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In the United States, approximately 20% of the 1 million annual hospital discharges for congestive heart failure (CHF) result in transfer to a skilled nursing facility (SNF). This study examined the risk factors associated with hospital readmissions for CHF patients patients receiving skilled nursing care in a bundled program and identified characteristics associated with readmission. Hospital readmission, within 90 days, was the primary outcome of interest and risk factors included gender, age, race, SNF location by region, SNF length of stay, and home health care use.

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Preferred post-acute provider networks play a critical role in both patient wellness and the efforts of curators to improve health care value. Preferred networks that work help reduce readmissions rates and lengths of stay as well as improve patient experience and the bottom lines of their partners. Yet, despite the proliferation of these networks and narrowing to what is presumed to be top-performing providers, many hospitals and health systems continue to face costly value-based penalties from payers. We conducted a nationwide survey of care managers to get their feedback on what's working with preferred networks and what's not. We then interviewed health care executives responsible for preferred provider strategy to get their feedback and best-practice insights.

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FROM THE EDITOR-IN-CHIEF

Gary S. Wolfe

Improving Patient-Centered Care Through Communication Skills

Communicating is a key competency for health care workers including case managers. Teaching and assessing communication skills are emphasized because much improvement is needed. In reality, little emphasis has been placed on communication skills when health care workers (including case managers) are trained. This has started to change but more needs to be done. Communication skills are needed if we are going to focus on patient-centered care.

The Institute of Medicine identified patient-centered care as 1 of the 6 elements of high-quality health care. A patient-centered approach is based on 3 goals: 1) eliciting the patient's perception of their illness; 2) understanding the patient's psychosocial context; and 3) reaching shared treatment goals based on the patient's values. Patient-centered care considers patient preferences, needs, and values, ensuring they guide all medical decisions in tandem with scientific evidence.

Good communication skills have a positive impact on a client's health and can affect the following:

- Patient satisfaction
- Recall, understanding, and adherence
- Health outcomes
- Communication and negative outcomes

How do you go about improving your communication skills? Based upon best practices, some simple steps start the process.

1. Introduce and develop rapport
2. Elicit the patient's agenda
3. List the patient's agenda items
4. Negotiate the agenda
5. Start discussing the patient's concerns with open-ended questions

The patient's views of his or her illness is a primary focus of patient-centered care. The patient's perspective includes feelings, ideas, concerns, impact, and expectations. Specific questions for your patient may include the following:

- What would you like to get out of today's visit?
- How did that make you feel?
- Can you tell me more about what is worrying you?
- What aspects of your health do you worry about?
- What more can I do for you today?

Exploring patients' feelings is important in assessing the emotional burden and psychosocial impact of illness. Addressing patients' feelings can build trust with their health care providers and have an impact on health outcomes. Being emphatic is part of the patient-centered process.

Exploring and understanding patients' illness and respecting their beliefs and expectations is at the core of patient-centered communication. Case managers play a pivotal role in this process. Incorporating good communication skills can help achieve patient-centered care and improve patient outcomes and satisfaction.

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ACCM: Improving Case Management Practice through Education

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Celebrating Nurses and Midwives Worldwide

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

CMSA membership represents case managers from many disciplines and care settings; more than 20, in fact, as our 2019 CMSA State of the Industry Survey indicates. Over 90% of those surveyed are nurses, which is consistent with our long-term membership statistics. While our organization is proud to support case managers of all disciplines, in this issue we pay special tribute to nurses and midwives.

The World Health Organization (WHO) has named 2020 "The Year of the Nurse and Midwife." Most case managers are registered nurses and contribute immensely to health care around the world. Nurses and midwives make so much of an impact on global health that the WHO has determined that 9 million additional nurses will be needed by the year 2030 to adequately care for all populations. Throughout this year, during National Nurses Week in early May and always, we are appreciative of our case managers whose backgrounds are in nursing.

The World Health Organization (WHO) has named 2020 "The Year of the Nurse and Midwife." Most case managers are registered nurses and contribute immensely to health care around the world. Nurses and midwives make so much of an impact on global health that the WHO has determined that 9 million additional nurses will be needed by the year 2030 to adequately care for all populations.

Regardless of the care setting, the nature of nursing work—including long and sometimes nontraditional shifts—makes nurses prone to a variety of health conditions. Lack of exercise, job-related stress, and sleep deficiency are some of the challenges resulting in nurses having higher instances of infections, disorders, and depression than the general public.

We at CMSA realize our responsibility to meet the needs of nurses and case managers of all backgrounds, and we have programs that support clinicians in taking care of themselves. In recent years, CMSA made a concerted effort to introduce resources in our publications and at the annual conference that go beyond traditional clinical continuing education. We believe that professional case managers are some of the hardest working and most dedicated clinicians in health care. It is imperative that our hard work be balanced with personal wellness if we are to provide our patients and clients with the highest level of care.

Since 2019, issues of *CMSA Today*™ magazine feature the Self-Care Series column, written by CMSA members on nonclinical topics. Overcoming fear and self-doubt, being grateful, and gaining peace and happiness are some of the themes covered in the column. As case managers, our wellness in these areas help us manage daily stress, leading to better care and outcomes for our patients.

In addition to the Self-Care column, our annual conference in Boston this summer features hands-on opportunities for wellness and learning. CMSA member Karen Kono, RN, COHN, will present "Stretching in the Workplace: Any Workplace!" In this interactive presentation, she will show what happens in the body during stretching and how movement results in physical, emotional, and mental health benefits. She'll make the case for workplace stretching programs in any care setting and take you through a series of stretches adaptable for any population.

In addition, after the success of morning yoga last summer in Las Vegas, we are expanding the program this year to all 3 main conference days. Brianne Wheeler, Registered Yoga Teacher, will lead you through energizing early morning practices to encourage deep breath and intention setting for your day ahead and show you movements to enable you to feel your best.

Regardless of whether your background is in nursing, we hope you find these initiatives helpful in assisting you to practice at the top of your credentials. As we serve case managers of every level, discipline, and care setting, CMSA will continue to find ways to support your practice in all ways possible.

In addition, if you join us in Boston this summer for education, networking, and wellness at our 30th Annual Conference & Expo, registration includes a 1-year CMSA membership.

If you are interested in learning more about the case management population, visit www.cmsa.org/membership/member-corner/ to download CMSA's 2019 State of the Industry Survey. If you're already a proud CMSA member, download the survey for free; nonmembers can access the survey for a fee.

Thank you, nurses and case managers, for your contributions to health care worldwide! CM

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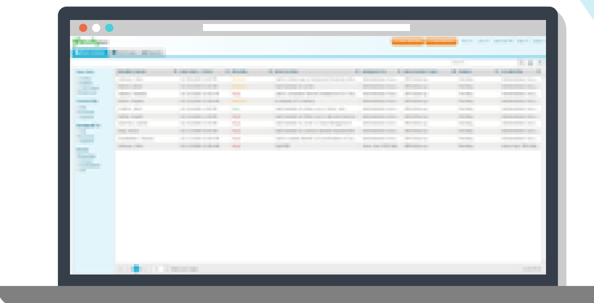

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THE COMMISSION FOR CASE MANAGER CERTIFICATION

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Staying Abreast of Relevant Issues in Case Management

By MaryBeth Kurland, CAE

Case management has a long history, spanning more than a century, of coordinating and providing care across health and human services. It is a legacy embraced by nurses and social workers and carried out today by multiple disciplines under the specialty practice of professional case management.

Advocacy for the individual is a cornerstone of that legacy. As stated in the Commission for Case Manager Certification's Code of Professional Conduct, professional case managers advocate on behalf of patients (the "clients" who receive services) through a "professional and collaborative process that assesses, plans, implements, coordinates, monitors, and evaluates the options and services required to meet an individual's health needs."

This is the foundation on which professional case management stands. Yet, the context in which case management is delivered across the spectrum of health and human services is ever-changing. For example, the emphasis on value-based care delivery and shifts in patient demographics require all professional case managers to stay abreast of these changes. Professionals in all practice settings and from varied disciplines—including those who hold the Certified Case Manager® (CCM®) or the Certified Disability Management Specialist (CDMS) credentials—must ensure that they stay relevant in their ability to advocate for and serve diverse populations.

In fact, the requirement to keep abreast of changes is not only a professional obligation, it can be considered an ethical one as well. The Commission states in its renewal requirements for the CCM credential that professional case managers are required to continue their education through courses and other activities that will help them serve their clients more effectively. By staying relevant, case managers are better equipped to act as "informed advisors" with in-depth knowledge of the issues in health care today.

The Commission, in its commitment to foster lifelong learning and deliver opportunities for continuing education, is putting these issues in the spotlight. (Our upcoming New World Symposium 2020 to be held March 12–14 in Colorado will be one of those opportunities.) As case managers avail themselves of the latest information about trends in health and human services, they can help individuals and their support systems make informed choices and decisions.

To illustrate, below are a few of the emerging trends requiring a case management response:

The Opioid Crisis

Opioid misuse is a national epidemic. Every day, more than 130 people in United States die after overdosing on opioids. In our education programs and articles on the opioid epidemic, the Commission stresses the importance of the role of the professional case manager. As our Commissioners wrote in a Professional Case Management article on the opioid crisis, this is a battle waged on 2 fronts: preventing misuse of and addiction to opioids prescribed for pain management and intervening with more resources to help combat the nonmedical use of prescription opioids and heroin. By taking a holistic, patient-centered approach, case managers can bring advocacy, education, and empowerment of patients and their families/support systems into discussions around individualized interventions. Those interventions may include more education and follow-up when patients are prescribed opioids as well as services for individuals who are addicted to nonmedical opioids and who may be entering the health care system.

The opioid epidemic is far larger than any one individual, organization, profession, or discipline. It takes a coordinated and comprehensive effort to understand and respond to this growing problem. Given their role on the front lines of care delivery, case managers, along with other health and human services professionals, must be prepared to interact with and advocate for individuals whose lives are impacted by the opioid epidemic.

MaryBeth Kurland, CAE, is CEO of the Commission for Case Manager Certification, the first and largest nationally accredited organization that certifies more than 46,000 professional case managers and nearly 2,500 disability management specialists. The Commission is a nonprofit, volunteer organization that oversees the process of case manager certification with its CCM® credential and the process of disability management specialist certification with its CDMS® credential.

The requirement to keep abreast of changes is not only a professional obligation, it can be considered an ethical one as well. The Commission states in its renewal requirements for the CCM credential that professional case managers are required to continue their education through courses and other activities that will help them serve their clients more effectively. By staying relevant, case managers are better equipped to act as "informed advisors" with in-depth knowledge of the issues in health care today.

Medical Cannabis

Changes in federal and state laws around cannabis use are sparking a new conversation in health care. Specifically, medical cannabis is entering the discussion in new ways. As Jared Young, PsyD, CAC, LCSW, CCM, chair-elect of the Commission, wrote in a recent Issue Brief: "When I first started my career, medical marijuana was never even discussed. Today, I work with a lot of clients from all walks of life who are using it or thinking about it and weighing the pros and cons." In response, professional case managers must understand the logistical, medical, and ethical implications of medical cannabis if they are to guide clients. Case managers and the patients/clients they serve must know how the body processes cannabis, which can be ingested, inhaled, or applied topically.

Each state has its own regulations and rules regarding medical marijuana. Other resources, including the American Cannabis Nurses Association (www.cannabisnurses.org) and Americans for Safe Access (www.safeaccessnow.org), provide regulatory and other information for staying current on research and best practices. As Vivian Campagna, MSN, RN-BC, CCM, the Commission's Chief Industry Relations Officer, noted, "One of the most important things for case managers to do is keep learning. The lifelong learning so valued by professional case managers is particularly vital when it comes to cannabis."

Transdisciplinary Teams

Not only are the issues faced by case managers changing, so is the way in which many professionals practice. An example, also discussed in a recent

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A New Year, A New Feeling of Wellness

Michelle Greene Rhodes, MHS, RN, CCM, CMCN

When it comes to nurses and especially nurse case managers, we have many tasks to deal with daily including meeting patients at their bedside and providing caregivers with transition to home training. We spend time teaching patients about their medications or disease processes, sometimes leaving little time for taking care of ourselves. We are nurturers and thrive off of helping others, period. What happens when you help others to the degree that it's hard to help yourself? Let's take a look at the picture of wellness—aka wholeness—and how we can incorporate it into our daily lives.

The National Wellness Institute shares information regarding wellness and what it means to be whole. In this article, we will look at 6 facets of wellness and what it means to incorporate each area into our lives. Occupational, intellectual, spiritual, physical, social, and emotional wellness all play a part in how our daily lives look and feel and eventually become our reality.

Activity:

I challenge you to spend 30 seconds before you read this article with your eyes closed. Make a positive affirmation to yourself during this brief period. Reconnect with your deepest thoughts to visualize a pleasant mental image. Use a few moments of silence as a jump-start to get you grounded.

Now, let's look at the 6 components of wellness.

***Michelle Rhodes** is a nurse entrepreneur and consultant. You can learn more about Michelle at GreeneRhodesConsulting.com.*

1. Occupational Wellness

I challenge you to take a look at your gifts and what you are truly called to do, be, and learn. This goes a long way when it comes to your occupation—knowing what you were truly meant to do and doing that every day. Your life's work not only creates meaning; it also makes work more purposeful for you. Begin to think about your ambitions, your profession, your job satisfaction, and even your personal performance. Is it at its peak? Are you doing what you truly love? If the answer is no, this might be a cause for some imbalance in your wellness. Briefly, let's discuss work-life balance. Remember that you love your job so much that it occupies other parts of life. Take a look at everything that you focus on during each day and see if you are in the middle of the spectrum. As a case manager, have you ever had a patient that was out of balance because of their occupation?

Occupational, intellectual, spiritual, physical, social, and emotional wellness all play a part in how our daily lives look and feel and eventually become our reality.

2. Intellectual Wellness

The wellness that comes from doing what your mind is capable of doing allows you to grow and learn every day, every week, every month, and every year. Are you challenging yourself to learn new things? Are you creative in your activities? Sometimes we go back to school to learn something new and to achieve a learning goal. The challenge here is to read new books, learn a new concept, and implement new ideas into your life. This is why we got certified and why we want to stay certified.

Find new ways to solve problems in your life using new strategies and common tools and tactics. It will take you further than you can imagine, not just in your wallet, but also in your mind, which we know is capable of being stretched to its fullest capacity. As a case manager, have you ever had a patient that hit a "brick wall" due to their inability to learn something new?

3. Spiritual Wellness

Self-care in this area could mean that we are examining the purpose of our very existence. Why are we here? What is the ultimate goal of our living? Are we leaving a legacy? Do we find meaning in life in everything that we do? Do we give outside of ourselves? How were you raised when it comes to your spiritual wellness? Sometimes culture and norms play a part in our belief system, whatever that means for you. Make sure your belief system aligns with your actions. Research has found that those who follow spiritual practices or gather in spiritual settings live a longer life. As a case manager, have you ever had a patient who was out of balance due a spiritual conflict?

4. Physical Wellness

Make sure you are using your time wisely to incorporate some sort of physical self-care. We know to do this, but we don't always follow through. See your doctor and get your annual screenings to make sure that everything is within normal limits based on your age, occupation,

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Reigning in CMS' Authority

By Elizabeth Hogue, Esq.

Home care providers remain concerned about the enormous power wielded by regulators, including the Centers for Medicare & Medicaid Services (CMS). In some instances, providers are concerned that regulators exceed the authority granted to them by Congress and essentially write law through regulations, guidance, interpretive guidelines, etc. The U.S. Supreme Court recently considered whether to reign in the authority of the executive branch of government exercised through agencies like CMS. In Gundy v. United States (No. 17-6086; U.S. Supreme Court; June 20, 2019), the Court essentially said that it was open to reigning in the power of federal agencies to interpret statutes, but wasn't going to do it in this case. In other words, the Court said, "Not quite yet!"

Home care providers remain concerned about the enormous power wielded by regulators, including the Centers for Medicare & Medicaid Services (CMS). In some instances, providers are concerned that regulators exceed the authority granted to them by Congress and essentially write law through regulations, guidance, interpretive guidelines, etc. The U.S. Supreme Court recently considered whether to reign in the authority of the executive branch of government exercised through agencies like CMS.

This case is based on the Sex Offender Registration and Notification Act (SORNA). Herman Gundy pled guilty to sexually assaulting a minor before SORNA was enacted and was imprisoned. He was released from prison in 2012 and moved to New York, where he did not register as a sex offender. A few years later, he was convicted of failing to register in violation of SORNA and appealed.

Gundy's appeal was based on the argument that Congress unconstitutionally delegated legislative power when it authorized the Attorney General to "specify the applicability" of SORNA's registration requirements to offenders convicted before the enactment of SORNA. The U.S. Constitution says that all legislative powers are vested in Congress and that Congressional powers cannot be further delegated. Congress cannot transfer to another branch, such as the executive branch, powers that are strictly and exclusively legislative.

At the same time, the Constitution does not deny Congress the necessary resources of flexibility and practicality to allow Congress to perform its functions. Congress may seek assistance from other branches of government in the form of substantial discretion to implement and enforce statutes. The U.S. Supreme Court has decided in many cases that statutory delegation from Congress to the executive branch is Constitutional as long as Congress establishes "intelligible principles" to which other branches of the government must conform. Statutory interpretation is essential to decide whether Congressional delegation is permitted. The key is to figure out what tasks Congress delegates and what instructions it provides. In the Gundy case, the U.S. Supreme Court decided that Congressional delegation to the Attorney General to decide what offenders convicted before enactment of SORNA must do was appropriate.

However, as Jeannie Suk Gersen pointed out in "The Supreme Court is One Vote Away From Changing How the U.S. is Governed," an article that appeared in *The New Yorker* on July 3, 2019, four liberal justices decided against Gundy. Three conservative Justices said that SORNA gave the Attorney General "free rein to write the rules" and was unconstitutional. Justice Alito cast the deciding vote that enabled liberals to prevail in this case, but his concurring opinion is an indicator that the victory may be short-lived. Justice Alito said that if the majority "were willing to reconsider the approach we have taken for the past 84 years, I would support that effort." A conservative majority was lacking in this case because the case was argued before Justice Kavanaugh was sworn in. Ms. Gerson says:

We are now explicitly on notice that the Court will likely abandon its long-standing tolerance of Congress delegating broadly to agencies. What's at stake is the potential upending of the constitutional foundation of the so-called "administrative state." Today's reality is that agencies, not Congress, make most

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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.*

CE I Examining Congestive Heart Failure Hospital Readmissions From Skilled Nursing Facilities

Katherine M. Day, PhD, RN, CCM, CHC

Background

In a recent study, I examined the risk factors associated with hospital readmissions of patients with congestive heart failure (CHF) who were receiving skilled nursing care in a bundled value-based program. The goal of this research was to explore whether readmission from the skilled nursing facility (SNF) was influenced by a set of risk factors, which included gender, age, race, SNF location by region, and SNF length of stay (LOS), and whether home health care was used. Therefore, I examined factors that put SNF patients at risk of hospital readmission as well as what case managers can do to improve the care for this population along the care continuum.[1-3]

In the United States, approximately 20% of the 1 million annual hospital discharges for CHF result in transfer to an SNF. Patients who are transferred to an SNF are generally elderly and are living with additional conditions or comorbidities compared with those who are discharged home.[4] There are a little over 6 million Americans with CHF, and among this population the hospitalization rate is approximately 18 per 1,000 patients over the age of 64.[5] Congestive heart failure results in high hospital readmission rates, with over 700,000 hospital admissions each year, and the number of readmissions is expected to increase 25% by 2030.[1,5-7]

Treating CHF requires an interdisciplinary care team throughout the continuum of care. The continuum of care represents not only an array of health care services but also the period that a patient may be monitored to provide coordinated care. It is also where inconsistent practice patterns and a fragmented care delivery system results in varied patient outcomes.[4,8,9] Skilled nursing facilities provide skilled care to CHF patients who are unable to go home once discharged from the hospital, and this level of care can make the difference between a timely transition home with home care or rehospitalization.

The Centers for Medicare & Medicaid Services (CMS) has identified skilled nursing care as one of the components within the care continuum available for CHF patients once they are discharged from the hospital.[10] There are opportunities for case managers to improve care at this level by developing health care industry partnerships along the care continuum. From a cost standpoint, SNFs account for approximately half of Medicare's overall posthospital spending.[11]

Katherine M. Day, PhD, RN, CCM, CHC, is the Director of Care Navigation Services and the Clinical Operations Leader for the Institutional Special Needs Plan at Trinity Health Continuing Care in Livonia, Michigan.

Bundled Payment

The Bundled Payments for Care Improvement initiative (BPCI) was an alternative payment model that combined fixed payments from CMS instead of paying for each service separately as in a fee-for-service model.[12] These value-driven programs encourage health systems to consider a coordinated, systems-thinking approach when providing health services.[13] The use of structured, evidence-supported systems engineering approaches used in other industries can also be applied to multiple levels of the health care organization organization.[14] Adaptation of these combined approaches, coupled with supportive care coordination, can improve care quality provided to the CHF population. Case managers play a key role in building bridges among health care professionals. By having the relevant skills to meet the medical and social needs of patients, case managers are central to preventing rehospitalizations, poor care experiences, and poor outcomes.. Today, case managers who work within health care systems are encouraged to embrace a systems-thinking approach.[15,16] As patients are discharged from the hospital to the SNF or into the surrounding communities, health care organizations are challenged to creatively provide services beyond the facility. Holistic approaches to understanding the risks associated with CHF patients being readmitted to the hospital after discharge should include multidisciplinary perspectives.[17,18]

Problem

The Affordable Care Act in 2010 shifted how health care organizations and health care professionals approach conditions such as CHF, including rethinking care delivery and payment models.[3] Previous studies have demonstrated the complex nature of CHF and have identified this condition as a major contributor to hospital readmissions and burden of care.[2,7] The repercussions of rehospitalization for health care organizations and post-acute partners have elevated the management of CHF in SNFs as a major policy priority.[4]

There are a little over 6 million Americans with CHF, and among this population the hospitalization rate is approximately 18 per 1,000 patients over the age of 64. Congestive heart failure results in high hospital readmission rates, with over 700,000 hospital admissions each year, and the number of readmissions is expected to increase 25% by 2030.

As evidenced by the BPCI initiative, CMS is moving toward value-based care models and away from the costlier siloed fee-for-service model to achieve the Triple Aim, consisting of improving population health by improving patient experience and reducing costs.[9,12,19,20]

Previous demonstration programs have been focused on the acute or hospital level of care.[21] Before this study, minimal research considered how SNF care, within a bundled value-based payment program, might impact the readmission risk for elderly patients with CHF and how hospital readmissions might vary by gender, age, race, geographic location, LOS, and home health intervention.[5,12]

Purpose of the Study

Early identification of the risk factors for hospital readmission due to progression of CHF will allow those who work most closely with the CHF population to provide appropriate education and care coordination as well as arrange for timely home health and primary care follow-up for patients and caregivers to better manage the condition. Although patient education and care coordination are part of the standards of care, these activities are not always completed and the extent to which such activities are carried out vary among SNF sites. Under fee-for-service reimbursement, Medicare allows SNFs to bill up to 100 days for patient care depending on the severity of the illness and rehabilitation needs. However, Medicare spending on post-acute SNF care within the first 30 days after a patient is discharged has grown between 4.5% to 8.5% between 1994 and 2009 and is unsustainable.[11]

It is also questionable whether keeping an elderly CHF patient in a SNF for a full 100 days is appropriate or medically necessary. Considering that CHF patients stay at an SNF for an average of 20 to 30 days, the ongoing variations in readmissions and use of SNF care require further research to determine when rehospitalization occurs the most. This is most likely why CMS continues to pilot test 30-, 60-, and 90-day time windows. Therefore, the purpose of this study was to examine the risk factors associated with hospital readmissions for CHF patients receiving skilled nursing care in a bundled program and to identify characteristics associated with readmission. Hospital readmission, within 90 days, was the primary outcome of interest (dependent variable) and risk factors (independent variables) included gender, age, race, SNF geographic location defined by region, SNF LOS, and home health care use.[1] This research was based on 2 foundational concepts: unbounded systems thinking and a systems-thinking approach.[15,16]

Research Questions

This research was conducted to answer 2 main questions.

Question 1: How are CHF patients who are in SNFs and who are readmitted within 90 days different from nonreadmitted CHF patients in terms of risk factors such as gender, age, race, SNF geographic location, length of SNF stay, and home health use participating in a bundled, value-based program?

Question 2: Among bundled program CHF patients, to what extent do patient characteristics (gender, age, race) and SNF characteristics (SNF geographic location, length of SNF stay, home health care use) predict 90-day hospital readmissions?

Research Method

This study applied a quantitative methodology and a retrospective cohort research design.[22] Data were extracted from proprietary care navigator logs and an electronic medical record (EMR) database. Demonstration or pilot programs in health care today use metrics to measure outcomes and analyze patterns (statistics) to evaluate programs.[1,23] Care navigator tracking logs were patient-tracking Excel spreadsheets containing program-specific data elements used during participation in BPCI to track clinical outcomes for patient populations diagnosed with various conditions including CHF. Logs allowed for real-time tracking and provided BPCI data elements such as CHF diagnosis, SNF location, SNF LOS, home health care use, and whether a CHF SNF resident experienced a readmission. The EMR provided and confirmed demographic information. There were 2 main objectives of the binary logistic regression analysis based on the research questions: (a) to determine the differences between CHF SNF patients who were readmitted and who were not readmitted and (b) to determine which independent predictor variables were significant and had an effect on the dependent criterion variable, readmission.[1]

Results

Of the 238 patients, 99 (41.6%) experienced a hospital readmission within 90 days of SNF admission and

TABLE 1 FREQUENCIES AND ASSOCIATIONS BETWEEN READMISSION AND NO READMISSION

Variable	N = 238	Readmission	No readmission	P value*
Total, n (%)		99 (41.6)	139 (58.4)	
Age (y), n (%)				0.388
65–79	52 (21.8)	25 (25.2)	26 (18.7)	
80–89	90 (37.8)	37 (37.3)	54 (38.8)	
90+	96 (40.3)	37 (38.6)	59 (42.4)	
Race, n (%)				0.352
Black	21 (8.8)	12 (57.1)	9 (42.9)	
Hispanic	6 (2.5)	1 (16.7)	5 (83.3)	
Asian	3 (1.3)	2 (66.7)	1 (33.3)	
White	208 (87.3)	84 (40.4)	124 (59.6)	
SNF region, n (%)				0.548
Great Lakes	118 (49.6)	48 (40.7)	70 (59.3)	
Midwest	62 (26.1)	24 (38.7)	38 (61.3)	
Northeast	58 (24.4)	27 (46.6)	31 (53.4)	
Home health, n (%)				0.144
Discharge home w/ HHC	119 (50)	45 (37.8)	74 (62.2)	
Discharge home w/out HHC	119 (50)	54 (45.4)	65 (54.6)	
Gender, n (%)				0.995
Female	154 (64.7)	64 (41.6)	90 (58.4)	
Male	84 (35.3)	35 (41.7)	49 (58.3)	
SNF LOS (days), mean ± SD	27.1 ± 19.6	27.1 ± 20.6	27 ± 19.0	0.802
Median (days)	22	21	23	

Abbreviations: HHC *= home health care;* ***LOS*** *= length of stay;* ***SD*** *= standard deviation;* ***SNF*** *= skilled nursing facility.*
**Statistically significant at P < .05.*

139 (58.4%) did not (Table 1). Although none of the risk factors were statistically significant and the strengths of the relationships were weak, findings suggest that the bundled program was associated with a reduction in rehospitalization for SNF patients with CHF (Table 2). Limitations of this study include the fact that it was retrospective and analyzed a relatively small and focused sample that was specific to the bundle program. In addition, all variables were categorical, except for SNF LOS, reducing granularity and the ability to detect small effects. The study was exploratory in nature and trends emerged from the results. These were worth noting and may have implications to case management professional practice.

Implications for Case Managers

The health care industry landscape continues to shift from volume to value-based care, emphasizing the importance of collaboration among all levels within the health care system to identify high-risk patients and deliver appropriate cost-effective care. Alternative payment models will drive these value-based programs. The results of this study indicate that older SNF patients with CHF are at higher risk for hospital readmission from the SNF, perhaps because this SNF population has higher levels of comorbidities. It is also possible that the severity of CHF disease or the severity of other specific comorbidities in patients who live in SNFs may affect the ability to estimate the association between specific risk factors and hospital readmission. This hypothesis was not tested in this study.[1]

The advanced age of study participants indicated that there is a need to determine which predictors of readmission may be significantly associated with readmission among elderly cardiac patients. This matters because geriatric-related syndromes and comorbidities affect older CHF patients and place this cohort at higher risk of rehospitalization. Frail elderly CHF patients face continuing disability, mobility impairment, and cognitive decline as the condition progresses. When the LOS is reduced at SNFs, many older CHF patients and their families have to make decisions about postdischarge services or whether to transition to the long-term care area of the nursing home if the patient cannot be cared for within the home setting. Health care system support to care for older CHF patients coupled with multidisciplinary input may allow SNF staff and case managers to provide the individualized attention required for this population. The goal of population health should be to improve the overall health of this cohort through geriatric skills training among SNF clinical staff and case management.

This study reinforced the fact that addressing the medical, social, and economic concerns of CHF SNF patients allows SNF staff and case managers to better meet patient preferences and goals of care. Bundled patients were monitored closely by regional care navigators, which made the difference in avoiding unnecessary hospital readmissions. Also, if health systems could invest in a shared medical record, such technology would assist case managers and care navigators to follow these complex patients more closely through their transitions of care.

Early identification of the risk factors for hospital readmission due to progression of CHF will allow those who work most closely with the CHF population to provide appropriate education and care coordination as well as arrange for timely home health and primary care follow-up for patients and caregivers to better manage the condition.

TABLE 2 BINARY LOGISTIC REGRESSION OUTPUT

						95% CI for OR	
	β	SE β	Wald χ2	P*	OR	Lower	Upper
Gender	0.002	0.285	0.000	0.995	1.002	0.574	1.750
Age (y)			1.891	0.388			
65–79	0.466	0.363	1.642	0.200	1.593	0.782	3.246
80–89	0.027	0.309	0.008	0.930	1.027	0.561	1.882
Race			3.270	0.352			
Black	0.340	0.472	0.520	0.471	1.405	0.557	3.546
Hispanic	-1.562	1.122	1.940	0.164	0.210	0.023	1.889
Asian	1.155	1.286	0.807	0.369	3.174	0.255	39.460
SNF LOS	0.002	0.007	0.063	0.802	1.002	0.988	1.016
With Home Health	-0.426	0.292	2.135	0.144	0.653	0.369	1.156
Region			1.201	0.548			
Midwest	-0.350	0.358	0.956	0.328	0.704	0.349	1.422
Northeast	0.016	0.362	0.002	0.964	1.016	0.500	2.066
Constant	-0.218	0.372	0.343	0.558	0.804		

Abbreviations: *β = unstandardized regression weight;* ***CI*** *= confidence interval for odds ratio (OR);*
LOS *= length of stay;* ***OR*** *= odds ratio, also measurement of association;*
SE *β = variation of the unstandardized regression weight;* ***Wald*** *χ2 = test statistic for individual predictor variables.*
**Statistically significant at $P < .05$.*

Improving outcomes for this population requires greater system-level technical and clinical integration and capacity building across the care continuum.

Conclusion

Consistent with this study, optimal CHF care for SNF patients requires collaboration with multiple stakeholders. This includes the patients themselves, their families or caregivers, health care providers, case managers, other health care professionals, and policymakers along the continuum of care. There is an urgent need for health care systems to become more integrated to assist case managers in providing coordinated care to wider populations of patients to achieve true health care transformation. Overall, this study addressed an important gap in the literature by examining SNF-level CHF patient hospital readmissions, within a bundled program, through a growing but still less explored systems theory lens. One of the greatest health care challenges facing this country and the world is ensuring that the aging population of CHF patients, as well as other elderly people with serious chronic conditions, is treated with respect, dignity, and in a manner that meets their care preferences. Case managers are well poised to address this challenge. **CE I**

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CE II

Network Not Work?

Insight into Building a Better Post-Acute Network

Laura Kukral, MBA, LNHA; Emily Nelson, MPH; and Bethany G. Lanese, PhD

Introduction

Preferred post-acute provider networks play a critical role in both patient wellness and the efforts of curators to improve health care value. Preferred networks that work help reduce readmissions rates and lengths of stay as well as improve patient experience and the bottom lines of their partners. Yet, despite the proliferation of these networks and narrowing to what is presumed to be top-performing providers, many hospitals and health systems continue to face costly value-based penalties from payers. Though strategies to improve value can fail at multiple points during implementation, frontline care managers often provide the earliest indicators when preferred networks do not work. Subsequently, we conducted a nationwide survey of care managers to get their feedback on what's working with preferred networks and what's not. We then interviewed health care executives responsible for preferred provider strategy to get their feedback and best-practice insights.

Background

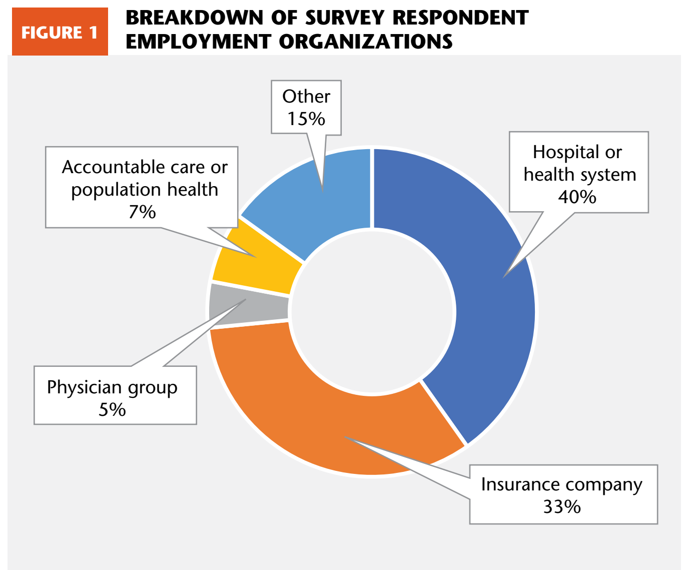
The U.S. Congress adopted the Deficit Reduction Act of 2005 requiring the Centers for Medicare and & Medicaid Services (CMS) to devise a plan for value-based purchasing (VBP) for hospitals by 2009. The Affordable Care Act, which was passed in 2010, introduced quality reporting requirements and proposed rules for accountable care organizations (ACO). In 2012, ACO rules were finalized, creating an opportunity for pioneer providers to experiment and identify best practices to improve value and prompting early attempts at hospital and postacute collaboration. Post-acute care providers saw an opportunity in ACO rules, which rewarded or penalized delivery systems for patient experience, care coordination, patient safety, preventative care, and outcomes related to at-risk patients diagnosed with diabetes, heart failure, coronary artery disease, hypertension, and/or chronic obstructive pulmonary disease. On January 26, 2015, CMS announced a specific VBP system indicating that by the end of 2018, 90% of traditional Medicare payments would be tied to value through the Hospital Value-Based Purchasing and Hospital Readmission Reductions programs.

These policies motivated care transformation efforts including preferred provider networks. So, what makes these networks work?

Preferred provider networks can impact patient choice. The methods used by curators to determine which providers are included are critically important to ensure appropriate and adequate access. According to our research, there are 2 common approaches to selecting preferred network members. Some curators use a "total points earned" formula where all post-acute care providers in the service area are given weighted scores for metrics in state Department of Health survey results, CMS star ratings, staffing, safety, complaints, readmission rates, and patient experience scores. Others use a "two-step qualifying" method where facilities must first qualify for consideration on some high-level outcome measure (like CMS star ratings) before value is evaluated. Despite the growing number of preferred networks in the United States, there is no standard formula for member selection. With this dearth of methodology, care managers offer critical experience in how networks are created and maintained.

Laura Kukral, MBA, is a consultant in health system strategic planning. She collaborated on this article with **Emily Nelson, MPH,** a PhD student, and **Bethany Lanese, PhD,** Associate Assistant Professor at the Kent State University College of Public Health. This is the fourth article on post-acute network management coauthored by Kent State University faculty and students with Laura Kukral *for* CareManagement *journal since 2016.*

FIGURE 1 BREAKDOWN OF SURVEY RESPONDENT EMPLOYMENT ORGANIZATIONS



Data source: Results of a survey of 420 readers of the *CareManagement* journal, August 22, 2019–October 16, 2019

Preferred post-acute provider networks play a critical role in both patient wellness and the efforts of curators to improve health care value. Preferred networks that work help reduce readmissions rates and lengths of stay as well as improve patient experience and the bottom lines of their partners. Yet, despite the proliferation of these networks and narrowing to what is presumed to be top-performing providers, many hospitals and health systems continue to face costly value-based penalties from payers.

Survey Results

A nationwide survey was sent to care manager readers of *CareManagement* regarding their thoughts on post-acute care networks. Most responses came from those who work with a health system or an insurance company (Figure 1), and nearly half of respondents were directly in charge of discharge planning; less than two thirds of respondents said their organization had a network (Table 1).

TABLE 1 Demographics from Fall 2019 *CareManagement* Journal Survey
POST-ACUTE NETWORK PERFORMANCE

	Total Responses	
What is your licensure status?	**No.**	**(%)**
Certified Care Manager	395	(94)
What best describes your current organization?		
Work for a hospital/health system	168	(40)
Work for an insurance company	139	(33)
Work for a physician group	19	(5)
Work for an accountable care/population health organization	29	(7)
Work for another organization	63	(15)
Does your organization have a designated preferred provider network for postdischarge care?		
Organization does have a network	254	(60)

Data source: Results of a survey of 420 readers of the *CareManagement* journal, August 22, 2019–October 16, 2019

We split responses regarding networks into the general population, insurance company employees, and health system employees to find striking differences between these populations (Table 2).

Regarding the existence of a network, 59% of health system workers said their organization had one, while 79% of insurance company workers had a network at their organization. More health system workers than insurance company workers were directly involved in discharge planning. Across the board, few respondents felt directly responsible for making decisions regarding their organization's network. A key difference between insurance and health system workers is that only 4% of insurance workers who answered this question had any amount of influence on the network, while 12% of health system workers had either some influence or direct responsibility for selecting network members.

Do these networks work?

We asked our respondents to give their organization's network a letter grade, and only 3% gave their network an A, while 14% gave it a B. With 9% of respondents giving their network a C and only 1% rating their network with a D, most respondents chose not to provide a grade at all. Nonresponse was split evenly among hospital/health care workers (119 nonresponses for this question), insurance companies (100 nonresponses for this question) and all others (91 nonresponses for this question). Unwillingness or inability to rate a network should be explored in future surveys because

TABLE 2 ANSWERS TO SURVEY QUESTIONS ON NETWORK AND ROLES, SEPARATED BY EMPLOYER

		Total Responses		Insurance Responses		Health System Responses	
Question from Survey:	**Response:**	**No.**	**(%)**	**No.**	**(%)**	**No.**	**(%)**
Does your organization have a network?	Yes	254	(60)	103	(79)	95	(59)
Level of involvement for discharge planning	I am not involved at all	102	(24)	33	(24)	23	(14)
	I am somewhat involved	110	(26)	45	(33)	36	(21)
	I am directly responsible	206	(49)	60	(43)	109	(65)
What was YOUR personal level of responsibility for making decisions about which post-acute care providers are in your organization's preferred network?	None	206	(49)	83	(92)	76	(82)
	Involved	12	(3)	3	(3)	6	(6)
	Influencer	18	(4)	4	(4)	10	(11)
	Decider	7	(2)	0	(0)	1	(1)

Data source: Results of a survey of 420 readers of the *CareManagement* journal, August 22, 2019–October 16, 2019

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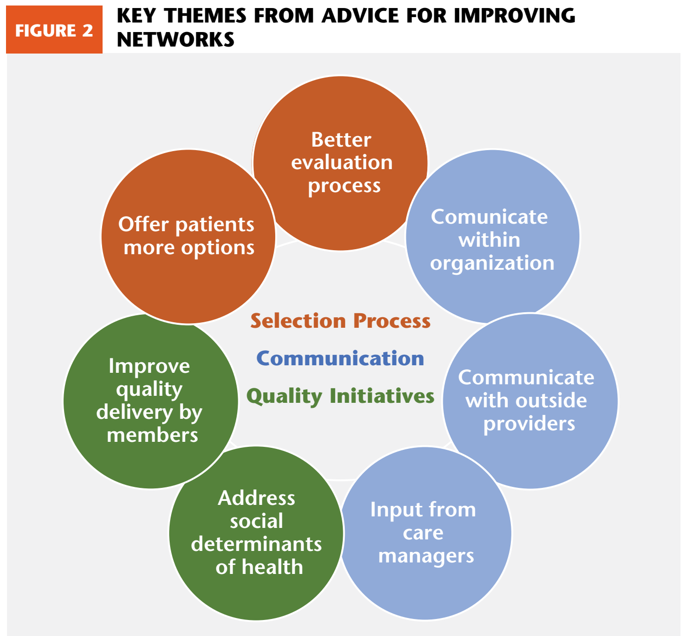
it was not clear from the data collected why this question had low response rates. However, respondents provided insight into network issues and advice for others on how to build or improve networks, which we analyzed below.

We also asked *CareManagement* reader respondents what advice they had for improving post-acute care provider networks. Some of the most-discussed topics included the following: adding more discharge options such as home health, improving communication within the organization and between the organization and outside providers, better evaluating skilled nursing facilities (SNFs), improving access to other social determinants of health such as mental health and transportation, and improving the SNFs themselves with better care metrics and more staffing. Another key theme was to increase input from care managers on which providers to choose. Combined, three overarching themes were developed from this input: improve process evaluation, improve communication, and improve quality of care and initiatives (Figure 2).

The Interviews

We also interviewed health care executives at hospitals where preferred post-acute care networks are a critical component of their value-based care strategies. The purpose of these interviews is to provide a response to the question, "How do executive leaders view these preferred networks?" We selected 3 representatives to focus on in this article: a chief clinical officer with a leading, regional health system; the executive director of payer strategy and population health for a "zero penalty" community hospital (multiple years with no VBP penalties from CMS); and the chief executive officer of a community network of service providers which partners with hospitals, insurance companies, and patients to navigate post-acute care and long-term care options. Similar key themes emerged from the executive interviews, including a need for improved member selection processes, communication, and quality of care initiatives.

FIGURE 2 KEY THEMES FROM ADVICE FOR IMPROVING NETWORKS



Data source: Results of a survey of 420 readers of the *CareManagement* journal, August 22, 2019–October 16, 2019

> **"Supporting post-acute providers with clinical expertise and breaking down care planning and delivery silos within the hospital itself have helped; and require regular evaluation, monitoring, and level-setting."**
>
> –***Peter Pronovost,*** *Chief Clinical Transformation Officer, University Hospitals Cleveland*

University Hospitals of Cleveland, a large regional health network, reduced the readmissions penalty rate at its Cleveland campuses by more than 25% since 2015 but trended upward again in the past 2 years. Peter Pronovost, MD, PhD, the Chief Clinical Transformation Officer, believes better communication with providers is essential to keeping network performance on goal. "Change progresses at the speed of trust," Pronovost reminds us. He explains that "supporting post-acute care providers with clinical expertise and breaking down care planning and delivery silos within the hospital itself have helped; and requires regular evaluation, monitoring, and level-setting."

Jill Barber, Executive Director of Payor Strategy & Population Health at Southwest General Hospital in Berea, Ohio, suggests that network curators use existing CMS ratings not only to "qualify" post-acute care providers for network consideration but also to actively engage all interested providers to achieve the hospital's own standards for performance. Efficiency is a significant criterion for network inclusion, and some high-performing providers achieve patient outcomes with 15 fewer length-of-stay days. She explains the preferred network includes top-tier skilled facilities that communicate

When preferred networks don't work, care managers are often the first to know. Including care managers when creating preferred provider networks will bring valuable expertise to the table and facilitate open communication and stakeholder engagement.

daily with the hospital on key aspects of the patient's care plan (eg, expected discharge, current length of stay, readmission risks). Providers not in the preferred network are routinely reevaluated, and Barber stressed that "patient choice still prevails but we really hope they choose top-performing post-acute providers too." The hospital had no readmission penalty from CMS in 2018 or 2019, a small penalty in 2020, and performs better than average on CMS VBP metrics.

Gary Cook, CEO of Direction Home Akron Canton Area Agency on Aging & Disabilities (Direction Home), has a unique perspective on post-acute care networks. "Our main job is to keep people out of nursing homes," Cook said. Direction Home evaluates patients for "go home" potential and ensures patients have access to home care and services to support social determinants of health. "One of the big headwinds to partnering on care transformation is the willingness and ability to share data," Cook notes. Restricted access to electronic medical records and lack of communication regarding patient readmissions and health changes can hamper his agency's ability to keep patients healthy postdischarge. Since they curate a care network used by numerous hospitals and payers, Direction Home recently contracted with a shared health information exchange to access patient medical histories as part of their effort to improve care management.

The New Standards

Southwest General Hospital is an independent, one hospital health system without the same level of horizontal or vertical integration as other systems and with a large number of independent physicians. Staffing the facilities and delivery of care at SNFs are not within the direct control of the hospital. Instead, Southwest General Hospital uses a multilayered scorecard for facilities that then qualify as a preferred provider. "Efficiency will be the standard," Barber anticipates. She suggests that by collaborating effectively with other top-performing providers across the care continuum, the collective health care delivery system can help patients achieve safer discharges home and get the right care at the right time toward that end.

At nearby University Hospitals Cleveland, Pronovost says "home is the default discharge location." About twice as many Medicare patients were discharged to their homes from University Hospitals Cleveland in the last 5 years than were admitted to SNFs.

Gary Cook agrees with home as the default setting for post-acute care. "Our magic sauce is sending a health coach out to the patient's home within 72 hours," Cook says. His agency found that to improve patient outcomes once they get home, services must also address the social determinants of health. Cook's organization strives to prevent the root causes of readmissions.

Barber views network curation as a work in progress that, for many organizations, began as a "mad experiment" to see what works and what doesn't. The hospital continues to learn and evolve all its value-based strategies. "We are taking advantage of being creative in setting these up now. We believe this is where care delivery is going in the future, and we don't want to have to change on a dime."

The Take Away

Best practices identified for optimizing post-acute care networks include designing a member selection process that equitably compares candidates using apples-to-apples data and considers both patient and health system objectives; establishing a meaningful communications strategy with clear goals; reassessing member participation and creating a mechanism for "improvers" to become preferred on a timely basis; and, perhaps most importantly, implementing quality improvement and lean initiatives across the care continuum to improve outcomes and value for patients.

When preferred networks don't work, care managers are often the first to know. Including care managers when creating preferred provider networks will bring valuable expertise to the table and facilitate open communication and stakeholder engagement. At the same time, system execs say "bear with us, we're all learning together." **CE II**

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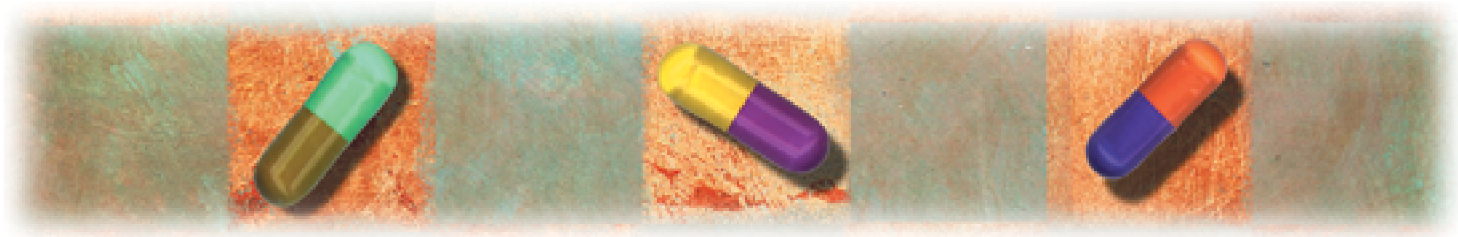
PharmaFacts for Case Managers



Trijardy™ XR (empagliflozin, linagliptin, and metformin hydrochloride extended-release tablets), for oral use

INDICATIONS AND USAGE

Trijardy XR is a combination of empagliflozin, linagliptin, and metformin hydrochloride (HCl) indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.

Limitations of Use

Trijardy XR is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. Trijardy XR has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using Trijardy XR.

> **WARNING: LACTIC ACIDOSIS**
>
> Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. The onset of metformin-associated lactic acidosis is often subtle, accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Metformin-associated lactic acidosis was characterized by elevated blood lactate levels (>5 mmol/Liter), anion gap acidosis (without evidence of ketonuria or ketonemia), an increased lactate/pyruvate ratio; and metformin plasma levels generally >5 mcg/mL.
>
> Risk factors for metformin-associated lactic acidosis include renal impairment, concomitant use of certain drugs (e.g., carbonic anhydrase inhibitors such as topiramate), age 65 years old or greater, having a radiological study with contrast, surgery and other procedures, hypoxic states (e.g., acute congestive heart failure), excessive alcohol intake, and hepatic impairment.
>
> Steps to reduce the risk of and manage metformin-associated lactic acidosis in these high-risk groups are provided in the full prescribing information.
>
> If metformin-associated lactic acidosis is suspected, immediately discontinue Trijardy XR and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended.

DOSAGE AND ADMINISTRATION

Prior to Initiation of Trijardy XR

- Assess renal function prior to initiation of Trijardy XR and periodically thereafter.
- In patients with volume depletion, correct this condition prior to initiation of Trijardy XR.

Recommended Dosage

- Individualize the starting dose of Trijardy XR based on the patient's current regimen:
  - In patients on metformin HCl, with or without linagliptin, switch to Trijardy XR containing a similar total daily dose of metformin HCl and a total daily dose of empagliflozin 10 mg and linagliptin 5 mg;
  - In patients on metformin HCl and any regimen containing empagliflozin, with or without linagliptin, switch to Trijardy XR containing a similar total daily dose of metformin HCl, the same total daily dose of empagliflozin and linagliptin 5 mg.
- Monitor effectiveness and tolerability, and adjust dosing as appropriate, not to exceed the maximum recommended daily dose of empagliflozin 25 mg, linagliptin 5 mg and metformin HCl 2000 mg.
- Take Trijardy XR orally, once daily with a meal in the morning.
  - Take Trijardy XR 10 mg/5 mg/1000 mg or Trijardy XR 25 mg/5 mg/1000 mg as a single tablet once daily.
  - Take Trijardy XR 5 mg/2.5 mg/1000 mg or Trijardy XR 12.5 mg/2.5 mg/1000 mg as two tablets together once daily.
- Swallow Trijardy XR tablets whole. Do not split, crush, dissolve, or chew.

Dosage Recommendations in Patients with Renal Impairment

No dose adjustment is needed in patients with an estimated glomerular filtration rate (eGFR) greater than or equal to 45 mL/min/1.73 m^2. Trijardy XR should not be initiated or continued in patients with an eGFR less than 45 mL/min/1.73 m^2. Trijardy XR is contraindicated in patients with an eGFR less than 30 mL/min/1.73 m^2.

Discontinuation for Iodinated Contrast Imaging Procedures
Discontinue Trijardy XR at the time of, or prior to, an iodinated contrast imaging procedure in patients with an eGFR less than 60 mL/min/1.73 m^2; in patients with a history of liver disease, alcoholism or heart failure; or in patients who will be administered intra-arterial iodinated contrast. Re-evaluate eGFR 48 hours after the imaging procedure; restart Trijardy XR if renal function is stable.

CONTRAINDICATIONS

Trijardy XR is contraindicated in patients with:

- Severe renal impairment (eGFR less than 30 mL/min/1.73 m^2), end-stage renal disease, or dialysis
- Acute or chronic metabolic acidosis, including diabetic ketoacidosis
- Hypersensitivity to empagliflozin, linagliptin, metformin or any of the excipients in Trijardy XR, reactions such as anaphylaxis, angioedema, exfoliative skin conditions, urticaria, or bronchial hyperreactivity have occurred

WARNINGS AND PRECAUTIONS

Lactic Acidosis

There have been postmarketing cases of metformin-associated lactic acidosis, including fatal cases. These cases had a subtle onset and were accompanied by nonspecific symptoms such as malaise, myalgias, abdominal pain, respiratory distress, or increased somnolence; however, hypothermia, hypotension, and resistant bradyarrhythmias have occurred with severe acidosis. Metformin-associated lactic acidosis was characterized by elevated blood lactate concentrations (>5 mmol/Liter), anion gap acidosis (without evidence of ketonuria or ketonemia), and an increased lactate: pyruvate ratio; metformin plasma levels generally >5 mcg/mL. Metformin decreases liver uptake of lactate increasing lactate blood levels, which may increase the risk of lactic acidosis, especially in patients at risk. If metformin-associated lactic acidosis is suspected, general supportive measures should be instituted promptly in a hospital setting, along with immediate discontinuation of Trijardy XR. In Trijardy XR-treated patients with a diagnosis or strong suspicion of lactic acidosis, prompt hemodialysis is recommended to correct the acidosis and remove accumulated metformin (metformin is dialyzable, with a clearance of up to 170 mL/minute under good hemodynamic conditions). Hemodialysis has often resulted in reversal of symptoms and recovery. Educate patients and their families about the symptoms of lactic acidosis and if these symptoms occur instruct them to discontinue Trijardy XR and report these symptoms to their healthcare provider.

For each of the known and possible risk factors for metformin-associated lactic acidosis, recommendations to reduce the risk of and manage metformin-associated lactic acidosis are provided below:

Renal Impairment: The postmarketing metformin-associated lactic acidosis cases primarily occurred in patients with significant renal impairment. The risk of metformin accumulation and metformin-associated lactic acidosis increases with the severity of renal impairment because metformin is substantially excreted by the kidney. Clinical recommendations based upon the patient's renal function include

- Before initiating Trijardy XR, obtain an estimated glomerular filtration rate (eGFR).
- Trijardy XR is contraindicated in patients with an eGFR below 30 mL/min/1.73 m^2.
- Obtain an eGFR at least annually in all patients taking Trijardy XR.
- In patients at increased risk for the development of renal impairment (e.g., the elderly), renal function should be assessed more frequently.

Drug Interactions:

The concomitant use of Trijardy XR with specific drugs may increase the risk of metformin-associated lactic acidosis: those that impair renal function, result in significant hemodynamic change, interfere with acid-base balance or increase metformin accumulation. Therefore, consider more frequent monitoring of patients.

Age 65 or Greater: The risk of metformin-associated lactic acidosis increases with the patient's age because elderly patients have a greater likelihood of having hepatic, renal, or cardiac impairment than younger patients. Assess renal function more frequently in elderly patients.

Radiological Studies with Contrast: Administration of intravascular iodinated contrast agents in metformin-treated patients has led to an acute decrease in renal function and the occurrence of lactic acidosis. Stop Trijardy XR at the time of, or prior to, an iodinated contrast imaging procedure in patients with an eGFR less than 60 mL/min/1.73 m^2; in patients with a history of hepatic impairment, alcoholism, or heart failure; or in patients who will be administered intra-arterial iodinated contrast. Re-evaluate eGFR 48 hours after the imaging procedure, and restart Trijardy XR if renal function is stable.

Surgery and Other Procedures: Withholding of food and fluids during surgical or other procedures may increase the risk for volume depletion, hypotension and renal impairment. Trijardy XR should be temporarily discontinued while patients have restricted food and fluid intake.

Hypoxic States: Several of the postmarketing cases of metformin-associated lactic acidosis occurred in the setting of acute congestive heart failure (particularly when accompanied by hypoperfusion and hypoxemia). Cardiovascular collapse (shock), acute myocardial infarction, sepsis, and other conditions associated with hypoxemia have been associated with lactic acidosis and may also cause prerenal azotemia. When such events occur, discontinue Trijardy XR.

Excessive Alcohol Intake: Alcohol potentiates the effect of metformin on lactate metabolism and this may increase the risk of

metformin-associated lactic acidosis. Warn patients against excessive alcohol intake while receiving Trijardy XR.

Hepatic Impairment: Patients with hepatic impairment have developed cases of metformin-associated lactic acidosis. This may be due to impaired lactate clearance resulting in higher lactate blood levels. Therefore, avoid use of Trijardy XR in patients with clinical or laboratory evidence of hepatic disease.

Pancreatitis

Acute pancreatitis, including fatal pancreatitis, has been reported in patients treated with linagliptin. In the CARMELINA trial, acute pancreatitis was reported in 9 (0.3%) patients treated with linagliptin and in 5 (0.1%) patients treated with placebo. Two patients treated with linagliptin in the CARMELINA trial had acute pancreatitis with a fatal outcome. There have been postmarketing reports of acute pancreatitis, including fatal pancreatitis, in patients treated with linagliptin. Take careful notice of potential signs and symptoms of pancreatitis. If pancreatitis is suspected, promptly discontinue Trijardy XR and initiate appropriate management. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using Trijardy XR.

Heart Failure

An association between DPP-4 inhibitor treatment and heart failure has been observed in cardiovascular outcomes trials for two other members of the DPP-4 inhibitor class. These trials evaluated patients with type 2 diabetes mellitus and atherosclerotic cardiovascular disease. Consider the risks and benefits of Trijardy XR prior to initiating treatment in patients at risk for heart failure, such as those with a prior history of heart failure and a history of renal impairment, and observe these patients for signs and symptoms of heart failure during therapy. Advise patients of the characteristic symptoms of heart failure and to immediately report such symptoms. If heart failure develops, evaluate and manage according to current standards of care and consider discontinuation of Trijardy XR.

Ketoacidosis

Reports of ketoacidosis, a serious life-threatening condition requiring urgent hospitalization have been identified in postmarketing surveillance in patients with type 1 and type 2 diabetes mellitus receiving sodium glucose co-transporter-2 (SGLT2) inhibitors, including empagliflozin. Fatal cases of ketoacidosis have been reported in patients taking empagliflozin. Trijardy XR is not indicated for the treatment of patients with type 1 diabetes mellitus. Patients treated with Trijardy XR who present with signs and symptoms consistent with severe metabolic acidosis should be assessed for ketoacidosis regardless of presenting blood glucose levels, as ketoacidosis associated with Trijardy XR may be present even if blood glucose levels are less than 250 mg/dL. If ketoacidosis is suspected, Trijardy XR should be discontinued, patient should be evaluated, and prompt treatment should be instituted. Treatment of ketoacidosis may require insulin, fluid and carbohydrate replacement. In many of the postmarketing reports, and particularly in patients with type 1 diabetes, the presence of ketoacidosis was not immediately recognized and institution of treatment was delayed because presenting blood glucose levels were below those typically expected for diabetic ketoacidosis (often less than 250 mg/dL). Signs and symptoms at presentation were consistent with dehydration and severe metabolic acidosis and included nausea, vomiting, abdominal pain, generalized malaise, and shortness of breath. In some but not all cases, factors predisposing to ketoacidosis such as insulin dose reduction, acute febrile illness, reduced caloric intake, surgery, pancreatic disorders suggesting insulin deficiency (e.g., type 1 diabetes, history of pancreatitis or pancreatic surgery), and alcohol abuse were identified. Before initiating Trijardy XR, consider factors in the patient history that may predispose to ketoacidosis including pancreatic insulin deficiency from any cause, caloric restriction, and alcohol abuse. For patients who undergo scheduled surgery, consider temporarily discontinuing Trijardy XR for at least 3 days prior to surgery. Consider monitoring for ketoacidosis and temporarily discontinuing Trijardy XR in other clinical situations known to predispose to ketoacidosis (e.g., prolonged fasting due to acute illness or post-surgery). Ensure risk factors for ketoacidosis are resolved prior to restarting Trijardy XR. Educate patients on the signs and symptoms of ketoacidosis and instruct patients to discontinue Trijardy XR and seek medical attention immediately if signs and symptoms occur.

Acute Kidney Injury

Empagliflozin causes intravascular volume contraction and can cause renal impairment. There have been postmarketing reports of acute kidney injury, some requiring hospitalization and dialysis, in patients receiving SGLT2 inhibitors, including empagliflozin; some reports involved patients younger than 65 years of age. Before initiating Trijardy XR, consider factors that may predispose patients to acute kidney injury including hypovolemia, chronic renal impairment, heart failure and concomitant medications (diuretics, ACE inhibitors, ARBs, NSAIDs). Consider temporarily discontinuing Trijardy XR in any setting of reduced oral intake (such as acute illness or fasting) or fluid losses (such as gastrointestinal illness or excessive heat exposure); monitor patients for signs and symptoms of acute kidney injury. If acute kidney injury occurs, discontinue Trijardy XR promptly and institute treatment. Empagliflozin increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Renal function abnormalities can occur after initiating Trijardy XR. Renal function should be evaluated prior to initiation of Trijardy XR and monitored periodically thereafter. More frequent renal function monitoring is recommended in patients with an eGFR below 60 mL/

min/1.73 m^2. Use of Trijardy XR is contraindicated in patients with an eGFR less than 30 mL/min/1.73 m^2.

ADVERSE REACTIONS

The following important adverse reactions are described below:

- Lactic Acidosis
- Pancreatitis
- Heart Failure
- Hypotension
- Ketoacidosis
- Acute Kidney Injury
- Urosepsis and Pyelonephritis
- Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues
- Necrotizing Fasciitis of the Perineum
- Genital Mycotic Infections
- Hypersensitivity Reactions
- Vitamin B12 Deficiency
- Severe and Disabling Arthralgia
- Bullous Pemphigoid

USE IN SPECIFIC POPULATIONS

Pregnancy: Based on animal data showing adverse renal effects from empagliflozin, Trijardy XR is not recommended during the second and third trimesters of pregnancy.

Lactation: There is limited information regarding the presence of Trijardy XR, or its components (empagliflozin, linagliptin, or metformin) in human milk, the effects on the breastfed infant, or the effects on milk production. Limited published studies report that metformin is present in human milk. Empagliflozin and linagliptin are present in rat milk. Since human kidney maturation occurs in utero and during the first 2 years of life when lactational exposure may occur, there may be risk to the developing human kidney. Because of the potential for serious adverse reactions in a breastfed infant, including the potential for empagliflozin to affect postnatal renal development, advise patients that use of Trijardy XR is not recommended while breastfeeding.

Pediatric Use

Safety and effectiveness of Trijardy XR in pediatric patients under 18 years of age have not been established.

Renal Impairment: Trijardy XR should not be initiated or continued in patients with an eGFR less than 45 mL/min/1.73 m^2 and is contraindicated in patients with severe renal impairment (eGFR less than 30 mL/min/1.73 m^2), end-stage renal disease, or dialysis.

Empagliflozin: The glucose lowering benefit of empagliflozin 25 mg decreased in patients with worsening renal function. The risks of renal impairment, volume depletion adverse reactions and urinary tract infection-related adverse reactions increased with worsening renal function.

Metformin HCl: Metformin is substantially excreted by the kidney, and the risk of metformin accumulation and lactic acidosis increases with the degree of renal impairment

CLINICAL STUDIES

Empagliflozin and Linagliptin Add-on Combination Therapy with Metformin for Glycemic Control

A total of 686 patients with type 2 diabetes participated in a double-blind, active-controlled study to evaluate the efficacy and safety of empagliflozin 10 mg or 25 mg in combination with linagliptin 5 mg, compared to the individual components. Patients with type 2 diabetes inadequately controlled on at least 1500 mg of metformin per day entered a single-blind placebo run-in period for 2 weeks. At the end of the run-in period, patients who remained inadequately controlled and had an HbA1c between 7 and 10.5% were randomized 1:1:1:1:1 to one of 5 active-treatment arms of empagliflozin 10 mg or 25 mg, linagliptin 5 mg, or linagliptin 5 mg in combination with 10 mg or 25 mg empagliflozin as a fixed dose combination tablet. At Week 24, empagliflozin 10 mg or 25 mg used in combination with linagliptin 5 mg provided statistically significant improvement in HbA1c compared to the individual components in patients who had been inadequately controlled on metformin. Treatment with empagliflozin 10 mg or 25 mg used in combination with linagliptin 5 mg also resulted in a statistically significant reduction in body weight compared to linagliptin 5 mg. There was no statistically significant difference compared to empagliflozin alone.

Empagliflozin Cardiovascular Outcome Study in Patients with Type 2 Diabetes Mellitus and Atherosclerotic Cardiovascular Disease

Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. The effect of empagliflozin on cardiovascular risk in adult patients with type 2 diabetes and established, stable, atherosclerotic cardiovascular disease is presented below. The EMPA-REG OUTCOME study, a multicenter, multi-national, randomized, double-blind parallel group trial compared the risk of experiencing a major adverse cardiovascular event (MACE) between empagliflozin and placebo when these were added to and used concomitantly with standard of care treatments for diabetes and atherosclerotic cardiovascular disease. Coadministered antidiabetic medications were to be kept stable for the first 12 weeks of the trial. Thereafter, antidiabetic and atherosclerotic therapies could be adjusted, at the discretion of investigators, to ensure participants were treated according to the standard care for these diseases. A total of 7020 patients were treated (empagliflozin 10 mg = 2345; empagliflozin 25 mg = 2342; placebo = 2333) and followed for a median of 3.1 years. Approximately 72% of the study population was Caucasian, 22% was Asian, and 5% was Black. The mean age was 63 years

continues on page 29

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Am J Cardiol. 2019 Dec 27. pii: S0002-9149(19)31495-X. doi: 10.1016/j.amjcard.2019.12.026. [Epub ahead of print]

Meta-analysis evaluating calcium channel blockers and the risk of peripheral arterial disease in patients with hypertension.

Shetty S, Malik AH, Feringa H, et al.

Clinical studies have shown that calcium channel blockers (CCB) can mitigate the progression of atherosclerosis. Their role in the primary prevention of peripheral artery disease (PAD) is unclear. We conducted a meta-analysis of randomized control trials (RCT) to compare the impact of CCB on the incidence of PAD in patients with hypertension. A comprehensive review of the literature was performed in PubMed and Cochrane registry. Studies were included if they were RCT and had outcome data on PAD with a follow-up duration of at least 6 months. CCB formed the intervention group, whereas the control group was constituted by either placebo or active treatment with any of the other antihypertensive medications. A random-effects meta-analysis was performed, and we report odds ratio as a measure of treatment effect. Our search identified 934 trials, of which 7 RCTs with 71,971 patients fulfilled the inclusion criteria. The mean duration of follow-up was 3.8 years. In patients receiving CCB, PAD events occurred in 547 out of 27,502 patients (2%) compared with 1,263 out of 42,659 patients in the control group (3%). Based on the random-effect model, the odds for development of PAD in hypertensive patients treated with CCB compared with the control group was 0.70 (95% confidence interval of 0.58 to 0.86, p = 0.0005). In conclusion, this meta-analysis of RCTs of hypertensive patients, we found that treatment with CCB was strongly associated with a decrease in the PAD compared with other antihypertensive agents or placebo.

J Infect Dis. 2020 Jan 20. pii: jiaa010. doi: 10.1093/infdis/jiaa010. [Epub ahead of print]

Frailty is associated with mortality and incident comorbidity among middle-aged HIV-positive and HIV-negative participants.

Verheij E, Kirk GD, Wit FW, et al.

BACKGROUND: Frailty is associated with mortality and morbidity in the general geriatric population, but less is known about its impact among the ageing but generally younger population with HIV (PWH).

METHODS: The impact of frailty on all-cause mortality, during 6 years of follow-up and incident comorbidity, during 4 years of follow-up was assessed among 598 HIV-positive and 550 comparable HIV-negative participants of the AGEhIV Cohort Study, aged ≥45 years. Frailty encompasses 5 domains; weight loss, low physical activity, exhaustion, decreased grip strength, and slow gait speed. Presence of ≥3 denotes frailty, 1-2 prefrailty and 0 robust. Multivariable Cox and logistic regression models were used to assess the independent relationships of frailty with both outcomes, adjusting for HIV-infection and traditional risk factors.

RESULTS: At baseline 7.5% (n=86) of participants were frail. During follow-up 38 participants died. Mortality rate was significantly higher among frail participants (frail 25.7/1,000 person-years of follow-up (PYFU; 95% confidence interval [95% CI] 14.2-46.4); prefrail 7.2/1,000 PYFU (95% CI, 4.7-11.2); robust 2.3/1,000 PYFU (95% CI, 1.1-4.9)). In fully adjusted analyses, frailty remained strongly associated with death (HR 4.6, 1.7-12.5) and incident comorbidity (OR 1.9, 1.1-3.1). No interactions were observed between frailty- and HIV-status in all analyses.

CONCLUSIONS: Frailty is a strong predictor of both mortality and incident comorbidity independent from other risk factors.

Dig Dis Sci. 2020 Jan 14. doi: 10.1007/s10620-019-06037-z. [Epub ahead of print]

Early treatment uptake and cost burden of hepatitis C therapies among newly diagnosed hepatitis C patients with a particular focus on HIV coinfection.

van Boemmel-Wegmann S, Lo Re V 3rd, Park H.

BACKGROUND: Despite the high efficacy and safety associated with direct-acting antivirals (DAAs), access to HCV treatment has been frequently restricted because of the high DAA drug costs.

OBJECTIVES: To (1) compare HCV treatment initiation rates between HCV monoinfected and HCV/HIV coinfected patients before (pre-DAA period) and after (post-DAA period) all-oral DAAs became available; and to (2) estimate the HCV treatment costs for payers and patients.

RESEARCH DESIGN AND METHODS: A retrospective analysis of the MarketScan® Databases (2009-2016) was conducted

for newly diagnosed HCV patients. Multivariable logistic regression was used to estimate the odds ratio (OR) of initiating HCV treatments during the pre-DAA and post-DAA periods. Kruskal-Wallis test was used to compare drug costs for dual, triple and all-oral therapies.

RESULTS: A total of 15,063 HCV patients [382 (2.5%) HIV coinfected] in the pre-DAA period and 14,896 [429 (2.9%) HIV coinfected] in the post-DAA period were included. HCV/HIV coinfected patients had lower odds of HCV treatment uptake compared to HCV monoinfected patients during the pre-DAA period [OR, 0.59; 95% confidence interval (CI), 0.45-0.78], but no significant difference in odds of HCV treatment uptake was observed during the post-DAA period (OR, 1.08; 95% CI, 0.87-1.33). From 2009 to 2016, average payers' treatment costs (dual, $20,820; all-oral DAAs, $99,661; $p < 0.001$) as well as average patients' copayments (dual, $593; all-oral DAAs $933; $p < 0.001$) increased significantly.

CONCLUSIONS: HCV treatment initiation rates increased, especially among HCV/HIV coinfected patients, from the pre-DAA to the post-DAA period. However, payers' expenditures per course of therapy saw an almost fivefold increase and patients' copayments increased by 55%.

Chest. 2020 Jan 17. pii: S0012-3692(20)30044-1. doi: 10.1016/j.chest.2019.12.020. [Epub ahead of print]

Update on apneas of heart failure with reduced ejection fraction: emphasis on the physiology of treatment part 2: central sleep apnea.

Javaheri S, Brown LK, Khayat RN.

Central sleep apnea/Hunter-Cheyne-Stokes Breathing (CSA/HCSB), is prevalent in patients with heart failure with reduced ejection fraction (HFrEF). The acute pathobiological consequences of CSA/HSCB eventually lead to sustained sympathetic over-activity, repeated hospitalization, and premature mortality. Few small randomized controlled trials (RCTs) have shown statistically significant and clinically important reduction in sympathetic activity when CSA/HCSB is attenuated by oxygen or positive airway pressure (PAP) therapy, both continuous PAP (CPAP) and Adaptive servo ventilation (ASV) devices. Yet, the two largest PAP trials in patients with HFrEF, one with CPAP and the other with an ASV, were negative with respect to their primary outcomes, and both associated with excess mortality. However, both trials suffered from significant deficiencies casting doubt on their results. A second RCT evaluating an ASV device with advanced algorithm is ongoing. A new modality of therapy, unilateral phrenic nerve stimulation, has undergone an RCT that demonstrated an improvement in CSA that was associated with a reduction in arousals, improvement in sleepiness and quality of life. However, a long-term mortality trial has not been performed with this modality. Most recently, the NIH funded a long-term, phase-III RCT of low flow oxygen vs. sham for the treatment of CSA/HCSB in HFrEF. The composite primary outcome includes all-cause mortality and hospitalization for worsening HF. In this article, we focus on various therapeutic options for the treatment of CSA/HCSB and, when appropriate, emphasize the importance of identifying CSA/HCSB phenotypes to tailor treatment.

J Am Coll Cardiol. 2020 Jan 21;75(2):148-158. doi: 10.1016/j.jacc.2019.10.058.

Incident heart failure and long-term risk for venous thromboembolism.

Fanola CL, Norby FL, Shah AM, et al.

BACKGROUND: Heart failure (HF) hospitalization places patients at increased short-term risk for venous thromboembolism (VTE). Long-term risk for VTE associated with incident HF, HF subtypes, or structural heart disease is unknown.

OBJECTIVES: In the ARIC (Atherosclerosis Risk In Communities) cohort, VTE risk associated with incident HF, HF subtypes, and abnormal echocardiographic measures in the absence of clinical HF was assessed.

METHODS: During follow-up, ARIC identified incident HF and subcategorized HF with preserved ejection fraction or reduced ejection fraction. At the fifth clinical examination, echocardiography was performed. Physicians adjudicated incident VTE using hospital records. Adjusted Cox proportional hazards models were used to evaluate the association between HF or echocardiographic exposures and VTE.

RESULTS: Over a mean of 22 years in 13,728 subjects, of whom 2,696 (20%) developed incident HF, 729 subsequent VTE events were identified. HF was associated with increased long-term risk for VTE (adjusted hazard ratio: 3.13; 95% confidence interval: 2.58 to 3.80). In 7,588 subjects followed for a mean of 10 years, the risk for VTE was similar for HF with preserved ejection fraction (adjusted hazard ratio: 4.71; 95% CI: 2.94 to 7.52) and HF with reduced ejection fraction (adjusted hazard ratio: 5.53; 95% confidence interval: 3.42 to 8.94). In 5,438 subjects without HF followed for a mean of 3.5 years, left ventricular relative wall thickness and mean left ventricular wall thickness were independent predictors of VTE.

CONCLUSIONS: In this prospective population-based study, incident hospitalized HF (including both heart failure with preserved ejection fraction and reduced ejection fraction), as well as echocardiographic indicators of left ventricular remodeling, were associated with greatly increased risk for VTE, which persisted through long-term follow-up. Evidence-based strategies to prevent long-term VTE in patients with HF, beyond time of hospitalization, are needed.

Clin Transplant. 2020 Jan 21. doi: 10.1111/ctr.13787. [Epub ahead of print]

Association between increased risk donor social behaviors and recipient outcomes after heart transplantation.

Okoh AK, Chan O, Schultheis M, et al.

BACKGROUND: This study aims to investigate the association between social behaviors of increased risk donors (IRD)and recipient outcomes after heart transplantation.

METHODS: The United Network for Organ Sharing (UNOS) database was queried to identify patients who received a heart transplant between 2004 and 2015. Patients were grouped based on donor's risk status (IRD vs standard risk donor (SRD)). Recipients of IRD were categorized on social behaviors (SB) and recipient survival was assessed. Cox regression analysis was used to identify associations between social behaviors of donors and recipient survival.

RESULTS: Out of 22,333 heart transplantations performed during the study period, 2,769 (12%) received an IRD graft with the following SB: Unprofessional tattoos or piercings (n=1722) (63%), cocaine use (n= 916) (33%), heavy smoking (n=437) (16%), heavy alcohol abuse (n= 610) (22%). Viral screens detected 72(3%) hepatitis B virus (HBV) positive, 12 (0.4%) hepatitis C virus (HCV) positive at donation. There was no difference in recipient survival based on both donor risk and their social behaviors. Cox regression analysis found only donor HCV infection and non-identical ABO mismatch to be associated with poor recipient survival among recipients of IR grafts.

CONCLUSION: Cardiac allografts from IRD, serologically negative for viruses, can safely be used. There is no association between social behaviors of IRD and recipient survival.

Diabetes Care. 2019 May;42(5):954-963. doi: 10.2337/dc18-2004. Epub 2019 Mar 12.

Risk of incident obstructive sleep apnea among patients with type 2 diabetes.

Subramanian A, Adderley NJ, Tracy A, et al.

OBJECTIVE: This study compared the incidence of obstructive sleep apnea (OSA) in patients with and without type 2 diabetes and investigated risk factors for OSA in patients with type 2 diabetes.

RESEARCH DESIGN AND METHODS: A retrospective cohort study was performed to compare OSA incidence between adult patients with and without type 2 diabetes matched for age, sex, and BMI. Patients with a prevalent OSA diagnosis were excluded. The study cohort was derived from The Health Improvement Network (THIN), a U.K. primary care database, from 1 January 2005 to 31 December 2017.

RESULTS: There were 3,110 (0.88%) and 5,968 (0.46%) incident OSA cases identified in the 360,250 exposed and 1,296,489 unexposed patient cohorts, respectively. Adjusted incidence rate ratio (aIRR) of OSA in patients with type 2 diabetes compared with those without was 1.48 (95% CI 1.42-1.55; P < 0.001). In a multivariate regression analysis of patients with type 2 diabetes, significant predictors of OSA were diabetes-related foot disease (1.23 [1.06-1.42]; P = 0.005), being prescribed insulin in the last 60 days (1.58 [1.42-1.75]; P < 0.001), male sex (2.27 [2.09-2.46]; P < 0.001), being overweight (2.02 [1.54-2.64]; P < 0.001) or obese (8.29 [6.42-10.69]; P < 0.001), heart failure (1.41 [1.18-1.70]; P < 0.001), ischemic heart disease (1.22 [1.11-1.34]; P < 0.001), atrial fibrillation (1.23 [1.04-1.46]; P = 0.015), hypertension (1.32 [1.23-1.43]; P < 0.001), and depression (1.75 [1.61-1.91]; P < 0.001).

CONCLUSIONS: When considered alongside previous evidence, this study indicates that the association between type 2 diabetes and OSA is bidirectional. In addition to known predictors of OSA, diabetes-related foot disease and insulin treatment were identified as risk factors in patients with type 2 diabetes.

Circ Cardiovasc Qual Outcomes. 2020 Jan;13(1):e005753. doi: 10.1161/CIRCOUTCOMES.119.005753. Epub 2020 Jan 20.

Over-testing for suspected pulmonary embolism in American emergency departments: the continuing epidemic.

Kline JA, Garrett JS, Sarmiento EJ, et al.

BACKGROUND:No recent data have investigated rates of diagnostic testing for pulmonary embolism (PE) in US emergency departments (EDs), and no data have examined computed tomographic pulmonary angiography (CTPA) rates in subgroups at high risk for adverse imaging outcomes, including young women and children. We hypothesized that over-testing for PE remains a problem.

METHODS AND RESULTS: We used electronic health record and billing data for 16 EDs in Indiana and 11 hospitals in the Dallas-Fort Worth area from 2016 to 2019 to locate ED patients who had any of the following: D-dimer, CTPA, scintillation ventilation perfusion lung scanning or formal pulmonary angiography. The primary outcomes were ED encounter volume-adjusted CTPA rate, PE yield rate with subgroup reporting for children (<18 years) and women under 45 years. We also examined the most frequent diagnoses. From a total visit volume of 1 828 010 patient encounters, 97 125 (5.3% of the total volume) had a diagnostic test for PE, including 25 870 patients who had CTPA order without D-dimer (59% of all tests for PE). The yield rate for PE from CTPA scans was 1.3% (1.1%-1.5%) in Indiana and 4.8% (4.2%-5.1%) in Dallas-Fort Worth (pooled rate 3.1%). Linear regression showed that increased D-dimer ordering correlated with increased PE yield rate (Pearson's R2=0.43; P<0.001). From the pooled sample, 59% of CTPAs done were in women, with 21% of all

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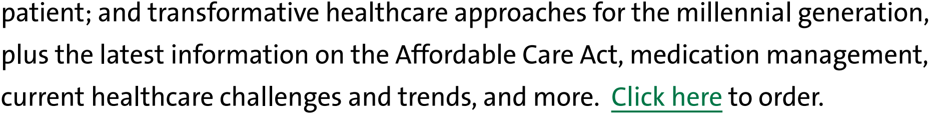

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CTPAs performed on women under 45 years of age, and 1.4% (1.3%-1.5%) on children. The most frequent diagnoses were symptom-based descriptions of chest pain (34%) and shortness of breath (6.5%) and the condition-based diagnosis of pneumonia (4.1%).

CONCLUSIONS: Over-testing for PE in American EDs remains a major public health problem. Centers with higher D-dimer ordering had higher yield of PE on CTPA. These data suggest the potential for implementation of D-dimer based protocols to reduce low-yield CTPA ordering.

Am J Epidemiol. 2020 Jan 23. pii: kwaa005. doi: 10.1093/aje/kwaa005. [Epub ahead of print]

Smoking and risk of colorectal cancer may differ by anatomical subsite and sex.

Gram IT, Park SY, Wilkens LR, et al.

The purpose of this study was to examine if the increased risk of colorectal cancer due to cigarette smoking differed by anatomical subsite and sex. We analyzed data from 188,052 participants (45% men, aged 45-75 years), who were enrolled in the Multiethnic Cohort Study in 1993-1996. During a mean follow-up of 16.7 years, we identified 4,879 incident cases of invasive colorectal adenocarcinoma. In multivariate Cox regression models, compared with never smokers of the same sex, male ever smokers had a 39% [hazard ratio (HR) =1.39; 95% Confidence interval (CI): 1.16,1.67] higher risk of left, but not of right (HR=1.03; 95% CI: 0.89,1.18) colon cancer, while female ever smokers, had a 20% (HR=1.20; 95% CI: 1.06,1.36) higher risk of right, but not of left (HR=0.96; 95% CI: 0.80,1.15) colon cancer. Compared with male smokers, female smokers had a greater increase in risk of rectal cancer with number of pack-years (Pheterogeneity = 0.03). Our results suggest that male smokers are at increased risk of left colon cancer and female smokers at increased risk of right colon cancer. Our study also suggests that females who smoke may have a higher risk of rectal cancer due to smoking than their male counterparts.

Cancer. 2020 Jan 23. doi: 10.1002/cncr.32710. [Epub ahead of print]

Prediagnosis social support, social integration, living status, and colorectal cancer mortality in postmenopausal women from the women's health initiative.

Kroenke CH, Paskett ED, Cené CW, et al.

BACKGROUND: We evaluated associations between perceived social support, social integration, living alone, and colorectal cancer (CRC) outcomes in postmenopausal women.

METHODS: The study included 1431 women from the Women's Health Initiative who were diagnosed from 1993 through 2017 with stage I through IV CRC and who responded to the Medical Outcomes Study Social Support survey before their CRC diagnosis. We used proportional hazards regression to evaluate associations of social support (tertiles) and types of support, assessed up to 6 years before diagnosis, with overall and CRC-specific mortality. We also assessed associations of social integration and living alone with outcomes also in a subset of 1141 women who had information available on social ties (marital/partner status, community and religious participation) and living situation.

RESULTS: In multivariable analyses, women with low (hazard ratio [HR], 1.52; 95% CI, 1.23-1.88) and moderate (HR, 1.21; 95% CI, 0.98-1.50) perceived social support had significantly higher overall mortality than those with high support (P [continuous] < .001). Similarly, women with low (HR, 1.42; 95% CI, 1.07-1.88) and moderate (HR, 1.28; 95% CI, 0.96-1.70) perceived social support had higher CRC mortality than those with high social support (P [continuous] = .007). Emotional, informational, and tangible support and positive interaction were all significantly associated with outcomes, whereas affection was not. In main-effects analyses, the level of social integration was related to overall mortality (P for trend = .02), but not CRC mortality (P for trend = .25), and living alone was not associated with mortality outcomes. However, both the level of social integration and living alone were related to outcomes in patients with rectal cancer.

CONCLUSIONS: Women with low perceived social support before diagnosis have higher overall and CRC-specific mortality.

Transplantation. 2020 Jan 13. doi: 10.1097/TP.0000000000003117. [Epub ahead of print]

Surveillance for HCC after liver transplantation: increased monitoring may yield aggressive treatment options and improved postrecurrence survival.

Lee DD, Sapisochin G, Mehta N, et al.

BACKGROUND: Currently, no surveillance guidelines for hepatocellular carcinoma (HCC) recurrence after liver transplantation (LT) exist. In this retrospective, multicenter study, we have investigated the role of surveillance imaging on postrecurrence outcomes.

METHODS: Patients with recurrent HCC after LT from 2002-2016 were reviewed from 3 transplant centers (UCSF, Mayo Clinic Florida, and University of Toronto). For this study, we proposed the term cumulative exposure to surveillance (CETS) as a way to define the cumulative sum of all the protected intervals that each surveillance test provides. In our analysis, CETS has been treated as a continuous variable in months.

RESULTS: 223 patients from 3 centers had recurrent HCC

post-LT. The median followup was 31.3 months and median time to recurrence was 13.3 months. Increasing CETS was associated with improved postrecurrence survival (HR 0.94, p < 0.01) as was treatment of recurrence with resection or ablation (HR 0.31, p<0.001). An ROC curve (AUC=0.64) for CETS covariate showed that 252 days of coverage (or 3 surveillance scans) within the first 24 months provided the highest probability for aggressive postrecurrence treatment.

CONCLUSION: In this review of 223 patients with post-LT HCC recurrence, we found that increasing CETS does lead to improved postrecurrence survival as well as a higher probability for aggressive recurrence treatment. We found that 252 days of monitoring (i.e. 3 surveillance scans) in the first 24 months was associated with the ability to offer potentially curative treatment.

Urol Oncol. 2020 Jan 14. pii: S1078-1439(19)30497-1. doi: 10.1016/j.urolonc.2019.12.010. [Epub ahead of print]

A simplified nomogram to assess risk of bladder cancer in patients with a new diagnosis of microscopic hematuria.

Matulewicz RS, Rademaker A, Meeks JJ.

INTRODUCTION: The vast majority of patients who undergo a diagnostic evaluation for microscopic hematuria (MH) do not have occult bladder cancer. Identifying patients with MH at high risk of harboring bladder cancer can allow for a risk adjusted approach to diagnostic interventions with the goal of safely reducing unnecessary evaluations.

METHODS: Patients with a new diagnosis of microhematuria during an 8.5-year period were retrospectively identified. All patients who had a complete MH evaluation were randomized to a training or a validation cohort. Logistic regression analysis was performed in the training cohort to identify factors related to a bladder cancer diagnosis and to develop our model. Receiver operating curves to identify bladder cancer were constructed for the training and validation cohort and tested for their ability to discriminate true cases. A nomogram to predict a bladder cancer diagnosis was created.

RESULTS: In 4,178 patients split into training and validation cohorts, those diagnosed with bladder cancer were shown to be older, have a greater degree of MH (more RBC/hpf), and were former or current smokers. A nomogram created using this model was able to predict risk of a bladder cancer diagnosis with good discrimination (areas under the curve 0.79, 95% CI 0.75-0.83). A cutoff of 0.01 probability demonstrated a sensitivity of 99.1% and a negative predictive value of 99.7%.

CONCLUSION:A nomogram can accurately predict the risk of bladder cancer diagnosed during the evaluation of MH and can potentially be used avoid a significant number of work ups in those at the lowest risk.

Cancer. 2019 Dec 15;125 Suppl 24:4578-4581. doi: 10.1002/cncr.32474.

Can we predict who lives long with ovarian cancer?

Bookman MA.

Women with ovarian cancer benefit from individualized management that incorporates advanced imaging technologies, sophisticated cytoreductive surgery integrated with combination chemotherapy, genetic risk assessment, and tumor molecular profiling. However, advanced ovarian cancer remains a highly lethal disease because of early peritoneal dissemination, rapid development of resistance to key therapeutic agents, and evasion of the host immune response. Over the last 15 years, several models and nomograms have been developed to predict surgical outcomes, progression-free survival, or overall survival on the basis of clinical and pathologic data available at the primary diagnosis and recurrence. Each of these models has its strengths and limitations, and they provide a basis for future models that will incorporate functional imaging and molecular characteristics.

Curr Opin Nephrol Hypertens. 2020 Jan 16. doi: 10.1097/MNH.0000000000000582. [Epub ahead of print]

Chronic kidney disease and kidney stones.

Uribarri J.

PURPOSE OF REVIEW: Both chronic kidney disease (CKD) and kidney stones are major public health problems, which are closely interrelated. Recurrent kidney stones predispose to CKD although CKD seems to decrease risk of further kidney stone formation. Herein, we review new information of this interrelationship.

RECENT FINDINGS: Several epidemiological studies in the past have shown an association between history of kidney stones and risk for CKD and CKD progression. Recent literature supports this concept and it is reviewed in this article. The issue of whether CKD protects against new kidney stone formation remains unsettled and there is no recent literature addressing it. In relation to stone risk factors in CKD, there are several interesting new articles that discuss mechanisms of hypocitraturia in early CKD before overt metabolic acidosis. Since hypocitraturia is an important risk factor for kidney stone formation we addressed these new data in detail. There are also new data supporting urinary oxalate excretion as a predictor of CKD progression.

SUMMARY: It seems clear that recurrent kidney stones should be avoided not only because of their immediate clinical manifestations but also because of their long-term predisposition to CKD progression. Mechanisms leading to hypocitraturia in early CKD still remain controversial.

CHRONIC Care Act Leads Some Medicare Advantage Plans to Incorporate Social Services

The CHRONIC Care Act, which kicked in fully on January 1, paves the way for Medicare Advantage plans to cover untraditional services and other benefits. It recognizes that many factors beyond medical care influence health. The CHRONIC Care Act gives plans new flexibility to offer nonmedical benefits, but it does not mandate plans do so or prescribe particular benefits. The new benefits must have a "reasonable expectation" of improving or maintaining beneficiaries' health or functioning by targeting their living conditions, nutrition, or other social determinants of health.

Starting in 2019: Plans were able to offer a broader range of benefits to any member, including adult day care, in-home personal care attendants, support for family caregivers, home safety and assistive devices (eg, grab bars or wheelchair ramps), and nonopioid pain management (eg, acupuncture or massage).

Starting in 2020: Plans may offer special supplemental benefits for the chronically ill. These are limited to members who (1) have at least one complex chronic condition that is life threatening or significantly limits overall health or function, (2) are at high risk of hospitalization or other adverse health outcomes, and (3) require intensive care coordination. These benefits could include services such as nonmedical transportation, home-delivered meals, help with daily activities, or minor home repairs. ■

KHN Launches "Pre$cription for Power"

Pharmaceutical companies gave at least $116 million to patient advocacy groups in a single year, reveals a new database logging 12,000 donations from large publicly traded drugmakers to such organizations. Even as these patient groups grow in number and political influence, their funding and their relationships to drugmakers are little understood. Unlike payments to doctors and lobbying expenses, companies do not have to report payments to the groups.

The database, called "Pre$cription for Power," shows that donations to patient advocacy groups tallied for 2015—the most recent full year in which documents required by the Internal Revenue Service were available—dwarfed the total amount the companies spent on federal lobbying. The 14 companies that contributed $116 million to patient advocacy groups reported only about $63 million in lobbying activities that same year.

Read more at https://khn.org/patient-advocacy/. ■

U.S. Department of Health and Human Services Offers Free HIV Prevention Drug

Kaiser Health News reports that the U.S. Department of Health and Human Services (HHS) has unveiled a plan to distribute HIV prevention medication free to individuals who do not have prescription drug insurance coverage. Called "Ready, Set, PrEP," the federal program will provide patients at risk of contracting HIV one of the two preexposure prophylaxis (PrEP) drugs. Those medications can reduce the chances of getting HIV through sex by more than 90%.

The medications, Truvada® and Descovy®, are made possible in part by a donation from the drugs' manufacturer, Gilead Sciences, that would cover the drugs for up to 200,000 uninsured individuals each year for the next 11 years. The federal government, however, is paying the drugmaker for several months to distribute the medications. ■

Patient and Nurse Safety Decrease Because of Increased Errors and Injuries Due to Fatigue, Says American Nurses Association

Nurses have a responsibility to themselves and their patients to be well-rested in order to provide the highest quality care possible. Working long shifts, night shifts, and rotating shifts, as well as mandatory or voluntary overtime, contributes to nurse fatigue, which results in accidents, mistakes, and errors.

But beyond the safety and ethical implications, fatigue can also lead to legal consequences, including loss of license. Although nurses are accountable for their individual practice, employers also have a responsibility to keep nurses, patients, the facility, and the public safe.

Suggested strategies are:

- Designing schedules and organizing work to reduce nurse fatigue
- Developing a fatigue management plan
- Educating staff on sleep hygiene
- Providing opportunities for staff to express concerns about fatigue and taking actions to address those concerns
- Making sure extended shifts have adequate staff support and rest periods ■

PACE Costs Less Than Nursing Home or Other Services

The Program of All-Inclusive Care for the Elderly (PACE) offers an alternative to caring for frail elders solely in their homes or in nursing homes. Elders visit PACE day centers where they can eat meals, exercise, take part in physical therapy, see their doctors, or receive other kinds of support. Data gathered by the National PACE Association show this approach costs states on average 13% less than paying for nursing homes or other community-based services. ■

Staying Abreast of Relevant Issues in Case Management *continued from page 7*

Issue Brief, is the emergence of the transdisciplinary model. A more familiar term may be the interdisciplinary team, in which professionals from varied disciplines and backgrounds contribute their specialized knowledge, skills, and expertise to meet the needs of the patient and advance his/her goals. A transdisciplinary team is the next step: understanding the roles and disciplines of each professional. Case managers, at the hub of the team, devote themselves to knowing more about what every team member does and manage communication to keep information flowing. In addition, case managers emphasize accountability on the part of the team for all measures and outcomes.

These three topics are but a sampling of the many issues and trends impacting health and human services and the delivery of case management today. It's up to each CCM and CDMS as well as other professionals to stay current with and knowledgeable about these trends. The Commission is here to help. As part of our CMLearning Network®, the Commission offers Issue Briefs, covering timely and relevant topics for today's professional case managers. The Issue Briefs are available online at no charge. In addition, the Commission will send a limited number of hard copies of Issue Briefs for use at meetings at no charge (see the website).

Lifelong learning and continued education are paramount, given the dynamic nature of health care today. By increasing their knowledge and understanding, case managers have the perspective and expertise to provide resources and information as they advocate for individuals and their support systems. CM

PharmaFacts for Case Managers

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and approximately 72% were male. All patients in the study had inadequately controlled type 2 diabetes mellitus at baseline (HbA1c greater than or equal to 7%). The mean HbA1c at baseline was 8.1% and 57% of participants had diabetes for more than 10 years. Approximately 31%, 22% and 20% reported a past history of neuropathy, retinopathy and nephropathy to investigators respectively and the mean eGFR was 74 mL/min/1.73 m^2. At baseline, patients were treated 34 with one (~30%) or more (~70%) antidiabetic medications including metformin (74%), insulin (48%), sulfonylurea (43%) and dipeptidyl peptidase-4 inhibitor (11%). All patients had established atherosclerotic cardiovascular disease at baseline including one (82%) or more (18%) of the following: a documented history of coronary artery disease (76%), stroke (23%) or peripheral artery disease (21%). At baseline, the mean systolic blood pressure was 136 mmHg, the mean diastolic blood pressure was 76 mmHg, the mean LDL was 86 mg/dL, the mean HDL was 44 mg/dL, and the mean urinary albumin to creatinine ratio (UACR) was 175 mg/g. At baseline, approximately 81% of patients were treated with renin angiotensin system inhibitors, 65% with beta-blockers, 43% with diuretics, 77% with statins, and 86% with antiplatelet agents (mostly aspirin). The primary endpoint in EMPA-REG OUTCOME was the time to first occurrence of a Major Adverse Cardiac Event (MACE). A major adverse cardiac event was defined as occurrence of either a cardiovascular death or a nonfatal myocardial infarction (MI) or a nonfatal stroke. The statistical analysis plan had pre-specified that the 10 and 25 mg doses would be combined. A Cox proportional hazards model was used to test for non-inferiority against the pre-specified risk margin of 1.3 for the hazard ratio of MACE and superiority on MACE if noninferiority was demonstrated. Type-1 error was controlled across multiples tests using a hierarchical testing strategy. Empagliflozin significantly reduced the risk of first occurrence of primary composite endpoint of cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke (HR: 0.86; 95% CI 0.74, 0.99). The treatment effect was due to a significant reduction in the risk of cardiovascular death in subjects randomized to empagliflozin (HR: 0.62; 95% CI 0.49, 0.77), with no change in the risk of non-fatal myocardial infarction or non-fatal stroke. Results for the 10 mg and 25 mg empagliflozin doses were consistent with results for the combined dose groups. The efficacy of empagliflozin on cardiovascular death was generally consistent across major demographic and disease subgroups. Vital status was obtained for 99.2% of subjects in the trial. A total of 463 deaths were recorded during the EMPA-REG OUTCOME trial. Most of these deaths were categorized as cardiovascular deaths. The noncardiovascular deaths were only a small proportion of deaths, and were balanced between the treatment groups (2.1% in patients treated with empagliflozin, and 2.4% of patients treated with placebo).

Linagliptin Cardiovascular Safety Trial

The cardiovascular risk of linagliptin was evaluated in CARMELINA (NCT0189753), a multi-national, multicenter, placebo-controlled, double-blind, parallel group trial comparing linagliptin (N=3494) to placebo (N=3485) in adult patients with type 2 diabetes mellitus and a history of established macrovascular and/or renal disease. The trial compared the risk of major adverse cardiovascular events (MACE) between linagliptin and placebo when these were added to standard of care treatments for diabetes and other cardiovascular risk factors. The trial was event driven, the median duration of follow-up was 2.2 years and vital status was obtained for 99.7% of patients. Patients were eligible to enter the trial if they were adults with type 2 diabetes, with

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A New Year, A New Feeling of Wellness *continued from page 8*

body mass, and personal and family history. It wouldn't hurt to implement small changes at this point before things get out of control. Are you drinking enough water? Do you have a regular exercise routine? What types of food do you eat? Do you get enough sleep? These are all things that we should consider when we look at our physical wellness.

What is your favorite thing to do in your free time? Sometimes our hobbies can also serve as physical activity. Try a new activity—perhaps it will become your new hobby. Get your body moving by trying yoga, a dance class, gardening, walking, or riding a bike. Why not try a new vegetable or protein or drink more water each week? Can you try going to bed early? As a case manager, have you ever had a patient who was out of balance due to their lack of physical wellness?

5. Social Wellness

How do you interact with others? Do respect others and set personal boundaries? Do you honor boundaries? Do you have a strong circle of friends or a support system? Do you feel as if you live in harmony with the environment and other people? A few positive examples of social wellness could look like:

- The ability to socialize with new friends
- Thriving and healthy relationships
- The ability to ask for help if when you need it

Isolation and avoiding social activities can lead to depression and, sometimes, poor choices, so be sure to take a look at your relationships both outwardly and inwardly once a quarter.

6. Emotional Wellness

Here are a few tips for self-care with regard to your emotional wellness. It is important to manage our stress daily. Stress is inevitable and often times leads to chronic disease and illness. However, by paying attention to our level of our stress and managing it, we can live a longer and healthier life. This is where boundaries come into effect; there are times where we need to take on fewer projects and learn to say no. We need to ensure that we are prioritizing our goals because sometimes we put ourselves last when we should put ourselves first.

It is important that we learn to let go of perfection. Although it seems like a strength, perfectionism can also be a weakness and lead to other problems. Just be yourself and allow yourself to make mistakes. Also consider learning what it means to be persistent and resilient because these traits will take you a long way in life. Oftentimes we simply need the strength to go on another day. However, by learning how to let some things go and moving on in spite of disappointments, we will cultivate emotional well-being.

When your emotions are in check, you learn how to deal with what you feel inside. If you feel emotionally numb or detached, you may be reacting negatively to your emotions. If you feel unexplainable sadness, continue to have flashbacks to a traumatic event, or have thoughts of harming yourself or others, now is the time to reach out to someone who you trust for help. To help improve your emotional health, you might try writing in a journal where you can be honest with yourself. Other coping mechanisms are learning stress management, practicing optimism, and asking for help when it is needed.

As a case manager, have you ever had a patient who was out of balance due to their lack of emotional wellness? How can you incorporate emotional wellness into your daily work?

I challenge you to finish this article with another 30 seconds of mindfulness. Take a moment to dim the lights, affirm yourself, reconnect with your voice within, meditate, and get grounded again. Just taking one minute daily for yourself can change your life and improve your wellness. What changes will you make for yourself so that you are well and whole while performing your duties as a case manager? CM

Excerpt from "When the Red Arrow Points Up: A Guide towards the Cost of Wellness at Work" Michelle Rhodes RN Media LLC.

Reigning in CMS' Authority *continued from page 9*

federal laws.

The next time a similar case is heard by the Court, there is likely to be a very different result. Watch for it! CM

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CE II **Network Not Work? Insight into Building a Better Post-Acute Network** *continued from page 17*

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PharmaFacts for Case Managers

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HbA1c of 6.5% to 10%, and had either albuminuria and previous macrovascular disease (39% of enrolled population), or evidence of impaired renal function by eGFR and Urinary Albumin Creatinine Ratio (UACR) criteria (42% of enrolled population), or both (18% of enrolled population).

At baseline the mean age was 66 years and the population was 63% male, 80% Caucasian, 9% Asian, and 6% Black. Mean HbA1c was 8.0% and mean duration of type 2 diabetes mellitus was 15 years. The trial population included 17% patients ≥75 years of age and 62% patients with renal impairment defined as eGFR < 60 mL/min/1.73 m^2. The mean eGFR was 55 mL/min/1.73 m^2 and 27% of patients had mild renal impairment, 47% of patients had moderate renal impairment, and 15% of patients had severe renal impairment. Patients were taking at least one antidiabetic drug (97%), and the most common were insulin and analogues (57%), metformin (54%) and sulfonylurea (32%). Patients were also taking antihypertensives (96%), lipid lowering drugs (76%) with 72% on statin, and aspirin (62%). The primary endpoint, MACE, was the time to first occurrence of one of three composite outcomes which included cardiovascular death, nonfatal myocardial infarction or nonfatal stroke. The study was designed as a non-inferiority trial with a pre-specified risk margin of 1.3 for the hazard ratio of MACE. The incidence rate of MACE in both treatment arms: 56.3 MACE per 1000 patient-years on placebo vs. 57.7 MACE per 1000 patient-years on linagliptin. The estimated hazard ratio for MACE associated with linagliptin relative to placebo was 1.02 with a 95% confidence interval of (0.89, 1.17). The upper bound of this confidence interval, 1.17, excluded the risk margin of 1.3.

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