CareManagement

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

Vol. 28, No. 4 August/September 2022

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Gary S. Wolfe

Case Management Fellows: Acknowledging Our Own

Last year the Case Management Society of American launched the CMSA Case Management Fellow program to elevate the professional practice of case management and to advance the standards of practice. Criteria to become a Fellow were developed with a focus on leadership, innovation, and scholarship, with specific emphasis on the following:

- Professional and volunteer leadership
- Leadership achievements and innovation
- Mentorship
- Community service
- Contributions to the field of case management
- Impact of contributions
- Special recognition

The selection process consists of written documentation of education, professional employment, volunteer service, and innovative contributions as well as leadership, scholarly contributions, and special recognition. The process is rigorous. A selection committee consisting of the Founding Fellows reviewed all the documentation, had discussions, and selected the Fellows for 2022.

Fellows are case management leaders in education, management, practice and research. Becoming a Fellow in Case Management acknowledges exemplary work and service achievements. Fellows are our esteemed colleagues. Fellows are recognized for their accomplishments, but they also have a responsibility to continue to make contributions and to be engaged in the professional practice of case management. Fellows use the FCM™ designation after their name indicating that they are a Fellow in Case Management.

The Case Management Fellow Class of 2022 consists of:

- Catherine Campbell, DNP, FCM
- Janet Coulter, MSN, CCM, FCM
- Colleen Morley, DNP, RN, CCM, CMAC, CMCN, ACM-RN, FCM
- Patricia Noonan, RN, MBA, CCM, FCM
- Melanie Prince, MSS, MSN, BSN, NE-BC-CCM, FAAN, FCM

I salute these individuals and congratulate them. They are recognized case management leaders and most of them have published in *CareManagement*. These visionary leaders will continue to be influential leaders and influencers within case management.

The Case Management Fellow Class of 2022 joins the CMSA Founding Fellows:

- Patricia Agius, BS, RN, CCM, CPHQ, FCM
- Jeanne Boling, MSN, CCM, CRRN, FCM
- Anne Liewellyn, MS, BHSA, RN, CCM, CRRN, FCM
- Catherine Mullahy, RN, BS, CRRN, CCM, FCM
- Mindy Owen, RN, CRRN, CCM, FCM
- Nancy Skinner, RN, CCM, CMGT-BC, ACM-RN, CMCN, FCM
- Hussein M. Tahan, PhD, RN, FAAN, FCM
- Gary Wolfe, RN, CCM, FCM

It is also with great pleasure that we recognize Elizabeth Hogue, a contributing editor of *CareManagement*, for being named a Fellow of the American Health Law Association (AHLA). She is recognized for her professional acumen as one of the top health professionals in the nation and her consistently high level of service. The AHLA is the largest educational organization devoted to legal issues in the health care field. The mission of the AHLA is to provide a collegial forum for interaction and information exchange to better serve clients, to provide

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Catherine M. Mullahy

Despite the Challenges, Case Managers Must Prioritize Their Patients' Care

While the title "case manager" has been a term that's used to describe our primary role and should be synonymous with it, its meaning seems to have been diminished. This is especially true in this postpandemic era.

This issue of *CareManagement* will underscore that time does not stand still for case managers, not even in the summer. We have a great deal of information in this issue, and hopefully you'll be able to find some time to read the contents. It's also important to take some time to renew our spirits and enjoy our family and friends, but today's staffing challenges are making it difficult for many case managers and other health care professionals to take vacation time. How will this impact you?

Staffing shortages persist and the "great resignation" continues. New graduates from nursing programs, social work programs, and medical schools will all be starting their first professional jobs, which often results in staff and resource reallocations and increasing stress for everyone. There will be pressures on existing staff, many of whom will be asked or assigned to be preceptors for inexperienced staff members. Experienced case managers will be mentoring those who will transition into their new roles. With these additional responsibilities, challenges will also increase, not just in one setting but across the care continuum. There used to be a saying, "Don't get sick in July." Sadly, this upheaval causes what health care workers call "The July Effect" in the United States and the "August Killing Season" in the United Kingdom (where the shift happens in August). The changeover harms patient care, increases medical and medication errors, and causes longer hospital stays. In July, U.S. death rates in teaching hospitals surge between 8% and 34%—between 1,500 and 2,750 deaths. UC San Diego researchers found that fatal medication errors "spike by 10% in July and in no other month." This is alarming and should cause all case managers to consider what they can do to help address this situation. Unfortunately, inexperienced staff members continue to have a direct impact on care, safety, and the patient experience. Of course, case managers continue to experience the repercussions and challenges associated with inexperienced staff members.

FIGURE 1

While we need to deliberately and actively position ourselves as advocates for our patients, I wonder if the term "advocate" has lost its impact. While the title "case manager" has been a term that's used to describe our primary role and should be synonymous with it, its meaning seems to have been diminished. This is especially true in this postpandemic era. Several prominent leaders in nursing, social work, case management, and medicine have expressed increased concern about the attitudes and demeanor of our colleagues and are calling for action. Their observations have been especially troubling as they relate to the diminished kindness, concern, and willingness by case management professionals and their colleagues (ie, nurses, social workers, and others on the patient's care team) to address these concerns. These leaders proposed that these problems need to be addressed in a decidedly direct and unique manner, and it was interesting that the terms being used—disruptive innovation and disruptive advocacy—were quite similar. Our colleagues have noticed and felt compelled to address their concerns in presentations, social media, and various publications. The image and description of the actions that were being proposed appears in Figure 1.

During the past few months, I

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Human Resources Professionals: Antitrust Guidance

Elizabeth Hogue, Esq.

The Federal Trade Commission (FTC) and U.S. Department of Justice (DOJ) mean business when it comes to antitrust violations! During his 2020 presidential campaign, President Biden said: "It's simple: companies should have to compete for workers just like they compete for customers. We should get rid of noncompete clauses and no-poaching agreements that do nothing but suppress wages." Then, in July of 2020, President Biden issued an Executive Order which, among other provisions, urged the FTC to regulate noncompete agreements. There has also been plenty of enforcement action.

Four home health managers at several agencies in Maine, for example, were recently indicted by a federal grand jury on felony charges related to antitrust violations. The providers agreed among themselves to pay personal care workers between $15 and $16 per hour, pressured other home health agencies to do the same, and threatened to report other managers to Maine's Medicaid Program if they didn't comply. According to the indictment, they conspired to suppress wages and limit job mobility by agreeing to fix workers' rates of pay and to refrain from hiring workers from each other's companies. They allegedly conspired to deprive workers of opportunities to earn better wages.

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In United States v. DaVita, Inc. [No. 1:21-cr-00229-RBJ (D. Colo. Jan. 28, 2022)], the government claimed that outpatient medical facilities agreed not to solicit each other's senior-level employees. The Judge in this case refused to grant DaVita's motion to dismiss on the basis that non-solicitation and no-hire agreements are unlawful when they are used as a basis for a naked agreement to allocate markets.

What should providers do? In 2016, the FTC and the DOJ jointly issued "Antitrust Guidance for HR Professionals." This Guidance includes "red flags" for human resource managers. Human resource managers and their colleagues should not:

- Agree with another company about employee salaries or other terms of compensation, either at a specific level or within a range
- Agree with another company to refuse to solicit or hire another company's employees
- Agree with another company about employee benefits to be provided
- Agree with another company on other terms of employment
- Urge competitors not to compete aggressively for employees
- Exchange specific information about employee compensation or terms of employment with another company for the purposes of agreeing to limit either
- Participate in meetings, including trade association meetings, during which the above topics are discussed
- Discuss the above topics with colleagues at other companies, including at social events or in other nonprofessional settings
- Review documents that contain another company's internal data about employee compensation

It's a new environment for anti-trust enforcement, especially in the healthcare industry. Providers should pay close attention to this issue. 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.*

Quality Improvement: "Escape Fire"

Elizabeth Hogue, Esq.

Sensemaking is the process by which the fluid, multilayered world is given order within which people can orient themselves, find purpose, and take effective action. According to Professor Karl E. Weick, organizations don't discover sense, they create it.

On December 9, 1999, Dr. Donald M. Berwick; the founder, President, and CEO of the Institute for Healthcare Improvement, gave an important address to the 11th Annual National Forum on Quality Improvement in Health Care. The wisdom of Dr. Berwick's words still rings true today and is important for all providers who are committed to improving the quality of patient care on a continuous basis.

Dr. Berwick began his speech with a description of the Mann Gulch fire in Montana on August 5, 1949. Thirteen young men lost their lives in this fire that did not develop as expected. At first, the fire appeared to be routine. The firefighters called it a "ten o'clock fire," which means that they expected to have the fire beaten by 10 o'clock in the morning. But they were wrong. The fire flanked them and cut off their escape route to the river.

The firefighters immediately changed course and hoped to get up a steep hill and over a ridge before the fire reached them. Their leader, Wag Dodge, recognized that his team would not make it over the ridge before the fire engulfed them. Here is Berwick's description of what Dodge did:

"With the fire barely 200 yards behind him, he did a strange and marvelous thing. He invented a solution. On the spot. His crew must be thought he had gone crazy as he took some matches out of his pocket, bent down, lit a match and set fire to the grass directly in front of him. The new fire spread quickly uphill ahead of him, and he stepped into the middle of the newly burnt area. He called to his crew to join him as he lay down in

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CMSA....Onward!

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

Having just returned from the CMSA National Conference in Orlando, Florida, where I was sworn in as President of the Case Management Society of America National Board of Directors, I am honored and thrilled to be taking on this role with the oldest and largest professional organization for the case management community.

Many years ago, as a new case manager, I did not understand the importance of the networking and connecting with other case managers across the continuum. Today, I can attest that it is not only important but a necessity in the professional case manager's toolbox. The value of belonging to and being involved with professional organizations cannot be understated.

2022 has already proven to be another great year for CMSA and we are only 6 months in! Thank you to our membership and volunteers who lead the local chapters, giving freely of their talent and time to add value to this organization. Here are just a few highlights of the year so far; stay up-to-date and find out more by visiting www.cmsa.org.

***Dr. Colleen Morley, DNP, RN, CCM, CMAC, CMCN, ACM-RN, FCM**, is the Regional Director of Case Management for Pipeline Health Systems/Chicago Market. She has held positions in acute care as Director of Case Management at several acute care facilities and managed care entities in Illinois, overseeing utilization review, case management, and social services. Her current passion is in the area of improving health literacy. She has recently authored her 1st book, "A Practical Guide to Acute Care Case Management", published by Blue Bayou Press.*

The CMSA Board of Directors and Strategic Plan Taskforce has been working with our association management group, Parthenon Management, to create a strategic plan to lead CMSA into the future. The core elements were revealed at the CMSA National Conference Annual Meeting.

CMSA Strategic Plan Unveiled!

The CMSA Board of Directors and Strategic Plan Taskforce has been working with our association management group, Parthenon Management, to create a strategic plan to lead CMSA into the future. The core elements were revealed at the CMSA National Conference Annual Meeting. It was EPIC!

Education. Continue to be the premier professional organization for case management–focused education and evidence-based practice dissemination

Public Policy. Build on our public policy platform and be the voice for case management across the continuum

Increase Membership. Stronger together! And leverage the talent of our membership to further the professional practice of case management.

Collaborative Partnerships. Continue to develop and build on collaborative partnerships, interdisciplinary care, and care across the continuum to ensure our patients/clients/members receive the best care we can provide as a healthcare system.

Standards of Practice for Case Management

Earlier this year, the CMSA Standards of Practice Task Force completed their comprehensive review of the latest version of the Standards last published in 2016. CMSA was the first case management professional organization to create Standards of Practice in 1995, with subsequent review and updates in 2002, 2010, and 2016. The 2022 updates were released this Spring and are now available at www.cmsa.org.

Public Policy

Earlier in the year, the Public Policy Committee held a successful 3-part webinar series on the legislative priorities of the association: telehealth, mental health, and workforce development. These webinars led up to the 2022 CMSA Virtual Hill Visits program, where over 45 CMSA members met with the offices of various Members of Congress in 28

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Understanding Disability Management and Absence Management

Ed Quick, MA, MBA, CDMS

In the world of workforce management, two frequently encountered terms are disability management and absence management. To those who are outside of these closely related disciplines, it may be difficult to distinguish between the two.

Disability management refers to services and solutions to help employees with illnesses, injuries, or disabilities return to work or stay at work. Traditionally, certified disability management specialists (CDMSs) advocated for employees who were covered by workers' compensation. Later, the practice expanded to also include individuals with nonoccupational illnesses and injuries who may have been covered by short- and long-term disability policies.

Absence management is a broader term that has come increasingly into use. It encompasses disability management as it pertains to short- and long-term disability but also extends to include employer policies and procedures that address time away from work for a variety of causes. Examples are absences covered by paid time off (PTO) or sick leave, Family and Medical Leave Act (FMLA), and other nondisability leaves, both paid and unpaid.

Disability management refers to services and solutions to help employees with illnesses, injuries, or disabilities return to work or stay at work. Absence management encompasses disability management as it pertains to short- and long-term disability but also extends to include employer policies and procedures that address time away from work for a variety of causes.

Absence management is also proactive, seeking to reduce employee absenteeism, avoid disruptions in the workplace, and maintain productivity among employees. Practices include helping employees stay on the job rather than go out on leave. An example would be a person who sustains a nonoccupational injury (e.g., a broken leg) and needs temporary job restrictions or modifications to stay at work and remain productive.

CDMS job functions span both disability management and absence management, as defined by four domains: disability and work interruption case management; workplace intervention for disability prevention; program development, management, and evaluation; and employment leaves and benefits administration.

Professional case managers might encounter disability management and absence management in two ways. The first is in advocating for and providing care coordination and other case management services to a person with an illness, injury, or disability who wants to return to work. The case manager may have some contact with a disability manager to explore support and programs that may be available from the employer to help the individual.

In addition, professional case managers may become ill or injured themselves, whether on or off the job, and require support in returning to or staying on the job. It is a good practice for every employee to learn more about the programs and policies offered by their employer, what state or federal statutory leaves may be available (both paid and unpaid), and how these benefits may be coordinated in terms of time, pay, and job protection. Most larger employers offer disability management and absence management through a third-party vendor, who may also provide assistance and guidance in navigating these leave nuances.

For more general information and an overview, please see:

- Hiring a CDMS

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Ed Quick, MA, MBA, CDMS, *is a Commissioner of the Commission for Case Manager Certification (CCMC), the first and largest nationally accredited organization that certifies more than 50,000 professional case managers and disability management specialists. He has more than 30 years of experience in disability and workforce management with Fortune 100 companies, and currently works as a global senior benefits manager.*

Unique Case Management Training Program Helps Professionals "GROW" Their Knowledge and Advocacy

MaryBeth Kurland, MPA, CAE, ICE-CCP

The Commission is proud to support General Relief Opportunities for Work (GROW) case managers in their daily work. We see this as yet another opportunity to promote professionalism and best practices across every case management setting and to help clients pursue their goals with success.

The principles and concepts of professional case management apply broadly across a wide range of settings in which clients are served, including acute care, primary care, mental health care, social services, the payer environment, workers' compensation, and more. Each setting reminds us that case management is increasingly becoming both professionally diverse and interdisciplinary.

A recent example is a unique training program that the Commission provided for the case management staff of the General Relief Opportunities for Work (GROW) program from the Department of Social Services in Los Angeles County. GROW helps people get the employment and training services they need to enter the workforce and pursue financial stability. A critical component of those services is receiving consultation and ongoing support from these case managers, who practice within the realm of health and human services.

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

The Commission's relationship with the Los Angeles County Department of Social Services began in 2018, when the department tapped into the Commission's expertise to enhance training for its case managers. This relationship expanded with the Commission providing customized professional training for GROW case managers. Offering this training is in keeping with the Commission's mission, which includes promoting excellence in professional case management and providing education programs and services as well as encouraging eligible professional case managers to get certified and stay certified.

Common Ground in Case Management

GROW case managers engage in assessing, planning, following up, transitioning, communicating, and evaluating outcomes as clients pursue their goals. Based on individual needs, the GROW case managers also help connect clients with other services to help further their goal of permanent employment. As this shows, GROW professionals apply the same case management principles as professional case managers in other settings. In both instances, the case management approach is client-centric, based on the needs and goals of each individual, and centered in advocacy.

Advocacy is a foundational value of case management. What that looks like may vary in practice but not in principle. Advocacy is an ethical obligation, particularly for board-certified case managers. It compels them to provide their clients with the right services at the right time and in the right place—whatever those services may be.

Customized Training

To meet the unique needs of the GROW program, the Commission engaged three subject matter experts to create a tailored professional development curriculum for about 200 GROW case managers. GROW professionals actively engaged in a 7-week interactive virtual training program guided by the Commission's

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Addressing Health Care Bias Among Case Managers

Kris Louque, DNP, RN, CNE, CCM

This week I was deeply saddened after reading a news article about a lawsuit in California against a large well-known medical organization for racial discrimination. The husband is suing the hospital in response to the death of his wife, who died shortly after giving birth to their second child during an elective cesarean section. The husband feels her death would not have occurred if his wife were White. I forwarded the article to my husband and two oldest daughters who are nurses. The article started a family discussion of our professional experiences and how bias affects the patients that we care for every day. The resulting dialog led to some honest self-evaluation and soul searching as I reflected on my 28-year career as a registered nurse. According to the Centers for Disease Control and Prevention, Black women are three times more likely to die from a pregnancy-related cause than White women. Because I had previously worked as a nurse educator on a postpartum unit, I asked myself, "Is it possible that my nursing unit provided different care based on the patient's skin color?" My immediate answer was "of course not," but after some self-reflection my answer changed to "I hope not, but I am concerned that maybe we did."

Implicit bias is the bias that a person is unaware of but causes unconscious negative attitudes towards certain groups. These unconscious biases can include race, gender, sexual identity, age, abilities, weight, socioeconomic status, education, and geographic location.

In 2001, the Institute of Medicine described six specific goals for health care that included equality. In 2016, the Institute for Healthcare Improvement (IHI) developed a white paper to guide health care organizations into achieving health equality because, as a system, we were still falling short of this goal. Within the framework developed by the IHI is the recommendation to reduce implicit bias. Implicit bias is the bias that a person is unaware of but causes unconscious negative attitudes towards certain groups. These unconscious biases can include race, gender, sexual identity, age, abilities, weight, socioeconomic status, education, and geographic location.

How often has implicit bias affected the care I provided to a patient with chronic pain or a transgender patient? How many times have I dreaded taking care of a chronic pain patient or prayed I was not assigned the patient with diabetic ketoacidosis who was readmitted for the third time in the last 6 months? These are obvious examples that were easy to self-identify during my reflection. However, a much less obvious example emerged as I reflected on my past experiences as a case manager.

The interaction occurred while I was working as an inpatient case manager and was assigned a high school-aged patient with type 1 diabetes who was a "frequent flyer." His history detailed multiple admissions, his noncompliance to the recommended health care regimen, and even some details about his home life, which included him not living with his parents but instead living with his friend and their parents. We discussed this patient in our morning rounds, and the provider requested that I make sure the patient enrolled in disease management services. I can remember thinking that once again I would be expected to visit a patient and wave my "magic wand" to get him to agree to something that he was not interested in starting. After all, this was his third admission in the last 6 months, and he had been offered disease management services with each admission. After reviewing his chart, I developed a mental picture of the

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***Kris Louque, DNP, RN, CNE, CCM**, has 12 years of inpatient and outpatient case management experience in both military and civilian facilities. She currently works as a nursing instructor and part-time inpatient acute rehabilitation case manager in San Angelo, Texas.*

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

Case Management for Long-Haul COVID Patients

Catherine M. Mullahy, RN, BSN, CRRN, CCM, FCM, and Jeanne Boling, RN, MSN, CRRN, CDMS, CCM, FCM

The COVID-19 pandemic was unprecedented in its impact on the world. While the virus and its variants continue to affect many individuals, there has been considerable progress in containing the virus' spread largely because millions of people have been vaccinated and boosted. Still, many individuals who were infected with the virus continue to suffer a wide range of symptoms: some symptoms are mild, but other symptoms are serious and involve ongoing medical care.

According to Charles Glassman, MD, Associate Medical Director, the Standard Insurance Company, up to 3.1 million people are expected to develop postacute sequelae of COVID-19 (PASC), the medical term for long COVID illness (CCMC, 2022). The high transmissibility of the Omicron variant has led many to believe there will be even more patients with PASC (Berg, 2022). These so-called COVID long-haulers require specific case management strategies and services. Case managers assigned to care for COVID long-haul patients should become familiar with the current state of thinking and activity on long-haul COVID as well as the symptoms, complications, and uncertainties they will encounter. Most importantly, they should learn about the best practices in case management for meeting the needs of these special patients.

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Long-Haul COVID and Current Findings

Right from the start, case managers should understand that there are still many unknowns regarding long-haul COVID. At a recent Commission for Case Manager Certification (CCMC) CM Learning Network program titled, "COVID-19 and the Effect on the Workplace: Return-To-Work Strategies and COVID Long-Haulers," presented by Charles Glassman, MD, Daniel Jolivet, PhD (Behavioral Health Director, The Standard Insurance Company), and Patricia Nunez, MA, CRC, CDMS, DDM (Secretary for CCMC), a few theories regarding long-haul COVID were presented (CCMC, 2022). One theory is that COVID-19 may involve an attack on the autonomic system that is related to a cytokine (chemicals that facilitate communication between cells) storm induced by the virus. Another theory is that COVID-19 is a blood vessel disease wherein the virus enters through vascular receptors in the respiratory tract, causing a form of vasculitis in the respiratory system and then spreading throughout the body's blood vessels. In this way, it would be similar to bacterial sepsis and distributed via intravascular coagulation.

There is minimal evidence on the appropriate management of COVID-19 after the first 3 weeks of infection. A general consensus is that long-haul COVID is a multisystem disease that can occur even after a mild acute illness. Treating long COVID requires a holistic whole-patient approach even though long-haul COVID patients may be classified into different categories from those with more serious symptoms (eg, thromboembolic complications) to those with less-specific symptoms that often include fatigue and breathing difficulties. Patients who experience long COVID have symptoms that vary widely, and how a patient experiences long-haul COVID is also influenced by his/her age, overall health, and whether they have other medical conditions or comorbidities.

In addition to the presence of various symptoms and an examination, blood tests are used to further make a long-haul COVID diagnosis. For example, to determine the presence of infection or inflammation, heart failure, thromboembolic disease, or myocarditis, tests are conducted for white blood cell

According to Charles Glassman, MD, Associate Medical Director of the Standard Insurance Company, up to 3.1 million people are expected to develop long-haul COVID.

counts, natriuretic peptides, D-Dimer, and troponin, respectively. Many patients do not report their long-haul symptoms until months after they have had the infection. This was noted in the April 2021 issue of the "Morbidity and Mortality Weekly Report" from the U.S. Centers for Disease Control and Prevention (CDC) (Hernandez-Romieu, 2021), which stated that 69% of nonhospitalized adult COVID patients in Georgia experiencing symptoms required one or more outpatient visits 28 to 180 days after their COVID diagnosis.

There are currently few established therapies for long-haul COVID symptoms, and clinicians are still relying on protocols used in treating conditions with symptoms similar to those experienced by long-haul COVID patients. What is apparent is that long-haul COVID has ongoing implications for a patient's physical and mental health, employment, and overall quality of life. Also known is that long-haul COVID symptoms appear to develop 1-2 months after a patient's initial COVID-19 infection and that individuals who are most susceptible to long-haul COVID are older, have preexisting medical conditions including obesity, and have lower incomes. Females seem to be more affected than males. Additionally, long-haul COVID is more likely to occur in patients who were not hospitalized for COVID but who have heart disease and/or chronic obstructive pulmonary disease (COPD). (CCMC, 2022).

The American Medical Association (AMA) elected to adopt a policy to support the development of an International Classification of Diseases, 10th Revision (ICD-10) code or family of codes to recognize PASC/long-haul COVID and other novel postviral syndromes as a distinct diagnosis. The policy adoption occurred at the AMA's June 2021 Special Meeting. (Berg, 2022)

COVID Long-Haul Symptoms

The role of case managers will be to care for their long-haul COVID patients and to be part of the "investigative" and educational team gathering and sharing more data to help the medical community better understand and treat long-haul COVID. The myriad of symptoms that can be experienced with PASC alone requires thorough reporting and documentation.

Long-haul COVID 19 symptoms can be categorized as the most common ones and those that are more inexplicable. The CDC lists the following as the most common long-haul COVID symptoms:

- Breathing difficulties
- Cough
- Fatigue
- Chest or stomach pain
- Joint or muscle pain
- Diarrhea
- Fever
- Dizziness
- Changes in taste and smell
- Pins and needles feeling
- Brain fog
- Sleeping difficulties
- Symptoms that get worse after physical or mental activities (CDC, 2022)

Of these most common symptoms, breathlessness and fatigue appear to be the most common regardless of the severity of the acute COVID-19 illness based on a United Kingdom cohort report (Arnold et al., 2021).

According to specialists in the multidisciplinary UCLA Health Long COVID Program, other long COVID symptoms include anxiety, depression, and posttraumatic stress disorder (UCLA Health).

The presenters (Glassman, Jolivet, and Nunez) in the previously cited CCMC Learning Network program, "COVID-19 and the Effect on the Workplace…," classified COVID patients in two groups. Those in Group 1 have symptoms that stem from multiorgan involvement and are caused by acute infections. These individuals sustain acute heart, kidney, liver and/or neurological injury, a breakdown of muscle tissue and blood clots. Their long and ongoing symptoms are evident and understood. Group 2 patients present without any apparent organ damage, do not initially have any severe infection, and have symptoms that are regarded as subjective. During the early stages of the pandemic, how sick these patients really were was questioned.

Infected patients who are likely be diagnosed with long-haul COVID are individuals who, independent of age or gender, present with more than five symptoms within the first week of acute infection based on the analysis of COVID cases and symptoms collected by the Covid Symptoms Study app (Sudre et al., medRxiv, 2020). Other studies have found that symptoms persist in patients who had been previously hospitalized as well as in those with mild to moderate acute COVID-19. For example, in a study that grouped patients

Long-haul COVID has ongoing implications for a patient's physical and mental health, employment, and overall quality of life.

based on their having mild, moderate, or severe acute COVID-19, and whether they required oxygen support and/or intensive care, it was found that 59% of the patients with mild COVID-19 still had symptoms at the 8–12 week mark from the onset of their symptoms, while 75% or patients in the moderate group and 89% of those in the severe acute group also had symptoms lasting to the 8–12 week mark (Arnold et al., 2021).

Less formal studies presenting anecdotal data also suggest that, for many who have contracted COVID-19, lingering symptoms are very real. As an example, the Body Politic COVID-19 Support Group's online survey conducted in the spring of 2020 found that 91% of its 640 respondents reported still not having fully recovered, with symptoms persisting, on average, to 40 days at the time of the survey (Rubin, 2020). For many patients who suffer from long-haul COVID, impaired memory and concentration, often paired with extreme fatigue, have been among the most debilitating and persistent symptoms.

For patients who develop long-haul COVID, their symptoms can last several months to a year, leading to several quality of life challenges that affect multiples aspects of their lives

Patient Quality-of-Life Issues

In a July 2020 COVID-10 webinar presented by the International AIDS Society, Anthony Fauci, MD, OMRI, director of the National Institute of Allergy and Infectious Diseases, stated that "Anecdotally, there's no question that there are a considerable number of individuals who have a post-viral syndrome that really, in many respects, can incapacitate them for weeks and weeks following so-called recovery and clearing of the virus" (Rubin, 2020).

Long-haul COVID patients have reported functional limitations preventing them from performing at their day-to-day pre-COVID levels, whether related to employment, academic, social or recreational activities. Many individuals state that they are less able to manage their usual tasks at work. Even young adults have indicated that they were unable to focus on their classroom studies or get back to their former athletic levels. In some of the more severe cases, long-haulers were diagnosed with posttraumatic stress syndrome, which further compromised their quality of life (Rivas-Vazquez et al., 2022).

It is widely accepted that long-haul COVID is a syndrome that is comprised of cognitive, bodily, and behavioral symptoms that can last for months or longer and can affect one's ability to perform their daily activities. To treat all of the related symptoms affecting the body's various systems—brain, heart, lungs, and nervous system—a multidisciplinary, coordinated care approach is essential. This approach will encompass clinicians from a variety of specialties, including internal medicine, neurology, cardiology, pulmonology, rheumatology, psychiatry, psychology, and infectious diseases. Additionally, there is a heightened need for case management with experienced RN case managers serving as patient advocates, coordinators, communicators, and connectors between all of these disciplines.

Long-haul COVID patients require ongoing support from their medical team members and personalized treatment plans that address each patient's specific symptoms and mitigates their individual quality of life challenges. This may encompass receiving disease management services, new medications, physical therapy, pulmonary and cardiac rehabilitation, psychiatric/psychological support, and various social services. The case manager will be at the center of the coordination of these resources and their patient's adherence to their treatment plans.

In a study of hospitalized COVID-19 patients in the United States in which the patients were surveyed using the PROMIS® Global Health-10 instruments to assess quality of life, many indicated having worse general health after their acute illness compared with a baseline. Their scores also indicated a reduced ability to carry out social activities 4 to 6 weeks after their hospitalization (Aiyegbusi et al., 2021). A cohort study of hospitalized patients who experienced COVID-19-related acute respiratory distress syndrome that was conducted 6 months after their hospitalization found that 67% had a decrease in their quality of life (Huang et al., 2021). The same cohort study further illustrated the diminished quality of life for many COVID-19 patients, with almost half of all patients surveyed noting they were emotionally affected by their long COVID experience 8 weeks after their acute infection (Huang et al., 2021). Another study conducted 6 months after the onset of symptoms found that 23% of those patients who had been hospitalized suffered from anxiety or depression (Huang et al., 2021).

There is no denying that long COVID negatively affects a patient's quality of life. For some, it stems from a lack of social support. In more-severe cases, this can lead to posttraumatic

Long-haul COVID patients require ongoing support from their medical team members and personalized treatment plans that address each patient's specific symptoms and mitigates their individual quality of life challenges. The case manager will be at the center of the coordination of these resources and their patient's adherence to their treatment plans.

stress syndrome symptoms (Poyraz et al., 2021).

Other studies revealed the impact on employment for long-haul COVID patients. It found that nearly 70% of previously hospitalized patients were unable to return to work 90 days after their hospitalization (Garrigues et al., 2020).

When caring for a long-haul COVID patient, case managers must take into account the wide range of medical, emotional, and social issues as well as the broader quality of life impacts their patients may be experiencing. Effectively coordinating care for these patients demands an integrated approach that recognizes and reflects a full understanding of PASC symptoms that can occur across a span of one to several months.

According to Daniel Jolivet, PhD, "What we see with our data in terms of long-term disability is that average long-term disability is duration for a PASC patient is about 90 days. However, almost 25% of claims continue for a very long duration for a post-infection claim" (CCMC, 2022).

Long-Haul COVID Patient Case Management

Charles Glassman, MD, stated that "Case management will require customized hands-on approaches. This is really important because we saw that there's going to be maybe a laundry list of symptoms [associated with PASC]" (CCMC, 2022).

The case management approach must be patient centric when caring for a PASC patient. This is not to suggest that dedicated case managers don't always place their patients at the center of their care, but in the case of PASC patients, it cannot be emphasized enough given the different symptoms that each patient may experience, the many unknowns that remain about long-haul COVID, and the many ways each patient can be affected.

Because of the lack of clinical information regarding PASC, case managers have a heightened responsibility to advocate for their patients and should be aware that a physician or other clinician on the patient's care team may not be taking the patient's accounting of what he/she may be experiencing as seriously as the patient would like. Unfortunately, there are some healthcare professionals who, when faced with unchartered territory, elect to dismiss a patient's feelings as overreacting or even fabricating a condition. In these instances, case managers must be firmly aligned with what their patient is saying and strive to help find the answers to relieve a patient's symptoms and/or concerns.

Patient and family education is an especially important aspect of the case manager's care for patients with PASC. Since this a new disease with new information unfolding every day, case managers must stay abreast of the latest developments and keep their patients informed of news that could have an impact on them.

Case managers also must assume an educational role in helping employers better understand the symptoms of PASC and the recovery process. Individuals who have contracted COVID-19 may experience negative repercussions relating to their employment. Some employers may not fully understand why their employee cannot return to work after being discharged from the hospital and recovering at home for a certain length of time. They may be suspicious about certain symptoms and about why their employee cannot return to work. Again, because of the lack of awareness regarding long-haul COVID, many people do not realize the breadth of symptoms that can be experienced months after the acute infection. Whether a case manager is employed by a business, managed care company, hospital, community-based organization, or case management firm, the first responsibility must be to the patient.

With that said, case managers should adhere to the foundational principles of case management and the standards put forth by the Case Management Society of America (CMSA) and the Commission for Case Manager Certification (CCMC) when caring for a long-haul COVID patient. They should be consistent with the CCM Domains of Knowledge in areas such as care delivery and reimbursement methods; psychosocial concepts and support systems; quality and outcomes evaluation and measurement; rehabilitation strategies; and ethical, legal, and practice standards. The case management plan for a PASC patient includes a thorough needs assessment that identifies the patient's problems and the goals, interventions, and authorizations required to achieve the best patient outcome. The plan must be focused and specific in its action items, with measurable and attainable objectives that conform with a fiscally responsible approach.

The implementation of the PASC patient's case management plan will require strong care coordination efforts. They must involve the patient's support system as well as other medical team members and service providers and will include tasks such as arranging for and coordinating services, communicating steps with other medical team members, monitoring the quality and timeliness of services being provided, and following up on referrals to specialty care providers. Patients must be fully engaged and informed about the plan and their responsibilities in their self-care (ie, adherence to their treatment plan). As always, good patient communication is extremely important and must take in account that some of the symptoms associated with long-haul COVID can be quite debilitating and cause some patients to become discouraged, depressed, and potentially noncompliant with their plans. This is where case managers must demonstrate their deep compassion and understanding and work to keep the patient engaged and in a positive state of mind.

For individuals whose plan is focused on returning them to work as soon as possible, case managers must remain supportive of their PASC patients and maintain communications with employers to best accommodate a gradual return to work. This may include a discussion of a flexible work schedule, an ergonomic assessment of the patient's workspace to see if any furnishing or equipment changes should be recommended, and becoming familiar with an employer's Employee Assistance Program (EAP) and what additional support could be offered to the patient.

Closing Remarks

Recognizing the many complexities and uncertainties involved in caring for PASC patients, it is incumbent upon case managers to continually learn about long-haul COVID and keep informed regarding the latest data and medical findings. Continuous self-education is paramount to providing high-quality case management services for PASC patients. Regularly check for new long COVID information on professional websites such as the AMA, CCMC, CMSA, National Institutes of Health (NIH), CDC, and the American Academy of Physical Medicine and Rehabilitation (AAPM&R). Share appropriate findings with your medical colleagues as well as your PASC patients and their families. This ongoing information flow is vital to promoting better understanding of PASC and care for long-haul COVID patients. CE1

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HIPAA (Part 2): Is it a Breach or Disclosure?

Kathleen Fraser, RN-BC, MSN, MHA, CCM, CRRN, FAAN

Compliance issues usually occur when there is a lack of policies, procedures, and, most importantly, a lack of care coordination. Compliance issues also occur when there are infrequent investigations after notification of a potential breach, policy and procedures are defunct, safeguards have lagged, and data are not being kept under "lock and key." Breaches are going to happen, but once systems are put in place, fear can be alleviated, and successful implementation can be achieved by following the seven elements (Figure 1). Complexity in segregating protected health information (PHI) does not excuse the obligation to provide access to the PHI to which the ground for denial does not apply. 45 CFR § 164.524. 45 C.F.R. § 164.530(i), 45 C.F.R. § 164.530(a), 45 C.F.R. §160.103. 67, 45 C.F.R. § 164.530(b), 68 45 C.F.R. § 164.530(e).

FIGURE 1 SEVEN ELEMENTS

1. Establish and adopt written policies and procedures to promote the organization's commitment to compliance.
2. Identify and appoint an individual to serve as compliance officer responsible for monitoring compliance efforts and enforcing practice standards.
3. Establish reporting systems to encourage individuals to make complaints regarding compliance violations without fear of retaliation.
4. Commit to conducting formal education and training programs for all employees.
5. Ongoing auditing and monitoring of systems to assess the effectiveness of the compliance program and identify issues.
6. Develop policies enforcing standards of conduct with disciplinary measures for employees who fail to comply with requirements.
7. When vulnerabilities are identified, corrective action must be conducted in response to potential violations.

Policy Restrictions:

- Covered entities must create policies and procedures that restrict access and use of PHI based on the roles of the workforce in question
- Policies and procedures must identify who in each workforce group needs access to PHI to carry out their duties
- Define categories of PHI that each workforce group needs to carry out their duties
- Special attention with coordinated care during discharge and capacity management planning
- Newly hired employees must receive training within 90 days of hire
- Material changes require retraining within one year

The 10 most common HIPAA violations according to the Office for Civil Rights (OCR) and how they can be avoided:

1. Keeping Unsecured Records

As part of your employee training, all staff members should be required to keep documents with PHI in a secure location. Physical files containing PHI should be locked in a desk, filing cabinet, or office. Digital files should require secure passwords to access them and should be encrypted whenever possible.

2. Unencrypted Data

Encrypting data is an added protection if a device containing PHI is lost or stolen. It offers an additional layer of security if a password-protected device is somehow accessed (eg, through hacking). Although it is not a strict HIPAA requirement, it is highly recommended. However, many states' HIPAA regulations have passed laws requiring electronic PHI (ePHI) and PHI to be encrypted, which would override the federal lack of requirement.

3. Hacking

Keeping antivirus software updated and active on all devices containing ePHI using firewalls adds another layer of protection, and creating unique passwords that are changed frequently is the third important measure to prevent hacking.

4. Loss or Theft of Devices

A case was settled in June 2016 where an iPhone containing a vast amount of ePHI, including social security numbers, treatment and diagnosis information, medications, and more, was stolen. The iPhone was neither password protected nor encrypted. Nursing home residents and family members totaling 412 people were affected by the data breach, and the facility was fined $650,000.

5. Lack of Employee Training

Employee HIPAA training is more than a recommendation—it is a requirement of the HIPAA law. All staff members must be well trained on the law as well as on the policies and procedures set forth by an individual practice. HIPAA violations often come about because of misunderstandings about HIPAA requirements. Referencing HIPAA when it doesn't apply is also a sign of poor understanding of the facts.

6. Gossiping/Sharing PHI

Medical practice employees with access to patient PHI need to be careful about the information they share with others. When discussing PHI, you should always be aware of who may be listening. Keep conversations about PHI behind closed doors and only with appropriate office personnel.

7. Employee Dishonesty

Although not always done with a malicious purpose, employees who try to access PHI that they are not authorized to view are violating HIPAA, and the punishment is the same regardless of the intent. Recent False Claims Act cases further highlight the nexus between the Anti-Kickback Statute (AKS) and HIPAA. The AKS makes it unlawful for a person to knowingly and willfully; offer, pay, solicit, or receive any remuneration (directly or indirectly); to induce or in return for a referral or for recommending a referral, or purchase or recommending or arranging for the purchase; of covered items or services; paid for by any federal health care program. 42 U.S.C. § 1320a-7b(b); Social Security Act § 1128B(b). Analogous to the AKS, it is prohibitive to receive directly or indirectly "remuneration from or on behalf of the recipient of the protected health information in exchange for the protected health information." 42 U.S.C. 164.502(a)(5)(ii). Both statutes provide for both civil and criminal penalties.

Case managers should be aware that pharmaceutical and medical device companies have resorted to wantonly disregard patient privacy protections and paying (directly or indirectly) to gain access to medical records to increase sales, a clear violation of both HIPAA and the AKS. If they fail to disclose everything to the patient and gain their consent, that could form the basis of a false claim, particularly when making referrals to facilities or durable medical equipment that is paid for by a government payer. In sum, case managers should assess both their HIPAA and AKS compliance simultaneously to reduce the risk of a HIPAA or AKS violation and make certain there is no potential for a False Claims Act case.

8. Improper Disposal of Records

Staff members should understand that all information that contains PHI (eg, social security numbers, medical procedures, and diagnoses) should be shredded, destroyed, and wiped from the hard drive. You can prevent improper disposal of records with proper employee training and enforcement by a compliance officer or other staff.

9. Unauthorized Release of Information

This violation most often occurs when members of the media release PHI regarding public figures and celebrities. It can also happen when medical personnel release PHI to family members who are unauthorized, as only dependents and those with a Power of Attorney are allowed access to a family member's PHI.

10. Third Party Disclosure of PHI

When it comes to discussing PHI, it should only be discussed with the people who need to know, such as the patient, the doctor(s), and/or the person(s) billing for the procedure, medication, or other related service. Another example of third-party disclosure would be if a staff member were to release the wrong patient's information due to human error. In this case, the act may be an accident, but the consequences would be like those for a purposeful violation. When most people think of HIPAA, they think of the privacy and security of PHI, establishing the requirement for a National Provider Identifier, and the portability of health insurance.

Kathleen Fraser, RN-BC, MSN, MHA, CCM, CRRN, FAAN, *is the Owner/CEO/President of Fraser Imagineers and a former Executive Director of CMSA. When the pandemic struck, Kathleen enrolled in law school and developed a passion for HIPAA. Although she knew that providers fear and resent the regulations and realized that the interplay of HIPAA with COVID-19 would make it worse, she wanted to demonstrate the true beauty of the laws for the patients and staff of the nation's health care organizations. Kathleen has a jurisprudence degree in Health Care Law, Policy, and Management.*

As part of your employee training, all staff members should be required to always keep documents with PHI in a secure location. Physical files containing PHI should be locked in a desk, filing cabinet, or office. Digital files should require secure passwords to access them and should be encrypted whenever possible.

Breaches, violations, and/or disclosures can be purposeful or accidental, and any of these can also be one or more of the above-listed incidents. However, there is one example that hits on all of the top 10 violations in some way, shape, or form. It is Walgreen Co. v. Abigail E. Hinchy, a case against a Walgreens pharmacist that lead to a $1.44 million HIPAA award. A HIPAA Privacy Rule breach resulted in confidential patient PHI being shared with unauthorized individuals. In July 2013, a Marion Superior Court jury awarded $1.44M in damages to Abigail Hinchy after a Walgreens pharmacist in Indianapolis improperly accessed her prescription history and shared the PHI with a third party.

Hinchy had once dated the pharmacist's husband and had his child, and the pharmacist knowingly accessed her prescription history and PHI and divulged that information to her husband. After receiving her PHI, he threatened to use that information in a paternity case. He also subsequently shared the information he had gained with at least three other people. Hinchy learned of what had happened and complained to Walgreens, who spoke to the pharmacist. She admitted accessing the files for personal reasons, and she received a written warning for unethical actions and was made to retake a training program on HIPAA rules and regulations. The court unanimously ruled that the pharmacist had violated "one of her most sacred duties by viewing the prescription records of a customer and divulging the information she learned from those records to the client's ex-boyfriend." The jury held Walgreen Co. liable.

Although appellate judges heard the appeal in which Walgreens believed the court should have released it from liability, the previous court ruling was upheld and it was unanimously agreed that "the trial court properly permitted the jury to consider Walgreen's liability." The ruling could set a legal precedent in future lawsuits where employees have violated HIPAA regulations; even if the employer has not violated HIPAA, there is vicarious liability on the part of the employer. Snooping on health care records is an obvious HIPAA violation and one that all health care employees who have received HIPAA training should know is a violation of their employer's policies and HIPAA rules. Walgreens only disciplinary action against the employee was "a write up" instead of termination, which HIPAA regulations suggest.

For our purpose, a breach in HIPAA is the acquisition, access, use, or disclosure of PHI in a manner not permitted that compromises the security or privacy of the PHI, 45 CFR 164.402. The actual Breach Notification Rule specifies that both the U.S. Department of Health and Human Services (HHS) and the affected patients must be notified when there is a protected health data breach. In addition, if the breach affected more than 500 people, the event must be published in the media. However, if less than 500 people were affected, only a "small-scale hack form" must be completed through the OCR website (official form no.: 960. Authorization for release of health information). And never forget to check your state laws as well as federal HIPAA laws; the most stringent law is the HIPAA law that must be followed. Also make sure there are methods in place to inform you of a breach (eg, hotline, special e-mail, or drop box).

The Enforcement Rule contains regulations that establish how HHS regulators determine liability and calculate fines for health care providers who have violated any of the HIPAA rules, which was determined following an investigation and administrative hearing. This rule introduced the ability for the HHS to fine organizations for avoidable ePHI breaches. HHS's OCR is responsible for this enforcement, which it achieves through compliance reviews, outreach to encourage compliance, and investigating complaints. Financial penalties act as a deterrent against HIPAA violations while ensuring that covered entities are held accountable for protecting patients' privacy and the confidentiality of health data and for providing patients with access to their health records on request. The penalty structure for HIPAA violations is tiered and based on the knowledge a covered entity had of the violation. The penalties for noncompliance are based on the level of negligence (reasonable cause or willful neglect) and can range from $100 per day to $50,000 per violation (or per record), with a maximum penalty of $1.5 million per year for violations of an identical provision. HIPAA violation levels are shown in Figure 2.

"Life is ten percent what happens to you and ninety percent how you respond to it."
—Lou Holtz

Reasonable Clause is an act or omission in which a covered entity or business associate knew, or by exercising reasonable

FIGURE 2 HIPAA VIOLATION LEVELS

The entity was unaware and would have remained unaware based on reasonable measures	$100 to $50,000
"Reasonable cause"– in which the violation was caused by an element that would prompt action in an ordinary person	$1,000 to $50,000
"Willful neglect" – in which the violation was caused by intentional avoidance but rectified within 30 days	$10,000 to $50,000
Willful neglect but not mitigated within 30 days	$50,000

diligence, would have known that the act or omission violated an administrative simplification provision but in which the covered entity or business associate was unaware. Willful Neglect is a conscious intentional failure or reckless indifference to the obligation to comply with the administrative simplification provision violated.

Risk management security measures that reduce risks and vulnerabilities to a sensible and suitable level must be implemented to ensure the confidentiality, integrity, and availability of all ePHI, to protect against reasonably anticipated threats to the integrity of ePHI, to protect against unpermitted unethical uses or disclosures of ePHI, to protect against uses or disclosures that are not required, and to ensure that the workforce complies with this subpart. Ongoing risk analysis of potential risks and vulnerability to the confidentiality, integrity, and availability of ePHI should be conducted. Other safeguards are to include workforce security, information access management, security awareness training, security incident procedures, contingency plans, evaluations, and assigned security responsibility. 45 CFR 164.308 (a)(1)(ii)(A) & (B). A Sanction Policy must also be put in place because the compliance program should have teeth! Appropriate disciplinary sanctions against workforce members who violate security rule policies and procedures must be applied. 45 CFR 164.308 (a)(1)(ii)(C). The most common HIPAA violations that have resulted in financial penalties are the failure to perform an organization-wide risk analysis to identify risks to the confidentiality, integrity, and availability of PHI; the failure to enter into a HIPAA-compliant business associate agreement; impermissible disclosures of PHI; delayed breach notifications; and the failure to safeguard PHI.

How are HIPAA violations discovered? There are three main ways: investigations into a data breach by OCR (or state attorneys general), investigations into complaints about covered entities and business associates, and HIPAA compliance audits. Even when a data breach does not involve a HIPAA violation or a complaint proves to be unfounded, OCR may uncover unrelated HIPAA violations that could warrant a financial penalty. Data breaches are now a fact of life. Even with multilayered cybersecurity defenses, data breaches are still likely to occur from time to time. OCR understands that health care organizations are being targeted by cybercriminals and that it is not possible to implement impregnable security defenses. Being HIPAA compliant is not about making sure that data breaches never happen. HIPAA compliance is about reducing risk to an appropriate and acceptable level. Just because an organization experiences a data breach, it does not mean the breach was the result of a HIPAA violation. HIPAA violations can continue for many months, or even years, before they are discovered. The longer they are allowed to persist, the greater the penalty will be when they are eventually discovered. It is critical (and required by the HIPAA law) for HIPAA-covered entities to conduct regular HIPAA compliance reviews to make sure HIPAA violations are discovered and corrected before they are identified by regulators.

HHS (affecting HIPAA) has proposed changes to support the ability to disclose PHI for case management, including addressing recent issues regarding disclosure of PHI to support social services.

- HHS proposes to amend the definition of health care operations to clarify that it includes all care coordination and case management by health plans, whether individual-level or population-based.
- HHS proposes to add an exception to the minimum necessary standard for disclosures to or requests by a health plan or covered health care provider for care coordination and case management so that the covered entity or business associate need not consider minimum necessary requirements in making such disclosures. This exception would only apply to individual-level care coordination and case management activities.
- HHS proposes to expressly permit covered entities to disclose PHI to social services agencies, community-based organizations, home- and community-based services providers, and other similar third parties that provide health or human services to specific individuals for individual-level care coordination and case management. Such disclosures would be permissible as a treatment activity of a covered health care provider or as a health care operations activity of a covered health care provider or health plan. Furthermore, under the Proposed Rule, a covered health care provider or health plan may disclose PHI to one of these third parties for the care coordination

Financial penalties act as a deterrent against HIPAA violations while ensuring that covered entities are held accountable for protecting patients' privacy and the confidentiality of health data and for providing patients with access to their health records on request. The penalty structure for HIPAA violations is tiered and based on the knowledge a covered entity had of the violation.

FIGURE 3 TOOLS TO HELP YOU UNDERSTAND HIPAA

and case management activities of another health care provider or health plan.

- Lastly, HHS/HIPAA currently permits a covered entity to use or disclose PHI of Armed Forces personnel for certain activities deemed necessary by appropriate military command authorities to assure the proper execution of a military mission. To facilitate care coordination and case management for all individuals serving in the Uniformed Services, HHS proposes to expand the provision to cover all uniformed services personnel, not just Armed Forces.

If you are feeling off balance and unsure of your level of comprehension of HIPAA, be honest. Know what you know and what you don't. Get help when you need it! Don't be afraid to cry uncle and seek help if you feel overwhelmed or confused with HIPAA regulations. Oftentimes the law is opaque. You can get help by asking for the assistance you need. Tools to help you understand HIPAA are shown in Figure 3.

When you need to ask for help:

- You do not have a lot of time on your hands
- You are not sure how to accomplish the task or the task is more complicated than anticipated and you do not have the time to learn what it is you need to learn to meet your HIPAA deliverable (eg, creating and conducting a risk assessment on your own).
- You are unsure of deadlines, you have more deliverables to address than time on your hands, and you don't know the deadline or are unsure what deadline you must adhere (eg, a medical records request).
- Go to those who know the subject matter
- Use available resources and tools
- Do what works for you!

Toolkit Resources

- Centers for Medicare & Medicaid Services is a resource
- HHR is a resource
- OCR is a resource

HIPAA is meant to protect your privacy, but misunderstandings about the law can cause unintended snags for you, your advocate, and your health care team. HIPAA stands for "Health Insurance Portability and Accountability Act" of 1996, which includes the HIPAA Privacy Rule. The Rule was not designed to get in your way, but well-meaning staff in medical settings can sometimes keep medical information from your loved ones and professional advocates in a misguided attempt to protect your privacy. As I stated in HIPAA part 1, think of HIPAA not as a burden but an extension of what we do to protect our patients. CE II

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The Importance of Oral Health: Increasing Awareness Among Case Managers

Jose Alejandro, PhD, RN, NEA-BC, CNE, CCM, FACHE, FAAN

I was abruptly woken with searing and throbbing tooth pain. It was some of the worse pain that I have ever experienced. And, of course, it was 3:12 a.m. on a Saturday morning. I have what I think is excellent dental insurance. Unfortunately, having dental coverage does not mean that you have actual access to an on-call dentist on a weekend morning. So I searched the internet and tried many dentists advertising "emergency care," but I guess that only applied to weekdays.

I called the customer service number on my insurance card. I was on hold for what seemed like hours and eventually received a voice recording to call back during regular business hours and to "seek help at the local emergency department." My years of case management experience told me that seeking care in the emergency department was not my best option. However, my experience clearly reminded me of the importance of whole-person care and the need to resolve my dental emergency.

Historical Perspective

Tooth decay is a national crisis and one of the most chronic diseases in the United States that affects all ages (Hannan, Ricks, Espinoza, & Weintraub, 2021). Healthy People 2030 objective OH-08: Increase Use of the Oral Health Care System has a baseline outcome measure of only 43% (Healthy People 2030, 2022). This low benchmark is an indicator of the grim expectations of improving this essential whole-person health indicator. The National Center for Health Statistics (2022) estimates that approximately 13% of children and 26% of adults in the United States have untreated dental caries.

Many advocacy groups were hopeful that with the implementation of the Affordable Care Act and the expansion of Medicaid, there would be an improvement in access to dental health services. Research by Elani, Sommers, & Kawachi (2020) found a slight improvement in access for White adults but no significant increase in access for other ethnicities. Their research provided further evidence that significant disparities remain and that we need to continue our work of reducing systemic structural bias and geographic variation within our healthcare delivery system.

Inequities Remain

The lack of dental care access in the United States is a clear example of the continuing inequity of our healthcare system (Vujicic & Fosse, 2022). In most cases, access to dental care services is determined by socioeconomic factors, where you live, and the ability to pay. Research consistently demonstrates that our most vulnerable populations frequently experience significant financial and structural barriers to preventative and acute dental care (D'Addazio et al., 2021).

Some of the structural barriers include living in rural and geographically isolated areas, living within a food desert, and limited access to dentists who speak the preferred language of the individual and family. COVID-19 further fueled disparities in access to dental care delivery. Upon recommendation of public health officials and professional associations, many dental practices closed for routine preventative dental care (Elster & Parsi, 2021).

There continue to be workforce issues that limit the availability of dentists who specialize in pediatric dentistry or who are bilingual (Floríndez et al., 2021). The U.S. Bureau of Labor Statistics (2022) estimates that there are about 5,000 openings for dentists each year moving forward. According to the ADA (2022), the dentist workforce continues to be predominantly White (70%), followed by Asian (18%), Hispanic (6%), and Black (4%).

There is clear evidence that social determinants significantly impact the prevalence of dental caries, gum disease, and oral cancer (Simmons et al., 2021). Where you live determines your ability to have timely access to dental health care services (Northridge, Kumar, & Kaur, 2020).

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Tooth decay is a national crisis and one of the most chronic diseases in the United States that affects all ages. The National Center for Health Statistics estimates that approximately 13% of children and 26% of adults in the United States have untreated dental caries.

However, there continue to be significant financial and structural barriers that further complicate the delivery of dental care services in the United States. Low-income individuals simply cannot afford dental care. For example, people of color have twice as many untreated cavities as non-Hispanic White adults (CDC, 2021).

Our market-driven healthcare system drives geographic variation in the delivery of essential dental healthcare services. Significant dental care variation is based on your geographic location and population density (urban vs. rural). Many dentists choose to work in more urban and affluent areas in order to have a higher practice profit margin—only about 11% of practicing dentists serve rural communities (Luo et al., 2021).

The National Academy for State Health Policy (2022) notes that currently three states do not offer dental care services under Medicaid, nine states provide limited emergency dental services, and fifteen states provide limited dental services to Medicaid enrollees. In addition, many dentists do not participate in Medicaid or accept new Medicaid patients in their practice due to low payment rates (Vujicic, Nasseh, & Fosse, 2021).

Elderly and disabled individuals also have profound dental access issues because traditional Medicare coverage does not cover dental services. Moreover, these insurance coverage gaps reduce our ability to provide safety-net services to the most fragile individuals. To compound access issues, many dental practices do not have experience treating individuals with special needs (Lim et al., 2022).

Impact of Poor Oral Health on Delivery of Whole-Person Care

Oral hygiene is essential at all stages of life. Unfortunately, it is an area that receives limited attention within the nursing and professional practice education curriculums. "Wholeness includes all our wounds. It includes all of our vulnerabilities" (Remen, 2020). Research and health outcome data continue to demonstrate that more attention must be given to bridging this knowledge deficit and void in clinical practice (Higgins, Hawkins, & Horvath, 2020). Our inability to recognize the impact of appropriate oral health has a detrimental effect on providing whole-person care.

For example, pregnant women have a higher risk of oral diseases related to fluctuations in hormonal levels, eating patterns, and psychological changes (Naavaal & Claibrone, 2021). Oral health disparities based on racial/ethnic minorities, level of education, and family income are profound for this vulnerable population (Lee et al., 2021). Periodontal disease is one of the most common comorbidities during pregnancy (Fakheran et al., 2020). Furthermore, parental oral health strongly predicts a child's oral health (Haber et al., 2022).

Individuals who are admitted for acute care hospitalization and long-term care typically have poorer oral health than individuals living in the community (Simon et al., 2021). From my clinical experience, patient assessment for dental hygiene and care is limited and is often not considered a priority. Many clinical staff have limited training and understanding of the connection between dental health and other comorbidities. This is despite clear evidence-based practice that daily oral hygiene can reduce hospital-acquired infections (Warren et al., 2019).

In many cases, heart valve replacement surgery and other types of organ replacement may be deferred until individuals receive appropriate dental care to reduce the risk of infective endocarditis (Carasso et al., 2019). Case management professionals may find it difficult to arrange dental treatment when an individual is admitted to an acute care hospital. On a number of occasions, this author has had to arrange outpatient dental care before elective cardiac surgery in an academic medical center environment.

Oral care is an essential component of end-of-life care. Dry mouth, thirst perception, and candidiasis are frequent conditions that individuals face during their last phase of life (Gustafsson, Skogsberg, & Rejno, 2021). Furthermore, terminal cancer patients typically need specialized dental evaluation and oral care to maintain and improve their quality of life (Furuya et al., 2022).

Whole-person case management requires us to consider all aspects of individual health, including dental health. Often forgotten, dental health is closely connected to many other chronic conditions like diabetes, obesity, and mental illness (Lau et al., 2021). In addition, the mouth is a key pathway for infectious and inflammatory diseases that needs to be considered in evidence-based practice (D'Souza, Collins, & Murthy, 2022). Poor oral health increases the risk of heart disease,

In most cases, access to dental care services is determined by socioeconomic factors, where you live, and the ability to pay. Research consistently demonstrates that our most vulnerable populations frequently experience significant financial and structural barriers to preventative and acute dental care.

stroke, and cerebral infections (Lee et al., 2021).

Oral health problems can severely impact an individual's quality of life. Poor dentition can reduce social interaction because of embarrassment and stigma. Dental issues can also lead to reduced nutrition intake (Janto et al., 2022). Therefore, we need to be mindful that many of our highest-risk patients lack the ability to communicate about their oral condition, which may lead to suffering and pain (Venkatasalu et al., 2020). In addition, research demonstrates a link between oral health, depression, and suicidal ideation (Chang et al., 2022; Aldosari et al., 2020).

Implications for Professional Case Management Practice

As professional case managers, we need to reduce our knowledge gaps about oral health and evaluate the dental health needs of the individual as we develop and advocate for effective care pathways and transitions of care. Nursing practice continues to struggle with recognizing, understanding, and promoting the importance of oral care. Whole-person care requires case management professionals to understand how developing effective early interventions and how consistent education can impact an individual's overall health (Azarshahri et al., 2022; Andersson, Wilde-Larsson, & Persenius, 2019). In addition, we all need to incorporate oral health assessment in our practice and advocate for our patients and clients as part of the transition of care plan.

As significant members and contributors within the interdisciplinary team, case management professionals need to consistently raise awareness about the importance of oral health within all practice settings. Incorporating systemic approaches that include oral assessment findings is key to raising awareness. In addition, considering oral health needs as part of a coordinated approach to transitions of care will support our goal of providing whole-person care.

Advocating for our most vulnerable individuals is one of the most essential duties in professional case management. Supporting consistent dental care at all phases of life improves physical and mental health and quality of life and promotes whole-person care across the continuum of care. Building generative knowledge about how we can incorporate evidence-based oral health practices demonstrates a commitment to improving whole-person care.

Recognizing that a market-based healthcare system promotes systemic and racial biases for vulnerable populations is a key foundation for advocacy. CE III

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Whole-person case management requires us to consider all aspects of individual health, including dental health. Often forgotten, dental health is closely connected to many other chronic conditions like diabetes, obesity, and mental illness. In addition, the mouth is a key pathway for infectious and inflammatory diseases that needs to be considered in evidence-based practice. Poor oral health increases the risk of heart disease, stroke, and cerebral infections.

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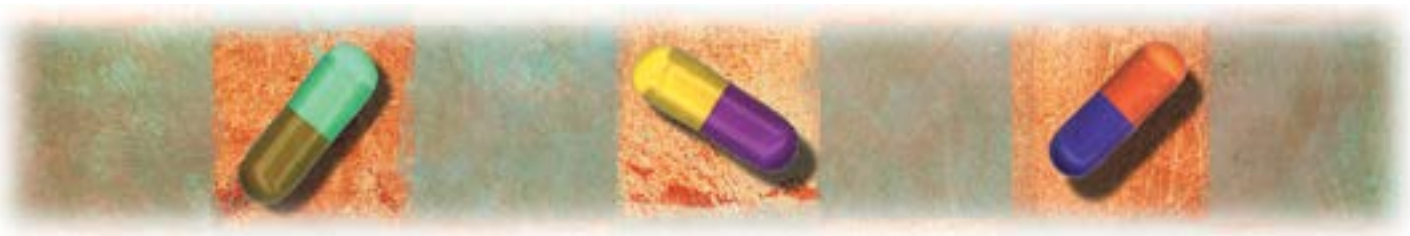
PharmaFacts for Case Managers



Mounjaro™-tirzepatide injection solution

INDICATIONS AND USAGE

Mounjaro™ is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

- Mounjaro has not been studied in patients with a history of pancreatitis.
- Mounjaro is not indicated for use in patients with type 1 diabetes mellitus.

WARNING: RISK OF THYROID C-CELL TUMORS

In both male and female rats, tirzepatide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Mounjaro causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined.

Mounjaro is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Mounjaro and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Mounjaro.

DOSAGE AND ADMINISTRATION

Dosage

- The recommended starting dosage of Mounjaro is 2.5 mg injected subcutaneously once weekly. The 2.5 mg dosage is for treatment initiation and is not intended for glycemic control.
- After 4 weeks, increase the dosage to 5 mg injected subcutaneously once weekly.
- If additional glycemic control is needed, increase the dosage in 2.5 mg increments after at least 4 weeks on the current dose.
- The maximum dosage of Mounjaro is 15 mg injected subcutaneously once weekly.
- If a dose is missed, instruct patients to administer Mounjaro as soon as possible within 4 days (96 hours) after the missed dose. If more than 4 days have passed, skip the missed dose and administer the next dose on the regularly scheduled day. In each case, patients can then resume their regular once weekly dosing schedule.
- The day of weekly administration can be changed, if necessary, as long as the time between the two doses is at least 3 days (72 hours).

Important Administration Instructions

- Administer Mounjaro once weekly, any time of day, with or without meals.
- Inject Mounjaro subcutaneously in the abdomen, thigh, or upper arm.
- Rotate injection sites with each dose.
- Inspect Mounjaro visually before use. It should appear clear and colorless to slightly yellow. Do not use Mounjaro if particulate matter or discoloration is seen.
- When using Mounjaro with insulin, administer as separate injections and never mix. It is acceptable to inject Mounjaro and insulin in the same body region, but the injections should not be adjacent to each other.

DOSAGE FORMS AND STRENGTHS

Injection: Clear, colorless to slightly yellow solution available in pre-filled single-dose pens of the following strengths:

- 2.5 mg/0.5 mL
- 5 mg/0.5 mL
- 7.5 mg/0.5 mL
- 10 mg/0.5 mL
- 12.5 mg/0.5 mL
- 15 mg/0.5 mL

CONTRAINDICATIONS

Mounjaro is contraindicated in patients with:

A personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)

Known serious hypersensitivity to tirzepatide or any of the excipients in Mounjaro

WARNINGS AND PRECAUTIONS

Risk of Thyroid C-Cell Tumors

- In both sexes of rats, tirzepatide caused a dose-dependent and treatment-duration-dependent increase in the incidence of thyroid C-cell tumors (adenomas and carcinomas) in a 2-year study at clinically relevant plasma exposures. It is unknown whether Mounjaro causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined.
- Mounjaro is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2. Counsel patients regarding the potential risk for MTC with the use of Mounjaro and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness).
- Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Mounjaro. Such monitoring may increase the risk of unnecessary procedures, due to the low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin values may indicate MTC and patients with MTC usually have calcitonin values >50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated.

Pancreatitis

- Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists.
- In clinical studies, 14 events of acute pancreatitis were confirmed by adjudication in 13 Mounjaro-treated patients (0.23 patients per 100 years of exposure) versus 3 events in 3 comparator-treated patients (0.11 patients per 100 years of exposure). Mounjaro has not been studied in patients with a prior history of pancreatitis. It is unknown if patients with a history of pancreatitis are at higher risk for development of pancreatitis on Mounjaro.
- After initiation of Mounjaro, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, discontinue Mounjaro and initiate appropriate management.

Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin

- Patients receiving Mounjaro in combination with an insulin secretagogue (e.g., sulfonylurea) or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia.
- The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogue) or insulin. Inform patients using these concomitant medications of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia.

Hypersensitivity Reactions

- Hypersensitivity reactions have been reported with Mounjaro in clinical trials (e.g., urticaria and eczema) and were sometimes severe. If hypersensitivity reactions occur, discontinue use of Mounjaro; treat promptly per standard of care, and monitor until signs and symptoms resolve. Do not use in patients with a previous serious hypersensitivity reaction to tirzepatide or any of the excipients in Mounjaro.
- Anaphylaxis and angioedema have been reported with GLP-1 receptor agonists. Use caution in patients with a history of angioedema or anaphylaxis with a GLP-1 receptor agonist because it is unknown whether such patients will be predisposed to these reactions with Mounjaro.

Acute Kidney Injury

- Mounjaro has been associated with gastrointestinal adverse reactions, which include nausea, vomiting, and diarrhea. These events may lead to dehydration, which if severe could cause acute kidney injury.
- In patients treated with GLP-1 receptor agonists, there have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of Mounjaro in patients with renal impairment reporting severe gastrointestinal adverse reactions.

Severe Gastrointestinal Disease

- Use of Mounjaro has been associated with gastrointestinal adverse reactions, sometimes severe. Mounjaro has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients.

Diabetic Retinopathy Complications in Patients with a History of Diabetic Retinopathy

- Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. Mounjaro has not been studied in patients with non-proliferative diabetic retinopathy requiring acute therapy,

proliferative diabetic retinopathy, or diabetic macular edema. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.

Acute Gallbladder Disease

- Acute events of gallbladder disease such as cholelithiasis or cholecystitis have been reported in GLP-1 receptor agonist trials and postmarketing.
- In Mounjaro placebo-controlled clinical trials, acute gallbladder disease (cholelithiasis, biliary colic, and cholecystectomy) was reported by 0.6% of Mounjaro-treated patients and 0% of placebo-treated patients. If cholelithiasis is suspected, gallbladder diagnostic studies and appropriate clinical follow-up are indicated.

Adverse Reactions

The following adverse reactions occurred in >5% of patients in clinical trials: nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia and abdominal pain.

DRUG INTERACTIONS

Concomitant Use with an Insulin Secretagogue (e.g., Sulfonylurea) or with Insulin

When initiating Mounjaro, consider reducing the dose of concomitantly administered insulin secretagogues (e.g., sulfonylureas) or insulin to reduce the risk of hypoglycemia.

Oral Medications

Mounjaro delays gastric emptying, and thereby has the potential to impact the absorption of concomitantly administered oral medications. Caution should be exercised when oral medications are concomitantly administered with Mounjaro.

Monitor patients on oral medications dependent on threshold concentrations for efficacy and those with a narrow therapeutic index (e.g., warfarin) when concomitantly administered with Mounjaro.

Advise patients using oral hormonal contraceptives to switch to a non-oral contraceptive method, or add a barrier method of contraception for 4 weeks after initiation and for 4 weeks after each dose escalation with Mounjaro. Hormonal contraceptives that are not administered orally should not be affected.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Available data with Mounjaro use in pregnant women are insufficient to evaluate for a drug-related risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There are risks to the mother and fetus associated with poorly controlled diabetes in pregnancy. Based on animal reproduction studies, there may be risks to the fetus from exposure to tirzepatide during pregnancy. Mounjaro should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

In pregnant rats administered tirzepatide during organogenesis, fetal growth reductions and fetal abnormalities occurred at clinical exposure in maternal rats based on AUC. In rabbits administered tirzepatide during organogenesis, fetal growth reductions were observed at clinically relevant exposures based on AUC. These adverse embryo/fetal effects in animals coincided with pharmacological effects on maternal weight and food consumption.

The estimated background risk of major birth defects is 6–10% in women with pre-gestational diabetes with an HbA1c >7% and has been reported to be as high as 20–25% in women with an HbA1c >10%. The estimated background risk of miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2–4% and 15–20%, respectively.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

Poorly controlled diabetes in pregnancy increases the maternal risk for diabetic ketoacidosis, pre-eclampsia, spontaneous abortions, preterm delivery and delivery complications. Poorly controlled diabetes increases the fetal risk for major birth defects, stillbirth, and macrosomia-related morbidity.

Data

Animal Data

In pregnant rats given twice weekly subcutaneous doses of 0.02, 0.1, and 0.5 mg/kg tirzepatide (0.03-, 0.07-, and 0.5-fold the MRHD of 15 mg once weekly based on AUC) during organogenesis, increased incidences of external, visceral, and skeletal malformations, increased incidences of visceral and skeletal developmental variations, and decreased fetal weights coincided with pharmacologically-mediated reductions in maternal body weights and food consumption at 0.5 mg/kg. In pregnant rabbits given once weekly subcutaneous doses of 0.01, 0.03, or 0.1 mg/kg tirzepatide (0.01-, 0.06-, and 0.2-fold the MRHD) during organogenesis, pharmacologically-mediated effects on the gastrointestinal system resulting in maternal mortality or abortion in a few rabbits occurred at all dose levels. Reduced fetal weights associated with decreased maternal food consumption and body weights were observed at 0.1 mg/kg. In a pre- and post-natal study in rats administered subcutaneous doses of 0.02, 0.10, or 0.25 mg/kg tirzepatide twice weekly from implantation through lactation, F1 pups from F0 maternal rats given 0.25 mg/kg tirzepatide had statistically significant lower mean body weight when compared to controls from post-natal day 7 through post-natal day 126 for males and post-natal day 56 for females.

Lactation

Risk Summary

There are no data on the presence of tirzepatide in animal or human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Mounjaro and any potential adverse effects on the breastfed infant from Mounjaro or from the underlying maternal condition.

Females and Males of Reproductive Potential

Contraception

Use of Mounjaro may reduce the efficacy of oral hormonal contraceptives due to delayed gastric emptying. This delay is largest after the first dose and diminishes over time. Advise patients using oral hormonal contraceptives to switch to a non-oral contraceptive method, or add a barrier method of contraception for 4 weeks after initiation and for 4 weeks after each dose escalation with Mounjaro.

Pediatric Use

Safety and effectiveness of Mounjaro have not been established in pediatric patients (younger than 18 years of age).

Geriatric Use

In the pool of seven clinical trials, 1539 (30.1%) Mounjaro-treated patients were 65 years of age or older, and 212 (4.1%) Mounjaro-treated patients were 75 years of age or older at baseline.

No overall differences in safety or efficacy were detected between these patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Renal Impairment

No dosage adjustment of Mounjaro is recommended for patients with renal impairment. In subjects with renal impairment including end-stage renal disease (ESRD), no change in tirzepatide pharmacokinetics (PK) was observed. Monitor renal function when initiating or escalating doses of Mounjaro in patients with renal impairment reporting severe adverse gastrointestinal reactions.

Hepatic Impairment

No dosage adjustment of Mounjaro is recommended for patients with hepatic impairment. In a clinical pharmacology study in subjects with varying degrees of hepatic impairment, no change in tirzepatide PK was observed

CLINICAL STUDIES

Overview of Clinical Studies

The effectiveness of Mounjaro as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus was established in five trials. In these trials, Mounjaro was studied as monotherapy (SURPASS-1); as an add-on to metformin, sulfonylureas, and/or sodium-glucose co-transporter 2 inhibitors (SGLT2 inhibitors) (SURPASS-2, -3, and -4); and in combination with basal insulin with or without metformin (SURPASS-5). In these trials, Mounjaro (5 mg, 10 mg, and 15 mg given subcutaneously once weekly) was compared with placebo, semaglutide 1 mg, insulin degludec, and/or insulin glargine.

In adult patients with type 2 diabetes mellitus, treatment with Mounjaro produced a statistically significant reduction from baseline in HbA1c compared to placebo. The effectiveness of Mounjaro was not impacted by age, gender, race, ethnicity, region, or by baseline BMI, HbA1c, diabetes duration, or renal function.

Monotherapy Use of Mounjaro in Adult Patients with Type 2 Diabetes Mellitus

SURPASS-1 (NCT03954834) was a 40-week double-blind trial that randomized 478 adult patients with type 2 diabetes mellitus with inadequate glycemic control with diet and exercise to Mounjaro 5 mg, Mounjaro 10 mg, Mounjaro 15 mg, or placebo once weekly.

Patients had a mean age of 54 years, and 52% were men. The mean duration of type 2 diabetes mellitus was 4.7 years, and the mean BMI was 32 kg/m^2. Overall, 36% were White, 35% were Asian, 25% were American Indians/Alaska Natives, and 5% were Black or African American; 43% identified as Hispanic or Latino ethnicity.

Monotherapy with Mounjaro 5 mg, 10 mg, and 15 mg once weekly for 40 weeks resulted in a statistically significant reduction in HbA1c compared with placebo.

Mounjaro Use in Combination with Metformin, Sulfonylureas, and/or SGLT2 Inhibitors in Adult Patients with Type 2 Diabetes Mellitus

Add-on to metformin

SURPASS-2 (NCT03987919) was a 40-week open-label trial (double-blind with respect to Mounjaro dose assignment) that randomized 1879 adult patients with type 2 diabetes mellitus with inadequate glycemic control on stable doses of metformin alone to the addition of Mounjaro 5 mg, Mounjaro 10 mg, or Mounjaro 15 mg once weekly or subcutaneous semaglutide 1 mg once weekly.

Patients had a mean age of 57 years and 47% were men. The mean duration of type 2 diabetes mellitus was 8.6 years, and the mean BMI was 34 kg/m^2. Overall, 83% were White, 4% were Black or African American, and 1% were Asian; 70% identified as Hispanic or Latino ethnicity.

Treatment with Mounjaro 10 mg and 15 mg once weekly for 40 weeks resulted in a statistically significant reduction in HbA1c compared with semaglutide 1 mg once weekly.

Add-on to metformin with or without SGLT2 inhibitor

SURPASS-3 (NCT03882970) was a 52-week open-label trial that randomized 1444 adult patients with type 2 diabetes mellitus

with inadequate glycemic control on stable doses of metformin with or without SGLT2 inhibitor to the addition of Mounjaro 5 mg, Mounjaro 10 mg, Mounjaro 15 mg once weekly, or insulin degludec 100 units/mL once daily. In this trial, 32% of patients were on SGLT2 inhibitor. Insulin degludec was initiated at 10 units once daily and adjusted weekly throughout the trial using a treat-to-target algorithm based on self-measured fasting blood glucose values. At Week 52, 26% of patients randomized to insulin degludec achieved the fasting serum glucose target of <90 mg/dL, and the mean daily insulin degludec dose was 49 U (0.5 U per kilogram).

Patients had a mean age of 57 years, and 56% were men. The mean duration of type 2 diabetes mellitus was 8.4 years, and the mean baseline BMI was 34 kg/m^2. Overall, 91% were White, 3% were Black or African American, and 5% were Asian; 29% identified as Hispanic or Latino ethnicity.

Treatment with Mounjaro 10 mg and 15 mg once weekly for 52 weeks resulted in a statistically significant reduction in HbA1c compared with daily insulin degludec.

Add-on to 1-3 oral anti-hyperglycemic agents (metformin, sulfonylurea or SGLT-2 inhibitor)

SURPASS-4 (NCT03730662) was a 104-week open-label trial (52-week primary endpoint) that randomized 2002 adult patients with type 2 diabetes mellitus with increased cardiovascular risk to Mounjaro 5 mg, Mounjaro 10 mg, Mounjaro 15 mg once weekly, or insulin glargine 100 units/mL once daily (1:1:1:3 ratio) on a background of metformin (95%) and/or sulfonylureas (54%) and/or SGLT2 inhibitors (25%).

Patients had a mean age of 64 years, and 63% were men. The mean duration of type 2 diabetes mellitus was 11.8 years, and the mean baseline BMI was 33 kg/m^2. Overall, 82% were White, 4% were Black or African American, and 4% were Asian; 48% identified as Hispanic or Latino ethnicity. Across all treatment groups, 87% had a history of cardiovascular disease. At baseline, eGFR was ≥90 mL/min/1.73 m^2 in 43%, 60 to 90 mL/min/1.73 m^2 in 40%, 45 to 60 mL/min/1.73 m^2 in 10%, and 30 to 45 mL/min/1.73 m^2 in 6% of patients.

Insulin glargine was initiated at 10 U once daily and adjusted weekly throughout the trial using a treat-to-target algorithm based on self-measured fasting blood glucose values. At Week 52, 30% of patients randomized to insulin glargine achieved the fasting serum glucose target of <100 mg/dL, and the mean daily insulin glargine dose was 44 U (0.5 U per kilogram).

Treatment with Mounjaro 10 mg and 15 mg once weekly for 52 weeks resulted in a statistically significant reduction in HbA1c compared with insulin glargine once daily.

Mounjaro Use in Combination with Basal Insulin with or without Metformin in Adult Patients with Type 2 Diabetes Mellitus

SURPASS-5 (NCT04039503) was a 40-week double-blind trial that randomized 475 patients with type 2 diabetes mellitus with inadequate glycemic control on insulin glargine 100 units/mL, with or without metformin, to Mounjaro 5 mg, Mounjaro 10 mg, Mounjaro 15 mg once weekly, or placebo. The dose of background insulin glargine was adjusted using a treat-to-target algorithm based on self-measured fasting blood glucose values, targeting <100 mg/dL.

Patients had a mean age of 61 years, and 56% were men. The mean duration of type 2 diabetes mellitus was 13.3 years, and the mean baseline BMI was 33 kg/m^2. Overall, 80% were White, 1% were Black or African American, and 18% were Asian; 5% identified as Hispanic or Latino ethnicity.

The mean dose of insulin glargine at baseline was 34, 32, 35, and 33 units/day for patients receiving Mounjaro 5 mg, 10 mg, 15 mg, and placebo, respectively. At randomization, the initial insulin glargine dose in patients with HbA1c ≤8.0% was reduced by 20%. At week 40, mean dose of insulin glargine was 38, 36, 29, and 59 units/day for patients receiving Mounjaro 5 mg, 10 mg, 15 mg, and placebo, respectively.

Treatment with Mounjaro 5 mg once weekly, 10 mg once weekly and 15 mg once weekly for 40 weeks resulted in a statistically significant reduction in HbA1c compared with placebo.

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

Mounjaro is a clear, colorless to slightly yellow solution available in pre-filled single-dose pens as follows (Table 1):

TABLE 1 TOTAL STRENGTH PER TOTAL VOLUME, CARTON CONTENTS, AND NDC FOR MOUNJARO.

Total Strength per Total Volume	Carton Contents	NDC
2.5 mg/0.5 mL	4 single-dose pens	0002-1506-80
5 mg/0.5 mL	4 single-dose pens	0002-1495-80
7.5 mg/0.5 mL	4 single-dose pens	0002-1484-80
10 mg/0.5 mL	4 single-dose pens	0002-1471-80
12.5 mg/0.5 mL	4 single-dose pens	0002-1460-80
15 mg/0.5 mL	4 single-dose pens	0002-1457-80

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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.

Clin Infect Dis. 2022 Jun 10;ciac466. doi: 10.1093/cid/ciac466. Online ahead of print.

Immunological, cognitive and psychiatric outcomes after initiating EFV- and DTG-based antiretroviral therapy during acute HIV infection

Chan P, Yoon B, Colby D, et al.

BACKGROUND: Efavirenz (EFV)- and Dolutegravir (DTG)-based antiretroviral therapy (ART) are the formerly and currently recommended regimen for treatment-naïve individuals with HIV-1. Whether they impact the immunological and neuropsychiatric profile differentially remains unclear.

METHODS: This retrospective analysis included 258 participants in the RV254 acute HIV-1 infection (AHI) cohort. Participants initiated one of three ART regimens during AHI: EFV-based (n = 131), DTG-based (n = 92), or DTG intensified with maraviroc (DTG/MVC, n = 35). All regimens included two nucleoside reverse transcriptase inhibitors and were maintained for 96 weeks. CD4 + and CD8+ T-cell counts, mood symptoms, and performance on a 4-test neuropsychological battery (NPZ-4) were compared.

RESULTS: At baseline, the median age was 26 years; 99% were male; 36% were enrolled during Fiebig stage I-II. Plasma viral suppression at weeks 24 and 96 was similar between the groups. Compared to the EFV group, the DTG group showed greater increments of CD4+ ($p < 0.001$) and CD8+ ($p = 0.015$) T-cell counts but similar increment in CD4/CD8 ratio at week 96. Improvement in NPZ-4 was similar between the two groups at week 24, but greater in the DTG group at week 96 ($p = 0.005$). Depressive mood and distress symptoms based on the Patient Health Questionnaire and distress thermometer were similar between the two groups at follow-up. Findings for the DTG/MVC group were comparable to those for the DTG group in comparison to the EFV group.

CONCLUSIONS: Among individuals with AHI, 96 weeks of DTG-based ART was associated with greater increments of CD4 + and CD8+ T-cell counts, and greater improvement in cognitive performance.

Clin Infect Dis. 2022 Jun 9;ciac427. doi: 10.1093/cid/ciac427. Online ahead of print.

Estimation of the lifetime quality-adjusted life years (QALYs) lost due to syphilis acquired in the United States in 2018

Lee K, You S, Li Y, et al.

BACKGROUND: The purpose of this study was to estimate the health impact of syphilis in the United States in terms of the number of quality-adjusted life years (QALYs) lost attributable to infections in 2018.

METHODS: We developed a Markov model which simulates the natural history and management of syphilis. The model was parameterized by sex and sexual orientation (women who have sex with men, men who have sex with women [MSW], and men who have sex with men [MSM]), and by age at primary infection. We developed a separate decision tree model to quantify health losses due to congenital syphilis. We estimated the average lifetime number of QALYs lost per infection, and the total expected lifetime number of QALYs lost due to syphilis acquired in 2018.

RESULTS: We estimated the average number of discounted lifetime QALYs lost per infection as 0.09 [0.03-0.19 95% uncertainty interval (UI)]. The total expected number of QALYs lost due to syphilis acquired in 2018 was 13,349[5,071-31,360]. While per-case loss was the lowest among MSM (0.06), MSM accounted for 47.7% of the overall burden. For each case of congenital syphilis, we estimated 1.79[1.43-2.16] and 0.06[0.01-0.14] QALYs lost in the child and the mother, respectively. We projected 2,332[1,871-2,825] and 79[17-177] QALYs lost for children and mothers, respectively, due to congenital syphilis in 2018.

CONCLUSIONS: Syphilis causes substantial health losses in adults and children. Quantifying these health losses in terms of QALYs can inform cost-effectiveness analyses and can facilitate comparisons of the burden of syphilis to that of other diseases.

Clin Infect Dis. 2022 Jun 2;ciac443. doi: 10.1093/cid/ciac443. Online ahead of print.

Effectiveness of paxlovid in reducing severe COVID-19 and mortality in high risk patients

Najjar-Debbiny R, Gronich N, Weber G, et al.

BACKGROUND: Paxlovid was granted emergency use authorization for the treatment of mild to moderate COVID-19, based on the interim analysis of EPIC-HR trial. Paxlovid effectiveness needs to be assessed in a noncontrolled setting. In this study we used population-based real world data to evaluate the effectiveness of Paxlovid.

METHODS: The database of the largest healthcare provider in Israel was used to identify all adults aged 18 years or older with first ever positive test for SARS-CoV-2 between January and February 2022, who were at high risk for severe COVID-19 and had no contraindications for Paxlovid use. Patients were included irrespective of their COVID-19 vaccination status. Cox hazard regression was used to estimate the 28 day HR for severe COVID-19 or mortality with Paxlovid examined as time-dependent variable.

RESULTS: Overall, 180,351 eligible were included, of them only 4,737 (2.6%) were treated with Paxlovid, and 135,482 (75.1%) had adequate COVID-19 vaccination status. Both Paxlovid and adequate COVID-19 vaccination status were associated with significant decrease in the rate of severe COVID-19 or mortality with adjusted HR 0.54 (95% CI, 0.39-0.75) and 0.20 (95% CI, 0.17-0.22), respectively. Paxlovid appears to be more effective in older patients, immunosuppressed patients, and patients with underlying neurological or cardiovascular disease (interaction p-value <0.05 for all). No significant interaction was detected between Paxlovid treatment and COVID-19 vaccination status.

CONCLUSIONS: This study suggests that in the era of omicron and in real life setting Paxlovid is highly effective in reducing the risk of severe COVID-19 or mortality.

Transplantation. 2022 May 27.doi: 10.1097/TP.0000000000004179. Online ahead of print.

Survival benefit in older patients transplanted with viremic hepatitis C positive kidneys when compared with high KDPI kidneys

Sibulesky L, Leca N, Limaye AP, et al.

BACKGROUND: Because of the continued demand in kidney transplantation, organs from donors with risk criteria for bloodborne viruses, high Kidney Donor Profile Index (KDPI) kidneys, and hepatitis C virus (HCV)-positive kidneys are being considered. There continues to be reluctance on the part of the providers and the candidates to accept HCV-positive kidneys.

METHODS: We conducted a retrospective analysis of the Organ Procurement and Transplantation Network database of all adult (≥18 y old) recipients undergoing kidney transplant from May 10, 2013, to June 30, 2021. We compared patient and graft survival in candidates who received HCV-positive kidneys versus non-hepatitis C (Hep C) high KDPI kidneys by estimated posttransplant survival (EPTS) groups.

RESULTS: HCV-viremic kidneys were transplanted in 5.6% of patients in the EPTS >61% group compared with 5.1% of patients in the 21%-60% EPTS group and 1.9% of 0%-20% EPTS group ($P < 0.001$). Of all transplants performed in the EPTS 61%-100% group, 11.9% were KDPI >85% compared with 5.2% in the EPTS 21%-60%, and 0.5% in the EPTS 0%-20%. Patient survival was significantly longer at 1, 3, and 5 y in the EPTS >61% group who received Hep C-viremic or -nonviremic allografts compared with non-Hep C kidneys with KDPI >85%. When it comes to listing, only 25% of candidates in the EPTS >61% group were listed for Hep C nucleic acid testing-positive kidneys in 2021.

CONCLUSIONS: Our findings could be used for counseling candidates on the types of kidneys they should consider for transplantation. Also, listing practices for viremic Hep C kidneys need continued re-evaluation.

Clin Exp Hypertens. 2022 Jun 14;1-12. doi: 10.1080/10641963.2022.2085737. Online ahead of print.

Red wine but not alcohol consumption improves cardiovascular function and oxidative stress of the hypertensive-SHR and diabetic-STZ rats

Souza Bomfim GH, Musial DC, Rocha K, et al.

AIMS: This raised the issue of whether in vivo long-term red wine treatment can act as a modulator of these targets.

MAIN METHODS: We monitored SBP, glucose tolerance, oxidative stress, and cardiovascular function. Aortic and atrial tissues from normotensive-WKY, hypertensive-SHR, and diabetic-STZ animals, chronically exposed to red wine (3.715 ml/kg/v.o/day) or alcohol (12%) for 21-days, were used to measure contractile/relaxation responses by force transducers.

KEY FINDINGS: Red wine, but not alcohol, prevented the increase of SBP and hyperglycemic peak. Additionally, was observed prevention of oxidative stress metabolites formation and an improvement in ROS scavenging antioxidant capacity of SHR. We also revealed that red wine intake enhances the endothelium-dependent relaxation, decreases the hypercontractile mediated by angiotensin-II in the aorta, and via β1-adrenoceptors in the atrium.

SIGNIFICANCE: The long-term consumption of red wine can

improve oxidative stress and the functionality of angiotensin-II and β1-adrenoceptors, inspiring new pharmacologic and dietetic therapeutic approaches for the treatment of hypertension and diabetes.

ABBREVIATION ACRONYMS and/or ABBREVIATIONS:
[Ca2+]cyt = Cytosolic Ca2+ Concentration
ACh = Acetylcholine
ANG II = Angiotensin II
AT1 = ANG II type 1 receptor
AUC = Area Under the Curve
Ca2+ = Calcium; Endo + = Endothelium Intact
Fen = Phenylephrine (1 μM); GTT = Glucose Tolerance Test
ISO = Isoprenaline (isoproterenol)
KHN = Krebs-Henseleit Nutrient
LA = Left Atria; LH = Lipid Hydroperoxide
NO = Nitric Oxide
RA = Right Atria
RAS = Renin-Angiotensin System
ROS = Reactive Oxygen Species; SBP = Systolic Blood Pressure
SHR = Spontaneously Hypertensive Rats
STZ = Streptozotocin
WKY = Normotensive Wistar Kyoto Rats

Am J Epidemiol. 2022 Jun 11;kwac102. doi: 10.1093/aje/kwac102. Online ahead of print.

Discrimination, mediating psychosocial or economic factors, and antihypertensive treatment: a 4-way decomposition analysis in the health and retirement study

Sims KD, Batty GD, Smit E, et al.

Untested psychosocial or economic factors mediate associations between perceived discrimination and suboptimal antihypertensive therapy. This study included two waves of data from the Health and Retirement Study participants with self-reported hypertension (N=8557, 73% Non-Hispanic White, 17% Non-Hispanic Black, and 10% Hispanic/Latino) over four years (2008-2014). Our primary exposures were frequency of experiencing discrimination in everyday life or across seven lifetime circumstances. Candidate mediators were self-reported depressive symptoms, subjective social standing, and household wealth. We evaluated with causal mediation methods the interactive and mediating associations between each discrimination measure and reported antihypertensive use at the subsequent wave. In unmediated analyses, everyday (OR; 95% CI: 0.86; 0.78, 0.95) as well as lifetime discrimination (OR; 95% CI: 0.91; 0.85, 0.98) were associated with a lower likelihood of antihypertensive use. Discrimination was associated with lower wealth, greater depressive symptoms, and decreased subjective social standing. Estimates for associations due to neither interaction nor mediation resembled unmediated associations for most discrimination-mediator combinations. Lifetime discrimination was indirectly associated with reduced antihypertensive use via depressive symptomology (OR; 95% CI: 0.99; 0.98, 1.00). In conclusion, the impact of lifetime discrimination on the underuse of antihypertensive therapy appears partially mediated by depressive symptoms.

Ann Thorac Surg. 2022 Jun 8;S0003-4975(22)00804-9. doi: 10.1016/j.athoracsur.2022.05.035. Online ahead of print.

Reintubation after lung cancer resection. Development and external validation of a predictive score

Linhardt FC, Santer P, Xu X, et al.

BACKGROUND: Reintubation after lung cancer resection is an important quality metric due to increased disability, mortality and cost. However, no validated predictive instrument is in use to reduce reintubation after lung resection. We aimed to create and validate the PRediction Of REintubation After Lung cancer resection (PROREAL) score.

METHODS: We analyzed lung resection cases from two university hospitals. The primary endpoint was reintubation within seven days after surgery. Predictors were selected through backward stepwise logistic regression and bootstrap resampling. We used reclassification and receiver operating characteristic curve analyses to assess score performance and compare it with an established score for all surgical patients (SPORC).

RESULTS: We included 2,672 lung cancer resection patients (1,754-development, 918-validation) between 2008 and 2020, of whom 71(2.7%) were reintubated within seven days after surgery. Identified score variables were surgical extent and approach, ASA physical status, heart failure, renal disease and diffusing capacity for CO. The score achieved excellent discrimination in the development (ROC-AUC:0.90; 95% CI:0.87-0.94) and good discrimination in the validation cohort (0.74, 95% CI:0.66-0.82), outperforming the SPORC in both cohorts (p<0.001 and p=0.018, respectively; Validation Cohort Net Reclassification Improvement: 0.39; 95% CI: 0.18-0.60; p=0.001). The score cutoff of ≥5 yielded a sensitivity of 88% (95% CI: 72-95) and a specificity of 81% (95% CI 79-83) in the development cohort.

CONCLUSIONS: A simple score (PROREAL) specific to lung cancer predicts postoperative reintubation more accurately than the nonspecific SPORC score. Operative candidates at risk may be identified for preventive intervention or alternative oncologic therapy.

Am Heart J. 2022 Jun 12;S0002-8703(22)00127-2. doi: 10.1016/j.ahj.2022.06.003. Online ahead of print.

Risk factors and outcomes of sudden cardiac arrest in pediatric heart transplant recipients

Hollander SA, Barkoff L, Giacone H, et al.

BACKGROUND: Sudden cardiac arrest (SCA) is a prevailing cause of mortality after pediatric heart transplant (HT) but remains understudied. We analyzed the incidence, outcomes, and risk factors for SCA at our center.

METHODS: Retrospective review of all pediatric HT patients at our center from 1/1/2009-9/1/2021. SCA was defined as an abrupt loss of cardiac function requiring cardiopulmonary resuscitation and/or mechanical circulatory support (MCS). Events that occurred in the setting of limited resuscitative wishes, or while on MCS were excluded. Patient characteristics and risk factors were analyzed.

RESULTS: Fourteen of 254 (6%) experienced SCA at a median of 3 (1, 4) years post-HT. Seven (50%) events occurred out-of-hospital. Eleven (79%) died from their initial event, 2 (18%) after failure to separate from extracorporeal membrane (ECMO). In univariate analysis, black race, younger donor age, prior acute cellular rejection (ACR) episode, pacemaker and/or ICD in place, and pre-mortem diagnosis of allograft vasculopathy were associated with SCA (P=0.003-0.02). In multivariable analysis, history of ACR, younger donor age, and black race retained significance. [OR=6.3, 95% CI: 1.6-25.4, P=0.01], [OR=0.9, 95% CI: 0.8-1, P=0.04], and [OR=7.3, 95% CI: 1.1-49.9, P=0.04], respectively. SCA occurred in 3 patients with a functioning ICD or pacemaker, which failed to restore a perfusing rhythm.

CONCLUSIONS: SCA occurs relatively early after pediatric HT and is usually fatal. Half of events happen at home. Those who received younger donors, have a history of ACR, or are of black race are at increased risk. ICDs/pacemakers may offer limited protection.

Am J Kidney Dis. 2022 Jun 1;S0272-6386(22)00706-5. doi: 10.1053/j.ajkd.2022.04.008. Online ahead of print.

Association Between long-term ambient $pm_{2.5}$ exposure and cardiovascular outcomes among US hemodialysis patients

Xi Y, Richardson DB, Kshirsagar AV, et al.

RATIONALE & OBJECTIVE: Ambient $PM_{2.5}$ is a ubiquitous air pollutant with established adverse cardiovascular (CV) effects. However, quantitative estimates of the association between $PM_{2.5}$ exposure and CV outcomes in the setting of kidney disease are limited. This study assessed the impact of long-term $PM_{2.5}$ on CV events and cardiovascular disease (CVD)-specific mortality among patients receiving maintenance in-center hemodialysis (HD).

STUDY DESIGN: Retrospective cohort study. Settings & participants: 314,079 adult kidney failure patients initiating HD between 2011 and 2016 were identified from the United State Renal Data System.

EXPOSURE: Estimated daily ZIP code-level $PM_{2.5}$ concentrations were used to calculate each participant›s annual-average $PM_{2.5}$ exposure based on the dialysis clinics visited during the 365 days prior to the outcome.

OUTCOMES: CV event and CVD-specific mortality were ascertained based on ICD-9/ICD-10 diagnostic codes and recorded cause of death from form 2746.

ANALYTICAL APPROACH: Discrete time hazards models were used to estimate hazards ratios (HRs) per 1 $\mu g/m^3$ in annual-average $PM_{2.5}$ adjusting for temperature, humidity, day of the week, season, age at baseline, race, employment status, and geographic region. Effect measure modification was assessed for age, sex, race, and baseline comorbidities.

RESULTS: A 1 $\mu g/m^3$ increase in annual-average $PM_{2.5}$ was associated with an increased rate of CV events (HR: 1.02, 95% CI: 1.01, 1.02) and CVD-specific mortality (1.02, 95% CI: 1.02, 1.03). The association was more pronounced for people who initiated dialysis at an older age, had COPD at baseline, or were Asian. Evidence of effect modification was also observed across strata of race, and other baseline comorbidities.

LIMITATIONS: Potential exposure misclassification and unmeasured confounding.

CONCLUSIONS: Long-term ambient $PM_{2.5}$ exposure was associated with CVD outcomes among patients receiving maintenance in-center HD. Stronger associations between long-term $PM_{2.5}$ exposure and adverse effects were observed among patients who were of advanced age, had COPD, or were Asian.

Am J Surg. 2022 Jun 8;S0002-9610(22)00399-3. doi: 10.1016/j.amjsurg.2022.06.005. Online ahead of print.

Access to telehealth services for colorectal cancer patients in the United States during the COVID-19 pandemic

Marks VA, Hsiang WR, Umer W, et al.

BACKGROUND: The COVID-19 pandemic yielded rapid telehealth deployment to improve healthcare access, including for surgical patients.

METHODS: We conducted a secret shopper study to assess telehealth availability for new patient and follow-up colorectal cancer care visits in a random national sample of Commission on Cancer

continues on page 34

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

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

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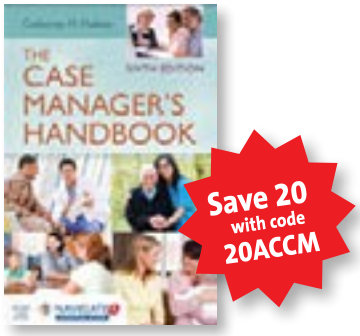

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The Importance of Oral Health: Increasing Awareness Among Case Managers *continued from page 23*

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LITSCAN FOR CASE MANAGERS

continued from page 32

accredited hospitals and investigated predictive facility-level factors.

RESULTS: Of 397 hospitals, 302 (76%) offered telehealth for colorectal cancer patients (75% for follow-up, 42% for new patients). For new patients, NCI-designated Cancer Programs offered telehealth more frequently than Integrated Network (OR: 0.20, p = 0.01), Academic Comprehensive (OR: 0.18, p = 0.001), Comprehensive Community (OR: 0.10, p < 0.001), and Community (OR: 0.11, p < 0.001) Cancer Programs. For follow-up, above average timeliness of care hospitals offered telehealth more frequently than average hospitals (OR: 2.87, p = 0.04).

CONCLUSIONS: We identified access disparities and predictive factors for telehealth availability for colorectal cancer care during the COVID-19 pandemic. These factors should be considered when constructing telehealth policies.

Gynecol Oncol. 2022 Jun 6;S0090-8258(22)00330-4. doi: 10.1016/j.ygyno.2022.05.019. Online ahead of print.

Use of hypnotics among women diagnosed with cervical cancer –A population-based cohort study

Horsbøl TA, Kjaer SK, Andersen EW, et al.

OBJECTIVE: Previous studies suggest that sleeping problems are frequent after cervical cancer. However, the evidence on the use of hypnotics is sparse. We investigated if women diagnosed with cervical cancer have an increased risk of using hypnotics and identified risk factors for prolonged use.

METHODS: In this nationwide register-based cohort study, 4264 women diagnosed with cervical cancer from 1997 to 2013 and 36,632 cancer-free women were followed in registers until 2016. Prolonged use of hypnotics was defined as more than three prescriptions with no more than three months in between. Data were analysed using Cox proportional hazards regression models and multistate Markov models separately for women with localized and advanced cervical cancer.

RESULTS: The rate of first use of hypnotics was substantially increased during the first year after cervical cancer diagnosis compared to cancer-free women (HRlocalized 4.4, 95% CI 3.9-5.1; HRadvanced 8.9, 95% CI 7.5-10.6) and remained markedly increased for up to five years after diagnosis. Dependent on stage of disease and age, 1.4 to 4.7 excess women per 100 with cervical cancer were prolonged users of hypnotics compared to cancer-free women one year after diagnosis. Risk factors for prolonged use of hypnotics were higher age, short education, previous use of antidepressants or anxiolytics, and advanced disease.

CONCLUSIONS: Women diagnosed with cervical cancer are at increased risk of prolonged use of hypnotics. For the majority, treatment with hypnotics is initiated within the first year after cancer diagnosis, but the rate of first use is increased for up to five years.

CE1

Case Management for Long-Haul COVID Patients

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PharmaFacts for Case Managers

continued from page 28

Storage and Handling

- Store Mounjaro in a refrigerator at 2°C to 8°C (36°F to 46°F).
- If needed, each single-dose pen can be stored unrefrigerated at temperatures not to exceed 30ºC (86ºF) for up to 21 days.
- Do not freeze Mounjaro. Do not use Mounjaro if frozen.
- Store Mounjaro in the original carton to protect from light.

Mounjaro is manufactured and distributed by Eli Lilly and Company. 

CE2

HIPAA (Part 2): Is it a Breach or Disclosure?

continued from page 20

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Despite the Challenges, Case Managers Must Prioritize Their Patients' Care *continued from page 3*

read various posts from colleagues who discussed what had happened to relatives, friends, and patients; the posts were disturbing, and as I read them I had growing frustration with what appeared to be an increase in the unwillingness of far too many case managers to get involved.

Where was the case manager, or if they were there, what did they do? Case managers must adhere to their Standards of Practice, which were revised and released during the CMSA annual conference in June 2022, which include serving as the patient advocate. Although case managers are not responsible for all actions and interventions on behalf of patients, it seems that many of them are "waiting" for someone else to act. Waiting for others is not advocacy, it is apathy!

Case management itself evolved because the current system of health care was not working. The solution was individuals who challenged the status quo—who did not accept "no," it can't work. Instead, they identified problems and were determined to create solutions to those problems. The results were creative, knowledgeable, empowered, and passionate professionals whose patients benefited from their caring hearts and intervention. They became the "disruptive advocates." We need them now…more than ever!

How will you respond?

Catherine M. Mullahy

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Quality Improvement: "Escape Fire" *continued from page 5*

the middle of the burnt ground…"

Dodge's team either did not hear him or ignored his calls and ran right past him. Only two of them, in addition to Dodge, survived. Dodge invented what is called an "escape fire," which soon became a standard part of training for firefighters.

Berwick goes on to point out that a key role of organizations is what he calls "sensemaking," a concept developed by Professor Karl E. Weick. Sensemaking is the process by which the fluid, multilayered world is given order within which people can orient themselves, find purpose, and take effective action. According to Weick, organizations don't discover sense, they create it.

Here are some of Berwick's principles of sensemaking in healthcare organizations:

- With regard to patients, the guiding principle must be "Nothing about me without me."
- From Dr. James Reinertsen, "All and only. We will promise to deliver, reliably and without error, all the care that will help, and only the care that will help."
- "Every patient is the only patient."
- "The patient is the source of all control."
- "By what right does a nurse, doctor, or manager make a decision that violates basic principles of human decency and caring?"

If providers follow the above guiding principles, just imagine how the quality of care provided to patients will improve. Let's go! CM

CMSA....Onward! *continued from page 6*

meetings during the week of February 21, 2022.

Case Management Fellow (CM Fellow)

The Case Management Fellow program launched last year with the announcement of the CMSA Founding Fellows. The 2022 Class of CM Fellows were announced in March and inducted in June during the CMSA Annual Conference. Case Management Fellows (FCM) represent a diverse community of thought leaders across the continuum of care that take an active role in identifying future trends and issues affecting case management, and they serve the public and the case management profession by advancing the standards of practice through excellence.

Case Managment Boot Camp

The inaugural presentation of CMSA CM Boot Camp was offered at CMSA National Conference Pre-Con day with 29 attendees. This day-long training was developed for case managers looking to build their skills and practice, ideally for those with less than 5 years of experience who were looking to change their area of practice. The program includes interactive exercises, activities, and case studies to provide real-life scenarios and practical application.

More to Come!

New programs, benefits, and opportunities are planned throughout the year, and we can't wait to share them all with you in future CMSA articles. And let's not forget to celebrate Case Management Week in October! I am looking forward to seeing and hearing all about the celebrations that will be going on. CM

Unique Case Management Training Program Helps Professionals "GROW" Their Knowledge and Advocacy *continued from page 8*

facilitators. The program included case studies and application of essential case management in their daily work.

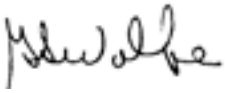
It was particularly gratifying to receive positive feedback on this program. As Antonia Jiménez, Director of the Department of Public Social Services (DPSS), said in a statement: "CCMC has done a wonderful job delivering the customized foundational training. DPSS had a vision and CCMC brought that vision to life. DPSS staff found the training to be unique and applicable to their daily work. We are confident the knowledge obtained from the trainings will equip case managers with the necessary skills and techniques to provide more engaging case management to our customers."

The Commission is proud to support GROW case managers in their daily work. We see this as yet another opportunity to promote professionalism and best practices across every case management setting and to help clients pursue their goals with success. CM

Case Management Fellows: Acknowledging Our Own *continued from page 2*

high-quality education programs, and to serve as a public resource concerning health care legal issues.

Congratulations to all!



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ACCM: Improving Case Management Practice through Education

Addressing Health Care Bias Among Case Managers *continued from page 9*

patient that I was about to meet and must somehow convince to enroll in services. Honestly, I expected to see a young, arrogant teenager who would rather be on his phone than talking to me about disease management services. As I walked in the room, I remember being shocked at the patient that I saw lying in the hospital bed. Instead of being an arrogant teenager, I encountered a polite young man who immediately reminded me of my own son. After sitting down and talking to him about the struggles with his health, he shared that his main issue was that he just wanted to be like all the other teenagers at his school. He also stated that his home life was not very supportive, so he had moved in with his friend's parents, who were better role models for him. After I completed my standard case management talk regarding our disease management program, I told him my first speech was talking to him like a nurse, but my second speech was going to talk to him like a mom. I told him that I had a brother who was diagnosed with type I diabetes when he was 7 years old, and I understood how hard it is to control diabetes, especially during your teenage years. Then I described some of the patients I had cared for during my years as a nurse who didn't manage their blood sugars well and required amputations or dialysis for renal failure. We had an honest, heartfelt discussion that I hoped changed his life for the better. But in hindsight, I realize now that this conversation could not have happened if I had allowed my initial bias to interfere with my case management role.

So how can we as case managers not allow implicit bias to alter the care we deliver to our patients? The IHI states that the first step in understanding health care bias is to better understand your own unique implicit bias and receive education on overcoming partiality. Project Implicit offers an Implicit Association Test that measures attitudes and beliefs and may allow you to identify biases that you were unaware existed. We will not improve in our industry until we are aware of the all the factors that affect our judgment in health care delivery. No family should ever feel that their loved one died because of their race, sexual orientation, or cultural beliefs. CM

Understanding Disability Management and Absence Management *continued from page 7*

- Coming to Terms with Long COVID in the Workplace: Disability Management Specialists Can Lead the Way

By gaining greater understanding of employer policies, case managers can help themselves in the event of an injury, illness, disability, or other cause of an unplanned absence. In addition, the more educated they become about such policies and leaves in general, the better they can leverage that understanding to help the clients for whom they advocate. CM

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