

# CareManagement

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Transferring care between providers can be uncertain, especially when unplanned, leaving skilled nursing facility patients vulnerable and susceptible to complications, transfer trauma, and unnecessary costs. Transferring care was further complicated because of the COVID-19 pandemic. These issues, however, can be overcome by more-strategic clinical programming, education, and intentional care coordination. Although theoretically providers understand the issues that ensure a seamless process, in the real world there are often pitfalls.

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Gary S. Wolfe

# Improving Transitions of Care

**T**ransitions of care should not be a new topic for case managers. As case managers, we coordinate care across the continuum of care on a regular basis. The American Geriatrics Society defines transitions of care as “a set of actions designed to insure the coordinated and continuity of health care as patients transfer between different locations and different levels of care.” Recognizing the best intentions of health-

challenges that you face daily. So many times, a particular provider or system is so interested in completing the procedure or moving the patient through the system that they forget to take into consideration the overall patient’s clinical status as well as the patient’s goals and preferences. Time is not taken to educate the patient and family. There is limited coordination between health professionals involved in the transition.

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**The American Geriatrics Society defines transitions of care as “a set of actions designed to insure the coordinated and continuity of health care as patients transfer between different locations and different levels of care.”**

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care professionals, each setting tends to operate independently, leaving professionals unaware and/or unsure of issues that impact care as patients move across the care continuum. Transitional care deficiencies are a reflection of our fragmented health care system. This is not new rhetoric. As case managers, we live in the world of a complex, highly specialized, and at times confusing healthcare system. We recognize these challenges and think about the challenges that patients experience.

A few of the familiar challenges include:

- More patients are elderly
- Brief medical encounters
- Healthcare literacy and education of the patient
- Failure in follow-up support and coordination of care
- Medication errors
- Fragmentation of care
- Social challenges

I am sure you could add many more

Poor transition of care can result in the following:

- Increase in mortality
- Increase in morbidity
- Increase in adverse events
- Delays in receiving appropriate treatment and community support
- Additional primary care and emergency department visits
- Additional or duplication of tests
- Preventable readmissions to the hospital
- Decrease in patient satisfaction
- Increased risk for patient safety
- Medication errors

Ultimately, poor transition of care results in additional healthcare costs.

Case managers have a pivotal role in improving transitions of care. Yes, it will take time and education, but the results will improve patient outcomes and be satisfying for the case manager. There is

[\*continues on page 37\*](#)

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Catherine M. Mullahy

# Asking Questions— Making a Difference

**O**ur world today seems filled with transitions. Some of us are watching our children and grandchildren transition from and to their various stages of development and the next chapter of their lives. Others have bid farewell to beloved family and friends who have left us due to aging or illness. In any case, we all experience firsthand the transitions of life. To be sure, these are very different experiences that result in uncertain feelings. What will happen next? What will be the outcome? How might our lives be impacted?

As I write this column, we have witnessed the end of our country's longest war, which spanned 20 years, and perhaps a transition to an even more uncertain future. The most recent and tragic loss of 13 young men and women who died in the service of our country during the final days of the war underscored the courage and selflessness of these individuals. This loss added to the countless other deaths and injuries that have resulted during these past 2 decades and are difficult to fully comprehend. Many of our case managers have provided care to those in the military and veteran healthcare settings. We can never repay the enormous debt of gratitude to the lives lost. May they rest in peace!

Many, if not all of us, can recall just what we were doing 20 years on 9/11. While we often hear, read, or perhaps even say to ourselves, "Never forget," there are likely more individuals today who were not yet born or were so young at the time that they have no meaningful knowledge of that day or

the subsequent ones that led us into that longest war. There is a saying, "Those who fail to learn from history are condemned to repeat it..." and there are significant reasons that we need to ensure that the attacks on 9/11 and the 20 years that followed are not forgotten. The transition from the end of this tumultuous time now

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**As case managers, we spend a good bit of time preparing our patients and their families for the various transitions that they will experience as they receive care and intervention from the numerous providers and care settings along today's care continuum.**

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and toward an uncertain future will likely have us again asking the same questions that were posed above: What will happen next? What will be the outcome? How might our lives be impacted?

As case managers, we spend a good bit of time preparing our patients and their families for the various transitions that they will experience as they receive care and intervention from the numerous providers and care settings along today's care continuum. Some of their experiences will be favorable, while others will result in an increase in complications, costly hospitalizations or readmissions, and a decrease in patient satisfaction. We do know,

all too well, what happens when there are interruptions in the continuity of care and we see them all too often. These adverse events occur more frequently and are more consequential among the most complex patients, the ones that should be in our caseloads. There are no "quick fixes" for these patients or their problems, but there are many resources that will help us avoid many problems and maximize the opportunities for improved outcomes. A notable resource for you and your patients is "The Seven Essential Intervention Categories" from the [National Transition of Care Coalition](#) (NTOCC). This resource has been covered more completely in articles that appear in the previous and current issue. As we are involved with a more complex patient population, we need to ask those highly relevant questions: What will happen next? What will be the outcome? How might their lives be impacted? Not paying attention to what went wrong and correcting those problems, will, unfortunately, result in history repeating itself.

As we celebrate Case Management Week (October 10<sup>th</sup>–October 16<sup>th</sup>), let's celebrate you; the intervention you and your colleagues provide and how you continue to make a real difference... one patient at a time!

*Catherine M. Mullahy*

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# Ready, Set, Go—Time!

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

**CMSA** has experienced a great year! The commitment of hundreds of volunteers and dedicated leaders at all levels has led to new initiatives, enhanced member benefits, and brand expansion. In the last issue I described many of CMSA's programs under development and am thrilled to announce that we are ready to launch. We have modernized our technology, introduced a fresh new logo, expanded the avenues to deliver in-the-moment information on trends and innovations, and connected case managers to educational content that has made a real difference in the workplace. CMSA's transition year afforded the association time to get ready and set itself up for renewed positioning within this complex healthcare landscape. It's go-time as we move forward with the new claims CMSA staked this year! Here are just a few highlights:

- New collaborative partnerships with the American College of Physician Advisors, URAC, Aging Life Care Association, and Nurses on Boards

*Melanie A. Prince, MSN, BSN, NE-BC, CCM, FAAN, is president of the Case Management Society of America.*

*Recently retired as an Air Force colonel, Melanie*



*has diverse experience in population health; case, disease and utilization management; public policy; trauma/violence prevention and organizational leadership. Melanie is a certified professional case manager and nurse executive and has master's degrees in nursing case management and military strategic studies.*

Coalition are exciting ways to spread the word about a community of professionals who support the practice of case management.

- Our 5-part workshop for aspiring writers will set clinicians up for success as they learn the skills required to publish effective articles to tell the stories of case managers everywhere.

much-anticipated project will deliver a critical resource for organizations and individuals to ensure high-quality professional care in case and care management.

As the leading, oldest, and largest membership association for case management, CMSA provides members access to professional development and

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**CMSA has modernized our technology, introduced a fresh new logo, expanded the avenues to deliver in-the-moment information on trends and innovations, and connected case managers to educational content that has made a real difference in the workplace.**

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- Novice case managers in all settings will be “ready to go” with the completion of our hands-on inspired boot camp scheduled for this fall.
- Policy leaders are hard at work building the case and posturing CMSA to advance an agenda for workforce development, telehealth, and mental health.
- A just-published adherence guide is here to help healthcare professionals gain and integrate skills and methods for even more comprehensive assessments of clients, families, and their support systems.
- Additional timely and relevant information for the case management community can be found in the newly launched CMSA Blog.
- Case management leaders are putting the final touches on the updated CMSA Standards of Practice, and these standards are set to launch by the end of the year. This

collaboration, practical resources and tools, and opportunities to influence public policy on issues vital to case managers practicing across the entire care continuum and at every level of practice—all to help you do your job better. With an ear to the ground and an eye to the future, it is the role of CMSA to collect and disseminate data for a more informed future.

CMSA is ready to take the lessons learned from a year of transition, adaptation, COVID response, and workforce adjustments and translate these lessons into actionable improvements for our members and case managers globally. A spotlight has revealed the need to address health disparities, diversity, inclusion and equity, socio-economic gaps, and health literacy for patients who rely on case managers during their most difficult moments. And while society as a whole is just now

*[continues on page 36](#)*



# Leadership Change and Transitions in the CARF Survey Process

**Terrence Carolan, MSPT**

**F**or the last several years, you've been able to hear Chris MacDonell speak to the relevance of CARF to case management across the spectrum of health and human services. I'm happy to share that after 30 years and a remarkable career, Chris has retired from her role as Managing Director of Medical Rehabilitation with CARF International. We wish her nothing but a stellar retirement and thank her for all of her contributions to the field and to this publication.

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**Case management is the common clinical thread that can be found in every section of CARF standards, and the advocacy and guidance that patients and family members receive from case managers is an indispensable part of the rehabilitation process.**

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My name is Terry Carolan and I thrilled to move into the Managing [continues on page 35](#)



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



## Populations at Risk: Optimizing Post-Acute Care Management

Over 90% of the nation's \$3.8 trillion in healthcare costs are related to chronic diseases. Download this white paper to explore the prevalence of chronic disease in the U.S. and types of care management programs that have shown evidence of effectiveness.

[Read the White Paper](#)



# The Benefits of Professional Diversity in Case Management

Jared Young, PsyD, CAADC, LCSW, CCM

**A**s a psychologist, I have found that being a Certified Case Manager (CCM) has helped me in my practice, particularly in taking a holistic approach as part of an inter-professional team.

My pathway into case management began earlier in my career when I went to work for a health insurance company. Many of my colleagues were case managers, and the insurer was migrating to mandatory certification. At the time, I was credentialed as a licensed clinical social worker (LCSW) and was looking for ways to further expand my background. That led me to pursue case management and board certification. Later, when I went into psychology, I kept up my credentials as a social worker and a case manager, believing that both spoke to the varied background I brought to my practice.

*Jared Young, PsyD, CAC, LCSW, CCM, is the 2021-2022 Chair of the Commission for Case Manager Certification (CCMC), the first and largest nationally*



*accredited organization that certifies more than 50,000 professional case managers and disability management specialists with its CCM<sup>®</sup> and CDMS<sup>®</sup> credentials. He is the founder and practitioner of an outpatient behavioral health practice in Camp Hill, Pennsylvania, and has more than 20 years of clinical experience in mental health and substance abuse treatment as well as behavioral health and physical health managed care.*

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**We must work to continue expanding the diversity of professional backgrounds among case managers. Such expansion is not only an imperative because of the rising demand for case managers but also to respond to healthcare trends.**

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Individuals with serious and potentially life-altering diagnoses commonly experience depression, anxiety, and other mental health issues. However, when clients' mental health is addressed, they are often better at engaging in self-care and complying with medication, rehabilitation, diet, exercise, and other aspects of treatment. An example is organ transplant patients, such as those who need kidney transplants. Psychological factors are very serious to consider in such cases, and individuals who are given support such as psychological counseling can be better prepared for transplantation and experience improved postsurgical outcomes (Young, 2021).

My case management background has also helped me integrate mental and physical health when working with a variety of clients. In addition, when I collaborate with others on the treatment team, I believe my perspective as a psychologist and a case manager also helps inform the discussion of the individual's goals and needs.

The broad array of backgrounds, experiences, and professional disciplines we each bring to case management enriches the overall practice. While most case managers are from nursing backgrounds, over the years there has been an increase in the representation of social workers and others in the practice. For example, in the 2019 role and function study from the Commission for Case Manager Certification (CCMC), 11.2% of survey respondents identified themselves as social workers, about double the percentage of respondents in the 2014 practice analysis survey (Tahan, Kurland, and Baker, 2020). Among the other 2019 respondents, occupational therapists and vocational rehabilitation counselors accounted for 1.45% and counselors and psychologists were another 1.26%. Although small, these percentages apply to a growing population of CCMs overall, currently numbering more than 49,000, an increase from 37,000 in 2014.

We must work to continue expanding the diversity of professional backgrounds among case managers. Such expansion is not only an imperative because of the rising demand for case managers but also to respond to healthcare trends. As case management is practiced in a wider variety of settings—acute and subacute care, home health, telephonic case management, community-based, mental health counseling, accountable care organizations, virtual and retail-based care sites, and others—case managers with

*continues on page 36*

# Complaints About Referrals Must Be Based on Facts

Elizabeth Hogue, Esq.

**T**he owner of a supplier of home medical equipment (HME) complained that her company did not receive referrals from TidalHealth Nanticoke Hospital [*United States ex rel. O'Bier v. TidalHealth Nanticoke, Inc.*, No. 1:19-cv-687-SB (D. Del. May 11, 2021)]. The Court dismissed the owner's lawsuit because she could not prove her claims. This case illustrates why providers who complain about practices of referral sources must have facts to support their claims.

The owner of the HME company filed a whistleblower lawsuit against the Hospital, a doctor and a nurse at the Hospital, and two competing companies. She claimed that referrals were made to other companies because the Hospital received kickbacks from them in violation of the federal Anti-Kickback Statute (AKS) and the Stark laws. The owner also claimed that the Hospital's refusal to refer patients to her violated patients' right to freedom of choice. Statutes governing the Medicare program say that individuals entitled to Medicare benefits may obtain health services from any Medicare provider if the provider undertakes to render services. In addition, the owner claimed that the Hospital rendered services that were not medically necessary. She said that the Hospital sometimes referred

patients who already had received equipment from her to her rivals, so patients did not need equipment from these competitors. Finally, the owner claimed that the above violated the federal False Claim Act (FCA).

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**The owner of a supplier of home medical equipment (HME) complained that her company did not receive referrals from TidalHealth Nanticoke Hospital. The fact remains that the owner of the HME company could not prove her case. The lesson for providers is that they must have facts to support allegations related to referrals.**

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First, the Court said that the owner did not plausibly allege that defendants violated the AKS or the Stark law. Her argument regarding violations was based on the theory that because the Hospital referred patients almost exclusively to competitors, it must be getting illegal kickbacks from them. "Not so," said the Court. There are countless other reasons why the Hospital might not want to refer patients to her.

The Court then said that the owner's premise was all wrong because the Hospital does, in fact, refer patients to her company. Of the thirteen referrals described in her complaint, five of them were referred to her by the Hospital. Only six patients were sent to

her competitors.

With regard to patients' right to freedom of choice, the Court said: "TidalHealth did not violate it. The hospital did not forbid anyone to deal with O'Bier; it just (sometimes) refused to help. The patients were still free to buy from her. They simply needed to find another hospital."

Finally, the Court said that the owner did not plausibly allege that anyone billed Medicare for unnecessary services. She claimed that her rivals twice sent breathing devices to patients who had already received them from her. In one example, however, the patient refused to accept the rival's equipment and the owner could not show that the Hospital billed for it anyway. In the other examples, patients took competitors' equipment and returned the equipment they had to the company. Therefore, said the Court, the other companies' products were medically necessary.

Based on the above, the Court dismissed the case.

Although it is certainly difficult to understand the Court's reasoning with regard to freedom of choice, the fact remains that the owner of the HME company could not prove her case. The lesson for providers is that they must have facts to support allegations related to referrals. **CM**

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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.*

# Nonsolicitation Agreements Under Fire

Elizabeth Hogue, Esq.

In *Aya Healthcare Services, Inc.; et al v. AMN Healthcare, Inc.; et al* [No. 20-55679, D.C. No. 3:17-cv-00205-MMA-MDD, August 19, 2021], the United States Court of Appeals for the Ninth Circuit concluded that the nonsolicitation provision in AMN's contract with Aya to provide temporary staffing to healthcare providers was valid. Both parties in this case are healthcare staffing agencies that place nurses on temporary assignments. Aya contracted with AMN to handle requests for nurses that AMN could not staff. The contract included a provision that prohibited Aya from soliciting AMN's employees.

Aya claimed that the nonsolicitation provision is an unreasonable restraint prohibited by Section 1 of the Sherman Antitrust Act. The Court decided, however, that the nonsolicitation clause in the contract was reasonably necessary to the parties' procompetitive collaboration. This meant that Aya had to show that the nonsolicitation clause violated the "rule-of reason" standard. The rule of reason weighs legitimate justifications for restraints against any anticompetitive effects.

The Court concluded that Aya failed to show a violation of the rule of reason. Aya did not show, through either direct or indirect evidence, that an issue of fact existed with respect to whether AMN's nonsolicitation agreement had a substantial anticompetitive effect that harmed consumers in relevant markets.

Aya signed a contract with AMN to help provide customers to AMN's customers in 2010. Aya eventually became

AMN's largest subcontractor. In 2015, Aya began to actively solicit AMN's nurse recruiters. This caused Aya and AMN to terminate their agreement.

Former employees of AMN who were employed by Aya signed an agreement with AMN as a condition of their

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## According to the Court, the nonsolicitation agreement promoted competitiveness in the healthcare staffing industry.

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employment with AMN that said:

"Employee covenants and agrees that during Employee's employment with the Company and for a period of [one year] or eighteen months after [termination], Employee shall not directly or indirectly solicit or induce, or cause others to solicit or induce, any employee of the Company...to leave the service of the Company."

The Court decided to uphold this provision because the challenged restraint is reasonably necessary to the parties' procompetitive collaboration. The nonsolicitation agreement is necessary to achieving that goal because it ensures that AMN will not lose its personnel during the collaboration.

AMN, said the Court, may want to guard its investments and establish relationships with only those agencies that agree not to abuse the relationship by proactively raiding AMN's employees, subcontractors and customers. Without the restraint,

AMN would likely be less willing or unwilling to deal with other agencies to supply nurses to its customers that already experience a chronic shortage of nurses. Based on the restraint, AMN can collaborate with its competitor for the benefit of its customers without "cutting its own throat."

According to the Court, the nonsolicitation agreement promoted competitiveness in the healthcare staffing industry. More customers received an increased number of nurses since the nonsolicitation agreement allowed AMN to give assignments to Aya without endangering its established network of recruiters, nurses, subcontractors, and customers.

Nonsolicitation agreements are likely to continue to come under fire for a variety of reasons. Watch for additional challenges! **CM**

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# Care Coordination and Integrated Case Management

Adrienne Weede, LCSW

The Veterans Health Administration (VHA) is the nation's largest integrated health care system. VHA uses innovative programs to deliver coordinated care to our nation's veterans. Over the past 2 decades, care coordination services have become increasingly specialized, targeting high-risk veteran populations who are frequent users of Veterans Affairs (VA) resources and community resources. The Care Coordination and Integrated Case Management (CC&ICM) framework was developed in partnership with the Offices of Nursing Services and Care Management and Social Work. The CC&ICM framework was tested at 12 VA medical centers to address fragmentation, variation, and gaps in care by introducing a systemwide integrated care coordination process.

The CC&ICM framework is described as a valued-care approach focusing on: 1) optimizing access to ensure veterans receive the right care in the right place at the right time, 2) building trusting relationships



**Adrienne Weede, LCSW,** is the National Program Manager for the Post-9/11 Military2VA (M2VA) Case Management Program within the VHA Office of Care Management

and Social Work under Patient Care Services. Ms. Weede also provides leadership for a key national initiative aimed at establishing an enterprise-wide care coordination system that includes integrated case management.

throughout the continuum of care, 3) integrating services to create a seamless continuum of care, 4) standardizing care coordination definitions, processes, and tools, and 5) using predictive analytics for a proactive population health approach.

for individual patients, based on complexity and level of care coordination needs, to improve communications and care engagement

As the number of veterans increases, so will access to care in VHA and the

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**At its core, Care Coordination and Integrated Case Management supports the High Reliability Organization values of the Veterans Health Administration through a commitment to fostering veteran safety and the coordination of veteran-centric care.**

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The valued-care approach of CC&ICM includes five milestones with 24 critical actions that are essential for successful implementation. The five milestones are: 1) leadership awareness, 2) facility readiness, 3) implementation preparedness, 4) systems and clinical integration, and 5) CC&ICM governance structure at the facility and veterans Integrated Services Network level. The milestones include critical actions that detail processes, tools, and training, thus optimizing facility success.

There are three key components in the CC&ICM framework:

1. Integrated, predictive analytics used to proactively identify veterans who might benefit from CC&ICM services
2. Facility Care Coordination Review Team(s) (CCRTs) to integrate and improve communication, collaboration, and coordination across the care continuum and during transitions of care
3. Lead Coordinator assignment(s)

community. This will increase the frequency of care transitions across settings and levels of care, heightening the demand for an improved case coordination infrastructure and mitigating any patient safety risks. In addition, as the population of aging veterans increases, their health care and complex conditions will require improvements in care coordination and high-quality services. At its core, CC&ICM supports the High Reliability Organization values of VHA through a commitment to fostering veteran safety and the coordination of veteran-centric care.

The CC&ICM framework directs a screening of each veteran to determine whether there is a need for service coordination or assistance and, if so, to identify the level required (eg, basic through care coordination; moderate through care management; complex through case management). If a veteran requires assistance, a Lead Coordinator (LC) is assigned. The

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# Path to Health: In Support of a Plant-Based Diet

Charlie Ross, DO, and Scott Wagnon, PA-C

**E**ating a healthy diet is one of the most important things you can do to protect your health. Your food choices influence whether you develop chronic diseases such as heart trouble, diabetes, cancer, obesity, stomach disorders, kidney disease, and many other health conditions. It was widely believed that our genes controlled most of these diseases, but it is now known that the genes that encourage development of these diseases can be turned on or off by our lifestyle choices. It has been said that “our genes load the gun, but our lifestyle choices pull the trigger.” It has been estimated that 70%–80% chronic disease is driven by lifestyle choices. And the good news is that by addressing the root causes of these chronic diseases, we can often actually reverse them, and the benefits of reversing these diseases include shedding the pills that are just treating the symptoms of these diseases.

We are bombarded by several myths about food, and misinformation is rampant. What or who are we to believe? What foods would we choose if we wanted to live the healthiest lifestyle and with the least burden of chronic disease? Dan Buettner discovered the five regions of the world—dubbed the Blue Zones—whose populations live into their 90s and 100s with little chronic disease. These groups had several factors in common: they ate a diet that was 95% plant based, moved throughout the day, and had good social support. Longevity studies reveal a 4-9 year increased life expectancy for those eating plant-based foods,<sup>1</sup> and a study in Finland revealed almost an 80% decline in mortality when the country stopped subsidizing the dairy industry and began subsidizing the berry industry.<sup>2</sup> In the United States, heart disease is the number one cause of death. There are two studies that document reversal of the clogging of the coronary arteries.<sup>3,4</sup> No other way of eating has documented reversal of heart disease, our number one killer. No other diet including Atkins, paleo, ketogenic, South Beach, Grain Brain, Wheat Belly, Zone, or any other of the popular diets have demonstrated reversal of heart disease. When we examined the science of both population and individual studies, we realized that whole food plant-based nutrition will provide us with the longest life with the least amount of chronic disease. That is why the American Medical Association; the American College of Cardiology; the American Association of Clinical Endocrinologists; the American Diabetes Association; the

American Institute for Cancer Research<sup>5</sup>; the Canada’s Food Guide; the dietary guidelines of Brazil, Germany, Qatar, and the Netherlands; as well as the Nordic Nutrition Recommendations (Denmark, Finland, Iceland, Norway, and Sweden) all recommend a plant-based diet for human health and for environmental sustainability.<sup>6</sup>

Consider this July 2017 AMA resolution for all US hospitals:

**RESOLVED**, That our American Medical Association hereby calls on US hospitals to improve the health of patients, staff, and visitors by (1) providing a variety of healthful food, including plant-based meals and meals that are low in fat, sodium, and added sugars, (2) eliminating processed meats from menus, and (3) providing and promoting healthful beverages.”

## How did the rates of chronic disease get so high?

If you review the statistics at the Centers for Disease Control and Prevention, you will see the trend toward obesity is frightening. About two-thirds of the US adult population is overweight, and one-third of the overweight population is obese, and obesity is worsening. Also, there is no region of the country in which <20% of children are overweight. Along with this increasing weight gain, cardiovascular disease, diabetes (one in four adults), and other chronic illnesses are increasing. This trend should be considered a public health problem, not just an individual problem.

In the latter part of the 20th century, increasing weight gain was believed to be due to an individual’s lack of will power. Individuals were told to “eat smaller portions” or

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**Eating a healthy diet is one of the most important things you can do to protect your health. Your food choices influence whether you develop chronic diseases such as heart trouble, diabetes, cancer, obesity, stomach disorders, kidney disease, and many other health conditions.**

“exercise more” or “go to a counselor and figure out what is troubling you and leading to overeating.” While this may be constructive advice, other very significant influences were largely ignored. Let’s look at some of these other factors.

Our food supply has been significantly altered.<sup>7</sup> The values below represent the average amount ingested per person in 1900 vs 2010.

	1900	2010
Sugar	5 lb/y	77+ lb/y
Oils/fats	4 lb/y	74 lb/y
Cheese	2 lb/y	30 lb/y
Fruits/veggies	131 lb/y	11 lb/y
Nutrient value	Decreased 40%–60%	
Soft drinks	0	53 gallons/y
Fiber	60+ g/d	14 g/d

Our level of activity in modern times has been drastically reduced. In 1900, the average individual did not watch any TV, whereas in 2010 the average individual watched 4 hours of TV per day.

Sitting at a desk has become much more common in modern times, and a generally sedentary lifestyle has been promoted by our transportation and work systems. Watch TV for 6 hours a day and lose 4 years of your life! This cultural influence on our health has been understated.

Food addiction is increasingly being recognized as playing a major role in our current health crisis. Food companies, in their striving for increased profit, have adjusted the sugar, fat, and salt content to the “bliss” point—the point that makes us crave and want to eat more so we will buy more.<sup>8</sup> Food ads are plastered all over billboards, the internet, TV, and other media. Is it any wonder that we are constantly craving food even as we are overeating?

But there is more to this story. We may be overeating calories because of the high calorie density foods that are promoted by our society, but we are still undernourished when it comes to the nutrient density of our foods. Nutrient density has decreased 40%–60% since 1900. What is this nutrient

density? It is the vitamins, minerals, phytonutrients, and micronutrients that we all need to be adequately nourished and satisfied. These elements boost our immune system to keep us healthy by fighting off viruses and killing off cancer cells. These come from eating a variety of foods like vegetables, fruits, whole grains, legumes, nuts, and seeds.

#### What direction does the evidence lead us?

1. Cardiovascular benefits. Check out the video titled [Forks Over Knives](#) and you will discover that deaths from cardiovascular disease in Denmark declined dramatically when the Nazis invaded the country and took all the animals for their own use. The Danes lived mainly on plants during the war, resulting in a sharp decline in their cardiovascular death rate. When the Nazis were defeated and the Danes started eating meat again, the cardiovascular death toll began to rise. Finland must have considered this when it chose to subsidize berries instead of the dairy industry. The drop in cardiovascular deaths and all-cause mortality was dramatic.<sup>2</sup>

About 25 years ago, Dean Ornish, MD, showed that coronary artery clogging could be reversed through diet, exercise, and stress management. Medicare has evaluated the evidence and is reimbursing this approach for cardiac rehabilitation. This initial Ornish study was confirmed using just a whole food plant-based diet, without added oil or significantly processed foods, by Caldwell Esselstyn, MD, at the Cleveland Clinic. A whole food plant-based diet is the only way of eating that has been shown (by angiographic analysis) to reverse the clogging of coronary arteries. No other way of eating has been demonstrated to reverse heart disease. Other diets may demonstrate weight loss but not reversal of heart disease. So, with the number one killer in our society being heart disease, wouldn’t it make public health sense to promote a whole food plant-based diet for our whole population?

2. Microbiome—The bacteria that we populate our colon with have a significant influence on our overall health.<sup>9</sup> TMAO (trimethylamine N-oxide) is produced from TMA (trimethylamine), which is produced by *Bacteroides* species. These are the predominant bacteria that populate our colon when we ingest meat, dairy, and eggs. Individuals

**Dan Buettner discovered the five regions of the world—dubbed the Blue Zones—whose populations live into their 90s and 100s with little chronic disease. These groups had several factors in common: they ate a diet that was 95% plant based, moved throughout the day, and had good social support. Longevity studies reveal a 4–9 year increased life expectancy for those eating plant-based foods.**

who eat the standard American diet raise their levels of this inflammatory compound when ingesting meat or eggs, whereas individuals who eat plant-based diets populate their colons with *Prevotella* species. *Prevotella* species do not produce TMA. Thus, if an individual does not want to raise his or her blood serum levels with TMAO (the inflammatory product that encourages atherosclerosis and cancer), then populating your colon with *Prevotella* species makes a lot of sense.<sup>10</sup>

The microbiome appears to be important in obesity. For hundreds of thousands of years, food equaled fiber. Our gut bacteria produce the chemical butyrate, which can signal back to our brain that we not only have good bacteria but that we have had enough to eat. If our brain does not receive the butyrate signal because of a lack of fiber in our diet, then we do not receive the message to stop eating so we eat...eat....and eat.<sup>11</sup> Increasing the amount of fiber in our diet is key to reversing our country's obesity epidemic.

3. The real deficiency in the standard American diet is not protein but rather fiber. The average American eats only about 14 grams of fiber a day although the USDA recommends closer to 35 gram of fiber per day. Adding fiber to the diet is one of the best strategies for reducing the risk of colon cancer, heart attack, and breast cancer.<sup>12,13</sup> For every 10 grams of fiber added to one's diet, the risk of colon cancer and heart attack will be reduced by about 10%. Adding 14 grams of fiber to one's diet reduces calorie requirements by about 10%. In summary, the American diet is deficient in fiber, and increased fiber in the American diet will reduce the incidence of chronic illness. Remember that fiber comes from plants, fruits, vegetables, legumes, whole grains, nuts, and seeds. There is no fiber in food that comes from an animal, so any time you eat animal foods, you are decreasing the amount of fiber that you eat that will likely reduce the risk from so many chronic diseases.
4. What about hormones? Insulin-like growth factor-1 (IGF-1) is a hormone found in all animal products, and it is one of the factors in cow's milk that enables a baby calf to grow into a full-grown cow. IGF-1 promotes growth not only in the species that it was intended for but also promotes the growth of cancer in humans. Higher rates of cancer are found in humans with higher levels of IGF-1.<sup>14</sup> You may want

### Example of using "Food as Medicine"

55-year-old male with type 2 diabetes, hypertension, obesity, and cardiomyopathy

Medications: Toujeo® insulin 300 units/mL at 12 units daily, glipizide, metformin, lisinopril, aspirin, and carvedilol

Blood pressure: 110/70 mm Hg; Weight: 226 lb (body mass index: 30.7)

Hemoglobin A1c: 13.8%

#### After 6 months on a whole food plant-based diet:

Off Toujeo insulin entirely; off glipizide and metformin; lisinopril dose cut in half

Blood pressure: 122/82 mm Hg; Weight: 206 lb (body mass index: 28.0) (-20 lb); Hemoglobin A1c: 7.4% (-6.4%)

Patient has much more energy and feels great!

This is just one example of the power of food. Food is really medicine, and thus it is important that anyone who is contemplating making a big change in his or her diet and lifestyle be in close communication with his or her medical provider. Your medical provider may need to lower your blood pressure medications to prevent your blood pressure from falling too low. If you take insulin or other medications for diabetes that lower blood sugar, you may need to have your medicines reduced or stopped to prevent your blood sugar from getting too low.

- to think twice when you reach for animal milk or milk products such as cheese or yogurt. IGF-1 is also found in meat.
5. There are a number of studies documenting improvement and even reversal of diabetes mellitus with a plant-based diet.<sup>15</sup> A cultural myth is that the carbohydrates in our diet are the primary cause of diabetes. Fat in our diet leads to insulin resistance, which leads to diabetes. Reducing the fat and refined carbohydrates in our diet is the best strategy for controlling and reversing diabetes type 2.
  6. There are studies documenting the benefit of a plant-based diet in individuals with kidney disease, gastrointestinal disorders, asthma, chronic obstructive pulmonary disease, and arthritis.

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7. Aging studies: Dean Ornish, MD, conducted a study showing that telomere length increases with plant-based eating, which could explain the increase in life expectancy for populations that eat plant-based diets (eg, populations in The Blue Zones). As we age, our telomeres shrink.
8. Environmental benefits to plant-based diets. The use of water resources, land utilization, impact on global warming, and dead zones in the worlds' oceans are a few of the issues that are impacted in a positive direction by choosing to eat plant-based foods rather than animal-based diets. Transitioning to whole plant foods will not only improve individual health but also the health of our planet.
9. Racial disparity: Most people of color are intolerant of dairy, but the dietary guidelines for Americans are still promoting dairy for everyone. This racial bias needs to be addressed. Look to the science of nutrition, become mindful of your food choices, and practice until you achieve your health goal. Changing your lifestyle is like learning to play a new sport or learning to play a musical instrument. These changes take practice, and a good teacher or coach can be a real asset in developing your skill level. Check out the resources listed. The best of health to you! **CE1**

### CE exams may be taken online!

Click the link below to take the test online and then immediately print your certificate after successfully completing the test.

**Members only benefit!** This exam expires April 15, 2022.

**Take this exam online >**

Members who prefer to print and mail exams, [click here](#). You must be an ACCM member to take the exam, [click here to join ACCM](#).

#### Print resources

[How Not To Die](#) by Michael Greger MD—the best single resource of evidenced-based nutrition in one book

[How To Prevent and Reverse Heart Disease](#) by Caldwell Esselstyn, MD

[Fiber Fueled](#) by Will Bulsiewicz, MD

[Your Body in Balance: The New Science of Food, Hormones, and Health](#) by Neal Barnard, MD

[Proteinaholic](#) by Garth Davis, MD

[The Starch Solution](#) by John McDougall, MD

[Whitewash](#) by Joseph Keon—Why dairy is not so healthy

[The Cheese Trap](#) by Neal Barnard, MD

[The Blue Zones](#) by Dan Buettner

[Salt, Sugar, Fat](#) by Michael Moss: How the food industry has altered our foods

[Eat To Live](#) by Joel Fuhrman, MD

[The China Study](#) by T. Colin Campbell, PhD

[The Mayo Clinic Guide to Stress-Free Living](#) by Amit Sood, MD—put this at the top of your list

[The How Not To Die Cookbook](#) by Michael Greger, MD

#### Internet resources

[www.nutritionfacts.org](http://www.nutritionfacts.org): Best evidenced-based nutrition science site in the world. This website is totally transparent. I asked every medical student who has ever rotated with me to find something wrong with this site, and they haven't been able to find one issue or problem over the last 5 years.

[www.pcrm.org](http://www.pcrm.org): This website has a 21-day kickstart program along with many valuable resources like handouts and educational videos.

[www.drmcDougall.com](http://www.drmcDougall.com): A great site for support, and a wonderful site for recipes from around the world.

[www.forksoverknives.com](http://www.forksoverknives.com): Another great site for recipes

[ucdintegrativemedicine.com](http://ucdintegrativemedicine.com): Support for a whole food plant-based lifestyle.

#### Film resources

[Forks Over Knives](#)

[What the Health](#)

[The Game Changers](#)

If you are interested in attending a free online Zoom class taught by Dr. Charlie Ross and Scott Wagnon, PA-C, you can join every Tuesday. The Zoom ID link is 8425055399. To review archived classes, go to <https://sites.google.com/view/whole-food-plant-based/home>. For additional information, contact Scott Wagnon, PA-C, at [sewscott@aol.com](mailto:sewscott@aol.com).

*References on page 34*

# Transitions of Care Issues in the COVID-19 Pandemic: Focus on the Long-Term Care Setting—Part 2

Jacqueline Vance, RNC, BSN, IP-BC, CDONA/LTC, CDP

In part 1 of this series—Issues and Considerations of Transitions of Care and the Seven Essential Elements of Care Transition Bundle—we learned that consistent gaps and barriers identified in transitions of care, such as inadequate medication lists, poor medication management, delays with transfer and exchange of information across settings and providers, and lack of patient and family caregiver engagement and education, can place vulnerable patients at risk and that these gaps and barriers are known to contribute to hospital readmission. We also learned that the National Transitions of Care Coalition (NTOCC) has defined solutions by addressing the gaps that impact safety and quality of care for transitioning patients. One of the key tools and resources developed by NTOCC is the Care Transition Bundle, which consists of Seven Essential Intervention Categories.<sup>1</sup> These categories were described in part 1 of this series.

At Mission Health Communities, these principles were applied to the COVID-19 pandemic, resulting in hospital transitions and mortality that were lower than the national average. These results will be shown throughout this article.

Mission Health manages 50 skilled nursing and assisted living communities in eight states. Mission Health communities have earned National Bronze and Silver Quality Awards from the American Health Care Association/National Center for Assisted Living (AHCA/NCAL), achieving 5-star status at several communities and receiving national recognition for outstanding customer experience scores. Over the past several years, Mission Health has also been proud to work with companies through Mission Management and to assist communities when additional clinical and operational oversight was necessary.

These accomplishments in quality measures, financial outcomes, and more are achieved through Mission Health's dedicated employees who make it their priority to live by its CARES values of Character, Attitude, Respect, Excellence, and Service while they deliver the Mission Experience of outstanding care every day.

All the Mission Health clinical programs include the *Care Transitions Bundle Seven Essential Intervention Categories* of

medication management, transitions planning, patient and family engagement/education, information transfer, follow-up care, healthcare provider engagement, and shared accountability across providers and organizations. This is evidenced in the breakdown below.

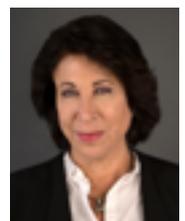
## Strategic clinical programs to care for the clinically complex patient: reducing unplanned returns to the hospital

Transferring care between providers can be uncertain, especially when unplanned, leaving skilled nursing facility (SNF) patients vulnerable and susceptible to complications, transfer trauma, and unnecessary costs. Transferring care was further complicated because of the COVID-19 pandemic. These issues, however, can be overcome by more-strategic clinical programming, education, and intentional care coordination. Although theoretically providers understand the issues that ensure a seamless process, in the real world there are often pitfalls.

Overcoming these barriers requires:

1. Strategic clinical programs to care for the clinically complex patient
2. Supporting competency through evidence-based mentorship programs
3. Improved patient assessment
4. Telehealth emergent virtual encounters and scheduled specialist rounding
5. Patient and family education for the postacute patient using tools and resources and building educational pathways
6. Follow-up care coordination upon return to the community
7. Medication reconciliation on every transition—educational concerns, medication reconciliation, and/or management and coordination.

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## Transferring care between providers can be uncertain, especially when unplanned, leaving skilled nursing facility patients vulnerable and susceptible to complications, transfer trauma, and unnecessary costs. Transferring care was further complicated because of the COVID-19 pandemic.

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One in four Medicare patients hospitalized for an acute medical illness is discharged to a SNF.<sup>2</sup> These patients are increasingly clinically complex. Gone are the stereotypes of little old ladies in rocking chairs who need assistance with activities of daily living. SNFs have become chronic care hospitals, behavioral health centers, or a combination of both. Patients are being discharged out of hospitals faster and sicker. Those of us in the SNF setting need to answer the call to be the postacute space beyond the hospital.<sup>3</sup> To meet that call, we must tailor our services to meet complex clinical needs that are complicated by behavioral issues. SNFs understand that if they want to be the facility that hospitals send these complex patients to, they need to ensure that their 30-day unplanned hospital readmission number is below the target set by the Centers for Medicare & Medicaid Services (CMS). This will require strategic clinical programs targeted to population health (the health outcomes of a group of individuals, including the distribution of such outcomes within the group) of the area. For example, the high incidence of chronic obstructive pulmonary disease (COPD) in the state of Georgia. In addition, they will need to analyze the clinical conditions of the patients that the SNF readmits after sending them to the hospital.

### Supporting competency through evidence-based mentorship programs

It is easy to understand why the more clinically competent the staff is, the lower the risk of unplanned hospital readmissions. There is a vast need to enhance nurses' skills so that they achieve competency to ensure high quality of care and preeminent health outcomes.<sup>4</sup> Mentorship programs provide education, training, supervision, and other forms of support for the first year of employment. Peer support in the form of a mentor/mentee relationship is a common component to improving professional competence. While many may take a reactive approach to competence (eg, when a facility receives a survey deficiency, there is a mad rush to get the staff signed off in the competency in that deficient area). However, a reactive approach is a "too late" approach. Therefore, there is a need to train senior staff as mentors and to establish qualification criteria encompassing competence, leadership skills,

communication skills, and a commitment to professional development.<sup>5</sup> The purpose of a mentorship program is to develop a professional relationship in which an experienced person (the mentor) assists another (the mentee) in developing specific skills and knowledge (competency) that will enhance the less-experienced person's professional and personal growth. This professional growth in turn enhances competency, which decreases the risk of unplanned hospital transitions.

### A need for improved patient assessment

In long-term care, RNs must delegate care to LPNs/LVNs and certified nursing assistants. Because of a fractured reimbursement system, most SNFs have a much larger LPN/LVN to RN ratio. The Nursing Home Reform Law of 1987 requires SNFs to have a registered nurse 8 consecutive hours, 7 days a week; licensed nurses 24 hours a day; and an undefined "sufficient" nursing staff to meet residents' needs. Federal standards have not been updated since the Reform Law was implemented over 30 years ago. While RNs are taught how to assess patients, LPNs/LVNs have just 1 year of schooling and evaluate a patient under the supervision of an RN. This intensifies the need to have an improved system that guides nurses in assessment.

Nurses continually must care for patients/residents with higher-level nursing and rehabilitation needs, including psychological needs. Among the dozens of tasks that nurses must do during their shifts are passing out medications, performing treatments (including IVs, tracheotomy care, monitoring blood glucose levels and giving insulin, managing oxygen levels, caring for wounds, and perhaps peritoneal dialysis), monitoring vital signs, documenting and transcribing orders, overseeing unlicensed staff, managing dementia-related psychosis, and assessing the patient's/resident's clinical conditions. With assessment comes care planning, documenting the findings of the assessment, notifying practitioners of changes, and implementing interventions as needed to prevent unplanned readmissions to an acute care hospital.

One intervention Mission Health Communities has done is to create their own user-defined assessments (UDAs) for complex clinical conditions in their electronic health records (EHRs) that are "all encompassing." Many of the assessments

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were built with the AMDA (Society for Post-Acute and Long-Term Care Medicine) clinical practice guidelines so that they would cover all areas of the clinical condition. For example, the diabetes assessment looks not only at blood glucose outcomes but also completely evaluates the body system and assesses all of the comorbid issues that often accompany diabetes (eg, cognitive changes; depression; decline in activities of daily living; foot, eye, and vascular changes; wounds; and oral health issues).

These assessments then create a person-centered care plan based on how the assessment questions are answered. The UDAs also create a structured progress note so that the nurse does not need to spend time creating additional documentation. In addition, the assessment creates alerts on the patient's/resident's dashboard; depending on how the assessment questions are answered, the nurse will be alerted to contact the practitioner and suggest a protocol related to that issue. These protocols were also derived from the AMDA's practice guidelines. For example, if the nurse checks "yes" to this question; "Has the patient/resident been on sliding scale insulin without a basal insulin for 5 days or more?" there will be an alert on the dashboard that states, "See Protocol: Diabetes—conversion of sliding scale to basal/bolus insulin regime. Send doctor 5 to 7 days' worth of blood glucose readings with insulin coverage and conversion factor." Or if the nurse checks "yes" to "Has the resident/patient had any eye problems (eg, blurring or loss of vision)?" then the alert will state "Protocol: Diabetes—Request order for ophthalmology consult and f/u as needed."

### **Telehealth—emergent virtual encounters and scheduled specialist rounding**

The coronavirus disease 2019 (COVID-19) pandemic has heightened the need for collaboration among SNFs and providers. With the evolving COVID-19 pandemic, SNFs were identified as high risk settings for severe outbreaks and poor outcomes. These facilities were particularly susceptible because many of their patients and residents are frail, older adults, and/or individuals with multiple chronic comorbidities or immunocompromised status.<sup>6</sup> Furthermore, staff members are frequently employed by multiple healthcare

facilities, increasing the risk of spread. This became more evident after the first outbreak in an SNF within King County, Washington, in February 2020.<sup>7</sup> The onset of the COVID-19 pandemic helped prove how valuable telehealth can be to SNFs while also demonstrating the vulnerabilities faced in caring for their patients. Traditionally, practitioners round at multiple nursing facilities and cannot always come into one SNF to make a medically necessary visit if they are across town at another SNF. When a patient's/resident's condition changes, the practitioner may elect to send the person to the emergency department for an evaluation if they cannot make it to the SNF for a timely visit. This is problematic at the best of times because a visit may prevent the unplanned transfer. With the COVID-19 pandemic, this problem was compounded as practitioners stopped rounding in many places. Telemedicine platforms allow SNFs to have their patients/residents evaluated and treated in place more effectively, reducing the need for hospital transitions, and allowing for access to specialty consults. Telemedicine permits facilities to care for more-complex patients in place. In addition, Mission Health Communities uses telehealth physicians to complete a medication reconciliation when the patient is admitted as well as assess the patient for medical complexities, further decreasing the risk for a 30-day bounce back to the hospital.

Since the COVID outbreak, SNFs using telemedicine platforms and tools have experienced better management of transitions of care, improved patient care, reduction of emergency transports and hospital readmissions, and improvement in the morale of patients, family, and staff. Although the United States government has loosened Medicare restrictions on telehealth in SNFs and made more funding available, those advances will continue only while the pandemic is ongoing. Once the pandemic is under control, those Medicare restrictions are supposed to return to pre-pandemic limits. It is more important than ever that SNFs put telehealth technology to work now while collecting data and tracking improved outcomes such as reduction of hospital readmissions to make a case for the continued support of telehealth beyond the pandemic. For those in long-term postacute care who have experienced telehealth and seen its positive outcomes, the genie has been let out of the bottle. We see telehealth as a necessity,

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## Collaboration between the hospital and the skilled nursing facility should lower rehospitalization rates and lead to better overall health outcomes.

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not a momentary luxury. One can only hope that CMS takes significant steps to fully embrace telemedicine as a viable option after the COVID-19 pandemic is over.

### Patient and family education for patients receiving postacute care

The process of building education pathways is significant in reducing the risk of readmission once the patient is transitioned back to the community. The NTOCC has free and valuable resources for assisting with transitions, including a COVID pathway titled “Safe and Effective COVID-19 Transitions of Care: Interprofessional Strategies Across the Spectrum of Illness and Healthcare Settings.”<sup>8</sup> This is a downloadable resource designed to navigate transitions and support care for patients with COVID-19. If not carefully guided, care transitions can reveal gaps in identifying risk factors for COVID-19 progression and complications, ensuring safe recovery at home or in postacute and long-term care facilities, managing comorbid conditions, and preventing readmission—all of which contribute to poor outcomes.

Another tool helps patients be active in taking care of their own health management or a person they care for. This tool is called “COVID-19 Health Management,” which includes NTOCC’s well-known one-page “My Medication List.”<sup>9</sup> The original form developed in 2008 was to assist patients and their family caregiver gather important information about their medications. Filling out the form before visiting their doctor or entering the hospital helped ensure that providers knew what medications they were already taking, which helped reduce problems with medication reconciliation. The “Taking Care of My Health Care” has been adapted multiple times to support specific disease states. In 2020, NTOCC adapted the form to the “COVID-19 Health Management,” which supported families in not only sharing their medication lists but also their symptoms, health status, and concerns about COVID-19. This resource could be used when calling the provider, emailing the provider, having a telehealth visit, or entering the emergency department or hospital.<sup>10</sup>

Another important area to focus on is educating the patient to care for their chronic clinical condition(s) once they are home. One cannot and should not focus solely on the hospital’s major diagnosis. For example, say a person with COPD had an exacerbation at home that led to a fall

resulting in a femoral fracture. At the hospital, an open reduction internal fixation was performed, and the patient received postacute care at an SNF primarily for rehabilitation. Traditionally, even with the advent of the Medicare Patient-Driven Payment Model, the focus would be on therapies. The problem is that the person had a fall due to the COPD exacerbation. Therefore, COPD self-management should be the primary focus of patient and family education, reducing the risk of a hospital readmission once the patient is transitioned back to the community.

Mission Health Communities created an every-third-day education assessment that automatically populates in the patient’s EHR and prompts the nursing staff to educate in “small bites,” beginning up to 30 days before transition back to the community. Along with this assessment are electronic folders of disease states with patient educational materials that are available on demand to the nursing staff. Since nurses have these materials at their fingertips, they can educate patients on their disease states and self-management.

### Follow-up care coordination upon return to the community

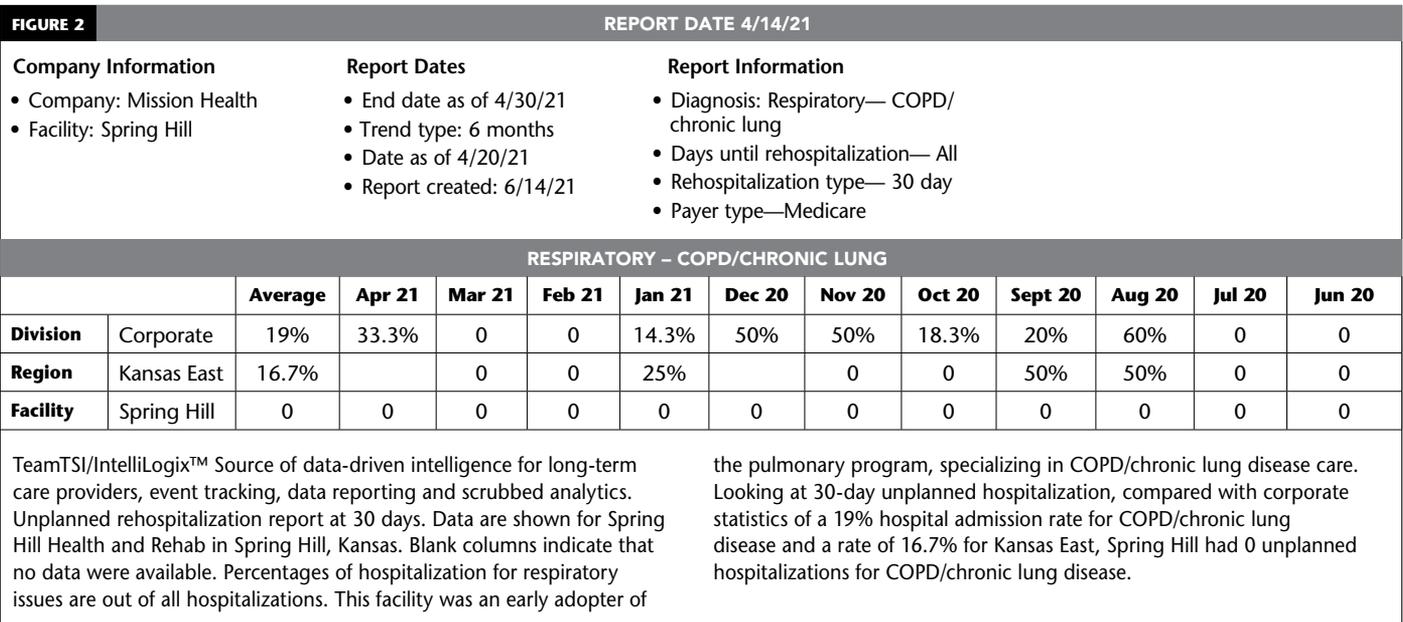
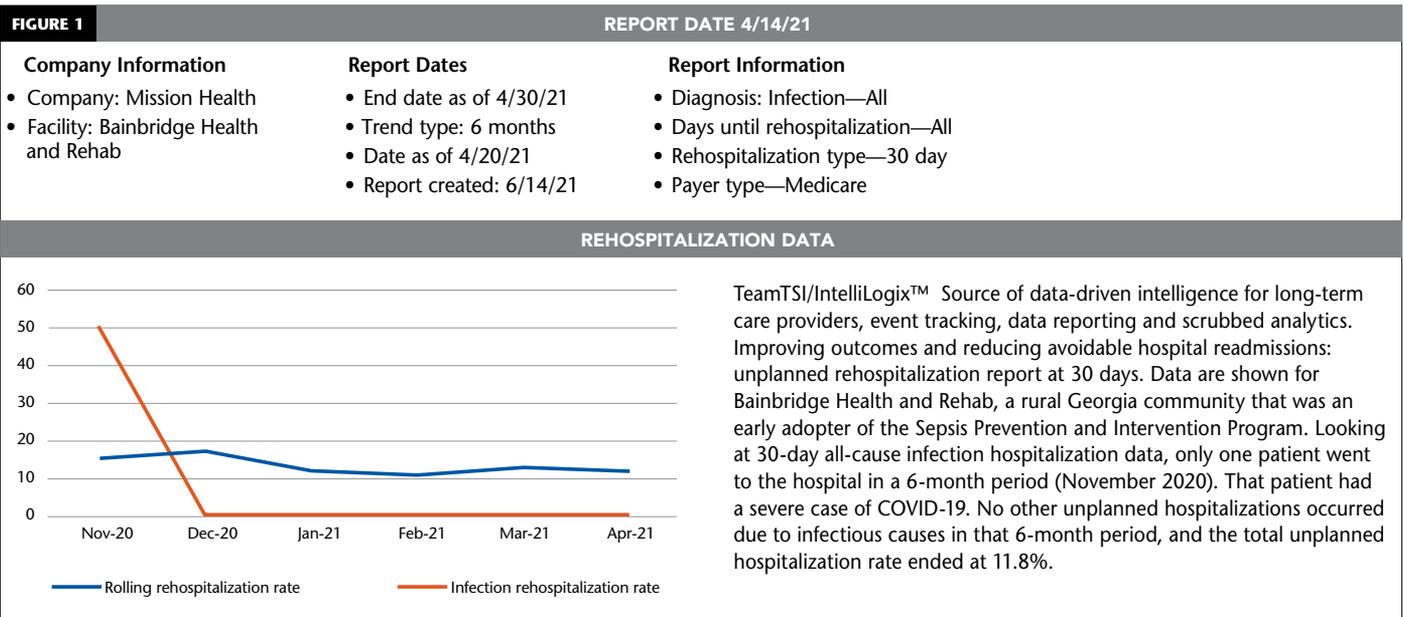
Follow-up care after the discharge/transition process is an important part of improving patient outcomes and reducing the risk of an unplanned hospital transition. Postdischarge/transition follow-up phone calls are an essential part of supporting the patient from the time of discharge/transition until their first appointment for follow-up care. This postdischarge/transition follow-up phone call allows for a review of the patient’s health history and discharge plan, the patient’s compliance with the home care plans, questions, any misunderstandings, ability to conform to plan, current health, medication adherence to be identified and addressed, and concerns from caregivers or family members. A best practice is to assign this task to a designated staff member, such as social service personnel, so that these calls will be made on the prescheduled basis. At Mission Health Communities, these calls are done at 24-72 hours posttransition home, then at 7 days, 14 days, 21 days, and 30 days. Mission Health created a Transition Summary and Instructions Assessment form in its EHR that records all pertinent information for social service personnel to review with the transitioned patient; this form helps the personnel refamiliarize themselves with the

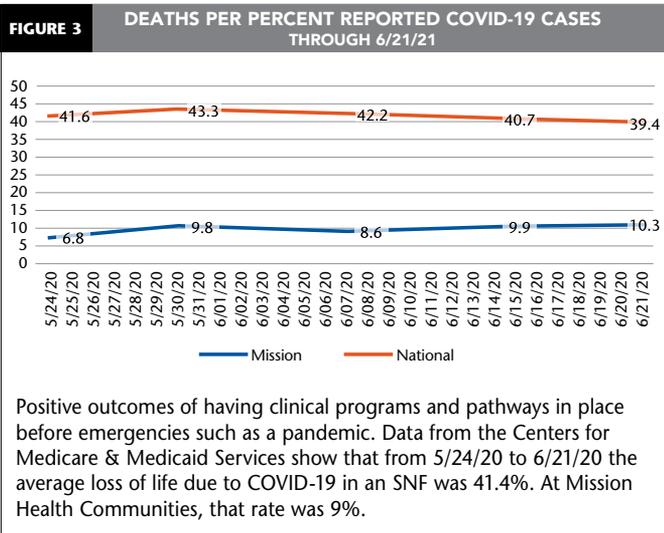
patient’s information. This includes the complete reconciled medication list at discharge with reason for the medication, dose and time to be taken, current treatment(s)/therapies needed with reason and frequency, physical functioning at time of discharge detailing how all activities of daily living are performed and any assistive devices used, a section on post-transition services (including home health and community resources if applicable), posttransition follow-up (laboratory/diagnostic appointments, practitioner appointments), and general wellness questions. Mission Health offers the choice

of coming back to postacute care rather than a hospital transfer if the patient’s condition is declining. This information is recorded on another assessment created in the EHR for ease of tracking.

**Improved patient engagement**

Medication reconciliation should occur at every level of transition to reduce the risk of unplanned hospital transition.<sup>11</sup> According to CMS, the definition of medication reconciliation is the process of identifying the most accurate list of all





medications that the patient is taking (including name, dosage, frequency, and route) by comparing the medical record to an external list of medications obtained from a patient, hospital, or other provider. Lately, there has been discussion on a formal role for pharmacists in transitions of care. While pharmacists are not always recognized for what they bring to the table, a consultant pharmacist can help a patient start an optimal therapy; provide educational information about the medication regimen; and form a relationship and communicate with all individuals on the patient's care team including the patient and their family caregiver. Pharmacists could assess social determinants of health to ensure the best clinical outcome for the patient because it is important to educate patients about changes in their medications during transitions of care.

### Postacute Care Clinical Programs

As mentioned earlier, patients in SNFs have increased levels of frailty and complexity. More older adults are living longer with complex health needs that calls for specialized care.<sup>12</sup> Building new clinical capabilities and developing new programs that serve complex care populations lets hospitals find better places for patients to recover, reducing time in the hospital.

Collaboration between the hospital and the SNF should lower rehospitalization rates and lead to better overall health outcomes. At Mission Health Communities, several postacute care clinical programs had been in place just before the COVID-19 outbreak, and Mission believes that these programs lessened the burden of disease in its communities.

Those programs were a pulmonary program that included a hypoxia prevention and recognition with intervention arm, a sepsis prevention and intervention program with a strong infection recognition and intervention arm, and an

all-community IV therapy certification/competency program. The pulmonary and sepsis programs had unique assessments within the EHR as described earlier. In addition, a specialized assessment completed daily for all patients with COVID-19 allowed for tracking of symptoms seen in elderly persons (eg, malaise, low-grade temperature, decrease in the ability to perform activities of daily living, anorexia, and other gastrointestinal symptoms as well as the respiratory symptoms of COVID-19). Coupling these programs with the daily symptom tracking sheet, Mission Health Communities added daily meetings on the community level with its practitioners, discussing each case and obtaining orders as appropriate. This allowed for most patients to be treated in place, and only those who needed intensive care were transitioned to the hospital. As seen in Figures 1 and 2, the application of these programs led to low avoidable hospital readmission rates in both all-cause infection (sepsis prevention and intervention program) and in patients/residents with chronic lung disease.

Additionally, Mission Health Communities experienced a much lower percentage of patient death due to COVID-19 compared with the rest of the county. For example, CMS data shows that from 5/24/20 to 6/21/20 the average loss of life in a SNF setting due to COVID-19 was 41.4%. At Mission Health Communities, that rate was 9% (Figure 3).

### Importance of having the Seven Essential Elements in place before COVID

Having the *Care Transitions Bundle Seven Essential Intervention Categories* in place before the pandemic was shown to be vital in preventing unplanned hospitalizations and managing patients who contracted COVID-19. We believe the outcomes shown in this article point to the positive outcomes of that incorporation. **CE II**

### CE exams may be taken online!

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### References

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*References continue on page 35*

# Medical Cannabis: Ethical and Legal Implications for Care Managers—Part II

Jennifer Crowley, BSN, RN, CLCP, CADDCT, CDP, CMC

Part 1 of this series, which can be found in the August/September 2021 issue of *Care Management*, provides a brief background on cannabis, the endocannabinoid system, common health conditions in which cannabis is used, and important considerations for the health and safety of individuals who use cannabis products.

Care managers may be involved with a client who is using cannabis products to relieve symptoms or who wants to add medical cannabis as a complement or alternative to their current treatment care plan. A 2-year study completed in New York found that 70% of medical marijuana program enrollees seek cannabis for the relief of chronic or severe pain and to avoid using prescription opioid medications (Arntsen, 2019). Because the number of states legalizing the medical and recreational use of cannabis is increasing, there is an anticipatory increase in the number of clients the care manager will encounter who want to use cannabis.

Considering the scope of practice and day-to-day range of responsibility medical providers have, there is a need for other capable healthcare professionals to provide a continuum of care outside the provider office. Care managers are an excellent choice and are more likely to have a clearer understanding of client characteristics and traits that impact the treatment plan.

The care manager should stay informed about cannabis and ensure that their clients know how cannabis works inside the body, what the safety considerations are for cannabis, and how to discuss their treatment plan with their medical provider. The care manager must balance their own personal bias, current laws and regulations, medical providers' viewpoints, and company policies while respecting the client's autonomy for decision-making and abiding with their professional code of ethics.

We can no longer ignore cannabis as a preferred alternative by many to synthetic prescription medications for the alleviation of symptoms, personal wellness, and health management.

Are we including medical cannabis in the care plan? It depends on whether the use of cannabis is solely directed by the individual or prescribed by the medical provider and a routine part of the discussion during medical visits.

## Role of the Care Manager

First and foremost, determine your own knowledge about cannabis and the rules and regulations in your state; also review or develop your company policies. This is just as important for the solo practitioner. This topic encompasses ethical, legal, medical, and financial areas of interest.

Care managers may offer cannabis specialty support and services after obtaining training through continuing education or specialty programs, which are widely available. It is a professional standard and responsibility to practice only within the boundaries of the professional role or competence, based on education, skills, and experience (Commission for Case Manager Certification® [CCMC®], 2015). Learn more and seek opportunities. There are several online cannabis courses and growing opportunities for continuing education on this topic.

The cannabis industry continues to undergo dramatic shifts. The healthcare industry has opposing views on the use of cannabis and its medicinal benefits, like those found among the public. The most recent survey has found 53% of the public is in favor of legalizing the use of marijuana, with the most popular reason being for its medicinal benefits and the belief that marijuana is no worse than other drugs, alcohol, and cigarettes (Pew Research Center, 2015). By contrast, the national survey by Pew Research Center found that members of the public who oppose legalization have always opposed use of cannabis and have concerns for the damage inflicted on people and society in general (Pew Research Center, 2015).



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**Care managers should stay informed about cannabis and ensure that their clients know how cannabis works inside the body, what the safety considerations are for cannabis, and how to discuss their treatment plan with their medical provider.**

The care manager will need to come to terms with their own views and how to navigate this complex and ever-present issue, adopting a methodology based on principles and standards of care within their area of practice. The principles of the Code of Professional Conduct for Case Managers/CDMS (Certified Disability Management Specialist) Code of Professional Conduct provide a relevant framework to apply, which is important in the context of cannabis (CCMC®, 2015) (Table 1).

**TABLE 1 PRINCIPLES OF THE CODE OF PROFESSIONAL CONDUCT FOR CASE MANAGERS**

<b>1</b>	Board-certified case managers will place the public interest above their own at all times.
<b>2</b>	Board-certified case managers will respect the rights and inherent dignity of all of their clients.
<b>3</b>	Board-certified case managers will always maintain objectivity in their relationships with clients.
<b>4</b>	Board-certified case managers will act with integrity and fidelity with clients and others.
<b>5</b>	Board-certified case managers will maintain their competency at a level that ensures their clients will receive the highest quality of service.
<b>6</b>	Board-certified case managers will honor the integrity of the CCM designation and adhere to the requirements for its use.
<b>7</b>	Board-certified case managers will obey all laws and regulations.
<b>8</b>	Board-certified case managers will help maintain the integrity of the Code, by responding to requests for public comments to review and revise the code, thus helping ensure its consistency with current practice.

Principles of the Code of Professional Conduct for Case Managers. The Commission for Case Manager Certification® (CCMC®). Reprinted with permission.

Care managers can also look to other leadership and professional organizations that provide support, education, and standards. For example, the National Council of State Boards of Nursing define six principles of essential knowledge about cannabis for nurse, advance practice nurses, and nursing students (Theisen & Konieczny, 2019).

1. The nurse shall have a working knowledge of the current state of legalization of medical and recreational cannabis use.
2. The nurse shall have a working knowledge of the jurisdiction's medical marijuana program.
3. The nurse shall have an understanding of the endocannabinoid system, the cannabinoid receptors, cannabinoids, and the interactions between them.
4. The nurse shall have an understanding of cannabis pharmacology and the research associated with the medical use of cannabis.
5. The nurse shall be able to identify the safety considerations for patient use of cannabis.
6. The nurse shall approach the patient without judgement regarding the patient's choice of treatment or preferences in managing pain and other distressing symptoms.

The care manager typically has the “inside view”, becoming familiar with the client's health and wellness routines, educational and social background, family dynamics, financial status, and other characteristics. These may be difficult for the medical provider to fully understand considering the limited time that they spend with each client. All these factors are important for advocacy, client engagement, and the safe and effective management of health conditions and symptomatology. The familiar disparities include lack of affordability, access, and education.

### Challenges

There are several limitations that cause barriers to the general acceptance and open scholarly discourse regarding the safe and appropriate use of medical cannabis. Concerns about licensure, lack of evidence-based standards, and inconsistent acceptance are some of the limitations. A fear of damaging one's reputation, legal repercussions, and losing customers as

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**Ethical considerations associated with cannabis include standardization, commercial interests, education, and medical management. Ethical considerations may also include cannabis in the workplace, cannabis use in the pediatric population, disparities in use of cannabis due to socioeconomic status, and lack of access.**

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well as referral partners often prevents many healthcare professionals from openly discussing the use of medical cannabis or from having any involvement with medical cannabis.

The healthcare industry is at a crossroad, trying to decide how to proceed in the context of a booming cannabis market and changing laws. The Federation of State Medical Boards (FSMB) recognizes the need for state medical boards to be responsible for the regulatory oversight of physicians choosing to incorporate the recommendation of marijuana in patient care and management. Guidelines were published by the FSMB in 2016, suggesting that providers establish a treatment agreement that outlines other measures for easing suffering, providing advice about the risks of using cannabis, providing education on the variability of the quality and concentration of cannabis, and providing ongoing monitoring and adjustment of the treatment plan accordingly (FSMB, 2016).

Healthcare's biggest challenge with respect to cannabis may be to educate and engage all stakeholders while supporting safe and effective care. Availability of information to understand the number of healthcare professionals that include or recognize medical cannabis as a part of the treatment plan is limited. There is a growing need for research and education across many disciplines.

### Care Managers will find increasing opportunities for cannabis education, care planning, advocacy, and professional management

Long-term care planning experts (eg, life care planners) have been discussing whether to include cannabis-related products in their comprehensive reports for years. Given the context of their work, often scrutinized through legal mechanisms such as the courts, medical cannabis continues to be an important topic and any progress or change related to acceptance of cannabis will have reverberating consequences throughout the industry. It may take years, if not decades, before cannabis has broad acceptance and admissibility equal to that of pharmaceuticals. Insurers may not want to disrupt their bottom line by associating with an actual or perceived risk, making it challenging for cannabis to gain established precedence (Kennedy-Simington, 2018).

Care managers often work collaboratively with other professionals to uniquely tailor their services for a person-family centered approach and rely on research, education, standards of

practice, and evidence-based guidelines for quality assurance and best practice (Crowley & Huber, 2021). The care manager can choose to refer to cannabis specialists who are familiar with the various products and understand the endocannabinoid system (ECS). It is beneficial for the care manager to have a rich referral network and build and rely on professional collaborative relationships that provide value to clients.

The care manager can also choose to become a cannabis specialist, adding cannabis consulting and care planning to their professional services. Completing education through a reputable organization and cannabis education program will help ensure competency and provide a mechanism for networking, mentorship, and continuing education.

If the care manager knows that his/her client is using cannabis to manage their own health, are they obligated to include this in the care plan or disclose this to the primary care provider? Many questions remain but reflect the everyday issues that a care manager may have to navigate: the sometimes awkward and difficult topics that end up being "danced around," depending on the client's wishes, primary concerns, and personal values. Cannabis, like end-of-life care, finances, and decision-making authority, may be a sensitive topic that the client is not open to discuss, which the care manager must respect.

Ethical considerations associated with cannabis include standardization, commercial interests, education, and medical management (Sagy, et al., 2018). The care manager will likely take note of the broad application of cannabis and cannabis-related research across multiple disciplines, including end-of-life and palliative care, dementia, and performance enhancement. Curiosity alone will not suffice. There is a growing need for studies examining cannabis use in various cohorts, along with an understanding that cannabis may not be the solution for everyone and in some cases may be contraindicated.

Other ethical considerations may also include cannabis in the workplace, cannabis use in the pediatric population, disparities in use of cannabis due to socioeconomic status, and lack of access. Those who use cannabis products regularly, whether inhaled or ingested, will often spend over \$300 per month on cannabis or cannabis-related products (American Addiction Centers, Oxford Treatment Center, 2020). Without medical precedence, cannabis remains a

**Not all care managers will have frequent contact with clients who use cannabis, but most care managers will become aware of this growing area of healthcare. Care managers need to understand and take into consideration the need to guide their own practice using the ethical principles of autonomy, beneficence, do no harm, personal rights, justice, obligation, and duty.**

luxury for many individuals who cannot afford it or lack options for safe access and support.

Modern healthcare is based on ethical principles that individuals have the right to make their own decisions that serve their own best interest. Often, amid an unforeseen event, individuals make decisions under duress, limiting the ability to pause for a more informed decision. With respect to cannabis, most clients don't have an immediate or lifesaving need for cannabis that necessitates an expedited decision, although there are some circumstances that may require a timelier consideration for the use of cannabis (eg, end-of-life care and cancer treatment). Care managers are challenged to have a process in place for dealing with cannabis use that necessitates an expedited decision. For example, the state of Illinois has a program for the terminally ill that allows patients who are certified by their physicians to have an expedited pathway to purchase and consume cannabis products from licensed dispensaries (Newton, 2021). Also on the horizon is the promising therapeutic potential for cannabis to modulate tumor growth, providing an anticancer effect, both with plant-derived and synthetic cannabinoids (Daris, et al., 2019).

Clients and the general population are likely to ask care managers for advice on cannabis, and care managers will thus benefit by reviewing their own personal beliefs, values, bias, and need for further education. Relying on Principle 1 and 2 of the Code of Professional Conduct for Case Managers/CDMS Code of Professional Conduct, the care manager will respect the rights and inherent dignity of all their clients and always place the public interest above their own (2015/2019). As cannabis is a new treatment area for many professionals, the care manager will benefit by remaining objective, providing person-centered advocacy for clients, and building upon a foundation of continued learning and professional development in this topic.

### Recommended Approach for the Care Manager:

1. Ensure there is a legal means for use of medical cannabis. If the client is using cannabis without a medical provider certification, ask the client to become an established user. Refer to medical cannabis specialist if necessary.
2. Review the client's history of cannabis use, experience, and outcomes as well as any other information to ensure a complete understanding. Learn as much as possible.

3. Create the care plan (Table 2).
4. Obtain authorization to discuss the treatment plan with the medical provider.
5. Schedule an appointment with the medical provider to discuss medications. (Suggest focus or reason for the medical visit. Be prepared for medical offices to ask the purpose of the visit when scheduling.)
6. Accompany the client to the medical provider appointment.
7. Help the client update their medication list with their primary provider. Review the current cannabis regimen, dosing, and other questions or concerns with the medical provider.
8. Ask the medical provider to include medical cannabis in the notes as part of the treatment plan and to be included as part of the routine medication reconciliation completed at each medical visit.
9. Ensure the appropriate follow ups are scheduled and coordinate referrals, as necessary.
10. Review the medical visit with the client, ensuring the care plan reflects the current treatment plan and any actions necessary.
11. Educate the client about cannabis and important safeguards, potential interactions or contraindications, and symptoms of withdrawal.
12. Encourage the client to participate in the care plan by using a log or diary for documenting symptoms and use of cannabis products, notable effects, outcome, or any reactions.
13. Help the client allocate funds, including cannabis products and accessories for use of their cannabis products, by costing out care needs.
14. Instruct the client to regularly review their care plan and discuss any concerns with their medical provider.

### The Care Plan

The care manager has the important task of learning about a client's situation through a comprehensive assessment and developing a person-centered care plan based on those findings. Care managers help define client goals, wishes, and strategies to maintain optimal wellness. This is done repeatedly

through regular review of the care plan while working with a client.

Care plans include everything from in-home support to equipment and medications. Any task or goal-directed activity for maintaining an individual's optimal well-being is typically included in a person-centered care plan. It is fundamentally important to understand the client's history of cannabis use and health status as well as to identify the client's current health-care team. When creating a care plan that includes medical cannabis, there should be a thorough review with the client about risks versus benefits, alternative treatment options when cannabis is not available, what to do when traveling, the impact on employment when applicable, contraindications, and potential interactions with medications (2020, Albee & Penilton).

The entirety of the care plan will depend on the specific situation and should be highly individualized. The care plan should facilitate the client goals, maximize outcomes, and decrease potential adverse effects (Theisen, 2019). The care plan should be developed with an understanding that it is a dynamic process. The care plan may change, depending on the health status, treatment plan changes, and outcomes. There should be a system in place for regular review of goals and recommendations to ensure completion or to help realign needs and reprioritize tasks.

Additional items in the care plan for cannabis may include:

- Type of product: (eg, edible, flower, oil, salve)
- Dosing: milligram per dose, how much, how often, sliding scale dosing based on symptoms
- Documentation of symptoms: pre- and postdosage, special notes
- Product information: terpenes, strains, and laboratory testing
- How to obtain the product: dispensary, mail order, state requirements
- Plan for review: (eg, weekly, monthly, or quarterly)
- Medical appointment follow-up: primary care review, recertification, complementary alternatives (eg, massage, acupuncture, yoga)

Be as detailed as possible, according to the needs of the

**TABLE 2** SAMPLE CARE PLAN FOR CANNABIS

<b>Area of concern (needs)</b>	<ul style="list-style-type: none"> <li>• Interested in trial use of medical cannabis because of chronic opioid use</li> </ul> <p><b>Notes:</b> No history of use in last 20 years; no previous knowledge; no exposure other than advertisements; has not discussed with provider</p>
<b>Goal(s)</b>	<p>_____ will learn about medical cannabis and understand the body's endocannabinoid system</p> <p>_____ will understand the various cannabis products and how to obtain them (legally)</p> <p>_____ will be compliant with the current guidelines and laws within their jurisdiction (obtain medical certification/register)</p> <p>_____ will discuss interest with current healthcare provider</p>
<b>Barrier(s)</b>	<ul style="list-style-type: none"> <li>• Time consuming</li> <li>• Overwhelming</li> <li>• State law vs federal law</li> <li>• Provider rejection</li> <li>• Fear of bad outcomes</li> </ul>
<b>Recommendation(s)</b>	<ul style="list-style-type: none"> <li>• Schedule 1 hour for education about the endocannabinoid system (time frame for completion: 7 days)</li> <li>• Schedule 1 hour for education about current jurisdiction and laws (7–14 days)</li> <li>• Review options in the community (use resource guide or local listing) (7–14 days)</li> <li>• Schedule accompanied field trip to dispensary (14 days)</li> <li>• Schedule appointment with the healthcare provider (7 days)</li> </ul>

individual. Using a consistent method and setting realistic time-sensitive goals helps clients stay on track for goal completion. Always refer to the foundational principle of each client being unique and having their own chemistry and response and use a method for observation and monitoring before, during, and after cannabis use.

### Summary

Not all care managers will have frequent contact with clients who use cannabis, but most care managers will become aware of this growing area of healthcare. Care managers must rely on their own scope of practice as a guideline for determining the level of their professional array of services. Care managers need to understand and take into consideration the need to guide their own practice using the ethical principles of autonomy, beneficence, do no harm, personal rights, justice, obligation, and duty (CCMC®, 2015/CDMS, 2019).

*continued on page 34*

# PharmaFacts for Case Managers



## Rezurock™ (belumosudil) tablets, for oral use

### INDICATIONS AND USAGE

Rezurock is indicated for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy.

### DOSAGE AND ADMINISTRATION

#### *Recommended Dosage*

The recommended dose of Rezurock is 200 mg given orally once daily until progression of chronic GVHD that requires new systemic therapy. Instruct the patient on the following:

- Swallow Rezurock tablets whole. Do not cut, crush, or chew tablets.
- Take Rezurock with a meal at approximately the same time each day.
- If a dose of Rezurock is missed, instruct the patient to not take extra doses to make up the missed dose.

Treatment with Rezurock has not been studied in patients with preexisting severe renal or hepatic impairment. For patients with preexisting severe renal or hepatic impairment, consider the risks and potential benefits before initiating treatment with Rezurock.

#### *Dose Modifications for Adverse Reactions*

Monitor total bilirubin, aspartate aminotransferase (AST), and alanine aminotransferase (ALT) at least monthly. Modify the Rezurock dosage for adverse reactions.

#### *Dosage Modification Due to Drug Interactions*

##### *Strong CYP3A Inducers*

Increase the dosage of Rezurock to 200 mg twice daily when coadministered with strong CYP3A inducers.

##### *Proton Pump Inhibitors*

Increase the dosage of Rezurock to 200 mg twice daily when coadministered with proton pump inhibitors.

### DOSAGE FORMS AND STRENGTHS

Each 200 mg tablet is a pale-yellow film-coated oblong tablet debossed with “KDM” on one side and “200” on the other side.

### CONTRAINDICATIONS

None.

### WARNINGS AND PRECAUTIONS

#### *Embryo-Fetal Toxicity*

Based on findings in animals and its mechanism of action, Rezurock can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of belumosudil to pregnant rats and rabbits during the period organogenesis caused adverse developmental outcomes including embryo-fetal mortality and malformations at maternal exposures (AUC) less than those in patients at the recommended dose. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with Rezurock and for at least one week after the last dose.

#### *Adverse Reactions*

The most common ( $\geq 20\%$ ) adverse reactions, including laboratory abnormalities, were infections, asthenia, nausea, diarrhea, dyspnea, cough, edema, hemorrhage, abdominal pain, musculoskeletal pain, headache, phosphate decreased, gamma glutamyl transferase increased, lymphocytes decreased, and hypertension.

### DRUG INTERACTIONS

#### *Effect of Other Drugs on Rezurock*

##### *Strong CYP3A Inducers*

Coadministration of Rezurock with strong CYP3A inducers decreases belumosudil exposure, which may reduce the efficacy of Rezurock. Increase the dosage of Rezurock when coadministered with strong CYP3A inducers.

##### *Proton Pump Inhibitors*

Coadministration of Rezurock with proton pump inhibitors decreases belumosudil exposure, which may reduce the efficacy of Rezurock. Increase the dosage of Rezurock when coadministered with proton pump inhibitors.

### USE IN SPECIFIC POPULATIONS

#### *Pregnancy*

##### *Risk Summary*

Based on findings from animal studies and the mechanism



of action, Rezurock can cause fetal harm when administered to pregnant women. There are no available human data on Rezurock use in pregnant women to evaluate for a drug-associated risk. In animal reproduction studies, administration of belumosudil to pregnant rats and rabbits during the period of organogenesis resulted in adverse developmental outcomes, including alterations to growth, embryo-fetal mortality, and embryo-fetal malformations at maternal exposures (AUC) approximately  $\geq 3$ - (rat) and  $\geq 0.07$  (rabbit) times the human exposure (AUC) at the recommended dose. Advise pregnant women and females of reproductive potential of the potential risk to the fetus.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

#### **Lactation**

##### *Risk Summary*

There are no data available on the presence of belumosudil or its metabolites in human milk or the effects on the breastfed child or milk production. Because of the potential for serious adverse reactions from belumosudil in the breastfed child, advise lactating women not to breastfeed during treatment with Rezurock and for at least one week after the last dose.

#### **Females and Males of Reproductive Potential**

Rezurock can cause fetal harm when administered to a pregnant woman.

##### *Pregnancy Testing*

Verify the pregnancy status of females of reproductive potential prior to initiating treatment with Rezurock.

##### *Contraception*

###### **Females**

Advise females of reproductive potential to use effective contraception during treatment with Rezurock and for at least one week after the last dose of Rezurock. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be informed of the potential hazard to a fetus.

###### **Males**

Advise males with female partners of reproductive potential to use effective contraception during treatment with Rezurock and for at least one week after the last dose of Rezurock.

##### *Infertility*

###### **Females**

Based on findings from rats, Rezurock may impair female fertility. The effect on fertility is reversible.

###### **Males**

Based on findings from rats and dogs, Rezurock may impair male fertility. The effects on fertility are reversible.

#### **Pediatric Use**

The safety and effectiveness of Rezurock have been established in pediatric patients 12 years and older. Use of Rezurock in this age group is supported by evidence from adequate and well-controlled studies of Rezurock in adults, with additional population pharmacokinetic data demonstrating that age and body weight had no clinically meaningful effect on the pharmacokinetics of drug substance, that the exposure of drug substance is expected to be similar between adults and pediatric patients age 12 years and older, and that the course of disease is sufficiently similar in adult and pediatric patients to allow extrapolation of data in adults to pediatric patients. The safety and effectiveness of Rezurock in pediatric patients less than 12 years old have not been established.

#### **Geriatric Use**

Of the 186 patients with chronic GVHD in clinical studies of Rezurock, 26% were 65 years and older. No clinically meaningful differences in safety or effectiveness of Rezurock were observed in comparison to younger patients.

#### **CLINICAL STUDIES**

##### **Chronic Graft versus Host Disease**

Study KD025-213 (NCT03640481) was a randomized, open-label, multicenter study of Rezurock for treatment of patients with chronic GVHD who had received 2 to 5 prior lines of systemic therapy and required additional treatment. Patients were excluded from the studies if platelets were  $<50 \times 10^9/L$ ; absolute neutrophil count  $<1.5 \times 10^9/L$ ; AST or ALT  $> 3 \times ULN$ ; total bilirubin  $>1.5 \times ULN$ ; QTc(F)  $> 480$  ms; eGFR  $< 30$  mL/min/1.73 m<sup>2</sup>; or FEV1  $\leq 39\%$ . There were 66 patients treated with Rezurock 200 mg taken orally once daily. Concomitant treatment with supportive care therapies for chronic GVHD was permitted. Concomitant treatment with GVHD prophylaxis and standard care systemic chronic GVHD therapies was permitted as long as the subject has been on a stable dose for at least 2 weeks prior to study. Initiation of new systemic chronic GVHD therapy while on study was not permitted.

The efficacy of Rezurock was based on overall response rate (ORR) through Cycle 7 Day 1 where overall response included complete response or partial response according to the 2014 NIH Response Criteria. The ORR was 75% (95% CI: 63, 85). The median duration of response, calculated from first response to progression, death, or new systemic therapies for chronic GVHD, was 1.9 months (95% CI: 1.2, 2.9). The median time to first response was 1.8 months (95% CI: 1.0, 1.9). In patients who achieved response, no death or new systemic therapy initiation occurred in 62% (95% CI: 46, 74) of patients for at least 12 months since response.

ORR results were supported by exploratory analyses of patient-reported symptom bother which showed at least a 7-point



decrease in the Lee Symptom Scale summary score through Cycle 7 Day 1 in 52% (95% CI: 40, 65) of patients.

#### HOW SUPPLIED/STORAGE AND HANDLING

Rezurock 200 mg tablets are supplied as pale-yellow film-coated oblong tablets containing 200 mg of belumosudil (equivalent to 242.5 mg belumosudil mesylate). Each tablet is debossed with “KDM” on one side and “200” on the other side and is packaged as follows: 200 mg tablets in 30 count bottle.

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

Dispense to patient in original container only. Store in original container to protect from moisture. Replace cap securely each time after opening. Do not discard desiccant.

For full prescribing information, please see product insert.

Rezurock is manufactured and distributed by Kadmon Pharmaceuticals, LLC.

### Saphnelo (anifrolumab-fnia) injection, for intravenous use

#### INDICATIONS AND USAGE

Saphnelo (anifrolumab-fnia) is indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE) who are receiving standard therapy.

##### Limitations of Use

The efficacy of Saphnelo has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Use of Saphnelo is not recommended in these situations.

#### DOSAGE AND ADMINISTRATION

##### Dosage Recommendations

Saphnelo must be diluted prior to intravenous administration.

The recommended dosage of Saphnelo is 300 mg, administered as an intravenous infusion over a 30-minute period, every 4 weeks.

##### Missed dose

If a planned infusion is missed, administer Saphnelo as soon as possible. Maintain a minimum interval of 14 days between infusions.

#### DOSAGE FORMS AND STRENGTHS

Injection: 300 mg/2 mL (150 mg/mL) as a clear to opalescent, colorless to slightly yellow, solution in a single-dose vial.

#### CONTRAINDICATIONS

Saphnelo is contraindicated in patients with a history of anaphylaxis with anifrolumab-fnia.

#### WARNINGS AND PRECAUTIONS

- **Serious Infections:** Serious and sometimes fatal infections have occurred in patients receiving Saphnelo. Saphnelo increases the

risk of respiratory infections and herpes zoster. Avoid initiating treatment during an active infection. Consider the individual benefit-risk if using in patients with severe or chronic infections. Consider interrupting therapy with Saphnelo if patients develop a new infection during treatment.

- **Hypersensitivity Reactions Including Anaphylaxis:** Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported.
- **Malignancy:** Consider the individual benefit-risk in patients with known risk factors for malignancy prior to prescribing Saphnelo.
- **Immunization:** Avoid use of live or live-attenuated vaccines in patients receiving Saphnelo.
- **Not Recommended for Use with Other Biologic Therapies**

#### ADVERSE REACTIONS

Most common adverse drug reactions (incidence  $\geq 5\%$ ) are nasopharyngitis, upper respiratory tract infections, bronchitis, infusion-related reactions, herpes zoster and cough.

#### USE IN SPECIFIC POPULATIONS

##### Pregnancy

##### Pregnancy Exposure Registry

A pregnancy exposure registry monitors pregnancy outcomes in women exposed to Saphnelo during pregnancy. For more information about the registry or to report a pregnancy while on Saphnelo, contact AstraZeneca at 1-877-693-9268.

##### Risk Summary

The limited human data with Saphnelo use in pregnant women are insufficient to inform on drug-associated risk for major birth defects, miscarriage, or adverse maternal or fetal outcome. Monoclonal IgG antibodies are known to be actively transported across the placenta as pregnancy progresses; therefore, anifrolumab-fnia exposure to the fetus may be greater during the third trimester of pregnancy.

In an enhanced pre- and post-natal development study with pregnant cynomolgus monkeys that received intravenous administration of anifrolumab-fnia, there was no evidence of embryotoxicity or fetal malformations with exposures up to approximately 28 times the exposure at the maximum recommended human dose (MRHD) on an Area Under Curve (AUC) basis.

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

##### Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk: Pregnant



women with SLE are at increased risk of adverse pregnancy outcomes, including worsening of the underlying disease, premature birth, miscarriage, and intrauterine growth restriction. Maternal lupus nephritis increases the risk of hypertension and pre-eclampsia/eclampsia. Passage of maternal autoantibodies across the placenta may result in adverse neonatal outcomes, including neonatal lupus and congenital heart block.

#### Lactation

##### Risk Summary

No data are available regarding the presence of Saphnelo in human milk, the effects on the breastfed child, or the effects on milk production. Anifrolumab-fnia was detected in the milk of female cynomolgus monkeys administered anifrolumab-fnia. Due to species-species differences in lactation physiology, animal data may not reliably predict drug levels in humans. Maternal IgG is known to be present in human milk. If anifrolumab-fnia is transferred into human milk, the effects of local gastrointestinal exposure and limited systemic exposure in the breastfed infant to anifrolumab-fnia are unknown.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for anifrolumab-fnia and any potential adverse effects on the breastfed child from anifrolumab-fnia or from the underlying maternal condition.

#### Pediatric Use

The safety and efficacy of Saphnelo in pediatric patients less than 18 years of age have not been established.

#### Geriatric Use

Of the 664 patients with SLE exposed to anifrolumab-fnia in clinical trials, 3% (n=20) were 65 and over. The number of patients aged 65 years of age and older was not sufficient to determine whether they respond differently from younger adult patients.

### CLINICAL STUDIES

The safety and efficacy of Saphnelo were evaluated in three 52-week treatment period, multicenter, randomized, double-blind, placebo-controlled studies (Trial 1 [NCT01438489], Trial 2 [NCT02446912] and Trial 3 [NCT02446899]). Patients were diagnosed with SLE according to the American College of Rheumatology (1982 revised) classification criteria. All patients were  $\geq 18$  years of age and had moderate to severe disease, with a SLE Disease Activity Index 2000 (SLEDAI-2K) score  $\geq 6$  points, organ level involvement based on BILAG assessment, and a Physician's Global Assessment [PGA] score  $\geq 1$ , despite receiving standard SLE therapy consisting of either one or any combination of oral corticosteroids (OCS), antimalarials, and/or immunosuppressants at baseline. Patients continued to receive their existing SLE therapy at stable doses during the clinical trials, with the exception of OCS (prednisone or equivalent) where tapering was

a component of the protocol. Patients who had severe active lupus nephritis and patients who had severe active central nervous system lupus were excluded. The use of other biologic agents and cyclophosphamide were not permitted during the trials; patients receiving other biologic therapies were required to complete a wash-out period of at least 5 half-lives prior to enrollment. All three studies were conducted in North America, Europe, South America, and Asia. Patients received anifrolumab-fnia or placebo, administered by intravenous infusion, every 4 weeks.

Efficacy of Saphnelo was established based on assessment of clinical response using the composite endpoints, the British Isles Lupus Assessment Group based Composite Lupus Assessment (BICLA), and the SLE Responder Index (SRI-4).

BICLA response at Week 52 was defined as improvement in all organ domains with moderate or severe activity at baseline:

- Reduction of all baseline BILAG A to B/C/D and baseline BILAG B to C/D, and no BILAG worsening in other organ systems, as defined by  $\geq 1$  new BILAG A or  $\geq 2$  new BILAG B;
- No worsening from baseline in SLEDAI-2K, where worsening is defined as an increase from baseline of  $>0$  points in SLEDAI-2K;
- No worsening from baseline in patients' lupus disease activity, where worsening is defined by an increase  $\geq 0.30$  points on a 3-point PGA VAS;
- No discontinuation of treatment;
- No use of restricted medication beyond the protocol-allowed threshold.

SRI-4 response was defined as meeting each of the following criteria at Week 52 compared with baseline:

- Reduction from baseline of  $\geq 4$  points in the SLEDAI-2K;
- No new organ system affected as defined by 1 or more BILAG A or 2 or more BILAG B items compared to baseline;
- No worsening from baseline in the patients' lupus disease activity defined by an increase  $\geq 0.30$  points on a 3-point PGA visual analogue scale (VAS);
- No discontinuation of treatment;
- No use of restricted medication beyond the protocol-allowed threshold.

Trial 1 randomized 305 patients (1:1:1) who received anifrolumab-fnia, 300 mg or 1000 mg, or placebo for up to 52 weeks. The primary endpoint was a combined assessment of the SRI-4 and the sustained reduction in OCS ( $<10$  mg/day and  $\leq$ OCS dose at week 1, sustained for 12 weeks) measured at Week 24.

Trial 2 and 3 were similar in design. Trial 2 randomized 457 patients who received anifrolumab-fnia 150 mg, 300 mg or placebo (1:2:2). Trial 3 randomized 362 patients (1:1) who received anifrolumab-fnia 300 mg or placebo. The primary endpoints were improvement in disease activity evaluated at 52 weeks, measured by SRI-4 in Trial 2 and BICLA in Trial 3 (defined above). The common secondary efficacy endpoints

[\*continues on page 37\*](#)



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

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*Clin Infect Dis.* 2021 Aug 16;73(4):680-688. doi: 10.1093/cid/ciab122.

[Baseline neurocognitive impairment \(NCI\) is associated with incident frailty but baseline frailty does not predict incident NCI in older persons with human immunodeficiency virus \(HIV\)](#)

Masters MC, Perez J, Wu K, et al.

**BACKGROUND:** Neurocognitive impairment (NCI) and frailty are more prevalent among persons with human immunodeficiency virus (HIV, PWH) compared to those without HIV. Frailty and NCI often overlap with one another. Whether frailty precedes declines in neurocognitive function among PWH or vice versa has not been well established.

**METHODS:** AIDS Clinical Trials Group (ACTG) A5322 is an observational cohort study of older PWH. Participants undergo annual assessments for NCI and frailty. ACTG A5322 participants who developed NCI as indexed by tests of impaired executive functioning and processing speed during the first 3 years were compared to persons who maintained normal cognitive function; those who demonstrated resolution of NCI were compared to those who had persistent NCI. Participants were similarly compared by frailty trajectory. We fit multinomial logistic regression models to assess associations between baseline covariates (including NCI) and frailty, and associations between baseline covariates (including frailty) and NCI.

**RESULTS:** In total, 929 participants were included with a median age of 51 years (interquartile range [IQR] 46-56). At study entry, 16% had NCI, and 6% were frail. Over 3 years, 6% of participants developed NCI; 5% developed frailty. NCI was associated with development of frailty (odds ratio [OR] = 2.06; 95% confidence interval [CI] = .94, 4.48;  $P = .07$ ). Further adjustment for confounding strengthened this association (OR = 2.79; 95% CI = 1.21, 6.43;  $P = .02$ ). Baseline frailty however was not associated with NCI development.

**CONCLUSIONS:** NCI was associated with increased risk of frailty, but frailty was not associated with development of NCI. These findings suggest that the presence of NCI in PWH should prompt monitoring for the development of frailty and interventions to prevent frailty in this population.

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*Clin Infect Dis.* 2021 Aug 19;ciab712. doi: 10.1093/cid/ciab712. Online ahead of print.

[Deconstructing the treatment effect of remdesivir in the adaptive COVID-19 treatment Trial-1: implications for critical care resource utilization](#)

Fintzi J, Bonnett T, Sweeney DA, et al.

**BACKGROUND:** The Adaptive COVID-19 Treatment Trial-1 (ACTT-1) found that remdesivir therapy hastened recovery in patients hospitalized with COVID-19, but the pathway for this improvement was not explored. We investigated how the dynamics of clinical progression changed along 4 pathways: recovery, improvement in respiratory therapy requirement, deterioration in respiratory therapy requirement, and death.

**METHODS:** We analyzed trajectories of daily ordinal severity scores reflecting oxygen requirements of 1051 patients hospitalized with COVID-19 who participated in ACTT-1. We developed competing risks models that estimate the effect of remdesivir therapy on cumulative incidence of clinical improvement and deterioration, and multistate models that utilize the entirety of each patient's clinical course to characterize the effect of remdesivir on progression along the 4 pathways above.

**RESULTS:** Based on a competing risks analysis, remdesivir reduced clinical deterioration (hazard ratio, 0.73; 95% CI, 0.59-0.91) and increased clinical improvement (hazard ratio, 1.22; 95% CI, 1.08, 1.39) relative to baseline. Our multistate models indicate that remdesivir inhibits worsening to ordinal scores of greater clinical severity among patients on room air or low-flow oxygen (hazard ratio, 0.74; 95% CI, 0.57-0.94) and among patients receiving mechanical ventilation or high-flow oxygen/noninvasive positive-pressure ventilation (hazard ratio, 0.73; 95% CI, 0.53-1.00) at baseline. We also find that remdesivir reduces expected intensive care respiratory therapy utilization among patients not mechanically ventilated at baseline.

**CONCLUSIONS:** Remdesivir speeds time to recovery by preventing worsening to clinical states that would extend the course of hospitalization and increase intensive respiratory support, thereby reducing the overall demand for hospital care.

*Clin Infect Dis*. 2021 Aug 16;73(4):e1018-e1028. doi: 10.1093/cid/ciab029.

### [A systematic review and network meta-analyses to assess the effectiveness of human immunodeficiency virus \(HIV\) self-testing distribution strategies](#)

Wilson-Eshun I, Jamil MS, Witzel TC, et al.

**BACKGROUND:** We conducted a systematic review and network meta-analysis to identify which human immunodeficiency virus (HIV) self-testing (HIVST) distribution strategies are most effective.

**METHODS:** We abstracted data from randomized controlled trials and observational studies published between 4 June 2006 and 4 June 2019.

**RESULTS:** We included 33 studies, yielding 6 HIVST distribution strategies. All distribution strategies increased testing uptake compared to standard testing; in sub-Saharan Africa, partner HIVST distribution ranked highest (78% probability); in North America, Asia, and the Pacific regions, web-based distribution ranked highest (93% probability), and facility based distribution ranked second in all settings. Across HIVST distribution strategies HIV positivity and linkage was similar to standard testing.

**CONCLUSIONS:** A range of HIVST distribution strategies are effective in increasing HIV testing. HIVST distribution by sexual partners, web-based distribution, as well as health facility distribution strategies should be considered for implementation to expand the reach of HIV testing services.

*Hepatology*. 2021 Aug 13. doi: 10.1002/hep.32111. Online ahead of print.

### [Interferon drives hepatitis C virus scarring of the epigenome and creates targetable vulnerabilities following viral clearance](#)

Hlady RA, Zhao X, El Khoury LY, et al.

**BACKGROUND & AIMS:** Chronic hepatitis C viral (HCV) infection is a leading etiologic driver of cirrhosis and ultimately hepatocellular carcinoma (HCC). Of the approximately 71 million individuals chronically infected with HCV, 10-20% are expected to develop severe liver complications in their lifetime. Epigenetic mechanisms including DNA methylation and histone modifications become profoundly disrupted in disease processes including liver disease.

**METHODS:** To understand how HCV infection influences the epigenome and whether these events remain as 'scars' following cure of chronic HCV infection, we mapped genome-wide DNA methylation, four key regulatory histone modifications (H3K4me3, H3K4me1, H3K27ac, and H3K27me3) and open chromatin by ATAC-seq in parental and HCV-infected immortalized hepatocytes and the Huh7.5

HCC cell line, along with DNA methylation and gene expression analyses following elimination of HCV in these models through treatment with interferon- $\alpha$  or a direct-acting antiviral (DAA).

**RESULTS:** Our data demonstrate that HCV infection profoundly impacts the epigenome (particularly enhancers), HCV shares epigenetic targets with interferon- $\alpha$  targets, an overwhelming majority of epigenetic changes induced by HCV remain as 'scars' on the epigenome following viral cure. Similar findings are observed in primary human patient samples cured of chronic HCV infection. Supplementation of interferon- $\alpha$ /DAA antiviral regimens with DNA methyltransferase inhibitor 5-aza-2'-deoxycytidine synergizes in reverting aberrant DNA methylation induced by HCV. Finally, both HCV-infected and cured cells displayed a blunted immune response, demonstrating a functional effect of epigenetic scarring.

**CONCLUSIONS:** Integration of epigenetic and transcriptional data elucidates key gene deregulation events driven by HCV infection and how this may underpin the long-term elevated risk for HCC in patients cured of HCV due to epigenome scarring.

*Hypertension*. 2021 Aug 15;HYPERTENSIONAHA12116506. doi: 10.1161/HYPERTENSIONAHA.121.16506. Online ahead of print.

### [Long-term cardiovascular disease risk in women after hypertensive disorders of pregnancy: recent advances in hypertension](#)

Khosla K, Heimberger S, Nieman KM, et al.

Patients with a history of hypertensive disorders of pregnancy (HDP) suffer higher rates of long-term cardiovascular events including heart failure, coronary artery disease, and stroke. Cardiovascular changes during pregnancy can act as a natural stress test, subsequently unmasking latent cardiovascular disease in the form of HDP. Because HDP now affect 10% of pregnancies in the United States, the American Heart Association has called for physicians who provide peripartum care to promote early identification and cardiovascular risk reduction. In this review, we discuss the epidemiology, pathophysiology, and outcomes of HDP-associated cardiovascular disease. In addition, we propose a multi-pronged approach to support cardiovascular risk reduction for women with a history of HDP. Additional research is warranted to define appropriate blood pressure targets in the postpartum period, optimize the use of pregnancy history in risk stratification tools, and clarify the effectiveness of preventive interventions. The highest rates of HDP are in populations with poor access to resources and quality health care, making it a major risk for inequity of care. Interventions to decrease long-term cardiovascular disease risk in women following HDP must also target disparity reduction.

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**Clin Transplant.** 2021 Aug 16. doi: 10.1111/ctr.14458. Online ahead of print.

[Changes in waitlist and posttransplant outcomes in patients with adult congenital heart disease after the new heart transplant allocation system](#)

Kainuma A, Ning Y, Kurlanksy PA, et al.

**OBJECTIVE:** In 2018, the United Network for Organ Sharing (UNOS) introduced new criteria for heart allocation. This study sought to assess the impact of this change on waitlist and posttransplant outcomes in adult congenital heart disease (ACHD) recipients.

**METHODS:** Between January 2010 and March 2020, we extracted first heart transplant ACHD patients listed from the UNOS database. We compared waitlist and post-transplant outcomes before and after the policy change.

**RESULTS:** A total of 1206 patients were listed, 951 under the old policy and 255 under the new policy. Prior to transplant, recipients under the new policy era were more likely to be treated with extracorporeal membrane oxygenation ( $p=0.018$ ), and have intra-aortic balloon pumps ( $p<0.001$ ), and less likely to have left ventricular assist devices ( $p=0.027$ ). Compared to patients waitlisted in the pre-policy change era, those waitlisted in the post policy change era were more likely to receive transplants ( $p=0.001$ ) with no significant difference in waiting list mortality ( $p=0.267$ ) or delisting ( $p=0.915$ ). There was no difference in 1-year survival post-transplant between the groups ( $p=0.791$ ).

**CONCLUSION:** The new policy altered the heart transplant cohort in the ACHD group, allowing them to receive transplants earlier with no changes in early outcomes after heart transplantation.

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**Acad Emerg Med.** 2021 Aug 17. doi: 10.1111/acem.14376. Online ahead of print.

[COVID-19 vaccine hesitancy among patients in two urban emergency departments](#)

Fernández-Penny FE, Jolkovsky EL, Shofer FS, et al.

**BACKGROUND:** Widespread vaccination is an essential component of the public health response to the COVID-19 pandemic, yet vaccine hesitancy remains pervasive. This prospective survey investigation aimed to measure the prevalence of vaccine hesitancy in a patient cohort at two urban Emergency Departments (EDs) and characterize underlying factors contributing to hesitancy.

**METHODS:** Adult ED patients with stable clinical status (Emergency Severity Index 3-5) and without active COVID-19 disease or altered mental status were considered for participation. Demographic elements were collected, as well as reported barriers/concerns related to vaccination and trusted sources of health

information. Data were collected in-person via a survey instrument proctored by trained research assistants.

**RESULTS:** 1,555 patients were approached, and 1,068 patients completed surveys (completion rate 68.7%). Mean age was 44.1 y (SD 15.5, range 18-93), 61% were female, and 70% were Black. 31.6% of ED patients reported vaccine hesitancy. Of note, 19.7% of the hesitant cohort were healthcare workers. In multivariable regression analysis, Black race (OR 4.24, 95%CI 2.62-6.85) and younger age (age 18-24 y, OR 4.57, 95%CI 2.66-7.86; age 25-35 y, OR 5.71, 95% CI 3.71-8.81) were independently associated with hesitancy, to a greater degree than level of education (high school education or less, OR 2.27, 95%CI 1.23-4.19). Hesitant patients were significantly less likely to trust governmental sources of vaccine information than non-hesitant patients (39.6% vs 78.9%,  $p<0.001$ ); less difference was noted in the domain of trust towards friends/family (51.1% vs. 61.0%,  $p=0.004$ ). Hesitant patients also reported perceived vaccine safety concerns and perceived insufficient research.

**CONCLUSIONS:** Vaccine hesitancy is common among ED patients, and more common among Black and younger patients, independent of education level. Hesitant patients report perceived safety concerns and low trust in government information sources, but less so friends or family. This suggests strategies to combat hesitancy may need tailoring to specific populations.

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**N Engl J Med.** 2021 Jul 29;385(5):416-426. doi: 10.1056/NEJMoa2100165.

[Long-term complications in youth-onset type 2 diabetes](#)

TODAY Study Group; Bjornstad P, Drews KL, Caprio S, et al.

**BACKGROUND:** The prevalence of type 2 diabetes in youth is increasing, but little is known regarding the occurrence of related complications as these youths transition to adulthood.

**METHODS:** We previously conducted a multicenter clinical trial (from 2004 to 2011) to evaluate the effects of one of three treatments (metformin, metformin plus rosiglitazone, or metformin plus an intensive lifestyle intervention) on the time to loss of glycemic control in participants who had onset of type 2 diabetes in youth. After completion of the trial, participants were transitioned to metformin with or without insulin and were enrolled in an observational follow-up study (performed from 2011 to 2020), which was conducted in two phases; the results of this follow-up study are reported here. Assessments for diabetic kidney disease, hypertension, dyslipidemia, and nerve disease were performed annually, and assessments for retinal disease were performed twice. Complications related to diabetes identified outside the study were confirmed and adjudicated.

**RESULTS:** At the end of the second phase of the follow-up study (January 2020), the mean ( $\pm$ SD) age of the 500 participants

who were included in the analyses was 26.4±2.8 years, and the mean time since the diagnosis of diabetes was 13.3±1.8 years. The cumulative incidence of hypertension was 67.5%, the incidence of dyslipidemia was 51.6%, the incidence of diabetic kidney disease was 54.8%, and the incidence of nerve disease was 32.4%. The prevalence of retinal disease, including more advanced stages, was 13.7% in the period from 2010 to 2011 and 51.0% in the period from 2017 to 2018. At least one complication occurred in 60.1% of the participants, and at least two complications occurred in 28.4%. Risk factors for the development of complications included minority race or ethnic group, hyperglycemia, hypertension, and dyslipidemia. No adverse events were recorded during follow-up.

**CONCLUSIONS:** Among participants who had onset of type 2 diabetes in youth, the risk of complications, including microvascular complications, increased steadily over time and affected most participants by the time of young adulthood. Complications were more common among participants of minority race and ethnic group and among those with hyperglycemia, hypertension, and dyslipidemia.

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**BMC Cancer.** 2021 Aug 13;21(1):917. doi: 10.1186/s12885-021-08651-5.

### [Sniffer dogs can identify lung cancer patients from breath and urine samples](#)

Feil C, Staib F, Berger MR, et al.

**BACKGROUND:** Lung cancer is the most common oncological cause of death in the Western world. Early diagnosis is critical for successful treatment. However, no effective screening methods exist. A promising approach could be the use of volatile organic compounds as diagnostic biomarkers. To date there are several studies, in which dogs were trained to discriminate cancer samples from controls. In this study we evaluated the abilities of specifically trained dogs to distinguish samples derived from lung cancer patients of various tumor stages from matched healthy controls.

**METHODS:** This single center, double-blind clinical trial was approved by the local ethics committee, project no FF20/2016. The dog was conditioned with urine and breath samples of 36 cancer patients and 150 controls; afterwards, further 246 patients were included: 41 lung cancer patients comprising all stages and 205 healthy controls. From each patient two breath and urine samples were collected and shock frozen. Only samples from new subjects were presented to the dog during study phase randomized, double-blinded. This resulted in a specific conditioned reaction pointing to the cancer sample.

**RESULTS:** Using a combination of urine and breath samples, the dog correctly predicted 40 out of 41 cancer samples, corresponding to an overall detection rate of cancer samples of 97.6%

(95% CI [87.1, 99.9%]). Using urine samples only the dog achieved a detection rate of 87.8% (95% CI [73.8, 95.9%]). With breath samples, the dog correctly identified cancer in 32 of 41 samples, resulting in a detection rate of 78% (95% CI [62.4, 89.4%]).

**CONCLUSIONS:** It is known from current literature that breath and urine samples carry VOCs pointing to cancer growth. We conclude that olfactory detection of lung cancer by specifically trained dogs is highly suggestive to be a simple and non-invasive tool to detect lung cancer. To translate this approach into practice further target compounds need to be identified.

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**Clin Nephrol.** 2021 Aug 17. doi: 10.5414/CN110523. Online ahead of print.

### [Impact of obesity on vascular calcification in patients with chronic kidney disease](#)

Uhlirnova J, Kuudeberg A, Denisova A, et al.

**AIM:** The aim of this study was to compare vascular calcification (VC) in obese and non-obese chronic kidney disease (CKD) patients, using three methods for measuring VC.

**MATERIALS AND METHODS:** The study included 168 consecutive patients with CKD. Patients were divided into two groups by body mass index (BMI) - group 1 (BMI ≥ 30 kg/m<sup>2</sup>) and group 2 (BMI < 30 kg/m<sup>2</sup>), and according to estimated glomerular filtration rate (eGFR) - subgroup A (eGFR ≥ 45 mL/min/1.73m<sup>2</sup>) and subgroup B (eGFR < 45 mL/min/1.73m<sup>2</sup>). VC was assessed by measuring abdominal aortic calcification (AAC), ankle-brachial index (ABI) and echocardiography.

**RESULTS:** Group 1 patients were older (p = 0.03). There was a relatively low number of diabetics in our study cohort: 41 patients, (24%). The number of diabetics was similar in both groups. The presence of AAC was more common in 1B and 2B than in 1A and 2A groups (p = 0.005 and p = 0.02) and in 1B group compared to 2B group (p = 0.05). In both groups, ABI ≥ 1.3 and ABI < 0.9 were more common in B subgroups. The presence of heart valvular lesions was very high in both groups. Spearman rank-order analysis of every cohort demonstrated significant correlation between AAC and heart valve lesions (Spearman R = 0.3; p = 0.01) and also between AAC and LVH (Spearman R = 0.3; p = 0.004). Analysis of variance of every cohort showed that in patients with ABI ≥ 1.3 and heart valve lesions, Kauppila score was significantly higher than in those with normal heart valves.

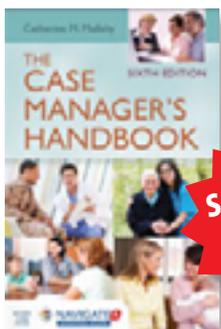
**CONCLUSION:** Our study shows that obesity is not an independent predictor of VC in CKD patients. VC, assessed by three different methods, was more pronounced in obese patients with lower kidney function. ■



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**Path to Health: In Support of a Plant-Based Diet***continued from page 13*

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**Medical Cannabis: Ethical and Legal Implications for Care Managers—Part II** *continued from page 24*

Care managers may find that the world of cannabis is complex but fascinating. There are ample opportunities among all disciplines to engage in discussion and research, to improve safety, and to enhance customer-client-stakeholder engagement. Care managers, who are already adept at handling complex tasks and deciphering multiple data while navigating clients through difficult topics and complex issues, may be integral and powerful team members for the safe and effective use of medical cannabis. **CE III**

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## Health Care Leadership in the Postpandemic Era *continued from page 5*

Director role at CARF and to contribute to these articles. As a CARF surveyor for 10 years, I'm been able to see how CARF accreditation helps organizations elevate their care and commitment to quality to a higher level. During my 20-year career at Kessler Institute for Rehabilitation in West Orange, New Jersey, and at Select Medical, I bore witness to the critical role that case management plays on the interdisciplinary team. At Kessler/Select I was a clinician (PT), a clinical manager, and an educator. As my work transitioned to support Select's 30 inpatient rehabilitation hospitals, my role shifted to focus on developing and

delivering clinical and leadership educational content and preparing rehabilitation programs to attain and achieve CARF accreditation.

CARF and case management are both historical agents of change, and the world that we live and work in continues to require that we are responsive to a dynamic and everchanging landscape. Beginning in September, CARF will begin offering on-site surveys once again. Recognizing that conditions on the ground may require an alternative, the Digitally Enabled Site Survey will continue to be an option for organizations undergoing surveys. This versatility will ensure that organizations and programs will continue to receive a meaningful and consultative survey experience whether it is an on-site or

virtual process. Regardless of the format, CARF has made a shift to using the Microsoft Teams platform to house documents that organizations use to demonstrate conformance. Gone are the days of overflowing 3 ring binders and rolling file carts, and I suspect that there are many in the field who will not miss those relics.

Case management is the common clinical thread that can be found in every section of CARF standards, and the advocacy and guidance that patients and family members receive from case managers is an indispensable part of the rehabilitation process. If you are interested in receiving more information about CARF accreditation in your setting, contact Terry Carolan at [tcarolan@carf.org](mailto:tcarolan@carf.org). 

## Ready, Set, Go—Time!

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waking to the clear realization of their importance, case managers have been fully aware of the challenges posed to our patients in receiving the best care possible. Case managers have taken on these challenges head-on, stepping into new roles when needed, and succeeding every step of the way.

I'd like to pause here and take a moment—and what better time than during Case Management Appreciation Month—to recognize the perseverance, compassion, and pure dedication of our case management community across all care settings. Thank you for being selfless, tireless, and fearless in pursuit of positive health outcomes for all our patients. The work you do is important and does not go unnoticed. On behalf of CMSA, please accept our eternal gratitude and appreciation for tackling the challenges of the past year.

And like you, we are also “ready to go.” CMSA has connected with many, collaborated with others, and found a way to strengthen the case management community such that healthcare professionals can continue to make a difference in the lives of patients and their families. Thanks for staking your claim, so that we at CMSA could stake ours. **CM**

## The Benefits of Professional Diversity in Case Management

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diverse backgrounds will be needed.

Equally important, case management needs to make greater strides in increasing overall diversity. The practice has been largely white and female, as the 2019 role and function study revealed. Attracting more professionals from diverse backgrounds—racial, ethnic, gender identity, age, sexual orientation, and professional discipline—will further enhance our practice. Outreach to diverse professionals opens the door to more opportunity for career advancement through case management. In addition, greater diversity ensures that case management promotes cultural affinity, which helps support satisfaction and access to care for all clients (Quick, Mann and Kurland, 2021).

Through personal and observation experiences, I have seen firsthand the importance of case management, how it shapes delivery of care, and serves to improve health outcomes. Case management is an integral function of health care. As we expand diversity of every kind across the practice, we expand our ability to connect with and serve the needs of individuals for whom we advocate. **CM**

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## Care Coordination and Integrated Case Management

[continued from page 9](#)

assignment of a LC serves as one voice for the veteran and delivers high-quality care coordination across the health care continuum. The proper alignment and use of standardized tools and processes enables case managers to coordinate veterans' care across programs and services. In turn, VHA will reduce health care utilization and increase the number of veterans served. The CC&ICM test facilities showed positive outcomes on key performance indicators that included: 1) decreased emergency department utilization, 2) decreased 30-day readmission rates, 3) decreased duplication of services, and 4) increased veterans' trust and satisfaction scores.

As the CC&ICM framework was socialized and implemented through a grassroots field-led effort, it showed positive outcomes for many vulnerable and medically complex veterans. In April 2021, the VHA Governance Board endorsed the CC&ICM framework. The newly endorsed framework is being implemented and integrated through national program offices to decrease siloed and fragmented care coordination.

The CC&ICM framework is being deployed through a phased approach with the goal of VA enterprisewide adoption of the framework within the next 18-36 months. This endorsement included human capital assets to assist facilities in the education and training of the CC&ICM framework. Subject matter experts will be identified to establish foundational milestones while building future sustainability processes in the care coordination of our nation's vulnerable veteran populations. **CM**

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included in both studies were the maintenance of OCS reduction, improvement in cutaneous SLE activity, and flare rate. During Weeks 8–40, patients with a baseline OCS  $\geq 10$  mg/day were required to taper their OCS dose to  $\leq 7.5$  mg/day unless there was worsening of disease activity. Both studies evaluated the efficacy of anifrolumab-fnia 300 mg versus placebo; a dose of 150 mg was also evaluated for dose response in Trial 2.

Patient demographics and disease characteristics were generally similar and balanced across treatment arms.

Randomization was stratified by disease severity (SLEDAI-2K score at baseline,  $< 10$  vs  $\geq 10$  points), OCS dose on Day 1 ( $< 10$  mg/day vs  $\geq 10$  mg/day prednisone or equivalent), and interferon gene signature test results (high vs low).

The reduction in disease activity seen in the BICLA and SRI-4 was related primarily to improvement in the mucocutaneous and musculoskeletal organ systems. Flare rate was reduced in patients receiving Saphnelo compared to patients who received placebo, although the difference was not statistically significant.

BICLA responder analysis: BICLA was the primary endpoint in Trial 3; anifrolumab-fnia 300 mg demonstrated statistically significant and clinically meaningful efficacy in overall disease activity compared with placebo, with greater improvements in all components of the composite endpoint. In Trial 1 and 2 BICLA was a prespecified analysis.

In Trial 3, examination of subgroups by age, race, gender, ethnicity, disease severity [SLEDAI-2K at baseline], and baseline OCS use did not identify differences in response to anifrolumab-fnia.

SRI-4 responder analysis: SRI-4 was the primary endpoint

in Trial 2; treatment with anifrolumab-fnia did not result in statistically significant improvements over placebo. In Trials 1 and 3, SRI-4 was a prespecified analysis

Effect on Concomitant Steroid Treatment: In Trial 3, among the 47% of patients with a baseline OCS use  $\geq 10$  mg/day, anifrolumab-fnia demonstrated a statistically significant difference in the proportion of patients able to reduce OCS use by at least 25% to  $\leq 7.5$  mg/day at Week 40 and maintain the reduction through Week 52 (p value = 0.004); 52% (45/87) of patients in the anifrolumab-fnia group versus 30% (25/83) in the placebo achieved this level of steroid reduction (difference 21% [95% CI 6.8, 35.7]). Consistent trends in favor of anifrolumab-fnia compared to placebo, on effect of reduction of OCS use, were observed in Trial 1 and 2, but the difference was not statistically significant.

#### HOW SUPPLIED/STORAGE AND HANDLING

Saphnelo (anifrolumab-fnia) injection is a sterile, preservative-free, clear to opalescent, colorless to slightly yellow solution for intravenous infusion. It is packaged in a 2 mL clear glass vial containing 300 mg/2 mL (150 mg/mL) of anifrolumab-fnia.

Saphnelo is available in a carton containing one single-dose vial (NDC-0310-3040-00). Store in a refrigerator at 36°F to 46°F (2°C to 8°C) in the original carton to protect from light.

Do not shake or freeze.

For full prescribing information, please see product insert.

Saphnelo is manufactured and distributed by AstraZeneca Pharmaceuticals. 

### Medical Cannabis: Ethical and Legal Implications for Care Managers—

#### Part II *continued from page 34*

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### Improving Transitions of Care

#### *continued from page 2*

a lot of work associated with transitioning a patient from one level of care or setting to another. Case managers have available checklists, toolboxes, and other resources to remind them that everything has been done to ensure a smooth transition of care. The key is to use the available resources.

In the August/September issue of *CareManagement*, we published “Issues and Considerations of Transition of Care and the Seven Essential Elements of Care Transition Bundle” by Cheri Lattimer, RN, BSN, Executive Director of the National Transitions of Care Coalition. In this issue of

*CareManagement*, we are publishing “Transitions of Care Issues in the COVID-19 Pandemic: Focus on the Long-Term Care Setting” by Jacqueline Vance, RNC, BSN, IP-BC, CDONA/LTC, CDP. Both of these articles provide valuable resources and knowledge for the case manager to improve your skills in transitions of care.

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