CareManagement

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Gary S. Wolfe

Case Management Fellow Program

The Case Management Society of America (CMSA) has launched a Case Management Fellow Program. The Fellow Program establishes a framework for recognizing individual case managers who have made a significant contribution to the professional practice of case management through practice, education, leadership, or research.

Establishment of the Fellow Program is an exciting development for the professional practice of case management. Case management in the modern era—probably since the late 1980s—has continued to grow and develop. Figuring out the chaos in the healthcare delivery system has pushed case management forward so that now almost all healthcare organizations and payers have some form of case management helping patients navigate the delivery system. Case management has developed and grown over time. Case management leaders and programs have emerged. It is now a logical step to recognize those individuals who have made a difference in case management. I think the Fellow Program is a logical step in the development of case management.

A working committee of distinguished thought leaders developed criteria to become a Fellow. Criteria to be a Fellow includes holding a certification in case management from a recognized body, being a member of CMSA, practicing case management for a minimum of 10 years, and documenting their contribution to the professional practice of case management. Examples of a significant contribution to the professional practice of case management can take many forms. It could be participating in a case management organization as an officer, board member, or committee member; being in a leadership position delivering case management services; developing innovative case management programs; educating case managers; writing articles about case management; speaking at conferences; or mentoring other case managers. Case managers must apply to the Fellow Program; the application must include a resume, a written explanation of their contributions, and letters of recommendation. A Fellow Selection Committee will review the application and score the findings based on a rubric. Case managers who become Fellows will be able to use the designation FCM™.

The CMSA Fellow Program establishes a framework for recognizing individual case managers who have made a significant contribution to the professional practice of case management through practice, education, leadership, or research.

Fellows will reflect a diverse community of thought leaders and will have not only made a significant contribution to case management but will also continue to be active leaders and identify future trends and issues affecting case

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Catherine M. Mullahy

Holiday Reflections and Cautious Optimism

Another year is coming to a close. Thankfully, it looks like the future is more hopeful with regard to the COVID-19 pandemic, although progress is being made more slowly than any of us might have imagined. There's a saying that perhaps you've heard, or even used, and that's: "…Not so fast…" in response to stating some good news. So, just as we seemed to be seeing a light at the end of the very long and seemingly endless COVID-19 tunnel, there has been the emergence of another variant: this one has been named Omicron. The impact of this variant is yet to be determined, but the uncertainty surrounding it is understandably concerning. Although more adults and children are being vaccinated, others continue to resist getting vaccinated for a variety of reasons. Although it is highly doubtful that we will achieve a 100% vaccination goal, there are other therapeutics that will be able to assist those who contract COVID-19. Breakthrough episodes and continuing concerns about the possibility of additional variants underscore the likelihood that our world will never be quite the same. Still as we cope with the realities of our day-to-day existence, we have become more resilient and determined to live each day as fully as possible.

Case managers continue to pursue opportunities to improve their day-to-day practice and to find greater fulfillment in their unique role in an ever-evolving healthcare system. It's more than a little challenging to stay abreast of evidence-based practice guidelines that would be appropriate for our patients' conditions. We hope to provide information that supports and educates case management professionals. While an essential role for *CareManagement* as the official publication for ACCM and CCMC and a member benefit for CMSA is to provide CE opportunities, we also realize

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that it's equally important to share the latest information concerning the dizzying array of pharmaceuticals (PharmaFacts); to scan the literature for the latest developments in medical literature and research (LitScan); to provide legal information that would impact your practice; and to present updates from our industry partners (CMSA, CCMC, CDMS, and CARF). We acknowledge that our most precious commodity, and the one that is least available, is time, and it is our hope that we continue to meet your ongoing needs. As Executive Editor, my goal is to solicit articles and mentor authors, especially those who are actively engaged in the practice of case management. Because there are many different professional disciplines in case management, we are hopeful that those who might be represented include the less well-known groups (eg, physical, occupational, speech, music, and recreational therapists). For example, we would welcome contributions from recreational therapists, so please consider this as an invitation. You can be the sole author or a coauthor within a case management team.

Because of the pandemic, the scope of care that patients have been receiving has changed considerably. While inpatient care was needed to treat the most complex COVID-19 patients, there were also efforts to treat more of those patients on an outpatient basis and to be able to provide more support services to those discharged for longer periods. Professionals such as social workers, pharmacists, pain management specialists, substance abuse team members, and, of course, our case management colleagues, have been valued yet often overstressed, both physically and emotionally. As the pandemic becomes more manageable, we are now just beginning to see the effects on individuals who were unable to receive the non-pandemic-related care that they needed in a timely manner. Needless to say, many are much sicker now. Once again, case managers will be needed to respond to this complex group of individuals. It is important that we take care of ourselves and our colleagues so that we can take care of others.

We hope that you will be able to take some much-needed time to enjoy the holidays with your family and friends. Also, take time to pause and reflect on the difference you have

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A Year of Resilience

Melanie A. Prince, MSN, BSN, NE-BC, CCM, FAAN

What a year this has been! One word that describes the year for many of us and for the Case Management Society of America (CMSA) is resilience. The year 2021 has ebbed and flowed with the pandemic; societal challenges; how we live, play, and work; our sense of well-being; and our ability to recover from life's confrontations. Our individual or organizational resilience can be a source of motivation for the future. CMSA's future is bright and filled with new ideas, revamped services, and innovative programs borne from the association's ability to be resilient in the face of challenges.

Some of these ideas, services, and programs have already launched and others are on the 2022 horizon. Do you know a case manager who has dedicated their career to excellence, professionalism, and advancement? We launched the CMSA Fellows program in October 2021 and will accept applications through January 2022. Recipients will earn the designation of FCM™, Case Management Fellow, a distinction that messages to the world that one has met the rigorous requirements to be identified as an impactful and influential leader in the field of case management.

While we recognized the expertise of established leaders with the CMSA Fellows program, we also acknowledge the need to develop a pipeline of case managers for our future. CMSA launched a Writer's Workshop for case managers to gain skills and tools in writing for publications. As we add to the authors' pool, we create opportunities for the industry to read about the value case managers bring to the system and the difference we make in people's lives.

On the horizon is our CMSA Boot Camp, which will ease the transition of novice case managers to experienced professionals. The CMSA Boot Camp will provide practical "real- world" content to allow novice case managers to "practice" and learn in an environment that includes expert coaching, advisement, and training. Stay tuned for the pending announcement and make plans to register for the preconference session during the annual meeting.

CMSA will host the 32nd Annual Conference and Membership Meeting on June 1-4, 2022, in Orlando, Florida at the Gaylord Palms Resort. We are excited to host the hybrid conference that will offer an in-person and virtual experience for attendees. The conference is packed with our renowned educational content, technological innovations to enhance the attendee experience, creative and modern networking events, impactful time with exhibitors and sponsors, and tools to make your jobs and careers the best they can be when you return home. CMSA will deliver a revised and enhanced set of Standards of Practice as well as new content in our Case Management Adherence Guidelines and Integrated Case Management program. The conference event has too much to describe here, but I would be remiss if I did not remind everyone about the amazing panel discussions we hosted this past year. The feedback received affirms that the CMSA panels are a "must attend" event where extraordinary speakers and leaders discuss current topics, provide answers to issues, and promote the advancement of case management practice.

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***Melanie A. Prince, MSN, BSN, NE-BC, CCM, FAAN**, is president of the Case Management Society of America. Recently retired as an Air Force colonel, Melanie has diverse experience in population health; case, disease and utilization management; public policy; trauma/violence prevention and organizational leadership. Melanie is a certified professional case manager and nurse executive and has master's degrees in nursing case management and military strategic studies.*

Interdisciplinary Pain Management and the Role of Case Management

Terrence Carolan, MSPT

The interdisciplinary treatment of chronic pain is an aspect of medical rehabilitation that is not as familiar to case managers as other components of the postacute spectrum of care like inpatient acute rehabilitation, outpatient medical rehabilitation, or home care rehabilitation. Interdisciplinary pain rehabilitation (IPR) is a unique approach to treating individuals with chronic pain that brings together a group of healthcare providers under one roof to provide coordinated care to address the complex needs of this patient population. This interdisciplinary team includes the person served, family members as appropriate, a physician, a pain psychologist, and a number of other healthcare providers that may include case managers, physical therapists, nurses, and occupational therapists. This team works to accomplish shared interdisciplinary goals related to function, impairment, activity limitations, participation restrictions, environmental factors, and personal factors. IPR uses a biopsychosocial approach that looks at the interconnection between biology, psychology, and socioenvironmental factors, and case managers play a vital role in coordinating care for individuals who participate in IPR programs as well as referral of these patients to IPR programs.

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

Interdisciplinary pain rehabilitation is a unique approach to treating individuals with chronic pain that brings together a group of healthcare providers under one roof to provide coordinated care to address the complex needs of this patient population.

In the 1980s and 1990s, IPR was a common strategy for addressing the needs of persons with chronic pain, and in the mid-1990s there was a rapid and significant decrease in the number of CARF-accredited IPR programs in the United States. Payers recognized that they could use interventions like spinal injections and prescription opioids that were less expensive than IPR, and funding for comprehensive inpatient and outpatient IPR programs became harder and harder for providers to obtain. Since then, research has shown that patients who participate in IPR programs have positive outcomes without the historically negative impacts of opioid use alone. IPR routinely achieves an 85% reduction in opioid intake, and opioid tapering is included in the CARF standards for IPR. A study conducted by U.S. Department of Veterans Affairs IPR programs in 2019 found reductions of 22% in pain-related domains of functioning (eg, mobility), a 31% reduction in pain catastrophizing, and a 16% reduction in sleep difficulties. Pain catastrophizing is the tendency to describe a pain experience in more exaggerated terms than the average person, to dwell on it more, and/or to feel more helpless about the experience, and increased pain catastrophizing is linked to higher levels of chronic pain, disability, and suicidal ideation.

IPR programs that are CARF accredited are committed to quality and performance improvement, including analyses of patient outcomes including medication management and achieving patient goals such as improving functional mobility, returning to work, and returning to important life roles. CARF-accredited IPR programs also carefully review no shows, drop outs, and cancellations to ensure that patients are able to participate in and benefit from all aspects of the program.

The field of IPR is expanding again, and the CARF IPR standards have been reviewed and revised by the field in 2021 to better reflect the high level of care and performance improvement that is needed to meet the needs of persons with chronic pain. It is important for all members of the healthcare spectrum to be aware of this unique field, and it can be an outstanding resource for case managers, primary care physicians, and

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3 Issues Top of Mind in Disability Management

Rebecca Fisco, CDMS, and **MaryBeth Kurland, MPA, CAE**

As 2021 draws to a close and we look ahead to 2022, three themes emerge as among the most urgent in disability management: state and federal leave laws; COVID-19 workplace policies and practices; and determining which jobs are and are not conducive to long-term remote work, including as an accommodation. Certified Disability Management Specialists (CDMSs) will continue to play key roles in guiding discussions around these issues as they advocate for ill and injured employees and those with disabilities and work closely with employers to minimize the impact of disability on productivity.

Rebecca Fisco, CDMS, *is manager of vocational services and operations for The Ohio State University. She currently sits on the Employer Advisory Committee for the Disability Management Employers Coalition, volunteers on CCMC's Certification Services Committee, and has participated in many different test development activities for the Certified Disability Management Specialist (CDMS) certification examination.*

MaryBeth Kurland, MPA, CAE, *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 with its CCM® and CDMS® credentials.*

Here is a brief summary of the three issues and the role of CDMSs in each area.

1. State and Federal Leave Laws

When employees take a leave of absence from work, state and local laws, in conjunction with employer policies, determine whether individuals are eligible for pay during their leave and how much they receive. California, for example, offers Paid Family Leave (PFL), which provides paid leave to eligible employees, while other states (eg, Ohio) do not currently have statewide paid leave mandates. Instead, employees in Ohio, like those in many other states, are only eligible for unpaid, job-protected leave under the federal Family and Medical Leave Act (FMLA). Other states have a variety of mandated leaves and benefits, which have their own eligibility requirements and benefit entitlements. As a result of these differences, employers face a patchwork of statutes. This impacts not only national companies with locations across the United States but also regional ones that may wish to tap into a more geographically diverse workforce through remote work. More changes may be coming, but this time at the federal level. New proposed federal legislation currently before Congress, if passed and signed into law, would provide 12 weeks of paid family and sick leave to most eligible employees regardless of state law. Amid this backdrop of complexity, CDMSs can help employers navigate the differences in local, state, and federal leave laws and unravel the interplay between any new regulations to ensure employees are protected and companies are compliant.

2. COVID-19 Intensifies Workplace Issues

The COVID-19 pandemic intersected the workplace in ways that intensified many existing issues related to paid time off, leaves of absence, job protection under the Americans with Disabilities Act Amendments Act, and other laws as well as workplace policies and practices. At the heart of this issue is protecting employees who become ill and cannot work, maintaining a safe and healthy environment, and ensuring that short-staffed employers can maintain productivity. Striking this balance has been and continues to be a challenge. Consider the example of an employee with a medical condition or disability who has already taken their full allotment of time off under FMLA. What happens if this employee then becomes ill with COVID-19 or is quarantined because of coronavirus exposure? If they have no remaining FMLA leave, but cannot yet return to work, will they lose their job? Or remain an employee but receive no pay? The Families First Coronavirus Response Act (FFCRA) and the Occupational Safety and Health Administration (OSHA) emergency temporary standards have both mandated certain leave and pay

As 2021 draws to a close and we look ahead to 2022, three themes emerge as among the most urgent in disability management: state and federal leave laws; COVID-19 workplace policies and practices; and determining which jobs are and are not conducive to long-term remote work, including as an accommodation.

protections for employees impacted by COVID-19; however, the FFCRA requirements have expired, and the OSHA regulations only cover certain medical workers. Unless employers make the decision to provide additional leave or pay protections, many workers may lose their job or their income. Once again, CDMSs find themselves on the front lines of weighing the need for job protection for employees while helping employers maintain a safe and healthy work environment that is staffed to meet the needs of the business.

3. Determining Remote and In-Person Work

After the "great remote work experiment" of the pandemic, as many companies shifted to widespread virtual work across their operations, employers are now looking to the future to determine where and how work can be performed. These discussions and decisions will be particularly impactful for individuals who have medical conditions or disabilities. The ability to work remotely may dramatically increase job opportunities for those who are unable to work in certain settings. On the opposite side, employers who have tolerated remote work because of the pandemic may start to require all staff return to the office, which could negatively impact individuals who are in need of ongoing remote work accommodations whether due to COVID-19 contagion risk or other medical conditions. At issue is whether certain jobs can continue to be performed remotely or if work is truly better suited to be carried out in person. For many jobs, there is a clear-cut answer, but for

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Case Managers Look Ahead to the "New Normal"

Teresa "Teri" Treiger, RN, MA, CCM, FABQAURP

As 2021 comes to a close, professional case manager are looking to 2022 with a desire for greater normalcy following the ongoing disruptions from the COVID-19 pandemic. This is the consensus I'm hearing from case managers across the country and in different care settings.

Disruptions occurred everywhere. For example, many hospital-based case managers were reassigned to bedside nursing because of staff shortages, while some workers compensation case managers were furloughed as workplaces shut down. Many case managers adopted a telehealth model instead of delivering services in person. Across health and human services, case managers are responding to COVID-19 with a sense of urgency because of escalating cases in some states and regions of the country as well as overall concerns about contagion risks.

Issues that are top of mind of professional case managers today include empathy and support for colleagues, emphasizing best practices, taking a learning inventory, and reaching out to others.

Despite the prolonged disruption of the pandemic, case managers are eager to take their experiences and apply these lessons learned as they prepare for the "new normal" of whatever comes next. Here are some issues that are top of mind of professional case managers today:

- **Empathy and support for colleagues.** The pandemic affected case managers not only professionally but also personally and in numerous ways from financial hardship to the loss of loved ones. A survey conducted by the Commission for Case Manager Certification early on in the pandemic offered a sobering snapshot: 30.5% of case managers surveyed at the time said they suffered a loss of income; 21%-22% reported clinical health issues or mental health issues; 16.6% said they experienced food scarcity; and 5.3% lost a loved one. As we interact with colleagues and other professionals, we are cognizant of the human toll. Having empathy for our colleagues must be a hallmark of the next normal as we interact as colleagues and members of interdisciplinary teams.
- **Emphasizing best practices.** The pandemic triggered "emergency triage" across health and human services, from evolving treatment protocols to learning how to mitigate contagion risks for clients, fellow case managers, and others. Case managers, like professionals everywhere, did the best they could in the face of a previously unknown pathogen and an absence of outcomes data. Now, as they anticipate a return to normalcy, professional case managers are emphasizing a return to best practices, drawing on research data and a recognized body of knowledge to manage cases and coordinate care.
- **Taking a learning inventory.** Amid so much change, it has been easy for case managers to lose track of their learning and skill-building needs. At year-end, however, it's an opportune time to assess our professional goals and our need for knowledge refreshment and skill development. Perhaps we've been reassigned in our jobs or we're coming back from a furlough. It may be that licensure and/or certification is up for renewal and we need to respond quickly. Every case manager should examine where they are in the renewal process, take an inventory of the CEs they've already attained, and identify education requirements. (For example, the Certified Case Manager (CCM) Renewal Guide is an essential resource). Beyond renewal

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Teresa "Teri" Treiger, RN, MA, CCM, FABQAURP, *is a Commissioner 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 is a nonprofit volunteer organization that oversees the process of case manager certification with its CCM® credential and the process of disability management specialist certification with its CDMS® credential. She is also a principal at Ascent Care Management.*

The Tools to Fix the Problems

Jennifer Zentner, BA, CCM

What is case management…if we are honest with ourselves, the answer changes depending on the day. Case management is advocacy, empowerment, facilitating autonomy, and assisting people in attaining their goals whether medically or personally. Case management can be a whirlwind of excitement, frustration, fulfillment, and reward all in the same day. A colleague of mine frequently describes case management as the junk drawer of the care team because "everything gets dumped on the case manager." When I think of a junk drawer, I think of the half pack of birthday candles, the random assortment of batteries that never seem to be the type I need, the pen that doesn't work, and the random thumbtack I don't need. I think of a drawer of useless possessions that don't have a place anywhere else. I don't think of case management as the junk drawer; I prefer to think of case management as the toolbox.

A toolbox is often stuffed full of random items, much like a junk drawer, but in the case of the toolbox, each item has a specific purpose. A well-organized toolbox is essential for resolving issues. Having the tool you need improves efficiency, increases productivity, and lowers frustration. A toolbox is put together with intention, each tool playing a part in fixing a problem. Sure, sometimes after a complicated job, the tools get thrown back in and don't look as pretty, but everything still has a useful purpose. As case managers with the toolbox, we are prepared for anything because on any given day, anything can happen. From suicidal individuals to sudden homelessness, we must adapt our tools to meet diverse needs.

Case management is advocacy, empowerment, facilitating autonomy, and assisting people in attaining their goals whether medically or personally.

Have you ever seen someone that fixes things for a living? Have you been in their workshop? Every tool has a home, every machine is well kept, and they can make seamless movements from one tool to another based on the need. An effective case manager has a strong organizational system and has all of their resources at their fingertips. We are responsible not only for managing whatever administrative requirements are placed on us given the field in which we work, but we are also responsible for lives. Lives that are at risk due to barriers to health, barriers to work, and often barriers to safety.

A case manager may often feel that they are being "dumped on," but in actuality they are being recognized as the essential person for the task at hand. Some days are harder than others. Some days our toolbox feels empty and filled with inadequate tools, but the beauty of case management is that those days are balanced with days where our tools are able to help fix barriers and make progress. Case management requires flexibility, resilience, patience, tenacity, and sometimes a nice margarita.

Case management looks different depending on the field or position in which the case manager works. Years ago, I was a case manager for adults with developmental disabilities. In that position, advocacy was 99% of my job. I advocated for their human rights. I advocated for their wants and needs. And in one instance, I advocated for appropriate legal counsel. In that situation, I had a 22-year-old young man with the cognitive capabilities of an 8-year-old who stood accused of a crime he did not even know about. He was arrested, questioned without a lawyer, and as a product of the foster system, had no family support to assist him. With no law degree, I had to open my toolbox and reflect on what I could do in order to assist this young man. With the support of my supervisor, we created a fundraiser to raise money for him to hire a new lawyer that could advocate for him

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Jennifer Zentner, BA, CCM, *has 10 years of case management experience and works primarily with the Medicaid population and specifically waiver programs. She is currently working as a LTSS Case Management Supervisor at Molina Healthcare.*

Can Hospitals Require Physicians to Direct Referrals?

Elizabeth Hogue, Esq.

Effective on January 19, 2021, new regulations related to the Stark laws expanded and underscored the ability of hospitals to require physicians to send referrals to particular providers. These new regulations also make it clear that providers can monitor and enforce requirements to direct referrals to designated providers.

Homecare providers of all types have often expressed concerns about hospitals that put pressure on physicians, especially those they employ or with whom they contract, to make referrals within the hospital system. Hospitals often view these activities in terms of prevention of "patient leakage." Are hospitals allowed to require physicians to direct referrals to designated providers?

The so-called Stark law and regulations permit hospitals that employ physicians or contract with them to require referrals of patients to particular providers as a condition of employment or independent contractor relationships. Effective on January 19, 2021, new regulations related to the Stark laws expanded and underscored the ability of hospitals to require physicians to send referrals to particular providers. These new regulations also make it clear that providers can monitor and enforce requirements to direct referrals to designated providers.

From a practical point of view, here are key issues with regard to requirements for direct referrals:

- Directed referral requirements must be in writing and signed by both parties. This requirement can be met by including requirements to direct referrals in physicians' employment or independent contractor agreements. If employed physicians do not enter into contracts with their employers, providers may also meet this requirement by asking physicians to sign an agreement that addresses issues related to directed referrals.
- Despite requirements to direct referrals, physicians should be free to refer to other than designated providers if: (1) patients express preferences to other providers; (2) patients' insurers determine that payment is contingent upon care from certain providers; or (3) physicians determine that referrals are not in the best interests of patients.
- Agreements between providers and physicians should include specific provisions about how compliance with referral requirements will be monitored.
- Targets for directed referrals should be established based on a percentage or ratio of referrals. Targets cannot, however, be based on the number of referrals physicians direct as required. Targets also cannot take into account the value of referrals directed by physicians.
- Establish bonuses or other financial incentives to encourage compliance with requirements to make directed referrals. Hospitals must make certain, however, that bonuses and other financial incentives do not take into account the volume or value of referrals or other business generated by physicians.
- If physicians do not comply with provisions regarding directed referrals, agreements with them may be terminated. As indicated above, however, termination may not be based on the value or number of referrals made.

Although home care providers may oppose relationships between hospitals and physicians that require physicians to direct referrals to designated providers, such relationships will "pass muster" if applicable requirements are met. 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.*

Vaccine Mandates: Recent Court Decisions

Elizabeth Hogue, Esq.

Legal challenges to vaccine mandates continue. One of the most recent challenges already addressed by the Court is *Klassen v. Trustees of Indiana University* [No. 21-2326, 2021 WL 3281209 (7th Cir. Aug. 2, 2021)]. In this case, the Court rejected students' request for an injunction to block vaccine mandates based on violations of the right to substantive due process under the Fourteenth Amendment of the U.S. Constitution.

In the Court's decision to refuse to grant an injunction, the Court rejected students' claims that they have a fundamental right to refuse vaccinations. The Court said that this case is easier to decide than the Jacobson case that we wrote about last week [*Jacobson v. Massachusetts*, 197 U.S. 11 (1905)] in which the Court decided in favor of mandatory vaccinations against smallpox.

First, the Court pointed out that there are a number of exceptions to the University's policy based on, for example, sincerely held religious beliefs, medical conditions, medical deferrals and online enrollment. Most of the students who filed the lawsuit qualified for an exception.

In addition, Indiana does not require all adults to be vaccinated. Rather, according to the Court, "Vaccination is instead a condition of attending Indiana University. People who do not want to be vaccinated may go elsewhere."

The Court also affirmed public policy as a basis for mandatory vaccination: "Vaccination protects not only the vaccinated persons but also those who come into contact with them, and at a university close contact is inevitable." In other words, the Court recognized that unvaccinated students may impact others through spread of the virus, and through imposition of remote learning and other measures that would not be necessary otherwise.

The Court said that the U.S. Constitution does not prohibit conditioning an education on compliance with mandates that are reasonably related to protecting public health. The Court also rejected students' objections to mask mandates and periodic testing.

The Court said:

"Other conditions of enrollment are normal and proper. The First Amendment means that a state cannot tell anyone what to read or write, but a state university may demand that students read things they prefer not to read and write things they prefer not to write. A student must read what a professor assigns, even if the student deems the books heretical, and must write exams or essays required. A student told to analyze the role of nihilism in Dostoevsky's The Possessed but who submits an essay about Iago's motivation in Othello will flunk.

If conditions of higher education may include surrendering property [i.e., tuition] and following instructions about what to read and write, it is hard to see a greater problem with medical conditions that help all students remain safe when learning."

In short, said the Court, the U.S. Constitution does not prohibit conditioning an education on compliance with mandates that are reasonably related to protecting public health.

The Court also rejected students' objections to mask mandates and periodic testing.

The students request to the U.S. Supreme Court for an emergency injunction was denied.

Like the students in this case, healthcare staff members who do not want to be vaccinated can go to work for providers who do not have vaccine mandates. However, as an increasing number of providers adopt vaccine mandates, the ability of staff members to work elsewhere will diminish. An increasing number of patients may also insist that staff members who care for them must be vaccinated.

The Courts continue to insist that the common good must prevail. CM

CE1 Approved for 1 hour of CCM, CDMS, and nursing education credit
Exam expires on June 15, 2022

Professional Case Management's Contribution Toward the National Quality Strategy

Patricia Noonan RN, MBA, CCM

Achieving quality healthcare in the United States (US) remains an important goal for Congress, public and private stakeholders, and healthcare consumers. According to the Centers for Medicare & Medicaid Services (CMS), "quality healthcare for people with Medicare is a high priority for the President, the Department of Health and Human Services, and the Centers for Medicare & Medicaid Services." (Centers for Medicare & Medicaid Services, 2021). CMS currently oversees the Medicare, Medicaid, and Children's Health Insurance Program covering 145 million beneficiaries and has a significant impact on the US population. CMS, along with the U.S. Department of Health and Human Services (HHS), works to promote quality healthcare and improved outcomes through various initiatives that incentivize providers to achieve quality outcomes. CMS uses quality measures endorsed by the National Quality Forum in its various programs that include quality improvement, pay for reporting, and public reporting.

How important is a National Quality Strategy (NQS) in the United States? According to CMS, "The U.S. Department of Health and Human Services and CMS are committed to leading the transition to a value-based healthcare system that is patient focused, coordinated, and cost-effective." (Centers for Medicare & Medicaid Services, 2020). Today, an NQS is paramount. A national quality agenda has been supported by Congress and endorsed through legislative funding as part of section 1890(e) of the Social Security Act and section 50206(b) of the Bipartisan Budget Act of 2018 "to ensure the Secretary of HHS uses effective, consensus-based quality measures in CMS administered programs." (CMS Report to Congress, 2019)

Patricia Noonan, RN, MBA, CCM, *is a registered nurse and certified professional case manager. Recently retired as the Director of Care Management, North Unit, at Beth Israel/Lahey Health Performance Network, she is currently serving as treasurer on the CMSA board and the CMSA Foundation board. Patricia is experienced in population health—ACO and employee care management program development and leadership.*

In a 2019 Government Accountability Office Report to Congress, $429.9 million was authorized through appropriations from 2009 to 2018 to fund CMS quality measure activities. In addition, the fiscal year 2021 budget request for CMS quality improvement activities is $144.4 million. (HHS, Fiscal Year 2021)

Background on the Quality Movement and National Quality Strategy

The background on the quality movement spans over a century in the United States. In particular, during the past half century, national stakeholder organizations have emerged along with congressional mandates as a call to action to achieve quality efficient healthcare. Notable efforts over the past 2 decades that advanced a quality strategy include the work published by the Institute of Medicine, the Joint Commission, and the National Quality Forum. The Patient Protection and Affordable Care Act, passed into law in 2010, contains provisions that promoted quality efficient healthcare while lowering costs. (Marjoua & Bozic, 2012) In 2011, the NQS emerged to align both public and private sectors in healthcare to achieve the Triple Aim. The NQS promoted three aims to be achieved: better care, healthy people/healthy communities, and affordable care. (Agency for Healthcare Research and Quality, 2017)

Toward a Quality Healthcare System

What are quality measures and what is considered quality care? According to CMS, "quality measures are tools that help to quantify healthcare processes, outcomes, patient perceptions, and organizational structure and/or systems associated with the ability to provide high-quality health care." (Centers for Medicare & Medicaid Services, 2020) Further, "a measurement strategy is critical to determining program value and ensuring the program is effective as possible." (Agency for Healthcare Research and Quality, 2017) What is considered quality care? According to the World Health Organization, "quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes." (World Health Organization, 2021) To achieve a high-quality health

Achieving quality healthcare in the United States remains an important goal for Congress, public and private stakeholders, and healthcare consumers.

system, healthcare must be "safe, effective, patient-centered, timely, efficient, and equitable." (Institute of Medicine, 2001)

In 2017, CMS launched the Meaningful Measures framework, which was a new approach to quality measurement. According to CMS, the goal was to "reduce the burden of measure reporting while rewarding value over volume." (Centers for Medicare & Medicaid Services, 2021)

In the CMS framework, six high priority areas (quality priorities) in healthcare for quality measurement and improvement were identified to achieve quality outcomes for patients, families, and providers (Table 1).

TABLE 1 ALIGNMENT OF GOALS FOR QUALITY CARE

CMSA Standards of Practice for Case Management

- Use a client-centered, collaborative partnership approach
- Facilitate the client's self-determination and self-management
- Use a comprehensive, holistic, compassionate approach
- Practice cultural competence and linguistic sensitivity
- Implement evidence-based care guidelines
- Promote optimal client safety
- Promote integration of behavioral change science and principles
- Facilitate connections to community supports and resources
- Foster safe navigation through the healthcare system
- Pursue professional practice excellence and maintain competence
- Support quality management and health outcomes improvement
- Maintain compliance with federal, state, local rules and regulation, accreditation, and certification standards
- Demonstrate knowledge, skills, competency in the application of case management standards of practice, codes of ethics, and professional conduct.

Source: cmsa.org/standardsofpractice

Alignment to CMS Goals and Contribution Toward the National Quality Strategy

CMSA's Standards of Practice for Case Management that are followed by professional case managers align well with the CMS Meaningful Measures overarching goals and quality priorities. Professional case managers working in all healthcare settings contribute to the NQS by supporting patients, families, and providers to achieve quality patient-centered goals. Professional case managers are perfectly positioned to achieve quality patient/client outcomes led by The Standards of Practice for Case Management. In daily practice, it is through application and adherence to the Standards of Practice and guiding principles that lead the professional case manager to "interventions and strategies that target the achievement of optimal wellness, function, and autonomy for the patient/client or caregiver." (CMSA SOP, 2016)

How Do Professional Case Managers Promote Effective Communication and Coordination of Care?

Case managers contribute to this quality goal every time a patient/client is supported through "safe and manageable navigation through the healthcare system to enhance the patient/client's timely access to services and achievement of successful outcomes." (CMSA SOP, 2016) Case managers contribute through provision of comprehensive case management services that include an assessment, care planning, care coordination, and evaluation of outcomes. An example is when a case manager contacts an elderly patient recently discharged from a hospital and learns through a comprehensive transitional assessment that the patient has neglected to fill his medications and follow the provider's treatment plan. The case manager communicates with the provider and coordinates same day home delivery of the medications with a pharmacy along with a Visiting Nurse Agency (VNA) skilled nursing visit to assist the patient in following the treatment plan. The case manager also arranges transportation with the patient's daughter to the primary care physician follow-up appointment. Through education and teach-back, the case manager is able to confirm that the patient knows how to follow the prescribed treatment plan.

Professional case managers working in all healthcare settings contribute to the National Quality Strategy by supporting patients, families, and providers to achieve quality patient-centered goals. Professional case managers are perfectly positioned to achieve quality patient/client outcomes led by The Standards of Practice for Case Management.

How Do Professional Case Managers Promote Effective Prevention and Treatment of Chronic Disease?

Case managers contribute to this quality goal every time they "use a comprehensive, holistic, compassionate approach to care delivery which integrates a client's medical, behavioral, social, psychological, functional, and other needs." (CMSA SOP, 2016) Case managers contribute through provision of comprehensive case management services that include an assessment, care planning, care coordination, and evaluation of outcomes. An example is when a case manager engages a patient with uncontrolled diabetes to enroll in a program to improve diabetes management. The case manager's use of motivational interviewing dialogue, collaboration, and goal setting enables the patient to reduce his A1C level from 9.5% to 8.0% in 5 months through diet, exercise, and medication. Through education and engagement, the case manager is able to support the patient to achieve the goal of improved diabetes self-management.

How Do Professional Case Managers Work with Communities to Promote Best Practices of Healthy Living?

Case managers contribute to this quality goal every time they "use a client-centric collaborative partnership approach that is responsive to the individual client's culture, preferences, needs, and values." (CMSA SOP, 2016) Case managers contribute through provision of comprehensive case management services that include an assessment, care planning, care coordination, and evaluation of outcomes. An example is when a case manager working with a morbidly obese non-English-speaking patient diagnosed with heart failure coordinates a provider visit with the patient's care team, which includes a cardiologist, nutritionist, the caregiver daughter, a formal interpreter, and the case manager. By arranging formal interpreter services at all scheduled appointments, the case manager is able to ensure the patient is able to understand and follow the treatment plan while making their needs and preferences known to the care team. The case manager also ensures that health resources and community support services are made available in the patient's language to promote optimal health outcomes.

How Do Professional Case Managers Make Care Affordable?

Case managers contribute to this quality goal every time they "facilitate awareness of and connections with community supports and resources." (CMSA SOP, 2016) Case managers contribute through provision of comprehensive case management services that include an assessment, care planning, care coordination, and evaluation of outcomes. An example is when a case manager working in an emergency department learns in a post emergency department call that an elderly patient has used the emergency department for nonurgent care 10 times in the last year because the patient doesn't have an established relationship with a primary care provider. Through education and engagement, the case manager is able to establish care with a new primary care physician per the patient's request and arranges an appointment. The case manager is able to educate the patient about the importance of preventive care and recommended immunizations. The patient's use of the emergency department for nonurgent care is reduced to just one visit over the next 6 months.

How Do Professional Case Managers Make Care Safer by Reducing Harm Caused in the Delivery of Care?

Case managers contribute to this quality goal every time they "promote optimal client safety at the individual, organizational, and community level." (CMSA SOP, 2016) Case managers contribute through provision of comprehensive case management services that include an assessment, care planning, care coordination, and evaluation of outcomes. An example is when the case manager working with a post-surgical elderly patient learns in an outreach call of a recent fall in the home. The case manager conducts an assessment and notes that the patient has symptoms of an infection. The surgeon is notified, sees the patient, and initiates a course of antibiotics. The case manager coordinates a physical therapy visit in the home to conduct a home safety evaluation along with a skilled nursing visit from the local VNA for a comprehensive medication review. The case manager is also able to engage and enroll the patient in a free community falls prevention program held at the local senior center. Through the support of the case manager, the patient is able to avoid harm and a readmission to the hospital.

Case managers contribute to quality goals through provision of comprehensive case management services that include an assessment, care planning, care coordination, and evaluation of outcomes.

How Do Professional Case Managers Strengthen Person and Family Engagement as Partners in Their Care?

Case managers contribute to this quality goal every time they "facilitate the clients self-determination and self-management through the tenets of advocacy, shared and informed decision making, counseling, and health education whenever possible." (CMSA SOP, 2016) Case managers contribute through provision of comprehensive case management services that include an assessment, care planning, care coordination, and evaluation of outcomes. An example is when a social work case manager working with a client recently diagnosed with a life-limiting condition learns that the client does not have a completed healthcare proxy or advance directive. The social worker is able to coordinate completion of the healthcare proxy with the client along with the health agent and provide a copy in the primary care physician's electronic medical record. The social worker is also able to arrange for the client, along with his or her primary care physician, to complete the state medical orders for life-sustaining treatment form that identifies the client's treatment preferences. With the support of the social worker, the client is able to exercise the right to self-determination regarding end-of-life treatment.

These examples illustrate just a few among countless examples of the professional case manager's interventions that occur daily across the United States and contribute to quality patient/client outcomes aligned with the national quality goals. At the core of quality outcomes is the professional case manager's ability to continually advocate for the patient/client and caregiver across the continuum of health care.

Call to Action

The NQS is expected to advance over the next decade, with the HHS goal to convert 90% of fee-for-service payment to value-based payment models that reward value over volume. (Health Affairs Blog, 2017) Here are important considerations for the professional case management community as a Call to Action:

- CMS continues to accelerate incentives toward value-based payment models focusing on quality outcomes.
- Targeting health equity for all and reducing disparities is a national priority.
- Professional case managers as leaders and exemplars are able to advance evidence-based practices that promote quality efficient healthcare and research.
- Currently there is no standard core measure set for case management programs to capture alignment with CMS quality goals.
- Currently, there is no method to quantify professional case management's contribution toward the CMS quality goals.
- There is a need for a national registry. A national registry of case management programs and outcomes can capture meaningful data to report to Congress on an annual basis.
- A report to Congress can serve to communicate vital information of case management's role and contribution toward the national quality goals.
- A report to Congress can also address the need for models that include professional case managers in both federal- and state-funded programs.

Professional case managers have the ability to impact health policy through engagement in public policy advocacy. What can the professional case management community do? Case managers can engage in a workplace quality improvement and/or research project that aligns with a national quality priority. Case managers can also reach out to their legislators to share their direct role in and contribution to the NQS. Finally, it is imperative that case managers engage in campaigns to advocate for case management intervention codes to capture case management's contribution to the NQS. In doing so, the case management community can begin to stake a claim in the national quality landscape. CE1

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Hospital Providers' Perceptions of the Role of Pediatric Case Managers: Results of a Single-Item Survey Event

Elaine Fay Williams, PhD, RN, Kimberly Drissel, MSN, RN, Jenelle Davis Jackson, MS, BSN, RN, NneAmaka Uzoma, Uba, MSN, RN, Rebecca Cully, BSN, RN, and **Rebecca Kabba, MSN, RN**

Introduction

Who are pediatric case managers?

Most case managers are nurses, although some social workers and other healthcare professionals can hold the title of case manager (Leonard & Miller, 2012). According to Woodward and Rice (2015), case management is "the process of planning, coordinating, and revising the care of an individual" and is like the nursing process, where implementation is crucial (Seçer & Karaca, 2021). At our setting, most pediatric case managers are registered nurses (RNs). Similar role titles in the literature include care coordinators, navigators, and case managers (Franko & Sminkey, 2014). Case management has strong roots in community and public health. In the 1860s, case management consisted of cards that catalogued the follow-up care needs of individuals and families (Alejandro, 2018; Stanhope & Lancaster, 2013). One of the goals of the Patient Protection and Affordable Care Act (ACA) was to incentivize the development of interventions and best practices that could improve health outcomes, member satisfaction, and cost efficiencies among individuals with the most complex needs (Meek, 2012). This goal is epitomized in the case management role.

As healthcare rapidly changes and evolves, pediatric case managers have been at the forefront. One of the overarching goals of Healthy People 2020 was improved access to comprehensive quality healthcare services for all (U.S. Department of Health & Human Services, 2021). Case management was created to reduce healthcare costs and improve healthcare outcomes (Meek, 2012; Moreo, 2021; Moreo et al., 2014; U.S. Department of Health & Human Services, 2021). This report coupled with the ACA indicate the federal level support for the case manager role.

The pediatric case manager shares certain core role functions with case managers for adult care but with important distinctions. Care planning, including discharge teaching, must take into consideration the developmental age, growth, and development of the pediatric patient as well as family resources including childcare issues because the case management guidance will involve and impact the entire family. Prior authorizations are commonly needed for the pediatric population because certain medications will need to be compounded, are prescribed outside of the typical dose parameters, or are not approved by the U.S. Food and Drug Administration for use in children (Kelly et al., 2019). Pediatric case managers may also be involved in guardianship or other legal issues as part of their discharge planning and may need to work with biological parents, stepparents, and/or foster parents who are caring for the same child in the home setting.

History of the Pediatric Case Management Department

Our department was established in 1999 secondary to a high volume of third-party payor denials and an internal assessment of a fragmented discharge planning system. Since the department's founding, it has evolved from less than 20 to more than 70 staff members. The roles in the department include discharge planners, utilization management (UM), ambulatory case managers, payor reimbursement (PR), clinical resource management associates (CRMA), clinical defense, ambulatory social workers, community health case workers, medical authorization analysts, and clinical documentation integrity specialists.

Regardless of individual roles, the entire department is focused on appropriate patient care. Many in the department have flexible roles—staff are trained to cover a variety of responsibilities. Our department facilitates the hospital discharges of approximately 40 patients daily, all of whom had case management activities, including several (generally 1%) who are transferred to a pediatric rehabilitation hospital.

All authors are staff members at Children's National Hospital in Washington, D. C., and Elaine Fay Williams is also an Assistant Professor of Pediatrics at the George Washington University School of Medicine and Health Sciences.

As healthcare rapidly changes and evolves, pediatric case managers have been at the forefront.

A national report published in 2016 of 0- to 21-year-old patients who were discharged from more than 2,423,000 hospitals in the United States indicated that approximately 122,673 patients who were discharged (5.1%) needed home care and 26,282 (1.1%) were transferred to rehabilitation care facilities (Berry, Hall & Dumas, et al., 2016). Our department's numbers are proportionately higher in terms of discharged patients needing case manager involvement for home care but similar to those in the national report for transfers to other facilities.

As a tertiary care hospital, Children's National Hospital is strategically situated to serve children from the District of Columbia, Maryland, Virginia, and West Virginia. Additionally, as a provider of internationally recognized programs, we also serve children and families from the military as well as many states and countries. Our language services department has interpreters for all languages, an essential service for discharge planning. Our primary goal is to reflect our hospital's core values (compassion, commitment, and connection) as we support families to achieve a timely and safe discharge.

Structure of the Discharge Planning Pediatric Case Managers within the Clinical Resource Department at Children's National Hospital

At Children's National Hospital, discharge planners are embedded in each of our hospital's inpatient care teams. All but one of our discharge planner case managers are RNs, and at an early point in the child's hospitalization we begin to facilitate a positive discharge transition. The motto for all case managers is that discharge planning begins at admission (Bankston-White, & Birmingham, 2015; Heath, Sturdy, & Cheesley, 2010). Along with the inpatient care teams, we are guided by the principles of patient- and family-centered care that helps us maintain a steady focus on positive patient health outcomes while at the same time using only the needed healthcare resources to avoid outcomes such as readmissions.

Our initial documented case management assessment is required for all patients with identified needs and for patients hospitalized for >7 days. Needs are identified during rounding with the medical teams, organized discharge planning huddles, family meetings, and by direct referrals. This assessment focuses on multiple aspects of the social and physical determinants of health described in Healthy People 2020 that impact a wide range of health, functioning, and quality-of-life outcomes (U.S. Department of Health & Human Services, 2021). We confirm the patient's health insurance and guide parents without insurance to the appropriate supportive agencies, including our financial department. We identify potential challenges in language, culture, and the hospitalized child's growth and development as well as strengths of both the child and family and any home care needs. This is the formal starting point of our partnership with the families and patients, during which time we assess what it will require to ensure a safe transition to home.

Considerable development of the case management role has occurred since the 1860s, but role functions and role barriers are incompletely described and few reports focus on pediatric case managers. Here we report the perceptions of healthcare staff of the role of pediatric case managers at one pediatric Magnet hospital. We compare those perceptions with the more known role functions, and we interpret the findings in the context of the sociocultural theory. This theory was selected for the interpretation phase because of its focus on the essential role of social interaction in helping others to make meaning of actions or knowledge, such as a role (in this case, the pediatric case manager) with which they may not be fully familiar (Copple & Bredekamp, 2009; McLeod, 2020; Ross & Smythe, 1995; Vygotsky, 1978).

Methods

Study Design

Using a one-time event approach, we used a single-item question to document the perceptions of the role of pediatric case managers. We administered the single-item question in person to all healthcare staff who were in our hospital's cafeteria during one lunch period on one day during National Case Management Week in 2019. A total of 213 professionals completed the single-item questionnaire. A similar single event approach to document perceptions was previously reported by Fraser (2018). We offered snack options as incentives to encourage staff to complete the single-item question. The completed written responses were placed in a collection box for subsequent analysis. The single-item question was: "What does case management mean to you?" Data were collected and analyzed and then interpreted by our team through the lens of the sociocultural theory. Institutional ethical review was not required for this study.

Using a one-time event approach, we used a single-item question to document the perceptions of the role of pediatric case managers. We administered the single-item question in person to all healthcare staff who were in our hospital's cafeteria during one lunch period on one day during National Case Management Week in 2019.

Data Analysis

A simple grid (Table 1) was used to organize the data resulting from the single-item question. The responses were first qualitatively analyzed for meaning and grouped by similarity of meaning.

Three pediatric RNs from our project team reviewed the responses to the single-item question and achieved consensus with coding for meaning. The grouped meanings were then compared to the definitions of the five themes in the sociocultural theory. The interpreted results were also examined at the level of each clinical care team, and overall summative totals of responses by meaning category and by theory theme were also calculated. Our project team jointly reviewed the categories of meaning and the frequencies of responses aligning with the themes of the theory and reflected on the findings for insights about the staff perceptions of the pediatric case manager role.

Results

A total of 213 surveys were collected, and 27 were not evaluable. A total of 186 responses (87%) were evaluable. The respondents were clustered in four main hospital employee groups: direct patient care (primarily RNs), service staff, administrative staff, and physicians. Only the physicians and RNs self-identified with specific titles on the questionnaire. The responses obtained from the specific departments completing the survey were: 106 (57%) from patient care staff; 25 (13%) from service staff; 37 (20%) from administrative staff, and 18 (10%) from physicians.

Five data groupings for meaning emerged: "Knowing how to put all the pieces together," "Willing to teach and share knowledge," "Helping families navigate chaotic healthcare systems," "Being available and approachable," and "Knowing goals and priorities of the healthcare system." Exemplar quotes are listed in Table 2. In the second step of analysis, interpreting categories of meaning within the context of the sociocultural theory, most comments (n = 112; 60%) and the largest category of meaning ("Knowing how to put all the pieces together") were in alignment with the theory theme of "the more knowledgeable other." The second largest set of responses was the meaning category of "being available and approachable," which aligned conceptually with the theory theme of social interaction (n = 35; 19%). The third meaning category in terms of number of responses was "Helping families navigate chaotic healthcare systems," which aligned with the theory theme of cooperative learning (n = 28; 15%). The fourth category of meaning, "Knowing goals and priorities of the healthcare system," (n = 9; 5%) aligned with the theory theme of Culture, and the fifth category of meaning, "Willing to teach and share knowledge" (2 responses, 1%), aligned conceptually with the theory theme of proximal development. The categories of meaning were then compared with the hospital's job description for the role of pediatric case manager. Matching functions between the two included coordination of care, discharge planning, and involvement in the care of vulnerable patients. Missing from the comparison were functions including assessments of needs, planning for technology to support care beyond discharge, and monitoring postdischarge.

Discussion

Our pediatric care teams consist of behavioral health, critical care, surgical, ambulatory, medical, and medical specialty units. We coordinate the required care for services and supplies based on the patient's insurance and the needs of the family. Our efforts are extensive and not limited to selecting vendors who can provide a variety of services such as central venous catheter care, formula for enteral feedings, ventilator, and other durable medical equipment. Approximately 60 minutes is spent obtaining a prior authorization for transfer or for a single uncomplicated medication. The prior authorization process for medication approval is time consuming, especially for high cost, frequent off-label use, and high toxicity drugs, which are all common in the pediatric population.

Using a single-item questionnaire during a single event, we were able to solicit how the pediatric case manager role at our freestanding pediatric Magnet hospital is perceived by 186 hospital staff. The qualitatively induced five categories of meaning from the item indicated that case managers are viewed as skillful in coordinating essential care services for patients and their families, a perception held by all clinical

TABLE 1 SOCIOCULTURAL THEORY

Department Names		N	Sociocultural Theory				
			The more knowledgeable other	Cooperative learning	Social interactions	The zone of proximal development	Culture
Patient Care							
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	Allergy and immunology	3	2		1		
	Cardiology	8	7		1		
	Case management	11	11				
	Genetics, gastroenterology	7	5	1	1		
	Hematology	2	1	1			
	Infection control	2	2				
	Intensive care/emergency medicine	22	15	3	4		
	Neurology services	23	10	11	2		
	Panda service	2	1	1			
	Psychiatry	3	1		1		1
	Surgical specialty	6	5	1			
	Orthopedic	6	6				
	Telemedicine	1	1				
	Urology/nephrology	5	5				
	Children's clinic	5	3	1	1		
	Subtotal	**106 (57)**	**75 (71)**	**19 (18)**	**11 (10)**	**0**	**1 (>1)**
Service areas							
	Dental	1	1				
	Dietary	5	3				2
	Environmental	4	4				
	Global	3	3				
	Echocardiogram						
	Laboratory medicine	2	1				1
	Language	1			1		
	Molecular diagnosis/radiology	3		2			1
	Pharmacy	4	4				
	Transfusion medicine	2	2				
	Subtotal	**25 (13)**	**18 (72)**	**2 (8)**	**1 (4)**	**0**	**4 (16)**
Administration							
	Admissions and welcome desk	2	1		1		
	Bioengineering	1			1		
	Communications/security	5			4		1
	Executive leadership/regulatory	1				1	
	Facilities/operations	6	4	1			1
	Foundation	4	3	1			
	Human resources	4		1	3		
	Informatics	1			1		
	Professional practice/research	1					1
	Quality and safety	6		4	1		1
	Patient access	2	1		1		
	Patient experience	2	2				
	Child Health Advocacy Institute	1	1				
	Bear Institute	1	1				
	Subtotal	**37 (20)**	**13 (35)**	**7 (19)**	**12 (32)**	**1 (3)**	**4 (11)**
Physicians	**Hospitalists/Residents**						
	Physicians	18	6	0	11	1	
	Subtotal	18 (10)	6 (33)	0	11 (61)	1 (6)	
	Total	**186 (87)**	**112 (60)**	**28 (15)**	**35 (19)**	**2 (1)**	**9 (5)**
	Nonresponses	**27 (13%)**					
	Total	**213**					

TABLE 2 CATEGORIES OF MEANING QUALITATIVELY DERIVED FROM THE SINGLE-ITEM RESPONSES

Meaning Categories	Exemplar Quotes
"Knowing how to put all the pieces together"	"Pulling all of the pieces together and making sure we get paid" "Making sure our families receive the resources they need" "They know what they do" "Coordinates care in the hospital" "Very important to connect with services" "Help us be compliant" "Essential, experienced, and a helping hand"
'Willing to teach and share knowledge"	"The glue that holds the team together" "DCP connects the dots between the Drs, RNs, patient, families, and the caregivers that go into care for the kids/parents" "Always willing to assist with our most vulnerable heart transplant patients"
"Helping families navigate chaotic healthcare systems"	"Sharing your knowledge with others" "Teaching the patient to take care of their needs" "To handle or facilitate something" "Helping the patient and families navigate the chaotic system of healthcare"
"Being available and approachable"	"Everyone is great and friendly" "Someone to lean on when times are hard" "That you are here" "Amazing, dedicated, delightful hard-working helpful people" "Providing compassionate care" "Magically makes things better" "You make the residents' lives, patients' lives, and parents' lives so much better. Thank you for everything you do to take care of all our babies"
"Knowing goals and priorities of the healthcare system"	"Transition of care is integral to our goals" "Holistic nursing" "Coordination of care"

services. Further, pediatric case managers were viewed as generous in sharing information and care strategies that would be needed to ensure a safe transition home, able to guide families through complex healthcare systems, personable and available to address needs, and having a working grasp of patient, family, and hospital priorities when coordinating care.

The five categories of meaning aligned with the five themes of the sociocultural theory. Of special note, by far the largest number of staff responses fit conceptually within the theme of "the more knowledgeable other." This high frequency of responses indicates that the more commonly held perception by staff is that pediatric case managers have a better understanding and higher ability to process discharge

Pediatric case managers were viewed as generous in sharing information and care strategies that would be needed to ensure a safe transition home, able to guide families through complex healthcare systems, personable and available to address needs, and having a working grasp of patient, family, and hospital priorities when coordinating care.

planning for children with complex conditions than do other clinical team members. The frequency of responses in the next four categories of meaning (and four theory themes) indicates that these role functions are less well known or perhaps infrequently observed. Some of these lesser reported functions are initiated and completed by case managers without direct observation from clinical care team members. These lower frequencies may indicate that the case manager completes such functions without reporting them to the clinical care teams. Most especially not reported by healthcare staff is the important role of pediatric case managers and care culture or knowing how to prepare the patient and family for a safe discharge while also avoiding incurring unnecessary healthcare costs. Informed by the patient-centered care model (Filler et al., 2020; McCormack et al., 2011), pediatric case managers are able to practice with the priorities of the child, family, and healthcare system in focus.

Limitations and Strengths of the Project

Certainly, project limitations would be the single item used on a single day and the dependence on the number and type of hospital staff who were in the hospital cafeteria that day. However, invited staff participated readily in the event as evidenced by the participation rate of 87% of staff who responded to the item. The variety of staff who participated is a strength and would not have likely resulted in clinical team sampling. Comparing the qualitatively induced categories of meaning with the theory themes helps to place the findings at a level of meaning that goes beyond a single item and a single event at a single setting.

Conclusion

Hospital staff have positive perceptions about pediatric case managers, including the skill set of these role holders and their personable natures. Certain aspects of the role appear to be unknown to hospital staff; these tend to be the role functions that are done independently by pediatric case managers. Reporting on these functions to clinical care teams may help make these functions more known and further facilitate partnering among pediatric case managers, pediatric patients their families, and clinical care team members.

Relevance to Clinical Practice:

Though not all role functions of pediatric case managers are known to healthcare staff, hospital staff regard the role in a positive light. Case managers likely need to describe their unseen functions to clinical care teams to contribute to a greater shared understanding of their role in treatment pediatric patients. CE II

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Critical Thinking for Care Managers

Thomas J. Blakely, PhD, LMSW

The first objective of this article is to highlight critical thinking as essential in the delivery of care management services. A second objective is to suggest a thinking process that may be useful in service delivery. A major desired outcome of care management is correcting erroneous assumptions about the self and others that often result from experiences of indifference, neglect, or rejection during developmental years. Critical thinking about these issues by both the client and care manager will contribute significantly to successful outcomes of services. Every care manager should demonstrate critical thinking skills and be able to teach clients to think critically and clearly about their problems. They also should understand theories of personality development and neuroscience and be able to teach clients enough about these concepts to aid in the resolution of emotional distress. A care manager who is able to accomplish these skills will help clients achieve more successful adaptation and social functioning.

Literature Review

Glaser wrote that critical thinking is being disposed to thinking about problems in one's experience and having knowledge and skill in the methods of logical inquiry and reasoning (Glaser, 1941). His definition of critical thinking has relevance to care management. There are two elements involved in critical thinking: disposition and internal motivation. "As such, a human disposition is a person's consistent internal motivation to act toward, or to respond to, persons, events or circumstances in habitual, and yet potentially malleable, ways" (Facione, Facione and Giancarlo, 2000). Both need to be developed and encouraged. Scheffer and Rubenfeld generated a list of critical thinking skills and activities for each skill that may be used by a social worker providing psychotherapy. The first skill is analyzing, the mutual discovery by client and clinician of all the parts of the presenting problem by answering the questions who, what, where, why, and when; second, applying a standard, the use of pertinent mental health theory to make a psychosocial diagnosis that also may involve physical health issues; third, discriminating, determining the strengths and weaknesses in a client's developmental history as they are related to the problem and the potential for its resolution; fourth, information seeking or synthesizing what is known so far with the use of evidence-based practice theory for mutual development of a care plan, interventions, and planned outcomes; fifth, logical reasoning, where to begin with the care plan and ordering interventions according to a problem-solving method; sixth, predicting, a decision about behaviors that demonstrate success in problem resolution; seventh, transforming knowledge, an evaluation of the entire process (Scheffer & Rubenfeld, 2000). Watanabe-Crockett (2016) developed a cheat sheet for critical thinking that care managers might find useful. Mathias (2015) wrote a seminal article on the meaning of critical thinking as it is applied to social workers that also could apply to care managers. The aim of his work was to discover patterns of meaning in the way social workers (or care managers) use the term critical thinking. Some social work literature may be useful to care managers. Gambrill (1990) wrote a book about critical thinking that promoted increasing the quality of services. Seelig (1991) wrote about more critical thinking for practice. Gibbs (1991) wrote about scientific reasoning (critical thinking) for social workers.

Most psychosocial problems involve distressed feelings about the self and others. A definition of feelings is that they are an emotional state or reaction, a spontaneous affective response of the mind to external or internal stimuli. Sometimes feelings are rational and other times they are irrational. Rational feelings have a reality base. Irrational feelings often arise from some past internalized emotional experience. A rational emotional response occurs following an interpretation of a behavior. Someone you respect compliments you about doing something well and you feel gratified.

Thomas J. Blakely, PhD, LMSW, *is Emeritus Professor, School of Social Work, Western Michigan University, and a self-employed independent clinical social worker.*

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The opposite is true when someone tells you something negative about yourself. You feel criticized and may get angry and make an erroneous feeling assumption about yourself and others that is stored in the emotional center of the brain (Kolb & Gibb, 2011).

Behavior is influenced by one's feelings and thoughts. Focusing on thinking and feeling and the difference between them and how each affect life decisions is one way to help a client responsibly change inappropriate behavior. According to Erikson (1968), most persons who have mental distress have a history of trauma characterized by indifference, neglect, and rejection in early developmental years and sometimes during adolescence when self-identity is formed. Ellis & Ellis (2014) wrote about irrational feelings. An example is the self-blame feelings a child or adolescent develops resulting from indifference, neglect, or rejection by either or both parents. These are erroneous assumptions that often result in emotional distress that sometimes is diagnosed as a mental illness. When patients are helped by a care manager to involve critical thinking about negative developmental experiences, erroneous assumptions may be corrected. This will result in relief from emotional distress.

Critical thinking about feelings also may generate a realization that whatever problematic feelings one has, even those that are the most negative, resentful, or harmful, the feelings are normative because they are the outcome of experience.

Attachment Theory and Critical Thinking Skills

Attachment theory and the findings of neuroscience research are aids to critical thinking. Attachment theory postulates that inherent in every person is the need to attach to a primary attachment figure (Bowlby, 1983). When the response of a primary attachment figure is characterized by indifference, neglect, or rejection, the theory postulates that this results in an insecure attachment style in which relationships are ambivalent, avoidant, or disorganized. A care manager can teach a client who is disposed to critical thinking about attachment theory so that they can reassess responses to negative emotional experiences and realize that these experiences were not their fault. This can be accomplished through examining the behaviors associated with insecure attachment styles because a client may apply critical thinking to these styles and recognize a need for behavioral change.

Kietaibl (2012) described attachment and its relationship to the working alliance in professional interactions. She proposed that understanding and using knowledge of a client's attachment style would promote the development of a strong working alliance that is essential to positive results. She also wrote about integrating factors about a client's culture into managing deactivation and hyperactivation responses. Deactivation is when a client deliberately avoids a discussion of threatening events or ideas to encourage feelings of independence. Hyperactivation is when a client pays close attention to emotional distress issues to ensure that the care manager is available as an attachment figure.

Interestingly, an attachment to a social worker (or care manager) may provide a pathway to mental health (Mikulincer, Shaver & Berant, 2013). A study by Sroufe, Egeland, Carlson & Collins (2005) revealed that insecurely attached adults could develop a secure style through a supportive adult relationship such as between a client and a care manager. Mallinkrodt, Porter & Kivlighan (2005) expressed the view that this outcome depends on the attachment styles of both the care manager and the client. Mallinkrodt, Gantt, & Coble (1995) developed an instrument to measure the client-care manager relationship that readers may wish to consult.

Knowledge of neuroscience is an aid to critical thinking. Many adult clients have memories of negative and rejecting experiences with one parent or both (Waters, Merrick, Treboux et al, 2000). A common reaction for children who are developing is to wonder what's wrong with them that caused their parents to react negatively or reject them. This negative self-assessment generates a reaction that contributes to an insecure attachment style that is reactivated repeatedly in other relationships. From the perspective of a neurophysiologist, these experiences form neural pathways that are stored in the amygdala, where they will influence behavior and feelings (Young, Klosko & Weishaar, 2003). Critical thinking about these experiences can result in developing new neural pathways that replace the old negative pathways. This change can result in problem resolution and improved

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adaptation and social functioning.

Graham described developmental experience as the priming of synaptic connections through relationships with caretakers. "It is essential to understand experience dependent maturation of the brain to understand the importance of early attachment experiences to shape the brain and our patterns of relating and to embrace the power of new attachment relationships in therapy to re-wire the memories learned with this part of the brain" (Graham, 2008). She also wrote: "The brain is a social organ, developed and changed in interactions with other brains" (Graham, 2008). She added that nurture leads to the formation of synaptic connections influenced by interactions with individuals with whom there is a close relationship. "This means that the very foundations of perception, particularly in regard to relationships, rely on the quality of these earliest interactions with our parents" (Graham, 2008). Grosjean (2005) reviewed advances in neuroscience in relation to the biological mechanisms involved. These observations indicate a connection between attachment theory and neuroscience (Graham, 2008).

An accurate assessment of a client's social functioning should be developed for clients because a behavior change procedure is largely defined by the assessment. Behavior change begins with assessment. A client must be aware of the care manager's assessment before change objectives can be established. The thinking process of context, explanation, and thinking that is described in the following also must be explained in language a client can understand. This process includes critical thinking in the third phase.

A Thinking Process

Critical thinking about feelings will be easier if an organized process is used. One thinking process is based on attachment theory (Bowlby, 1969), rational emotive behavior theory (Ellis & Ellis, 2014) and cognitive theory (Beck, 1995) that has three parts: context, explanation, and thinking.

Context is using attachment theory to remember difficulties with attachment to primary and secondary attachment figures and the development of an attachment style. Explanation is using attachment theory and rational emotive behavior theory to help a client understand why a particular attachment style resulted and is related to assumptions made about the self and others following indifferent, neglectful, or rejecting experiences that formed working models.

Explanation provides a framework for thinking about context so one can rethink and relearn reactions to developmental and environmental experiences.

Thinking follows explanation. Using cognitive therapy thinking about attachment issues and erroneous assumptions will promote a new and more objective perspective about them. Achieving this understanding can bring relief from emotional distress and provide an opportunity for feelings to become secondary to thinking, which will promote normative adaptation and social functioning.

The thinking process may not be appropriate for every client as some may not be disposed to think critically about their feelings. Clients who have a difficult history of parental indifference, neglect, or rejection may have a well-structured system of defenses that would make change difficult. These defenses may occur in the context of a mental illness or character disorder that would have to be ameliorated before a client can become disposed to critical thinking. It is important for the care manager to carefully assess the presence of any active thinking disorder that would make critical thinking inappropriate.

In summary, this critical thinking process begins with context or the gathering of all relevant factors that have contributed to emotional distress. This is followed by explanation for which the objective is to provide a practical and reasoned approach to explain the pathway that led to the development of emotional difficulties. During thinking a client will rethink and relearn using knowledge gleaned during the explanation phase. The objective is to provide a reality orientation to these events so there is relief from negative and dysfunctional behaviors and feelings. All the critical thinking skills and activities are involved in implementing the process.

Summary and Recommendations

This article has recommended that critical thinking skills and a process for thinking be used during care management sessions. For most clients this will mean teaching them about the skills and activities of critical thinking and the basics of the theory of personality development used during initial

Attachment theory and the findings of neuroscience research are aids to critical thinking. Attachment theory postulates that inherent in every person is the need to attach to a primary attachment figure.

sessions. This is an empowering process because the client will feel a sense of involvement in the process as the client and the care manager join together in seeking explanations for the client's emotional distress. As the client gains understanding of critical thinking, and gives evidence of using it, the care manager presents information about the process for thinking. This will provide an organized approach for behavior change. The introductory sessions during which critical thinking and the model for thinking are presented are important in engaging the client in the therapeutic process. The client will come to understand that the partnership with the care manager can have two outcomes. First, it reduces the power effect that clients often perceive in care managers. Secondly, it clarifies the responsibility of the client for behavior change as the care manager is a facilitator of the process but the client makes the change.

The critical thinking skills and activities may be presented within the framework of the process for thinking. The critical skills activities of analyzing, applying standards, and discriminating are appropriate for context. This is the phase of the thinking process when all the information about those developmental events during which a client experienced indifference, neglect, or rejection by primary and/or secondary attachment figures or others occurred. Information seeking and logical reasoning are appropriate for the explanation phase. During this phase, attachment theory (Bowlby, 1983) is used to synthesize facts learned during context to arrive at an explanation for the emotional distress. The client will develop an understanding of the causative nature of developmental experiences and the erroneous assumptions made about self and others that followed.

Predicting and transforming knowledge are appropriate for the thinking phase. During this phase the client and the care manager work together to help the client think realistically about feelings. This will result in relief of anxiousness or depression as the client will come to a new perspective on self and others. Thinking will break the connection between feelings and behavior. The thinking phase concludes with a summary review of what has transpired during the behavior change sessions. A plan for following up on the client's progress should be made. Further sessions may be necessary to review the change process and reinforce the client's gains.

An Example of Successful Use of This Model

Frank, a middle-age married male, is an example of the successful use of this model. As he thought about context he realized his developmental history was difficult. His parents separated when he was very young. His mother was not mentally stable, so even as a child he was her primary support system. His father was an alcoholic who didn't offer a positive relationship. As a teen, Frank got a job and an apartment and functioned fairly well although he felt lonely and continuously had negative thoughts and felt like a failure. He married at age 21 but divorced a few years later. He married again but problems developed because Frank was quite angry with his wife's children. During explanation, Frank saw the connection between his negative feelings and thoughts as self-blame for his parents' failures as attachment figures. His spontaneous negative feelings continued but were diminished. Through thinking about the origin of his feelings he was able to control his reaction to them most of the time; he realized that learned negative self-feelings as a child and blamed himself for perceived failures when neglect and rejection were the real causes. He recognized that his feelings followed his experiences. By thinking he realized the error of his assumption of self-blame, and thus his self-assessment became much more positive. As a result his relationship with his stepchildren also became more positive. Throughout his process of self-examination his wife was very supportive. She reminded him about the importance of thinking about his feelings. She genuinely cared for him. Her secure attachment style helped him to become more secure. Progress continued and his behavior stabilized at a more normative level. CE III

References on page 34

PharmaFacts for Case Managers

Tavneos (avacopan) capsules, for oral use

INDICATIONS AND USAGE

Tavneos is indicated as an adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. Tavneos does not eliminate glucocorticoid use.

DOSAGE AND ADMINISTRATION

Recommended Evaluations Prior to Treatment Initiation

Before initiating Tavneos, consider performing the following evaluations:

- Liver Function Tests: Obtain liver test panel (serum alanine aminotransferase [ALT], aspartate aminotransferase [AST], alkaline phosphatase, and total bilirubin) before initiating Tavneos. Tavneos is not recommended for use in patients with cirrhosis, especially those with severe hepatic impairment (Child-Pugh C).
- Hepatitis B (HBV) Serology: Screen patients for HBV infection by measuring HBsAg and anti-HBc. For patients with evidence of prior or current HBV infection, consult with a physician with expertise in managing hepatitis B regarding monitoring and consideration for HBV antiviral therapy before or during treatment with Tavneos.

Recommended Dosage and Administration

The recommended dose of Tavneos is 30 mg (three 10 mg capsules) twice daily, with food. Advise patients that Tavneos capsules should not be crushed, chewed or opened. If a dose is missed, instruct the patient to wait until the usual scheduled time to take the next regular dose. Instruct the patient not to double the next dose.

Dosage Modifications Due to CYP3A4 Inhibitors

Reduce the dosage of Tavneos to 30 mg once daily when used concomitantly with strong CYP3A4 inhibitors.

DOSAGE FORMS AND STRENGTHS

Capsules: 10 mg, opaque, yellow and light orange with CCX168 printed in black.

CONTRAINDICATIONS

Tavneos is contraindicated in patients with serious hypersensitivity reaction to avacopan or to any of the excipients.

WARNINGS AND PRECAUTIONS

Hepatotoxicity

Serious cases of hepatic injury have been observed in patients taking Tavneos. During controlled trials, the Tavneos treatment group had a higher incidence of transaminase elevations and hepatobiliary events, including serious and life-threatening events.

Obtain liver test panel (serum alanine aminotransferase [ALT], aspartate aminotransferase [AST], alkaline phosphatase, and total bilirubin) before initiating Tavneos, every 4 weeks after start of therapy for the first 6 months of treatment and as clinically indicated thereafter.

If a patient receiving treatment with Tavneos presents with an elevation in ALT or AST to >3 times the upper limit of normal, evaluate promptly and consider pausing treatment as clinically indicated.

If AST or ALT is >5 times the upper limit of normal, or if a patient develops transaminases >3 times the upper limit of normal with elevation of bilirubin to >2 times the upper limit of normal, discontinue Tavneos until Tavneos-induced liver injury is ruled out.

Tavneos is not recommended for patients with active, untreated and/or uncontrolled chronic liver disease (e.g., chronic active hepatitis B, untreated hepatitis C, uncontrolled autoimmune hepatitis) and cirrhosis. Consider the risk and benefit before administering this drug to a patient with liver disease. Monitor patients closely for hepatic adverse reactions.

Hypersensitivity Reactions

Tavneos may cause angioedema. In clinical trials, two cases of angioedema occurred, including one serious event requiring hospitalization. If angioedema occurs, discontinue Tavneos immediately, provide appropriate therapy, and monitor for airway compromise. Tavneos must not be readministered unless another cause has been established.

Educate patients on recognizing the signs and symptoms of a hypersensitivity reaction and to seek immediate medical care should they develop.

Hepatitis B Virus (HBV) Reactivation

Hepatitis B virus (HBV) reactivation, including life threatening hepatitis B, was observed in the clinical program.

HBV reactivation is defined as an abrupt increase in HBV replication, manifesting as a rapid increase in serum HBV DNA levels or detection of HBsAg, in a person who was previously HBsAg negative and anti-HBc positive. Reactivation of HBV replication is often followed by hepatitis, i.e., increase in transaminase levels. In severe cases, increase in bilirubin levels, liver failure, and death can occur.

Screen patients for HBV infection by measuring HBsAg and anti-HBc before initiating treatment with Tavneos. For patients who show evidence of prior hepatitis B infection (HBsAg positive [regardless of antibody status] or HBsAg negative but anti-HBc positive), consult with physicians with expertise in managing hepatitis B regarding monitoring and consideration for HBV antiviral therapy before and/or during Tavneos treatment.

Monitor patients with evidence of current or prior HBV infection for clinical and laboratory signs of hepatitis or HBV reactivation during and for six months following Tavneos therapy.

In patients who develop reactivation of HBV while on Tavneos, immediately discontinue Tavneos and any concomitant therapy associated with HBV reactivation and institute appropriate treatment. Insufficient data exist regarding the safety of resuming Tavneos treatment in patients who develop HBV reactivation. Resumption of Tavneos treatment in patients whose HBV reactivation resolves should be discussed with physicians with expertise in managing HBV.

Serious Infections

Serious infections, including fatal infections, have been reported in patients receiving Tavneos. The most common serious infections reported in the Tavneos group were pneumonia and urinary tract infections.

Avoid use of Tavneos in patients with an active, serious infection, including localized infections. Consider the risks and benefits of treatment prior to initiating Tavneos in patients:

- with chronic or recurrent infection
- who have been exposed to tuberculosis
- with a history of a serious or an opportunistic infection
- who have resided or traveled in areas of endemic tuberculosis or endemic mycoses; or
- with underlying conditions that may predispose them to infection.

Closely monitor patients for the development of signs and symptoms of infection during and after treatment with Tavneos. Interrupt Tavneos if a patient develops a serious or opportunistic infection. A patient who develops a new infection during treatment with Tavneos should undergo prompt and complete diagnostic testing appropriate for an immunocompromised patient; appropriate antimicrobial therapy should be initiated, the patient should be closely monitored, and Tavneos should be interrupted if the patient is not responding to antimicrobial therapy. Tavneos may be resumed once the infection is controlled.

ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail above:

- Hepatotoxicity
- Hypersensitivity reactions
- Hepatitis B virus (HBV) reactivation
- Serious infections

Other adverse reactions reported in clinical trials included: fatigue, upper abdominal pain, dizziness, blood creatinine increase, and paresthesia.

DRUG INTERACTIONS

CYP3A4 Inducers

Avacopan exposure is decreased when coadministered with strong CYP3A4 enzyme inducers such as rifampin. Avoid coadministration of strong and moderate CYP3A4 inducers with Tavneos.

CYP3A4 Inhibitors

Avacopan exposure is increased when coadministered with strong CYP3A4 enzyme inhibitors such as itraconazole. Administer Tavneos 30 mg once daily when coadministered with strong CYP3A4 inhibitors.

CYP3A4 Substrates

Avacopan is a CYP3A4 inhibitor. Closely monitor patients for adverse reactions and consider dose reduction of sensitive CYP3A4 substrates with a narrow therapeutic window when coadministered with Tavneos.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no adequate and well-controlled studies with Tavneos in pregnant women to inform a drug-associated risk. In animal reproduction studies, oral administration of avacopan to pregnant hamsters and rabbits during the period of organogenesis produced no evidence of fetal harm with exposures up to approximately 5 and 0.6 times, respectively, the exposure at the maximum recommended human dose (MRHD) of 30 mg twice daily (on an area

under the curve [AUC] basis). Avacopan caused an increase in the number of abortions in rabbits at an exposure 0.6 times the MRHD.

The background risk of major birth defects and miscarriage for the indicated population are 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.

Lactation

Risk Summary

There are no available data on the effects of avacopan on the breastfed child or on milk production. It is unknown whether avacopan is secreted in human milk. Avacopan was detected in the plasma of undosed hamster pups nursing from drug-treated dams. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Tavneos and any potential adverse effects on the breastfed infant from Tavneos or from the underlying maternal condition.

Pediatric Use

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

Geriatric Use

Of the 86 geriatric patients who received Tavneos in the phase 3 randomized clinical trial for ANCA-associated vasculitis, 62 patients were between 65–74 years and 24 were 75 years or older. No overall differences in safety or effectiveness were observed between geriatric patients and younger patients.

Patients with Renal Impairment

No dose adjustment is required for patients with mild, moderate, or severe renal impairment. Tavneos has not been studied in patients with ANCA-associated vasculitis who are on dialysis.

Patients with Hepatic Impairment

No dosage adjustment is recommended for patients with mild or moderate (as indicated by the Child-Pugh method) hepatic impairment. Tavneos has not been studied in patients with severe hepatic impairment (Child-Pugh Class C).

CLINICAL STUDIES

The efficacy and safety of Tavneos was evaluated in a double-blind, active-controlled, phase 3 clinical trial (NCT02994927) in 330 patients with newly diagnosed or relapsed ANCA-associated vasculitis who were randomized 1:1 to one of the following treatment groups:

- Tavneos group (N=166): Patients received 30 mg avacopan twice daily for 52 weeks plus prednisone-matching placebo for 20 weeks
- Prednisone group (N=164): Patients received avacopan-matched placebo twice daily for 52 weeks plus prednisone (tapered from 60 mg/day to 0 over 20 weeks)

All patients in both groups received one of the following standard immunosuppressive regimens:

- IV cyclophosphamide 15 mg/kg IV up to 1.2 g maximum every 2 to 3 weeks for 13 weeks followed by oral azathioprine 1 mg/kg/day with titration up to 2 mg/kg/day (or mycophenolate mofetil at a target dose of 2 g/day if azathioprine was contraindicated) from Week 15 onwards
- Oral cyclophosphamide 2 mg/kg/day (maximum 200 mg/day) for 14 weeks followed by azathioprine 1 mg/kg/day with titration up to 2 mg/kg/day (or mycophenolate mofetil at a target dose of 2 g/day if azathioprine was contraindicated) from Week 15 onwards
- IV rituximab 375 mg/m2 once weekly for 4 weeks without azathioprine or mycophenolate mofetil

Glucocorticoids were allowed as premedication for rituximab to reduce hypersensitivity reactions, taper after glucocorticoids given during the screening period, treatment of persistent vasculitis, worsening of vasculitis, or relapses, as well as for nonvasculitis reasons such as adrenal insufficiency.

Randomization was stratified based on 3 factors: newly diagnosed or relapsing ANCA-associated vasculitis, proteinase 3 positive or myeloperoxidase positive ANCA-associated vasculitis, and standard immunosuppressive regimen. The primary endpoints of the study were disease remission at Week 26 and sustained disease remission at Week 52. Disease remission was defined as achieving a Birmingham Vasculitis Activity Score (BVAS) of 0 and no use of glucocorticoids for treatment of ANCA-associated vasculitis from Week 22 to Week 26.

Sustained remission was defined as remission at Week 26 and remission at Week 52, without relapse between Week 26 and Week 52. Remission at Week 52 was defined as BVAS of 0 and no use of glucocorticoids for treatment of ANCA-associated vasculitis from Week 48 to Week 52. Relapse was defined as occurrence of one major item, at least 3 non-major items, or 1 or 2 non-major items for at least 2 consecutive visits on the BVAS after remission (BVAS of 0) had been achieved.

The two treatment groups were well balanced regarding baseline demographics and disease characteristics of patients in this trial. The mean patient age was 60.9 years. Most patients were male (56.4%), Caucasian (84.2%), and had newly diagnosed disease (69.4%). Patients had either GPA (54.8%) or MPA (45.2%) and had presence of anti-PR3 (43.0%) or anti-MPO (57.0%) antibodies. Mean baseline BVAS was 16.2; patients most commonly had manifestations within the renal component (81.2%), general component

(68.2%), ear/nose/throat component (43.6%), and chest component (43.0%). Approximately 65% of patients received rituximab, 31% received IV cyclophosphamide, and 4% received oral cyclophosphamide.

Remission at Week 26 and Sustained Remission at Week 52
Remission was achieved by 72.3% of patients in the Tavneos group and 70.1% of patients in the prednisone group at Week 26 (treatment difference: 3.4%, 95% CI [-6.0%, 12.8%]). At Week 52, a significantly higher percentage of patients had sustained remission in Tavneos group (65.7%) compared to the prednisone group (54.9%).

In prespecified subgroup efficacy analyses, sustained remission at 52 weeks in patients was examined based on stratification factors and GPA/MPA disease.

HOW SUPPLIED/STORAGE AND HANDLING
Tavneos (avacopan) capsule is supplied as a 10 mg, hard, opaque yellow and light orange capsule with "CCX168" printed in black.

Bottle containing 180 capsules with child resistant induction seal closure (NDC 73556-168-01)

Bottle containing 30 capsules with child resistant induction seal closure (NDC 73556-168-02)

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).

Do not use if seal is broken or missing.

Tavneos is manufactured for ChemoCentryx by Thermo Fisher Scientific.

For full prescribing information, please read the Product Insert.

New Indications and Dosage Forms

***Dyanavel XR* (amphetamine) Extended-Release Oral Suspension and Extended-Release Tablets**
New Dosage Form Approved: November 4, 2021
Date of Original Approval: October 19, 2015

Dyanavel XR (amphetamine) is an extended-release central nervous system (CNS) stimulant for the treatment of attention deficit hyperactivity disorder (ADHD).

- FDA approval of Dyanavel XR (amphetamine) once-daily extended-release oral tablets, CII, for ADHD

***Dupixent* (dupilumab) Injection**
Patient Population Altered: October 20, 2021
Date of Original Approval: March 28, 2017

Dupixent (dupilumab) is an interleukin-4 receptor alpha antagonist used for the treatment of atopic dermatitis, asthma, and chronic rhinosinusitis with nasal polyposis (CRSwNP).

- FDA expands approval of Dupixent (dupilumab) to include children aged 6 to 11 years with moderate-to-severe asthma

***Cyltezo* (adalimumab-adbm) Injection**
Labeling Revision Approved: October 15, 2021
Date of Original Approval: August 25, 2017

Cyltezo (adalimumab-adbm) is an anti-TNF-alpha monoclonal antibody biosimilar to Humira, approved for the treatment of various inflammatory diseases including rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, and plaque psoriasis.

- FDA approves Cyltezo (adalimumab-adbm) as first interchangeable biosimilar with Humira

***Verzenio* (abemaciclib) Tablets**
New Indication Approved: October 13, 2021
Date of Original Approval: September 28, 2017

Verzenio (abemaciclib) is a selective ATP-competitive inhibitor of cyclin dependent kinases (CDK) 4 and 6 indicated for the treatment of patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer.

- FDA approves Verzenio (abemaciclib) as the first and only cdk4/6 inhibitor for certain people with HR+ HER2- high risk early breast cancer

***Keytruda* (pembrolizumab) for Injection**
New Indication Approved: October 13, 2021
Date of Original Approval: September 4, 2014

Keytruda (pembrolizumab) is a human PD-1 (programmed death receptor-1)-blocking antibody indicated for the treatment of melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer, microsatellite instability-high or mismatch repair deficient colorectal cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high (TMB-H) cancer, cutaneous squamous cell carcinoma, and triple-negative breast cancer.

- FDA approves Merck's Keytruda (pembrolizumab) plus chemotherapy, with or without bevacizumab, as treatment for patients with persistent, recurrent or metastatic cervical cancer whose tumors express PD-L1 (CPS ≥1)

***Biktarvy* (bictegravir, emtricitabine and tenofovir alafenamide) Tablets**
Patient Population Altered: October 7, 2021
Date of Original Approval: February 7, 2018

Biktarvy (bictegravir, emtricitabine and tenofovir alafenamide) is a combination of an integrase strand transfer

continues on page 37

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.

Int J Infect Dis. 2021 Oct 12;S1201-9712(21)00798-0.

The effect of melatonin on thrombosis, sepsis and mortality rate in COVID-19 patients

Hasan ZT, Al Atrakji MQYMA, Mehuaiden AK, et al.

The purpose of this study is to determine the effect of melatonin on thrombosis, sepsis, and mortality rate in adult patients with severe coronavirus infection (COVID-19).

METHODS: This single-center, prospective, randomized clinical trial was conducted from 1 December 2020 to 1 June 2021 at Al-Shifaa hospital in Mosul, Iraq. There were 158 patients with severe COVID-19 included in the study, 82 in the melatonin group (who received 10 mg melatonin in addition to standard therapeutic care), and 76 in the control group (given standard therapeutic care only). Patients were chosen by blocked randomization design. The physician then evaluated and recorded the incidence of thrombosis, sepsis, and mortality rate on days 5, 11, and 17 of symptoms.

RESULTS: The intervention group consisted of 82 patients, while the control group consisted of 76 patients. In comparison to the control group, thrombosis and sepsis developed significantly less frequently ($P < 0.05$) in the melatonin group during the second week of infection, while mortality was significantly higher in the control group ($P < 0.05$).

CONCLUSIONS: Adjuvant use of melatonin may help reduce thrombosis, sepsis, and mortality in COVID-19 patients.

AIDS Res Hum Retroviruses. 2021 Oct 15.

Predictive value of HIV-related versus traditional risk factors for coronary atherosclerosis in people aging with HIV

Pereira B, Mazzitelli M, Milinkovic A, et al.

BACKGROUND: Cardiovascular disease (CVD) is an important cause of morbidity in people living with HIV (PLWH). We compared the predictive value of HIV-related and traditional CVD risk factors to assess which factors best predict the presence of subclinical coronary atherosclerosis in PLWH.

METHODS: Cross-sectional study in PLWH over 50 years of age who performed CT coronary artery calcium (CAC) scoring between 2009-2019 at Chelsea and Westminster Hospital. The following outcomes were analyzed: CAC=0 (no calcification), CAC >0 (any calcification), CAC >100 (moderate calcification) and CAC >400 (severe calcification). Univariate and multivariate logistic regression analyses were performed to assess predictors of coronary calcification.

RESULTS: A total of 744 patients were included (mean age 56 ± 5.7 years, 94.8% male, 84% white). A CAC >0 was found in 392 (52.7%), CAC >100 in 90 (12.1%) and CAC >400 in 42 (5.6%) subjects. CAC >100 was strongly associated with hypertension [odds ratio OR: 2.91, (95% confidence interval CI: 1.93-4.36), $P < 0.001$], dyslipidemia [2.71 (1.81-4.06), $P < 0.001$] and diabetes [2.53 (1.29-4.96), $P = 0.01$]. Regarding HIV-specific factors, a significant association was found with exposure (> 6 years) to protease inhibitors [1.67 (1.06-2.61), $P = 0.05$] whereas exposure to tenofovir (> 8 years) was negatively associated with CAC >100 [0.54 (0.30-0.98), $P = 0.05$]. Despite the high prevalence of hypertension (45.4%), only 21.5% were on anti-hypertensives whereas only 29.2% of eligible candidates were receiving lipid lowering drugs for primary prevention of CVD.

CONCLUSIONS: Traditional cardio-metabolic risk factors remain the strongest predictors of coronary atherosclerosis in PLWH as in the general population. These results underscore the importance of optimizing treatment of hypertension and promoting primary prevention strategies that may be underused in PLWH.

Clin Infect Dis. 2021 Oct 5;73(7):e1927-e1935.

Cost-effectiveness of frequent HIV screening among high-risk young men who have sex with men in the United States

Neilan AM, Bulteel AJB, Hosek SG, et al.

BACKGROUND: Of new HIV infections in the US, 20% occur among young men who have sex with men (YMSM, ages 13-24), but >50% of YMSM with HIV are unaware of their status. Using Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) data, we projected the clinical benefit and cost-effectiveness of frequent HIV screening among high-risk YMSM from age 15.

METHODS: Using a mathematical simulation, we examined 3 screening strategies: Yearly, 6-monthly, and 3-monthly, each in addition to the Status quo (SQ, 0.7-10.3% screened/year, stratified by age). We used published data (YMSM-specific when available) including: HIV incidences (0.91-6.41/100PY); screen acceptance (80%), linkage-to-care/antiretroviral therapy (ART) initiation (76%), HIV transmission (0.3-86.1/100PY, by HIV RNA), monthly ART costs ($2290-$3780), and HIV per-screen costs ($38). Projected outcomes included CD4 count at diagnosis, primary HIV transmissions from ages 15-30, quality-adjusted life expectancy, costs, and incremental cost-effectiveness ratios (ICERs, $/quality-adjusted life-year saved [QALY]; threshold ≤$100 000/QALY).

RESULTS: Compared to SQ, all strategies increased projected CD4 at diagnosis (296 to 477-515 cells/μL) and quality-adjusted life expectancy from age 15 (44.4 to 48.3-48.7 years) among YMSM acquiring HIV. Compared to SQ, all strategies increased discounted lifetime cost for the entire population ($170 800 to $178 100-$185 000/person). Screening 3-monthly was cost-effective (ICER: $4500/QALY) compared to SQ and reduced primary transmissions through age 30 by 40%. Results were most sensitive to transmission rates; excluding the impact of transmissions, screening Yearly was ≤$100 000/QALY (ICER: $70 900/QALY).

CONCLUSIONS: For high-risk YMSM in the US, HIV screening 3-monthly compared to less frequent screening will improve clinical outcomes and be cost-effective.

J Virol. 2021 Oct 20;JVI0106321.

Functional effects of cardiomyocyte injury in COVID-19

Siddiq MF, Chan AT, Miorin L, et al.

COVID-19 affects multiple organs. Clinical data from the Mount Sinai Health System shows that substantial numbers of COVID-19 patients without prior heart disease develop cardiac dysfunction. How COVID-19 patients develop cardiac disease is not known. We integrated cell biological and physiological analyses of human cardiomyocytes differentiated from human induced pluripotent stem cells (hiPSCs) infected with SARS-CoV-2 in the presence of interleukins, with clinical findings related to laboratory values in COVID-19 patients, to identify plausible mechanisms of cardiac disease in COVID-19 patients. We infected hiPSC-derived cardiomyocytes, from healthy human subjects, with SARS-CoV-2 in the absence and presence of IL-6 and IL-1β. Infection resulted in increased numbers of multinucleated cells. Interleukin treatment and infection resulted in disorganization of myofibrils, extracellular release of troponin-I, and reduced and erratic beating. Infection resulted in decreased expression of mRNA encoding key proteins of the cardiomyocyte contractile apparatus. Although interleukins did not increase the extent of infection, they increased the contractile dysfunction associated with viral infection of cardiomyocytes resulting in cessation of beating. Clinical data from hospitalized patients from the Mount Sinai Health System show that a significant portion of COVID-19 patients without prior history of heart disease, have elevated troponin and interleukin levels. A substantial subset of these patients showed reduced left ventricular function by echocardiography. Our laboratory observations, combined with the clinical data, indicate that direct effects on cardiomyocytes by interleukins and SARS-CoV-2 infection might underlie heart disease in COVID-19 patients. SARS-CoV-2 infects multiple organs including the heart. Analyses of hospitalized patients show that a substantial number without prior indication of heart disease or comorbidities show significant injury to heart tissue assessed by increased levels of troponin in blood. We studied the cell biological and physiological effects of virus infection of healthy human iPSC cardiomyocytes in culture. Virus infection with interleukins disorganizes myofibrils, increases cell size and the numbers of multinucleated cells, suppresses the expression of proteins of the contractile apparatus. Viral infection of cardiomyocytes in culture triggers release of troponin similar to elevation in levels of COVID-19 patients with heart disease. Viral infection in the presence of interleukins slows down and desynchronizes the beating of cardiomyocytes in culture. The cell level physiological changes are similar to decreases in left ventricular ejection seen in imaging of patients' hearts. These observations suggest that direct injury to heart tissue by virus can be one underlying cause of heart disease in COVID-19.

Circ Cardiovasc Qual Outcomes. 2021 Apr;14(4):e006769.

Estimating long-term health utility scores and expenditures for cardiovascular disease from the Medical Expenditure Panel Survey

Morey JR, Jiang S, Klein S, et al.

BACKGROUND: Long-term health utility scores and costs used in cost-effectiveness analyses of cardiovascular disease prevention and management can be inconsistent, outdated, or invalid for the diverse population of the United States. Our aim was to develop a user friendly, standardized, publicly available code and catalog to derive more valid long-term values for health utility and expenditures following cardiovascular disease events.

METHODS: Individual-level Short Form-12 version 2 health-related quality of life and expenditure data were obtained from the pooled 2011 to 2016 Medical Expenditure Panel Surveys. We developed code using the R programming language to estimate preference-weighted Short Form-6D utility scores from the Short Form-12 for quality-adjusted life year calculations and predict annual health care expenditures. Result predictors included cardiovascular disease

diagnosis (myocardial infarction, ischemic stroke, heart failure, cardiac dysrhythmias, angina pectoris, and peripheral artery disease), sociodemographic factors, and comorbidity variables.

RESULTS: The cardiovascular disease diagnoses with the lowest utility scores were heart failure (0.635 [95% CI, 0.615-0.655]), angina pectoris (0.649 [95% CI, 0.630-0.667]), and ischemic stroke (0.649 [95% CI, 0.635-0.663]). The highest annual expenditures were for heart failure ($20 764 [95% CI, $17 500-$24 027]), angina pectoris ($18 428 [95% CI, $16 102-$20 754]), and ischemic stroke ($16 925 [95% CI, $15 672-$20 616]). Conclusions: The developed code and catalog may improve the quality and comparability of cost-effectiveness analyses by providing standardized methods for extracting long-term health utility scores and expenditures from Medical Expenditure Panel Survey data, which are more current and representative of the US population than previous sources.

Transplant Proc. Jul-Aug 2021;53(6):1981-1988.

Risk prediction model for basal cell carcinoma in cardiac allograft recipients

Nair N, Hu Z, Du D, et al.

BACKGROUND: Basal cell carcinoma (BCC) is the second most common skin cancers in posttransplant patients. Long-term immunosuppression predisposes the patients to higher risk. This study was undertaken to develop a risk prediction model using the United Network for Organ Sharing (UNOS) database.

MATERIALS AND METHODS: Heart transplant recipients (2000-2015) from the UNOS database were analyzed. The Cox proportional hazards model was applied to screen the predictors associated with the development of BCC. Stepwise forward selection with Akaike information criterion was done to obtain the multivariate model. Area under the curve was derived from the receiver operating characteristics curve to assess the quality of the prediction model. A risk scoring system was developed to stratify patients into different risk groups, and the occurrence rates of posttransplant BCC among different groups were compared.

RESULTS: There were 24,374 patients who received heart transplantation within this study period, and 1211 recipients have been reported with BCC. The multivariate model provides area under the curves at 5, 8, and 10 years posttransplant of 0.77, 0.76, and 0.76, respectively, in the derivation set and 0.75, 0.74, and 0.74, respectively, in the validation set. The predicted and observed probabilities of developing BCC in 5 years agree well across different risk groups. Kaplan-Meier survival curves were generated, which demonstrate significant differences between subjects in different risk groups.

CONCLUSION: A risk prediction model has been generated for the first time for BCC with a c-statistic of ≥0.74 in both derivation and validation sets, making it a good tool for risk stratification.

Circ Cardiovasc Qual Outcomes. 2021 May;14(5):e007015.

Text message medication adherence reminders automated and delivered at scale across two institutions: testing the nudge system: pilot study

Luong P, Glorioso TJ, Grunwald GK, et al.

BACKGROUND: Medication refill behavior in patients with cardiovascular diseases is suboptimal. Brief behavioral interventions called Nudges may impact medication refill behavior and can be delivered at scale to patients using text messaging.

METHODS: Patients who were prescribed and filled at least one medication for hypertension, hyperlipidemia, diabetes, atrial fibrillation, and coronary artery disease were identified for the pilot study. Patients eligible for the pilot (N=400) were enrolled with an opportunity to opt out. In phase I of the pilot, we tested text message delivery to 60 patients. In phase II, we tested intervention feasibility by identifying those with refill gap of ≥7 days and randomized them to intervention or control arms. Patients were texted Nudges and assessed whether they refilled their medications.

RESULTS: Of 400 patients sent study invitations, 56 (14%) opted out. In phase I, we successfully delivered text messages to 58 of 60 patients and captured patient responses via text. In phase II, 207 of 286 (72.4%) patients had a medication gap ≥7 days for one or more cardiovascular medications and were randomized to intervention or control. Enrolled patients averaged 61.7 years old, were primarily male (69.1%) and White (72.5%) with hypertension being the most prevalent qualifying condition (78.7%). There was a trend towards intervention patients being more likely to refill at least 1 gapping medication (30.6% versus 18.0%; P=0.12) and all gapping medications (17.8% versus 10.0%; P=0.27).

CONCLUSIONS: It is possible to set up automated processes within health care delivery systems to identify patients with gaps in medication adherence and send Nudges to facilitate medication refills. Text message Nudges could potentially be a feasible and effective method to facilitate medication refills. A large multi-site randomized trial to determine the impact of text-based Nudges on overall CVD morbidity and mortality is now underway to explore this further.

Cardiorenal Med. 2021;11(2):109-118.

Right ventricular dysfunction and adverse outcomes after renal transplantation

Joseph MS, Tinney F, Naik A, et al.

INTRODUCTION: Pulmonary hypertension is common among patients with end-stage renal disease, although data regarding the impact of right ventricular (RV) failure on postoperative outcomes remain limited. We hypothesized that echocardiographic findings

of RV dilation and dysfunction are associated with adverse clinical outcomes after renal transplant.

METHODS: A retrospective review of adult renal transplant recipients at a single institution from January 2008 to June 2010 was conducted. Patients with transthoracic echocardiograms (TTEs) within 1 year leading up to transplant were included. The primary end point was a composite of delayed graft function, graft failure, and all-cause mortality.

RESULTS: Eighty patients were included. Mean follow-up time was 9.4 ± 0.8 years. Eight patients (100%) with qualitative RV dysfunction met the primary end point, while 39/65 patients (60.0%) without RV dysfunction met the end point (p = 0.026). Qualitative RV dilation was associated with a significantly shorter time to all-cause graft failure (p = 0.03) and death (p = 0.048). RV systolic pressure was not measurable in 45/80 patients (56%) and was not associated with outcomes in the remaining patients.

CONCLUSION: RV dilation and dysfunction are associated with adverse outcomes after renal transplant. TTE assessment of RV size and function should be a standard part of the pre-kidney transplant cardiovascular risk assessment.

J Vasc Surg Venous Lymphat Disord. 2021 Oct 9;S2213-333X(21)00507-2.

Risk factors for venous thromboembolism after vascular surgery and implications for chemoprophylaxis strategies

Matthay ZA, Flanagan CP, Sanders K, et al.

OBJECTIVE: Venous thromboembolism (VTE) is an important cause of postoperative morbidity and mortality, but the reported incidence after major vascular surgery ranges from as low as 1% to upwards of 10%. Further, little is known about optimal chemoprophylaxis regimens or rates of post-discharge VTE in this population. This study aimed to better characterize in-hospital and post-discharge VTE after major vascular surgery, the role of chemoprophylaxis timing, and the association of VTE with mortality.

METHODS: A single center retrospective study of 1,449 major vascular operations (2013-2020) was performed, and included 189 EVARs (13%), 169 TEVARs (12%), 318 open aortic operations (22%), 640 lower extremity bypasses (44%), and 133 femoral endarterectomies (9%). Baseline characteristics, anticoagulant/antiplatelet medications, and outcomes were abstracted from an electronic data warehouse with medical chart auditing. Post-operative VTE (pulmonary embolism [PE] and deep vein thrombosis [DVT]) within 90-days of surgery was classified based on location, symptoms, and treatment. Cut point analysis using Youden's index identified the most VTE discriminating timing of chemoprophylaxis (including therapeutic/prophylactic anticoagulant and antiplatelet medications) and Caprini score. Multivariable logistic regression tested the association of VTE with chemoprophylaxis timing, Caprini score, and additional risk factors. Cox proportional hazard modeling measured the association between VTE and mortality.

RESULTS: Overall VTE incidence was 3.4% (65% DVTs, 25% PEs, 10% both) and 37% were post-discharge. The rate of symptomatic VTE was 2.4%, which was lowest for EVAR (0.0%) and highest for open aortic operations (4.1%, p=0.02). Individuals who developed VTE had longer length of stay, higher rates of end-stage renal disease, prior VTE, and higher Caprini scores (8 vs 5 points) (all p<0.01). Individuals who developed VTE were also more likely to receive >2 units of blood postoperatively, have an unplanned return to the operating room, have delayed chemoprophylaxis/anticoagulation/antiplatelet initiation >4 days postoperatively, and had increased 90-day mortality (all p<0.01). Caprini score >7 (29% of patients) was associated with post-discharge VTE (2.6% vs 0.7%, p=0.01), and chemoprophylaxis/anticoagulation/antiplatelet timing >4 days was associated with increased adjusted odds of VTE (odds ratio 2.4 [1.1-4.9]). Although no fatal VTEs were identified, VTE was an independent predictor of 90-day mortality (adjusted hazard ratio 2.7 [1.3-5.9]).

CONCLUSIONS: These data highlight that patients undergoing major vascular surgery are particularly prone to VTE with frequent hypercoagulable comorbidities and earlier initiation of chemoprophylaxis is associated with reduced risk of development of VTE. Furthermore, post-discharge VTE rates may reach thresholds warranting post-discharge chemoprophylaxis, particularly for patients with Caprini scores >7.

Am J Surg. 2021 Oct 15;S0002-9610(21)00614-0.

The impact of social determinants of health on management of stage I non-small cell lung cancer

Namburi N, Timsina L, Ninad N, et al.

BACKGROUND: Social Determinants of Health (SDOH) can be important contributors in health care outcomes. We hypothesized that certain SDOH independently impact the management and outcomes of stage I Non-Small Cell Lung Cancer (NSCLC).

STUDY DESIGN: Patients with clinical stage I NSCLC were identified from the National Cancer Database. The impact of SDOH factors on utilization of surgery, perioperative outcomes and overall survival were examined, both in bivariate and multivariable analyses.

RESULTS: A total of 236,140 patients were identified. In multivariate analysis, SDOH marginalization were associated with less frequent use of surgery, lower 5-year survival and, in surgical patients, more frequent use of open surgery and lower 90-day postoperative survival.

CONCLUSION: SDOH disparities have a significant impact

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Professional Case Management's Contribution Toward the National Quality Strategy *continued from page 15*

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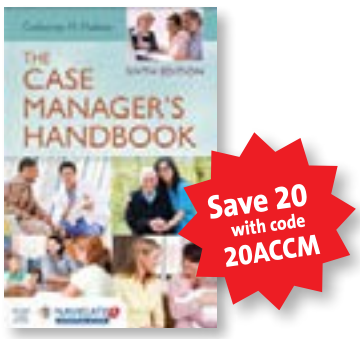

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inhibitor (bictegravir) and two HIV-1 nucleoside analog reverse transcriptase inhibitors (emtricitabine and tenofovir alafenamide) used for the treatment of HIV-1 infection.

- FDA approves expanded indication of Gilead's Biktarvy for treatment of HIV-1 in pediatric populations

***Repatha* (evolocumab) Injection**

Patient Population Altered: September 24, 2021
Date of Original Approval: August 27, 2015

Repatha (evolocumab) is a monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9) used for the treatment of familial hypercholesterolemia (heterozygous and homozygous), and to reduce the risk of adverse cardiovascular events in adults with established cardiovascular disease (CVD).

- FDA approves Repatha (evolocumab) in pediatric patients age 10 and older with heterozygous familial hypercholesterolemia

***Jakafi* (ruxolitinib) Tablets**

New Indication Approved: September 22, 2021
Date of Original Approval: November 16, 2011

Jakafi (ruxolitinib) is a Janus kinase (JAK) inhibitor used for the treatment of myelofibrosis, polycythemia vera, and graft-versus-host disease.

- FDA approves Jakafi (ruxolitinib) for treatment of chronic graft-versus-host disease (GVHD)

***Cabometyx* (cabozantinib) Tablets**

New Indication Approved: September 17, 2021
Date of Original Approval: April 25, 2016

Cabometyx (cabozantinib) is a tyrosine kinase inhibitor used for the treatment of advanced renal cell carcinoma (RCC), hepatocellular carcinoma (HCC), and differentiated thyroid cancer (DTC).

- FDA approves Cabometyx (cabozantinib) for patients with previously treated radioactive iodine-refractory differentiated thyroid cancer

***Briviact* (brivaracetam)**

Patient Population Altered: August 30, 2021
Date of Original Approval: February 19, 2016

Briviact (brivaracetam) is a selective, high-affinity synaptic vesicle protein 2A ligand and analog of levetiracetam indicated for the treatment of partial-onset seizures in patients with epilepsy.

- FDA-approved to treat partial-onset seizures in pediatric patients one month of age and older

LitScan for Case Managers

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in the management and outcomes of stage I NSCL C. We identified SDOH patient groups particularly impacted by such disparities, in which higher utilization of surgery and minimally invasive approaches may lead to improved outcomes.

J Hepatol. 2021 Oct 13;S0168-8278(21)02111-5.

A genetic risk score and diabetes predict development of alcohol-related cirrhosis in drinkers

Whitfield JB, Schwantes-An T-H, Darlay R, et al.

BACKGROUND & AIMS: Only a minority of excess alcohol drinkers develop cirrhosis. We developed and evaluated risk stratification scores to identify those at highest risk.

METHODS: Three cohorts (GenomALC-1: n=1690, GenomALC-2: n=3037, UK Biobank: relevant n=6898) with a history of heavy alcohol consumption (≥80 g/day (men), ≥50 g/day (women), for ≥10 years) were included. Cases were participants with alcohol-related cirrhosis. Controls had a history of similar alcohol consumption but no evidence of liver disease. Risk scores were computed from up to eight genetic loci identified previously as associated with alcohol-related cirrhosis and three clinical risk factors. Score performance for the stratification of alcohol-related cirrhosis risk was assessed and compared across the alcohol-related liver disease spectrum, including hepatocellular carcinoma (HCC).

RESULTS: A combination of three single nucleotide polymorphisms (SNPs) (PNPLA3:rs738409, SUGP1-TM6SF2:rs10401969, HSD17B13:rs6834314) and diabetes status best discriminated for cirrhosis risk. The odds ratio (OR) and 95% confidence intervals (CI) for the extreme score quintiles (Q1-Q5) of the 3-SNP score, based on independent allelic effect size estimates, were 5.99 (4.18;8.60) (GenomALC-1); 2.81 (2.03;3.89) (GenomALC-2); and 3.10 (2.32;4.14) (UK Biobank). Patients with diabetes and high-risk score, compared to those without diabetes and a low-risk score, had ORs increased to 14.7 (7.69;28.1) (GenomALC-1) and 17.1 (11.3;25.7) (UK Biobank). Patients with cirrhosis and HCC had significantly higher mean risk scores than patients with cirrhosis alone (0.76±0.06 versus 0.61±0.02, p=0.007). Score performance was not significantly enhanced by information on additional genetic risk variants, body mass index or coffee consumption.

CONCLUSIONS: A risk score based on three genetic risk variants and diabetes status can provide meaningful risk stratification for cirrhosis in excess drinkers, allowing earlier prevention planning including intensive intervention.

The Tools to Fix the Problems

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in a way that I could not. It would be easy to think of the added responsibility as "one more thing added to the junk drawer," but I chose to see it as a chance to learn another facet of advocacy. One more tool in my toolbox with the added bonus of helping someone in need. Sometimes case management is knowing that we are not the appropriate ones to meet their needs at that moment and facilitating the appropriate transition. This experience taught me that effective case management is balanced.

Case management is a field where balance is key. When a case manager is able to effectively attain a work/life balance they are better able to think clearly and develop creative plans to help others. On a regular basis, I have individuals tell me "you are my angel" or "you saved my life." Those are the moments when I know I am not a junk drawer; those moments remind me that case management is essential. These moments help provide balance to the moments when my toolbox is empty and I have used all of my tools with no success. Case managers must understand that we can't fix everything.

In case management, the only constant is change. Change in expectations, change in work level, change in resources, just CHANGE. Case management is flexible. In every case management position, I have worked across different fields, being flexible wasn't just a good idea, it was necessary. On any given day we may be asked to change the assessment we are using, the process we use, or the way we document something. COVID-19 has required more flexibility than ever before. But we are flexible with a purpose; as a case manager, we understand that our flexibility allows us to continue to provide the individuals the assistance they need no matter what changes we are being asked to make.

To me, thinking of case management as the junk drawer just doesn't fit. The junk drawer has such a negative connotation. We are not junk. Sure, we are pulled in a lot of directions, and some days it may feel like things are just thrown on us continually. But if case management was the junk drawer we wouldn't be given the opportunity to step up and meet the need. As case managers, we are optimistic and enthusiastic. We are the toolbox, the essential backbone of the care team. We use our tools of being organized, resourceful, flexible, creative, resilient, patient, tenacious, and balanced. We take on the tasks that no one else wants because we know they are essential and life-changing. The next time you start feeling like the junk drawer, remember—nothing about you is junk. Case management is definitely the toolbox. CM

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Interdisciplinary Pain Management and the Role of Case Management

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others who come into contact with these patients and often struggle with meeting their complex needs. Referral to IPR programs can provide a "one-stop shop" where all aspects of these patients' needs can be met without having to visit multiple care providers in different locations. If you are interested in receiving more information about CARF accreditation in your setting or to identify IPR programs in your area, contact Terry Carolan at tcarolan@carf.org. CM

Case Managers Look Ahead to the "New Normal"

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requirements, building knowledge and skills benefits us as professionals and elevates the professionalism of the practice.

- **Reaching out to others.** Prepandemic I often received an email or phone call every month or so from people who wanted to know more about case management. That type of outreach, however, all but dried up in early 2020. The need, however, has not gone away. With so many of us working and learning virtually without opportunities to network in person, we need to be more intentional in our efforts to reach out to others to share information and insights about case management practice and certification. We know that demographic changes, such as the aging of the population and the increase in chronic health conditions, are increasing demand for case managers. It's up to all of us, especially those with knowledge and experience to share, to help develop others. This is how case management will grow and thrive in 2022 and in the years to come. CM

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A Year of Resilience

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CMSA's resilience and ability to transform challenges into opportunities resulted in more services, enhanced programs, and the use of cutting-edge technology to connect with members and nonmembers around the world. From Hong Kong to England and all of the 50 states, CMSA has reconnected with legacy partners, connected with new organizations, and built alliances with groups who share the belief that case management is a game changer for the healthcare industry. A look back on 2021 is a reflection of celebration, excellence, and resiliency. We are ready for 2022! CM

3 Issues Top of Mind in Disability Management

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some positions the determination is complicated, involving in-depth individualized discussions with multiple stakeholders and delineating between preference and data-based facts. With their knowledge and expertise in accommodations and evaluation of essential job functions, the CDMS will play an invaluable role in helping employees and employers navigate these new challenges.

Disability management professionals have been compared to the center of a complex web, connecting all the different stakeholders, issues, and changing workplace needs. This comparison has become even truer since the onset of the pandemic. As we look to the close of 2021 and into 2022, CDMSs will continue to be on the front lines of helping employers and employees navigate the most pressing issues around leave laws, company policies, and flexible work arrangements. CM

Case Management Fellow Program

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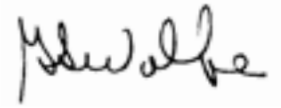
management. Fellows will be recognized leaders of the case management community as well as ambassadors for the field; they will be visionary, strategic thinkers, mentors, authors, speakers, and facilitators.

It will be an honor and a distinction to be named a Fellow. For more information and an application, go to https://CMSA.org/CM-fellow. Applications are due January 14, 2022.

CMSA announced the following as Founding Fellows:

- Patricia Agius, BS, RN, CCM, CPHQ, FCM
- Jeanne Boling, MSN, CCM, CRRN, FCM
- Anne Llewellyn, MS, BHSA, RN, CCM, CRRN, FCM
- Catherine Mullahy, RN, BS, CRRN, CCM, FCM (Executive Editor of *CareManagement*)
- 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 (Editor-in-Chief of *CareManagement*)

If you have made a significant contribution to the professional practice of case management through practice, leadership, education, or research, I invite you to apply to the Fellow Program.



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

ACCM: Improving Case Management Practice through Education

Holiday Reflections and Cautious Optimism

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made and continue to make—one patient at a time!

Warmest regards,

Catherine M. Mullahy, RN, BS, CCRN, CCM,FCM, Executive Editor
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Editor-in-Chief/Executive Vice President:
GARY S. WOLFE, RN, CCM, FCM
541-505-6380
email: gwolfe@academyccm.org

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

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

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

Copy Editor: Esther Tazartes
e-mail: justice@dslextreme.com

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

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

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

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

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