordination. CMs are expected to stay abreast of all the changes mentioned to meet the needs of patients and families.

The CM's role differs from other health professionals in that awareness of all aspects of care are within the scope of case management: treatment options for health conditions, nonmedical resources to support health, reimbursement structures, quality measurement, and collaboration with other health care professionals involved in a patient's care. Case managers must have access to continuing education to function effectively and achieve practice excellence.

According to the Case Management Society of America's (CMSA's) Standards of Practice for Case Management, Standard B, Professional Responsibilities, CMs are encouraged to engage in activities that identify best practices, explore research, and build competencies that result in increased knowledge and skills to further improve patient outcomes. (CMSA, 2022)

Above and Beyond

Nearly all health care professionals are required to participate in continuing education to maintain licensure or certification. While completing only the minimum to maintain licensure and certification may provide some new or important information, this action lacks the commitment to excellence and reduces the potential for professional growth and development. Making a commitment to excellence and taking ownership of your professional growth means you participate in more than what is required; you are committed to performing better than what is needed, exceeding bare minimum expectations.

Choosing a career in health care requires professionals to be nimble, flexible, and current. The practice of professional case management has grown in visibility and demand. CMs hail from multiple professional disciplines with licensure and certification requirements, but case management practice exceeds the confines of any one professional discipline; CMs need to be well-informed in multiple areas of health. Today's health care climate is competitive for CMs, so to be competitive, CMs must invest in the skills and knowledge that will demonstrate that commitment to excellence.

Professional Growth

Professional growth happens when an effort is made to expand knowledge and skills by pursuing competence. Gaining competence requires being enthusiastic in the pursuit of needed or desired knowledge and skills. Passion and enthusiasm are the result of interest. When areas of interest are pursued and completed, there is a sense of satisfaction and personal pride, all of which are components of professional growth.

The professional growth of a CM not only is exclusively beneficial but also positively impacts the health and satisfaction of patients and families served. When CMs are able to support and coordinate high-quality care, patient outcomes improve, and an organization's bottom line also improves. CMs should never get too comfortable with the pursuit of knowledge—lifelong learning is a requirement. There is always room to grow, so professional growth and development do not end. No one will ever know everything, and even if they did, something would change, and new information would be needed.

Developmental Paradox

To maintain competency, CMs should continue to actively engage in continuing professional development supporting high practice standards. A question often raised is: who is responsible for the maintenance of licensure, certification, and professional development? Ultimately, the professional is responsible, but employers may or may not help by making

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Unlike other industries, health care is one that changes rapidly and frequently. Health care professionals must stay up-to-date and informed about changing clinical practices, reimbursement, quality measures, accreditation standards, and policy.

available some learning or educational opportunities. However, some employers are realizing that providing growth opportunities results in loyal employees that are satisfied and productive, while other employers believe that if they invest too much in their employees, they will leave the organization with new marketable skills.

According to an article in *Business News Daily*, when employers and employees commit to growing skills and knowledge, the result is mutually beneficial. (Meyer, 2023). Employers supporting professional development not only fill gaps in the workplace but cultivate loyal employees. (Meyer, 2023) However, there are organizations that believe providing educational opportunities to improve staff skills, knowledge, and abilities increases staff marketability and results in high turnover rates. (Ng, 2022) These employers see this as an overinvestment of resources, and employees are more likely to exit to the competition. (Ng, 2022) A study by the software company Akumina demonstrated that Millennials and Generation Z change jobs frequently. But by empowering younger employees to succeed and advance in their current role, this trend would diminish. (Meyer, 2023)

Ng and colleagues studied the benefits of employer-sponsored career development and examined what they termed the "developmental paradox" as the phenomenon that resulted in employee exodus. (Ng, 2022) Their research found conflicting views. Some employers included in their project believed that investing in employee development only led to employees taking their newly acquired skills and moving on to the competition. Ng and coauthors argued that the developmental paradox should be viewed from a reciprocal viewpoint in which employer-sponsored educational offerings strengthen employee loyalty, boost productivity, and decrease turnover. (Ng, 2022) Loyal and productive employees are more likely to see themselves as a partner with their employer. Conversely, employees who view themselves as marketable, regardless of employer support, are more likely to leave an organization. (Ng, 2022)

Employers that foster favorable feelings from their employees saw dedication, accountability, and support for the organization. These behaviors strengthened relationships and are seen as the key to reducing turnover. (Ng, 2022) When employers make available content that is important and meaningful to employees, the message delivered is one of benevolence, especially if the content supports long-term career growth and not just job- or process-focused training. (Ng, 2022) Employers who shy away from career-focused training instead make process-focused or job-related training a priority. These trainings are important but accomplish short-term goals and do not necessarily foster loyalty and commitment.

Your Career Fate Is Within Your Control

The fate of your career is within your control, even if your employer does not support professional growth and development activities. Take time to discern where you want your career to go and what your top three goals are because knowing these will define what development activities you need. If you have a supportive supervisor, discuss your goals and solicit advice for achievement. Look for a mentor within your organization or professional circle. Mentors can be very supportive, knowledgeable, and unbiased in their guidance. When looking for support, consider joining a professional association. Benefits of membership can include access to continuing education and networking opportunities. Costs related to professional association membership are typically very affordable when compared to purchasing ad hoc continuing education courses.

An excellent practice for determining career goals and achieving them is to create a professional development plan (PDP). Creating a PDP is not unlike the case management process: a PDP helps you to complete an assessment, define goals, find resources, develop strategies, and evaluate the outcome.

Assessment

The assessment process requires you to honestly examine where you are in your career, your current skillset, where improvement is needed, and what skills or learning will help you achieve your next career goals.

Goal Setting

Now, think about your goals—you have determined where you are; now where do you want to go? Determining personal goals for professional development may be harder than developing a care plan with your patient and family.

CMs hail from multiple professional disciplines with licensure and certification requirements, but case management practice exceeds the confines of any one professional discipline; CMs need to be well-informed in multiple areas of health.

You see things very clearly for them, but maybe not for yourself. If your plan is to advance your career in your current organization, begin by examining the company's organizational chart to see how professional development flows. If your goals are outside of your organization, look for information about how or where your resources will originate.

When developing your plan, remember that your life or your interests may change, and so may your goals need to change. What is important is to work toward something that you value, but do not stubbornly work toward a goal that is no longer relevant. Having high aspirations is admirable, but balance these with realism and be flexible.

Resources

You will need resources to achieve your goals and you may need guidance on where and how to locate them. Ask supervisors, a mentor, or peers what resources they used to increase their knowledge and skills. Your employer may offer opportunities, but if not, look to a professional association or university classes, or conduct an internet search for offerings on your preferred topics. There are many sites that offer continuing education for purchase. If you are looking for specific or specialized education or training, options may be more limited.

Strategy

Develop your strategy for addressing the small steps between goals. Developing your goals using the SMART framework (Specific, Measurable, Attainable, Relevant, and Time-based) can assist with this. Goals can be specific or small and can direct application of the resources identified. Whether your goal is small or specific, the SMART framework assists in mapping out how to measure progress, if the goal is reasonable, if it is relevant to your overall plan, and when you believe the goals might be achieved.

Evaluation

When evaluating your plan, it is not unlike evaluating the effectiveness of a care plan developed with your patient and family. If your plan is meant to be achieved in 1 year, you should evaluate your progress every 3 months and make any necessary adjustments. If your plan extends over more than 1 year, begin by evaluating progress every 6 months, at least for the first year just to make sure you are on track for the duration. After that, once a year is likely sufficient. And again, make adjustments as soon as you determine there is a need to ensure continued success.

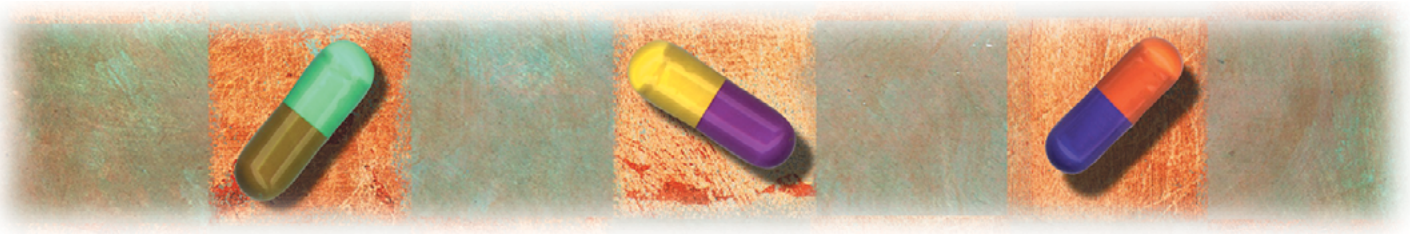
As organizations continue to struggle to find and retain qualified CMs, your personal investment in professional growth and development will increase your opportunities for career advancement. Investing in knowledge and skills elevates your professionalism, and you become more effective in your work, feel successful, and gain personal satisfaction in your work. Do not rely on your employer to meet all of your professional growth needs. So much more can be learned when information is sought outside of your comfort zone or work environment. Employers who value your initiative for professional growth will be more likely to provide support and will foster loyalty. For those employers that do not support professional growth, you have a choice whether or not to stay, but again, it is not your employer's responsibility to advance your career. By taking ownership of your career and its development, you have the satisfaction of knowing that you are doing everything possible to be a consummate professional. Take pride in your accomplishments and know that your patients will also reap the benefits of your efforts. CM

References

CMSA. *Standards of Practice for Case Management.* Case Management

References on page 37

PharmaFacts for Case Managers



ZURZUVAE™ (zuranolone) capsules, for oral use, [controlled substance schedule pending]

INDICATIONS AND USAGE

ZURZUVAE is indicated for the treatment of postpartum depression (PPD) in adults.

DOSAGE AND ADMINISTRATION

Recommended Dosage

The recommended dosage of ZURZUVAE is 50 mg taken orally once daily in the evening for 14 days. Administer ZURZUVAE with fat-containing food (eg, 400 to 1,000 calories, 25% to 50% fat) [see Clinical Pharmacology (12.3)]. If patients experience CNS depressant effects within the 14-day period, consider reducing the dosage to 40 mg once daily in the evening within the 14-day period.

ZURZUVAE can be used alone or as an adjunct to oral antidepressant therapy.

The safety and effectiveness of ZURZUVAE use beyond 14 days in a single treatment course have not been established.

Dosage Modifications for Concomitant Use with CYP3A4 Inducers or CYP3A4 Inhibitors

CYP3A4 Inducers

Avoid concomitant use of ZURZUVAE with CYP3A4 inducers [see Drug Interactions (7) and Clinical Pharmacology].

CYP3A4 Inhibitors

Reduce the ZURZUVAE dosage to 30 mg orally once daily in the evening for 14 days when used concomitantly with a strong CYP3A4 inhibitor. No dosage modification is recommended when ZURZUVAE is concomitantly used with a moderate CYP3A4 inhibitor.

Recommended Dosage in Patients With Hepatic Impairment

The recommended dosage of ZURZUVAE in patients with severe hepatic impairment (Child- Pugh C) is 30 mg orally once daily in the evening for 14 days [see Use in Specific Populations (8.6) and Clinical Pharmacology (12.3)]. The recommended dosage in patients with mild (Child- Pugh A) or moderate (Child-Pugh B) hepatic impairment is the same as those in patients with normal hepatic function.

Recommended Dosage in Patients With Renal Impairment

The recommended dosage of ZURZUVAE in patients with moderate or severe renal impairment (eGFR < 60 mL/min/1.73 m2) is 30 mg orally once daily in the evening for 14 days.

The recommended dosage in patients with mild renal impairment (eGFR 60 to 89 mL/min/1.73 m2) is the same as those in patients with normal renal function.

Recommendations Regarding a Missed Dose

If a ZURZUVAE evening dose is missed, take the next dose at the regular time the following evening. Do not take extra capsules on the same day to make up for the missed dose. Continue taking ZURZUVAE once daily until the remainder of the 14-day treatment course is completed.

DOSAGE FORMS AND STRENGTHS

Capsules:

- 20 mg: light-orange cap, ivory to light-yellow body, printed with "S-217 20 mg" on body of capsule in black
- 25 mg: light-orange cap, light-orange body, printed with "S-217 25 mg" on body of capsule in black
- 30 mg: orange cap, light-orange body, printed with "S-217 30 mg" on body of capsule in black

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Impaired Ability to Drive or Engage in Other Potentially Hazardous Activities

ZURZUVAE causes driving impairment due to central nervous system (CNS) depressant effects. In two driving simulation studies, the driving ability of healthy adults was impaired in a dose-dependent manner following repeat nighttime administration of 30 mg of ZURZUVAE (0.6 times the recommended dose) for five days as well as 50 mg of ZURZUVAE (recommended dose) for seven days.

Advise patients not to drive a motor vehicle or engage in other potentially hazardous activities requiring complete mental alertness, such as operating machinery, until at least 12 hours after ZURZUVAE administration for the duration of the 14-day treatment course. Inform patients that they may not be able to assess their own driving competence or the degree of driving impairment caused by ZURZUVAE.

Central Nervous System Depressant Effects

ZURZUVAE can cause CNS depressant effects such as somnolence and confusion.

In Study 1, 36% of patients who received 50 mg of ZURZUVAE and 6% of patients who received placebo daily developed somnolence. In Study 2, 19% of patients who received another zuranolone capsule formulation (approximately equivalent to 40 mg of ZURZUVAE) and 11% of patients who received placebo daily developed somnolence. In each clinical study, some ZURZUVAE-treated patients developed confusional state. One of these cases was severe, and was also associated with somnolence, dizziness, and gait disturbance. A higher percentage of ZURZUVAE-treated patients, compared to placebo-treated patients, experienced somnolence, dizziness, or confusion that required dosage reduction, interruption, or discontinuation.

Because ZURZUVAE can cause CNS depressant effects, patients may be at higher risk of falls.

Other CNS depressants such as alcohol, benzodiazepines, opioids, tricyclic antidepressants, or drugs that increase zuranolone concentration, may increase impairment of psychomotor performance or CNS depressant effects such as somnolence, cognitive impairment, and the risk of respiratory depression in ZURZUVAE-treated patients.

To reduce the risk of CNS depressant effects and/or mitigate CNS depressant effects that occurs with ZURZUVAE treatment:

- If patients develop CNS depressant effects, consider dosage reduction or discontinuation of ZURZUVAE.
- If use with another CNS depressant is unavoidable, consider dosage reduction.
- Reduce the ZURZUVAE dosage in patients taking strong CYP3A4 inhibitors.

Suicidal Thoughts and Behavior

In pooled analyses of placebo-controlled trials of chronically administered antidepressant drugs (SSRIs and other antidepressant classes) that included approximately 77,000 adult patients and 4,500 pediatric patients, the incidence of suicidal thoughts and behaviors in antidepressant- treated patients age 24 years and younger was greater than in placebo-treated patients. There was considerable variation in risk of suicidal thoughts and behaviors among drugs, but there was an increased risk identified in young patients for most drugs studied. There were differences in absolute risk of suicidal thoughts and behaviors across the different indications, with the highest incidence in patients with major depressive disorder (MDD). The drug-placebo differences in the number of cases of suicidal thoughts and behaviors per 1000 patients treated are provided in Table 1.

ZURZUVAE does not directly affect monoaminergic systems. Consider changing the therapeutic regimen, including discontinuing ZURZUVAE, in patients whose depression becomes worse or who experience emergent suicidal thoughts and behaviors.

RISK DIFFERENCES OF THE NUMBER OF PATIENTS WITH SUICIDAL THOUGHTS OR BEHAVIORS IN THE POOLED PLACEBO-CONTROLLED TRIALS OF ANTIDEPRESSANTS IN PEDIATRIC* AND ADULT PATIENTS

Age Range (years)	Drug-Placebo Difference in Number of Patients With Suicidal Thoughts or Behaviors per 1000 Patients Treated
Increases Compared to Placebo	
< 18	14 additional patients
18–24	5 additional patients
Decreases Compared to Placebo	
25–64	1 fewer patient

**ZURZUVAE is not approved in pediatric patients.*

Embryo-fetal Toxicity

Based on findings from animal studies, ZURZUVAE may cause fetal harm when administered to a pregnant woman. In rat studies following exposure during gestation or throughout gestation and lactation, adverse effects on development (fetal malformations, embryofetal and offspring mortality, growth deficits) were observed. In addition, neuronal death was observed in rats exposed to zuranolone during a period of brain development that in humans begins during the third trimester of pregnancy and continues during the first few years after birth

Advise a pregnant woman of the potential risk to an infant exposed to ZURZUVAE in utero. Advise females of reproductive potential to use effective contraception during treatment with ZURZUVAE and for one week after the final dose.

Adverse Reactions

Black Box Warning

ZURZUVAE causes driving impairment due to central nervous system (CNS) depressant effects].

WARNING: IMPAIRED ABILITY TO DRIVE OR ENGAGE IN OTHER POTENTIALLY HAZARDOUS ACTIVITIES

Advise patients not to drive or engage in other potentially hazardous activities until at least 12 hours after ZURZUVAE administration for the duration of the 14-day treatment course. Inform patients that they may not be able to assess their own driving competence, or the degree of driving impairment caused by ZURZUVAE.

Across PPD clinical studies at all doses studied (Studies 1 and 2), serious adverse reactions included confusional state (1%).

In Study 1, the incidence of adverse reactions that led to discontinuation in patients treated with 50 mg of ZURZUVAE and placebo was 2% and 1%, respectively. The most com-

mon adverse reaction leading to treatment discontinuation in ZURZUVAE-treated patients was somnolence.

Dosage reduction due to an adverse reaction occurred in 14% of ZURZUVAE-treated patients. The most common adverse reactions leading to dosage reduction in ZURZUVAE-treated patients were somnolence (10%) and dizziness (6%).

The most common adverse reactions (≥5% and greater than placebo) in ZURZUVAE-treated patients were somnolence, dizziness, diarrhea, fatigue, and urinary tract infection.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to antidepressants, including ZURZUVAE, during pregnancy. Health care providers are encouraged to register patients by calling the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visiting online at https://womensmentalhealth.org/research/pregnancyregistry/antidepressants/

Risk Summary

Based on findings from animal studies, ZURZUVAE may cause fetal harm. Advise pregnant women of the potential risk to a fetus. Available data on ZURZUVAE use in pregnant women from the clinical development program are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.

In animals, oral administration of zuranolone to pregnant rats during organogenesis resulted in developmental toxicity, including embryofetal death and fetal malformations, with a no adverse effect level (NOAEL) associated with maternal plasma exposures 7 times greater than in humans at the maximum recommended human dose (MRHD) of 50 mg. Oral administration of zuranolone to rats during pregnancy and lactation resulted in developmental toxicity in the offspring, including, perinatal mortality, at maternal exposures similar to that in humans at the MRHD. Developmental toxicity was observed at doses that were also maternally toxic. Neuronal death was observed in rats exposed to zuranolone during a period of brain development that begins during the third trimester of pregnancy in humans and continues up to a few years after birth.

Lactation

Risk Summary

Available data from a clinical lactation study in 14 women indicate that zuranolone is present in low levels in human milk (see Data). There are no data on the effects of zuranolone on a breastfed infant and limited data on the effects on milk production.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ZURZUVAE and any potential adverse effects on the breastfed child from ZURZUVAE or from the underlying maternal condition.

Females and Males of Reproductive Potential

Based on animal studies, ZURZUVAE may cause embryo-fetal harm when administered to a pregnant woman [see Warnings and Precautions (5.4) and Use in Specific Populations (8.1)].

Contraception

Advise female patients of reproductive potential to use effective contraception during treatment with ZURZUVAE and for one week after the final dose.

Pediatric Use

The safety and effectiveness of ZURZUVAE in pediatric patients have not been established.

Geriatric Use

PPD is a condition associated with pregnancy; there is no geriatric experience with ZURZUVAE in patients with PPD.

Hepatic Impairment

Exposure to zuranolone was increased in patients with severe hepatic impairment. The recommended ZURZUVAE dosage in patients with severe hepatic impairment (Child-Pugh C) is lower than patients with normal hepatic function

The recommended ZURZUVAE dosage in patients with mild or moderate hepatic impairment (Child-Pugh A or Child-Pugh B) is the same as those with normal hepatic function.

Renal Impairment

Exposure to zuranolone was increased in patients with moderate (eGFR 30 to 59 mL/min/1.73 m2) and severe (eGFR 15 to 29 mL/min/1.73 m2) renal impairment

The recommended ZURZUVAE dosage in patients with moderate and severe renal impairment is lower than those with normal renal function]. The recommended dosage in patients with mild renal impairment (eGFR 60 to 89 mL/min/1.73 m2) is the same as those in patients with normal renal function. ZURZUVAE has not been studied in patients with eGFR of < 15 mL/min/1.73 m2 or patients requiring dialysis.

DRUG ABUSE AND DEPENDENCE

Controlled Substance

ZURZUVAE contains zuranolone (Controlled substance schedule to be determined after review by the Drug Enforcement Administration.)

Abuse

Zuranolone has abuse potential with associated risks of misuse, abuse, and substance use disorder including addiction. Abuse is the intentional nontherapeutic use of a drug, even once, for its desired psychological or physiological effects. Misuse is the intentional use, for therapeutic purposes, of a drug by an individual in a way other than prescribed by a health care provider or for whom it was not prescribed. Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that

may include a strong desire to take the drug, difficulties in controlling drug use (e.g., continuing drug use despite harmful consequences, giving a higher priority to drug use than other activities and obligations), and possible tolerance or physical dependence. Individuals with a history of drug abuse or substance use disorders may be at a greater risk of these outcomes with ZURZUVAE.

In a human abuse potential study, single oral doses of 30 mg, 60 mg, and 90 mg of ZURZUVAE (0.6 times, 1.2 times, and 1.8 times the recommended daily dose, respectively) were compared to single oral doses of alprazolam (1.5 mg and 3 mg) and placebo in healthy, nondependent individuals with a history of recreational CNS depressant use. The study demonstrated that ZURZUVAE has dose-dependent abuse potential comparable to alprazolam and greater abuse potential than placebo on positive subjective measures of "drug liking," "overall drug liking," "take drug again," "high," and "good drug effects." In the human abuse potential study, dose-dependent, abuse-related adverse reactions, including euphoric mood, feeling drunk, and somnolence, were reported with ZURZUVAE use.

Dependence

ZURZUVAE may produce physical dependence. Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction of a drug.

Adverse reactions reported upon discontinuation of zuranolone in healthy subjects who received 50 mg of zuranolone for 5 to 7 days (on the 7th day subjects received 50 mg or 100 mg) included: insomnia, palpitations, decreased appetite, nightmare, nausea, hyperhidrosis, and paranoia. These adverse reactions indicate a potential for physical dependence with zuranolone. These adverse reactions were mild-to-moderate in severity.

The risk for developing physical dependence and a subsequent withdrawal syndrome upon abrupt ZURZUVAE discontinuation for individuals who take a higher than recommended dosage and/or use ZURZUVAE for a longer duration than recommended has not been evaluated in clinical studies. However, convulsions were observed in a dog upon abrupt zuranolone discontinuation after dogs were administered zuranolone for 14 days at doses that produced exposures higher than the maximum recommended human dose.

OVERDOSAGE

There was a case of intentional overdose with ZURZUVAE reported during premarketing clinical trials. The patient took 330 mg (6.5 times the maximum recommended dose) of ZURZUVAE and was reported to be in an altered state of consciousness. The event resolved the next day, following treatment with intravenous fluids.

Overdosage with ZURZUVAE may result in excessive CNS depressant effects such as somnolence and disturbance in consciousness. There is no specific antidote for ZURZUVAE overdosage.

Consider contacting the Poison Help Line (1-800-222-1222) or a medical toxicologist for additional overdosage management recommendations.

CLINICAL STUDIES

Postpartum Depression

The efficacy of ZURZUVAE for the treatment of postpartum depression (PPD) in adults was demonstrated in two randomized, placebo-controlled, double-blind, multicenter studies (Study 1, NCT04442503 and Study 2, NCT02978326) in women with PPD who met the Diagnostic and Statistical Manual of Mental Disorders criteria for a major depressive episode (DSM-5 for Study 1, and DSM-IV for Study 2) with onset of symptoms in the third trimester or within 4 weeks of delivery. In these studies, concomitant use of existing oral antidepressants was allowed for patients taking a stable dose of oral antidepressant for at least 30 days before baseline. These studies included patients with HAMD-17 scores ≥ 26 at baseline.

In Study 1, patients received 50 mg of ZURZUVAE (N=98) or placebo (N = 97) once daily in the evening with fat-containing food for 14 days, with the option to reduce the dosage based on tolerability to 40 mg once daily of ZURZUVAE or placebo. The patients were followed for a minimum of 4 weeks after the 14-day treatment course.

In Study 2, patients received another zuranolone capsule formulation (approximately equivalent to 40 mg of ZURZUVAE) (N = 76) or placebo (N = 74) once daily in the evening with fat-containing food for 14 days, with the option to reduce the dosage based on tolerability to 40 mg once daily of zuranolone or placebo. The patients were followed for a minimum of 4 weeks after the 14-day treatment course.

Baseline Demographics and Disease Characteristics

In Studies 1 and 2, the baseline demographic and disease characteristics of patients were similar between the ZURZUVAE and placebo groups. In Study 1, patients had a mean age of 30 years (range 19 to 44 years); were 70% White, 22% Black or African American, 1% Asian, and 7% were other races; and 38% were of Hispanic or Latino ethnicity. Baseline use of stable oral antidepressants was reported in 15% of patients. In Study 2, patients had a mean age of 28 years (range 18 to 44 years); were 56% White, 41% Black or African American, 1% Asian, and 2% were other races; and 23% were of Hispanic or Latino ethnicity. Baseline use of stable oral antidepressants was reported in 19% of patients.

The primary endpoint for Studies 1 and 2 was the change from baseline in depressive symptoms as measured by the HAMD-17 total score at Day 15. In these studies, patients in the ZURZUVAE groups experienced statistically significantly greater improvement on the primary endpoint compared to patients in the placebo groups, as shown in table below. For

TABLE 1 **RESULTS FOR THE PRIMARY ENDPOINT: CHANGE FROM BASELINE IN THE HAMD-17 TOTAL SCORE AT DAY 15 (STUDIES 1 AND 2 IN WOMEN WITH PPD)**

Study Number	Treatment Group	N	Mean Baseline Score (SD)	LS Mean Change from Baseline (SE)	Placebo-subtracted Difference (95% CI)
1	50 mg of ZURZUVAE	98	28.6 (2.49)	-15.6 (0.82)	-4.0 (-6.3, -1.7)
	Placebo	97	28.8 (2.34)	-11.6 (0.82)	
2	Zuranolone (another capsule formulation)*	76	28.4 (2.09)	-17.8 (1.04)	-4.2 (-6.9, -1.5)
	Placebo	74	28.8 (2.32)	-13.6 (1.07)	

HAMD-17: 17-item Hamilton depression rating scale; SD: standard deviation; LS: least squares; SE: standard error; CI: confidence interval

**This capsule formulation of zuranolone is approximately equivalent to 40 mg of ZURZUVAE.*

Study 1, the key secondary endpoints included change from baseline in HAMD-17 total score at Days 3, 28, and 45 (Table 1).

Subgroup analyses of the primary endpoint did not suggest differences in response to 50 mg of ZURZUVAE for age, race, or BMI.

Effects on Driving

Two randomized, double-blind, placebo- and active-controlled, four-way crossover studies (Study 3 and Study 4) evaluated the effects of nighttime ZURZUVAE administration on next- morning driving performance, 9 hours after dosing, using a computer-based driving simulation.

Study 3

In Study 3, 50 mg of ZURZUVAE was administered for six consecutive nights and on the seventh night a single dose of 50 mg or 100 mg (two times the recommended dose) was administered. The primary driving performance outcome measure was the change in Standard Deviation of Lateral Position (SDLP) (a measure of driving impairment) in the ZURZUVAE group compared to the placebo group on Days 2 and 8 (after a single dose and repeat doses, respectively).

Study 3 included 67 healthy participants. The median age was 45 years old (age ranged from 22 to 81 years old; 7 participants were ≥ 65 years of age); there were 38 males and 29 females; 88% were White, 5% were Black or African American, 3% were Asian, and 5% were other races; and 12% were of Hispanic/Latino ethnicity.

A single 50 mg dose of ZURZUVAE caused statistically significant impairment in next-morning driving performance compared to placebo. Statistically significant effects on driving were also observed on Day 8 following daily administration of 50 mg of ZURZUVAE. Administration of 100 mg of ZURZUVAE (twice the maximum recommended dose) on the final night increased impairment in driving ability .

The exposure-response analysis for driving impairment in Study 3 suggested that the projected mean placebo-adjusted SDLP at 12 hours post-dose would be less than the threshold associated with driving impairment.

Study 4

In Study 4, 30 mg of ZURZUVAE (0.6 times the maximum recommended daily dose) was administered for four consecutive nights and on the fifth night a single dose of 30 mg or 60 mg (1.2 times the recommended daily dose) was administered. The primary driving performance outcome measure was the change in SDLP in the ZURZUVAE group compared to the placebo group on Days 2 and 6 (after a single dose and repeat doses, respectively).

Study 4 included 60 participants; 60% and 40% were male and female, respectively; the median age was 41 years old (range was 22 to 62 years old); 90% were White, 5% were Black or African American, 3% were Asian, and 2% were other races; and 15% were of Hispanic/Latino ethnicity.

A single 30-mg dose of ZURZUVAE caused a statistically significant impairment in next- morning driving performance compared to placebo. The mean effect on driving performance was not statistically significantly different following 30 mg of ZURZUVAE compared to placebo on Day 6; however, driving ability was impaired in some participants taking ZURZUVAE. Administration of 60 mg of ZURZUVAE (1.2 times the maximum recommended dose) on the final night caused statistically significant impairment in next-morning driving performance compared to placebo.

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

ZURZUVAE (zuranolone) is supplied as 20 mg, 25 mg, and 30 mg capsules (Table 2).

continues on page 35

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.

J Infect Dis. 2023 Aug 22;jiad364. doi: 10.1093/infdis/jiad364. Online ahead of print.

Impact of cannabis use on immune cell populations and the viral reservoir in people with HIV on suppressive antiretroviral therapy

Falcinelli SD, Cooper-Volkheimer AD, Semenova L, et al.

BACKGROUND: HIV infection remains incurable due to the persistence of a viral reservoir despite antiretroviral therapy (ART). Cannabis (CB) use is prevalent amongst people with HIV (PWH), but the impact of CB on the latent HIV reservoir has not been investigated.

METHODS: Peripheral blood cells from a cohort of PWH who use CB and a matched cohort of PWH who do not use CB on ART were evaluated for expression of maturation/activation markers, HIV-specific T cell responses, and intact proviral DNA.

RESULTS: CB use was associated with increased abundance of naïve T cells, reduced effector T cells, and reduced expression of activation markers. CB use was also associated with reduced levels of exhausted and senescent T cells compared to non-using controls. HIV-specific T cell responses were unaffected by CB use. CB use was not associated with intact or total HIV DNA frequency in CD4 T cells.

CONCLUSIONS: This analysis is consistent with the hypothesis that CB use reduces activation, exhaustion and senescence in the T cells of PWH, and does not impair HIV-specific CD8 T cell responses. Longitudinal and interventional studies with evaluation of CB exposure are needed to fully evaluate the impact of CB use on the HIV reservoir.

BMJ. 2023 Aug 16;382:e073713. doi: 10.1136/bmj-2022-073713.

Effect of a smartphone intervention as a secondary prevention for use among university students with unhealthy alcohol use: randomised controlled trial

Bertholet N, Schmutz E, Studer J, et al.

OBJECTIVE: To estimate the effects of providing access to an alcohol intervention based on a smartphone.

DESIGN: Randomised controlled trial..

SETTING: Four higher education institutions in Switzerland.

PARTICIPANTS: 1770 students (≥18 years) who screened positive for unhealthy alcohol use (ie, a score on the alcohol use disorders identification test-consumption (AUDIT-C) of ≥4 for men and ≥3 for women) were randomly assigned by 1:1 allocation ratio in blocks of 10.

INTERVENTION: Providing access to a brief, smartphone based alcohol intervention.

OUTCOME MEASURES: The primary outcome studied was number of standard drinks per week at six months and the secondary outcome was number of heavy drinking days (past 30 days). Additional outcomes were maximum number of drinks consumed on one occasion, alcohol related consequences, and academic performance. Follow-up assessments occurred at months three, six, and 12. Data were analysed by intention to treat and by using generalised linear mixed models with random intercepts for the recruitment site and participants nested within the recruitment site, and with intervention (v control), time (three months v six months; 12 months v six months), and baseline outcome values as fixed effects.

RESULTS: Between 26 April 26 2021 and 30 May 2022, 1770 participants (intervention group (n = 884); control group (n = 886)) were included. Mean age was 22.4 years (standard deviation 3.07); 958 (54.1%) were women; and 1169 (66.0%) were undergraduate students, 533 (30.1%) were studying for a master's degree, 43 (2.4%) were studying for a doctorate, and 25 (1.4%) were students of other higher education programme. The baseline mean number of standard drinks per week was 8.59 (standard deviation 8.18); the baseline number of heavy drinking days was 3.53 (4.02). Of 1770 participants, follow-up rates were 1706 (96.4%) at three months, 1697 (95.9%) at six months, and 1660 (93.8%) at 12 months. Of 884 students randomly assigned to the intervention group, 738 (83.5%) downloaded the smartphone application. The intervention had a significant overall effect on the number of standard drinks per week (incidence rate ratio 0.90 (95% confidence interval 0.85 to 0.96)), heavy drinking days (0.89 (0.83 to 0.96)), and the maximum number of drinks consumed on one occasion (0.96 (0.93 to 1.00), P=0.029), indicating significantly lower drinking outcomes in the intervention group than in the control group during the follow-up period. The intervention did not affect alcohol related consequences or academic performance.

CONCLUSIONS: Providing access to the smartphone application throughout the 12 month follow-up was effective at limiting the average drinking volume of university students who had self-reported unhealthy alcohol use at baseline.

Infect Control Hosp Epidemiol. 2023 Aug 23;1-6.

Comparison of virus aerosol concentrations across a face shield worn on a healthcare personnel during a simulated patient cough

Pratt AA, Brown GD, Perencevich EN, Diekema DJ, Nonnenmann NW.

BACKGROUND: Patients diagnosed with coronavirus disease 2019 (COVID-19) aerosolize severe acute respiratory coronavirus virus 2 (SARS-CoV-2) via respiratory efforts, expose, and possibly infect healthcare personnel (HCP). To prevent transmission of SARS-CoV-2, HCP have been required to wear personal protective equipment (PPE) during patient care. Early in the COVID-19 pandemic, face shields were used as an approach to control HCP exposure to SARS-CoV-2, including eye protection.

METHODS: An MS2 bacteriophage was used as a surrogate for SARS-CoV-2 and was aerosolized using a coughing machine. A simulated HCP wearing a disposable plastic face shield was placed 0.41 m (16 inches) away from the coughing machine. The aerosolized virus was sampled using SKC biosamplers on the inside (near the mouth of the simulated HCP) and the outside of the face shield. The aerosolized virus collected by the SKC Biosampler was analyzed using a viability assay. Optical particle counters (OPCs) were placed next to the biosamplers to measure the particle concentration.

RESULTS: There was a statistically significant reduction ($P < .0006$) in viable virus concentration on the inside of the face shield compared to the outside of the face shield. The particle concentration was significantly lower on the inside of the face shield compared to the outside of the face shield for 12 of the 16 particle sizes measured ($P < .05$).

CONCLUSIONS: Reductions in virus and particle concentrations were observed on the inside of the face shield; however, viable virus was measured on the inside of the face shield, in the breathing zone of the HCP. Therefore, other exposure control methods need to be used to prevent transmission from virus aerosol.

Am J Cardiol. 2023 Aug 19;205:111-119. doi: 10.1016/j.amjcard.2023.07.161. Online ahead of print.

Aortic valve replacement in patients with ESRD and heart failure with reduced ejection fraction

Warner ED, Riley J, Liotta M, et al.

Transcatheter aortic valve replacement (TAVR) has become the standard of care for the treatment of all patients with calcific aortic stenosis. Patients with end-stage renal disease (ESRD) on hemodialysis were excluded from participation in many of the seminal trials proving the safety and efficacy of TAVR. The outcomes of TAVR in the ESRD population from a national registry showed significantly higher in-hospital and 1-year mortality compared with patients not on hemodialysis. Comparisons of outcomes for surgical versus transcatheter interventions in patients with ESRD and heart failure with reduced ejection fraction (HFrEF) are limited. Using the United States Renal Data System, we identified all ESRD patients with aortic stenosis and HFrEF who underwent TAVR, surgical aortic valve replacement (SAVR), or those with HFrEF and aortic stenosis initiated on dialysis after the year 2012 to compare survival. Propensity score matching was performed, and groups were compared using Kaplan-Meier curves. The study population consisted of 7,660 patients, of which 5,064 (66.1%) were male. The median age at initiation of dialysis was 73 years (interquartile range: 65 to 80). There were 1,108 (14.5%) who underwent TAVR and 695 (9.1%) who underwent SAVR. After matching, patients who underwent TAVR had increased survival relative to those who were medically managed. In-hospital outcomes favored TAVR with less mortality and fewer complications when compared with SAVR. TAVR had improved mortality relative to SAVR in the early period, but survival curves crossed at approximately 9 months and SAVR had better mortality in the long-term. TAVR is a safe and effective procedure and is associated with improved mortality when compared with medical management. In conclusion, TAVR and SAVR are both viable options for patients with ESRD and HF with TAVR having better short-term outcomes and SAVR better long-term outcomes.

Am J Cardiol. 2023 Aug 19;205:176-181. doi: 10.1016/j.amjcard.2023.07.173. Online ahead of print.

Use of intravascular ultrasound and coronary angiography to measure the prevalence of myocardial bridge in heart transplant patients

Medina F, Estrada A, Fernandez C, et al.

Myoardial bridge (MB) detection rates vary across methods and most studies that have assessed MB include symptomatic patients. Intravascular ultrasound (IVUS) is a sensitive tool for MB detection and donor hearts may serve as a surrogate measure of asymptomatic patients. We used IVUS and coronary angiography to measure MB prevalence in heart transplant patients during routine follow-up invasive coronary assessments. This was a retrospective, single-center study of heart transplant patients who received follow-up coronary assessments at the University of Chicago Heart and Vascular Center between December 2014 and December 2021. A single experienced interventional cardiologist assessed incidental findings of MB in IVUS and coronary angiography. Detection rates were compared with meta-analysis-reported prevalence. Of 129 patients, IVUS-detected MB in 87 patients (67.4%), whereas coronary angiography detected 41 (31.8%). All MB found by coronary angiography were detected

by IVUS. Some level of cardiac allograft vasculopathy was found in 92 patients (71.3%). Our IVUS-detected MB prevalence was greater than meta-analysis-reported pooled prevalence across all methods: autopsy, computed tomography angiography, and coronary angiography (67.4% [95% confidence interval [CI] 59.4 to 75.5] vs 42% [95% CI 30 to 55]; 22% [95% CI 18 to 25]; 6% [95% CI 5 to 8], p ≤0.005). The difference between our observed IVUS-detected MB prevalence and meta-analysis autopsy reported MB prevalence was 1.25 (95% CI 1.11 to 1.40). In conclusion, the high prevalence of MB recorded in donor hearts emphasizes the need to further investigate the causes of chest pain in patients who are found to have MB.

J Heart Lung Transplant. 2023 Aug 17;S1053-2498(23)01968-X. doi: 10.1016/j.healun.2023.08.008. Online ahead of print.

Impact of size matching on survival post heart transplant in infants: estimated total cardiac volume ratio outperforms donor recipient weight ratio

Dani A, Ahmed HF, Guzman-Gomez A, et al.

PURPOSE: Cardiac volume-based estimation offers an alternative to donor-recipient weight ratio (DRWR) in pediatric heart transplantation (HT), but has not been correlated to post-transplant outcomes. We sought to determine whether estimated Total Cardiac Volume (eTCV) ratio is associated with HT survival in infants.

METHODS: The UNOS database was used to identify infants (age: < 1 year) who received HT in 1987-2020. Donor and recipient eTCV were calculated from weight using previously published data. Patient cohort was divided according to the significant range of eTCV ratio; characteristics and survival were compared.

RESULTS: 2845 infants were identified. Hazard ratio with cubic spline showed prognostic relationship of eTCV ratio and DRWR with the overall survival. The cut-point method determined an optimal eTCV ratio range predictive of infant survival was 1.05-1.85, whereas no range for DRWR was predictive. 75.6% patients had an optimal TCV ratio, while 18.1% were in the lower (LR) and 6.3% in the higher (HR) group. Kaplan-Meier analysis showed better survival for patients within the optimal vs LR (p = 0.0017), and a similar significantly better survival when compared to HR (p = 0.0053). The optimal eTCV ratio group (n = 2151) had DRWR ranging from 1.09-5; 34.3% had DRWR 2-3, and 5.0% DRWR > 3.

CONCLUSION: Currently, an upper DRWR limit has not been established in infants. Therefore, determining the optimal eTCV range is important to identifying an upper limit that significantly predicts survival benefit. This finding suggests a potential increase in donor pool for infant recipients since over 40% of donors in the optimal eTCV range includes DRWR values > 2 that are traditionally not considered for candidate listing.

Hypertension. 2023 Aug 21. doi: 10.1161/HYPERTENSIONAHA.123.21174. Online ahead of print.

Incidence of new-onset hypertension post-COVID-19: comparison with influenza

Zhang V, Fisher M, Hou W, Zhang L, Duong TQ.

BACKGROUND: SARS-CoV-2 may trigger new-onset persistent hypertension. This study investigated the incidence and risk factors associated with new-onset persistent hypertension during COVID-19 hospitalization and at ≈6-month follow-up compared with influenza.

METHODS: This retrospective observational study was conducted in a major academic health system in New York City. Participants included 45 398 patients with COVID-19 (March 2020 to August 2022) and 13 864 influenza patients (January 2018 to August 2022) without a history of hypertension.

RESULTS: At 6-month follow-up, new-onset persistent hypertension was seen in 20.6% of hospitalized patients with COVID-19 and 10.85% of nonhospitalized patients with COVID-19. Persistent hypertension incidence among hospitalized patients did not vary across the pandemic, whereas that among hospitalized patients decreased from 20% in March 2020 to ≈10% in October 2020 (R2 = 0.79, P = 0.003) and then plateaued thereafter. Hospitalized patients with COVID-19 were 2.23 ([95% CI, 1.48-3.54]; P < 0.001) times and nonhospitalized patients with COVID-19 were 1.52 ([95% CI, 1.22-1.90]; P < 0.01) times more likely to develop persistent hypertension than influenza counterparts. Persistent hypertension was more common among older adults, males, patients with preexisting comorbidities (chronic obstructive pulmonary disease, coronary artery disease, chronic kidney disease), and those who were treated with pressor and corticosteroid medications. Mathematical models predicted persistent hypertension with 79% to 86% accuracy. In addition, 21.0% of hospitalized patients with COVID-19 with no prior hypertension developed hypertension during COVID-19 hospitalization.

CONCLUSIONS: Incidence of new-onset persistent hypertension in patients with COVID-19 is higher than in those with influenza, likely constituting a major health burden given the sheer number of patients with COVID-19. Screening at-risk patients for hypertension following COVID-19 illness may be warranted.

J Clin Endocrinol Metab. 2023 Aug 18;108(9):2262-2271. doi: 10.1210/clinem/dgad139.

Defining predictors of weight loss response to lorcaserin

Gugger AS, Dimino C, Panigrahi SK, et al.

CONTEXT: Individual responses to weight loss (WL) medications

vary widely and prediction of response remains elusive.

OBJECTIVE: We investigated biomarkers associated with use of lorcaserin (LOR), a 5HT2cR agonist that targets proopiomelanocortin (POMC) neurons that regulate energy and glucose homeostasis, to identify predictors of clinical efficacy.

METHODS: Thirty individuals with obesity were treated with 7 days of placebo and LOR in a randomized crossover study. Nineteen participants continued on LOR for 6 months. Cerebrospinal fluid (CSF) POMC peptide measurements were used to identify potential biomarkers that predict WL. Insulin, leptin, and food intake during a meal were also studied.

RESULTS: LOR induced a significant decrease in CSF levels of the POMC prohormone and an increase in its processed peptide β-endorphin after 7 days; β-endorphin/POMC increased by 30% ($P < .001$). This was accompanied by a substantial decrease in insulin, glucose, and homeostasis model assessment of insulin resistance before WL. Changes in CSF POMC peptides persisted after WL (6.9%) at 6 months that were distinct from prior reports after diet alone. Changes in POMC, food intake, or other hormones did not predict WL. However, baseline CSF POMC correlated negatively with WL ($P = .07$) and a cutoff level of CSF POMC was identified that predicted more than 10% WL.

CONCLUSION: Our results provide evidence that LOR affects the brain melanocortin system in humans and that effectiveness is increased in individuals with lower melanocortin activity. Furthermore, early changes in CSF POMC parallel WL-independent improvements in glycemic indexes. Thus, assessment of melanocortin activity could provide a way to personalize pharmacotherapy of obesity with 5HT2cR agonists.

Clin Orthop Relat Res. 2023 Aug 18. doi: 10.1097/CORR.0000000000002767. Online ahead of print.

Does preoperative pharmacogenomic testing of patients undergoing TKA improve postoperative pain? A randomized trial

Kraus MB, Bingham JS, Kekic J, et al.

BACKGROUND: Pharmacogenomics is an emerging and affordable tool that may improve postoperative pain control. One challenge to successful pain control is the large interindividual variability among analgesics in their efficacy and adverse drug events. Whether preoperative pharmacogenomic testing is worthwhile for patients undergoing TKA is unclear.

QUESTIONS/PURPOSES: (1) Are the results of preoperative pharmacogenetic testing associated with lower postoperative pain scores as measured by the Overall Benefit of Analgesic Score (OBAS)? (2) Do the results of preoperative pharmacogenomic testing lead to less total opioids given? (3) Do the results of preoperative pharmacogenomic testing lead to changes in opioid prescribing patterns?

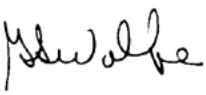
METHODS: Participants of this randomized trial were enrolled from September 2018 through December 2021 if they were aged 18 to 80 years and were undergoing primary TKA under general anesthesia. Patients were excluded if they had chronic kidney disease, a history of chronic pain or narcotic use before surgery, or if they were undergoing robotic surgery. Preoperatively, patients completed pharmacogenomic testing (RightMed, OneOME) and a questionnaire and were randomly assigned to the experimental group or control group. Of 99 patients screened, 23 were excluded, one before randomization; 11 allocated patients in each group did not receive their allocated interventions for reasons such as surgery canceled, patients ultimately undergoing spinal anesthesia, and change in surgery plan. Another four patients in each group were excluded from the analysis because they were missing an OBAS report. This left 30 patients for analysis in the control group and 38 patients in the experimental group. The control and experimental groups were similar in age, gender, and race. Pharmacogenomic test results for patients in the experimental group were reviewed before surgery by a pharmacist, who recommended perioperative medications to the clinical team. A pharmacist also assessed for clinically relevant drug-gene interactions and recommended drug and dose selection according to guidelines from the Clinical Pharmacogenomics Implementation Consortium for each patient enrolled in the study. Patients were unaware of their pharmacogenomic results. Pharmacogenomic test results for patients in the control group were not reviewed before surgery; instead, standard perioperative medications were administered in adherence to our institutional care pathways. The OBAS (maximum 28 points) was the primary outcome measure, recorded 24 hours postoperatively. A two-sample t-test was used to compare the mean OBAS between groups. Secondary measures were the mean 24-hour pain score, total morphine milligram equivalent, and frequency of opioid use. Postoperatively, patients were assessed for pain with a VAS (range 0 to 10). Opioid use was recorded preoperatively, intraoperatively, in the postanesthesia care unit, and 24 hours after discharge from the postanesthesia care unit. Changes in perioperative opioid use based on pharmacogenomic testing were recorded, as were changes in prescription patterns for postoperative pain control. Preoperative characteristics were also compared between patients with and without various phenotypes ascertained from pharmacogenomic test results.

RESULTS: The mean OBAS did not differ between groups (mean ± SD 4.7 ± 3.7 in the control group versus 4.2 ± 2.8 in the experimental group, mean difference 0.5 [95% CI -1.1 to 2.1]; $p = 0.55$). Total opioids given did not differ between groups or at any single perioperative timepoint (preoperative, intraoperative,

continues on page 35

Celebrating National Case Management Week
continued from page 2

I commend, salute, and implore you to recognize yourself and what you do not just this National Case Management Week but every week. Rejoice and be grateful for what you do. YOU ARE MAKING A DIFFERENCE! THANK YOU!



Gary S. Wolfe, RN, CCM, FCM
Editor-in-Chief
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ACCM: Improving Case Management Practice through Education

Celebrate National Case Management Week: Keeping the Person at the Heart of Collaborative Care
continued from page 6

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

CMS Issues Memo to Hospitals About Requirement to Provide Information to Post-Acute Providers
continued from page 8

- Conduct case reviews of previous discharges to improve outcomes of future discharges

Enable access to patient information in electronic health records (EHRs) by PAC providers so necessary information can be accessed to improve transitions.

Discharge planners/case managers should be prepared for increased scrutiny regarding these issues during surveys. CM

Always a Nurse, Forever a Case Manager *continued from page 7*

I developed a care plan that she could follow, allowing her to become more independent in her home.

I was the contact person for the home health nurse to call after drawing her INR levels and then I'd adjust her warfarin according to the doctor's orders. A huge frustration for my neighbor was her oxygen therapy, and she desperately wanted to wean herself off. I got an order from her nurse practitioner to start weaning, and I set up a log with columns where she would document how many minutes/hours she was off her oxygen, her activity level, and then her oxygen saturation level taken with the home device I gave her.

She felt empowered knowing that she was working towards weaning herself off of her oxygen therapy.

The last step towards gaining more independence at home was her medication setup. I was doing the medication setup every week and when her medications were stable, she and I set up the medications together. The following week she return-demonstrated setting up her own medications and was confident with her self-care at home. My neighbor would call me several times a day in the beginning, but as I helped her gain her independence at home, the calls decreased to once or twice a week. Throughout my neighbor's recovery to independence and self-care she was always the center of her health care, making her own decisions along with the expertise of her medical team. She's doing very well now, driving herself to outpatient cardiac rehab and has her independence thanks to a retired nurse/case manager, home health care, and all of her friends.

The takeaway point here is the importance of having a case manager to navigate a patient through the health care system, guide the patient towards independence, and help the patient reach their optimal level of health. CM

Speaking With One Voice: 3 Case Management Organizations Celebrate Case Managers
continued from page 5

consciousness, and other goals of value-based care delivery. They bring to case management their expertise from any number of professional backgrounds: nursing; social work; vocational rehabilitation; disability management; counseling; occupational, physical, and respiratory therapy; pharmacy; and others. They hold a broad array of job titles, practice in several care settings, and often hold specializations. All of this comes together under the broad umbrella of case management, with high standards of professionalism and ethical practice.

As we look to the future, we know that the health care system will rely even more on the contribution of case managers. In recognition of this vital role, CCMC proudly raises its voice with CMSA and ACMA to salute case managers in all they do. CM

continued from page 29

TABLE 1

Capsule Strength	Capsule Colors	Capsule Markings	Packaging Configuration	NDC
20 mg	light-orange cap ivory to light-yellow body	Black "S-217 20 mg" on body	Bottle of 14	64406-029-01
25 mg	light-orange cap light-orange body	Black "S-217 25 mg" on body	Bottle of 14	64406-030-01
			Blister pack of 28	64406-030-02
30 mg	orange cap light-orange body	Black "S-217 30 mg" on body	Bottle of 14	64406-031-01

Storage
Store at room temperature 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F)

For full prescribing information, please see Product Insert.

Zurzuvae is manufactured for Biogen, Inc., Cambridge, MA.

LITSCAN FOR CASE MANAGERS

continued from page 33

or postoperative). We found no difference in opioid prescribing pattern. After adjusting for multiple comparisons, no difference was observed between the treatment and control groups in tramadol use (41% versus 71%, proportion difference 0.29 [95% CI 0.05 to 0.53]; nominal p = 0.02; adjusted p > 0.99).

CONCLUSION: Routine use of pharmacogenomic testing for patients undergoing TKA did not lead to better pain control or decreased opioid consumption. Future studies might focus on at-risk populations, such as patients with chronic pain or those undergoing complex, painful surgical procedures, to test whether pharmacogenomic results might be beneficial in certain circumstances.

Mov Disord. 2023 Aug 21. doi: 10.1002/mds.29580. Online ahead of print.

Plant-based dietary patterns and Parkinson's disease: a prospective analysis of the UK biobank

Tresserra-Rimbau A, Thompson AS, Bondonno N, et al.

BACKGROUND: Plant-based diets have been associated with a lower risk of several chronic diseases, but the relationship with PD is unknown.

OBJECTIVES: We examined the association of three different plant-based diets with PD incidence in the UK Biobank cohort.

METHODS: We conducted a prospective study among 126,283 participants from the UK Biobank cohort. Three plant-based diet indices (overall plant-based diet index, PDI; healthful plant-based diet index, hPDI; and unhealthful plant-based diet index, uPDI) were derived from 24-hour dietary recalls based on 17 food groups. Multivariable Cox regression models were used to estimate the risk of PD across quartiles of the PDIs and for each of

continues on page 37

Professional Development, Interprofessional Collaboration, and Case Management Recognition

continued from page 4

contributor and now also a member of our Editorial Advisory Board, provides a compelling discussion of just how quickly technology is becoming more involved in mental health support. It underscores the importance of both understanding the advantages of this technology and ensuring that we are mindful of our Code of Professional Conduct for Case Managers and Disability Management Specialists. Mann provides specific considerations so that we can advocate for appropriate, safe, and ethical treatment.

As we acknowledge and celebrate the contributions that case managers make each and every day, remember to take a few moments to enjoy a bit of time to care for YOU…you deserve it!!

We can and do make a difference… one patient at a time!

Catherine M. Mullahy

Catherine M. Mullahy, RN, BS, CRRN, CCM, FCM, *Executive Editor*
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In summary, nursing, social work, navigation, and pharmacist services are integral in the TOC process and require an all-hands-on-deck approach. No one member is more important than the next, but each one is essential in ensuring a safe and effective transition across settings.

All Hands on Deck: An Interprofessional Collaboration Model for Successful Transitions of Care

continued from page 21

settings, including inpatient, ambulatory, longitudinal care, and community pharmacist-run programs. The strength of these principles is to guide pharmacists in supporting patients and care teams during TOC regardless of the setting.

Our TOC model uses pharmacists as both consultants and direct patient care practitioners. We have used and will continue to use these pharmacist TOC principles, even though the pharmacist services in our model of care are continuously evolving.

In summary, nursing, social work, navigation, and pharmacist services are integral in the TOC process and require an all-hands-on-deck approach. No one member is more important than the next, but each one is essential in ensuring a safe and effective transition across settings. This model addresses the barriers to TOC by improving communication breakdowns among health care practitioners, increasing patient education and understanding, and reducing medication reconciliation errors. By focusing on these barriers, patient outcomes improve, and unnecessary utilization and readmissions are reduced.

As one of our care team members stated, *"What makes our care management model a success is our unique team approach. Utilizing the expertise of each discipline and role has allowed us to focus on all areas of need for a patient and provides the wraparound care that supports an environment of healing and better health."* CE II

The thoughts and opinions offered in this article are those of the authors and do not necessarily represent the official position of The American Medical Association.

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LITSCAN FOR CASE MANAGERS

continued from page 35

the food groups that constituted the score. Further analyses were carried out to assess potential heterogeneity in associations between hPDI and PD across strata of some hypothesized effect modifiers.

RESULTS: During 11.8 years of follow-up (1,490,139 person-years), 577 cases of PD incidence were reported. After multivariable adjustment, participants in the highest hPDI and overall PDI quartile had lower risk of PD (22% and 18%, respectively), whereas a higher uPDI was associated with a 38% higher PD risk. In food-based analyses, higher intakes of vegetables, nuts, and tea were associated with a lower risk of PD (28%, 31%, and 25%, respectively). Stratifying by Polygenic Risk Score (PRS), results were significant only for those with a lower PRS for PD.

CONCLUSIONS: Following a healthful plant-based diet and in particular the inclusion of readily achievable intakes of vegetables, nuts, and tea in the habitual diet are associated with a lower risk of PD.

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Effects of joint mobilization combined with acupuncture on pain, physical function, and depression in stroke patients with chronic neuropathic pain: a randomized controlled trial

Lee J-E, Akimoto T, Chang J, Lee HS.

OBJECTIVE: To investigate the effectiveness of joint mobilization (JM) combined with acupuncture (AC) for the treatment of pain, physical function and depression in poststroke patients.

METHODS: A total of 69 poststroke patients were randomly assigned to the JM+AC group (n = 23), the JM group (n = 23), and the control group (n = 23). Patients in the JM+AC group and the JM group received JM for 30 minutes, twice a week for 12 weeks, and the JM+AC group received AC for 30 minutes separately once a week. The control group did not receive JM or AC. Pain (visual analog scale, shoulder pain and disability index, Western Ontario and McMaster universities osteoarthritis index), physical function (range of motion, 10-m walking speed test, functional gait assessment, manual function test, activities of daily living scale, instrumental activities of daily living scale), and depression (center for epidemiologic studies depression scale, Beck depression inventory) were assessed for each patient before and after the 12 weeks of intervention.

RESULTS: Pain and physical function were improved significantly in the JM+AC group compared with the JM and control groups. Physical function and depression were improved significantly in the JM+AC and JM groups compared with the control group.

CONCLUSION: The treatment of JM combined with AC improved pain, depression, and physical function of poststroke patients with chronic neuropathic pain in this study. This valuable finding provides empirical evidence for the designing therapeutic interventions and identifying potential therapeutic targets.

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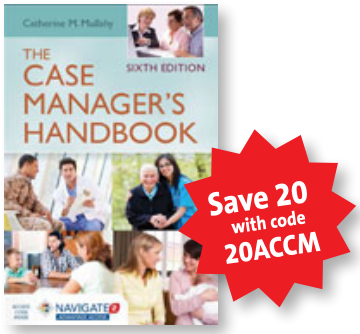

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