CareManagement

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Gary S. Wolfe

Case Management in 2022

The year 2021 is behind us and we are in 2022. What lies ahead for case managers in 2022? Let's take a brief look back. In 2021, the COVID-19 pandemic continued to change our lives. Almost everything we did was influenced by the COVID-19 pandemic, including how we worked and how we lived. Some believe that the new normal is here.

Here are some things we have learned in 2021.

- Technology plays an increasingly important role in our lives
- Self-care is important
- Relationships matter
- We can work anywhere
- We gather carefully

As we look ahead, what challenges will we face as case managers? The COVID-19 pandemic will be with us for all of 2022 to a greater or lesser degree. It is hard to predict, but we know it will be present. Along with the pandemic and other health care trends, what should case managers look to for 2022?

- **Preventive care:** The promotion of preventive care will grow. We will see more screening, and healthy habits will be encouraged.
- **Virtual care:** Virtual care is the future of the health care landscape. We have seen a dramatic increase in telehealth. For people with the right internet connection, it is easy, efficient, and cost effective.
- **New technologies:** We will see the introduction of new technologies, including the expansion of artificial intelligence for health care. Electronic connectivity will be key.
- **Labor shortages:** Labor shortages in health care will continue to increase and become critical. New delivery models will emerge. Some tasks will become automated. Programs will be developed to foster resiliency and workforce well-being. With acute labor shortages, salaries and benefits will increase, and those costs will be passed on to the consumer.
- **Value-based care:** The shift to value-based and outcome-oriented care will accelerate. The traditional fee-for-service program will be replaced with value-based programs where the emphasis is on patient outcomes not on just doing a procedure, test, or visit.
- **Behavioral health:** Behavioral health will continue to increase in importance. The separation between behavioral and physical health will dwindle. More behavioral health is needed with an emphasis on availability and reimbursement.
- **Health equality:** Work toward health equity and eliminating health disparities will continue.
- **Acquisition of knowledge:** The acquisition of knowledge for the case manager will change from the traditional attendance of in-person programs to virtual programs using

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Catherine M. Mullahy

Can You Spell Resilience?

The pandemic continues to have a sobering impact on those who have chosen health care as their career. All across the continuum of care, we are enduring what seems to be a never-ending pandemic, and we are not sure if the "new normal" is here yet. Just as we were breathing a sigh of relief when the Delta strain was decreasing, the Omicron strain appeared, and now we wonder when and where the next variant will appear.

While we were hopeful that vaccines, boosters, and the disease itself would protect us from new infections, especially among the most vulnerable, what we saw was that, regardless of the level of immunity or protection, the Omicron strain was able to penetrate that shield. The numbers of individuals who did everything that they were told to do (ie, get 2 vaccine doses and a booster) were incredibly and understandably disappointed when they tested positive and/or became ill. The level of concern, frustration, and, unfortunately, the erosion of confidence in the organizations and institutions that were providing guidance and direction increased. Some of us in health care were questioning this as well. We are an evidence-based profession that relies on science to make sound judgments and care for our patients, ourselves, and our family members. The science surrounding COVID-19 and its variants, however, appears to be ever-changing and evolving. How do we know what is best practice? A recent CDC study revealed that natural immunity was more effective against the Delta variant than vaccines alone. One, therefore, wonders if that might be true for Omicron and future variants. Surely, some of this thinking flies in the face of what we were told and wanted to believe.

Health care professionals, especially those on the frontlines, were coping with the physical and emotional challenges that they were facing day after day over a protracted period. Because we are human beings, there is just so much that we can withstand. That's not a character flaw but rather the acknowledgement of one's limitations.

Typically, resilience is defined as the capacity to recover from difficult life events. The "bouncing back" during these tumultuous times may make some of us feel as if we are on a trampoline or a roller coaster—one that we'd like to get off!

In this issue, Coulter and Ott publish an article titled "Health Care Provider Suicide: Another Tragic Toll of Coronavirus Pandemic." Also discussed in this issue, in a proactive effort to support and guide case managers, is CCMC's launch of "Push Pause Response—and Reboot," an innovative and inspirational campaign to promote self-care. Initially released in 2020 and rereleased in 2021, the campaign will be continued into 2022.

Although we recognize the severity of COVID-19-related issues and, of course, want to support our colleagues who are dealing with these issues, as case managers we are also problem solvers who continuously strive to find or create solutions. Thus, acknowledging the issues that we and our colleagues are facing is an important first step, but creating pathways toward resilience is essential. The 7 Cs of resilience are competence, confidence, connections, character, contribute, coping, and control, and there are strategies to nurture those characteristics of resilience.

Typically, resilience is defined as the capacity to recover from difficult life events. The "bouncing back" during these tumultuous times may make some of us feel as if we are on a trampoline or a roller coaster—one that we'd like to get off! We need to care for ourselves so that we can care for others, and that needs to start now. You are worth it, so why wait?

While we are still in the tunnel of this pandemic, we can and must remain hopeful. Easier said than done, you say? We can embrace the following:

- **Get connected.** During difficult times, reach out to family, friends, and colleagues.
- **Make every day meaningful.** Know that each day holds the promise of something wonderful and that it is possible to achieve our goals, even the difficult ones.
- **Learn from experience.** Whether that experience is good or not so good, we can learn something from it.
- **Remain hopeful.** You can't change the past, but you can look toward the future.
- **Be proactive.** Acknowledge your problems and figure out what needs to be done, one step at a time.

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The Burden of *Clostridioides difficile*

Rebecca Perez, MSN, RN, CCM

The most common cause of diarrhea occurring in a health care setting is *Clostridioides difficile (C. diff)*, which is also the cause of antibiotic-associated colitis (McDonald, 2021). The infection results from a disruption in the microbial flora of the gastrointestinal tract, mainly after antibiotic use or some other medications such as proton pump inhibitors. As a result, infected individuals are colonized and shed the spores into the environment and infect others; thus, the goals of treatment focus on reducing the exposure and individual susceptibility.

Of the estimated 500,000 annual cases, most were infected while hospitalized (Kelly, 2021). Hospitalizations have increased 339%, causing extended lengths of stay (Scoble, 2021). The risk of infection increases with antibiotic use in the elderly and infants with a history of severe illness, weakened immune system, and Crohn's disease or ulcerative colitis (Kelly, 2021). In addition, individuals recovering from *C. diff* are at the highest risk of recurrence (CDC, 2021). Annual costs for acute care facilities are estimated at $6.3 million annually, with individual episodes costing $8911 to $30,049 (Scoble, 2021). With the first occurrence of *C. diff*, >30% will have a second occurrence, and of those individuals, 40%-60% will have a third occurrence. These costs and potential high medication copays contribute to the individual's suffering and continue to drain the use of health care resources (Kamal Desai, 2016).

The most common cause of diarrhea occurring in a health care setting is *Clostridioides difficile (C. diff),* which is also the cause of antibiotic-associated colitis. The infection results from a disruption in the microbial flora of the gastrointestinal tract, mainly after antibiotic use or some other medications such as proton pump inhibitors.

Although the incidence of *C. diff* is stable, recurrence is increasing significantly, with severe complications also a concern. The increased incidence and potential for life-threatening conditions require reducing initial exposure, supporting prescribed treatment, and preventing recurrence.

Effective and efficient care transitions and coordination are the solutions to reducing the incidence and adverse events. Case managers need to take a primary role in the transition and care coordination processes, including patient and support system education, coordination of any postdischarge services, connection to providers, adherence support activities, and follow-up for improvement or changes in condition. Supportive adherence activities and prevention education will result in the avoidance of recurrence.

Case managers are well equipped to locate resources to assist patients who have difficulty paying for medications as well as those who are unable to attend appointments or access basic needs. While not directly related to *C. diff*, these challenges contribute to recurrence and readmission. Mitigating risk for readmission and recurrence results in an improved quality of life.

Case managers are professionals prepared to address prevention, transitions, care coordination, social determinants, and inequities. Case managers are found in every health care setting, and by way of their training, they can and do address all aspects of an individual's care journey. When equipped with the latest evidence and best practices, case

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***Rebecca Perez, MSN, RN, CCM**, is member of the Gamma Omega Chapter of Sigma Theta Tau International Nursing Honor Society. She is the author of numerous professional articles, a coauthor of CMSA's Integrated Case Management: A Manual for Case Managers by Case Managers, developer of the Integrated Case Management Training Program, and Master Trainer. She joined the Parthenon Management Group in 2020 as the Senior Manager of Education and Strategic Partnerships for the Case Management Society of America.*

Using Information and Communication Technology Standards to Deliver Care Effectively in a Virtual Environment

Terrence Carolan, MSPT

A strong starting point for any approach to information and communication technology includes robust policies to direct the use of that technology. Acquiring the consent of the patient and confirming that both providers and patients have the needed technology are two important starting points for this type of service delivery. As with any technology in a clinical setting, the competency of staff in the use of the technology is important to assess.

The last 2 years has seen a remarkable and unforeseen increase in the use of information and communication technologies to deliver care in nearly every healthcare arena. At the beginning of the pandemic, organizations and programs used technology in a "catch as catch can" fashion, using any available technology to communicate with patients and caregivers, provide care, or give patients an opportunity to connect with family members when in person visits weren't possible. As time as passed and COVID surges have ebbed and flowed, programs have been able to pause to reflect on how this technology is chosen and utilized.

For organizations that have been accredited by CARF International, there is a section of standards that speaks to the need to incorporate technology and a technology plan into business processes and practices, privacy and security of protected information, service delivery, performance management and improvement and satisfaction of persons served, personnel, and other stakeholders. These standards also speak to the need to have a strategy to manage information and communication technologies if they are used within the program.

Depending on the type of program, a variety of terminology (eg, telepractice, telehealth, telemental health, telerehabilitation, and telespeech) may be used to describe the use of information and communication technologies to deliver service. Based on the individual plan for the person served, the use of information and communication technologies allows providers to see, hear, and/or interact with persons served, family/support system members, and other providers in remote settings. The provision of services via information and communication technologies may:

- Include services such as assessment, individual planning, monitoring, prevention, intervention, follow-up, supervision, education, consultation, and counseling
- Involve a variety of professionals such as case managers/service coordinators, social workers, psychologists, speech-language pathologists, occupational therapists, physical therapists, physicians, nurses, rehabilitation engineers, assistive technologists, and teachers
- Encompass settings such as:
  - –Hospitals, clinics, professional offices, and other organization-based settings
  - –Schools, work sites, libraries, community centers, and other community settings
  - –Congregate living, individual homes, and other residential settings

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Terrence Carolan, MSPT, *is the Managing Director of Medical Rehabilitation in Tucson, Arizona. He is part of the medical rehabilitation team responsible for the training of CARF surveyors and for the development and revision of CARF standards.*

New Ways to Serve a New Generation of Veterans: **How Two VA Programs Are Making the Transition From the Military to VA Care Seamless**

Adrienne Weede, LCSW

More than 2 decades after the September 11, 2001, terrorist attacks, our nation has a new generation of veterans. With approximately 20% of today's veterans represented by men and women who served during the post-9/11 era, veteran care has been profoundly influenced.

Although veterans across generations share many commonalities, each era of military veterans is unique. For example, the veterans of Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF) were the first required to serve multiple deployments in a combat zone; some have had upwards of seven deployments. They are also among the most diverse in our nation's history. Additionally, OEF and OIF were the largest and longest lasting mobilizations of the Reserve and National Guard since the Korean War.

These features of the Global War on Terror have shaped a new generation of veterans and taught us a great deal about the need for transition and reintegration support.

Adrienne Weede, LCSW, *is the National Program Manager for the Post-9/11 Military2VA (M2VA) Case Management Program within the VHA Office of Care Management and Social Work under Patient Care Services. In this position, Ms. Weede provides oversight and program management for the Post-9/11 M2VA Case Management Programs located at VA medical centers nationwide.*

VA Serving Those Who Served

Because of advancements in body armor technology and battlefield medicine, more lives have been saved in combat. As seriously injured service members returned home from Afghanistan and Iraq, the Department of Defense (DoD) and Veterans Health Administration (VHA) collaborated on how to care for them.

Through this partnership, the VA Liaison Program and Post-9/11 Military2VA Case Management Program (originally OEF/OIF Program) were created. Together, the two programs operate with a shared mission: "Bridging the gap between the DoD and VHA to support transitioning service members and post-9/11 era veterans."

Established in 2003, VA Liaisons for Healthcare are assigned to military treatment facilities to coordinate the transition of care for returning service members. Their objective—which has remained unchanged—is to ensure safe, effective, and high-quality transitions of care for injured and ill service members from the DoD to VHA.

The VA Liaisons for Healthcare collaborate with DoD providers to understand service members' ongoing care needs and, once determined, provide direct access to coordinated and personalized VA healthcare.

Ensuring a Smooth Handoff

The VA Liaison starts the process by connecting with a Post-9/11 Military2VA Case Management team at the receiving VHA facility, who then engages with the service member. The handoff between the programs ensures the service member is registered and scheduled for an initial VA healthcare appointment before their military discharge date. Having a Post-9/11 M2VA Case Management Program embedded within every VA health care system supports service members' seamless transition across all 50 states.

Following the transition of care, the Post-9/11 Military2VA Case Management Program's case management process begins. This includes identification, screening, assessing, care planning, coordinating care, monitoring, and evaluating. Case management professionals also learn about a veteran's military history, which is invaluable in making a connection and helps to better understand a veteran's whole health care needs.

Using a standardized national data tool, Post-9/11 Military2VA Case Management teams identify all transitioning service members and post-9/11 era veterans who are new to a VA health care facility and those who have not yet been screened for case management.

During the last fiscal year, Post-9/11 Military2VA Case Management teams screened 211,366 post-9/11 era veterans for case management needs. More than 40,000 of these veterans received

The VA Liaisons for Healthcare collaborate with Department of Defense providers to understand service members' ongoing care needs and, once determined, provide direct access to coordinated and personalized VA healthcare.

longitudinal case management services, which included the Military2VA case manager serving as the "Lead Coordinator." Within VHA, the Lead Coordinator serves as the main point of contact for a veteran, their family, and their caregiver and oversees their holistic and integrated care planning.

Case Management Innovation During a Pandemic

Delivering comprehensive care coordination and case management during a pandemic challenged case management professionals in unimaginable ways. Fortunately, because of the nature of case management practice, Post-9/11 Military2VA Case Management teams were well equipped to innovate and elevate their practice.

This included adopting new virtual care platforms to ensure convenient and safe access to care and monitoring of the most vulnerable and high-risk veterans. Key attributes, such as resourcefulness, creativity, adaptability, and being mission-driven, paved the way for teams to support emergency response activities.

When the first wave of forces deployed in support of OEF, a new generation responded to the call to fight terrorism. Some gave their lives in answer to that call. For the many who have survived, they live with lasting impacts of their physical and mental injuries. Within the VA Liaison Program and Post-9/11 Military2VA

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Life on the COVID-19 Roller Coaster: Promoting Self-Care and Resilience

Vivian Campagna, DNP, RN-BC, CCM

As professional case managers continue to find themselves at the center of the COVID-19 response, they will no doubt face more professional and personal burdens. Education, support, and self-care remain critical. Through its expanded Push Pause campaign and other resources, the Commission remains committed to supporting the professional case management community.

In 2019, the National Academy of Medicine called on all health care organizations, educational institutions, specialty certification boards, and others to help combat what it called an epidemic of burnout among clinicians. A year later, the health care industry faced one of its biggest and longest-lasting challenges: the ongoing COVID-19 pandemic.

By the start of 2021, health and human services professionals were able to breathe a bit more easily with the rollout of vaccines and improved treatment protocols. But within a few months, the onset of the Delta variant and concerns over other coronavirus mutations put healthcare professionals back on an emotional rollercoaster. Surges in patient populations, including more children, occurred throughout the year. In response, clinical professionals have been redeployed, sometimes in areas outside their experience, while others continue to work remotely. Adding to their stresses, many of these professionals, including case managers, have experienced upsets in their personal lives, impacting their physical, mental, emotional, and financial health.

Vivian Campagna, DNP, RN-BC, CCM, *is the Chief Industry Relations Officer for the Commission for Case Manager Certification, the first and largest nationally accredited organization that certifies more than 50,000 professional case managers and disability management specialists. Vivian has also been involved in case management for almost 30 years and has held staff and administrative positions on both the independent and acute care side of the industry.*

From the onset of the pandemic, the Commission for Case Manager Certification (CCMC) has provided outreach to our population of board-certified case managers (CCMs). As part of those efforts, our 2020 surveys of 6,000 CCMs have been aligned with the National Academy of Medicine recommendations to find out what health and human services professionals need and provide them with education and resources.

The Commission's surveys conducted throughout the pandemic revealed both dramatic changes in how CCMs work and an increase in the personal burdens they carry. Together, they paint a sobering picture of what CCMs have faced for nearly 2 years, including by those who have been on the front line of response to the pandemic.

The Commission had the opportunity to present these findings at the recent Emory-AAPINA International Nursing Research Conference, cosponsored by the Asian American/Pacific Islander Nurses Association (AAPINA) and Emory University's Nell Hodgson School of Nursing. While most of the conference presentations involved quantitative research, the inclusion of the Commission's qualitative survey results acknowledged the importance and relevance of these findings.

Case Managers Bear Professional Burdens

Given the massive response to the pandemic across health and human services, as expected the survey results showed mounting professional burdens and personal stressors among CCMs. Results from survey respondents revealed:

- Almost 60% of board-certified case managers were working remotely, and 55% reported having limited contact with clients (known as patients in some care settings)
- Some, however, were called to work on the frontlines of the COVID-19 response

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What is Case Management?

Angela Gottschalk, BSN, RN, CCM

I have tried to answer this question many times over the span of my career. Due to the ever-changing healthcare environment in which we live, the answer seems to get more complex every year. How can something so complex with so many moving pieces be explained? If you are a leader in a case management department and interviewing candidates for a case management position, how do you explain what case management is without scaring people away? I am the Director of Case Management in an acute care hospital setting with close to 10 years of experience, and I still have trouble answering this question.

Let me start by explaining what case management is not. Case management is not always a Monday through Friday job. The hours are not always 8 am-4:30 pm. Depending on the organization the case manager chooses to work for, an acute care hospital, for example, they may be required to work on weekends and holidays. And if you are a leader in your department, you may even get a phone call for guidance on cases after hours. Case managers are not only nurses; they are social workers, therapists, or other licensed personnel. But wait, there's more!

Time for the good stuff. Case management is advocating for a patient when they are most vulnerable and cannot advocate for themselves. It is calling the local sheriff's office to fingerprint a John Doe trauma patient with hopes of being able to identify the patient so their loved ones are able to be notified. Case management is helping a patient and their caregiver understand how to better manage their illness by providing education and connecting them to resources in their community. It is knowing you can spend an extra ten minutes talking to your patient who may be lonely because some of the things on your to-do list can wait until tomorrow. Case management is taking a few extra minutes to help your patient use the bedside phone to call their family because they keep forgetting to press "9" before dialing the number. It is honoring the patient's right to refuse the most perfect discharge plan, even though they were agreeable to it two hours ago and you worked really hard on it. Case management is listening with your ears and assessing with your eyes. It is knowing when to recognize when something is not right and taking the time to dig a little deeper until you get to the root of the problem. Case management is giving patients and their caregivers the tools they need to maintain or improve their health so they may manage their health in the outpatient setting rather than coming to the emergency room and waiting for hours.

Case management is advocating for a patient when they are most vulnerable and cannot advocate for themselves. Case management is also helping a patient and their caregiver understand how to better manage their illness by providing education and connecting them to resources in their community.

Case management is knowing how to communicate effectively. It is recognizing complex discharges with barriers. It is coordinating meetings, better sooner than later, for the family and the treatment team to sit down together to discuss goals of care and options. Case management is having difficult conversations, happy conversations, celebratory conversations, and tearful conversations. It is communicating risks and benefits of adherence to a recommended treatment plan truthfully while still being compassionate and empathetic all while recognizing the patient's right to self-determination.

Case management is knowing how to collaborate with others on the treatment team. It is helping physicians transition patients to the lowest level of care that safely meets their patient's needs. It is helping the treatment team be good stewards of healthcare dollars spent. Case management is helping

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Part I: Updated Pharmaceutical Industry Marketing Code May Help All Providers Understand Current Standards

Elizabeth Hogue, Esq.

PhRMA, a trade association whose members are pharmaceutical research and biotechnology companies, recently updated its Code on Interactions with Health Care Professionals. The revised Code takes effect on January 1, 2022. Although the Code applies only to members of PhRMA who voluntarily agree to follow it, the Code may help providers to understand current standards regarding acceptable marketing practices.

With regard to taking lunches to physicians' offices, for example, the revised Code says that PhRMA members who elect to adhere to the Code may present information to healthcare professionals and their staff members during the workday, including at mealtimes. In connection with such presentations or discussions, the Code also says that it is appropriate for occasional meals to be offered as a business courtesy to the participants. The presentations must, however, provide scientific or educational value and meals must meet the following standards:

- Modest, by local standards
- Not part of an entertainment or recreational event
- Provided in a manner conducive to informational communication
- Limited to in-office or in-hospital settings
- Meetings do not include significant others or guests
- Incidental meals are provided only when there is a reasonable expectation and reasonable steps are taken to confirm that each attendee has a substantive interaction or discussion with representatives of the company. Consequently, "grab-and-go" meals are not appropriate.

With regard to entertainment and recreation, the Code says that to ensure the appropriate focus on education and informational exchange and to avoid the appearance of impropriety, companies should not provide any entertainment or recreational items to the theater or sporting events, sporting equipment, or leisure or vacation trips to any healthcare professional who is not a salaried employee of the company that receives the items.

PhRMA, a trade association whose members are pharmaceutical research and biotechnology companies, recently updated its Code on Interactions with Health Care Professionals. The revised Code took effect on January 1, 2022.

The Code also says that entertainment and recreational benefits should not be offered, regardless of:

- The value of the items
- Whether the company engages the healthcare professional as a speaker or consultant
- Whether the entertainment or recreation is secondary to an educational purpose

Home health agencies, hospices, private duty agencies, and home medical equipment (HME) companies may be especially interested in what the Code says about payments to healthcare consultants, including physicians.

The Code recognizes a legitimate need for providers to obtain information or advice from medical experts. The Code also points out, however, that decisions regarding the selection or retention of healthcare professionals as consultants should be made based on defined criteria such as general medical expertise, reputation or knowledge, and experience regarding particular therapeutic areas.

In addition to legal requirements included in applicable criteria of the safe harbors of the federal anti-kickback statute and exceptions to the Stark laws, the Code specifically requires members of PhRMA who voluntarily adhere to it to meet the following additional requirements:

- Enter into a written contract that specifies the nature of the consulting services to be provided and the basis for payment of those services
- There must be a legitimate need for the consulting services that has been clearly identified in advance of requesting the services and entering

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Part II: Updated Pharmaceutical Industry Marketing Code May Help All Providers Understand Current Standards

Elizabeth Hogue, Esq.

PhRMA, a trade association whose members are pharmaceutical research and biotechnology companies, recently updated its Code on Interactions with Health Care Professionals. The revised Code took effect on January 1, 2022. Although the Code applies only to members of PhRMA who voluntarily agree to follow it, the Code may help providers to understand current standards regarding acceptable marketing practices.

Providers may be interested to know that the Code includes a blanket prohibition on giving healthcare professionals any items that do not advance disease or treatment education, including practice-related items of minimal value such as pens, notepads, mugs, and similar "reminder" items with company or product logos. The reason for this recommended prohibition is that such items may create a misperception that interactions between providers are not based on informing them about medical and scientific issues. Consequently, noneducation items, such as those described above, should not be offered to health care professionals or their staff members, even if they are accompanied by patient or physician educational materials.

Providers may be interested to know that the updated Pharmaceutical Marketing Industry Code includes a blanket prohibition on giving healthcare professionals any items that do not advance disease or treatment education, including practice-related items of minimal value such as pens, notepads, mugs, and similar "reminder" items with company or product logos.

Likewise, the revised PHRMA Code says that providers who voluntarily adhere to the Code should not give referral sources items intended for the personal benefit of health care professionals such as floral arrangements, artwork, or tickets to sporting events.

With regard to items given to referral sources, the Code also says that cash equivalents such as gift certificates should not be provided either directly or indirectly. The basis for this recommendation is that they can create a potential appearance of impropriety or conflict of interest.

Members of PhRMA who decide to voluntarily adhere to the Code may, however, offer items designed primarily for the education of patients or healthcare professionals if the items are not of substantial value (i.e., $100.00 or less) and do not have value to healthcare professionals outside of their professional responsibilities. One example of a permitted item would be an anatomical model for use in an examination room for the education of patients. Items intended primarily for the education of patients and/or health care practitioners should, according to the revised Code, be offered on an occasional basis only, even if each individual item is appropriate.

Although the Code described above applies only to members of PhRMA who voluntarily agree to adhere to it, to the extent that the Code represents standards for marketing in the healthcare industry, it is helpful for all providers to know about it. CM

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

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Pandemic Era Developments for Postacute Care Networks: Part I

Laura Kukral, MBA, LNHA, and Ben Frank, MHA, FACHE

The COVID-19 pandemic brought profound changes to provider operations. Ethical dilemmas such as prioritizing patients for care went from preparedness discussions to reality. Supply chain best practices no longer assume products will be available from a favored vendor. Visitors lost open access to family and friends who were admitted to care facilities. Telehealth encounters rose 8,336% in 2020 over 2019 levels (Bellemare, 2021). In addition, unit organization, staffing practices, and organizational charts have been radically altered by many provider organizations to address the chaos created by multiple COVID-19 surges.

It is therefore not surprising that the postacute care networks ("networks") curated before the pandemic have been tested by the impacts of COVID-19, which have been significant across the continuum-of-care. Network structures, size, membership, goals, and use of technology are changing across the nation in response to the pandemic and local needs. Perhaps the most notable change for networks is the heightened importance health systems place on having a comprehensive senior care strategy in place.

Seniors represent a significant opportunity for both health system growth and risk, making the cohort a key target market. If more sickly seniors are served, postacute care networks

TABLE 1 PANDEMIC ERA DEVELOPMENTS FOR POSTACUTE CARE NETWORKS.

NETWORK DEVELOPMENTS	OBJECTIVES
1. Refocus from postacute strategy to community-wide "senior care strategy"	• Address needs of growing senior population, prepare for impact of delays in care during the pandemic, respond to constraints in postacute care access
2. Inclusive quality networks and referral exemptions become more common	• Reduce barriers to highest quality care available. Respond quickly to changes in quality or infection rates among postacute care providers.
3. Broadening goals	• Reduce transitions of care. • Address impact of increased care fragmentation caused by the pandemic.
4. Integrating with community-based organizations	• Collaborate on overlapping goals and share resources. • Refocus initiatives from postacute care to posthospital opportunities.
5. Technology: data	• Predict demand, specialty planning, hotspotting, network member evaluation, predictive care management.
6. Technology: telehealth	• After-hours urgent telehealth to reduce readmissions; specialty chronic care visits via telehealth to reduce costs and improve outcomes.
7. Technology: communication	• Bidirectional care management referrals and tracking between care settings and community-based organizations; early change-in-condition alerts and response; improved outcomes; and optimized revenue capture.
8. Technology: integration and interoperability	• Integrate device data into electronic health records; establish shared electronic health records between providers.
9. Alignment with Specialty Centers of Excellence ("Super Skilled Nursing Facilities")	• Facilitate hospital inpatient capacity; ensure postacute care specialty care access; improve length of stay, outcomes, and comanage costs of highest acuity patients.
10. Align strategies	• Network goals and workplans aligned to both sponsor and members.

Postacute care networks curated before the pandemic have been tested by the impacts of COVID-19, which have been significant across the continuum-of-care. Network structures, size, membership, goals, and use of technology are changing across the nation in response to the pandemic and local needs.

will need to address problems far bigger than reducing readmissions from nursing homes. Demographic trends, the uncertainties of pandemic surges, and widespread delays in care for seniors demand that postacute care networks be part of an integrated community-wide strategy for senior care. Whatever network characteristics we might have expected before the pandemic is evolving into something new. Table 1 lists developments and objectives for postacute care networks.

A Critical Role: Expanding Networks and Exemptions

Postacute care networks proliferated with the popularity of value-based payment programs. Some networks became extremely narrow, and during COVID-19 surges care managers struggled to find placements in skilled nursing facilities (SNFs), inpatient rehabilitation facilities, long-term care hospitals, and home healthcare. Hospitals responded by adding more providers to preferred lists, evaluating network membership more frequently, and changing the network model to an open and inclusive quality collaborative (rather than preferred or limited networks). Payors, like Blue Cross Blue Shield of Michigan, also recognized the need for flexible postacute care access during pandemic surges and the need to periodically suspend clinical review requirements for discharges to SNFs (Blue Care, 2021). The bottom line is that adequate access to postacute care safeguards hospital inpatient capacity and is a critical resource to hospitals, especially during public health emergencies.

Broadening Goals: Avoiding Transitions and Fragmentation

Almost half (47%) of all hospitals face costly penalties for readmissions for Medicare inpatients through September 2022 (Rau, 2021). Reducing unnecessary hospital readmissions is subsequently a leading goal of postacute care networks. However, COVID-19 inspired new conversations about reducing all types of patient transfers between care settings. Full hospitals, emergency department diversions, long waits for ambulance transports, and calls for the sick to quarantine at home to avoid the spread of COVID-19 propelled the need to provide care for patients where they live whenever possible.

COVID-19 made provider systems and patients vulnerable to heightened care fragmentation, especially when the system engages in risk arrangements. At times, patients must seek care from "any available" clinic, specialty physician, nursing home, or hospital regardless of network affiliation. Fragmentation is associated with increased costs of care, duplication of services such as diagnostic tests, and preventable readmissions (Frandsen et al., 2015). Network managers are responding to patient leakage by expediting communication between members and nonmembers, sharing real-time data through interoperable electronic records systems, broadly disseminating care protocols, and connecting patients to community-based organizations for social support.

During an American Hospital Association online seminar on May 7, 2020, executives from Highland Hospital in Rochester, New York, explained how their postacute care services program changed in reaction to the COVID-19 pandemic. They quickly organized a team of both postacute

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Adequate access to postacute care safeguards hospital inpatient capacity and is a critical resource to hospitals, especially during public health emergencies.

care and hospital staff to organize and manage available beds. The team then collaborated with county staff to find facilities with open beds, repurposed a 120-bed SNF that had been closed to house COVID-19 patients, and developed a tracking system of facilities with COVID-19 positive and negative status to discharge patients accordingly (American Hospital Association, 2021).

Like Highland Hospital, networks across the nation have had to revisit the meaning of "right patient, right time, right place," as they deal with bed shortages, fearful patients, and short supplies of therapeutic drugs, staff, and personal protective equipment The answers they came up include changing the network model and partnering in new ways with other providers. These changes look to be durable.

Integrating the Network: Community-Based Organizations Are Also Postacute Care

Clinical-community linkages can support network goals. Expanded posthospital networks of both health and social service providers acknowledge services such as housing, food assistance, behavioral health, transportation, utilities, pharmacy, and chronic care as necessary services to avoid hospitalization (Raths, 2020).

One example of how hospitals are integrating community-based-organizations into their posthospital strategies is The Medical Respite at Faith Mission (the "Mission"), supported by OhioHealth in Columbus, Ohio. It provides space for people who would typically be discharged home from the hospital but do not have a home to go to. The medical respite opened 9 months after the emergency declaration of the pandemic in the United States by the Federal Emergency Management Agency (FEMA). Up to 16 posthospital individuals at the Mission receive posthospital care for a maximum of 45 days under the supervision of a nurse and case manager. The program frees up hospital beds and helps the homeless connect to community resources and overcome homelessness. The OhioHealth Foundation provides financial support for the program and the community-based organization manages the Mission (LSS Network, 2021).

Another hospital, MetroHealth in Cleveland, Ohio, has also embraced the importance of a community-wide strategy to keep people out of the hospital. MetroHealth's Institute for H.O.P.E.™ developed a referral network with community-based organizations (MetroHealth, June 12, 2020) and received a grant to expand its hospital-at-home program (MetroHealth, June 17, 2020). In February 2021 MetroHealth announced a joint venture with ProMedica to develop a new SNF (MetroHealth, 2021). Then in September 2021, the health system announced the opening of a new Senior Health Center to transform how primary care is delivered to seniors by offering physical therapy, pharmacy, yoga, health coaches, and more (Fields, 2021). The initiatives are part of a 10-year enterprise and community-wide strategy including the building of a state-of-the art medical campus, investments in community organizations, social determinants of health, beautification projects, and senior care innovations and partnerships.

Leveraging Technology: Communication, Data, and Telehealth

Communication: interoperability and bidirectional referrals

Health systems and accountable care organizations continue to invest in electronic health records solutions and add-ons that enable disparate providers from multiple organizations to share records, integrate device data, and send alerts and data bidirectionally across the continuum-of-care. Public or state-run health information exchanges like CliniSync in Ohio, Health Current in Arizona, and HEALTHeLINK in New York can include the secure sharing of patient health information across the continuum of care. The IMPACT Act passed in 2014 requires that postacute care assessment data elements be interoperable and that vendors continue to offer improved solutions.

Interestingly, when the network is primarily comprised of postacute care providers, the network sponsor often dictates communication platforms. When community-based organizations dominate the member model, the members often collaboratively select platforms. For example, The Utah Alliance for the Determinants of Health, convened and funded by Intermountain Healthcare, selected the UniteUs platform to connect hospital clinicians to other providers and social service organizations in 2019. The pilot expanded in 2020 and 2021, partly in response to the interrelation of COVID-19 and social determinants of health. The network now includes multisystem partners including Select Health, HCA MountainStar, Molina Healthcare, and more.

Data: managing networks, specialty planning, Smart SNFs, and remote patient monitoring

Data has long been used by postacute care network curators to select members, monitor outcomes, and manage quality improvement efforts. The availability of affordable data has improved for network curators, with several vendors now providing access to 100% Medicare fee-for-service, Medicare Advantage, and commercial claims data covering 90% of covered lives 65+ in the United States. Cloud-based solutions allow network curators to extract detailed data on patient discharges by diagnosis, destination, network leakage, and provider performance including length of stay and other metrics. Postacute care databases were available before the pandemic and COVID-19 drove the business case for their advancement and adoption.

Data are also used to identify and address gaps in postacute care specialty services. Skilled care partners previously relied on a referring hospital to identify unmet needs and drive specialty program development. New data sources enable skilled care operators to assess entire geographic areas for specialty gaps with a comprehensive view of the needs of all the hospitals they serve. Though a single hospital might not recognize a viable gap, the clinical nature of need among multiple hospitals or a broader geography might collectively support development of a skilled specialty program. From the network curator's perspective, these more robust platforms can define and inform future network requirements.

Network curators also benefit from Smart SNFs in postpandemic networks. Smart SNFs use data to predict and prevent adverse events, including COVID-19. Their electronic health records systems integrate with data analytics platforms using artificial intelligence to identify residents at risk for falls, pressure ulcers, hospitalizations, and readmissions to skilled nursing after discharge to the community.

Telehealth: urgent and chronic care applications

Telehealth in postacute care has been used for several years to reduce unnecessary hospitalizations through after-hours urgent care. During the pandemic, more providers began to add scheduled chronic care telehealth services to their solution set. The Centers for Disease Control and Prevention, Community Preventive Services Task Force recommends telehealth interventions for cardiovascular disease, high blood pressure, diabetes, HIV infection, end-stage renal disease, asthma, and obesity (CDC, 2021). Telehealth interventions for chronic disease management have been shown to improve medication adherence, clinical outcomes, and dietary outcomes (CDC, 2021). For SNFs, remote patient visits for specialty physician care reduce transportation costs, potential infection exposure, stress on the patient, and administrative burden.

Regional Approaches—Super SNFs

Regional centers of excellence are a recognized operating model for health systems in which providers concentrate specialty expertise and resources in a particular location and deliver comprehensive care in an interdisciplinary manner. Typically, hospitals develop centers of excellence in cancer care, neurological services, cardiology, and other specialties. The typical standards for centers of excellence include a comprehensive clinical continuum of care, quality differentiation, commitment to education and research, community impact, clinical leadership, and community impact. Throughout the United States some nursing facilities became informal centers of excellence for COVID-19 care because widespread infection among existing residents led them to be "experts" out of necessity. Other SNFs were chosen by parent organizations to serve as a central destination for COVID-19 care to reduce potential spread and to colocate highly skilled personnel and equipment as efficiently as possible for the parent company.

Regional centers of excellence ("super SNFs") provide several types of specialty care and are not new. However, these facilities became a critical resource during the pandemic because they provide near-hospital level care and facilitate hospital inpatient capacity throughout a broad geographic region. One example is Andover Village Skilled Nursing & Rehabilitation, a five-star rated facility located in rural eastern Ohio. It draws patients from Cleveland, Pittsburgh, and Columbus by colocating ventilator services with a freestanding dialysis center operated by DaVita. The facility established a widespread referral base by developing a history in ventilator weaning, recovery from end-stage renal disease, and getting patients off dialysis in the first 90 days of acute kidney injury. Postpandemic network curators often include these regional super SNFs in their preferred networks to ensure access to high value specialty care for patients with the highest risk of costly care and readmission.

Going Forward

Postacute care networks fulfill enterprise-level strategic goals by directing patients to the right level of care and at the right place and time, ensuring clinical communication. Successful networks reduce readmissions, improve outcomes, reduce costs, prevent financial penalties, and enhance the patient and family experience. Although network curators may have found COVID-19 distracting, if not disruptive, to network strategy and results going forward, future networks will be more inclusive, more collaborative, and possibly with community-wide governance and goals.

The playbook for developing a postacute care network starts with understanding the enterprise strategy. As we shift from a postacute care to posthospital focus, executive leadership will decide what the network needs to do (goals).

Postacute care networks fulfill enterprise-level strategic goals by directing patients to the right level of care and at the right place and time, ensuring clinical communication. Successful networks reduce readmissions, improve outcomes, reduce costs, prevent financial penalties, and enhance the patient and family experience.

Managers formulate how to achieve it (plans). And the front-line decides if the plan is implemented.

The C-suite, including the chief financial officer, evaluates the business case of "build, buy, or partner" for the enterprises' network strategy. It may very well include owning SNFs and other postacute care entities. High-level plans are based on revenues, costs, savings, the time needed to operationalize, and enterprise goals.

Goal setting for the network is left to the curator or care management team and should involve a cascade process. Goals need to connect to the overall strategy of the organization. Ask, "what enterprise goals can this network help meet? How do we set our own key performance measures that show us how we're contributing to the enterprise goals?"

To align and integrate your network strategy with other postacute care and community-based organizations consider the following:

- Set a limited number of goals that are specific, measurable, actionable, realistic, and timebound (SMART)
- Use an advanced data analytics platform for strategic decision making
- Identify initiatives that are mindful of all network members' budgets, time frames, and other resources
- Engage senior leaders, partners, and members of your team in developing work plans
- Determine when and how you will evaluate your network program

As a final thought, remember that the most crucial step you'll take in network development and optimization going forward is to bring together and engage all types of organizations involved in posthospital services as equal partners to your success. CE1

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Health Care Provider Suicide:
Another Tragic Toll of the Coronavirus Pandemic

Janet Coulter, MSN, MS, RN, CCM, and Maryann Ott, RN, CCM, CPC, CEAC

Amid the coronavirus pandemic, suicide is quietly killing frontline health workers. According to the Centers for Disease Control and Prevention (CDC), there have been over 800,000 deaths in the United States due to COVID-19. CDC researchers have identified a substantial increase in anxiety and depression among health care providers (CDC, 2021). This group of essential workers has been identified as having a disproportionately high risk for suicide ideation and increased high levels of anxiety as they are worried about their own health, exposing their families to COVID-19, sick colleagues, not having enough personal protective equipment, and feeling that they are not doing enough for their patients. A study was conducted of 1,257 health care providers in 34 hospitals in China. The study looked at their mental health after the COVID-19 outbreak. More than 4,600 persons had died there. This study found that 50% of the health care providers showed signs of depression, 45% reported anxiety, and 72% had some form of psychological distress (Ortega, 2020) (Psycom, 2021). Although health care providers deal with death on a daily basis, they rarely witness it in such high numbers. These essential workers are experiencing firsthand trauma, posttraumatic stress disorder (PTSD), and feelings of helplessness in facing this virus. The pandemic has inflicted a personal toll on every health care worker. It appears that the COVID-19 virus will be affecting health care workers in the near future.

When the pandemic started, health care providers were described as "heroes." The "Thank you for all you do" has been replaced by frustration from patients and family members. Health care providers continue to deal with sicker patients of all ages, more deaths, and families who are unable to see their loved ones in the hospital. In addition, people are not happy with the testing procedure for COVID-19 or the wait time to get the results, and some are questioning the accuracy of the results. Making a decision to vaccinate or not has become very controversial. Health care providers cannot control these issues.

Dealing with the lack of appreciation and respect as well as the collateral effects of the pandemic will have a lasting effect on health care providers. Incidents of violence and harassment against health care providers has increased as well as the risk for workplace violence. Health care providers are feeling increased stress and fatigue. The burden of placing patients in isolation, giving negative prognoses, and being unable to have loved ones at a dying patient's bedside has taken a toll on many health care providers. In addition, severe staffing shortages, missing time with their families, and the fear of carrying the virus home to loved ones has increased health care providers' stress and anxiety. Health care providers are working longer hours and harder than ever before. There are so many stressors and not a ton of "wins." Many have experienced burn out.

For some health care providers it is beyond burnout,

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Frontline health workers have been identified as having a disproportionately high risk for suicide ideation and increased high levels of anxiety as they are worried about their own health, exposing their families to COVID-19, sick colleagues, not having enough personal protective equipment, and feeling that they are not doing enough for their patients.

beyond stress, beyond anxiety. It's trauma. Trauma from watching countless people die despite heroic efforts to keep them alive. Trauma from ceaseless work, feelings of powerlessness, and fear of becoming ill or infecting family members. Trauma from not knowing when this will end. Unfortunately, some have turned to suicide. The COVID-19 pandemic has exacerbated mental health issues for health care providers at an astonishing rate. Tragically, there has been a 35% increase in suicides nationwide (CDC, 2021). Health care providers are experiencing more stress and darker emotions. Our profession will be struggling with the emotional impact, mental fallout, and varying degrees of PTSD for the foreseeable future. The need for mental health care is more critical now than ever. The COVID-19 pandemic continues to take its toll on the well-being and work satisfaction of health care providers. Receiving appropriate mental health care is crucial to healing.

Throughout the COVID-19 pandemic, Mental Health America (MHA) has witnessed increasing numbers of individuals with anxiety, depression, loneliness, and other mental health concerns. In a survey of 1,119 health care providers from June 1-September 1, 2020, MHA found that most (76%) respondents were young adults ages 18–44. The largest groups of respondents were other health care staff (30%) and nurses (22%). Of all respondents, 19% identified their position as "other," which included mental health professionals, social workers, and pharmacy staff (Mental Health America, 2021).

Over half of healthcare providers were receiving emotional support from family (57%) and friends (53%). Many health care providers also reported receiving emotional support from their same-level coworkers (38%). Nurses are less likely than other health care providers to report that they had adequate emotional support; 45% reported that they did not have adequate emotional support (Mental Health America, 2021). Health care providers may avoid accessing mental health care because of the associated stigma and disparity of mental health services.

The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) is a federal law that generally prevents group health plans and health insurance issuers that provide mental health or substance use disorder (MH/SUD) benefits from imposing less favorable benefit limitations on those benefits than on medical/surgical benefits (MHPA, 2008). Insurance catastrophic plans must cover the essential health benefits as required by section 1302(b) of the Patient Protection and Affordable Care Act, subject to certain limitations. COVID-19 has had a profound negative effect on the mental health of the nation, especially among those who are faced with combatting the virus (CMS, 2008). There's now a new mental health disparity group that's growing in numbers. They are the healthcare providers that work in all facets of the industry.

What is Posttraumatic Stress Disorder?

Posttraumatic stress disorder (PTSD) is a mental health condition caused by witnessing or experiencing actual or threatened death, serious injury, or violence. It is normal to be affected by these types of events. Someone may have PTSD if the thoughts or memories of these events start to persistently affect the person's life long after the event (American Psychiatric Association, 2021). Post COVID-19 stress disorder (PCSD) is a new term. It refers to COVID-19-related anxiety and depression and it is expected to linger for years after the pandemic is over. Triggers of increased anxiety and PTSD in health care providers include people, places, particular feelings, objects, smells, sounds, and significant dates. PTSD triggers are associated with an extreme fear response (Crosby, 2021).

Additional stressors experienced by health care providers:

- increased workload-related stress resulting from taking care of patients infected with COVID-19
- stressed about possibly infecting their family and friends
- fewer available staff due to absenteeism and turnover
- presenteeism (working while ill)
- firsthand trauma
- feelings of helplessness in facing a virus with few known treatments
- fear of losing their job/income
- prolonged use of personal protective equipment
- increased hostility and violence
- increased exposure to toxins because of increased use of disinfectants
- stigma
- forced redeployment to jobs with higher levels of risk

A study of 1,257 health care providers in 34 hospitals in China found that after the COVID-19 outbreak, 50% of the health care providers showed signs of depression, 45% reported anxiety, and 72% had some form of psychological distress.

• the impact of the pandemic on their personal lifestyle (Suicidology, 2019)

Health care providers are experiencing an unprecedented amount of burnout, depression, and anxiety due to the pandemic. About 1 in 5 health care providers have considered quitting because of the pandemic. Health care providers expose themselves to the virus every day and are experiencing conditions that have been compared to a war zone, continuously witnessing the direct effects of the pandemic as it spreads throughout communities (Medscape, 2021).

The pandemic has had a dramatic impact on case managers. Case managers have reported being assigned to unfamiliar clinical areas. Many case managers reported being reassigned to direct patient care at the bedside with little or no orientation while other case managers began working remotely and telephonically using new communication platforms. Caseloads were increased and included patients with extremely complex conditions. In addition to these role changes, the stress of collaborating with families that were overwhelmed, frightened, and sometimes angry, the stress of finding placement for patients when resources were very limited, and the high mortality rate of their patients all affected the emotional well-being, anxiety levels, and burnout of case managers.

Suicide risk among health care providers is a real and current phenomenon. According to the Centers for Disease Control and Prevention (CDC), the United States lost 48,500 citizens to suicide in 2021. That is approximately one death every 11 minutes. These statistics make death by suicide one of the top leading causes of death in the United States (CDC, 2021).

In 2017, the CDC reported suicide rates had jumped 33% since 1999. This included 2,374 nurses, 857 physicians, and 156,141 individuals in the general population (age, ≥30 years). The suicide incidence rates per 100,000 in 2017-2018 among women were 17.1 for nurses, 10.1 for physicians, and 8.6 for the general population. The suicide incidence rates per 100,000 in 2017-2018 among men were 31.1 for nurses, 31.5 for physicians, and 32.6 for the general population. The suicide risk compared with the general population was significantly increased for nurses but not for physicians. Nurses are the largest component of the health care workforce in the United States. This recent research suggests that nurses may be at high risk for suicide, although there are few studies on this topic. Suicide is the 10th leading cause of death in the United States (CDC, 2021). The suicide rate is expected to increase by 8.4% in 2020-2021 because of social isolation and depression related to COVID-19. COVID-19 has left no one untouched (McIntyre, R. & Lee, Y., 2020).

A Paradigm Shift from Crisis Intervention to Mental Health Promotion and Prevention

Burnout, depression, PTSD, and acute stress disorder are occupational phenomena that must be addressed to maintain mental well-being in health care providers. This mental health crisis has been very costly. Focus needs to be on interventions to intensify mental health promotion. Examples include creating a positive work environment, reducing administrative burden, promoting staying in the moment and being aware of your feelings, receiving support from management, receiving assistance with familial responsibilities (childcare, education for children), telecommuting policies, scheduling flexibility, and expanding employee support programs.

When a Coworker Commits Suicide

This is a psychiatric emergency for coworkers who will be grieving the loss. Coworkers will go through the grieving process and will need support to avoid suppressing emotions. Psychological First Aid is described as supportive responses that can lead to short- and long-term coping and adaptive behaviors (Sims & Wang, 2021). The goal is to provide resources and a toolbox for empowering action during psychological distress. Suicide postvention provides assistance to those who have been impacted by suicide to reduce the harmful effects of exposure to suicide (Jordan, 2017).

Professional and ethical conduct after a coworker commits suicide includes maintaining confidentiality, being respectful to the family and other coworkers, remaining objective about the situation, protecting the dignity and integrity of the coworker, practicing active listening, showing concern for the family and other coworkers, working through the stages of grief, and showing compassion as others work through the stages of grief.

Health care providers need to be protected from chronic stress and poor mental health so that they can support patients as well as themselves. Maintaining mental health can be facilitated by rotating staff from higher-stress to lower-stress functions, partnering inexperienced staff with more experienced colleagues, implementing a flexible sick leave policy, providing rest/relaxation areas, and modifying work schedules and traditional roles.

Management and leadership can play a major role in providing support to health care providers during this stressful time. Staff should be encouraged to speak openly about their concerns, ask questions, and seek peer support among colleagues. A structured group session might be helpful in increasing coping and support. Other effective interventions include providing access to employee assistance programs and developing a system where a staff member is trained to monitor the staffs' well-being and psychosocial status to identify risks and emerging issues and to adaptively respond to their needs. The use of telehealth services and referrals to support groups and professional mental health services/counselors should also be available. Above all, the health care worker should be treated with compassion, respect, empathy, and integrity while respecting the individual's rights and dignity (Carson J. Spencer Foundation, 2013)

Health care providers need to be protected from chronic stress and poor mental health so that they can support patients as well as themselves. Maintaining mental health can be facilitated by rotating staff from higher-stress to lower-stress functions, partnering inexperienced staff with more experienced colleagues, implementing a flexible sick leave policy, providing rest/relaxation areas, and modifying work schedules and traditional roles. In addition, holding brief regular forums to update staff on the status of COVID-related issues and how management is addressing these challenges and ensuring that quality communication and accurate information updates are provided to all health care providers is important. Health care providers should be encouraged to take care of themselves and to vent anger, guilt, sadness, and other emotions related to their coworker's suicide. (Carson, 2013).

Summary

The COVID-19 pandemic has taken a toll on the well-being of health care providers. The long-term effects on health care providers will present many challenges. Just as we case manage and care for our patients, so must we do the same for our own health care group. As case managers, we must protect the welfare of all the groups we serve, maintain objectivity, and act with integrity.

We hope this information highlighted the broad impact of the pandemic on health care providers; the need to identify, prevent, and treat health care providers; the need to address mental health disparities; and the need to lessen mental health consequences as the pandemic evolves. As case managers we need to continue to be aware of our professional ethical behavior as it relates to caring for coworkers and other health care providers. Collaborating and supporting other health care providers, respecting diversity, and displaying ethical conduct and decision making are among the outstanding qualities and professional values of case managers.

It is hoped that bringing attention to suicide and emphasizing the broad impact of the pandemic on health care providers will highlight the need to identify, prevent, and treat health care providers, to address mental health disparities, and to lessen mental health consequences as the pandemic evolves. CE II

Resources

- American Foundation for Suicide Prevention (https://afsp.org)
- Suicide Prevention resource center (https://sprc.org/resources-programs/resources-suicide-postvention-planning)
- Survivors of Suicide Loss (https://www.soslsd.orCE2g/)

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Improving Patient Outcomes by Addressing Malnutrition

Rajitha Bommakanti, RN, CCM

Food is the most important of the basic human needs; it nourishes and heals the body and allows our body to grow and survive. The risk of malnutrition and food insecurity issues in patients is often not addressed when patients are admitted to hospital. Malnutrition is simply defined as a nutritional imbalance: either undernutrition or overnutrition.[16] When patients are sick and admitted to the hospital it is as important to eat nutritious food for healing and well-being as it is to take prescribed medications.

Historically, health care facilities are not known for good food options. While patients are sick and laying in bed, the food tray does not look very appetizing, and patients often do not finish their food. Malnutrition is often not recognized as a health problem in health care facilities. A 2019 study showed that about 1 in 3 patients who are hospitalized in the United States are at risk for malnutrition.[1] The impact of malnutrition has many negative outcomes, including immune suppression, increased infection rate, impaired wound healing, high risk for pressure ulcers, muscle wasting, increased length of hospital stay, increased cost of treatment, higher readmission rates, and high mortality.[2]

Many of the adverse outcomes influenced by malnutrition are preventable. If a patient's nutritional status is addressed in a timely manner, adverse events can be prevented and can reduce the length of hospital stay, decrease morbidity and mortality, and reduce the hospital's liability risk.[16] According to a study published in 2019, malnutrition affects 30%-50% of hospitalized patients worldwide.[1] Konturek et al. conducted a study to review the prevalence of malnutrition in hospitals.[21] The results of this study showed that 53.6% of patients had malnutrition and that the prevalence of malnutrition was increased in patients with gastrointestinal diseases and with depression or dementia.[21]

It is disconcerting to see that nutritional status is not being addressed while patients are in a health care facility to heal; this results in poorer outcomes for both the patient and the hospital. A study conducted by Ramos, Fontanilla, and Lat (2011) showed that noncritical adult malnourished patients with type 2 diabetes had a significantly longer length of hospital stay than well-nourished patients.[3] Malnutrition in hospitalized patients is widespread: it is estimated that at least one third of patients have some degree of malnutrition on admission and if untreated these patients' nutritional status will decline during their inpatient stay.[16] There is a lack of awareness about malnutrition in hospitalized patients, and thus medical staff need to be educated on the importance of nutrition in patients.[14]

Malnutrition is not seen as a standard practice, so it is often missed as a diagnosis and, therefore, it is not treated.[14] The risk of malnutrition increases while patients are hospitalized.[21] Clear protocols need to be established to address the underreported and hidden problem of malnutrition.[14] If malnutrition screening is included during initial patient assessment, not only would nutritional therapy be improved, but with appropriate coding, financial reimbursement could be maximized.[21]

Nutrition care goes unaddressed because physicians are not trained to look at nutrition as a part of healing. Medical students get about 20-25 hours of nutrition education, and medical students report that they are not well prepared to address nutritional needs of patients.[22] Traditionally, registered dietitians are responsible for reviewing a patient's nutritional status and for giving recommendations to physicians who write the order. Hospital data review shows that recommendations from registered dieticians are not being ordered by physicians.[1] Patients and family would be more receptive to nutritional advice if the conversation is initiated by a physician, after which the dietitian can provide additional information and resources. It is important that

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The risk of malnutrition and food insecurity issues in patients is often not addressed when patients are admitted to hospital. When patients are sick and admitted to the hospital it is as important to eat nutritious food for healing and well-being as it is to take prescribed medications.

nutritional recommendations be implemented in a timely manner to see improvements in nutritional outcomes.[15]

To improve nutritional outcomes in patients, it is not just about a physician writing the order—it requires a multidisciplinary approach.[15] Once the order is written, it needs to be implemented, and ongoing monitoring is needed for data collection to review the effectiveness of the nutritional recommendations.[15] For accurate data collection, other members of the health care team who are more involved with the food intake need to be held accountable. These include the nurse, nursing assistant, food service aide, and even family members who assist with feeding or bringing in food to the patient. Improving nutritional outcomes also involves a shift in health care culture; patients at risk must be recognized and diagnosed, the nutritional care plan must be communicated and implemented without delay, and a discharge nutritional care plan that also includes patient education should be developed.[16] If patient nutritional care is improved by addressing every malnourished or at-risk patient, barriers that impact the provision of nutritional care can be identified.[16] Malnutrition is a dilemma and challenge faced by hospitals all around the world.[23] A study of 120 patients showed that the initial prevalence of malnutrition was 30% on admission to the hospital and increased to 33.3% at the time of discharge.[23]

How can the health care team bring the patient nutritional status awareness to the forefront during daily multidisciplinary rounds?

Since multidisciplinary rounds represent different disciplines who come together to discuss the care of patients in real time, that might be the optimal time to discuss the possibility of malnutrition. Malnutrition can be addressed during multidisciplinary rounds for patients by reviewing their nutritional status. Prevention, identification, and treatment of malnutrition in patients will benefit from a multidisciplinary approach.[6] Malnutrition in hospitals can be influenced by implementing a systemic nutrition assessment risk screening that targets identification of malnutrition and its treatment.[4] The dietitian can use the risk screening tool in making the recommendations to optimize a patient's nutritional status. The dietitian can streamline the screening tool, which categorizes patients into three groups: those who are not at risk and who are appropriate for standard care, those who are at risk and who are appropriate for supportive nutrition care, and those who are likely to benefit from nutritional interventions customized to their needs.[7] Since the physician must sign off on the recommendations from the dietitian, orders can be signed during multidisciplinary rounds so that they can be implemented without much delay.

Hospital food is often not aligned with patients' diverse cultural or religious backgrounds Hospital food is often heavily processed and high in fat. Without culturally inclusive menus, patients might be deprived of food and undernourished, which can lead to malnourishment. Offering culturally inclusive foods in health care facilities may improve patients' nutritional status, promote joy, and foster a sense of belonging. The hospital environment and patients' food habits and preferences also influence undernourishment of patients. It is well known that more than half of hospitalized patients don't finish their meals[16] and that some need assistance with eating their meals. Inadequate taste and the dietary quality of hospital meals is one of the leading causes of mortality in the United States.[13]

As all the medical disciplines are present during multidisciplinary rounds, each discipline can contribute towards the delivery of optimal food and nutritional considerations. For the successful evaluation and intervention concerning a patient's nutritional status, it is imperative to involve various disciplines.[5] This interdisciplinary meeting can improve communication, information sharing, and management support to facilitate collaborative work towards improved patient outcomes.[5] Providing healthy nutritious food options to hospitalized patients can be used to teach patients about good food options when they are discharged.[13] This is the responsibility of every health care professional; it's not a job to be delegated to others. All clinicians need to be empowered to recognize and diagnose patients at risk of malnutrition.[16] Shared goal setting and decision making is integral to patient-centered care.[6] The population in the United States is becoming more diverse and multicultural, and so are the patients in health care facilities. Food plays a powerful role in determining if a health care system is inclusive and

A 2019 study analysis showed that about 1 in 3 patients who are hospitalized in the United States are at risk for malnutrition. The impact of malnutrition has many negative outcomes, including immune suppression, increased infection rate, impaired wound healing, high risk for pressure ulcers, muscle wasting, increased length of hospital stays, increased cost of treatment, higher readmission rates, and high mortality.

equitable. Addressing various cultural food needs will help build a strong and inclusive health care system.

When case managers are addressing discharge planning needs for their patients, assessment of patient's cultural background and food insecurity should be considered. This needs to be a part of the discharge planning assessment tool to provide resources and help patients achieve their optimal nutritional requirements. Nutrition assessment screening by case managers should focus on proactive ways of identifying preventable health crises; these screenings also benefit the hospital because they could decrease morbidity and mortality rates, length of hospital stay, and health care costs.[7] These assessment tools are also beneficial to communicate nutrition-related needs to providers and other health care team members.[7] During the food assessment screening, the case manager also needs to assess for barriers (eg, cultural foods and religious restrictions) and help patients address them. Engaging the patient, family, and friends should take priority, and case managers need to step outside their comfort zones to find solutions and suggest food resources. The case manager's role is also to manage care conflicts and unrealistic expectations of the patient, the patient's family, or the patient's friends.[6] Case managers also need to consider some of the patient's potential risk factors such as loss of interest in life, access to meals, texture-modified diet, difficulty chewing, dental health, alcohol consumption, psychological distress, anxiety, loneliness, ethnicity, and access to transportation.[6] Nutrition assessment is vital to detect, remove, or reduce barriers to a patient's food intake. Figure 1 highlights direct and indirect factors that influence malnutrition in older adults.[6]

As case managers assess patients, they need to ask deeper questions about food insecurities. Food insecurity can be due to a number of factors including limited household income, limited food access in the community, and limited social networks.[6] Food deserts occur in poor urban areas with limited or no access to fresh, healthful, and affordable food options.[6]

Case managers should use the initial assessment as a guide to plan for discharge referrals and resources. Each patient is unique and has numerous variables that must be considered to develop the best customized nutritional plan. Case managers should gather patients' information from the chart, use the assessment tool recommendations documented by a dietitian during interdisciplinary rounds, and conduct

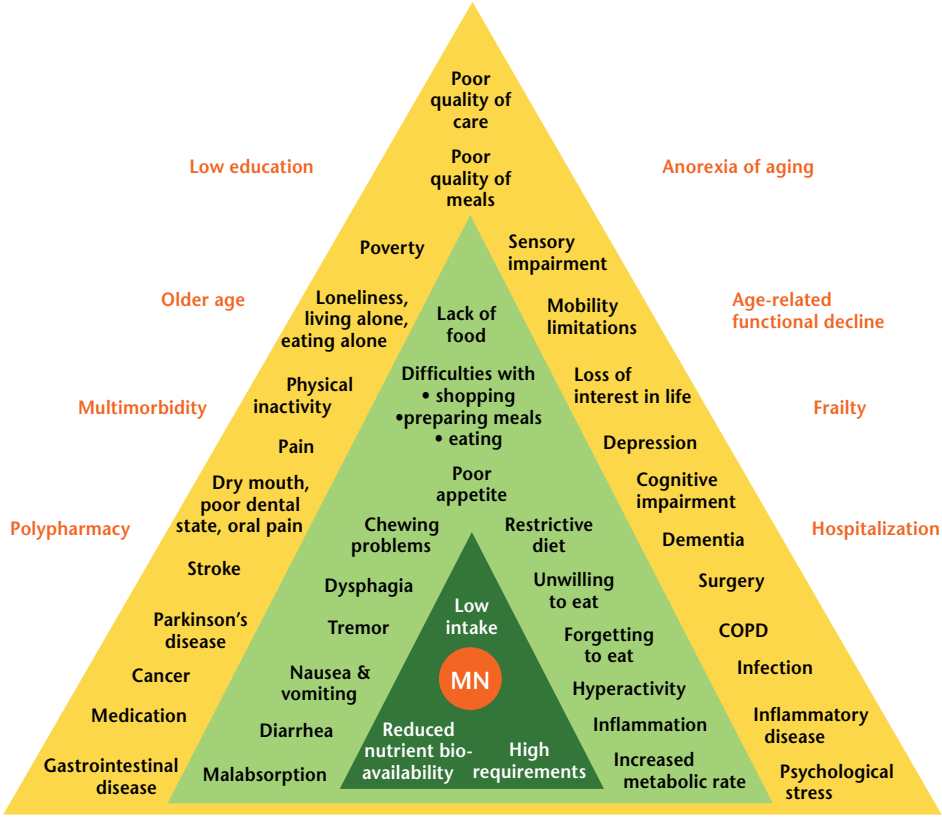

FIGURE 1: DoMAP model: DETERMINANTS OF MALNUTRITION IN AGED PERSONS

Moving towards an evidence-based plant-based diet is an effective strategy to reduce the risk of chronic conditions and improve the nutritional status of patients. Case managers can also refer patients to a nutritionist to help patients build a diet plan that meets their needs and tastes.

patient interviews to develop a plan that is focused on optimal nutrition for healing and recovery.[6]

Studies have shown that a plant-based diet can help prevent and treat chronic diseases and can help people live longer.[8] Research shows that eating whole grain plant-based foods can halt and reverse diseases.[8] The current medical treatment for chronic conditions consists of drugs, stents, and surgeries that do not halt or reverse disease and are expensive.[8] Daily consumption of three portions of whole grain foods can reduce blood pressure, which can reduce the incidence of coronary artery disease and stroke by more than 15%.[9] Whole grains like oats, barley, quinoa, and millets are complex carbohydrates that provide energy and phytonutrients, and they also have anti-inflammatory compounds.[9]

Research shows that plant-based foods have more antioxidants than animal foods.[10] Many people wonder how to get protein without eating animal products. In a whole-foods plant-based diet, proteins come from beans and legumes, which are packed with fiber and have powerful phytonutrients that help lower cholesterol and protect heart health.[10] Aurora Meadows, a nutritionist, says that the average protein recommendation is 50 grams, which can be easily achieved by eating legumes and beans.[11]

In 2012 the New York City Department of Health initiated the Healthy Hospital Food Initiative program, which intended to improve the nutritious value of food served in hospitals, and more than 30 hospitals participated in the initiative.[17] The goal of this initiative was for hospitals to reduce fat and sodium and increase whole grains, fresh foods, and fresh vegetables.[17] The participating hospitals in New York City had to adopt New York City Food Standards when purchasing, preparing, and serving foods.[17] A study conducted after the New York City Healthy Hospital Food Initiative was implemented showed a significant improvement in the nutritional quality of patient meals.[17] In 2017, the American Medical Association made recommendations for hospitals to adopt plant-based diets with emphasis on fresh fruits, vegetables, legumes, grains, reduction in animal fats, and moderate sodium intake.[18] By serving healthful diets the American Medical Association says that hospitalization can model a "teachable moment" for patients to follow postdischarge and as a healing process.[18] More and more health organizations are calling for hospitals to offer plant-based food options to patients, visitors, and their employees. Healthcare professional organizations in United States have come together to support and help hospitals serve plant-based food.[24] The Humane Society of United States is offering training for chefs, dietitians, and physicians, with a goal of having hospitals commit to having 50% of their daily meals be plant based by 2025.[24] The Physicians Committee for Responsible Medicine is offering lunch and learn and employee wellness programs in hospitals.[24] Oldways is another organization that developed a free plant plate healthcare toolkit that includes recipes and menu plans.[24] Meatless Monday is an initiative that encourages everyone to reduce meat intake on Mondays.[24]

Hospitals have many organizations that are supporting and helping them to transition to plant-based meals to improve patient outcomes. In 2021, six countries conducted a study to see if there is an association between dietary patterns and severity of COVID-19.[19] The results of the study showed that individuals who followed plant-based diet and/or pescatarian diets that included more vegetables, legumes, and nuts and less poultry, red meat, and processed meats had 73% and 59% lower odds of moderate-to-severe COVID-19, respectively, compared with patients who did not follow these diets.[19] These two healthful dietary patterns can be considered for protection against severe COVID-19.[19] Many studies are showing that people who consumed diets that include increased amounts of fruits, vegetables, legumes, and whole grains and reduced amounts of animal fats have better health outcomes.

COVID-19 continues to spread across the country, and economic instability and the resulting health crisis has increased the rate of food insecurity.[11] Employees of meat and poultry processing plants have had outbreaks of COVID-19, which has led to supply chain issues for beef, chicken, and pork, resulting in soaring prices of meat.[11] As the food bank lines are stretching longer and longer and interruptions in supply chains are leaving shelves empty, food insecurity can lead to hunger, which in turn can lead to obesity, malnutrition, and other metabolic diseases. Food insecurity is more than consuming calories, it is also about what a person eats. Typically, less expensive food provides calorie dense nutrition that is nutrient poor.

Grocery prices have increased since the pandemic, which impacts low-income shoppers the most.[12] According to the Department of Agriculture, the price for beef protein per

gram costs 28% more than eggs; although beef, pork, and poultry increased in price during the pandemic, many plant-based proteins such as lentils, beans, and nuts did not.[11] As the price of meat is going up and there are supply chain issues with meat, this can be a good time for patients to shift towards a plant-based diet to improve their health with cheaper protein options that cause less pollution.[11]

Moving towards an evidence-based plant-based diet is an effective strategy to reduce the risk of chronic conditions and improve patients' nutritional status. Case managers can also refer patients to a nutritionist to help them build a diet plan that meets their needs and tastes. Case managers can provide resources to patients on how they can stretch their dollars to get a month's worth of healthy and satiating foods. Plant foods are not only budget friendly and good for one's health; they can also be easily stored for a long period. Even patients who live in a food desert can buy beans, legumes, whole grains, and canned food in bulk, all of which have a long shelf life. People living in food deserts may lack fresh fruits and vegetables, but they can use canned goods for healthy plant-based meals. Many people assume that healthy means expensive, but case managers can help prove that myth wrong by directing their patients to websites like Mad Rabbits.[20] This comprehensive website provides plant-based budget-friendly options and easy recipes to cook at home.[20]

Once the case manager develops a nutrition plan and offers it to the patient, they need to be willing to modify the plan to meet the patient's needs. If the patient is willing to accept the plan, then they have the ownership of the plan to follow through and be more compliant with it.

Physicians can review the evidence-based recommendations and take that into consideration to address malnutrition and prescribe a plant-based diet for patients. This increases patient awareness, and patients can fill their physician' prescriptions for fresh produce in local food pantries or farmers markets.

Is a plant-based diet right for patients? Can they afford a plant-based diet?

There is growing body of evidence showing that a plant-based diet helps to suspend and reverse diseases, and a plant-based diet is sustainable and affordable. Patients can successfully implement a plant-based diet after discharge with follow-up and support from the health care team. Patients who want to slowly transition to a plant-based diet can start with meatless Mondays to reduce meat consumption. Providing nutritional support has been shown to be a highly effective treatment option for patients with malnutrition.14 Early nutritional intervention has shown to be cost effective, and providing patients with a personalized nutrition plan during discharge has shown to lower hospital readmission rates.[14] CE III

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PharmaFacts for Case Managers

Paxlovid-nirmatrelvir and ritonavir

EMERGENCY USE AUTHORIZATION

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of the unapproved product Paxlovid for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

LIMITATIONS OF AUTHORIZED USE

Paxlovid is not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19.

- Paxlovid is not authorized for use as pre-exposure or post-exposure prophylaxis for prevention of COVID-19.
- Paxlovid is not authorized for use for longer than 5 consecutive days.

DOSAGE AND ADMINISTRATION

- Paxlovid is nirmatrelvir tablets copackaged with ritonavir tablets.
- Nirmatrelvir must be coadministered with ritonavir. Failure to correctly coadminister nirmatrelvir with ritonavir may result in plasma levels of nirmatrelvir that are insufficient to achieve the desired therapeutic effect.
- The dosage for Paxlovid is 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) with all three tablets taken together orally twice daily for 5 days. Prescriptions should specify the numeric dose of each active ingredient within Paxlovid. Completion of the full 5-day treatment course and continued isolation in accordance with public health recommendations are important to maximize viral clearance and minimize transmission of SARS-CoV-2.
- The 5-day treatment course of Paxlovid should be initiated as soon as possible after a diagnosis of COVID-19 has been made, and within 5 days of symptom onset. Should a patient require hospitalization due to severe or critical COVID-19 after starting treatment with Paxlovid, the patient should complete the full 5-day treatment course per the healthcare provider's discretion.
- If the patient misses a dose of Paxlovid within 8 hours of the time it is usually taken, the patient should take it as soon as possible and resume the normal dosing schedule. If the patient misses a dose by more than 8 hours, the patient should not take the missed dose and instead take the next dose at the regularly scheduled time. The patient should not double the dose to make up for a missed dose.
- Paxlovid (both nirmatrelvir and ritonavir tablets) can be taken with or without food. The tablets should be swallowed whole and not chewed, broken, or crushed

CONTRAINDICATIONS

Paxlovid is contraindicated in patients with a history of clinically significant hypersensitivity reactions [e.g., toxic epidermal necrolysis (TEN) or Stevens-Johnson syndrome] to its active ingredients (nirmatrelvir or ritonavir) or any other components of the product.

Paxlovid is contraindicated with drugs that are highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions:

- Alpha1-adrenoreceptor antagonist: alfuzosin
- Analgesics: pethidine, piroxicam, propoxyphene
- Antianginal: ranolazine
- Antiarrhythmic: amiodarone, dronedarone, flecainide, propafenone, quinidine
- Anti-gout: colchicine
- Antipsychotics: lurasidone, pimozide, clozapine
- Ergot derivatives: dihydroergotamine, ergotamine, methylergonovine
- HMG-CoA reductase inhibitors: lovastatin, simvastatin
- PDE5 inhibitor: sildenafil (Revatio®) when used for pulmonary arterial hypertension (PAH)
- Sedative/hypnotics: triazolam, oral midazolam

Paxlovid is contraindicated with drugs that are potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the

potential for loss of virologic response and possible resistance. Paxlovid cannot be started immediately after discontinuation of any of the following medications due to the delayed offset of the recently discontinued CYP3A inducer:

- Anticancer drugs: apalutamide
- Anticonvulsant: carbamazepine, phenobarbital, phenytoin
- Antimycobacterials: rifampin
- Herbal products: St. John's Wort *(hypericum perforatum)*

WARNINGS AND PRECAUTIONS

There are limited clinical data available for Paxlovid. Serious and unexpected adverse events may occur that have not been previously reported with Paxlovid use.

Risk of Serious Adverse Reactions Due to Drug Interactions

Initiation of Paxlovid, a CYP3A inhibitor, in patients receiving medications metabolized by CYP3A or initiation of medications metabolized by CYP3A in patients already receiving Paxlovid, may increase plasma concentrations of medications metabolized by CYP3A.

Initiation of medications that inhibit or induce CYP3A may increase or decrease concentrations of Paxlovid, respectively.

These interactions may lead to:

- Clinically significant adverse reactions, potentially leading to severe, life-threatening, or fatal events from greater exposures of concomitant medications.
- Clinically significant adverse reactions from greater exposures of Paxlovid.
- Loss of therapeutic effect of Paxlovid and possible development of viral resistance.

ADVERSE REACTIONS in Clinical Studies

Adverse events (all grades regardless of causality) in the Paxlovid group (≥1%) that occurred at a greater frequency (≥5 subject difference) than in the placebo group were dysgeusia (6% and <1%, respectively), diarrhea (3% and 2%), hypertension (1% and <1%), and myalgia (1% and <1%).

The proportions of subjects who discontinued treatment due to an adverse event were 2% in the Paxlovid group and 4% in the placebo group.

DRUG INTERACTIONS

Potential for Paxlovid to Affect Other Drugs

Paxlovid (nirmatrelvir copackaged with ritonavir) is an inhibitor of CYP3A and may increase plasma concentrations of drugs that are primarily metabolized by CYP3A. Coadministration of Paxlovid with drugs highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events is contraindicated. Coadministration with other CYP3A substrates may require a dose adjustment or additional monitoring as shown in Table 1.

Potential for Other Drugs to Affect Paxlovid

Nirmatrelvir and ritonavir are CYP3A substrates; therefore, drugs that induce CYP3A may decrease nirmatrelvir and ritonavir plasma concentrations and reduce Paxlovid therapeutic effect.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no available human data on the use of nirmatrelvir during pregnancy to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Published observational studies on ritonavir use in pregnant women have not identified an increase in the risk of major birth defects. Published studies with ritonavir are insufficient to identify a drug-associated risk of miscarriage. There are maternal and fetal risks associated with untreated COVID-19 in pregnancy.

In an embryo-fetal development study with nirmatrelvir, reduced fetal body weights following oral administration of nirmatrelvir to pregnant rabbits were observed at systemic exposures (AUC) approximately 10 times higher than clinical exposure at the authorized human dose of Paxlovid. No other adverse developmental outcomes were observed in animal reproduction studies with nirmatrelvir at systemic exposures (AUC) greater than or equal to 3 times higher than clinical exposure at the authorized human dose of Paxlovid.

In animal reproduction studies with ritonavir, no evidence of adverse developmental outcomes was observed following oral administration of ritonavir to pregnant rats and rabbits at doses (based on body surface area conversions) or systemic exposures (AUC) greater than or equal to 3 times higher than clinical doses or exposure at the authorized human dose of Paxlovid.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Lactation

Risk Summary

There are no available data on the presence of nirmatrelvir in human or animal milk, the effects on the breastfed infant, or the effects on milk production. A transient decrease in body weight was observed in the nursing offspring of rats administered nirmatrelvir. Limited published data reports that ritonavir is present in human milk. There is no information on the effects of ritonavir on the breastfed infant or the effects of the

drug on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Paxlovid and any potential adverse effects on the breastfed infant from Paxlovid or from the underlying maternal condition. Breastfeeding individuals with COVID-19 should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

Females and Males of Reproductive Potential

Contraception

Use of ritonavir may reduce the efficacy of combined hormonal contraceptives. Advise patients using combined hormonal contraceptives to use an effective alternative contraceptive method or an additional barrier method of contraception

Pediatric Use

Paxlovid is not authorized for use in pediatric patients younger than 12 years of age or weighing less than 40 kg. The safety and effectiveness of Paxlovid have not been established in pediatric patients. The authorized adult dosing regimen is expected to result in comparable serum exposures of nirmatrelvir and ritonavir in patients 12 years of age and older and weighing at least 40 kg as observed in adults, and adults with similar body weight were included in the trial EPIC-HR.

Geriatric Use

Clinical studies of Paxlovid include subjects 65 years of age and older and their data contributes to the overall assessment of safety and efficacy. Of the total number of subjects in EPIC-HR randomized to receive Paxlovid (N=1,120), 13% were 65 years of age and older and 3% were 75 years of age and older.

Renal Impairment

Systemic exposure of nirmatrelvir increases in renally impaired patients with increase in the severity of renal impairment.

No dosage adjustment is needed in patients with mild renal impairment. In patients with moderate renal impairment (eGFR ≥30 to <60 mL/min), reduce the dose of Paxlovid to 150 mg nirmatrelvir and 100 mg ritonavir twice daily for 5 days. Prescriptions should specify the numeric dose of each active ingredient within Paxlovid. Providers should counsel patients about renal dosing instructions.

Paxlovid is not recommended in patients with severe renal impairment (eGFR <30 mL/min based on CKD-EPI formula) until more data are available; the appropriate dosage for patients with severe renal impairment has not been determined.

8.7 Hepatic Impairment

No dosage adjustment of Paxlovid is needed for patients with either mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment. No pharmacokinetic or safety data are available regarding the use of nirmatrelvir or ritonavir in subjects with severe hepatic impairment (Child-Pugh Class C); therefore, Paxlovid is not recommended for use in patients with severe hepatic impairment.

CLINICAL STUDIES

Efficacy in Subjects at High Risk of Progressing to Severe COVID-19 Illness

The data supporting this EUA are based on the analysis of EPIC-HR (NCT04960202), a Phase 2/3, randomized, double-blind, placebo-controlled study in non-hospitalized symptomatic adult subjects with a laboratory confirmed diagnosis of SARS-CoV-2 infection. Eligible subjects were 18 years of age and older with at least 1 of the following risk factors for progression to severe disease: diabetes, overweight (BMI >25), chronic lung disease (including asthma), chronic kidney disease, current smoker, immunosuppressive disease or immunosuppressive treatment, cardiovascular disease, hypertension, sickle cell disease, neurodevelopmental disorders, active cancer, medically-related technological dependence, or were 60 years of age and older regardless of comorbidities. Subjects with COVID-19 symptom onset of ≤5 days were included in the study. Subjects were randomized (1:1) to receive Paxlovid (nirmatrelvir/ritonavir 300 mg/100 mg) or placebo orally every 12 hours for 5 days. The study excluded individuals with a history of prior COVID-19 infection or vaccination. The primary efficacy endpoint was the proportion of subjects with COVID-19 related hospitalization or death from any cause through Day 28. The analysis was conducted in the modified intent-to-treat (mITT) analysis set (all treated subjects with onset of symptoms ≤3 days who at baseline did not receive nor were expected to receive COVID-19 therapeutic mAb treatment), the mITT1 analysis set (all treated subjects with onset of symptoms ≤5 days who at baseline did not receive nor were expected to receive COVID-19 therapeutic mAb treatment), and the mITT2 analysis set (all treated subjects with onset of symptoms ≤5 days).

A total of 2,246 subjects were randomized to receive either Paxlovid or placebo. At baseline, mean age was 46 years; 51% were male; 72% were White, 5% were Black, and 14% were Asian; 45% were Hispanic or Latino; 66% of subjects had onset of symptoms ≤3 days from initiation of study treatment; 47% of subjects were serological negative at baseline; the mean (SD) baseline viral load was 4.63 log10 copies/mL (2.87); 26% of subjects had a baseline viral load of >10^7 (units); 6% of subjects either received or were expected to receive COVID-19 therapeutic monoclonal

antibody treatment at the time of randomization and were excluded from the mITT and mITT1 analyses.

The baseline demographic and disease characteristics were balanced between the Paxlovid and placebo groups.

Table 1 provides results of the primary endpoint in mITT1 analysis population.

TABLE 1 Efficacy Results in Nonhospitalized Adults with COVID-19 Dosed within 5 Days of Symptom Onset who Did Not Receive COVID-19 Monoclonal Antibody Treatment at Baseline

	Paxlovid N=1,039	Placebo N=1,046
COVID-19-related hospitalizations or death from any cause through Day 28	8 (0.8%)	66 (6.3%)
All-cause mortality through Day 28	0	12 (1.1%)

For the primary endpoint, the relative risk reduction in the mITT1 analysis population for Paxlovid compared to placebo was 88% (95% CI: 75%, 94%).

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

Paxlovid is nirmatrelvir tablets copackaged with ritonavir tablets.

- Nirmatrelvir tablets, 150 mg are oval, pink immediate-release, film-coated tablets debossed with "PFE" on one side and "3CL" on the other side.
- Ritonavir tablets, 100 mg are white film-coated ovaloid tablets debossed with the "a" logo and the code NK.

Nirmatrelvir tablets and ritonavir tablets are supplied in separate blister cavities within the same child-resistant blister card.

Each carton contains 30 tablets divided in 5 daily-dose blister cards (NDC number: 0069-1085-30).

Each daily blister card (NDC number: 0069-1085-06) contains 4 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each) and indicates which tablets need to be taken in the morning and evening.

Storage and Handling

Store at USP controlled 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 more information about Paxlovid, see Fact Sheet for Healthcare Providers.

Paxlovid is distributed by Pfizer Labs, a division of Pfizer, Inc.

New Indications

Xarelto® (rivaroxaban)

The FDA has approved two pediatric indications for Xarelto (rivaroxaban): the treatment of venous thromboembolism (VTE, or blood clots) and reduction in the risk of recurrent VTE in patients from birth to less than 18 years after at least five days of initial parenteral (injected or intravenous) anticoagulant treatment; and thromboprophylaxis (prevention of blood clots and blood-clot related events) in children aged two years and older with congenital heart disease who have undergone the Fontan procedure.

Otezla® (apremilast)

The FDA has approved Otezla (apremilast) for the treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy. With this expanded indication, Otezla is now the first and only oral treatment approved in adult patients with plaque psoriasis across all severities, including mild, moderate and severe.

Cosentyx® (secukinumab)

The FDA has approved Cosentyx (secukinumab) for the treatment of active enthesitis-related arthritis (ERA) in patients four years and older, and active psoriatic arthritis (PsA) in patients two years and older. Cosentyx is now the first biologic indicated for ERA and the only biologic treatment approved for both ERA and PsA in pediatric patients in the United States.

Oxbryta® (voxelotor)

The FDA has granted accelerated approval of a supplemental New Drug Application (sNDA) for Oxbryta (voxelotor) tablets for the treatment of sickle cell disease (SCD) in children ages 4 to less than 12 years. This approval expands the previously approved use of Oxbryta to treat SCD in patients ages 12 years and older in the United States.

Zynrelef® (bupivacaine)

The FDA has approved its supplemental New Drug Application (sNDA) for Zynrelef (bupivacaine and meloxicam) extended-release solution to significantly expand the indication. Zynrelef is now indicated in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical procedures.

Biktarvy

The FDA has approved a new low-dose tablet dosage form of Biktarvy (bictegravir 30 mg/emtricitabine 120 mg/tenofovir alafenamide 15 mg tablets) for pediatric patients weighing at least 14 kg to less than 25 kg who are virologically suppressed or new to antiretroviral therapy. The approval of this supplemental New Drug Application (sNDA) expands the

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LitScan for Case Managers

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

Am J Obstet Gynecol. 2021 Dec 20;S0002-9378(21)02696-X. doi: 10.1016/j.ajog.2021.12.032. Online ahead of print.

Diabetes mellitus, maternal adiposity, and insulin-dependent gestational diabetes are associated with Covid-19 in pregnancy: The INTERCOVID Study

Eskenazi B, Rauch S, Iurlaro E, et al.

BACKGROUND: Among non-pregnant individuals, diabetes mellitus (DM) and high body mass index (BMI) increase the risk of Covid-19 and its severity. Objective: To determine whether DM and high BMI are risk factors for Covid-19 in pregnancy and whether gestational diabetes mellitus (GDM) is also associated with covid-19 diagnosis.

STUDY DESIGN: INTERCOVID was a multinational study, conducted between March 2020 and February 2021 in 43 institutions from 18 countries, enrolling 2184 pregnant women ≥18 years; 2071 were included in these analyses. For each woman diagnosed with Covid-19, two non-diagnosed women delivering or initiating antenatal care at the same institution were also enrolled. Main exposures were pre-existing DM or high BMI (overweight/obesity defined as ≥25 kg/m2), and GDM in pregnancy. Main outcome was a confirmed diagnosis of Covid-19 based on an RT-PCR test, antigen test, antibody test, radiological pulmonary findings, or ≥2 predefined Covid-19 symptoms at any time during pregnancy or delivery. Relationships of exposures and Covid-19 diagnosis were assessed using generalized linear models with a Poisson distribution and log link function, with robust standard errors to account for model misspecification. We also conducted sensitivity analyses: 1) restricted to those with an RT-PCR or antigen test in the last week of pregnancy; 2) restricted to those with an RT-PCR or antigen test during the entire pregnancy; 3) generating values for missing data using multiple imputation; and 4) analyses controlling for month of enrollment. In addition, among those who were diagnosed with Covid-19, we examined whether having GDM, DM, or high BMI, increased risk for having symptomatic vs. asymptomatic Covid-19.

RESULTS: Covid-19 was associated with preexisting DM (RR=1.94, 95% CI=1.55, 2.42), overweight/obesity (RR=1.20; 95% CI=1.06, 1.37), and GDM (RR=1.21; 95% CI=0.99, 1.46). The GDM association was specifically among women requiring insulin, whether they were of normal-weight (RR=1.79, 95% CI=1.06, 3.01) or overweight/obese (RR=1.77, 95% CI=1.28, 2.45). A somewhat stronger association with Covid-19 diagnosis was observed among women with pre-existing DM, whether they were of normal weight (RR=1.93, 95% CI=1.18, 3.17) or overweight/obese (RR=2.32, 95% CI=1.82, 2.97). When the sample was restricted to those with a RT-PCR or antigen test in the week before delivery or during the entire pregnancy, including missing variables using imputation, or controlling for month of enrollment, the observed associations were comparable. Conclusion: DM and overweight/obesity are risk factors for Covid-19 diagnosis in pregnancy, and insulin-dependent GDM is also associated with the disease. It is therefore essential that those women with these co-morbidities are vaccinated.

AIDS. 2021 Dec 17.doi: 10.1097/AD.0000000000003151. Online ahead of print.

Anal cancer incidence in MSM with HIV: are black men at higher risk?

Mcneil CJ, Lee JS, Cole SR, et al.

OBJECTIVE: To assess differences in anal cancer incidence between racial/ethnic groups among a clinical cohort of men with HIV who have sex with men.

DESIGN: Clinical cohort study.

METHODS: We studied men who have sex with men (MSM) in the Centers for AIDS Research Network of Integrated Clinical Systems (CNICS) who initiated antiretroviral therapy (ART) under HIV care in CNICS. We compared anal cancer incidence between Black and non-Black men and calculated hazard ratios controlling for demographic characteristics (age, CNICS site, year of ART initiation), HIV disease indicators (nadir CD4, peak HIV RNA), and co-infection/behavioral factors including hepatitis B virus (HBV), hepatitis C virus (HCV), tobacco smoking and alcohol abuse.

RESULTS: We studied 7,473 MSM with HIV who contributed 41,810 person-years of follow-up after initiating ART between 1996 and 2014 in CNICS. Forty-one individuals had an incident diagnosis of anal cancer under observation. Crude rates of anal cancer were 204 versus 61 per 100,000 person-years among Black versus non-Black MSM. The weighted hazard ratio for anal cancer in Black

MSM (adjusting for demographics, HIV disease factors, and co-infection/behavioral factors) was 2.37 (95% CI: 1.17, 4.82) compared to non-Black MSM.

CONCLUSIONS: In this large multicenter cohort, Black MSM were at significantly increased risk for anal cancer compared to non-Black MSM. Further detailed studies evaluating factors impacting anal cancer incidence and outcomes in Black men with HIV are necessary. Inclusion of more diverse study cohorts may elucidate modifiable factors associated with increased anal cancer risk experienced by Black MSM.

AIDS. 2021 Dec 13.doi: 10.1097/QAD.0000000000003147. Online ahead of print.

Increased reengagement of out-of-care HIV patients using lost & found, a clinic-based intervention

Linthwaite B, Kronfli N, Marbaniang I, et al.

BACKGROUND: Negative health outcomes associated with being out of HIV care (OOC) warrant reengagement strategies. We aimed to assess effectiveness of Lost & Found (L&F), a clinic-based intervention to identify and reengage OOC patients.

METHODS: Developed and delivered using implementation science, L&F consists of two core elements: i) identification, operationalized through nurse validation of a real-time list of possible OOC patients; and ii) contact, via nurse-led phone calls. It was delivered over a 12-month period (2018-2019) at the Chronic Viral Illness Service, McGill University Health Centre (CVIS-MUHC) during a type-II implementation-effectiveness hybrid pilot study. Descriptive outcomes of interest were identification as possibly OOC, OOC confirmation, contact, and successful reengagement. We present results from a pre-post analysis comparing overall reengagement to the year prior, using robust Poisson regression controlled for sex, age, and Canadian birth. Time to reengagement is reported using a Cox proportional hazards model.

RESULTS: Over half (56%; 1312/2354) of CVIS-MUHC patients were identified as possibly OOC. Among these, 44% (n = 578) were followed elsewhere, 19% (n = 249) engaged in care, 3% (n = 33) deceased, 2% (n = 29) otherwise not followed, and 32% (n = 423) OOC. Of OOC patients contacted (85%; 359/423), 250 (70%) reengaged and 40 (11%) had upcoming appointments; the remainder were unreachable, declined care, or missed given appointments. Pre-post results indicate people who received L&F were 1.18 (95%CI: 1.02-1.36) times more likely to reengage, and reengaged a median 55 days (95%CI: 14-98) sooner.

CONCLUSION: L&F may be a viable clinic-based reengagement intervention for OOC patients. More robust evaluations are needed.

AIDS. 2022 Feb 1;36(2):277-286. doi: 10.1097/QAD.0000000000003069.

Virologic outcomes among adults with HIV using integrase inhibitor-based antiretroviral therapy

Lu H, Cole SR, Westreich D, et al.

BACKGROUND: Integrase strand transfer inhibitor (InSTI)-based regimens have been recommended as first-line antiretroviral therapy (ART) for adults with HIV. But data on long-term effects of InSTI-based regimens on virologic outcomes remain limited. Here we examined whether InSTI improved long-term virologic outcomes compared with efavirenz (EFV).

METHODS: We included adults from the North American AIDS Cohort Collaboration on Research and Design who initiated their first ART regimen containing either InSTI or EFV between 2009 and 2016. We estimated differences in the proportion virologically suppressed up to 7 years of follow-up in observational intention-to-treat and per-protocol analyses.

RESULTS: Of 15 318 participants, 5519 (36%) initiated an InSTI-based regimen and 9799 (64%) initiated the EFV-based regimen. In observational intention-to-treat analysis, 81.3% of patients in the InSTI group and 67.3% in the EFV group experienced virologic suppression at 3 months after ART initiation, corresponding to a difference of 14.0% (95% CI 12.4-15.6). At 1 year after ART initiation, the proportion virologically suppressed was 89.5% in the InSTI group and 90.2% in the EFV group, corresponding to a difference of -0.7% (95% CI -2.1 to 0.8). At 7 years, the proportion virologically suppressed was 94.5% in the InSTI group and 92.5% in the EFV group, corresponding to a difference of 2.0% (95% CI -7.3 to 11.3). The observational per-protocol results were similar to intention-to-treat analyses.

CONCLUSIONS: Although InSTI-based initial ART regimens had more rapid virologic response than EFV-based regimens, the long-term virologic effect was similar. Our findings may inform guidelines regarding preferred initial regimens for HIV treatment.

Am Heart J. 2021 Dec 18;S0002-8703(21)00476-2. doi: 10.1016/j.ahj.2021.12.003. Online ahead of print.

Clinical trajectory of patients with a worsening heart failure event and reduced ventricular ejection fraction

Carnicelli AP, Clare RM, Hofmann P, et al.

BACKGROUND: Recent data suggest that patients with heart failure with reduced ejection fraction (HFrEF) and worsening heart failure (WHF) have potential for greater benefit from newer HF therapies. We investigated characteristics and outcomes of patients with HFrEF and WHF by severity of left ventricular dysfunction.

METHODS: We identified patients with chronic symptomatic HFrEF (left ventricular ejection fraction [LVEF] ≤35%) and evidence of WHF (emergency department visit or hospitalization for acute HF within 12 months of index echocardiogram) treated at Duke University between 1/2009 and 12/2018. Patients were stratified by LVEF≤25% or 26-35%. Cox models were used to estimate cause-specific hazard ratios and 5-year event incidence of death and hospitalization across the range of LVEF.

RESULTS: Of 2823 patients with HFrEF and WHF, 1620 (57.4%) had an LVEF≤25% and 1203 (42.6%) had an LVEF 26-35%. Compared to patients with LVEF 26-35%, those with LVEF≤25% were younger and more commonly men with a lower cardiovascular comorbidity burden. Patients with LVEF≤25% were less commonly on beta blockers (85.9% vs 90.5%) but more commonly treated with mineralocorticoid receptor antagonists (49.3% vs 41.1%) and implantable defibrillators (41.3% vs 28.2%). Patients with LVEF≤25% had significantly higher hazards for death (HR 1.24 [95% CI 1.11-1.38]), all-cause hospitalization (HR 1.21 [95% CI 1.10-1.33]), and HF hospitalization (HR 1.25 [95% CI 1.14-1.38]) through 5-years.

CONCLUSIONS: More than half of patients with chronic HFrEF and WHF have severe LV dysfunction. Important differences in comorbidities, HF therapies, and outcomes exist between those with LVEF≤25% and those with LVEF 26-35%.

Am J Cardiol. 2021 Dec 7;S0002-9149(21)01097-3. doi: 10.1016/j.amjcard.2021.10.041. Online ahead of print.

Impact of acute and chronic kidney disease on heart failure hospitalizations after acute myocardial infarction

Yandrapalli S, Christy J, Malik A, et al.

A few studies evaluated the impact of acute kidney injury (AKI) and chronic kidney disease (CKD) on heart failure (HF) hospitalization risk following an acute myocardial infarction (AMI). For this retrospective cohort analysis, we identified adult AMI survivors from January to June 2014 from the United States Nationwide Readmissions Database. Outcomes were a 6-month HF, fatal HF, composite of HF during the AMI or a 6-month HF, and a composite of 6-month HF or death during a non-HF-related admission. We analyzed differences in outcomes across categories of patients without renal injury, AKI without CKD, stable CKD, AKI on CKD, and end-stage renal disease (ESRD). Of 237,549 AMI survivors, AKI was present in 13.8%, CKD in 16.5%, ESRD in 3.4%, and AKI on CKD in 7.7%. Patients with renal failure had lower coronary revascularization rates and higher in-hospital HF. A 6-month HF hospitalization occurred in 12,934 patients (5.4%). Compared with patients without renal failure (3.3%), 6-month HF admission rate was higher in patients with AKI on CKD (14.6%; odds ratio [OR] 1.99; 95% confidence interval [CI] 1.81 to 2.19), ESRD (11.2%; OR 1.57; 95% CI 1.36 to 1.81), stable CKD (10.7%; OR 1.72; 95% CI 1.56 to 1.88), and AKI (8.6%; OR 1.52; 95% CI 1.36 to 1.70). Results were generally homogenous in prespecified subgroups and for the other outcomes. In conclusion, 1 in 4 AMI survivors had either acute or chronic renal failure. The presence of any form of renal failure was associated with a substantially increased risk of 6-month HF hospitalizations and associated mortality with the highest risk associated with AKI on CKD.

Ann Surg. 2021 Dec 1;274(6):e605-e609.doi: 10.1097/SLA.0000000000003795.

Pneumonectomy for pediatric tumors-a Pediatric Surgical Oncology Research Collaborative Study

Polites SF, Heaton TE, LaQuaglia MP, et al.

OBJECTIVE: To describe utilization and long-term outcomes of pneumonectomy in children and adolescents with cancer. Summary background data: Pneumonectomy in adults is associated with significant morbidity and mortality. Little is known about the indications and outcomes of pneumonectomy for pediatric tumors.

METHODS: The Pediatric Surgical Oncology Research Collaborative (PSORC) identified pediatric patients <21 years of age who underwent pneumonectomy from 1990 to 2017 for primary or metastatic tumors at 12 institutions. Clinical information was collected; outcomes included operative complications, long-term function, recurrence, and survival. Univariate log rank, and multivariable Cox analyses determined factors associated with survival.

RESULTS: Thirty-eight patients (mean 12 ± 6 yrs) were identified; median (IQR) follow-up was 19 (5-38) months. Twenty-six patients (68%) underwent pneumonectomy for primary tumors and 12 (32%) for metastases. The most frequent histologies were osteosarcoma (n = 6), inflammatory myofibroblastic tumors (IMT; n = 6), and pleuropulmonary blastoma (n = 5). Median postoperative ventilator days were 0 (0-1), intensive care 2 (1-3), and hospital 8 (5-16). Early postoperative complications occurred in 10 patients including 1 death. Of 25 (66%) patients alive at 1 year, 15 reported return to preoperative pulmonary status. All IMT patients survived while all osteosarcoma patients died during follow-up. On multivariable analysis, metastatic indications were associated with nonsurvival (HR = 3.37, P = 0.045). Conclusion: This is the largest review of children who underwent pneumonectomy for cancer. There is decreased procedure-related morbidity and mortality than reported for adults. Survival is worse with preoperative metastatic disease, especially osteosarcoma.

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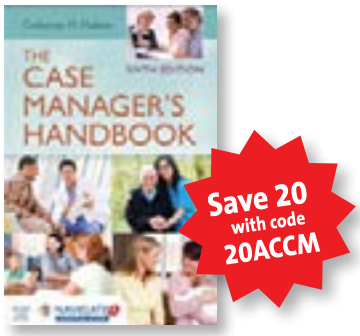

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Clin Transplant. 2021 Dec 19;e14559. doi: 10.1111/ctr.14559. Online ahead of print.

Benefits of both physical assessment and electronic health record review to assess frailty prior to heart transplant

Lee YK, Shukman M, Biniwale R, et al.

Frailty status affects outcomes after heart transplantation, but the optimal way to assess frailty prior to transplant remains unknown. This single-center, observational study assessed 44 heart transplant candidates for frailty using three methods. The Short Physical Performance Battery (SPPB) and Fried Frailty Phenotype (FFP) were used as two physical assessments of frailty. The Frailty Risk Score (FRS) was used as a chart-review based assessment measuring 20 different biopsychosocial and functional components, including biomarkers, depression, cognitive impairment, and sleep. We determined the correlation between FRS, SPPB, and FFP and how each correlated with clinical outcomes. Of 44 participants, mean age was 60 years. FRS correlated with SPPB and FFP ($p = 0.043$, $p < 0.001$, respectively). Higher frailty as measured by SPPB and FRS was significantly associated with lack of achieving waitlist status ($p = 0.022$; $p = 0.002$) and not being transplanted ($p = 0.026$; $p = 0.008$). Higher frailty by SPPB and FFP was also associated with mortality ($p = 0.010$; $p = 0.025$). SPPB and chart-review FRS showed potential for predicting waitlist and transplant status of heart transplant candidates, while SPPB and FFP were associated with mortality. Additional studies may serve to validate these observations.

Am J Cardiol. 2021 Dec 11;S0002-9149(21)01104-8.doi: 10.1016/j.amjcard.2021.10.049. Online ahead of print.

Beta-blocker use in hypertension and heart failure (a secondary analysis of the systolic blood pressure intervention trial)

Silverman DN, de Lavallaz JDF, Plante TB, et al.

Given the concern that beta-blocker use may be associated with an increased risk for heart failure (HF) in populations with normal left ventricular systolic function, we evaluated the association between beta-blocker use and incident HF events, as well as loop diuretic initiation in the Systolic Blood Pressure Intervention Trial (SPRINT). SPRINT demonstrated that a blood pressure target of <120 mm Hg reduced cardiovascular outcomes compared with <140 mm Hg in adults with at least one cardiovascular risk factor and without HF. The lower rate of the composite primary outcome in the 120 mm Hg group was primarily driven by a reduction in HF events. Subjects on a beta blocker for the entire trial duration were compared with subjects who never received a beta blocker after 1:1 propensity score matching. A competing risk survival analysis by beta-blocker status was performed to estimate the effect of the drug on incident HF and was then repeated for a secondary end point of cardiovascular disease death. Among the 3,284 propensity score-matched subjects, beta-blocker exposure was associated with an increased HF risk (hazard ratio 5.86; 95% confidence interval 2.73 to 13.04; $p < 0.001$). A sensitivity analysis of propensity score-matched cohorts with a history of coronary artery disease or atrial fibrillation revealed the same association (hazard ratio 3.49; 95% confidence interval 1.15 to 10.06; $p = 0.028$). In conclusion, beta-blocker exposure in this secondary analysis was associated with increased incident HF in subjects with hypertension without HF at baseline.

Am J Respir Cell Mol Biol. 2021 Dec;65(6):603-614. doi: 10.1165/rcmb.2020-0520OC.

HDAC6 Activates ERK in airway and pulmonary vascular remodeling of chronic obstructive pulmonary disease

Su Y, Han W, Kovacs-Kasa A, et al.

Chronic obstructive pulmonary disease (COPD) is a multisystemic respiratory disease that is associated with progressive airway and pulmonary vascular remodeling due to the increased proliferation of bronchial smooth muscles cells (BSMCs) and pulmonary arterial smooth muscle cells (PASMCs) and the overproduction of extracellular matrix (e.g., collagen). Cigarette smoke (CS) and several mediators, such as PDGF (platelet-derived growth factor) and IL-6, play critical roles in COPD pathogenesis. HDAC6 has been shown to be implicated in vascular remodeling. However, the role of airway HDAC6 signaling in pulmonary vascular remodeling in COPD and the underlying mechanisms remain undetermined. Here, we show that HDAC6 expression is upregulated in the lungs of patients with COPD and a COPD animal model. We also found that CS extract (CSE), PDGF, and IL-6 increase the protein levels and activation of HDAC6 in BSMCs and PASMCs. Furthermore, CSE and these stimulants induced deacetylation and phosphorylation of ERK1/2 and increased collagen synthesis and BSMC and PASMC proliferation, which were outcomes that were prevented by HDAC6 inhibition. Inhibition of ERK1/2 also diminished the CSE-, PDGF-, and IL-6-caused elevation in collagen levels and cell proliferation. Pharmacologic HDAC6 inhibition with tubastatin A prevented the CS-stimulated increases in the thickness of the bronchial and pulmonary arterial wall, airway resistance, emphysema, and right ventricular systolic pressure and right ventricular hypertrophy in a rat model of COPD. These data demonstrate that the upregulated HDAC6 governs the collagen synthesis and BSMC and PASMC proliferation that lead to airway and vascular remodeling in COPD.

Am J Surg. Dec 4;S0002-9610(21)00712-1. doi: 10.1016/j.amjsurg.2021.11.027. Online ahead of print.

Multidisciplinary clinics for colorectal cancer may not provide more efficient coordination of care

Bajpai S, Wood L, Cannon JA, et al.

BACKGROUND: This retrospective study compares a multidisciplinary clinic (MDC) to standard care for time to treatment of colorectal cancer.

METHODS: We queried our institutional ACS-NSQIP database for patients undergoing surgery for colorectal cancer from 2017 to 2020. Patients were stratified by initial clinic visit (MDC vs control). Primary endpoint was the time to start treatment (TST), either neoadjuvant therapy or surgery, from the date of diagnosis by colonoscopy.

RESULTS: A total of 405 patients were evaluated (115 MDC, 290 Control). TST from diagnosis was not significantly shorter for the MDC cohort (MDC 30 days, Control 37 days; p = 0.07) even when stratified by type of initial treatment of neoadjuvant therapy (MDC 30, Control 34 days; p = 0.28) or surgery (MDC 32.5 days, Control 38 days; p = 0.35).

CONCLUSION: Implementation of an MDC provides insignificant reduction in delay to start treatment for colorectal cancer patients as compared to standard care colorectal surgery clinics.

Am Surg. 2021 Dec;87(10):1684-1689. doi: 10.1177/00031348211024658. Epub 2021 Jun 15.

The utility of extended criteria donor livers in high acuity liver transplant recipients

Guorgui J, Ito T, Younan S, et al.

BACKGROUND: Although the use of extended criteria donor (ECD) liver allografts has gained momentum as a potential method by which to expand the donor pool, their use largely remains relegated to low acuity liver transplant (LT) recipients. Thus, we sought to examine whether such grafts also have utility in high acuity (Model for End-Stage Liver Disease [MELD] ≥ 35) recipients.

STUDY DESIGN: Extended criteria donors were defined as donor age > 60 years, hepatitis C virus positive donor, split livers, livers with cold ischemia time > 12 h, donor after cardiac death livers, or having macrosteatosis
>30%. Outcomes were compared between standard liver (SL) and ECD grafts in recipients with MELD ≥ 35.

RESULTS: Of 225 patients, 46 (20.4%) received an ECD liver and 179 (79.6%) received a SL. Extended criteria donor graft recipients had significantly higher levels of post-LT maximal transaminases and rate of early allograft dysfunction. Nonetheless, high acuity ECD graft recipients had similar short- and long-term patient survival compared to SL recipients, with 1-,3-, and 5-year survivals of 86.9%, 82.3%, 79.3% and 86.9%, 80.5%, and 75.4%, respectively (P = .674). There were also no significant differences in graft survival or rejection-free survival between the 2 groups. Conclusion: The lack of inferior patient/graft survival among high acuity ECD graft recipients suggests that ECD livers present a viable method by which to expand the donor pool for this group of patients.

Leuk Lymphoma. 2021 Dec 10;1-8.doi: 10.1080/10428194.2021.2012660. Online ahead of print.

Treatment patterns for relapsed and refractory Hodgkin lymphoma in a community oncology setting

Kumar AJ, Chao CR, Rodday AM, et al.

There is little data about treatment practices for relapsed/refractory Hodgkin Lymphoma (HL) in nonacademic settings. We describe sequential treatments and outcomes among HL patients who experienced treatment failure in an integrated community-oncology setting. We performed a retrospective cohort study among patients ≥12 years diagnosed with Stage II-IV HL from 2007 to 2012 at Kaiser Permanente Southern California (KPSC). Of 463 HL patients, 75 (16.1%) experienced treatment failure. Patients with failure received between 1 and 8 salvage therapies; 28% received ≥4 lines of therapy. Fifty-nine of 75 (79%) were initially salvaged with ifosfamide-based therapy, 44 of whom underwent hematopoietic cell transplant. Ultimately, 47% of patients died, with most deaths due to HL. Survival was shorter with increasing age at diagnosis (p = 0.02) and with greater number of lines of therapy (p = 0.02). In a community oncology setting, HL patients received multiple lines of salvage. Despite extensive treatment, nearly half of patients died of HL following relapsed/refractory disease.

Am J Cardiol. 2021 Dec 6;S0002-9149(21)01093-6. doi: 10.1016/j.amjcard.2021.11.005. Online ahead of print.

Relation of diabetes mellitus to incident dementia in patients with atrial fibrillation (from the Atherosclerosis Risk in Communities Study)

Jiayaspathi A, Chen LY, Selvin E, et al.

The association of diabetes mellitus (DM), an established risk factor for dementia in the general population, with incident dementia in patients with atrial fibrillation (AF) has not been explored. We performed a cohort study where we identified subjects with incident AF in the Atherosclerosis Risk in Communities cohort (1987 to

2017) and determined their DM status, fasting blood glucose before AF diagnosis and hemoglobin A1c levels using information from the closest previous study visit. Incident dementia was expert adjudicated using information from cognitive assessments, informant interviews and hospitalization surveillance. We calculated hazard ratios (HRs) and 95% confidence intervals (CIs) of incident dementia for each level of exposure using Cox models and adjusting for potential confounders. We analyzed 3,020 patients with AF in the Atherosclerosis Risk in Communities cohort (808 with DM) and 530 had incident dementia after a mean follow-up of 5.3 years after AF diagnosis. After multivariable adjustment, patients with AF with prevalent DM had higher rates of dementia than those without DM, HR 1.45 (95% CI 1.16 to 1.80). A value of hemoglobin A1c ≥6.5% was associated with a HR 1.29 (95% CI 0.97 to 1.71) of dementia. However, fasting blood glucose was not associated with rates of dementia independent of DM status. In conclusion, DM was associated with higher rates of dementia in patients with AF. DM prevention and control could be a promising avenue for reducing risk of dementia in AF.

Behav Med. Jan-Mar 2021;47(1):21-30. doi: 10.1080/08964289.2019.1604489. Epub 2019 May 29.

Benefits of yoga on IL-6: findings from a randomized controlled trial of yoga for depression

Nugent NR, Brick L, Armey MF, et al.

The present research sought to examine whether hatha yoga, implemented as an adjunctive intervention for major depression, influences markers of inflammation. A subset of 84 participants who were enrolled in a randomized controlled trial (RCT) of hatha yoga vs. health education control provided blood samples at baseline (pre-treatment) and at 3-(during treatment) and 10-week (end of treatment) follow-up visits. To be eligible for the RCT, participants met criteria for a current or recent (past two years) major depressive episode, had current elevated depression symptoms, and current antidepressant medication use. Venous blood was drawn between 2 and 6 pm and following at least one hour of fasting, and inflammatory markers (IL-6, CRP, and TNF-α) were assayed. Effects of participation in yoga relative to health education on inflammatory markers over time were examined with latent growth analyses. We observed a significant reduction in IL-6 concentrations in the yoga treatment group relative to the health education control group as demonstrated by a negative interaction between treatment group and slope of IL-6. TNF-α and CRP did not evidence significant interactions of treatment group by mean slope or intercept. In addition to the benefits of hatha yoga as an adjunctive intervention for individuals who have shown inadequate response to antidepressant medications, our findings point to possible benefits of yoga on IL-6 in depressed populations. Further research is needed to explore the effects of hatha yoga on immune function over time.

Health Care Provider Suicide: Another Tragic Toll of the Coronavirus Pandemic *continued from page 20*

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New Ways to Serve a New Generation of Veterans: How Two VA Programs Are Making the Transition From the Military to VA Care Seamless *continued from page 7*

Case Management Program, we commit ourselves to serve these men and women as well as their families and caregivers to ensure access to VA health care and to optimize their transition and reintegration to civilian life.

To learn more, please visit: Post-9/11 Transition and Case Management Home (va.gov). CM

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What is Case Management? *continued from page 9*

providers prevent duplication of services, diagnostics, and treatments. It is knowing how to become partners in healthcare and being able to build valuable relationships with post-acute providers in the community. Case management is often not revenue generating, but it is revenue saving when done effectively. It is knowing when to use your voice and knowing when to observe and listen.

Lastly, Case management is continuing education and never-ending opportunity for professional growth. It is being innovative and thinking "outside the box". It is not being afraid to share a crazy idea that may improve a patient outcome, because a case manager knows something great might grow from that seed. Case management is an important part of patient care and patient outcomes. It is rewarding in so many ways. Case management is here to stay, and I am honored to be a part of it. CM

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Readers

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

PharmaFacts for Case Managers

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indication for Biktarvy to include younger children living with HIV-1 infection and will help to close the gap between HIV treatment options available for adults and children.

Briviact (brivaracetam)
The FDA has approved an expanded indication for Briviact (brivaracetam) CV tablets, oral solution, and injection to treat partial-onset seizures in patients as young as one month of age. This is the first time that the IV formulation of Briviact will be available for pediatric patients when oral administration is temporarily not feasible and is the only IV formulation FDA-approved to treat partial-onset seizures in children one month of age and older in nearly 7 years.

Brukinsa® (zanubrutinib)
The FDA has approved Brukinsa for the treatment in adult patients with Waldenstrom's macroglobulinemia. The approval of Brukinsa in Waldenstrom's macroglobulinemia is the second therapy approved specifically for the treatment of this rare type of lymphoma.

Gvoke® Kit
The FDA has approved a supplemental new drug application (sNDA) of Gvoke Kit for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes ages 2 years and above. Gvoke Kit will be available as a 1 mg/0.2 mL single dose vial and syringe kit. Gvoke Kit contains one (1) single-dose sterile syringe with markings for 0.1 mL (0.5 mg pediatric dose) and 0.2 mL (1 mg adult dose), and one single-dose vial containing 0.2 mL of solution.

Lyumjev® (insulin lispro-aabc injection)
The FDA approved an expanded label for rapid-acting insulin, Lyumjev (insulin lispro-aabc injection) 100 units/mL indicated to improve glycemic control in adults with type 1 and type 2 diabetes, to include administration via continuous subcutaneous insulin infusion (CSII) with an insulin pump.

Jardiance® (empagliflozin)
Jardiance (empaglifloxin)10 mg has been approved by the FDA to reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure with reduced injection fracture (HFrEF). Jardiance can now be initiated in adults with HFrEF with an eGFR as low as 20 mL/min/1.73 m^2.

Improving Patient Outcomes by Addressing Malnutrition

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The Burden of Clostridioides difficile

continued from page 4

managers can assimilate knowledge and skills to the patient, support system, and care delivery system, resulting in improved health outcomes and quality of life.

Coming soon: Case Management Adherence and Care Transition Guide for *Clostridioides difficile,* or, CMAG-TOC for *C. diff* from the Case Management Society of America (CMSA). CM

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Life on the COVID-19 Roller Coaster: Promoting Self-Care and Resilience *continued from page 8*

- Regardless of where they worked, about 40% fielded more questions than ever from clients
- 15% were dealing with staff shortages
- 28% faced a lack of supplies

Professional Case Managers Face Personal Pressures

Despite these pressures, CCMs rose to the challenge, as they continued to advocate for clients and connect them to the resources they needed. Often, they did so despite increased personal challenges. Results from survey respondents revealed:

- 17% experienced food scarcity
- Nearly one-third reported a loss of income
- More than 21% reported clinical health issues
- Notably, 5% of respondents reported the practice or organization they worked for had shut down completely
- Most distressing of all, more than 5% of the case managers responding to the survey—many more than we had expected—reported losing loved ones to Covid-19.

It has been a difficult time for many in our profession, and yet, as we move forward with resilience and commitment, we find sources of encouragement. For example, CCMs wanted to learn more about the coronavirus so they can be trusted resources for clients and colleagues, and perhaps for friends and family as well.

The Commission's Push Pause Response—and Reboot

Throughout the pandemic, the Commission sought to respond to the needs of all professional case managers, such as with a curated list of available resources to help them facilitate rapidly changing care. The Commission provided information and updates on changes in regulations, real-time information on the virus and vaccinations, and several CE courses.

Importantly, and as we've highlighted previously in *CareManagement*, the Commission produced the CCMC Push Pause series to promote self-care, which is always important and became critical during the pandemic. We invited some of the nation's top inspirational speakers to record short messages of wisdom, hope, and resilience. These moments were designed to help reframe the grind into grace, to rejuvenate daily life, and to help reflect on the tangible support case managers bring to clients every day.

The first videos were initially posted to social media from October to December 2020, with over 26,000 views during this period. They were rereleased in March and April 2021, with an additional 10,000+ views. The response to this campaign has been extremely positive. With such inherent value in these videos, the Commission has decided to continue the program through 2022. We have already recorded a second series, and as of late 2021 have begun to release the new videos.

The beginning of 2022 marks 2 years since COVID-19 emerged into a global health concern, and nearly 2 years since the pandemic was declared. While much progress has been made, including vaccines, treatment protocols, and efforts to control contagion, there is still uncertainty. As professional case managers continue to find themselves at the center of the COVID-19 response, they will no doubt face more professional and personal burdens. Education, support, and self-care remain critical. Through its expanded Push Pause campaign and other resources, the Commission remains committed to supporting the professional case management community. CM

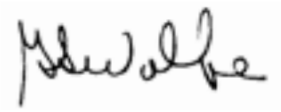
Using Information and Communication Technologies to Deliver Care *continued from page 5*

delivery. As with any technology in a clinical setting, the competency of staff in the use of the technology is important to assess. Providers should be competent in the setup, use, maintenance, safety considerations, infection control and troubleshooting of the technology. Once provider competency is ensured, the program can move on to the training of patients and caregivers in the use of technology. FaceTime and other communication technologies seem intuitive, although the program cannot assume that all persons served will have a thorough understanding of the use of the technology. Providers also need to be aware of the service that is being delivered and how it can be adjusted to ensure its adequate delivery. In the instance of an emergency occurring when the information and communication technologies are being used, the program will also need to have an understanding of emergency procedure at the location of the persons served as well as emergency contact information if an emergency does occur. We can anticipate that this technology will be part of our practice in the near and distant future, and these steps will ensure that care provided virtually can match the safety and effectiveness of care delivered in person. If you are interested in receiving more information about CARF accreditation in your setting or to identify IPR programs in your area, contact Terry Carolan at tcarolan@carf.org. CM

Case Management in 2022 *continued from page 2*

technology and self-study. We will continue to see a proliferation of new diseases, new treatments, and new therapies, and case managers must stay informed.

With the changes coming in 2022 coupled with the COVID-19 pandemic, the year will be challenging. At times it will seem like it is overwhelming, but let us not become overwhelmed. The year 2022 will be a demanding year but a good year for case managers. The need for case managers will continue to increase. There will be more opportunities and greater flexibility, and we must remember to take care of ourselves. With resiliency and focus, 2022 will be a great year!



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ACCM: Improving Case Management Practice through Education

Can You Spell Resilience? *continued from page 3*

Better days are ahead, and we can make a difference, for ourselves, our colleagues, and our patients, one day at a time!

Warmest regards,

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

Updated Pharmaceutical Industry Marketing Code May Help All Providers Understand Current Standards *continued from page 10*

into arrangements with prospective consultants

- Criteria for selecting consultants must be directly related to the identified purpose and persons responsible for selecting consultants must have the expertise necessary to evaluate whether particular health care professionals meet those criteria
- The number of health professionals retained is not greater than the number reasonably necessary to achieve identified purposes of the services
- Providers that pay consultants maintain records concerning and make appropriate use of the services provided by consultants
- The venue and circumstances of any meeting with consultants are conducive to the consulting services and activities related to the services are the primary focus of the meeting. Resorts are inappropriate venues, according to the Code.

Although the Code described above applies only to members of PhRMA who voluntarily agree to adhere to it, the Code may be viewed as establishing standards in the industry regarding relationships with referral sources. CM

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