CareManagement

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Gary S. Wolfe

The Diabetes Pandemic

Diabetes is perhaps the largest epidemic in the United States. Although diabetes has a tremendous impact on patients' health and the cost of treating this disease is enormous, appropriate intervention can improve patient health and reduce the costs of treatment. Healthcare practitioners must increase their awareness of the risk factors and drivers of diabetes and assume responsibility to make changes. Case managers are in an ideal position to increase early awareness about diabetes and to prevent diabetes, which can save lives and money. The case manager should educate all his or her patients about diabetes, regardless of whether they have a primary diagnosis of diabetes, a secondary diagnosis of diabetes, prediabetes, or are at risk for diabetes.

Some staggering statistics:

- In 2015, 30.3 million Americans or 9.4% of the US population had diabetes. Approximately 1.25 million American adults and children have type 1 diabetes.
- Of the 30.3 million Americans with diabetes, 23.1 million were diagnosed and 7.2 million were undiagnosed.
- More than one quarter (25.2%) of Americans aged 65 and older or 12 million seniors have diabetes (diagnosed and undiagnosed).
- 1.5 million new cases of diabetes are diagnosed in Americans each year.
- In 2015, 84.1 million Americans age 18 and older had prediabetes.
- Diabetes remains the seventh leading cause of death in 2015 in the United States.
- Rates of diabetes are higher in Asian Americans, Hispanics, Native Americans, and Blacks than in Caucasians.
- The total costs of diagnosed diabetes in 2017 was $327 billion, which reflects more than 20% of healthcare spending.
- It is estimated that half of Americans will develop diabetes or prediabetes by 2020.
- Diabetes is the leading cause of kidney failure, lower limb amputation, and adult-onset blindness.
- People with diabetes are twice as likely to have heart disease or stroke as people without diabetes and at an earlier age.

Some of the leading drivers of type 2 diabetes include:

- Lifestyle
- Inactivity
- Caloric excess
- Obesity
- Aging
- Familial history
- Ever having gestational diabetes or giving birth to a baby who weighed 9 pounds or more

What can case managers do to make a difference?

- Be well informed and educated about risk factors, prevention, and treatment of diabetes
- Evaluate each of your patients for prediabetes/diabetes on an ongoing basis
- Educate clients who are at risk of diabetes

Strategies focused solely on treating diabetes will be far too costly. The solution must include prevention with an emphasis on healthy eating and exercise. It is not easy, and we have not

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CCMC Webinars Provide "On-Demand" Learning

MaryBeth Kurland, CAE, CEO, Commission for Case Manager Certification

Training and professional development are major priorities across every industry and business sector today, especially health and human services. Educational resources must be both effective and efficient, providing meaningful content in a time-efficient manner.

On-demand learning allows professionals to gain access to knowledge-based content anywhere, any time. To help satisfy the need for on-demand learning for professional case managers, particularly those who are board certified, the Commission for Case Manager Certification (CCMC) offers webinars that enable participants to engage with subject matter experts on highly relevant topics.

Professional case managers, particularly those who are board certified, need on-demand learning. To help satisfy the need for on-demand learning, the Commission for Case Manager Certification (CCMC) offers webinars that enable participants to engage with subject matter experts on highly relevant topics.

The Commission's webinar series is part of its CMLearning Network, which also includes other educational resources such as its Issue Briefs, the CCMC New World Symposium, and Case Management Body of Knowledge® (CMBOK). Together, these unique learning opportunities showcase CCMC's commitment to ongoing professional development and to offer options to earn continuing education units (CEUs), which can be applied to maintain certification.

Through our webinars, the Commission offers on-demand learning in an "easily digestible" and time-efficient format, while contributing meaningfully to lifelong learning. These programs are aimed at both refreshing skills that may not be used frequently as well as certification preparation and continuing education. The Commission will hold 6 webinars this year; topics for webinars during 2018 include team communication, the 21st Century Cures Act, ethics and resilience, patient engagement, and empowerment.

The webinars seek to educate and raise awareness of current issues and solutions for case managers as well as other clinicians. These online offerings, which are free, attract around 500 participants; board-certified case managers who want to earn continuing education credit may do so for a small fee. As on-demand learning, the seminars available on the CCMC website can be viewed at any time after the initial webcast.

One of the key elements of webinars is the opportunity for peer-to-peer learning. The Commission seeks out experts, thought leaders, and innovators in case management and related fields to present webinars. This is a unique opportunity for case managers to engage with experts from public policy, major health systems, academics, and other related fields. As relevant and compelling as the presentations are, the 20-minute Q&A section is a favorite feature because it allows case managers to interact directly with these experts.

The Commission is particularly interested in featuring experts who understand and appreciate the importance of the role of case managers, especially in pursuit of the quadruple aim. The quadruple aim encompasses the initial 3 interrelated goals of improving population health, increasing patient satisfaction, and smarter health care spending, as well as the fourth aim of greater satisfaction for clinicians and health care providers. This approach seeks to improve health care for all, at every level of the system, to keep pace with the changing demands of modern health care.

The health care system in the United States is the costliest in the world, and systemic change is required in multiple areas. Benefits of the quadruple aim include more coordinated care, reduction in the per-capita cost of health care, better patient outcomes, and improvements in population health.

As time goes on, the technology and processes used across health and human services will become outdated, and case managers will have to adapt. This will be key in the transformation of health care, its systems, and those who work in it. As this transformation unfolds, the Commission remains committed to offering education resources to help case managers remain well informed and relevant in their field. CM

MaryBeth Kurland, CAE, *is the CEO of the Commission for Case Manager Certification (CCMC), the first and largest nationally accredited organization that certifies case managers. More than 45,000 board-certified case managers (CCMs) are in practice today.*

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Why Monday May Not Be the Best Return-to-Work Start Date

Lisa Scotton, MJ, RN, CCM, CDMS, COHN

When an individual is ready to return to work after a health-related absence, it's often assumed that the optimal start date is a Monday—a new week and a fresh start to get back to work. But Mondays are not always the best day to return to work.

A more strategic approach is a slightly earlier return to work (RTW) in the middle or end of the prior week. This allows the employee to work a few days and then have the weekend to recover before returning to the usual workweek. For the employee, gradual ramp-up can help both physically and mentally as he/she eases back to work.

This seemingly simple concept can help Certified Disability Management Specialists (CDMSs) and disability case managers achieve more successful and sustainable outcomes when implementing and assisting with RTW plans. The role of the CDMS is to "analyze, prevent, and mitigate the human and economic impact of injury, illness, and disability for employees and employers to optimize quality of care, productivity, organizational health, and regulatory compliance." With occupational and nonoccupational absences (ie, those that are work-related and those that are not), the CDMS typically engages the individual, health care provider, and the employer to facilitate a safe and timely return to work. The CDMS has the experience and qualifications to assist and facilitate RTW plans. But once a plan is in place, the question becomes the start date—and that's where the "Monday assumption" often comes into play.

Mondays are not always the best day to return to work. A more strategic approach is a slightly earlier return to work in the middle or end of the prior week. This allows the employee to work a few days and then have the weekend to recover before returning to the usual workweek.

There is no requirement, of course, for RTW plans to start on Mondays. Flexibility and creative thinking point to a different conclusion. Consider, for example, a person who has been away from work for an enjoyable week-long vacation. On Sunday night, looking to the week ahead, the person could experience a letdown or even dread at the thought of leaving vacation behind for the pressures of work. These feelings usually intensify for the individual who has had a prolonged absence due to illness or injury and has endured symptoms, treatment, recuperation, and recovery. The prospect of resuming normal work duties can be daunting, exhausting, and potentially detrimental to a successful return to productivity.

Rather than face these negative feelings at the start of a full week, the strategic approach of a mid-week or end-of-week start day can help increase the success of the RTW plan. For example, the CDMS or disability case manager can suggest that the employee return on the Wednesday or Thursday prior to the proposed Monday start date to ease back into the workplace.

With a prolonged absence, a tiered ramp-up may be appropriate to bring the employee back to full productivity: for example, a 3-day workweek for 2 weeks, then a 4-day workweek for 2 weeks, and then resumption of a normal work schedule. This can be especially helpful for an individual who is returning after aggressive treatment (eg, chemotherapy and radiation treatments for cancer, which are both physically and emotionally taxing). Regaining stamina after any aggressive treatment takes time. A gradual reentry to the workplace supports reconditioning and "work hardening," which is part of the recuperation process.

While this may only reduce the individual's absence duration by a few days, by so doing it contributes to overall reductions in lost work days and direct and indirect costs for the employer. These costs are significant: The Centers for Disease Control and Prevention reports that productivity losses linked to absenteeism cost employers $225.8

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Lisa Scotton, MJ, RN, CCM, CDMS, *has more than 15 years of experience in disability management, absence management, and benefits, working with major employers. She is active with CCMC, which manages and governs the Certified Disability Management Specialist (CDMS) credential.*

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CMSA Celebrates National Case Management Week

Kathleen Fraser, RN-BC, MSN, MHA, CCM, CRRN, CMSA Executive Director

In October 2018, the Case Management Society of America (CMSA) and the greater case management community will celebrate National Case Management Week, a time to honor and recognize all professional case managers across the continuum of care in the United States. Case management has been practiced in the United States for over half of a century, and through that period we have assisted our patients and our clients in developing their plans to "move to wellness."

This year's National Case Management Week logo reflects that movement; just as the CMSA's Standards of Practice for Case Management prescribe, we assess, plan, collaborate, implement, monitor, and evaluate our patients and clients to achieve improved outcomes. True professional case management requires a patient- or client-centered approach, with influencers assisting along the way.

If someone asked you to describe "what you do" in more detail, what would you say? What is the true value of a case manager from the perspective of the patient or family caregiver? While we know our value, here are some facts to ponder about our very significant work.

Kathleen Fraser, RN-BC, MSN, MHA, CCM, CRRN, is the Executive Director of the Case Management Society of America

Case Management Services

Case management serves as a means for achieving client wellness and autonomy through advocacy, communication, education, identification of service resources, and service facilitation. The case manager helps identify appropriate providers and facilities throughout the continuum of services, while using available resources in a timely and cost-effective manner to obtain optimum value for both the patient and the reimbursement source.

In October 2018, the Case Management Society of America and the greater case management community will celebrate National Case Management Week, a time to honor and recognize all professional case managers across the continuum of care in the United States

Coordination of care, managing multidisciplinary teams, and achieving better transitions of care are the pillars of effective case management. We provide expertise and clarity for complex medical issues, we identify obstacles to the delivery of prompt quality healthcare treatment, and we coordinate resources.

We are professionals who provide strategies to address challenges and ensure that care is patient-centered, safe, and effective. The key is in the coordination of care, with identified time frames for accomplishing appropriate care outcomes. Case management also provides a well-coordinated care experience to improve the care outcome, decrease the length of stay, and use multiple disciplines and services efficiently.

Transitions of care for people with multiple serious chronic illnesses are critical points for promoting quality of care and reducing preventable, expensive, and debilitating hospital admissions and readmissions as well as avoidable emergency department visits. Most people with multiple chronic illnesses, which are often accompanied by functional and cognitive deficits, cannot manage their care on their own. Wherever and however they originate, care transitions are about addressing change over time; this must be addressed in healthcare reform, which must support reimbursements accordingly.

Case management is neither linear nor a one-way exercise but rather a longitudinal approach across healthcare settings that is imperative to coordinate inpatient and postdischarge care. Facilitation, coordination, and collaboration occurs throughout the client's healthcare encounter.

Legal and Care Reform

From a legal perspective, there is a myth and faulty belief among case managers and other experts that the standard of care is static, fixed, and permanent. The standard of care is a very important legal construct because

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Unprecedented Changes Coming to Medicaid Program

By Elizabeth Hogue, Esq.

In an editorial in *The Washington Post* on February 4, 2018, entitled "Making Medicaid a Pathway Out of Poverty," Seema Verma, the Administrator of the Centers for Medicare & Medicaid Services (CMS) described changes to the Medicaid Program that she expects to be made. Providers that care for patients covered by Medicaid need to know about these changes.

First, Ms. Verma reminds us that the Medicaid Program was created in 1965 as part of President Lyndon B. Johnson's War on Poverty. The Medicaid Program initially provided health services for seniors in need, pregnant mothers, low-income children and parents, and people with disabilities. In other words, the Medicaid Program was originally conceived as a safety net. As Johnson said, "Our aim is not only to relieve the symptoms of poverty, but to cure it and, above all, to prevent it."

With the passage of the Affordable Care Act (ACA) in 2010, however, Medicaid Programs were fundamentally changed by shifting predominantly low-income adults who often don't have children and are healthy and of working age into programs that weren't really designed for them.

Consequently, Ms. Verma is committed to allowing states that know the unique needs of their citizens to design programs that don't just provide Medicaid coverage but include care that "allows people to rise out of poverty and no longer need public assistance." As Ronald Reagan put it, the aim of government programs for the poor "should be to eliminate, as far as possible, the need for its own existence."

The new overall goal of the Centers for Medicare & Medicaid Services with regard to the Medicaid Program is to restore a strong state-federal relationship while also modernizing the Program to deliver better outcomes for all populations served.

According to Verma, the new overall goal of CMS with regard to the Medicaid Program is to restore a strong state-federal relationship while also modernizing the Program to deliver better outcomes for all populations served. The first step is to recognize that only the states know what is best for their citizens. The states should be empowered to work with communities, providers, and citizens to design innovative programs that meet their diverse needs while holding them accountable for achieving positive outcomes.

States, says Verma, have been seeking flexibility to add work and community-engagement incentives for able-bodied, working-age Medicaid beneficiaries. Mounting evidence demonstrates that work and community engagement can have a major positive impact on health and wellness. Eleven states governed by both Republicans and Democrats have now submitted proposals to implement work and community-engagement requirements for their nondisabled, working-age populations. According to Verma, CMS supports these efforts.

Guidance released last month by CMS is intended to help states develop and evaluate their programs. The guidance provides flexibility but also details necessary protections that states must include for persons with disabilities or other health issues that may prevent them from participating in a community-engagement requirement, including those with opioid addiction and other substance abuse disorders. The guidance also requires states to address local economic conditions that may impact individuals' ability to become employed.

Anticipating criticism of this approach, Verma then says:

"It is unfortunate that some

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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.*

Principles of Person-Centered Care

Christine M. MacDonell, FACRM

CARF International considers the 10.3 million people served in our accredited programs as the moral owners of CARF. As a not-for-profit organization, we do not have shareholders but moral owners. The question we answered to determine who these owners were was "Who can we not fail to protect?" This has led CARF International to explore the theories, philosophies, and the impact of person-centered care on the industries we accredit.

Currently the term is being used globally in a variety of settings and marketing efforts to promote a care delivery model that resonates with many individuals seeking health and human services. In many cases, it takes a massive change in an organization from leadership to front line workforce to actually implement and practice person-centered care on a daily basis.

The core values of person-centered care that need be in place and practiced are:

- The person served is the expert
- The person served is respected
- Information is gathered and utilized from the person served to develop their individual plan
- Establish and maintain care to enable collaboration with the person served

Actual person-centered practices are:

- Collaborative
- Aimed at cooperation with persons served by demonstrating respect and empowering and involving them in decision making
- Advocating with and for them to meet their needs
- Recognizing the person's experiences and knowledge–they are the expert of their life
- Involving the team and organization factors

In reviewing the principles of this practice we look at the person served, the organization, and the workforce. Ten guiding principles have evolved from our work in this area. As you read this, think about the organizations you work in, own, or manage and consider how these principles work in your particular area of case management.

Principle One: Person First

- Partnership in achieving safe, accessible, timely, and quality services across the continuum of care

Principle Two: Safety

- Identification and control of risks to achieve effective results for both the person served and the workforce

Principle Three: Person Responsibility

- Person served learns how to take personal responsibility for their own health and other health needs

Principle Four: Define Authority

- Every individual in the workforce understands the scope and authority that they have to carry out their responsibilities and respond to person-served needs

Principle Five: Clear Accountability

- Individuals, committees, and functional groups agree, are clear, and are accountable to the person served.

Principle Six: Leadership

- Motivate toward the common goal of person-centered care; drive necessary and sustainable change to ensure high-quality delivery of person-centered social and clinical care.

Principle Seven: Interdisciplinary Work

- Work processes that support unique contributions of each team member; focuses on interdependence between individuals and groups delivering services, requires proactive collaboration between all members of the team and includes the person served as a valued team member in all activities.

Principle Eight: Supporting Performance

- Have a continuous process in place to manage performance and measure both the person served and workforce experience

Principle Nine: Open Culture

- Respectful and caring environment where achievements are recognized; adverse events are part of everyday open communications: workforce willing to report adverse events and errors; and focus is on learning, improvement, research, and appropriate action taking.

Principle Ten: Continuous Performance Improvement

- Learning environment and system that seeks to improve services; emphasis is on maintaining quality, not just controlling processes; involves setting objectives, indicators, and targets that are measured, reviewed, and included in education for continuous improvement.

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Chris MacDonell, FACRM, *is the Managing Director, Medical Rehabilitation and International Aging Services/Medical Rehabilitation, CARF International.*

Health Care Professionals and Suicide: An Occupational Hazard

Ellen Fink-Samnick, MSW, ACSW, LCSW, CCM, CRP

The recent suicides of two celebrities has captured the public's attention. The statistics for suicide in the United States are glaring:

- 10th leading cause of death
- Cause of 44,965 deaths annually, with 123 suicides a day
- The rate is highest for those in middle age, especially men.

Globally, the numbers do not abate:

- 800,000 deaths annually, with one person every 40 seconds
- 2nd leading cause of death among 15–19 year olds
- 17th cause of death overall.

The tragic nature of these numbers are one of many reasons I embarked on a clinical social work path, striving to understand and enhance the human condition. I never thought I'd be extending my lens to focus on the escalating suicide rate of my valued colleagues across the health care workforce, including all health and behavioral health professionals.

The Interprofessional Evidence

The causes of suicide range from the reality of occupational pressures to safety concerns. The increased uptick in workplace bullying has considerably impacted many professionals, with those subjected to bullying more prone to suicidal ideation and twice as likely to take their own life. A prior blog discussed the influence of mass violence episodes on workforce trauma and subsequently on frontline practitioners. Stress from the profound accountability experienced in the scope of treating clients (or patients) becomes another driver. For those reading this blog, consider how often you have become frustrated, if not outright depressed, by a client's treatment or intervention that does not go as well as expected. A medical complication develops unexpectedly or a psychological trigger sends a stable client down a rabbit hole of despair and suicidal ideation. It becomes tough to reconcile the inability to cure, fix, or enhance every client's condition. We have all shared this common experience, independent of professional discipline.

Studies have shown that being a social worker increases the odds of death by suicide by 55.6%.

Close to 400 physicians die annually, with nurses more likely to commit suicide than women in general. Studies have shown that being a social worker increases the odds of death by suicide by 55.6%. In a list of the top 20 professions with the highest suicide rates, health and behavioral health professionals are prominently featured:

- #12: Doctors, dentists, health care professionals
- #15: Nurses, medical assistants, health care support workers
- #16: Social workers and other social service workers

The fact that today's health care professional is fried to a crisp is not an overgeneralization. The 2018 Medscape National Physician Burnout & Depression Report had over 15,000 respondents. Forty-two percent admitted to burnout, with 12% colloquially depressed and 3% clinically depressed. At the top of the specialty list for those physicians most impacted by stress were:

- Critical care: 48%
- Neurology: 48%
- Family medicine: 47%
- Ob/gyn: 46%
- Internal medicine: 46%
- Emergency medicine: 45%

Women were more impacted than their male colleagues (48% versus 38%). The average age of the health care professional with the highest rate of burnout was 45–54 years. Bar none, the job itself was the highest contributor to level of depression for physicians. Over 40% of physicians reported that their depression affected professional relationships with colleagues or staff, and less than 24% reported obtaining clinical support for problems with mood.

A Traditional Culture of Caring Takes a Toll

Moving around the interprofessional landscape yields similar concerns.

Ellen Fink-Samnick, MSW, ACSW, LCSW, CCM, CRP, *is owner of EFS Supervision Strategies, LLC, and is known and respected as "The Ethical Compass of Professional Case Management." She is a popular presenter with hundreds of offerings to her credit and the author of over 100 publications. This column has been reprinted with permission from Ellen's blog at Ellen's Ethical Lens.™*

The intense psychological stress experienced by social workers and other mental health professionals because of the extreme needs and circumstances of their clients pose considerable risks. While professional education focuses on the development and maintenance of critical boundaries and the importance of all disciplines to self-protect, constant exposure to client realities remains an occupational hazard. Although no one is immune from feeling like their boundary armor has weakened, independent of years of experience, expertise, or training, most professionals put the client first and themselves last. They go beyond that point of no return. The lessons that health care professional are taught about limit setting and self-protection go out the window when faced with having to prioritize their own self-care over rendering care to clients.

The desire to improve the human condition brings many health care professionals to the industry. It is fascinating to ask students entering the field why they have chosen these professions. With few exceptions, the answer is a unanimously "to help people," which is evidence of their respect for humanity and a desire to serve. However, that desire to help is a blessing and a curse because it drives talented professionals to dire actions. Nobody has an endless reserve to help. That is far too great a burden to bear, particularly when dealing continuously with life, death, and the reality of the human circumstance.

The pressures faced by the collective health care workforce start early on during academic preparation. There are stressors due to academic pressures of failing classes and competition to obtain quality practicums, residencies, internships, and fellowships. Upon graduation there are licensure and credentialing examinations to pass. Then the work world greets us, plunging us into assessing the pathophysiology and psychopathology of physical illness and behavioral health respectively, if not comorbidly. We reconcile the various faces of human suffering, from trauma to the social determinants of health to countless other complex population challenges across the biological, psychological, sociological, and spiritual domains. Changing demographics, cultural considerations, and complications await us at every turn.

The juggling of regulatory and organizational requirements along with professional ethics and personal values breeds the essence of moral distress. Reimbursement and the fiscal focus of care is a prominent theme, with pressures to treat and swiftly discharge, at times prematurely. Reconciling medical and medication errors as well as treatment variances amid the drive for successful outcomes is a triple threat. Last but certainly not least come those documentation requirements, which no amount of technology has been able to reduce. Too often I hear of colleagues putting in 14–16 hour days, only to then bring home assessments yet to complete.

The power of technology has provided us the ability to document remotely from home, which is not always such a benefit. One colleague shared how the scribes hired by the practice to document in the electronic medical record were an asset, with a big caveat. After completing a full day of seeing patients, he returned home to view his sleeping children, then began to review and sign off on the scribe documentation, thus tacking on another 2 hours onto the day. Getting insufficient sleep only compounds the challenges faced, with limited ability to recharge from one day to the next.

Change the Culture

No health care professional is immune from the stresses and strains of the job. The mantra of some may be to "tough it out" or "make it to vacation," but being responsible for the care of others mandates that we pay attention to our own needs first and foremost. A vacation can do wonders but helps for the short-term only. Health care professionals are the consummate rationalizers. Common phrases typically heard include, "I'm in the biz and know what I need" or "What's a therapist going to tell me that I don't already know?" These are faulty rationalizations at best. No one can be objective about their own situation. The main reason to seek counseling is to gain an unbiased perspective from a professionally educated and trained clinician who is an expert in rendering mental health care.

I recognize that some health care practitioners may perceive that their organizations and/or professions do not support their request for help or acknowledge the need for behavioral health support. The industry *must* get past

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RESOURCES:

American Psychiatric Association: Employee Assistance Programs

Mental Health America

Mental Health.gov: Local Organizations with Mental Health Experience

National Alliance on Mental Illness: Top 25 Helpline Resources

National Institute of Mental Illness

National Suicide Prevention Lifeline

Psychology Today: Find a Therapist

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Healthcare Professional Burnout, Depression and Suicide Prevention: American Foundation for Suicide Prevention

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Preoperative Prothrombin Times and Difficulty Managing Postoperative Warfarin Therapy in Patients with Mechanical Valve Replacements

Keri Draganic, DNP, APRN, ACNP-BC, Sonja Stutzman, PhD, Haley Legg, BSN, RN, Kristina Duxbury, BSN, RN, and DaiWai Olson, PhD, RN, CCRN, FNCS

Background

The prevalence of valvular heart disease continues to increase, mostly because of degenerative valve disease that occurs in an aging population.[1] Annually, over 100,000 people will undergo a heart valve replacement in the United States.[2] The number of heart valve interventions is expected to continue to increase to more than 800,000 procedures worldwide by 2050.[3] The mitral and aortic valves are the most commonly replaced heart valves because they are on the left side of the heart and experience higher pressures than the tricuspid and pulmonic valves.[2]

There are two types of valve replacements, which include mechanical or bioprosthetic valves.[4] Mechanical indicates that the valve is manmade with a bileaflet design and is constructed with pyrolytic carbon.[5] Bioprosthetic valves are created using tissue from a cow or pig valve and do not require any anticoagulation postoperatively but are known to degrade after 15–20 years.[6] Mechanical valves will last the lifetime of the patient, which decreases a patient's risk of reoperation, but are associated with an increased risk of thromboembolic and bleeding events compared with bioprosthetic valves because of the need for lifelong anticoagulation.[7]

When a mechanical valve replacement is chosen, it requires lifelong anticoagulation to prevent a blood clot from forming.[8] The most common anticoagulant used today is warfarin.[9] The dosage of warfarin is different for every patient and is affected by many variables, but the goal international normalized ratio (INR) will be 2–3 for mechanical aortic valve replacements and 2.5–3.5 for mechanical mitral valves replacements.[10] Warfarin reduces the formation of blood clots by reducing clotting factors produced by the liver, which include factors II, VII, IX, and X as well as the anticoagulant proteins C and S.[11]

Vitamin K is critical to the synthesis of these coagulation factors. Warfarin is a vitamin K antagonist that inhibits the production of factors II, VII, IX, and X.[12] Hence, when a patient has high levels of Vitamin K, this will complicate postoperative warfarin dosing.[12] Vitamin K levels can be assessed by evaluating prothrombin time (PT).[13] Vitamin K is influenced by diet, dietary supplements, body metabolism, and medication interactions. The dynamic relationship of warfarin and vitamin K requires the practitioner to assess PT/INR levels to ensure that patients, especially those with mechanical valves, are maintained at therapeutic levels.[14] This can ultimately make warfarin titration in this patient population more difficult to manage postoperatively.

Keri Draganic *is an acute care nurse practitioner in cardiothoracic surgery at UT Southwestern Medical Center. She was a research fellow with the 2016 Neuroscience fellowship. As the principal investigator she designed, collected data, interpreted results, and wrote this manuscript with the assistance of the Neuroscience fellowship mentors, Daiwai Olson and Sonja Stutzman.*

Sonja Stutzman *is the Program Manager for the Neuroscience Nursing Research Center at UT Southwestern. She was responsible for protocol development, interpretation of results, and manuscript assistance.*

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Over 100,000 people will undergo a heart valve replacement in the United States every year.

Therefore, if a person has high vitamin K levels they will have a lower PT preoperatively, making warfarin titration postoperatively more difficult and challenging.

When a patient undergoes preoperative testing, a baseline coagulation panel is drawn that includes PT, partial thromboplastin time (PTT), and INR. However, there is no evidence assessing preoperative prothrombin times in patients who undergo mechanical valve replacement surgery and postoperative warfarin dosing. Therefore, this study examined the association between preoperative prothrombin times and the difficulty of managing postoperative warfarin therapy in patients undergoing mechanical heart valve replacement surgery.

Methods

This retrospective analysis was approved by the Institutional Review Board before any data collection. The Society of Thoracic Surgeons database includes most of the variables in this analysis and was the primary source of data for this study. Variables not included in the Society of Thoracic Surgeons database were abstracted from the electronic medical record Epic. The hypothesis is that, in patients who require mechanical valve replacement, their preoperative PT will affect length of stay because of postoperative warfarin titration. The PT level will be operationally defined as the preoperative prothrombin times obtained before valve replacement surgery. Length of stay will be operationally defined as the number of hospital days after midnight after valve replacement surgery, with surgery day being day zero. Warfarin titration will be operationally defined as number of warfarin doses received after valve replacement surgery.

The primary outcome of this study was length of stay and warfarin regulation. For a one-level test with power 0.80, α 0.05, and effect size = 0.50, there was a requirement of at least 64 subjects per group. Data were abstracted from January 1, 2013, to December 31, 2015. Patients were included in the database if they were prescribed warfarin postoperatively and underwent a mechanical valve replacement. Patients were excluded if: 1) warfarin was discontinued within 14 days of the surgery because of allergy or intolerance of warfarin, 2) they had complications due to bleeding, 3) reoperation or delayed chest closure occurred, 4) death occurred before the first dose of warfarin or death occurred postoperatively because of ventricular fibrillation, ventricular tachycardia, or pulseless electrical activity, and 5) infection occurred within 14 days of operation. Patients were identified using the Society of Thoracic Surgeons database, and data were abstracted from this database to an electronic spreadsheet. Additional data was then abstracted from the electronic medical record and merged into a single spreadsheet. Data were uploaded to SAS v 9.4 (SAS Institute, Cary, NC) for statistical analysis.

There were 169 patients who met the inclusion criteria; 1 subject was <18 years old and was excluded, 1 subject was excluded because of a length of stay >100 days, and 1 was excluded because of a warfarin start dose after day 50. Therefore, the sample for data analysis was based on 166 patients. Interval and ratio data were analyzed using descriptive measurements of mean, standard deviation, median, and range.

Results

Demographics within the aortic, mitral, and both aortic and mitral valve replacement groups were consistent. The aortic and mitral valve replacement group was slightly younger, with an average age of 46.9 years, and the mitral valve replacement group was older, with an average age of 54.4 years (Table 1). There were more females in the aortic valve replacement group (70%) than in the mitral and aortic valve replacement group (46.1%) (Table 1). The mitral and aortic valve replacement group was more likely to have diabetes and prior warfarin use but had less nonsteroidal inflammatory drug use preoperatively compared with the other groups (Table 1).

Univariate regression revealed a statistically significant association between PT and length of stay in the subset of patients who underwent aortic valve replacement ($P = 0.0053$). There was no statistically significant association between PT and length of stay among subjects who underwent mitral valve replacement ($P = 0.5720$) or among patients who underwent both aortic and mitral valve replacements ($P = 0.4006$). A total of 90 (54%) patients received a mechanical aortic valve (Table 1). The mean presurgery PT was 13.2 (SD [standard deviation] = 5.1) seconds,

TABLE 1 **Demographics of patients who underwent aortic valve replacement, mitral valve replacement, or both**

Variable	Aortic Valve (n=90)	Mitral Valve (n=63)	Both (n=13)
Age (mean ± SD)	50.3 ± 11.9	54.4 ± 12.5	46.9 ± 9.46
Percent Female:	70.0%	54.0%	46.1%
History of:			
Diabetes	24.4%	27.0%	38.5%
Smoking	28.9%	30.2%	15.4%
NSAID use	25.6%	33.3%	7.7%
Warfarin use	13.3%	28.6%	30.8%

NSAID: nonsteroidal anti-inflammatory drug.

TABLE 2 **Results for patients undergoing aortic valve replacement, mitral valve replacement, or both**

Variable	Aortic Valve (n=90)	Mitral Valve (n=63)	Both (n=13)
Pre PT/INR			
PT level	13.2 ± 5.1	13.9 ± 5.2	14.1 ± 5.4
INR	1.2 ± 0.5	1.3 ± 0.6	1.3 ± 0.6
Post PT/INR			
PT level	21.8 ± 5.8	27.1 ± 2.6	25.4 ± 4.4
INR	2.0 ± 0.5	2.6 ± 0.6	2.4 ± 0.4
Days to reach therapeutic warfarin dose:	5.6 ± 2.3	6.0 ± 2.5	6.4 ± 3.5
Warfarin dose at discharge (mg):	5.1 ± 2.8	5.2 ± 2.7	3.9 ± 2.2
Hospital LOS (d)	9.6 ± 5.8	11.3 ± 7.7	8.3 ± 3.5

d = days; LOS = length of stay; PT/INR = prothrombin time/international normalized ratio.

TABLE 3 **Postoperative complications in patients who underwent aortic valve replacement, mitral valve replacement, or both**

Postoperative Complication	Aortic Valve (n=90)	Mitral Valve (n=63)	Both (n=13)
Stroke	3.3%	1.6%	15.4%
Hemorrhage	1.1%	1.6%	15.4%
Bleeding	8.9%	11.1%	0%
Supratherapeutic INR	6.7%	14.3%	7.7%
Death	1.1%	3.2%	0%

INR = international normalized ratio.

and INR was 1.2 (SD = 0.5) (Table 2). Warfarin was started on average 1.2 days after surgery (postoperative day 1). These patients received a mean number of 5.6 doses of warfarin before hospital discharge and had an average length of stay of 9.6 (SD = 5.8) days in the hospital. The mean PT on the day of discharge was 21.8 (SD = 5.8) seconds, and the mean INR was 2.1 (SD = 0.5) (therapeutic goal is 2.0–3.0). As shown in Table 3, postoperative complications were more prevalent in patients who underwent both aortic and mitral valve replacement. Patients who received mechanical aortic valves had postoperative complications that included stroke (3.3%), hemorrhage (1.1%), bleeding (8.9%), supratherapeutic INR (6.7%), and death (1.1%).

A total of 63 (35%) patients received a mechanical mitral valve (Table 1). The mean (SD) presurgery PT was 13.9 (5.2) seconds, and the mean (SD) INR was 1.3 (0.6) (Table 2). Warfarin was started on average 1.4 days after surgery (postoperative day 1). These patients received an average of 5.98 (SD = 2.5) doses of warfarin before discharge and had a mean (SD) length of stay of 11.3 (7.7) days in the hospital. The mean (SD) PT on the day of discharge was 27.1 (6.5) seconds, and the mean (SD) INR was 2.6 (0.6) (therapeutic goal is 2.5-3.5). As noted in Table 3, postoperative complications among patients who underwent mitral valve replacement included stroke (1.6%), hemorrhage (1.6%), bleeding (11.1%), supratherapeutic INR (14.3%), and death (3.2%).

Thirteen (8%) patients underwent mechanical aortic and mitral valve replacement (Table 1). The mean (SD) presurgery PT was 14.1 (5.4) seconds, and the mean (SD) INR was 1.3 (0.6) (Table 2). Warfarin was started on average 0.92 days after surgery (postoperative day 1), and patients

Mechanical valves will last the lifetime of the patient, which decreases a patient's risk of reoperation, but are associated with an increased risk of thromboembolic and bleeding events compared with bioprosthetic valves because of the need for lifelong anticoagulation.

received an average of 6.4 (SD = 3.5) doses of warfarin before discharge. The mean length of stay was 8.3 (SD = 3.5) days in the hospital. The mean (SD) PT on the day of discharge was 25.4 (4.4) seconds, and the mean (SD) INR was 2.4 (0.4) (therapeutic goal = 2.5–3.5). This group had no postoperative complications of bleeding or death but did experience stroke (15.4%), hemorrhage (15.4%), and supratherapeutic INR (7.7%; Table 3).

Discussion

Although the data did not support the hypothesis in all patients who require mechanical valve replacement, there was a statistically significant association between patients' preoperative prothrombin times and length of hospital stay in the aortic valve replacement group. There are several explanations for this finding: lack of representativeness of the sample, complication rates, and differences in the therapeutic INR levels between the types of valves. Mechanical aortic valve replacement requires a lower therapeutic INR level postoperatively compared with mitral valve replacement and both (aortic and mitral) valve replacements. The therapeutic INR level is 2–3 for mechanical aortic valves and 2.5–3.5 for mechanical mitral valves.[10] Other studies have found that postoperative complications rates can increase length of stay.[15-18] This can be a factor that ultimately affected the final results.

There are several limitations to

When a mechanical valve replacement is chosen, it requires lifelong anticoagulation to prevent a blood clot from forming. The most common anticoagulant used today is warfarin.

this study. It was a retrospective chart review and patients were recruited through convenience sampling. This study cannot determine causation but only association between preoperative PT and hospital length of stay. There was also the possibility of error within the data abstraction process, which can lead to misclassification bias. Although the power analysis resulted in an estimated sample size of 64 patients per group, this sample size estimate was based on a pooled estimate including aortic and mitral valve patients. The results from this study suggest that two separate sample size estimates may provide a more comprehensive analysis.

This study was conducted at a single hospital, and therefore the results may not be generalized to other clinical environments. Also, this study was not randomized, and it could be possible that there were unmeasured or confounding variables that were not accounted for that could affect the final results. More research is needed to better understand the association between preoperative prothrombin times and length of stay in mechanical valve replacement patients.

Conclusion

The aortic valve replacement group had a statistically significant association between preoperative prothrombin times and length of hospital stay. This study adds to evidence for treating aortic valve replacement and mechanical valve replacement patients by testing the hypothesis that patients who undergo mechanical heart valve replacement surgery and have preoperative prothrombin times that are normal to below normal will have greater difficulty managing their postoperative warfarin therapy. This information can be applied to practice by revising existing protocols and allocation of resources in the preoperative phase of care. Nurses and advanced practice nurses play a key role in managing and improving cardiac clinical services.[19] The ability to predict length of stay, in part, based on admission assessment can be increased by allocating resources aimed to coordinate discharge planning and transition of care. The protocol revisions may also reduce erroneous laboratory testing in patients who were not previously receiving anticoagulation medications. The absence of a statistical association between preoperative prothrombin times and length of hospital stay within the mitral valve replacement group and the both (aortic and mitral) valve replacement group requires additional evaluation with a larger cohort. **CE 1**

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CE II Comorbidities and Work-Related Injuries: Ethical Considerations

Chikita Mann, MSN, RN, CCM

Scenario: A 55-year-old male warehouse worker falls while he is at work and sustains an ankle fracture. When he is taken to the emergency department, diagnostic laboratory values reveal a blood sugar level of 350 mg/dL and preexisting arthritic changes in his ankle. He weighs over 250 pounds. During the intake interview, it is discovered that he has known for the past 2 years that he has diabetes but he has not been receiving treatment for it. He also does not have a primary care physician, and he has been having issues with foot ulcers.

This scenario has begun to become the norm with work-related cases. Chronic medical conditions are on the rise in the United States, and they are becoming the leading causes of death and disability. According to the Centers for Disease Control and Prevention, 1 in 4 Americans has multiple chronic conditions. The increased prevalence of multiple chronic conditions is partly due to our rapidly aging population, poor nutrition, and increased life expectancy. Other reasons include a high prevalence of risk factors such as tobacco use and inactivity.[1] Chronic medical conditions occurring simultaneously are described as a comorbidity. Therefore, in this article we will refer to chronic medical conditions as comorbidities.

We have begun to see the effects of comorbidities in the workers' compensation arena. Common comorbidities that have become prevalent with workers' compensation cases are hypertension, diabetes, obesity, and arthritis. Why should we be concerned with the increasing prevalence of comorbidities? Illness affects the quality and quantity of work done. Illness can affect the ability to meet the physical demands of a job and the psychosocial demands of the job.[2] Comorbidities contribute to reduced work productivity in the form of absenteeism (habitual loss of time away from work) and presenteeism (reduced productivity when at work). Although is obvious that time away from work has an effect on productivity,[3] research has shown that the cost of presenteeism is more than $150 billion a year,[4] and thus individuals who coordinate medical treatment and return to work must be aware of how comorbidities affect how we perform case management services.

There is a strong relationship between diabetes, hypertension, and obesity. Why? Because individuals who have at least 1 of these conditions are at risk of developing or having 1 or 2 of the 3 conditions. With the aging of the workforce and increasing rates of obesity, arthritis is a growing additional concern. In this article, we define each comorbidity and discuss how each one can negatively affect medical treatment for the injured worker. We will also expound on best practices in accordance with the CCMC Code of Professional Conduct[5] and the CDMC Code of Professional Conduct.[6]

Diabetes

Diabetes is a condition in which the body does not make enough insulin or is unable to use insulin as it should. In the last 2 decades, the number of adults diagnosed with diabetes has tripled because the US population is aging and because more individuals are overweight or obese.[7] According to the Centers for Disease and Prevention, 30.3 million people in the United States have diabetes (9.4% of the US population). Unfortunately, 7.2 million of the 30.3 million are undiagnosed, and it is estimated that 84.1 million people have prediabetes. Prediabetes means that blood glucose levels are higher than they should be.[8]

Diabetes is a disease that can negatively affect every single organ in the body. Diabetic retinopathy can cause vision impairments. Diabetes can hinder circulation, which in turn can lead to impaired healing of wounds, burns, and fractures. This impaired circulation raises the risk for infection. Diabetes can lead to nerve compression syndromes, and diabetic neuropathy can mimic carpal tunnel syndrome. For individuals whose job entails a great deal of walking, diabetes can predispose them to developing foot ulcers.[9] Poorly controlled blood sugar can contribute to

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Chronic medical conditions are on the rise in the United States, and they are becoming the leading causes of death and disability. According to the Centers for Disease Control and Prevention, 1 in 4 Americans has multiple chronic conditions.

bone deterioration.[10] A common complication of diabetes is Charcot joint, which mainly affects the feet. Charcot joint can be problematic for individuals whose job requires a great deal of walking and standing.[11] Additionally, individuals with poorly controlled blood sugar levels have a high chance of not being able to receive medical clearance to proceed with surgical intervention. Lastly, insulin can interfere with medication commonly taken for workers' compensation injuries such as opioids and nonsteroidal inflammatory medications.

Hypertension

Hypertension is a condition in which the blood flowing through the blood vessels is greater than normal. Close to 75 million people in the United States have high blood pressure, but only half of these individuals have their high blood pressure under control. Hypertension is known as the "silent killer" because there are often no warning symptoms. Sixty percent of individuals with diabetes have high blood pressure. The most common type of hypertension is classified as primary high blood pressure. This type tends to develop as a person ages and accounts for 90%–95% of adult cases. Secondary hypertension usually occurs as a result of another medical condition or use of certain medications. It usually resolves after the cause is treated or removed.[12]

There are unique challenges that can occur with the diagnosis of hypertension. First, depending on the jurisdiction of the workers' compensation case and the worker's occupation, hypertension can be considered as a workers' compensation injury. Another challenge is that hypertension can be insidious—slowly developing over time and remain undetected for years. Lastly, it is usually accompanied by at least one other comorbidity—usually diabetes or obesity or both.

Obesity

Obesity is a condition associated with an excess amount of body fat. If an individual's body weight is over 20% of what it should be, then he or she is considered as obese. According to the American Heart Association, more than 78 million adults in the United States are obese. Health consequences for obese individuals include type 2 diabetes, osteoarthritis, high blood pressure, and difficulty with physical functioning.[13] As little as a 10-pound weight gain can increase mechanical stress on the ankles and feet, which are 2 of the primary weight-bearing joints. This extra weight can also weaken tendons and ligaments, increasing the risk for falls. Workers who are obese may not be able to correctly wear protective gear. Excess weight can hinder gait and correct physical functioning. Increased abdominal girth can affect balance, which also increases the risk for falls.[14]

Medical treatment can be delayed when a physician recommends weight loss before proceeding with medically necessary surgical intervention. Diagnostic studies could be delayed because of an inability to find equipment that can accommodate the patient's size. Postoperatively, research has shown that obese patients have an increased risk of delayed wound healing and increased risk for infection due to excess adipose tissue and decreased tissue perfusion. Malnutrition also puts the obese patient at risk for postoperative complications.

Arthritis

Arthritis, joint inflammation that causes joint pain and stiffness, is the leading cause of disability in the United States. Loss of range of motion is also associated with arthritis. More than 50 million adults have some form of arthritis. The most common form of arthritis is degenerative arthritis or osteoarthritis. Osteoarthritis can be primary or secondary. Primary osteoarthritis generally occurs as a result of wear and tear and is associated with aging. Secondary arthritis usually occurs because of an injury or trauma.[15] It is not uncommon for secondary arthritis to surface after a traumatic fracture or as a result of a hormonal imbalance. Individuals with certain occupations that include a lot of activity that can stress the joints, such as kneeling, squatting, or lifting heavy weights (55 pounds or more), are more likely to develop osteoarthritis.

Arthritis can present a unique set of challenges. The worker can be unaware of arthritic changes until imaging occurs for the work-related injury. Another complicating issue with arthritis is that a work injury can aggravate or

There is a strong relationship between diabetes, hypertension, and obesity. Individuals who have at least 1 of these conditions are at risk of developing or having 1 or 2 of the 3 conditions.

exacerbate preexisting arthritic changes. Aggravation is a worsening of a preexisting condition. Exacerbation is a temporary increase in symptoms, after which the patient goes back to their previous baseline status. If the patient has limited and painful range of motion due to arthritis, he or she is at increased risk of developing other comorbidities such as diabetes or obesity.

Application of CCMC and CDMS Code of Professional Conduct

Before we address best practices for case managers who are coordinating medical treatment for injured workers with comorbidities, we will address ethical components according to the CCMC and the CDMS Code of Professional Conduct. One underlying tenet of the CCMC Code of Professional Conduct is that case management is a vehicle for improving wellness and self-determination through advocacy, communication, education, recognition of service resources, and service collaboration. Using the CCMC Code of Professional Conduct as a foundation, we will highlight 3 principles that a board-certified case manager/disability specialist should pay special attention to. First, the board-certified case manager/disability specialist should complete an all-inclusive assessment to identify the injured worker's needs. This will give a comprehensive view of all factors that need to be contemplated with care coordination.

Another standard is that the board-certified case manager/disability specialist should provide appropriate information to enlighten and empower clients to make informed decisions. This standard involves the board-certified case manager/disability specialist incorporating the ethical principles of veracity, advocacy, and autonomy. Advocacy includes informing the client of a free or low-income clinic that may provide treatment for the comorbidity. Veracity entails informing the injured worker that the workers' compensation carrier may not pay for these services. The board-certified case manager/disability specialist needs to respect the patient's wish for autonomy. This means understanding that the injured worker has the right to refuse to seek treatment for the comorbidity regardless of being directed to do so by a physician. Another special deliberation is that of confidentiality and privacy.

The third standard to reflect upon is that the board-certified case manager/disability specialist should disclose to the injured worker that information may be shared with the workers' compensation carrier, especially if it could be seen as a factor in the injured worker's lack of progress. If the injured worker resists sharing this information with their employer, the case manager would need to act according to their state's jurisdictional regulations regarding who has access to the injured worker's health information.

Best Practices

Best practices for the case manager coordinating care for the injured worker with comorbidities include the following:

1. Secure a signed medical release that allows the case manager to speak with the physician treating the patient for the non-work-related injury regarding the comorbidity. The case manager should also disclose to the injured worker that the physician treating him or her for the work-related injury would be provided this information as well.
2. Obtain a thorough medical history by incorporating motivational interviewing skills. Open-ended questions will usually elicit more detailed information from the injured worker. This enables the case manager to coordinate medical treatment with knowledge of all factors that could hinder timely healing and recovery.
3. Be diligent in performing medication reconciliation. Patients with comorbidities are usually at risk for polypharmacy, which is simultaneous use of numerous medications for more than 1 condition. This can help make sure that the patient is not been overmedicated and that the patient doesn't have adverse drug interactions.
4. If surgery is involved, make sure that the physician thoroughly explains to the injured worker the challenges that could occur due to comorbidity. Be proactive in seeking medical clearance from the primary care physician.
5. Contact the injured worker frequently, especially postoperatively. The obese or arthritic patient may be less motivated to move around, which could increase the risk for developing deep vein thrombosis.

Comorbidities contribute to reduced work productivity in the form of absenteeism (habitual loss of time away from work) and presenteeism (reduced productivity when at work).

6. With the comorbidity of arthritis, the case manager can assist in obtaining information from the treating physician to help determine if there is exacerbation or aggravation of the arthritis.
7. A vocational case manager can assist with performing ergonomic evaluations to ensure proper posture and body mechanics.
8. For the injured worker with diabetes, the vocational case manager may want to consult the Department of Transportation Diabetes Exemption Program when coordinating return to work. (https://www.fmcsa.dot.gov/medical/driver-medical-requirements/diabetes-exemption-application).

Conclusion

This article provides useful information for case managers who are coordinating care for patients with a work-related injury with a comorbidity. Understanding the disease process and using this information to coordinate care can increase the chances of uncomplicated recovery. The ethical principles of advocacy, veracity, confidentiality, and respecting the patient's autonomy greatly benefit the case manager in being successful with coordinating care. CE II

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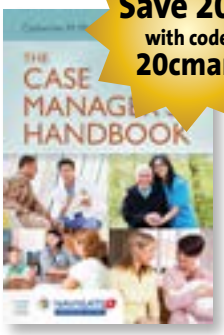

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- Nephrotoxicity has been reported with Zemdri. The risk of nephrotoxicity is greater in patients with impaired renal function, the elderly, and in those receiving concomitant nephrotoxic medications. Assess creatinine clearance in all patients prior to initiating therapy and daily during therapy. Therapeutic Drug Monitoring (TDM) is recommended for complicated urinary tract infection (cUTI) patients with CLcr <90 mL/min to avoid potentially toxic levels.
- Ototoxicity, manifested as hearing loss, tinnitus, and/or vertigo, has been reported with Zemdri. Symptoms of aminoglycoside-associated ototoxicity may be irreversible and may not become evident until after completion of therapy. Aminoglycoside-associated ototoxicity has been observed primarily in patients with a family history of hearing loss, patients with renal impairment, and in patients receiving higher doses and/or longer durations of therapy than recommended.
- Aminoglycosides have been associated with neuromuscular blockade. During therapy with Zemdri, monitor for adverse reactions associated with neuromuscular blockade, particularly in high-risk patients, such as patients with underlying neuromuscular disorders (including myasthenia gravis) or in patients concomitantly receiving neuromuscular blocking agents.
- Aminoglycosides, including Zemdri, can cause fetal harm when administered to a pregnant woman.

INDICATIONS AND USAGE

Complicated Urinary Tract Infections (cUTI), including pyelonephritis

Zemdri is indicated in patients ≥18 years of age for the treatment of complicated urinary tract infections, including pyelonephritis caused by the following susceptible microorganism(s): *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, and Enterobacter cloacae.* As only limited clinical safety and efficacy data for Zemdri are currently available, reserve Zemdri for use in cUTI patients who have limited or no alternative treatment options.

Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Zemdri and other antibacterial drugs, Zemdri should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

DOSAGE AND ADMINISTRATION

Recommended Dosage

The recommended dosage regimen of Zemdri is 15 mg/kg administered every 24 hours by intravenous (IV) infusion over 30 minutes in patients ≥18 years of age and with creatinine clearance (CLcr) ≥90 mL/min. The duration of therapy should be guided by the severity of infection and the patient's clinical status for up to 7 days. During treatment, dosage adjustments may be required based on change in renal function

Monitoring of Renal Function

Assess creatinine clearance in all patients before initiating therapy and daily during therapy with Zemdri.
See prescribing information for patients with renal impairment. https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210303Orig1s000lbl.pdf

Preparation of Diluted Solutions of Zemdri

Zemdri is supplied as a single-dose fliptop 10-mL vial that contains plazomicin sulfate equivalent to 500 mg plazomicin freebase in 10 mL Water for Injection (concentration of 50 mg/mL). The appropriate volume of Zemdri solution (50 mg/mL) for the required dose should be diluted in 0.9% Sodium Chloride Injection, USP or Lactated Ringer's Injection, USP to achieve a final volume of 50 mL for IV infusion. The stability of Zemdri solution in the compatible diluents is described below.

Zemdri does not contain preservatives. Aseptic technique must be followed in preparing the infusion solution. Discard unused portion of the Zemdri vial.
Parenteral drug products should be inspected visually for particulate matter and discoloration before administration, whenever solution and container permit.

Stability of Zemdri Solution in Intravenous Fluids

After dilution, Zemdri solution for administration is stable for 24

hours at room temperature at concentrations of 2.5 mg/mL to 45 mg/mL in the following solutions:

- 0.9% Sodium Chloride Injection, USP
- Lactated Ringer's Injection, USP

Drug Compatibility

Compatibility of Zemdri for administration with other drugs has not been established. Zemdri should not be mixed with other drugs or physically added to solutions containing other drugs. Other medications should not be infused simultaneously with Zemdri through the same IV line.

DOSAGE FORMS AND STRENGTHS

Zemdri injection 500 mg/10 mL (50 mg/mL) is a sterile, clear, colorless-to-yellow solution supplied in a single-dose vial. Each single-dose vial contains plazomicin sulfate equivalent to 500 mg plazomicin freebase.

CONTRAINDICATIONS

Zemdri is contraindicated in patients with known hypersensitivity to any aminoglycoside.

WARNINGS AND PRECAUTIONS

Nephrotoxicity

Nephrotoxicity has been reported with the use of Zemdri. Most serum creatinine increases were ≤1 mg/dL above baseline and reversible.

Serum creatinine increases of 0.5 mg/dL or greater above baseline occurred in 7% (21/300) of Zemdri-treated patients compared with 4% (12/297) of meropenem-treated patients. These increases mainly occurred in patients with CLcr ≤ 90 mL/min and were associated with a plazomicin trough level (Cmin) ≥3 µg/mL.

Assess CLcr in all patients before initiating therapy and daily during therapy with Zemdri, particularly in those at increased risk of nephrotoxicity, such as those with renal impairment, the elderly, and those receiving concomitant potentially nephrotoxic medications. In the setting of worsening renal function, the benefit of continuing Zemdri should be assessed.

Adjust the initial dosage regimen in cUTI patients with CLcr ≥15 mL/min and <60 mL/min. For subsequent doses, TDM is recommended for patients with CLcr ≥15 mL/min and <90 mL/min.

Ototoxicity

Ototoxicity, manifested as hearing loss, tinnitus, and/or vertigo, has been reported with Zemdri. Symptoms of aminoglycoside-associated ototoxicity may be irreversible and may not become evident until after completion of therapy.

Aminoglycoside-associated ototoxicity has been observed primarily in patients with a family history of hearing loss (excluding age-related hearing loss), patients with renal impairment, and in patients receiving higher doses and/or for longer periods than recommended. In Trial 1 and Trial 2, patients with a history of hearing loss, with the exception of age-related hearing loss, were excluded. The benefit-risk of Zemdri therapy should be considered in these patients.

Neuromuscular Blockade

Aminoglycosides have been associated with exacerbation of muscle weakness in patients with underlying neuromuscular disorders or delay in recovery of neuromuscular function in patients receiving concomitant neuromuscular-blocking agents.

During therapy with Zemdri, monitor for adverse reactions associated with neuromuscular blockade, particularly in high-risk patients, such as patients with underlying neuromuscular disorders (including myasthenia gravis) or those patients concomitantly receiving neuromuscular blocking agents.

Fetal Harm

Aminoglycosides, including Zemdri, can cause fetal harm when administered to a pregnant woman. Aminoglycosides cross the placenta and streptomycin has been associated with several reports of total, irreversible, bilateral congenital deafness in pediatric patients exposed in utero. Patients who use Zemdri during pregnancy or become pregnant while taking Zemdri should be apprised of the potential hazard to the fetus.

Hypersensitivity Reactions

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving aminoglycoside antibacterial drugs. Before therapy with Zemdri is instituted, careful inquiry about previous hypersensitivity reactions to other aminoglycosides should be made. A history of hypersensitivity to other aminoglycosides is a contraindication to the use of Zemdri because cross-sensitivity among aminoglycoside antibacterial drugs has been established. Discontinue Zemdri if an allergic reaction occurs.

Clostridium difficile-*Associated Diarrhea*

Clostridium difficile (C. difficile)-associated diarrhea (CDAD) has been reported for nearly all systemic antibacterial drugs and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial drugs alters the normal flora of the colon and may permit overgrowth of *C. difficile.*

C. difficile produces toxins A and B that contribute to the development of CDAD. Hypertoxin-producing strains of *C. difficile* cause increased morbidity and mortality because these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial use. Careful medical history is necessary because CDAD has been reported to occur more than 2 months after the administration of antibacterial drugs.

If CDAD is suspected or confirmed, antibacterial drugs not directed against *C. difficile* may need to be discontinued. Manage fluid and electrolyte levels as appropriate, supplement protein intake, monitor antibacterial treatment of *C. difficile,* and institute surgical evaluation as clinically indicated.

Development of Drug-Resistant Bacteria

Prescribing Zemdri in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

ADVERSE REACTIONS

The following important adverse reactions are discussed in greater detail in the Warnings and Precautions section of the prescribing information.

- Nephrotoxicity
- Ototoxicity
- Neuromuscular blockade
- Fetal harm
- Hypersensitivity reactions
- *Clostridium difficile*-associated diarrhea

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Aminoglycosides, including Zemdri, can cause fetal harm when administered to a pregnant woman. There are no available data on the use of Zemdri in pregnant women to inform a drug-associated risk of adverse developmental outcomes. Published literature reports of streptomycin, an aminoglycoside, state that it can cause total, irreversible, bilateral congenital deafness in children whose mothers received streptomycin during pregnancy. Advise pregnant women of the potential risk to a fetus.

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

Lactation

Risk Summary

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

Pediatric Use

The safety and effectiveness of Zemdri in patients <18 years of age have not been established.

Renal Impairment

Plazomicin total body clearance was significantly decreased in patients with CLcr ≥15 to ≥60 mL/min compared to patients with CLcr ≥60 mL/min. Monitor CLcr daily and adjust Zemdri dosage accordingly. There is insufficient information to recommend a dosage regimen in patients with CLcr ≤15 mL/min or on renal replacement therapy, including hemodialysis or continuous renal replacement therapy.

For patients with CLcr ≥15 mL/min and <90 mL/min, TDM is recommended. Monitor plazomicin trough concentrations and adjust Zemdri dosage accordingly,

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

Zemdri injection 500 mg/10 mL (50 mg/mL) is supplied in single-dose, 10-mL vials fitted with flip-off seals with royal blue polypropylene buttons as a clear, colorless-to-yellow, sterile solution. Each vial contains plazomicin sulfate equivalent to 500 mg plazomicin freebase at a concentration of 50 mg/mL plazomicin in Water for Injection. Each vial contains sodium hydroxide for pH adjustment to 6.5. The solution may become yellow in color; this does not indicate a decrease in potency.

Storage and Handling

Store Zemdri injection 500 mg/10 mL (50 mg/mL) refrigerated at 2°C to 8°C (36°F to 46°F).

Zemdri is manufactured for Achaogen, Inc.

Epidiolex (cannabidiol) Oral Solution.

Epidiolex (cannabidiol) is a prescription pharmaceutical formulation of highly purified marijuana plant derived cannabidiol (CBD).

INDICATIONS AND USAGE

Epidiolex is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in patients 2 years of age and older.

DOSAGE AND ADMINISTRATION

Assessments Before Initiating Epidiolex

Because of the risk of hepatocellular injury, obtain serum transaminases (ALT and AST) and total bilirubin levels in all patients before starting treatment with Epidiolex.

Dosage Information

- Epidiolex is to be administered orally.
- The starting dosage is 2.5 mg/kg twice daily (5 mg/kg/day).
- After 1 week, the dosage can be increased to a maintenance dosage of 5 mg/kg twice daily (10 mg/kg/day).
- Patients who are tolerating Epidiolex at 5 mg/kg twice daily and require further reduction of seizures may benefit from a dosage increase up to a maximum recommended maintenance dosage of 10 mg/kg twice daily (20 mg/kg/day), in weekly increments of 2.5 mg/kg twice daily (5 mg/kg/day), as tolerated. For patients in whom a more rapid titration from 10 mg/kg/day to 20 mg/kg/day is warranted, the dosage may be increased no more frequently than every other day. Administration of the 20 mg/kg/day dosage

resulted in somewhat greater reductions in seizure rates than the recommended maintenance dosage of 10 mg/kg/day, but with an increase in adverse reactions.

Administration Instructions

Food may affect Epidiolex levels.

A calibrated measuring device (either 5 mL or 1 mL oral syringe) will be provided and is recommended to measure and deliver the prescribed dose accurately. A household teaspoon or tablespoon is not an adequate measuring device.

Discard any unused Epidiolex remaining 12 weeks after first opening the bottle.

Discontinuation of Epidiolex

When discontinuing Epidiolex, the dose should be decreased gradually. As with all antiepileptic drugs, abrupt discontinuation should be avoided when possible to minimize the risk of increased seizure frequency and status epilepticus.

Patients with Hepatic Impairment

Dose adjustment is recommended in patients with moderate (Child-Pugh B) hepatic impairment or severe (Child-Pugh C) hepatic impairment. It may be necessary to have slower dose titration in patients with moderate or severe hepatic impairment than in patients without hepatic impairment.

Epidiolex does not require dose adjustment in patients with mild (Child-Pugh A) hepatic impairment.

DOSAGE FORMS AND STRENGTHS

Cannabidiol oral solution: 100 mg/mL for oral administration. Each bottle contains 100 mL of a clear colorless-to-yellow solution.

CONTRAINDICATIONS

Epidiolex is contraindicated in patients with a history of hypersensitivity to cannabidiol or any of the ingredients in the product.

WARNINGS AND PRECAUTIONS

Hepatocellular Injury

Epidiolex causes dose-related elevations of liver transaminases (alanine aminotransferase [ALT] and/or aspartate aminotransferase [AST]).

Risk Factors for Transaminase Elevation

Concomitant Valproate and Clobazam: Most ALT elevations occurred in patients taking concomitant valproate. Concomitant use of clobazam also increased the incidence of transaminase elevations, although to a lesser extent than valproate. In Epidiolex-treated patients, the incidence of ALT elevations >3 times the ULN was 30% in patients taking both concomitant valproate and clobazam, 21% in patients taking concomitant valproate (without clobazam), 4% in patients taking concomitant clobazam (without valproate), and 3% in patients taking neither drug. Consider discontinuation or dose adjustment of valproate or clobazam if liver enzyme elevations occur.

Dose: Transaminase elevations are dose-related. Overall, ALT elevations >3 times the ULN were reported in 17% of patients taking Epidiolex 20 mg/kg/day compared with 1% in patients taking Epidiolex 10 mg/kg/day.

Baseline Transaminase Elevations: Patients with baseline transaminase levels above the ULN had higher rates of transaminase elevations when taking Epidiolex. In controlled trials in patients taking Epidiolex 20 mg/kg/day, the frequency of treatment-emergent ALT elevations greater than 3 times the ULN was 30% when ALT was above the ULN at baseline, compared to 12% when ALT was within the normal range at baseline. No patients taking Epidiolex 10 mg/kg/day experienced ALT elevations greater than 3 times the ULN when ALT was above the ULN at baseline, compared with 2% of patients in whom ALT was within the normal range at baseline.

Monitoring

In general, transaminase elevations of >3 times the ULN in the presence of elevated bilirubin without an alternative explanation are an important predictor of severe liver injury. Early identification of elevated liver enzymes may decrease the risk of a serious outcome. Patients with elevated baseline transaminase levels above 3 times the ULN, accompanied by elevations in bilirubin above 2 times the ULN, should be evaluated before initiation of Epidiolex treatment.

Before starting treatment with Epidiolex, obtain serum transaminases (ALT and AST) and total bilirubin levels. Serum transaminases and total bilirubin levels should be obtained at 1 month, 3 months, and 6 months after initiation of treatment with Epidiolex, and periodically thereafter or as clinically indicated. Serum transaminases and total bilirubin levels should also be obtained within 1 month following changes in Epidiolex dosage and addition of or changes in medications that are known to impact the liver. Consider more frequent monitoring of serum transaminases and bilirubin in patients who are taking valproate or who have elevated liver enzymes at baseline.

If a patient develops clinical signs or symptoms suggestive of hepatic dysfunction (e.g., unexplained nausea, vomiting, right upper quadrant abdominal pain, fatigue, anorexia, or jaundice and/or dark urine), promptly measure serum transaminases and total bilirubin and interrupt or discontinue treatment with Epidiolex, as appropriate. Discontinue Epidiolex in any patients with elevations of transaminase levels >3 times the ULN and bilirubin levels >2 times the ULN. Patients with sustained transaminase elevations of >5 times the ULN should also have treatment discontinued. Patients with prolonged elevations of serum transaminases should be evaluated for other possible causes. Consider dosage adjustment of any coadministered medication that is known to affect the liver (e.g., valproate and clobazam).

Somnolence and Sedation

Epidiolex can cause somnolence and sedation. In controlled studies for LGS and DS, the incidence of somnolence and sedation (includ-

ing lethargy) was 32% in Epidiolex-treated patients compared with 11% in patients on placebo and was dose-related (34% of patients taking Epidiolex 20 mg/kg/day, compared with 27% in patients taking Epidiolex 10 mg/kg/day). The rate was higher in patients on concomitant clobazam (46% in Epidiolex-treated patients taking clobazam compared with 16% in Epidiolex-treated patients not on clobazam). In general, these effects were more common early in treatment and may diminish with continued treatment. Other CNS depressants, including alcohol, could potentiate the somnolence and sedation effect of Epidiolex. Prescribers should monitor patients for somnolence and sedation and should advise patients not to drive or operate machinery until they have gained sufficient experience on Epidiolex to gauge whether it adversely affects their ability to drive or operate machinery.

Suicidal Behavior and Ideation

Antiepileptic drugs (AEDs), including Epidiolex, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with an AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, or any unusual changes in mood or behavior.

The increased risk of suicidal thoughts or behavior with AEDs was observed as early as 1 week after starting drug treatment with AEDs and persisted for the duration of treatment assessed. Because most trials included in the analysis did not extend beyond 24 weeks, the risk of suicidal thoughts or behavior beyond 24 weeks could not be assessed.

The risk of suicidal thoughts or behavior was generally consistent among drugs in the data analyzed. The finding of increased risk with AEDs of varying mechanisms of action and across a range of indications suggests that the risk applies to all AEDs used for any indication. The risk did not vary substantially by age (5–100 years) in the clinical trials analyzed.

The relative risk for suicidal thoughts or behavior was higher in clinical trials in patients with epilepsy than in clinical trials in patients with psychiatric or other conditions, but the absolute risk differences were similar for the epilepsy and psychiatric indications.

Anyone considering prescribing Epidiolex or any other AED must balance the risk of suicidal thoughts or behaviors with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Should suicidal thoughts and behavior emerge during treatment, consider whether the emergence of these symptoms in any given patient may be related to the illness being treated.

Hypersensitivity Reactions

Epidiolex can cause hypersensitivity reactions. One subject in the Epidiolex clinical trials had pruritus, erythema, and angioedema requiring treatment with antihistamines. Patients with known or suspected hypersensitivity to any ingredients of Epidiolex were excluded from the clinical trials. If a patient develops hypersensitivity reactions after treatment with Epidiolex, the drug should be discontinued. Epidiolex is contraindicated in patients with a prior hypersensitivity reaction to cannabidiol or any of the ingredients in the product, which includes sesame seed oil.

Withdrawal of Antiepileptic Drugs

As with most AEDs, Epidiolex should generally be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus. But if withdrawal is needed because of a serious adverse event, rapid discontinuation can be considered.

ADVERSE REACTIONS

The following important adverse reactions are described elsewhere in labeling:

- Hepatocellular injury
- Somnolence and sedation
- Suicidal behavior and ideation
- Hypersensitivity reactions
- Withdrawal of AEDs

USE IN SPECIFIC POPULATIONS:

See full prescribing information

CLINICAL STUDIES

Lennox–Gastaut Syndrome

The effectiveness of Epidiolex for the treatment of seizures associated with LGS was established in two randomized, double-blind, placebo-controlled trials in patients aged 2 to 55 years.

Dravet Syndrome

The effectiveness of Epidiolex for the treatment of seizures associated with DS was demonstrated in a single randomized, double-blind, placebo-controlled trial in 120 patients aged 2 to 18 years.

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

Epidiolex is a strawberry-flavored clear colorless-to-yellow solution supplied in a 105-mL amber glass bottle with a child-resistant closure containing 100 mL of oral solution (NDC 70127-100-01). Each mL contains 100 mg of cannabidiol. Epidiolex is packaged in a carton with two 5 mL calibrated oral dosing syringes and a bottle adapter (NDC 70127-100-10). The pharmacy will provide 1 mL calibrated oral dosing syringes when doses <1 mL are required.

Storage and Handling

Store Epidiolex in its original bottle in an upright position at 20°C to 25°C (68°F to 77°F); excursions are permitted between 15°C to 30°C (59°F to 86°F). [See USP Controlled Room Temperature]. Do not refrigerate or freeze. Keep the cap tightly closed. Use within 12 weeks of first opening the bottle, then discard any remainder.

Epidiolex is marketed by Greenwich Biosciences, Inc.

LITSCAN FOR CASE MANAGERS

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

Circ Cardiovasc Qual Outcomes. 2018 Jul;11(7):e004729. doi: 10.1161/CIRCOUTCOMES.118.004729.

Association of the Affordable Care Act's Medicaid expansion with care quality and outcomes for low-income patients hospitalized with heart failure.

Wadhera RK, Joynt Maddox KE, Fonarow GC, et al.

BACKGROUND: Heart failure (HF) is the leading cause of morbidity and mortality in the United States. Despite advancement in the management of HF, outcomes remain suboptimal, particularly among the uninsured. In 2014, the Affordable Care Act expanded Medicaid eligibility, and millions of low-income adults gained insurance. Little is known about Medicaid expansion's effect on inpatient HF care. METHODS AND RESULTS: We used the American Heart Association's Get With The Guidelines-Heart Failure registry to assess changes in inpatient care quality and outcomes among low-income patients (<65 years old) hospitalized for HF after Medicaid expansion, in expansion, and nonexpansion states. Patients were classified as low income if covered by Medicaid, uninsured, or missing insurance. Expansion states were those that implemented expansion in 2014. Piecewise logistic multivariable regression models were constructed to track quarterly trends of quality and outcome measures in the pre (January 1, 2010-December 31, 2013) and postexpansion (January 1, 2014-June 30, 2017) periods. These measures were compared between expansion versus nonexpansion states during the postexpansion period. The cohort included 58 804 patients hospitalized across 391 sites. In states that expanded Medicaid, uninsured HF hospitalizations declined from 7.9% to 4.4% and Medicaid HF hospitalizations increased from 18.3% to 34.6%. Defect-free HF care was increasing during the preexpansion period (adjusted odds ratio/quarter, 1.06; 95% confidence interval, 1.03-1.08) but did not change after expansion (adjusted odds ratio, 0.99; 95% confidence interval, 0.97-1.02). Patterns were similar for other quality measures. There were no quality measures for which the rate of improvement sped up after expansion. In-hospital mortality rates remained similar during the preexpansion (adjusted odds ratio, 0.99; 95% confidence interval, 0.96-1.02) and postexpansion periods (adjusted odds ratio, 1.00; 95% confidence interval, 0.97-1.03). Among nonexpansion states, uninsured HF hospitalizations increased (11.6% to 16.7%) as did Medicaid HF hospitalizations (17.9% to 26.6%), and no quarterly improvement was observed for most quality measures in the post compared with preexpansion period. During the postexpansion period, defect-free care and mortality did not differ between expansion and nonexpansion states. CONCLUSIONS: Medicaid expansion was associated with a significant decline in uninsured HF hospitalizations but not improvements in quality of care or in-hospital mortality among sites participating in a national quality improvement initiative. Efforts beyond insurance expansion are needed to improve in-hospital outcomes for low-income patients with HF.

J Acquir Immune Defic Syndr. 2018 Aug 1;78(4):441-449. doi: 10.1097/QAI.0000000000001692.

HIV infection is associated with abnormal bone microarchitecture: measurement of trabecular bone score in the women's interagency HIV Study.

Sharma A, Ma Y, Tien PC, et al.

OBJECTIVES: We compared skeletal microarchitecture using trabecular bone score (TBS) and evaluated relationships between change in TBS and lumbar spine (LS) bone mineral density (BMD) in women with and without HIV. METHODS: Dual-energy X-ray absorptiometry was performed on 319 women with HIV and 118 without HIV in the Women's Interagency HIV Study at baseline and 2 and 5 years to measure regional BMD and lean and fat mass. TBS was extracted from LS dual-energy X-ray absorptiometry images and examined continuously and categorically [normal (≥1.35), intermediate (1.20-1.35), or degraded (≤1.20) microarchitecture]. Pearson correlation and linear regression examined associations of TBS with regional BMD at baseline and over time. RESULTS: Women with HIV were older (43 vs. 37 years), more likely to be postmenopausal (27% vs. 4%), have lower baseline total fat mass, trunk fat, and leg fat than uninfected women, degraded microarchitecture (27% vs. 9%, P = 0.001), and lower baseline mean TBS (1.3 ± 0.1 vs. 1.4 ± 0.1,

P < 0.001). After adjusting for age, race, menopause status, and body mass index, TBS remained lower in women with HIV (P < 0.0001). Annual change in TBS correlated with LS BMD change among women with HIV (r = 0.36, P < 0.0001) and without HIV (r = 0.26, P = 0.02); however, mean % annual TBS change did not differ by HIV status (-1.0%/yr ± 2.9% for HIV+ vs. -0.8%/yr ± 1.7% for HIV-, P = 0.42). CONCLUSIONS: Women with HIV have worse bone microarchitecture than uninfected women, but annual percent change in LS BMD or TBS was similar. Use of TBS as an adjunct to BMD to improve prediction of fragility fractures in women with HIV merits further

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Circulation. 2018 Jun 22. pii: CIRCULATIONAHA.118.034763. doi: 10.1161/CIRCULATIONAHA.118.034763. [Epub ahead of print]

Heart Failure After Ischemic Stroke or TIA in Insulin-Resistant Patients Without Diabetes Treated with Pioglitazone.

Young LH, Viscoli CM, Schwartz GG, et al.; IRIS Investigators.

BACKGROUND: The Insulin Resistance Intervention after Stroke (IRIS) trial demonstrated that pioglitazone reduced risk for both cardiovascular events and diabetes in insulin resistant patients. However, concern remains that pioglitazone may increase risk for heart failure (HF) in susceptible individuals. METHODS: In IRIS, patients with insulin resistance but without diabetes were randomized to pioglitazone or placebo (1:1) within 180 days of an ischemic stroke or TIA and followed for up to 5 years. To identify patients at higher HF risk with pioglitazone we performed a secondary analysis of IRIS participants without HF history at entry. HF episodes were adjudicated by an external review and treatment effects were analyzed using time-to-event methods. A baseline HF risk score was constructed from a Cox model estimated using stepwise selection. Baseline patient features (individually and summarized in risk score) and post-randomization events were examined as possible modifiers of the effect of pioglitazone. Net cardiovascular benefit was estimated for the composite of stroke, myocardial infarction (MI) and hospitalized HF. RESULTS: Among 3851 patients, mean age was 63 years and 65% were male. The 5-year HF risk did not differ by treatment (4.1% pioglitazone; 4.2% placebo). Risk for hospitalized HF was low and not significantly greater in pioglitazone compared to placebo groups (2.9% vs. 2.3%, p=0.36). Older age, atrial fibrillation, hypertension, obesity, edema, high C-reactive protein, and smoking were risk factors for HF. However, the effect of pioglitazone did not differ across levels of baseline HF risk (hazard ratio [95% confidence interval] for pioglitazone vs. placebo for patients at low, moderate and high risk: 1.03 [0.61, 1.73], 1.10 [0.56, 2.15], 1.08 [0.58, 2.01]; interaction p-value, 0.98). HF risk was increased in patients with vs. those without incident MI in both groups (pioglitazone: 31.4% vs. 2.7%; placebo: 25.7% vs. 2.4%, p<0.0001). Edema, dyspnea and weight gain in the trial did not predict HF hospitalization, but led to more study drug dose reduction with a lower mean dose of pioglitazone vs. placebo (29±17 mg vs. 33±15 mg; p<0.0001). Pioglitazone reduced the composite outcome of stroke, MI or hospitalized HF (HR, 0.78; p=0.007). CONCLUSIONS: In IRIS, with surveillance and dose adjustments, pioglitazone did not increase risk of HF, and conferred net cardiovascular benefit in patients with insulin resistance and cerebrovascular disease. The risk of HF with pioglitazone was not modified by baseline HF risk. The IRIS experience may be instructive for maximizing the net benefit of this therapy. Clinical Trial Registration -URL: www.clinicaltrials.gov Unique identifier: NCT00091949.

J Acquir Immune Defic Syndr. 2018 Jun 26. doi: 10.1097/QAI.0000000000001790. [Epub ahead of print]

Cognitive performance and frailty in older HIV-positive adults.

Paul RH, Cooley SA, Garcia-Egan PM, Ances BM.

OBJECTIVE: The present study examined the relative contribution of cognitive status to frailty among older individuals infected with human immunodeficiency virus (HIV+). DESIGN: Participants included 122 HIV+ individuals (mean age = 57.5 (6.6) with a median CD4 cell count of 546. Undetectable viral load (< 50 copies per mL) was observed in 94% of the sample. The sample was defined as frail (n=21) and non-frail (n=101) according to the Fried phenotype criteria. Cognitive tests included measures of Executive Function, Motor/Psychomotor, Language, Learning, and Memory. Performances were converted to standardized scores and averaged to calculate individual domain scores and a global index of cognitive function. METHODS: Logistic and hierarchical regressions were completed to separately determine the associations between clinical, demographic, and cognitive variables with regards to frailty status. RESULTS: Results of the logistic regressions revealed that lower Executive Function, female sex, and higher symptoms of depression were associated with frailty. The hierarchical analysis revealed no significant contribution of Executive Function to frailty status after accounting

for female sex and symptoms of depression (Nagelkerke R = 0.15). CONCLUSIONS:These results emphasize the importance of sex distribution and mental health in explanatory models of frailty in HIV. Further, interventions targeting symptoms of depression may increase resilience in older HIV+ individuals.

J Heart Lung Transplant. 2018 Apr 26. pii: S1053-2498(18)31438-4. doi: 10.1016/j.healun.2018.04.008. [Epub ahead of print]

Incidence of temporary mechanical circulatory support before heart transplantation and impact on post-transplant outcomes.

Ouyang D, Gulati G, Ha R, Banerjee D.

BACKGROUND:Proposed changes to the United Network for Organ Sharing heart transplant allocation protocol will prioritize patients receiving temporary mechanical circulatory support (tMCS), including extracorporeal membrane oxygenation (ECMO), percutaneous ventricular assist devices (PVADs), and intra-aortic balloon pumps (IABPs). We sought to evaluate contemporary trends in the incidence and outcomes of patients who required tMCS during the hospitalization before heart transplantation. METHODS: Using the National Inpatient Sample from 1998 to 2014, we identified 6,892 patients who received an orthotopic heart transplant and classified them by pre-transplant ECMO, PVAD, or IABP placement or no pre-transplant tMCS. We compared baseline characteristics and in-hospital outcomes between patients who underwent pre-transplant ECMO, PVAD, or IABP and patients who did not receive tMCS before heart transplantation. RESULTS: Of patients who underwent heart transplantation, 456 (6.6%) received tMCS before transplant. During the study period, the use of tMCS more than doubled, from 17 cases per year from 1998 to 2002 to 40 cases per year from 2012 to 2014 ($p < 0.001$ for trend). Of patients with tMCS, 341 (74.8%) were supported by IABP, 130 (28.5%) were supported by ECMO, and 21 (4.6%) were supported by PVAD. Before 2007, patients who required tMCS had higher in-hospital mortality than patients who did not require tMCS before transplant (14.3% vs 7.5%, $p = 0.05$). In the subsequent era (2007 to 2014), mortality was not significantly different (4.7% vs 5.1%, $p = 0.9$). Hospital mortality improved over time for all patients but most significantly in patients who required tMCS (9.6% absolute risk reduction). However, patients who received tMCS had increased lengths of stays and rates of acute renal, hepatic, and respiratory failure, sepsis, bleeding complications, and surgical reoperations. CONCLUSIONS: The use of tMCS before cardiac transplantation is increasing, with no difference in in-patient post-transplant mortality in the recent era between patients who did and did not receive tMCS but with increased complication rates among those who received tMCS. These data support the use of tMCS before cardiac transplantation in appropriately selected patients. Clinicians should balance the above outcomes when making decisions to implant tMCS, given the impending changes to the United Network for Organ Sharing heart allocation protocol.

J Hypertens. 2018 Aug;36(8):1671-1679. doi: 10.1097/HJH.0000000000001737

Long-term yogurt consumption and risk of incident hypertension in adults.

Buendia JR, Li Y, Hu FB, Cabral HJ, et al.

OBJECTIVE: To evaluate the relation between yogurt consumption as well as cheese, milk, and total dairy, and high blood pressure (HBP) in two Nurses' Health Study cohorts (NHS, n=69298), NHS II (n=84368) and the Health Professionals Follow-Up Study (HPFS, n=30512). METHODS: NHS, NHS II, and HPFS participants were followed for incident HBP for up to 30, 20, and 24 years, respectively. Hazard ratios were calculated using time-dependent multivariate-adjusted Cox proportional hazards models. Pooled risk estimates were derived from fixed effects meta-analyses. RESULTS: Participants consuming at least five servings per week (vs. <1 serving per month) of yogurt in NHS, NHS II, and HPFS had 19% (95% CI 0.75-0.87), 17% (95% CI 0.77-0.90), and 6% (95% CI 0.83-1.07) lower HBP risks, respectively. In pooled analyses of these cohorts, higher yogurt consumption was linked with 16% (95% CI 0.80-0.88) lower HBP risk; higher total dairy (3 to <6 vs. <0.5servings/day), milk (2 to <6/day vs. <4/week) and cheese (1 to 4/day vs. <1/week) were associated with 16% (95% CI 0.81-0.87), 12% (95% CI 0.86-0.90), and 6% (95% CI 0.90-0.97) lower HBP risks, respectively. After controlling for BMI as a possible causal intermediate, total dairy, yogurt, milk, and cheese were associated with 13, 10, 8, and 8% lower HBP risks, respectively. The combination of higher yogurt intake and higher DASH ('Dietary Approaches to Stop Hypertension') diet scores was associated with 30% (95% CI 0.66-0.75) lower HBP risk compared with lower levels of both factors. CONCLUSION: Higher total dairy intake, especially in the form of yogurt, was associated with lower risk of incident HBP in middle-aged and older adult men and women.

Ann Thorac Surg. 2018 Jun 27. pii: S0003-4975(18)30885-3. doi: 10.1016/j.athoracsur.2018.05.066. [Epub ahead of print]

Higher utilization of surgery confers superior survival in stage I non-small cell lung cancer.

Mulvihill MS, Cox ML, Becerra DC, et al.

BACKGROUND: Lobar resection is the gold standard therapy for medically fit patients with stage I non-small cell lung cancer (NSCLC). However, significant variability exists in utilization of surgery. This study tested the hypothesis that center-based variation in utilization of surgery impacts survival in NSCLC. METHODS: We queried the National Cancer Database for patients with stage I NSCLC. Mixed-effects multivariable models were developed to establish the per-center adjusted rate of surgery. Patients were stratified into quartiles based on treating center's adjusted rate of surgery. Survival was estimated and then tested using Kaplan-Meier and the log-rank test. Multivariable Cox proportional hazard models were developed to estimate the effect of rate of surgery on overall survival. RESULTS: 139,802 patients met criteria. There was wide variation in the per-center rate of surgical resection in the highest (80.8%) v. lowest quartile (41.4%, p<0.001). Across cohorts, patients were similar in age (mean 68.8 years in highest v. 69.7 in lowest) and Charleson-Deyo Score ≥2 (15.1% in highest v. 14.4% in lowest). Five-year survival was higher for patients treated at high-utilization centers (52.7% v 36.7%, p<0.001). Following adjustment, an adjusted rate of surgery in the lowest 25th percentile was associated with lower survival (AHR 1.40, 95% CI 1.37-1.40, p<0.001). CONCLUSIONS: Treatment at a center with a higher rate of surgery confers a significant survival advantage, even after adjustment for hospital volume, surgical approach, and other confounders. Targeted efforts to improve adherence to guidelines regarding provision of surgery in early-stage NSCLC may represent a meaningful opportunity to improve outcomes.

Int J Cancer. 2018 Jun 26. doi: 10.1002/ijc.31632. [Epub ahead of print]

Inhaled corticosteroids in COPD and the risk of lung cancer.

Lee YM, Kim SJ, Lee JH, Ha E.

Inhaled corticosteroids (ICS) might reduce the risk of lung cancer by controlling airway inflammation in patients with chronic obstructive pulmonary disease (COPD) because both are associated with chronic inflammation. The objective was to assess the impact of ICS on lung cancer risk reduction in COPD patients. We performed a nested case-control study based on the database of the National Health Insurance Service-National Sample Cohort, a nationally representative cohort of 1,125,691 participants in Korea followed over 11 years. The eligible population was patients aged 30 to 89 years who were newly diagnosed with COPD and initiated inhaled medications after diagnosis. Cases were defined as individuals diagnosed with lung cancer after the initiation of inhaled medications and were matched with controls by propensity score at a 1:4 ratio. We identified 265 individuals with lung cancer, matched with 1,060 controls. Use of ICS was associated with reduced risk of lung cancer (adjusted hazard ratio [aHR] 0.74, 95% CI 0.57-0.96). The high cumulative ICS dose group, defined as those above the third quartile of ICS dose distribution, had a lower risk of lung cancer than the low cumulative dose group (aHR 0.51, 95% CI 0.34-0.75). The effect of ICS on lung cancer risk reduction was more remarkable in former smokers than current smokers. Additionally, the result was consistent in men regardless of the classification according to ICS use, while it was not significant in women. ICS, particularly at high cumulative dose, might be associated with decreased risk of lung cancer in patients with COPD.

Pediatr Nephrol. 2018 Jun 14. doi: 10.1007/s00467-018-3962-y. [Epub ahead of print]

Parental health literacy and progression of chronic kidney disease in children.

Ricardo AC, Pereira LN, Betoka A, et al; Chronic Kidney Disease in Children (CKid) Cohort Investigators.

BACKGROUND: Limited health literacy has been associated with adverse outcomes in children. We evaluated this association in the setting of chronic kidney disease (CKD). METHODS: We assessed the parental health literacy of 367 children enrolled in the Chronic Kidney Disease in Children (CKiD) Study, using the Short Test of Functional Health Literacy (STOFHLA). We evaluated the association between parental health literacy and CKD progression, defined as time to the composite event of renal replacement therapy (RRT, dialysis, or kidney transplant) or 50% decline in estimated glomerular filtration rate (eGFR). RESULTS: Median CKiD participant age was 9.5 years, 63% were male, and 59% non-Hispanic white. Median eGFR at baseline was

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Knee Osteoarthritis: Periosteal Electrical Dry Needling Plus Exercise and Manual Therapy Cut Disability and Drug Use

Knee osteoarthritis is 11th top contributor to global disability. A randomized, multicenter clinical trial of periosteal electrical dry needling plus exercise and manual therapy (dry needling group, n=121) compared with exercise and manual therapy alone (n=121) for 8–10 sessions over the course of 6 weeks showed that periosteal electrical dry needling combined with exercise and manual therapy (passive joint mobilization, muscle stretching) trumps exercise and manual therapy alone in reducing disability and pain medication use in patients with knee osteoarthritis. The primary outcome was disability as assessed by the Western Ontario and McMaster Universities (WOMAC) osteoarthritis index at 3 months (WOMAC has 3 subscales: pain, stiffness, physical function). The dry needling group had significantly lower disability than the exercise and manual therapy group (WOMAC: F, 35.504; P < .001), with –10.4 point difference (P < .001) at 6 weeks and –13.9 point difference (P < .001) at 3 months. The dry needling group was more likely to have completely stopped pain medication at 3 months (OR, 1.6; P = .001). Finally, the dry needling group had significantly superior Global Rating of Change scores (X2, 14.887; P < .001). ■

Metformin Associated With Lower Fracture Risk in Patients with Diabetes Mellitus in Real-World Settings

Despite normal-to-high bone mineral density, patients with type 2 diabetes mellitus (T2DM) are at increased risk for fragility fractures. Metformin monotherapy in patients with T2DM has been linked to neutral or lower risk. A large case-control study (12,277 Spanish patients with incident type 2 DM) in real-world settings found that insulin monotherapy raises bone fracture risk relative to metformin monotherapy. Insulin monotherapy was associated with a 63% higher fracture risk than metformin monotherapy (adjusted OR, 1.63; 95% CI, 1.30-2.04). No other drugs, alone or in combination, had significantly higher fracture risk than metformin monotherapy. ■

Exacerbation of Chronic Obstructive Pulmonary Disease After Discharge from the Emergency Department: Readmission Predictors

In a single-center retrospective study, patients with chronic obstructive pulmonary disease (COPD) treated for acute exacerbation (AECOPD) and discharged from the emergency department (ED) were likelier to return to the ED than their admitted counterparts. Confirming previous work, ED adherence to AECOPD guidelines was poor. In the ED, 49.1% received bronchodilators, antibiotics, and steroids (all 3); 68% were referred for follow-up. The ED-discharge group was younger and disproportionately single, had milder COPD, encompassed more smokers and substance users, and had more comorbidities and more mental illness than patients who were admitted. ■

Two-Thirds of Stroke Survivors Do Not Receive Outpatient Rehabilitation

Even though stroke is the leading cause of disability nationally, only about a third of stroke survivors received outpatient rehabilitation in 2013 and 2015. A cross-sectional cohort study of adult stroke survivors from the Behavioral Risk Factor Surveillance System analyzed outcomes of 6743 stroke survivors from 20 states and the District of Columbia in 2013 and 729 stroke survivors from 4 states in 2015. The main outcome was receipt of outpatient rehabilitation after discharge. Adjusted rate of receipt of outpatient rehabilitation was 31.2% in 2013, with variation across states (P = .012). Among the same 4 states (Georgia, Iowa, Maine, Oregon), rate increased from 27.4% in 2013 to 35.5% in 2015 (P < .05), again with variation across states (P = .0004 and P =.008, respectively). No significant differences were noted by age group, insurance coverage, or number of cardiovascular disease risk factors. ■

New Guidelines for Screening with Electrocardiography

According to the US Preventive Services Task Force (USPSTF), screening with electrocardiography is not necessary in people with low risk and no symptoms of cardiovascular disease (CVD). These patients have a low CVD risk (10-year CVD event risk <10%). Evidence is also lacking, says USPSTF, to determine risk-benefits of electrocardiography in asymptomatic adults at intermediate or high risk of CVD. The findings update the 2012 recommendations of USPSTF. ■

Why Monday May Not Be the Best Return-to-Work Start Date
continued from page 6

billion annually in the United States, or $1,685 per employee. It's a win-win for all: the individual is able to ease back into the workforce, and the employer regains productivity and savings.

Throughout the process, the CDMS's goal is to facilitate the employee's return to work—safely, timely, successfully, and sustainably. Achieving that objective often requires creative thinking, while applying expert knowledge, skills, resources, and tools. CM

Principles of Person-Centered Care
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Organizations that excel in person-centered practices speak about the constant work needed to follow and implement these guiding principles. It is a commitment to those you serve, and the results move an organization to perform at a more meaningful level. Case management is an industry that would not have moved forward without these practices, but it is always good to ensure that your person-centered practices have not become a marketing tool only! CM

Health Care Professionals and Suicide: An Occupational Hazard
continued from page 13

the stigma of mental health treatment. Seeking treatment is not a weakness but an indisputable strength. *We must attend to our own human condition to be responsible for the human condition of so many others.* The alternative? We lose more talented health care professionals, who succumb to the occupational hazards and realities of their roles, becoming numbers added to the growing suicide tally.

My esteemed colleagues, that option should not be the preferred choice for any of us. ***#MustDoBetter*** CM

Unprecedented Changes Coming to Medicaid Program
continued from page 10

automatically assume that low-income Americans are incapable of contributing to their communities, especially when many of them already do or want to do so. It is even more shameful that they would dress up this unflattering view of their fellow citizens in the guise of compassion. True compassion is lifting Americans most in need out of difficult circumstances...This administration stands for a policy that makes Medicaid a path out of poverty...We owe it to these Americans to try whatever may help them achieve the dignity and self-sufficiency they deserve."

Based on Ms. Verma's editorial, it's clear that major changes will likely be made to Medicaid Programs. Changes proposed so far include time limits to stay on Programs, coverage of fewer people, drug testing, and limits on prescription drugs covered. It is also clear that the states will exercise a lot of control over these changes. Home care providers should, therefore, prepare to work with state Medicaid Programs on changes that may impact their patients. CM

CE 1 Preoperative Prothrombin Times and Difficulty Managing Postoperative Warfarin Therapy in Patients with Mechanical Valve Replacements
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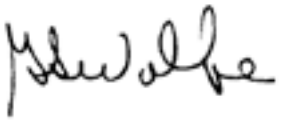
The Diabetes Pandemic
continued from page 2

been successful in preventing diabetes. Now is the time to take action. Do what case managers do best: evaluate, plan, implement, educate, and evaluate. You can make a difference by helping your patients reduce their risk of diabetes.



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ACCM: Improving Case Management Practice through Education

LITSCAN
FOR CASE MANAGERS

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63 ml/min/1.73 m2, and median urine protein-to-creatinine ratio was 0.22. The median STOFHLA score was 98. Over a median follow-up of 3.7 years, the overall CKD progression rate was 2.8 per 100 person-years. After adjustment for demographic and clinical factors, the relative time to CKD progression was 28% longer per 1 SD increase in STOFHLA score (relative time, 95% CI, 1.28, 1.06-1.53). CONCLUSIONS: In this cohort of children with CKD, higher parental health literacy was associated with a nearly 30% longer time to the composite CKD progression outcome.

CMSA Celebrates National Case Management Week
continued from page 8

it is the standard against which we are judged in malpractice suits and licensing board hearings. Most broadly, the standard of care is defined as the usual and customary professional standard practice in the community. It describes the qualities and conditions that prevail, or should prevail, in a particular mental health service and that a reasonable, average, and prudent practitioner follows.

Generally, as more therapists practice in a new and unique way, this new way gradually becomes part of the standard of care. The standard of care is derived from statutes, case law, licensing board regulations, consensus of professionals, and community and ethical codes. The standard of care is not a standard of perfection, black and white, determined by outcome, permanent, or fixed. It does not follow any particular theoretical orientation nor is it guided by risk management principles.

Healthcare and case management are constantly changing, and it is our job as professionals, clinicians, and community members to make sure that we can continue to provide the highest level of care coordination possible for our citizens. We at CMSA feel that we are doing our best work to ensure that the role of the professional case manager is known and respected by all healthcare professionals, policymakers, and consumers of healthcare services.

Future of Case Management

Readers of this article will recognize the importance, weight, and responsibility involved in being a case manager. The practice of case management is not easy, but the reward of rich relationships with clients, their families, and their colleagues is immeasurable. We have come a long way in our educational endeavors, but we have more work that needs to be accomplished.

If you are not already a member of CMSA, please visit cmsa.org to learn not only about how we are celebrating National Case Management Week but also about all of the resources we make available for you to be successful throughout the year in this wonderful practice.

I am truly blessed to be a member and leader of CMSA and to learn from our membership each and every day. I often say that you were born caring, you worked hard to gain the experience, and with the right tools we can change the world.

Finally, when you're having a rough day, remember this phrase: "I'm not saying I'm wonder woman, I'm just saying no one has ever seen me and wonder woman in a room together." We are wonder women and wonder men!

During National Case Management Week 2018, we will celebrate the fabulous world of case management, right alongside you! CM

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