CareManagement

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

Vol. 30, No. 4 August/September

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Case Management Fellows – Class of 2024; Explaining Case Management

Case Management Fellows

The 2024 class of Case Management Fellows was announced in June at the Annual CMSA Conference. Fellows are case managers who have made a significant contribution to the professional practice of case management through leadership, practice, research, and education. Fellows are influencers, visionaries, strategic thinkers, recognized leaders, and ambassadors. Congratulations to the Class of 2024!

CMSA Case Management Fellows – Class of 2024

Michele O'Brien, MSW, LCSW, CCM, FCM Laura Ostrowsky, RN, CCM, FCM Lisa Simmons-Fields, DNP, RN, CCM, CPHQ, FCM

Samantha Walker, DNP, RN, CCM, FCM

Explaining Case Management

You are probably regularly confronted with the question: What do you do? This question comes from almost everyone: patients, families, health care providers, other people you work with and your family and friends. If you say you are a registered nurse, social worker, or other recognized health professional, people have a pretty good understanding of what you do-but not when you introduce yourself as a case manager. You know what you do, but much of the universe is still wondering. There are some good reasons why people don't understand case management. There is significant terminological variation in case management—for example, even in your title. You might be called a case manager, a patient

care coordinator, a care manager, a discharge planner, a navigator, and the list continues. There is lack of a common language in case management. Case managers operate in different settings. Case managers come from many different disciplines. There are different case management models and theories. All of this adds to the confusion when people try to understand what you do as a case manager.

You know as a case manager what you do. You know you make a difference in people's lives and have an impact on the health care system regardless of your practice setting. You assess, plan, coordinate, evaluate, advocate, and document to meet your patient's needs. The process is the same with every patient, but each patient's needs have many nuances.

The Case Management Society of American Public Information Committee has been addressing the problem of how we explain case management and what case managers do. I have been fortunate to be a member of the Public Information Committee. The Committee has developed 2 fact sheets to help you, the case manager, explain case management. Each fact sheet is intended for a specific audience. The Fact Sheet: Case Management at a Glance is intended to be used to help educate the consumer—patients and families. It is a 1-page fact sheet that talks about what case management is, who case managers are, how a case manager has helped others, how a case manager can help the patient, and how to find a case manager. I see a real practical

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Vol. 30, No. 4, August/September 2024. CareManagement (ISSN #1531-037X) is published electronically six times a year, February, April, June, August, October, and December, and its contents are copyrighted by Academy of Certified Case Managers, 2740 SW Martin Downs Blvd. #330, Palm City, FL 34990; Tel: 203-454-1333; Fax: 203-547-7273.

Subscription rates: \$130 per year for ACCM members; \$150 for institutions.

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CareManagement is indexed in the CINAHL®

Database and Cumulative Index to Nursing & Allied
Health Literature™ Print Index and in RNdex.™

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Catherine M. Mullahy

Navigating Remote Case Management

By Catherine M. Mullahy, RN, BS, CRRN, CCM, FCM

he nursing shortage is something the US and many other nations have been experiencing for many years. The pandemic exacerbates the problem, prompting many exhausted, overworked, and emotionally drained health care professionals to leave their positions. Countless surveys and studies have attempted to document just how bad the shortages are and will become...

- The American Nurses Association reported that more registered nurse (RNs) jobs would be available than any other profession in the US.
- An AMN Healthcare survey found that 72% of nurse leaders say they are burned out, with 31% considering leaving their hospital jobs.
- The US Bureau of Labor Statistics projects that over 275,000 nurses would be needed by 2030 and that employment opportunities would grow at a faster rate than any other profession through 2026.
- The National Council of State Boards of Nursing's (NCSBN) data found that 100,000 nurses left the workforce during the pandemic and by 2027, almost 900,000, or almost one-fifth of 4.5 million total registered nurses, intend to leave the workforce, threatening the national health care system at large if solutions are not enacted.
- In its 2023 State of Nursing survey, nurse.org found that 91% of nurses believe the nursing shortage is getting worse.

As a result of current and projected

By leveraging today's advanced medical technologies, including AI and its predictive analytics, health care providers can rely on remote case management as a cost-effective, patient-centered care approach.

nurse shortages, many health care providers have turned to contracting remote nurses/nurse case managers to perform a wide range of functions. For nurse case managers, this trend offers a new and likely more flexible career path. It does, however, require the ability to meet related challenges and adopt approaches that help achieve quality patient care and outcomes.

Nursing Shortage Drivers

Current market conditions are further driving nurse shortages and the greater use of remote case management. Our population is getting older and with that comes more medical conditions. Unfortunately, the incidence of patients with comorbidities is also rising along with a growing number of Americans with complex, critical illnesses such as cancer, chronic obstructive pulmonary disease, diabetes, heart disease, and more. Another factor that is fueling the nursing shortage is the lack of qualified nurse educators, coupled with diminishing educational resources, which many nursing schools are currently experiencing. Of course, the pandemic was a major cause of so many health care professionals leaving their job due to burnout from that experience. Baby boomer RNs have

already retired or will be retiring soon, thereby widening the gap between nurses needed and availability.

Remote Nurse Case Management

What many case managers may not know is remote case management, also referred to a remote patient monitoring (RPM), dates back to the 19th century. Over the years, it has evolved considerably in both home- and community-based models. The development of telecommunications made it possible for RNs/case managers and other health care providers to reach patients in various settings (eg, at home, in community-based programs, hospitals). More recently, the introduction and ongoing advancement of telemedicine has further supported the growth of remote case management. For example, the Veterans Affairs (VA): the VA case managers developed a program that provides veterans with personalized patient education and monitoring and feedback using a remote disease management and clinical team approach buoyed by telehealth technology.

Although the VA program was developed over a decade ago, there has since been the introduction of many new

A Career Path into Disability Management: Advocating for III or Injured Employees in the Workplace

By Ed Quick, MA, MBA, CDMS

hirty years ago, I began my career in vocational rehabilitation, helping individuals with disabilities explore job opportunities and remain employed. As my career developed, I have worked in disability management and absence management, including for some of the largest companies in the US. As a Certified Disability Management Specialist (CDMS), my work encompasses the health and well-being of employees and the productivity of employers.

Today, I am the global senior leader in integrated leave, disability, and time away for a large technology company. I am also the immediate past chair of the Commission for Case Manager Certification (CCMC), which administers both the Certified Case Manager (CCM) and the CDMS certification



Ed Quick, MA, MBA, CDMS, is the immediate past chair of the Commission for Case Manager Certification, the first and largest nationally accredited organization that

certifies more than 50,000 professional case managers and disability management specialists. The Commission oversees the process of case manager certification with its CCM® credential and disability management specialist certification with its CDMS® credential. With nearly 30 years of experience in disability and workforce management, he is currently a global senior benefits manager for a Fortune 100 company.

I saw that it isn't enough for employees to receive treatment to improve their health. They also need advocacy and support to return to work after recuperation and recovery, or to stay at work whenever possible through the healing process.

examinations.

Looking back, my earliest influence was that of my parents, who both worked for a large company in our small hometown. I clearly remember an event my dad went through as a manager at that company. One of his direct reports struggled with alcohol abuse, which impacted his work. Under the company's health plan, the employee was able to receive treatment, but when the employee came back from the recovery program, the company let him go for having been under the influence while on the job, which was a policy violation.

These were the days before the Americans with Disabilities Act (ADA) and Family and Medical Leave Act (FMLA)—and the job protections they offer. The employee had no recourse.

My dad was unhappy with these actions and argued with upper management over how this employee had been treated. "This kind of practice isn't good for the employee or for the company," I can remember my dad saying. We discussed this at some length as he engaged in soul-searching over whether management was the right fit for him. Eventually, he decided to exit management but finished a 30-year career with

the company as an independent contributor.

Reflecting on my dad's experience as a manager who could not save the job of a valued employee, I can see it had a profound impact on me. Long before I ever entered the vocational rehabilitation field or even heard the term *disability management*, I saw that it isn't enough for employees to receive treatment to improve their health. They also need advocacy and support to return to work after recuperation and recovery, or to stay at work whenever possible through the healing process.

Entering the Field

After graduating college with a psychology degree, I went to graduate school where I got a degree in vocational rehabilitation counseling. While waiting for the next opportunity, I was teaching an exercise class on the side. One of my students approached me and, knowing my background, suggested I apply for a job in the human resources department of her employer—a financial services organization that provided mortgage financing. I applied and was given an interview but was not hired. When I asked for

A Career Path into Disability Management: Advocating for Ill or Injured Employees in the Workplace continued from page 5

feedback to learn what I could have done better or differently, I was told that the other candidate had an MBA.

That sealed it for me. I went back to school, getting an MBA in HR and finance from American University. It was the mid-1990s, and that degree opened the door for me. By this time, the ADA and FMLA were among the regulatory changes that employers had to navigate and employees needed to understand.

My career path led to implementing return-to-work and stay-at-work programs that help employees who are ill, injured, or have disabilities stay productive. Over time, I expanded my knowledge of human resources, learning more about workforce management and administering workplace programs and policies. These experiences combined became a valuable foundation for becoming a CDMS, acting as an advocate for employees—and helping employers mitigate the cost and impact of disability and unplanned workplace absences.

I have had the good fortune of working with large companies that really step up to the plate in providing generous, competitive benefits to their workforce. At the same time, however, the complexity of federal and state-mandated leaves (which differ from state to state) can make it very hard for employers to understand and employees to utilize. Given the magnitude of that regulatory complexity, as well as the potential for overlap, employers need to ensure they are compliant with the law.

Added to those intricacies were challenges, such as the COVID-19 pandemic and its impact on the physical and mental health of employees, as well as temporary regulatory paid and

unpaid COVID leave laws. The leave and time away landscape continues to become more complex.

As I share in my personal statement on the Commission's website: "The post-COVID frontier will find us as case managers and disability management specialists navigating an undefined chronic disease course. We will have to be both creative and flexible to help both employers and employees in returning to a new and yet to be redefined world of work." In addition, new assistive technologies and advancements in treatment protocols will help more employees come back to the workplace—safely and as medically advised—in ways not considered before.

For me, this captures my passion throughout my career: helping employees return to their highest level of functioning—vocationally, financially, and socially—while pursuing their goals to achieve outcomes that are in the best interest of all.

Advocacy on the Middle Ground

From my earliest days as a vocational rehabilitation consultant, I have always tried to understand the perspectives and motivations of both the employee and the employer. By working in the middle ground, I helped both parties identify their goals and priorities and, whenever possible, arrive at accommodations and job modifications.

However, there is often a fine line between what the individual wants and what the regulations or coverage allows. This is particularly true in workers' compensation and other state-regulated programs that require specific actions, such as treatment and rehabilitation being completed in a timely manner. Often, this requires educating the employee and their support system. For example, employees may assume that their care will be covered by their regular health care benefits. What they may not realize

is that, if the underlying condition is work related, the health care insurer may reject the claim. As a result, the employee may be responsible for the cost of care and often without the benefit of negotiated rates or fee schedules that lower the cost of care.

Educating employees about the rules and their choices supports autonomy, which is a value in both disability management and case management. Autonomy means enabling people to make the decisions that best serve them by empowering them with information and knowledge of their choices.

The Case Manager-Disability Manager Partnership

Managing the personal and professional impact of an illness, injury, or disability is greatly enhanced when professional case managers and disability managers work together. Through their collaboration, a CCM and a CDMS bring complementary skill sets that address the needs of the whole person. Too often, though, instead of collaboration, there is only a handoff from the case manager who has coordinated inpatient or outpatient care to the disability manager who steps in with assistance for returning to work. This is a missed opportunity for an interprofessional approach. Ideally, when both professionals advocate for the individual, the person's goals for returning to work can be part of the care plan.

In addition, advocacy can also extend to the support system or family that is impacted by the sudden change in the person's health and ability to work. An example I've shared from earlier in my career was when an employee of a large company was critically injured while driving his personal car on the job. He suffered catastrophic injuries and was hospitalized for many weeks before dying from those injuries.

Legal Updates

By Elizabeth E. Hogue, Esq.

Imposters!

Approximately 1 year ago, the FBI and the Department of Justice conducted "Operation Nightingale," which focused on a scheme to issue fake nursing degrees at 3 schools. While still operational, the schools issued 7600 fraudulent diplomas and transcripts that were sold to aspiring nurses who paid up to \$10,000 for them but did not complete the necessary coursework. Florence Nightingale would be horrified, indeed!

These nurses are not the only imposters among us. In March, a teenager posed as a PA at several Texas hospitals. A Michigan woman currently faces 7 years in prison for using another person's identity to gain employment as a nurse.

What should providers do to identify imposters? First, they must comply with requirements in the states in which they do business. In addition, providers likely need to take actions that may include:

- Federal background checks
- Verification of all required education, licenses, and certifications
- Monthly licensure checks that may be accomplished by using bots
- Reports from patients and coworkers about anything they see that may call practitioners' licensure into question
- Frequent competency checks
- Criminal background checks
- FBI background checks

Elizabeth E. 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. • Verification of employment for the past three years.

In other words, vigilance is needed. Inevitably, despite concerted efforts by providers, imposters will slip through the cracks.

There are many implications of services provided by imposters. One is the possibility of injuries to patients. Also, providers may wonder if they are liable under the False Claims Act for services provided by unlicensed individuals.

Southern Maryland Home Health Services hired an individual as a physical therapist (PT) who was unlicensed, even though she claimed to be a fully qualified PT. She used the name of an actual licensed PT as her own and provided false references from purported former employers so she could be hired. In addition, the provider's hiring agent who interviewed the PT said that the PT was familiar with PT terminology and procedures. While she was employed, the provider did not receive any complaints about the unlicensed PT that would have put the provider on notice that she was an imposter.

Consequently, the US District Court for Maryland concluded that providers are only liable for false claims for services provided by imposters if some degree of culpability other than simply employing an imposter is attributable to employers. In other words, as long as providers comply with their internal policies and procedures and state and federal requirements and nothing occurs that puts employers on notice that staff members are imposters, it appears likely that providers will not have any liability for filing false claims for services provided by imposters.

It's scary to think about the provision of health care services by unlicensed personnel. The consequences could certainly be dire for both patients and providers. Vigilance by providers, however, will undoubtedly pay off.

Preventing Violence: More Action Items

According to a recent analysis of Bureau of Labor Statistics data, health care is one of the most dangerous places to work. Homecare field staff members who provide services on behalf of private duty agencies, hospices, Medicare-certified home health agencies, and home medical equipment (HME) companies may be especially vulnerable. Contributing to their vulnerability is the fact that they work alone on territory that may be unfamiliar and over which they have little control. Staff members certainly need as much protection as possible.

First, regardless of practice setting, management should develop a written policy of zero tolerance for all incidents of violence, regardless of source. The policy should include animals. The policy must require employees and contractors to report and document all incidents of threatened or actual violence, no matter how minor. Emphasis should be placed on both reporting and documenting. Employees must provide as much detail as possible. The policy should also include zero tolerance for visible weapons. Caregivers must be required to report the

Case Managers Are...

By Lilly Flatgard, BSN, RN, CCM

ase managers are a difficult group to describe. We take on roles like a chameleonever-changing to meet the needs that are as complex as the populations we serve. Our role is often misunderstood or even invisible to the professionals that rely on the work that we do. Our efforts are understated yet incredibly important in assisting those that would be lost through the cracks.

I have often tried explaining what I do as a case manager, but my descriptions never seem to do the profession justice. Our role is sometimes difficult to conceptualize because it falls into so many different categories and overlaps with multiple other professions. Most people I speak with are vaguely aware of the term, but most are unaware of what a case manager does. Sometimes people will ask me if I am still a nurse. I'm not at the bedside dressing wounds or administering medications. I work at a computer, and some days I stay in my pajamas all day, with Kitty slippers and all.

Despite this, I am still a nurse. To be precise, I am a nurse case manager. I am using my skills and working under a license just as I did before, only the work that I perform now is

Lilly Flatgard, BSN, RN, CCM, is a complex case manager with Kaiser Permanente of Washington. She works with a team of nurses in the outpatient setting who prioritize patient advocacy, educa-



We meet our clients where they are and connect them to where they need to be.

strictly mental and knowledge-based rather than procedural. I am using my experience and expertise to make sure that my clients are getting appropriate care, that they are taking the right steps to care for themselves, and that they know what to do when things fall apart. Of course, not all case managers are nurses. We are social workers and mental health specialists, among many other professions. We work at clinics, hospitals, and offices, and some visit clients in their homes. One thing that we all have in common is that we are first and foremost advocates for the individuals we serve. We meet our clients where they are and connect them to where they need to be.

This is not always an easy task, and few understand the nuances and complexities of what we do. Our work can be frustrating, and it sometimes leaves us feeling like we are spinning in circles. Despite this, we keep moving forward. If nothing else, case managers are patient and empathetic people. Our work draws us toward society's most vulnerable. We hold a safe space for these individuals so that they can let us know what they need without fear or inhibition. Once they are open to accepting help, a case manager can do what they do best-connect them to the care and services they need.

I believe most case managers share a set of qualities that make us

well-suited to the work that we do. Case managers are problem solvers and have an innate sense of curiosity. We will research tirelessly to find resources and think of new ways to help our clients. If we don't know the solution to a problem, then you can bet we will do all that we can to find it. We love to share our knowledge with anyone that would benefit. All case managers are educators. As a nurse, I teach my patients about their disease process, and how to manage their condition, and I teach them how to navigate health care and social systems to get the help that they need. Case managers also educate each other. Most are a wealth of knowledge and many of us have a running database in our minds of the local resources and how these can be linked to any given client in need.

Case managers are collaborators. Never in my life have I worked with a group of nurses so ready to step in and share their knowledge to help solve a problem. Our most seasoned case managers readily share what they have learned over the years yet remain open to the new ideas and concepts that come from a fresh perspective. Case managers are creatives. We spend an enormous amount of mental energy trying to come up with solutions to increasingly complex problems. There is no road map for case management and though each of us might inevitably take a different path, our goal remains the same, helping our clients get the support that they need. We are strong listeners and communicators. Though



Case Management Society of America National Conference 2024 Recap

By Colleen Morley-Grabowski, DNP, RN, CCM, CMAC, CMCN, CMGT-BC, ACM, RN, IQCI, FCM, FAACM

he Case Management Society of America (CMSA) National Conference, held in Providence, RI, from June 3-7, 2024, was a landmark event that brought together a diverse group of professionals dedicated to the practice of case management. The conference theme, "The Future of Health: Powered by Case Management," set the tone for a week of learning, networking, and professional development. The conference served as an opportunity for case managers to support their professional licensure and certification or recertification through the 79 continuing education credits that were offered.

The conference kicked off with a series of preconference workshops designed to provide intensive learning experiences in various areas of case management. These workshops covered topics such as the Annual Writer's Workshop, motivational interviewing training by Dr Bruce Berger, and bonus sessions on the topics of workplace microaggressions, the use of AI to improve discharge for patients with depression, and family and individual dynamics of brain injury.

The keynote sessions were a

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of the Case Management
Society of America National
Board of Directors and principal of Altra
Healthcare Consulting in CO).

Dr Melanie A Prince received the CMSA Lifetime Achievement Award, and Joyace Ussin was honored with the CMSA Award of Service Excellence.

highlight of the conference, featuring renowned speakers who shared their insights on the future of health care and the role of case management in improving patient outcomes. Justin Jones-Fosu, Curtis Hill, and Dr Burns Blaxall all brought their "A-Game" to inspire us to greatness—through laughter, tears, and technology.

The conference offered a variety of educational tracks and breakout sessions tailored to the diverse interests and specializations within case management. The incredible content provided by many CMSA members covered a variety of topics to fulfill these learning objectives:

- Focus on the latest evidence-based practices for managing complex clinical scenarios, including chronic disease management and behavioral health integration.
- Explore the legal and ethical dilemmas case managers face, with sessions on patient autonomy, privacy laws, and ethical decision-making frameworks.
- Examine the role of data analytics, electronic health records, and patient engagement technologies in enhancing case management practices.
- Address the latest developments in health care policy and the role of case managers as advocates for patient-centered care and health equity.

• Discuss diversity, equity, inclusion, and belonging (DEIB) concepts, implicit bias, and "medical gaslighting."

Poster presentations provided a platform for case managers to show-case their research and quality improvement projects. Attendees could browse the posters, engage with the presenters, and exchange ideas on innovative approaches to case management. And who knows...take the idea home to implement it themselves!!

And what would CMSA be without its incredible networking? Networking events were woven throughout the conference, offering attendees the chance to connect with peers, mentors, and industry leaders. The popular "Networking Roundtable" from the 2023 conference returned and was expanded to 2 separate events. The exhibit hall featured vendors showcasing the latest products and services in health care, from advanced software solutions to patient education tools.

Annual Meeting

I was thrilled to host the CMSA Annual Membership Meeting. Our first order of business was for Mindy Owen to lead us in recognizing and honoring those we lost this past year. We remember Bett Buechel, Sheila Cottle, Mary Hughes, Terry



Beyond Binary: Ethical Considerations in Caring for Transgender Youth

By Chikita Mann, MSN, RN, CCM

n today's health care landscape, the provision of quality care to transgender youth demands not only clinical expertise but also a profound commitment to ethical practice. Defined as individuals whose gender identity differs from the sex assigned to them at birth, transgender youth navigate a unique set of challenges in pursuit of affirming health care. Research estimates that almost 2% of US students identify as transgender (Pampati et al., 2021). Ethical considerations form the infrastructure on which compassionate and effective care is built, guiding health care providers in navigating the complexities of gender identity, autonomy, and societal norms.

In this article we embark on a journey to unravel the intricate web of ethical considerations inherent in providing health care for transgender youth. As society's understanding of gender evolves beyond traditional binary constructs, health care providers are tasked with navigating a complex array of ethical dilemmas and responsibilities. This introductory exploration sets the stage by defining transgender youth and contextualizing their health care needs within a broader understanding of gender identity. Moreover, it highlights the evolving understanding of gender and the imperative role of ethical considerations in guiding compassionate and inclusive care practices. Through an exploration of ethical principles, informed consent, gender-affirming care, mental health support, confidentiality, cultural competence, and advocacy, this article aims to illuminate the multifaceted ethical dimensions of caring for transgender youth and to foster a deeper understanding of the responsibilities inherent in providing affirming and respectful health care.

Defining Transgender

Transgender is a term used to describe individuals whose gender identity does not align with the sex they were assigned at birth. Gender identity refers to a deeply felt sense of being male, female, a combination of both, or neither, which may or may not correspond with the sex assigned at birth. Transgender people may identify as male, female, both, neither, or somewhere along the gender spectrum. It's crucial to understand that gender identity is distinct from sexual orientation. Being transgender is not about one's sexual orientation but rather about how one experiences and

expresses their gender.

Understanding transgender identity is essential for providing affirming and inclusive health care for transgender individuals. At its core, transgender identity refers to an individual whose gender identity differs from the sex assigned to them at birth. This misalignment between assigned sex and gender identity can lead to profound feelings of dysphoria and discomfort, underscoring the importance of acknowledging and affirming transgender identities. It's crucial to recognize the diversity within transgender communities, as gender identity is multifaceted and varies widely among individuals. Transgender communities encompass individuals with a range of gender identities, expressions, and experiences, highlighting the need for culturally competent and inclusive health care practices. Additionally, transgender youth face unique challenges, including discrimination, stigma, lack of access to affirming health care, and family rejection. These challenges can have profound effects on the mental health and well-being of transgender youth, underscoring the importance of creating supportive and affirming environments that address their unique needs and experiences.

Pubertal Development

Medical intervention for transgender youth often involves a staged approach based on pubertal development, with the goal of aligning their physical characteristics with their gender identity while minimizing the development of secondary sex characteristics that may cause distress. This staged approach typically includes the following phases:



Chikita Mann, MSN, RN, CCM, served as a Commissioner of the Commission for Case Manager Certification (CCMC). The CCMC is the first and largest nationally accredited organization that certifies case managers with its Certified Case Manager[®] (CCM®) certification. With more than 25 years of

experience in case management, Chikita is currently program manager with Empatha Care Management. Empatha delivers evidence-based biopsychosocial programs and delayed recovery solutions for injured workers, disability claimants, veterans, employers and insurers.

Through an exploration of ethical principles, informed consent, gender-affirming care, mental health support, confidentiality, cultural competence, and advocacy, this article aims to illuminate the multifaceted ethical dimensions of caring for transgender youth and to foster a deeper understanding of the responsibilities inherent in providing affirming and respectful health care.

Prepubertal Stage

Before puberty begins, transgender youth may have the option to undergo interventions to delay the onset of puberty. Puberty blockers, also known as GnRH agonists, are medications that temporarily suppress the production of sex hormones, such as estrogen and testosterone, effectively delaying the physical changes associated with puberty. This prepubertal stage provides transgender youth with additional time to explore their gender identity and make informed decisions about their future medical care without the irreversible effects of puberty (O'Connell et al., 2022).

Early Pubertal Stage

During the early stages of puberty, transgender youth may begin hormone therapy to induce the development of secondary sex characteristics consistent with their gender identity. For transgender girls (assigned male at birth, identifying as female), this may involve the administration of estrogen to promote breast development, redistribute body fat, and soften skin texture. For transgender boys (assigned female at birth, identifying as male), testosterone therapy may be initiated to deepen the voice, increase muscle mass, and promote facial and body hair growth. Hormone therapy during the early pubertal stage allows transgender youth to undergo gender-affirming changes that align with their gender identity and reduce the distress associated with developing secondary sex characteristics incongruent with their gender (O'Connell et al., 20).

Late Pubertal Stage

For transgender youth who have already undergone significant pubertal development, additional interventions may be necessary to further align their physical characteristics with their gender identity. This may include gender-affirming surgeries, such as chest masculinization or breast augmentation surgeries to modify the chest contour, or genital reconstruction surgery (bottom surgery) to align the genitals with the individual's gender identity. The timing and type of surgical interventions depends on factors such as the youth's age, medical eligibility, and individual preferences (O'Connell et al., 2022).

Masculinizing Effects in Transgender Males

The timeline of masculinizing effects in transgender males, who are assigned female at birth and undergo testosterone therapy as part of their gender-affirming care, can vary from person to person. However, there are general patterns of physical changes that typically occur over time. It's important to note that individual responses to testosterone can vary, and some effects may occur earlier or later than indicated in the timeline that follows.

First Few Months

Within the first few weeks to months of starting testosterone therapy, transgender males may experience changes in mood, energy levels, and libido. Some individuals may notice early physical changes such as increased oiliness of the skin and acne. Clitoral enlargement may begin, resulting in increased sensitivity and growth of the clitoris (Salas-Humara et al., 2019).

Three to Six Months

Facial and body hair growth may become more noticeable, with the appearance of coarse, dark hair on the face, chest, abdomen, and limbs. Voice deepening may commence, with the vocal cords thickening and the voice becoming lower in pitch. Muscle mass may start to increase, leading to changes in body composition and strength. Redistribution of body fat may begin, resulting in a more masculine distribution of fat, with decreased subcutaneous fat in the hips and thighs (Salas-Humara et al., 2019).

Six Months to One Year

Facial hair growth continues to progress, with increased density and coverage. Voice deepening typically becomes more pronounced, with further lowering of pitch and resonance. Muscle mass continues to increase, contributing to a more masculine physique. Clitoral enlargement may continue, although the rate of growth may slow down (Salas-Humara et al., 2019).

One Year and Beyond

Facial and body hair growth typically reaches its peak, although individuals may continue to see some new hair

growth over time. Voice deepening stabilizes, with the voice settling into a lower pitch and resonance. Muscle mass may continue to increase gradually, with ongoing strength gains. Changes in body fat redistribution become more apparent, resulting in a more masculine body shape. Clitoral enlargement may plateau, with some individuals experiencing further growth beyond the first year of testosterone therapy (Salas-Humara et al., 2019).

It's important for transgender males undergoing testosterone therapy to be monitored regularly by health care providers to assess for the effectiveness of treatment or for any potential adverse effects or complications, and to adjust hormone dosages as needed.

Feminizing Effects in Transgender Females

The timeline of feminizing effects in transgender females, who are assigned male at birth and undergo hormone therapy as part of their gender-affirming care, can vary from person to person. However, there are general patterns of physical changes that typically occur over time. Note, however, that individual responses to hormone therapy can vary, and some effects may occur earlier or later than indicated in this timeline:

First Few Months

Within the first few weeks to months of starting hormone therapy (typically estrogen and an anti-androgen), transgender females may experience changes in mood, energy levels, and libido. Some individuals may notice early physical changes such as softening of the skin and decreased body hair growth. Breast development may begin, with the appearance of breast buds and enlargement of the areola (Salas-Humara et al., 2019).

Three to Six Months

Breast development progresses, with continued enlargement and shaping of the breasts. Fat redistribution may begin, resulting in a more feminine distribution of fat, with increased subcutaneous fat in the hips, thighs, and buttocks. Muscle mass may start to decrease, leading to changes in body composition and strength. Skin changes become more noticeable, with further softening and increased hydration (Salas-Humara et al., 2019).

Six Months to One Year

Breast development continues to progress, with further enlargement and shaping of the breasts. Fat redistribution becomes more apparent, with continued feminization of body shape. Decreased muscle mass may become more noticeable, contributing to a more feminine physique. Changes in body hair growth may become more pronounced, with decreased

density and coverage of body hair. Facial features may begin to soften, with changes in facial fat distribution and reduction in facial hair growth (Salas-Humara et al., 2019).

One Year and Beyond

Breast development typically stabilizes, although individuals may continue to see some growth over time. Fat redistribution reaches its peak, resulting in a more feminine body shape. Muscle mass may continue to decrease gradually, with ongoing changes in body composition. Skin changes become more pronounced, with continued softening and increased elasticity. Facial features may continue to soften, with further reduction in facial hair growth and changes in facial bone structure (Salas-Humara et al., 2019).

Health care providers need to regularly monitor transgender females undergoing hormone therapy to assess for the effectiveness of treatment and for any potential adverse effects or complications, and to adjust hormone dosages as needed.

Special Concerns for Transgender Youth

Transgender youth face significant mental health disparities compared to their cisgender peers, with higher rates of depression, anxiety, suicidality, and other mental health concerns.

Mental Health Disparities Among Transgender Youth

These disparities are often attributed to experiences of minority stress, including discrimination, stigma, harassment, and social rejection based on their gender identity. Internalized transphobia and feelings of dysphoria related to incongruence between their gender identity and assigned sex at birth can also contribute to poor mental health outcomes. Additionally, barriers to health care access, lack of social support, and family rejection may exacerbate mental health disparities among transgender youth. It's essential for health care providers to recognize and address these mental health disparities by providing affirming and culturally competent care, offering mental health support services, and advocating for policies and practices that promote mental health equity for transgender youth (Tordoff et al., 2022; Wittlin et al., 2023)

Substance Misuse/Abuse

Substance misuse and related disorders are in part associated with some transgender people's reliance on substances to cope with the psychological toll of discrimination. Several factors contribute to this heightened risk.

• **Minority Stress:** Transgender youth often experience minority stress, stemming from societal discrimination, stigma, and marginalization. These stressors can lead to feelings of isolation, anxiety, depression, and low



It's crucial to understand that gender identity is distinct from sexual orientation. Being transgender is not about one's sexual orientation but rather about how one experiences and expresses their gender.

self-esteem. To cope with these stressors, some transgender youth may turn to substances as a means of self-medication or escape.

- Coping with Gender Dysphoria: Gender dysphoria, the distress experienced due to a misalignment between one's gender identity and sex assigned at birth, can be profound for transgender youth. Substance use may serve as a maladaptive coping mechanism to manage the distressing feelings associated with gender dysphoria.
- Family Rejection and Lack of Support: Family rejection is unfortunately common among transgender youth, with many facing negative reactions from their families when coming out. This lack of familial support can lead to feelings of alienation and increase the likelihood of engaging in substance use to cope with emotional pain and distress.
- Social Isolation and Peer Dynamics: Transgender youth
 may face social isolation and difficulties in forming supportive peer networks due to stigma and discrimination.
 This isolation can exacerbate feelings of loneliness and lead
 to increased susceptibility to substance abuse as a means of
 seeking social connection or fitting in with peer groups.
- Barriers to Accessing Affirming Health Care:

 Transgender youth may encounter barriers when attempting to access affirming health care, including substance abuse treatment services. These barriers can include lack of culturally competent care, discrimination from health care providers, and challenges navigating the health care system. As a result, transgender youth may be less likely to seek help for substance abuse issues, further exacerbating the problem.

Gender-Affirming Care

Gender-affirming care for transgender youth was introduced in the late 20th century (Carswell et al., 2022). Gender-affirming care addresses gender dysphoria that often manifests before an individual decides to undergo social and physical transition. *Gender dysphoria* (GD) occurs when an individual's assigned gender at birth does not align with their self-identified gender (Bizic et al., 2018).

Social Transition

Social transition for GD involves the process through which a youth begins to live and present themselves in a manner

consistent with their gender identity rather than the gender assigned to them at birth. This transition can encompass various aspects of a youth's life, including changes in clothing, hairstyle, name, pronouns, and social roles. Social transition allows transgender youth to express their true gender identity and may provide relief from feelings of dysphoria associated with living in a gender role that does not align with their internal sense of self (Olson et al., 2022).

For many transgender youth, social transition represents an important step towards affirming their gender identity and fostering a sense of authenticity and well-being. It allows them to live more authentically and openly, improving their mental health outcomes and overall quality of life. Social transition can also facilitate social acceptance and support from family members, peers, and community members, which are crucial factors in a youth's well-being (Olson et al., 2022).

Note that social transition is a deeply personal process, and the timing and extent of transition varies for everyone. Some transgender youth may choose to socially transition gradually, while others may prefer to make more immediate changes. Additionally, not all transgender youth will choose to socially transition, and that's okay—transitioning is a deeply individual decision that should be made based on the needs and preferences of the youth in question (Olson et al., 2022).

Social transition for GD often occurs in conjunction with other forms of gender-affirming care, such as therapy, hormone therapy, and possibly gender-affirming surgeries. The goal of social transition is to support transgender youth in living authentically and comfortably in their gender identity while also providing them with the necessary resources and support to navigate any challenges or obstacles they may encounter along the way. By affirming and supporting transgender youth in their social transition, caregivers, educators, and health care providers can play a crucial role in promoting their well-being and ensuring they can thrive (Olson et al., 2022).

Physiological Aspect of Gender-Affirming Care

The physiological aspect of gender-affirming care for transgender youth involves medical interventions and treatments aimed at aligning their physical characteristics with their gender identity. These interventions are designed to alleviate gender dysphoria, improve mental health outcomes, and Medical intervention for transgender youth often involves a staged approach based on pubertal development, with the goal of aligning their physical characteristics with their gender identity while minimizing the development of secondary sex characteristics that may cause distress.

enhance overall well-being. There are several key components to the physiological aspect of gender-affirming care (Poteat et al., 2023).

- Hormone Therapy: Hormone therapy, mentioned previously, is a common intervention for transgender youth seeking to align their physical characteristics with their gender identity. For transgender boys (assigned female at birth, identifying as male), testosterone therapy may be prescribed to induce masculinizing changes such as deepening of the voice, increased muscle mass, and facial hair growth. For transgender girls (assigned male at birth, identifying as female), estrogen therapy may be prescribed to induce feminizing changes such as breast development, redistribution of body fat, and softening of the skin. Hormone therapy can have significant physiological effects and is often a key component of gender-affirming care for transgender youth (Salas-Humara et al., 2019).
- **Puberty Blockers:** Puberty blockers, or GnRH agonists, are medications that can temporarily halt the onset of puberty (see, too, the timeline section). For transgender youth who have not yet undergone puberty, puberty blockers can delay the development of secondary sex characteristics that may not align with their gender identity. This gives transgender youth more time to explore their gender identity and make informed decisions about their future medical care. Puberty blockers are reversible, and if discontinued, puberty will resume as normal (O'Connell et al., 2022).
- Gender-Affirming Surgeries: Some transgender youth may choose to undergo gender-affirming surgeries to modify their bodies in ways that align with their gender identity (previously mentioned). The types of surgeries available to transgender youth depend on factors such as age, medical eligibility, and individual preferences. For example, transgender boys may undergo chest masculinization surgery (top surgery) to remove breast tissue, while transgender girls may undergo breast augmentation surgery. Other surgeries, such as genital reconstruction surgery (bottom surgery), may be options for transgender youth as they reach adulthood and meet specific criteria (Salas-Humara et al., 2019).
- Voice Therapy: For transgender individuals seeking to modify their voice to better align with their gender identity, voice therapy may be recommended. Voice therapists work

with transgender individuals to develop techniques for altering pitch, resonance, and speech patterns to achieve a voice that feels more authentic and comfortable. Voice therapy can be particularly beneficial for transgender youth who may experience dysphoria related to their voice (Coleman et al., 2022).

Overall, the physiological aspect of gender-affirming care for transgender youth involves a range of medical interventions aimed at aligning their physical characteristics with their gender identity. These interventions can have significant effects on both the physical body and mental well-being, ultimately contributing to improved quality of life for transgender youth. It's important for transgender youth to have access to comprehensive and affirming health care that addresses their unique needs and supports their journey of self-discovery and self-expression.

Psychosocial Aspects of Gender-Affirming Care

The psychosocial aspect of gender-affirming care encompasses the psychological and social dimensions of providing support and interventions that align with an individual's gender identity. Gender-affirming care aims to alleviate gender dysphoria—the distress that arises when a person's gender identity does not align with the sex assigned at birth—and promote the mental health and well-being of transgender individuals (Coyne et al., 2023).

One crucial aspect of psychosocial support in gender-affirming care is affirming and validating a person's gender identity. This involves respecting their self-identified gender, using their chosen name and pronouns, and acknowledging their experiences and feelings without judgment. Affirmation from health care providers, family members, peers, and society at large plays a significant role in reducing feelings of isolation, shame, and stigma commonly experienced by transgender individuals (Coyne et al., 2023).

Moreover, gender-affirming care often involves mental health support to address the unique psychosocial challenges faced by transgender individuals. Mental health professionals can provide therapy, counseling, and support groups to help transgender individuals navigate issues such as gender dysphoria, identity exploration, coming out, and discrimination and stigma. Additionally, mental health professionals can assess for co-occurring mental health conditions, such as depression, anxiety, and post-traumatic stress disorder, and provide appropriate interventions and support (Bhatt et al, 2022).

Social support is another critical component of the psychosocial aspect of gender-affirming care. Building supportive networks of friends, family, peers, and community organizations can provide transgender individuals with validation, acceptance, and solidarity. Social support networks can offer practical assistance, emotional support, advocacy, and a sense of belonging, which are essential for promoting resilience and well-being.

Furthermore, gender-affirming medical interventions, such as hormone therapy and surgeries, can have profound psychosocial effects. For many transgender individuals, these interventions alleviate gender dysphoria, improve body satisfaction, and enhance overall quality of life. Feeling more congruent with one's gender identity can lead to increased self-esteem, self-confidence, and sense of authenticity.

Overall, the psychosocial aspect of gender-affirming care recognizes the interconnectedness of psychological, social, and medical factors in promoting the health and well-being of transgender individuals. By providing affirming support, mental health services, social networks, and gender-affirming medical interventions, gender-affirming care addresses the unique psychosocial needs of transgender individuals and fosters resilience, empowerment, and self-actualization.

Ethical Considerations

For the board-certified Case Manager, the CCMC Code of Professional Conduct and the CDMS Code of Professional Conduct, as well as their respective licensing agency's ethical standards, provide a strong basis for ethical behavior (CCMC,® 2023) (Table 1). Gender-affirming care protocols also provide an ethical basis for care coordination for transgender youth. The relationship between gender-affirming care and ethical care coordination for transgender youth is deeply intertwined, reflecting the ethical imperative to prioritize the well-being, autonomy, and dignity of transgender individuals. Gender-affirming care encompasses a range of interventions and support services aimed at aligning a person's physical characteristics with their gender identity, reducing gender dysphoria, and improving overall quality of life. Ethical care coordination ensures that transgender youth have access to timely, respectful, and comprehensive gender-affirming care that is tailored to their unique needs and preferences.

Autonomy

Ethical care coordination acknowledges the autonomy of transgender youth in decision-making regarding their health care journey. It involves actively engaging them in treatment planning, respecting their gender identity, and centering

TABLE 1

PRINCIPLES OF THE CODE OF PROFESSIONAL CONDUCT FOR CASE MANAGERS

- Board-certified case managers will place the public interest above their own at all times.
- Board-certified case managers will respect the rights and inherent dignity of all of their clients.
- 3. Board-certified case managers will always maintain objectivity in their relationships with clients.
- Board-certified case managers will act with integrity and fidelity with clients and others.
- Board-certified case managers will maintain their competency at a level that ensures their clients will receive the highest quality of service.
- 6. Board-certified case managers will honor the integrity of the CCM designation and adhere to the requirements for its use.
- 7. Board-certified case managers will obey all laws and regulations.
- 8. 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.

their preferences and goals throughout the care process. This approach fosters a sense of empowerment and agency, allowing transgender youth to make informed choices about their health care options.

Beneficence

Ethical care coordination prioritizes beneficence by promoting interventions that enhance the well-being and quality of life of transgender youth. Gender-affirming care has been shown to significantly improve mental health outcomes, self-esteem, and overall satisfaction with life among transgender individuals. By facilitating access to gender-affirming interventions such as hormone therapy, puberty blockers, and gender-affirming surgeries, ethical care coordination seeks to alleviate gender dysphoria and promote positive psychosocial outcomes for transgender youth.

Nonmaleficence

Nonmaleficence is another key ethical principle that underpins care coordination for transgender youth. It requires care providers to minimize the risk of harm, including physical and psychological harm, associated with health care interventions. This involves providing culturally competent and affirming care that respects the identity and experiences of transgender youth, as well as ensures that interventions are evidence-based and conducted by qualified health care professionals. Additionally, ethical care coordination involves creating safe and supportive health care environments that mitigate the risk of discrimination, stigma, and harassment.

Transgender youth face significant mental health disparities compared to their cisgender peers, with higher rates of depression, anxiety, suicidality, and other mental health concerns. These disparities are often attributed to experiences of minority stress, including discrimination, stigma, harassment, and social rejection based on their gender identity.

Justice

Ethical care coordination embodies principles of justice by advocating for equitable access to gender-affirming care for all transgender youth. This includes addressing systemic barriers such as lack of insurance coverage, geographic disparities in health care access, and discrimination within health care settings. By advocating for policy changes, challenging discriminatory practices, and promoting inclusive health care policies, ethical care coordination works to ensure that all transgender youth have access to the care they need to thrive.

In essence, the relationship between gender-affirming care and ethical care coordination for transgender youth is symbiotic, with each reinforcing the other in the pursuit of promoting the health, well-being, and dignity of transgender individuals. By upholding ethical principles such as autonomy, beneficence, nonmaleficence, and justice, care coordination can facilitate access to affirming and culturally competent care that affirms the identities and experiences of transgender youth.

Advocacy and Empowerment

Advocacy and empowerment are fundamental aspects of providing comprehensive and affirming health care for transgender youth. This section addresses the active role that health care providers play in advocating for the rights and well-being of transgender youth, empowering them to make informed decisions about their health care and addressing systemic barriers through advocacy efforts.

Role of Health Care Providers as Advocates for Transgender Youth

Health care providers serve as allies and advocates for transgender youth, leveraging their position to champion the rights, dignity, and access to quality care for this vulnerable population. This advocacy role involves not only providing medical treatment but also advocating for policies and practices that promote inclusivity, equity, and respect for transgender individuals. Health care providers can advocate for transgender-affirming health care practices within their institutions, educate colleagues and staff about transgender health needs, and advocate for systemic changes at local,

regional, and national levels. By amplifying the voices of transgender youth and advocating for their rights, health care providers can contribute to creating a more affirming and supportive health care environment.

Empowering Transgender Youth in Health Care Decision-Making

Empowering transgender youth in health care decision-making is essential for fostering autonomy, self-advocacy, and well-being. Health care providers can empower transgender youth by providing them with accurate information about their health care options, discussing treatment plans and goals in a supportive and affirming manner, and involving them in decision-making processes. This may involve exploring the youth's values, preferences, and goals, discussing the potential risks and benefits of different treatment options, and ensuring that their voices are heard and respected throughout the health care journey. Empowering transgender youth to actively participate in their own health care decisions not only promotes their autonomy and self-determination but also fosters a sense of agency and ownership over their own hodies and health.

Informed Consent

Informed consent and decision-making are pivotal aspects of providing health care for transgender youth. This section addresses the critical importance of respecting the autonomy and decision-making capacity of transgender youth, while also considering the role of parental involvement in their health care journey.

Importance of Informed Consent in Transgender Health Care

Informed consent is a cornerstone of ethical health care practice, particularly in the context of transgender health care. It acknowledges the rights of transgender youth to make informed decisions about their own bodies and medical care. Rather than relying solely on traditional gatekeeping models in which health care providers have sole discretion over treatment decisions, informed consent empowers transgender youth to actively participate in decisions regarding their gender-affirming care. This approach ensures that youth are fully informed about the risks, benefits, and alternatives of



available treatments, allowing them to make decisions that align with their own values, preferences, and goals.

Capacity of Transgender Youth to Make Health Care Decisions

Transgender youth can make informed health care decisions about their own bodies and medical care, just like any other individual. Despite misconceptions that may exist, their gender identity does not invalidate their ability to understand their health care needs or make decisions about their treatment. It's essential for health care providers to recognize and respect the decision-making capacity of transgender youth, providing them with the necessary support and information to make informed choices about their health care. This may involve discussing treatment options, potential risks, and benefits, and exploring the youth's goals and preferences in a supportive and affirming manner.

Balancing Parental Involvement With Youth Autonomy

While respecting the autonomy of transgender youth is paramount, it's also important to recognize the role of parents or guardians in the health care decision-making process, particularly for minors. Balancing parental involvement with youth autonomy involves finding a middle ground in which the youth's rights and autonomy are respected while also acknowledging the need for parental support and guidance. In some cases, transgender youth may choose to involve their parents or guardians in their health care decisions, while in others, they may prefer to maintain confidentiality or seek support from other trusted adults. Health care providers should engage in open and honest communication with both the youth and their parents, fostering a collaborative approach that prioritizes the youth's well-being while also addressing any concerns or questions that parents may have. Ultimately, the goal is to support transgender youth in making informed decisions about their health care while also fostering positive relationships and communication within their support network.

Confidentiality and Privacy

Confidentiality and privacy are predominant considerations in providing health care for transgender youth because they play a crucial role in fostering trust, safety, and autonomy within the health care setting. This section explores the importance of confidentiality for transgender youth, the delicate balance between confidentiality and parental involvement, and the legal and ethical considerations in protecting privacy.

Importance of Confidentiality for Transgender Youth Confidentiality is essential for transgender youth seeking health care because it ensures that their privacy is respected and their personal information is kept confidential. Many transgender youth may be hesitant to seek health care services due to fears of discrimination, stigma, or breaches of confidentiality. Ensuring confidentiality creates a safe and supportive environment in which transgender youth can openly discuss their gender identity, health concerns, and treatment options without fear of judgment or disclosure. Confidentiality also promotes trust between health care providers and transgender youth, which is essential for building a therapeutic relationship and facilitating open communication.

Balancing Confidentiality With Parental Involvement

Balancing confidentiality with parental involvement can be challenging, particularly for transgender youth who may not have supportive or affirming parents or guardians. While confidentiality is crucial for protecting the privacy and autonomy of transgender youth, it's also important to consider the potential benefits of involving parents or guardians in their health care decisions. In some cases, parental involvement may be necessary to ensure access to health care services, financial support, or emotional support for the youth. However, health care providers must assess each situation individually and consider factors such as the youth's age, maturity, and level of independence, as well as the nature of their relationship with their parents or guardians. Whenever possible, health care providers should involve transgender youth in discussions about confidentiality and seek their input on how to navigate issues related to parental involvement.

Legal and Ethical Considerations in Protecting Privacy

Health care providers have a legal and ethical obligation to protect the privacy and confidentiality of their patients, including transgender youth. This includes adhering to laws and regulations related to health information privacy, such as the Health Insurance Portability and Accountability Act (HIPAA) in the US, which sets standards for the protection of sensitive health information. Additionally, health care providers must adhere to ethical principles that prioritize the autonomy, dignity, and well-being of their patients, including the right to privacy and confidentiality. This may involve obtaining informed consent from transgender youth before sharing information with parents or guardians, ensuring that electronic health records are secure and encrypted, and providing clear information about privacy policies and procedures to patients and their families. By upholding legal and ethical standards related to privacy and confidentiality, health care providers can create a safe and trusting environment in which transgender youth feel comfortable



While confidentiality is crucial for protecting the privacy and autonomy of transgender youth, it's also important to consider the potential benefits of involving parents or guardians in their health care decisions.

seeking care and disclosing information about their gender identity and health care needs.

Cultural Competence

Cultural competence and sensitivity are essential components of providing effective and affirming health care for transgender individuals. Care managers must understand the importance of considering the cultural contexts of transgender identities, the significance of cultural competence in health care, and strategies for fostering a culturally sensitive health care environment.

Understanding Cultural Contexts of Transgender Identities

Transgender identities are deeply influenced by cultural, social, and historical contexts, and it's crucial for health care providers to have a nuanced understanding of these factors. Cultural contexts may include societal attitudes towards gender diversity, religious beliefs, family dynamics, and cultural norms surrounding gender expression and identity. Understanding the cultural contexts of transgender identities allows health care providers to provide care that is respectful, affirming, and tailored to the unique needs and experiences of transgender individuals from diverse backgrounds. This may involve acknowledging the intersectionality of gender identity with other aspects of identity, such as race, ethnicity, sexual orientation, and socioeconomic status, and recognizing how these intersecting identities shape a person's experiences and health care needs.

Importance of Cultural Competence in Health Care

Cultural competence is the ability of health care providers to effectively navigate the cultural and social contexts of their patients, communicate effectively across cultural differences, and provide care that is sensitive to the needs and preferences of diverse populations. In the context of transgender health care, cultural competence is essential for building trust, fostering open communication, and providing affirming and inclusive care. Culturally competent health care providers recognize the importance of addressing systemic barriers to health care access, such as discrimination, stigma, and lack of culturally competent care, and work to create a health care environment that is welcoming and affirming for transgender individuals. By developing cultural competence, health care

providers can better understand and address the unique health care needs and experiences of transgender individuals and provide care that is respectful, affirming, and effective.

Strategies for Fostering a Culturally Sensitive Health Care Environment

There are several strategies that health care providers can employ to foster a culturally sensitive health care environment for transgender individuals. These include:

- Education and Training: Providing and obtaining education and training to health care providers about transgender identities, experiences, and health care needs can help increase awareness and understanding of transgender issues and promote cultural competence.
- Language and Communication: Using affirming and inclusive language, such as asking patients for their preferred name and pronouns, can help create a welcoming and affirming health care environment. Health care providers should also be mindful of their communication style and be sensitive to cultural differences in communication norms.
- **Respect and Dignity:** Respecting the autonomy, dignity, and self-determination of transgender patients is essential for providing affirming and respectful care. This includes listening to patients' concerns and preferences, involving them in decision-making about their child's health care, and treating them with respect and empathy.
- Access to Care: Addressing systemic barriers to health care access, such as lack of insurance coverage, discrimination, and lack of culturally competent care, is crucial for ensuring that transgender individuals can access the care they need. Health care providers can advocate for policy changes, provide resources and referrals to transgender-friendly health care providers, and work to create a health care environment that is inclusive and welcoming for transgender individuals.

By implementing these strategies and fostering a culturally sensitive health care environment, health care providers can improve the quality of care and outcomes for transgender individuals and create a health care system that is affirming, inclusive, and equitable for all.

Exam expires on February 15, 2025



Understanding and Managing Resistance: A Guide for Case Managers

By Mark Naghsh, LMSW, CMC

Introduction

In the dynamic landscape of clinical settings, case managers are pivotal in navigating complex challenges, notably resistance to patient treatment. Resistance, characterized by patient behaviors that impede therapeutic interventions, represents a significant barrier to effective treatment and case management outcomes. It can manifest as overt noncompliance, subtle avoidance, or passive behaviors that disrupt the therapeutic process. This resistance hinders patient progress and complicates the responsibilities of case managers, who must employ a nuanced understanding of human behavior and therapeutic techniques.

Therefore, understanding and managing resistance is critical for enhancing therapeutic efficacy and achieving successful treatment outcomes. This educational article aims to equip case managers with a robust understanding of the various forms of resistance, their underlying causes, and the practical strategies for overcoming them. Through a comprehensive exploration of theoretical insights and integration of practical examples, this article will facilitate more effective interventions by case managers in their clinical practice.

The significance of addressing resistance is underscored by a wealth of psychological research and theoretical models that provide a framework for understanding this complex phenomenon. For instance, the Stages of Change Model developed by Prochaska and DiClemente (1983) outlines different readiness levels for change, which can help case managers identify and address specific forms of resistance. Additionally, psychodynamic theories offer insights into how unconscious defense mechanisms may play a role in a patient's resistance to change (Freud, 1923), while cognitive-behavioral approaches focus on the influence of maladaptive beliefs and behaviors that need to be addressed (Beck, 1979).

Moreover, empirical studies have highlighted the impact of effective resistance management on treatment outcomes. For example, research has demonstrated that understanding the root causes of resistance and applying tailored intervention strategies can significantly improve patient engagement and compliance (Miller & Rollnick, 2013). These studies

suggest that case managers skilled in identifying and mitigating resistance are better positioned to support their patients' journeys toward recovery and well-being.

By delving into the various dimensions of resistance and offering actionable strategies to manage it, this article serves as a vital resource for case managers seeking to refine their skills and enhance their effectiveness in clinical settings. Integrating theory, evidence-based practices, and real-world applications aims to foster a deeper understanding and more adept management of resistance, paving the way for improved clinical outcomes and patient satisfaction.

Understanding Resistance

Resistance to treatment can manifest in several forms, each presenting unique challenges for case management outcomes. Understanding the type of resistance a patient is experiencing can assist in identifying an applicable approach to improve outcomes and reduce friction points.

Superficial engagement: A patient may seem compliant—attending sessions and nodding in agreement—but fail to engage on a deeper, more meaningful level. For instance, a patient named John attends dialysis sessions but consistently diverts conversations away from discussing his feelings about his recent divorce and its impact on dietary compliance, a key issue in his situation. By understanding this type of



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education of social workers and case managers. Additionally, he serves as a court evaluator with over 28 years of experience in guardianship planning. He is a board member for the Case Management Society of America and Aging Life Care Association, developing programs for the social work, case management, and nursing communities in NYC and beyond. He is currently president of Affinialcare Psychotherapy Services.

In the dynamic landscape of clinical settings, case managers are pivotal in navigating complex challenges, notably resistance to patient treatment.

resistance, a case manager might use the alignment approach to assist the patient in understanding what they might be doing. An example to use here would be to compliment the patient for showing up for all their appointments but point out that they tend to move away each time the dietary topic is discussed. Exploring deeper into the feelings behind the behavior can assist the patient to see their feelings. Psychoeducation on the therapeutic dyad could also help here, which means explaining resistance as the avoidance of a complex topic.

Misleading information: Patients might provide inaccurate details about their feelings or situations. Consider a case in which a patient, Lisa, reports adherence to her medication regimen but, in reality, frequently skips doses, impacting her treatment outcomes. The case manager would want to look at Lisa's behavior versus what she shared with the clinician in this situation. Remain curious about why the medication is not working rather than ask the patient directly if they are taking it, which is likely to trigger more resistance. A possible question to ask might be, "I am really at a loss as to why this medication is not working; it works for all the other patients I see. What do you think might be happening?" Remaining curious or puzzled will remove the confrontational element and shift to a mutual goal to find the root cause of the lack of effectiveness.

Obstructing logistics: A patient might regularly arrive late or cancel appointments, disrupting the follow-up procedures. An example is Michael, who sets appointments during work hours and then cancels, citing unavoidable conflicts. Similarly, as above, the case manager must focus on the behavior while setting boundaries. In this situation, think about the varying elements that might be preventing him from showing and not progressing. What are the real reasons for his inconsistent attendance? Is his wife making him come in? Or does he not feel safe?

Communication styles: Resistance can also appear in how patients communicate, such as using excessive detail to avoid significant topics or giving minimal responses. Sarah, for example, talks at length about minor stresses at work so she can avoid discussing her anxiety disorder. In this situation, the case manager may want to look under the hood of what the patient is exhibiting, and say, "You seem to get agitated at work a lot for this is a topic you bring in weekly. Are there

other situations that make you feel the same way?"

By working to recognize these forms of resistance, clinicians can tailor their approach to each patient's type of resistance. Although remaining curious, focusing on the behavior, and listening with intent are essential in moving past these types of resistance, the case manager must also be mindful of their own reactions and interactions with their patients in a clinical setting.

Theoretical Perspectives on Resistance

Understanding the theoretical underpinnings of resistance can also enhance a case manager's ability to address it effectively.

Stages of Change Model: Developed by Prochaska and DiClemente (1983), this model suggests that resistance may indicate a patient's stage of readiness for change. It breaks it down into stages of change: precontemplation, contemplation, preparation, action, maintenance, and termination. A patient in the contemplation stage might acknowledge the need for change but feel ambivalent about acting on it, thus showing resistance through procrastination or skepticism about the benefits of treatment. They may not see it as a problem in the precontemplative stage yet. What we might see as resistance could be them not being aware it is a problem.

Psychodynamic theories: From this perspective, resistance might stem from unconscious defense mechanisms protecting the individual from perceived threats linked to change. For instance, a patient might resist discussing traumatic experiences that are central to their psychological issues—one example, the session described here is with a patient who could not access his empathy for his partner, for he was hiding his fears of sadness around loss. Despite being faced with losing his partner, he still could not access them until the risk of loss was removed via individual sessions. The trigger was the potential loss of his wife, which made his resistance grow stronger and less communicative of his feelings. He ostensibly had created a protective ego that presented self-confidence, which masked his fear of loss and abandonment.

Cognitive-behavioral approaches: Here, resistance is often viewed as resulting from maladaptive beliefs. For example, patients may resist engaging in cognitive-behavioral therapy exercises because they believe that their problems

These studies suggest that case managers skilled in identifying and mitigating resistance are better positioned to support their patients' journeys toward recovery and well-being.

are unsolvable. This thought is what would be considered a recurring thought or cognitive distortion. In this case, reality testing can be beneficial. One could remind them that everything worked out fine every time they had the same procedure in the past. Alternatively, challenge the distortion by asking if there was a negative outcome they had experienced. This approach could help them discuss the fear more openly.

Comprehensive Causes of Resistance

Resistance can arise from a variety of sources, which may include:

Emotional Barriers

Emotional barriers are often rooted in a patient's fear of the unknown or a reluctance to confront harrowing emotions. For example, a patient, Emma, may resist discussing her history of abuse during treatment due to the intense discomfort and emotional pain these memories evoke. Her fear of revisiting traumatic memories manifests as avoidance behaviors she may change the subject or become visibly distressed when nearing sensitive topics. Addressing these emotional barriers requires a sensitive approach, in which the clinician gradually helps Emma build resilience and comfort through techniques like grounding and controlled exposure.

Cognitive Barriers

Cognitive barriers arise when there is a lack of understanding or misconceptions about the therapy process or its benefits. A patient named Alex may doubt the efficacy of therapy because he does not understand how talking about his problems can improve his situation. He might think, "How can discussing my past change what is happening now?" Effective communication about the therapeutic process and the specific ways it can help is crucial to overcome such resistance. Educating Alex about cognitive restructuring and how altering thought patterns can change emotional responses and behaviors might reduce his skepticism.

Relational Barriers

Relational barriers often develop from mistrust in the therapeutic process or of the clinician. This resistance could be due to previous negative experiences with health care providers or general skepticism about mental health treatment. For

instance, Maria, who had an unsupportive experience with a previous clinician, may enter a new therapeutic relationship with a defensive attitude, doubting the clinician's intentions. Building a solid therapeutic alliance is essential here and involves consistent, open communication and demonstrating empathy and nonjudgmental understanding. Over time, this approach can help Maria feel more secure and valued in the therapeutic relationship.

Motivational Barriers

Motivational barriers typically involve a lack of drive or energy, often exacerbated by mental health conditions like depression. John, suffering from severe depression, might find it overwhelming to engage in treatment or a treatment plan. He could perceive discussions about his future or making changes as futile, reflecting his depressive symptoms of hopelessness and low energy. In such cases, addressing the root of the motivational issues through pharmacologic treatment and motivational interviewing can be beneficial. These methods can help to incrementally increase John's engagement and willingness to participate in the process.

Contextual Barriers

Contextual barriers include external factors such as cultural stigma or family pressures that discourage seeking psychological help. Consider Priya, who comes from a cultural background in which mental health issues are stigmatized and seeking therapy is viewed as a sign of weakness. She might resist engaging in therapy for fear of being ostracized or judged by her community and family. Integrating culturally sensitive practices and possibly involving family members in the therapeutic process, when appropriate, can help overcome these barriers. Educating the patient and their family about the nature of mental health issues and the benefits of therapy can also reduce stigma and resistance.

Strategies for Managing Resistance

Effective strategies case managers can employ include:

Developing a therapeutic alliance: Building rapport and trust with patients and showing empathy and understanding can help reduce resistance. Consistently showing empathy towards a patient's concerns can gradually break down barriers of mistrust and fear. This process may appear

Psychoeducation on the therapeutic dyad could also help here, which means explaining resistance as the avoidance of a complex topic.

complicated because our days are busy, and we need more time to do other tasks. It is understood that we need to be more efficient, so taking the time to build rapport seems counterintuitive. Being honest with a patient can go a long way. For instance, instead of showing frustration and anxiety when a patient is making things take longer, be honest with them and show your authentic self. You might tell the patient, "I understand that this is hard for you and want to help you understand this plan better, but unfortunately, I need to see another patient. Is there something I can do while I am away?" Although this may not stop the resistance, you are laying the groundwork for the next time you meet with them for you let them know they were important.

Patient-centered empathy: Actively listening and validating the patient's feelings without judgment encourages more open communication. Using the patient's vernacular or word choices typically helps them trust you more. In addition, you could respond to exactly what you heard and ask them if you were correct. This also lets them know you are listening to them and that what they are telling you is essential. This approach can increase the chances that they share more, for they know what they say matters to the clinician. Also, couples therapy techniques such as "I statements" can assist with a more therapeutic alliance. An example might be if you are frustrated, just letting your patient know that you are not frustrated with them, but that you get this way when you cannot help someone. An example statement might be, "I am not upset with you, but I am frustrated right now, for I do this work because I want to help."

Collaborative goal setting: Involving patients in setting their own goals for therapy can increase their investment and reduce resistance. For example, you may be working with a patient to set small, manageable goals for improving social interactions if they suffer from social anxiety. Another term for this is *mutuality*. Creating joint goals goes a long way to making progress, for you each have a stake, and it takes all the burden off the patient.

Involving other professionals: Collaboration with psychiatrists, therapists, and other health care professionals can provide a comprehensive approach to addressing complex cases of resistance. In a previous setting, our team had interdisciplinary care plan meetings where everyone brought

unique perspectives. This strategy can help create objectivity, for we are more likely to lose our perspective when we must do things alone.

Conclusion

Effective resistance management is a pivotal skill for case managers in clinical settings. Throughout this article, we have explored the multifaceted nature of resistance, delving into its various manifestations—from superficial engagement and misleading information to obstructive logistics and evasive communication styles. By integrating theoretical insights from the Stages of Change Model, psychodynamic theories, and cognitive-behavioral approaches, we have outlined a robust framework for understanding the deep-seated origins of resistance and its complex psychological underpinnings.

We have examined the comprehensive causes of resistance, identifying emotional, cognitive, relational, motivational, and contextual barriers. Each area presents unique challenges and opportunities for case managers to apply targeted strategies to foster engagement and facilitate therapeutic progress. Case managers can transform resistance from a stumbling block into a stepping-stone toward positive outcomes by employing methods such as developing a solid therapeutic alliance, practicing patient-centered empathy, setting collaborative goals, and involving other professionals.

This article presented practical strategies backed by empirical research and highlighted the importance of a compassionate, informed approach to case management. The examples and scenarios provided serve as a blueprint for case managers to enhance their practice and achieve better patient outcomes.

In closing, understanding and managing resistance is more than a clinical skill—it is an art that requires sensitivity, patience, and perseverance. As case managers continue to engage with this dynamic aspect of therapy, they must remain adaptable and informed by ongoing research and developments in the field. By viewing resistance not as a barrier but as an opportunity for growth and understanding, case managers can significantly contribute to the transformative impact on clinical outcomes, leading to more profound and lasting changes in the lives of those they serve. CEII



Exam expires on February 15, 2025



Horse-Human Interaction: The Neurobiological **Miracle That Supports Equine-Assisted Therapies**

By Rebecca Perez, MSN, RN, CCM, FCM

eople with disabilities need access to health care and health programs to stay well, active, and part of a community, just like those not living with disabilities (CDC, n.d.). Depending on the disability, individuals may need access to specialized therapies and services for adjunct wellness. Most health care professionals understand what therapies may be prescribed for a specific condition or health issue. However, there are therapies outside of the mainstream that can be beneficial, whether the disability is mental, emotional, or physical. One such therapy will be discussed here: equine-assisted therapy. Because horses can be intimidating for some people simply because of their size, their therapeutic impact is not always understood. This article illustrates the therapeutic benefit of spending time with horses and why they are amazing therapy partners.

"There's something about the outside of the horse that is good for the inside of the man." —Winston Churchill

Spending time with animals is beneficial. We know our pets are good for our mental and physical health, largely due to the unconditional love we receive from them. We usually attribute dogs and cats as animals that help and comfort us, but horses can be valuable partners in some forms of therapy. The reasons may be surprising.



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Horses and Humans

Humans and horses have been interacting for millennia, but their ability to carry humans has the greatest impact on this relationship (Merkies K, 2021). Historically, horses have been used for work, sport, and companionship (Merkies K, 2021). As we learn to better understand horse-human interactions, we can create avenues to optimize their welfare as well as our own. First let's look at the horse's sensory capabilities and how they pertain to human interaction.

Evidence suggests that horses can read humans through body odor, posture, facial expressions, and attentiveness (Merkies K, 2021). The literature also suggests horses can remember previous experiences with humans. Horses are natural biofeedback monitors: They communicate by electromagnetic fields generated through their circulatory systems, and the same goes for humans with the heart and nonverbal communication (Merkies K, 2021).

Horses have an incredible capacity to sense what is going on inside us and react accordingly (Merkies K, 2021). They do not judge us, so we can adjust our presence and behavior until the connection feels good for both. More recent investigations demonstrate that horses help us regulate our emotions and positively impact our heart rate, blood pressure, cardiovascular health, and nervous system. Connecting with horses can cause the brain to release positive neurotransmitters: oxytocin, serotonin, and dopamine (Body and Soul, 2020). A connection to horses can also reduce cortisol levels, ameliorating stress and feelings of fear, anxiety, and even depression (Body and Soul, 2020).

A horse trained with kindness, expertise, and encouragement is a willing and equal partner. Horses with their "prey brains" and humans with their "predator brains" share invisible signals through body language (Jones, 2022). These signals are received and transmitted to the horse and human spinal cord through peripheral nerves (Jones, 2022). The signals are interpreted, and collaborative neural actions form a biofeedback loop. An example of this neural communication is when a horse and rider are in the show ring. A spectator opens an umbrella, which startles the horse. The neural signals from the horse's eyes carry that frightening incident to its brain. Those signals result in the horse "shying" or

jumping. This might cause the rider to fall, but when a rider is sensitive to a horse's physical reactions, the human rider senses the equine motor reaction that results in unwanted movement. That neural signal from the horse is transmitted up the human's spinal cord to the brain (Jones, 2022). The rider can now respond by relaxing their muscles and intercepting the horse's fright; that response mitigates the horse's fear (Jones, 2022). These "conversations" allow horses and humans to achieve an intended goal. Whether the goal is to become an athletic team or therapy partner, deep bonds of mutual trust can be developed, and we learn to communicate using body language, knowledge, and empathy. Humans are the evolutionary enemy of the horse yet are inclined to become a friend.

Horses have astounding touch detection. Receptor cells in the horse's skin and muscles convert external pressure, body temperature, and position to neural impulses the horse can understand. The average horse can detect less pressure against their skin than a human fingertip can (Jones, 2022). This is why horses prefer to be stroked or gently patted.

Body language is a primary form of communication for horses. The flick of an ear can communicate irritation or domination from one horse to another (Jones, 2022). A younger, less-experienced horse may not understand that ear flick and may find themselves with two completely flattened ears and a blood-drawing bite (Jones, 2022). Touch, sensitivity, and body language form the tripod of communication support (Jones, 2022). By nature, horses are learning machines. Unlike humans, they learn in a rapid, pure form that allows them to be taught human cues that can shape their behavior.

As mentioned previously, horses have a "prey brain," and humans have a "predator brain" (Jones, 2022). Horses are prey animals. They are constantly looking out for danger and want comfort and safety. They prefer not to have to think too hard or make decisions (Jones, 2022). They are herd animals, and as such, their safety and survival depend on the herd. They want a benevolent leader who will provide them with security and comfort (Jones, 2022).

Humans have difficulty understanding this, even though horses have been domesticated for thousands of years. We have done a poor job of easing their instinct to flee danger. They always look for something around every corner, believing a predator awaits them.

Horse-Human Interactions

It is difficult for humans to know what a horse is truly thinking but paying attention to subtle behavioral signals can inform how horses prefer humans to interact with them (Jones, 2022). Humans must be open to evolving and altering their behaviors and actions to create a positive experience.

Horses are better at perceiving human actions than humans are at perceiving theirs (Jones, 2022). For example, a human approaching a horse straight on using a lead rope will cause the horse to move in a different direction. An indirect approach reduces the horse's instinct to move away.

Horses are likelier to exhibit a left-eye gaze when a human is angry or sad. So, if a horse looks at you with only his left eye, he perceives your less-than-positive mood. They will approach attentive humans or walk around and nudge the inattentive person to gain attention (Jones, 2022). Developing a positive horse-human relationship requires the human caring for the horse with housing, feeding, social contact, and training methods. Deficits in these lead to problems and concerns like biting, kicking, rearing, bucking, etc. These behaviors often result from the horse's experience of abuse.

The love of horses permeates human culture. A simple internet search can reveal many examples of a horse saving a person's life, touching someone's soul, teaching life skills, and finding inner strength and peace. Regardless of where humans are, their race, age, gender, or ethnicity, these beliefs and results are consistent.

Neurobiology of Horse-Human Interactions

Andrea Beetz and colleagues (2012) conducted an exhaustive review of existing research to discover that the underlying physiologic and psychological outcomes related to animal-assisted interventions are the activation of the oxytocinergic system. This system positively affects hormones like cortisol, neurotransmitters such as epinephrine, norepinephrine, and dopamine, and the autonomic nervous system, thereby reduces blood pressure, heart rate, fear, and anxiety.

Horses have evolved to become extremely sensitive to their environment, other animals, and humans. They provide feedback through various behaviors and are sensitive to inconsistency, agitation, and arousal or panic, which signal imminent danger. A horse's reactions to human actions, emotions, and body language can help enhance human insight and awareness.

The horse-human bonding process starts with the human's self-tuning of emotions on others' emotions. For humans, this is known as emotional intelligence (EI). EI influences relationships, and the more emotionally intelligent one is, the more likely one is to develop emotional competencies. Acquiring EI helps us to anticipate how we react and to better manage responses, especially during tense encounters. Exposure to horses can teach EI because our emotions and reactions are perceived by horses, and they have evolved to have the ability to react to them. Horses remember past encounters with humans based on the quality of those interactions. For example, if a treat is given with an encounter, the horse usually will engage, but if the horse remembers

We usually attribute dogs and cats as animals that help us [mentally and physically], but horses have increasingly been recognized as valuable partners in some physical and mental health therapies.

negative encounters, they will be hesitant to engage or may display more aggressive or negative behaviors. Awareness of our emotional state and its impact on the horse can help us acquire positive behaviors.

The horse-human bond has been described previously, and it is this bond that is one factor contributing to the benefits of equine-assisted therapy (EAT). According to research, it specifically benefits individuals struggling with anxiety, depression, grief, and post-traumatic stress disorder (PTSD), although this is not an exhaustive list (WebMD, 2021). The formation of this bond is thought to be possible because horses are herd animals, and herd animals must bond, communicate, and cooperate to function within a social hierarchal organization (Merkies K, 2021). Horses and humans share many life-cycle processes, such as friendship, courtship, rejection, reproduction, and death. These similarities, along with domestication, allow horses to perceive humans as herd members, which then results in the ability to bond and for the bond to endure (Merkies K, 2021). Horses easily give kindness, comfort, compassion, and love, and they do not expect anything but safety in return.

Even if only for a short duration, the bonding of horses and humans has been shown to provide positive feelings and emotions and a connection to another being (White-Lewis, 2020). The safe and nonjudgmental connection between humans and horses allows humans to express thoughts, feelings, and emotions more easily.

Horses, simply because of their size, can be very intimidating, but a horse-human relationship requires the human to take leadership. Anxiety may be the initial response, but as EAT participants learn to work through these challenges with the horse, positive outcomes include increased confidence, autonomy, leadership, and self-control (White-Lewis, 2020). The simple act of grooming has been found to reduce the groomer's (the human's) heart rate (Scopa, 2019). This interspecific relationship can promote healthy neurobiological development through touch and proximity for both human and horse (Scopa, 2019). Human insight and awareness can be enhanced because horses react to human actions, emotions, and body language.

Equine-Assisted Therapy

Therapeutic Riding

Hippotherapy (or EAT) involves activities with horses guided by a

professional. This does not always include riding as part of the therapy. Equine-assisted therapies have demonstrated mental, occupational, and physical health, and skill-building benefits.

Rigorous scientific research is lacking, but preliminary evidence demonstrates two main parallel branches of equine-assisted interventions: the occurrence of coordination and the brain-heart-hormonal reactions for both humans and horses (Beetz, 2012).

Hippotherapy is a form of physical, occupational, and speech therapy whereby the horse's movement provides motor and sensory input. A therapist trained in hippotherapy works with the individual. The movement of a horse's pelvis during riding provides motor and sensory inputs to the human body. Coordination, posture, and facial expressions play a role in social interactions, which are also a part of therapeutic riding (Koca, 2015).

Rhythmic and repetitive movements provide physical and sensory feedback from horse to rider. These movements improve coordination, muscle tone, postural balance, stiffness, flexibility, endurance, strength (including core strength), correction of abnormal movements, gait, and balance. Contact between the human pelvis and horse pelvis reinforces spine movement, improving motor responsiveness in the human trunk and pelvis (Koca, 2015). Additional benefits include exposure to a large spectrum of sensory and motor input from the horse and the therapist.

Conditions That Benefit From Therapeutic Riding

- Amputation
- Autism
- Cerebral palsy (CP)
- Down's syndrome
- Muscular dystrophy
- Paralysis
- Spina bifida
- Spinal cord injury
- Traumatic brain injury (TBI)
- Visual and auditory disabilities

Nonriding Equine-Assisted Therapy

Whether therapies are riding or nonriding, either can help an individual achieve personal or professional goals by observing horse behavior and learning lessons in horse care. The therapies help the individual learn to associate how a

Anxiety may be the initial response, but as EAT participants learn to work through these challenges with the horse, positive outcomes include increased confidence, autonomy, leadership, and self-control.

horse behaves with how humans behave.

Many positive effects have been reported for patients with social, communication/language, and stress/behavior disorders (Scopa, 2019). The benefits of EAT have been well researched for PTSD and anxiety disorders, especially among veterans (Scopa, 2019). The horse is the integrated complement that helps build the connection between the patient and therapist. The horse has been seen as a facilitator for other social interactions, which decreases resistance to other interactions and provides a safer approach to the patient's environment (Scopa, 2019).

Using horses or other animals in therapeutic settings builds therapeutic alliances and helps to unlock delicate issues like unconscious worries and fear (Scopa, 2019). Therapists may partner patients with a history of abuse with an animal with a past of abusive. The patient can relate to the animal, projecting their emotions onto the animal. Animals may be laden with many subjective meanings of a person's emotions or feelings that are hard to express and more likely to be repressed (Scopa, 2019). And again, because horses are herd animals, they are sensitive to others and easily engage in social behaviors (Scopa, 2019).

Positive interactions between horses and humans begin with nonverbal communication, meaning they begin to work as one, resulting in synchronized neural activities. These neural activities include predicting the other's actions and communication through gestures and facial expressions. Brain mapping of horses and humans has shown that the interactions become more synchronized: horse encephalography begins to match those of a human who is standing close to a horse, petting a horse, and grooming a horse (Scopa, 2019). The success of these interventions is reliant on a trustbased bond. The horse-human interaction can mimic other significant relationships in the human's life.

Mental health conditions that can benefit from nonriding EAT include:

- Behavioral health problems
- Relationship issues
- Grief
- Anxiety
- Depression
- Attention deficit disorder/attention deficit hyperactivity disorder

- Addiction
- Eating disorders
- PTSD

In the early 20th century, German biologist Jakob von Uexkull (yks kyl) coined the term umwelt, which refers to the perception of one's environment by one's own senses and nervous system. He believed organisms create and shape their own *umwelt* guided by their evolutionary histories and experiences. Humans believe horses are sentient beings with feelings and emotions (Merkies K, 2021).

What Does EAT Look Like?

Equine-assisted therapies use the connection between humans and horses to enhance physical and emotional healing. Horses are incorporated into therapeutic processes and activities like grooming, feeding, and leading. Many assume EAT is only about riding, which is, of course, very therapeutic for many conditions. However, EAT is not exclusive to therapeutic activities.

Therapeutic riding became a popular therapeutic modality in the 1950s and 1960s. In 1969, the North America Riding for Handicapped Association was formed, and it later became the Professional Association of Therapeutic Horsemanship International (PATH). The movement experienced when on horseback and combined with proper positioning can lead to cognitive, physical, emotional, and social improvements. Conditions that benefit from the rapeutic riding include:

- **Hypertonia:** spasticity seen in cerebral palsy (CP), stroke, spinal cord injury, and traumatic brain injury (TBI). The movement of the horse mirrors our motion at walking speed. Riding a horse helps the person with spasticity to relax and improve balance and flexibility.
- **Hypotonia**: decreased muscle tone, especially in the trunk, is seen in ataxic conditions, hypotonic CP, Down's syndrome, multiple sclerosis, and TBI. These individuals are often paired with a large horse with a longer gait or less smooth movement. These individuals often cannot support themselves in the saddle, so they will require a "walker" to help hold them upright in the saddle. However, core muscles strengthen over time due to the therapy, and enough strength can be gained to negate the need for a walker.

For those challenged with cognitive impairment or learning disabilities, interaction with the riding instructor/

[The horse-human bond] specifically benefits individuals struggling with anxiety, depression, grief, and post-traumatic stress disorder (PTSD).

therapist and horse to practice riding skills or play games to introduce riding skills increases body awareness, spatial relationships, self-confidence, and independence.

In general, the physical benefits of therapeutic riding improve balance, coordination, muscle strength, circulation, and range of motion. The psychological benefits include improved self-confidence: a sense of well-being, patience, emotional control, and companionship.

Nonriding equine therapy has demonstrated improvements in a host of psychosocial challenges. It has been shown and studied to be of great benefit to those suffering from PTSD, especially among combat veterans (Li, 2023).

US military veterans experience high rates of psychiatric and substance use disorders, with PTSD being the most prevalent. The high risk of trauma resulting from combat, injury, captivity, and sexual assault faced by many military personnel increases the prevalence of PTSD from 10% in the civilian population to 30% in the military population (Li, 2023).

According to the Diagnostic and Statistical Manual of Mental Disorders-5th edition (DSM-V), PTSD can result from re-experiencing traumatic events, avoiding thoughts or feelings associated with traumatic events, having negative thoughts such as self-blame or a pessimistic outlook, and sustaining outbursts of rage (Li, 2023). The effects of PTSD are often associated with poor quality of life, substance use, suicide, unhealthy behaviors, loss of productivity, domestic violence, and impaired relationships (Li, 2023).

According to the US Department of Veteran Affairs, the number of veterans with PTSD varies by service area. For veterans of Operation Iraqi Freedom and Enduring Freedom, 29% of veterans will experience PTSD; 21% of veterans from Desert Storm have experienced PTSD at some point in their lifetimes, and 10% of Vietnam veterans experienced PTSD at some point (Department of Veterans Affairs, 2023).

Li and Sanchez-Garcia reviewed multiple EAT studies with veterans (Li, 2023):

- Burton et al. studied a group in EAT, and participants reported enhanced levels of trust, relaxation, and patience.
- Malinowsk et al. studied individual EAT, which resulted in a marked decrease in PTSD symptoms as early as day 2 of therapy, and the horses experienced decreased heart rate and stable cortisol levels, indicating the involvement with humans was not stressful.

• Shelef et al. also studied group EAT, noting improvements in daily functioning and coping skills, and the development of a healthier, stronger self-image.

Veterans' Experiences

The following are testimonials from veterans (Kucera, 2022): "I moved home to Montgomery (Texas) after my time as a Marine," said Kody Wall, "and very little went well. I had a really hard time adapting, so it wasn't long until I was divorced and sleeping on an air mattress at my sister's house."

During this time, Wall was battling suicidal thoughts, wanting to just give up. Though he had been getting routine care at a Houston VA outpatient clinic, he did not feel comfortable going into an office or working through appointments over the phone. While hopelessness set in, the darkness would soon clear thanks to a unique therapeutic approach focused on his relationship with a horse.

"My sister pushed me to visit Sunny Creek Ranch because she knew how much I enjoyed being around horses. It was the best thing that could've happened for me," said Wall. "I've been attending sessions since 2016 and spend any extra time I have to help." He also shares his own experiences with other veterans attending sessions, which can help them open up.

According to US Army veteran Andrew Gitzlaff, EAT helped him battle depression; he said he was more willing to open up to others, especially when he was in a group session with others who had the same problems (Walter, 2023). "It feels good to connect with an animal this big. That takes trust (Walter, 2023).

Another veteran noted that working with the horses taught him to slow down. He shared that initially, he was rushing the horse because his mindset was very task oriented. This resulted in him becoming anxious instead of relaxing. With effort, he could adjust and "be in the moment." He was able to translate this to the rest of his life (Walter, 2023).

A barn doesn't seem to be the typical location for therapy, but many find such a location very therapeutic. Equine therapies allow the individual to work with a horse by learning how to care for them. Working with horses is similar to cognitive-behavioral and experiential therapies. Caring for and working with horses requires concentration, selflessness, and teamwork. These areas of focus result in improved self-esteem, self-awareness, confidence, and empathy.

More research is needed, but the current evidence is

compelling that EAT is beneficial for PTSD and other mental health and behavioral conditions.

Is EAT Covered by Insurance?

EAT, if coded as "Hippotherapy," may be covered by some payers and waiver programs (S8940). However, large payer organizations typically exclude coverage. Many EAT providers have funds to support those who would benefit, and some individuals privately pay. An internet search should provide available programs in your region to facilitate EAT for your patients.

EAT may be available through the VA, depending on the area. Check availability at: https://www.veteranscrisisline.net/ GetHelp/ResourceLocator.aspx

Implications for Case Managers

Case managers working with any of the populations listed in this article should investigate if their patients may benefit from EAT. You may want to begin by speaking with your patients' treating providers about their thoughts on whether these therapeutic options would enhance their current services. Taking this step first is recommended before discussing with the patient and their family or caregiver in case the therapies are contraindicated, there are no EAT facilities in their region, or no reimbursement is available.

If the therapies are approved by the treating providers, explore coverage with the patient's reimbursement source. If no reimbursement is available, explore other reimbursement sources that may be available through the EAT provider, such as scholarships or private sliding-scale payments based on income. Funds may be available for children with special needs from state waivers.

Veterans Health Administration may reimburse or make available EAT. Case managers working with veteran populations can explore the availability of these services, especially for those with PTSD, anxiety, and depression.

Case managers should, first and foremost, be advocates for those they serve. That may mean looking at care and services that may be out of the mainstream but bring about improved outcomes. EAT may be a form of therapy that will positively impact a patient's recovery and well-being,

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PharmaFacts for Case Managers



KISUNLA (donanemab-azbt) injection, for intravenous use

WARNING: AMYLOID RELATED IMAGING ABNORMALITIES

Monoclonal antibodies directed against aggregated forms of beta amyloid, including KISUNLA, can cause amyloid related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). Incidence and timing of ARIA vary among treatments. ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events rarely can occur. Serious intracerebral hemorrhages >1 cm, some of which have been fatal, have been observed in patients treated with this class of medications. Because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke, treating clinicians should consider whether such symptoms could be due to ARIA-E before giving thrombolytic therapy in a patient being treated with KISUNLA.

ApoE ε4 Homozygotes

Patients who are apolipoprotein E ϵ 4 (ApoE ϵ 4) homozygotes (approximately 15% of Alzheimer's disease patients) treated with this class of medications, including KISUNLA, have a higher incidence of ARIA, including symptomatic, serious, and severe radiographic ARIA, compared to heterozygotes and noncarriers. Testing for ApoE ϵ 4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results. Prescribers should inform patients that if genotype testing is not performed, they can still be treated with KISUNLA; however, it cannot be determined if they are ApoE ϵ 4 homozygotes and at higher risk for ARIA.

Consider the benefit of KISUNLA for the treatment of Alzheimer's disease and potential risk of serious adverse events associated with ARIA when deciding to initiate treatment with KISUNLA.

INDICATIONS AND USAGE

KISUNLATM is indicated for the treatment of Alzheimer's disease. Treatment with KISUNLA should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials.

DOSAGE AND ADMINISTRATION

Patient Selection

Confirm the presence of amyloid beta pathology prior to initiating treatment.

Dosing Instructions

The recommended dosage of KISUNLA is 700 mg every 4 weeks for 3 doses, then 1400 mg every 4 weeks (*see* Table 1). KISUNLA is administered every 4 weeks as an intravenous infusion over approximately 30 minutes. KISUNLA must be diluted prior to administration.

TABLE 1	DOSING SCHEDULE		
Intravenous Infusion (every 4 weeks)		KISUNLA Dosage (administered over approxi- mately 30 minutes)	
Inf	usions 1, 2, and 3	700 mg	
Infu	sion 4 and beyond	d 1400 mg	

Consider stopping dosing with KISUNLA based on reduction of amyloid plaques to minimal levels on amyloid PET imaging. In Study 1, dosing was stopped based on a reduction of amyloid levels below predefined thresholds on PET imaging.

If an infusion is missed, resume administration every 4 weeks at the same dose as soon as possible.

Monitoring and Dosing Interruption for Amyloid Related Imaging Abnormalities

KISUNLA can cause amyloid related imaging abnormalities-edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H).

Monitoring for ARIA

Obtain a recent baseline brain magnetic resonance imaging (MRI) prior to initiating treatment with KISUNLA. Obtain an MRI prior to the 2nd, 3rd, 4th, and 7th infusions. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including an MRI if indicated.

Recommendations for Dosing Interruptions in Patients with ARIA ARIA-F.

The recommendations for dosing interruptions for patients with ARIA-E are provided in Table 2.

TABLE 2		DOSING RECOMMENDATIONS FOR PATIENTS WITH ARIA-E		
Clinical		ARIA-E Severity on MRI		
Symptom Severity ^a		Mild	Moderate	Severe
Asymptomatic		May continue dosing at current dose and schedule	Suspend dosing ^b	Suspend
Mild		May continue dosing based on clinical judgment	Suspend dosing ^b	dosing ^b
Moderate o	or		Suspend dosing ^b	

- a Mild: discomfort noticed, but no disruption of normal daily activity. Moderate: discomfort sufficient to reduce or affect normal daily activity. Severe: incapacitating, with inability to work or to perform normal daily activity.
- b Suspend until MRI demonstrates radiographic resolution and symptoms, if present, resolve; consider a follow-up MRI to assess for resolution 2 to 4 months after initial identification. Resumption of dosing should be guided by clinical judgment.

ARIA-H

The recommendations for dosing interruptions for patients with ARIA-H are provided in Table 3.

DOCING DECOMMENDATIONS FOR DATIENTS WITH

TABLE 3		DOSING RECOMMENDATIONS FOR PATIENTS WITH ARIA-H		
Clinical Symptom Severity		ARIA-H Severity on MRI		
		Mild	Moderate	Severe
Asymptomatic		May continue dosing at current dose and schedule	Suspend dosing ^a	Suspend dosing ^b
Symptoma	tic	Suspend	Suspend	

- a Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; resumption of dosing should be guided by clinical judgment; consider a follow-up MRI to assess for stabilization 2 to 4 months after initial identification.
- b Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve. Use clinical judgment when considering whether to continue treatment or permanently discontinue KISUNLA.

In patients who develop intracerebral hemorrhage greater than 1 cm in diameter during treatment with KISUNLA, suspend dosing until MRI demonstrates radiographic stabilization and symptoms, if present, resolve. Resumption of dosing should be guided by clinical judgment.

DOSAGE FORMS AND STRENGTHS

Injection: 350 mg/20 mL (17.5 mg/mL) clear to opalescent, colorless to slightly yellow to slightly brown solution in a single-dose vial.

CONTRAINDICATIONS

KISUNLA is contraindicated in patients with known serious hypersensitivity to donanemab-azbt or to any of the excipients. Reactions have included anaphylaxis.

WARNINGS AND PRECAUTIONS

Amyloid Related Imaging Abnormalities

Monoclonal antibodies directed against aggregated forms of beta amyloid, including KISUNLA, can cause amyloid related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E), which can be observed on MRI as brain edema or sulcal effusions, and ARIA with hemosiderin deposition (ARIA-H), which includes microhemorrhage and superficial siderosis. ARIA can occur spontaneously in patients with Alzheimer's disease, particularly in patients with MRI findings suggestive of cerebral amyloid angiopathy, such as pretreatment microhemorrhage or superficial siderosis. ARIA-H associated with monoclonal antibodies directed against aggregated forms of beta amyloid generally occurs in association with an occurrence of ARIA-E. ARIA-H of any cause and ARIA-E can occur together.

ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, rarely can occur. When present, reported symptoms associated with ARIA may include, but are not limited to, headache, confusion, visual changes, dizziness, nausea, and gait difficulty. Focal neurologic deficits may also occur. Symptoms associated with ARIA usually resolve over time. In addition to ARIA, intracerebral hemorrhages greater than 1 cm in diameter have occurred in patients treated with KISUNLA.

Consider the benefit of KISUNLA for the treatment of Alzheimer's disease and potential risk of serious adverse events associated with ARIA when deciding to initiate treatment with KISUNLA.

Incidence of ARIA

Symptomatic ARIA occurred in 6% (52/853) of patients treated with KISUNLA in Study 1. Clinical symptoms associated with ARIA resolved in approximately 85% (44/52) of patients.

Including asymptomatic radiographic events, ARIA was observed in 36% (307/853) of patients treated with KISUNLA, compared to 14% (122/874) of patients on placebo in Study 1. ARIA-E was observed in 24% (201/853) of patients treated with KISUNLA compared with 2% (17/874) of patients on placebo. ARIA-H was observed in 31% (263/853) of patients treated with KISUNLA compared with 13% (111/874) of patients on placebo. There was no increase in isolated ARIA-H (ie, ARIA-H in patients who did not also experience ARIA-E) for KISUNLA compared to placebo.

Incidence of Intracerebral Hemorrhage

Intracerebral hemorrhage greater than 1 cm in diameter was reported in 0.5% (4/853) of patients in Study 1 after treatment

with KISUNLA compared with 0.2% (2/874) of patients on placebo. Fatal events of intracerebral hemorrhage in patients taking KISUNLA have been observed.

Risk Factors for ARIA and Intracerebral Hemorrhage -ApoE ε4 Carrier Status

The risk of ARIA, including symptomatic and serious ARIA, is increased in apolipoprotein Ε ε4 (ApoE ε4) homozygotes. Approximately 15% of Alzheimer's disease patients are ApoE ε4 homozygotes. In Study 1, 17% (143/850) of patients in the KISUNLA arm were apolipoprotein Ε ε4 (ApoE ε4) homozygotes, 53% (452/850) were heterozygotes, and 30% (255/850) were noncarriers. The incidence of ARIA was higher in ApoE ε4 homozygotes (55% on KISUNLA vs 22% on placebo) than in heterozygotes (36% on KISUNLA vs 13% on placebo) and noncarriers (25% on KISUNLA vs 12% on placebo). Among patients treated with KISUNLA, symptomatic ARIA-E occurred in 8% of ApoE &4 homozygotes compared with 7% of heterozygotes and 4% of noncarriers. Serious events of ARIA occurred in 3% of ApoE &4 homozygotes, 2% of heterozygotes, and 1% of noncarriers. The recommendations for management of ARIA do not differ between ApoE &4 carriers and noncarriers (see Dosage and Administration). Testing for ApoE &4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results. Prescribers should inform patients that if genotype testing is not performed, they can still be treated with KISUNLA; however, it cannot be determined if they are ApoE &4 homozygotes and at a higher risk for ARIA. An FDA-authorized test for detection of ApoE &4 alleles to identify patients at risk of ARIA if treated with KISUNLA is not currently available. Currently available tests used to identify ApoE ε4 alleles may vary in accuracy and design.

–Radiographic Findings of Cerebral Amyloid Angiopathy (CAA) Neuroimaging findings that may indicate CAA include evidence of prior intracerebral hemorrhage, cerebral microhemorrhage, and cortical superficial siderosis. CAA has an increased risk for intracerebral hemorrhage. The presence of an ApoE ε4 allele is also associated with cerebral amyloid angiopathy.

In Study 1, the baseline presence of at least 2 microhemorrhages or the presence of at least 1 area of superficial siderosis on MRI, which may be suggestive of CAA, were identified as risk factors for ARIA. Patients were excluded from enrollment in Study 1 for findings on neuroimaging of prior intracerebral hemorrhage greater than 1 cm in diameter, more than 4 microhemorrhages, more than 1 area of superficial siderosis, severe white matter disease, and vasogenic edema.

-Concomitant Antithrombotic or Thrombolytic Medication In Study 1, baseline use of antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) was allowed. Most exposures to antithrombotic medications were to aspirin. The incidence of ARIA-H was 30% (106/349) in patients taking KISUNLA with a concomitant antithrombotic medication within 30 days compared to 29% (148/504) who did not receive an antithrombotic within 30 days of an ARIA-H event. The incidence of intracerebral hemorrhage greater than 1 cm in diameter was 0.6% (2/349 patients) in patients taking KISUNLA with a concomitant antithrombotic medication compared to 0.4% (2/504) in those who did not receive an antithrombotic. The number of events and the limited exposure to nonaspirin antithrombotic medications limit definitive conclusions about the risk of ARIA or intracerebral hemorrhage in patients taking antithrombotic medications.

One fatal intracerebral hemorrhage occurred in a patient taking KISUNLA in the setting of focal neurologic symptoms of ARIA and the use of a thrombolytic agent. Additional caution should be exercised when considering the administration of antithrombotics or a thrombolytic agent (eg, tissue plasminogen activator) to a patient already being treated with KISUNLA. Because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke, treating clinicians should consider whether such symptoms could be due to ARIA-E before giving thrombolytic therapy in a patient being treated with KISUNLA.

Caution should be exercised when considering the use of KISUNLA in patients with factors that indicate an increased risk for intracerebral hemorrhage and, in particular, for patients who need to be on anticoagulant therapy or patients with findings on MRI that are suggestive of cerebral amyloid angiopathy.

Radiographic Severity

The radiographic severity of ARIA associated with KISUNLA was classified by the criteria shown in Table 4.

The majority of ARIA-E radiographic events in Study 1 occurred early in treatment (within the first 24 weeks), although ARIA can occur at any time and patients can have more than 1 episode. The maximum radiographic severity of ARIA-E in patients treated with KISUNLA was mild in 7% (59/853) of patients, moderate in 15% (128/853) of patients, and severe in 2% (14/853) of patients. Resolution on MRI after the first ARIA-E event occurred in 63% of patients treated with KISUNLA by 12 weeks, 80% by 20 weeks, and 83% overall after detection. The maximum radiographic severity of ARIA-H microhemorrhage in patients treated with KISUNLA was mild in 17% (143/853) of patients, moderate in 4% (34/853) of patients, and severe in 5% (40/853) of patients. The maximum radiographic severity of ARIA-H superficial siderosis in patients treated with KISUNLA was mild in 6% (47/853) of patients, moderate in 4% (32/853) of patients, and severe in 5%

TABLE 4	ARIA MRI CLASS	IFICATION CRITERIA

ARIA Type	Radiographic Severity		
	Mild	Moderate	Severe
ARIA-E	FLAIR hyperintensity confined to sulcus and/or cortex/subcortex white matter in 1 location <5 cm	FLAIR hyperintensity 5-10 cm in single greatest dimension, or more than 1 site of involvement, each measuring <10 cm	FLAIR hyperintensity >10 cm with associated gyral swelling and sulcal effacement. One or more separate/ independent sites of involvement may be noted
ARIA-H microhemorrhage	Less than or equal to 4 new ncident microhemorrhages	5-9 new incident microhemorrhages	10 or more new incident microhemorrhages
ARIA-H superficial siderosis	1 new ^a focal area of superficial siderosis	2 new focal areas of superficial siderosis	Greater than 2 new focal areas of superficial siderosis

a Includes new or worsening superficial siderosis.

(46/853) of patients. Among patients treated with KISUNLA, the rate of severe radiographic ARIA-E was highest in ApoE ε4 homozygotes 3% (4/143) compared with heterozygotes 2% (9/452) or noncarriers 0.4% (1/255). Among patients treated with KISUNLA, the rate of severe radiographic ARIA-H was highest in ApoE ε4 homozygotes 22% (31/143) compared with heterozygotes 8% (38/452) or noncarriers 4% (9/255).

Monitoring and Dose Management Guidelines

Recommendations for dosing in patients with ARIA-E depend on clinical symptoms and radiographic severity (see Dosage and Administration). Recommendations for dosing in patients with ARIA-H depend on the type of ARIA-H and radiographic severity (see Dosage and Administration). Use clinical judgment in considering whether to continue dosing in patients with recurrent ARIA-E.

Baseline brain MRI and periodic monitoring with MRI are recommended (see Dosage and Administration). Enhanced clinical vigilance for ARIA is recommended during the first 24 weeks of treatment with KISUNLA. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI if indicated. If ARIA is observed on MRI, careful clinical evaluation should be performed prior to continuing treatment.

There is limited experience in patients who continued dosing through asymptomatic but radiographically mild to moderate ARIA-E. There are limited data for dosing patients who have experienced recurrent episodes of ARIA-E.

Providers should encourage patients to participate in real-world data collection (eg, registries) to help further the understanding of Alzheimer's disease and the impact of Alzheimer's disease treatments. Providers and patients can contact 1-800-LillyRx (1-800-545-5979) for a list of currently enrolling programs.

Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis and angioedema, have occurred in patients who were treated with KISUNLA. Promptly discontinue the infusion upon the first

observation of any signs or symptoms consistent with a hypersensitivity reaction and initiate appropriate therapy. KISUNLA is contraindicated in patients with a history of serious hypersensitivity to donanemab-azbt or to any of the excipients of KISUNLA.

Infusion-Related Reactions

In Study 1, infusion-related reactions were observed in 9% (74/853) of patients treated with KISUNLA compared to 0.5% (4/874) of patients on placebo; the majority (70%, 52/74) occurred within the first 4 infusions. Infusion reactions typically occur during infusion or within 30 minutes postinfusion. Infusion-related reactions were mostly mild (57%) or moderate (39%) in severity. Infusion-related reactions resulted in discontinuations in 4% (31/853) of patients treated with KISUNLA. Signs and symptoms of infusion-related reactions include chills, erythema, nausea/vomiting, difficulty breathing/dyspnea, sweating, elevated blood pressure, headache, chest pain, and low blood pressure.

In the event of an infusion-related reaction, the infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy initiated as clinically indicated. Pretreatment with antihistamines, acetaminophen, or corticosteroids prior to subsequent dosing may be considered.

ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Amyloid Related Imaging Abnormalities
- Hypersensitivity Reactions
- · Infusion-Related Reactions

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no adequate data on KISUNLA use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. No animal studies have been conducted to assess the potential reproductive or developmental toxicity of KISUNLA.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

In Study 1, the age of patients exposed to KISUNLA ranged from 59 to 86 years, with a mean age of 73 years; 90% were 65 years and older, and 41% were 75 years and older. No overall differences in safety or effectiveness of KISUNLA have been observed between patients 65 years of age and older and younger adult patients.

CLINICAL STUDIES

The efficacy of KISUNLA was evaluated in a double-blind, placebo-controlled, parallel-group study (Study 1, NCT04437511) in patients with Alzheimer's disease (patients with confirmed presence of amyloid pathology and mild cognitive impairment or mild dementia stage of disease, consistent with Stage 3 and Stage 4 Alzheimer's disease). Patients were enrolled with a Mini-Mental State Examination (MMSE) score of ≥20 and ≤28 and had a progressive change in memory function for at least 6 months. Patients were included in the study based on visual assessment of tau PET imaging with flortaucipir and standardized uptake value ratio (SUVR). Patients were enrolled with or without concomitant approved therapies (cholinesterase inhibitors and the N-methyl-D-aspartate antagonist memantine) for Alzheimer's disease. Patients could enroll in an optional, long-term extension.

In Study 1, 1736 patients were randomized 1:1 to receive 700 mg of KISUNLA every 4 weeks for the first 3 doses, and then 1400 mg every 4 weeks (N = 860) or placebo (N = 876) for a total of up to 72 weeks. The treatment was switched to placebo based on amyloid PET levels measured at Week 24, Week 52, and Week 76. If the amyloid plaque level was <11 Centiloids on a single PET scan or 11 to <25 Centiloids on 2 consecutive PET scans, the patient was eligible to be switched to placebo.

Additionally, dose adjustments were allowed for treatment-emergent ARIA or symptoms that then showed ARIA-E or ARIA-H on MRI.

At baseline, mean age was 73 years, with a range of 59 to 86 years. Of the total number of patients randomized, 68% had low/medium tau level and 32% had high tau level; 71% were ApoE ε4 carriers, and 29% were ApoE ε4 noncarriers. Fifty-seven percent of patients were female, 91% were White, 6% were Asian, 4% were Hispanic or Latino, and 2% were Black or African American.

The primary efficacy endpoint was change in the integrated Alzheimer's Disease Rating Scale (iADRS) score from baseline to 76 weeks. The iADRS is a combination of two scores: the Alzheimer's Disease Assessment Scale-Cognitive subscale (ADAS-Cog13) and the Alzheimer's Disease Cooperative Study – instrumental Activities of Daily Living (ADCS- iADL) scale. The total score ranges from 0 to 144, with lower scores reflecting worse cognitive and functional performance. Other efficacy

endpoints included Clinical Dementia Rating Scale – Sum of Boxes (CDR-SB), ADAS-Cog13, and ADCS-iADL.

There were two primary analysis populations based on tau PET imaging with flortaucipir: 1) low/medium tau level population (defined by visual assessment and SUVR of ≥1.10 and ≤1.46), and 2) combined population of low/medium plus high tau (defined by visual assessment and SUVR >1.46) population.

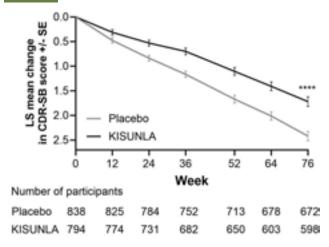
Patients treated with KISUNLA demonstrated a statistically significant reduction in clinical decline on iADRS compared to placebo at Week 76 in the combined population (2.92, p<0.0001) and the low/medium tau population (3.25, p<0.0001).

Patients treated with KISUNLA demonstrated a statistically significant reduction in clinical decline on CDR-SB compared to placebo at Week 76 in the combined population (-0.70, p<0.0001) (see Figure 1 and Table 5). There were also statistically significant differences (p<0.001) between treatment groups as measured by ADAS-Cog13 and ADCS-iADL at Week 76 (see Table 5).

Dosing was continued or stopped in response to observed effects on amyloid imaging. The percentages of patients eligible for switch to placebo based on amyloid PET levels at Week 24, Week 52, and Week 76 timepoints were 17%, 47%, and 69%, respectively. Amyloid PET values may increase after treatment with donanemab is stopped. There is no data beyond the 76-week duration of Study 1 to guide whether additional dosing with KISUNLA may be needed for longer-term clinical benefits.

FIGURE 1

CDR-SB CHANGE FROM BASELINE IN COMBINED POPULATION THROUGH 76 WEEKS IN STUDY 12



a ****p<0.0001 versus placebo.

HOW SUPPLIED/STORAGE AND HANDLING How Supplied

KISUNLA (donanemab-azbt) injection is a sterile, preservative-free, clear to opalescent, colorless to slightly yellow to continues on page 38



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

Clin Infect Dis. 2024 Jun 24:ciae333. doi: 10.1093/cid/ciae333

Efficacy and Safety of Remdesivir in People
With Impaired Kidney Function Hospitalized
for COVID-19 Pneumonia: A Randomized Clinical
Trial

Sise ME, Ramon Santos J, Goldman JD, et al; REDPINE Investigators

BACKGROUND: Few antiviral therapies have been studied in patients with COVID-19 and kidney impairment. Herein, efficacy, safety, and pharmacokinetics of remdesivir, its metabolites, and sulfobutylether-beta-cyclodextrin excipient were evaluated in hospitalized patients with COVID-19 and severe kidney impairment.

METHODS: In REDPINE, a phase 3, randomized, double-blind, placebo-controlled study, participants aged ≥12 years hospitalized for COVID-19 pneumonia with acute kidney injury (AKI), chronic kidney disease (CKD), or kidney failure were randomized 2:1 to receive intravenous remdesivir (200 mg on Day 1; 100 mg daily up to Day 5) or placebo (enrollment: March 2021-March 2022). The primary efficacy endpoint was the composite of all-cause mortality or invasive mechanical ventilation (IMV) through Day 29. Safety was evaluated through Day 60.

RESULTS: Although enrollment concluded early, 243 participants were enrolled and treated (remdesivir, n = 163; placebo, n = 80). At baseline, 90 (37.0%) participants had AKI (remdesivir, 60; placebo, 30), 64 (26.3%) had CKD (remdesivir, 44; placebo, 20), and 89 (36.6%) had kidney failure (remdesivir, 59; placebo, 30); 31 (12.8%) were COVID-19 vaccinated. Composite all-cause mortality or IMV through Day 29 was 29.4% and 32.5% in the remdesivir and placebo group, respectively (P = 0.61). Treatment-emergent adverse events were reported in 80.4% versus 77.5% and serious adverse events in 50.3% versus 50.0% of participants who received remdesivir versus placebo, respectively. Pharmacokinetic plasma exposure to remdesivir was not affected by kidney function.

CONCLUSIONS: Although underpowered, no significant difference in efficacy was observed between treatment groups. REDPINE demonstrated that remdesivir is safe in those with COVID-19 and severe kidney impairment.

Circ Arrhythm Electrophysiol. 2024 Jun 28:e012842. doi: 10.1161/CIRCEP.124.012842

Temporal Association Between Atrial
Fibrillation Burden in Cardiac Implantable
Electronic Devices and the Risk of Heart Failure
Hospitalization

Ahluwalia N, Koehler J, Sarkar S, et al

BACKGROUND: Atrial fibrillation (AF) events in cardiac implantable electronic devices (CIEDs) are temporally associated with stroke risk. This study explores temporal differences in AF burden associated with HF hospitalization risk in patients with CIEDs.

METHODS: Patients with HF events from the Optum de-identified Electronic Health Records from 2007 to 2021 and 120 days of preceding CIED-derived rhythm data from a linked manufacturer's data warehouse were included. AF burden ≥5.5 h/d was defined as an AF event. The AF event burden in the case period (days 1-30 immediately before the HF event) was considered temporally associated with the HF event and compared with the AF event burden in a temporally dissociated control period (days 91-120 before the HF event). The odds ratio for temporally associated HF events and the odds ratio associated with poorly rate-controlled AF (>110 bpm) were calculated.

RESULTS: In total, 7257 HF events with prerequisite CIED data were included; 957 (13.2%) patients had AF events recorded only in either their case (763 [10.5%]) or control (194 [2.7%]) periods, but not both. The odds ratio for a temporally associated HF event was 3.93 (95% CI, 3.36-4.60). This was greater for an HF event with a longer stay of >3 days (odds ratio, 4.51 [95% CI, 3.57-5.68]). In patients with AF during both the control and case periods, poor AF rate control during the case period also increased HF event risk (1.78 [95% CI, 1.22-2.61]). In all, 222 of 4759 (5%) patients without AF events before their HF event had an AF event in the 10 days following.

CONCLUSIONS: In a large real-world population of patients with CIED devices, AF burden was associated with HF hospitalization risk in the subsequent 30 days. The risk is increased with AF and an uncontrolled ventricular rate. Our findings support AF monitoring in CIED algorithms to prevent HF admissions.



AIDS. 2024 Jun 26. doi: 10.1097/QAD.000000000003970.

Risk Factors for Progression From Prediabetes to Diabetes Among Older Persons With HIV

Masters MC, Tassiopoulos K, Bao Y, et al; ACTG A5322 Study Team

OBJECTIVE: Risk factors for progression from prediabetes (pre-DM) to diabetes (DM) among people with HIV (PWH) receiving modern antiretroviral therapy (ART) require better characterization.

DESIGN: AIDS Clinical Trials Group (ACTG) A5322 (HAILO) was an observational cohort study of PWH ≥40 years old. Participants initiated ART through ACTG randomized clinical trials.

METHODS: We used Cox proportional hazards regression models to identify risk factors for development of DM among HAILO participants with pre-DM.

RESULTS: Among 1035 HAILO participants, 74 (7%) had pre-DM at entry and another 679 (66%) developed pre-DM during follow-up. Of 753 PWH with pre-DM, 167 (22%) developed DM. In multivariable models, the risk of developing DM was greater with higher BMI, lower CD4 count (≤200 cells/ mm³), hypertriglyceridemia, or higher waist circumference at pre-DM diagnosis (P < 0.01).

CONCLUSION: Rates of pre-DM and progression to DM remain high among virally suppressed PWH receiving modern ART regimens. Traditional risks for DM, such as higher BMI or waist circumference, are associated with increased risk of incident DM among PWH with pre-DM. The association between lower CD4 and progression to DM suggests a role for advanced immunodeficiency and inflammation. Further investigation of interventions aimed at preventing DM among PWH with pre-DM is needed. Optimizing prevention and treatment for DM may be an intervenable opportunity to improve long-term outcomes for PWH.

J Acquir Immune Defic Syndr. 2024 Aug 1;96(4):326-333. doi: 10.1097/QAI.000000000003444

Associations of Sleep Deficiency With Sexual Risk Behaviors and HIV Treatment Outcomes Among Men Who Have Sex With Men Living With or at High Risk of Acquiring HIV

Rosen AD, Javanbakht M, Shoptaw SJ, Seamans MJ, Gorbach PM

BACKGROUND: Associations of sleep deficiency and methamphetamine use with sexual health and HIV treatment outcomes are poorly understood.

SETTING: A longitudinal cohort of men who have sex with men at risk for or living with HIV (the mSTUDY) was analyzed. This analysis included 1445 study visits among 382 participants. Data were collected from June 2018 to February 2022.

METHODS: Semiannual study visits included self-interviews for sleep deficiency, sexual behaviors, substance use, and HIV treatment. Sleep deficiency was measured using the Pittsburgh Sleep Quality Index. Participants provided specimens for HIV viral load and sexually transmitted infection (STI) testing (chlamydia, gonorrhea, syphilis). Associations between sleep deficiency and STI/HIV outcomes were estimated using multiple logistic regression.

RESULTS: Across visits, the prevalence of sleep deficiency was 56%, with 33% reporting methamphetamine use and 55% living with HIV. Sleep deficiency was associated with reporting at least 1 new anal sex partner (aOR = 1.62, 95% CI: 1.21 to 2.15), exchange sex (aOR = 2.71, 95% CI: 1.15 to 6.39), sex party attendance (aOR = 2.60, 95% CI: 1.68 to 4.04), and missing HIV medications (aOR = 1.91, 95% CI: 1.16 to 3.14). The association between sleep deficiency and exchange sex differed for participants who did and did not report the use of methamphetamine (P = 0.09).

CONCLUSION: Sleep deficiency was associated with sexual health and HIV treatment behaviors after accounting for methamphetamine use. Sleep health should be considered in STI/HIV prevention, particularly for those who use methamphetamine.

Nature. 2024 Jul;631(8019):179-188. Epub 2024 Jun 26. doi: 10.1038/s41586-024-07591-x

Megastudy Shows That Reminders Boost Vaccination But Adding Free Rides Does Not

Milkman KL, Ellis SF, Gromet DM, et al

Encouraging routine COVID-19 vaccinations is likely to be a crucial policy challenge for decades to come. To avert hundreds of thousands of unnecessary hospitalizations and deaths, adoption will need to be higher than it was in the autumn of 2022 or 2023, when less than one-fifth of Americans received booster vaccines. One approach to encouraging vaccination is to eliminate the friction of transportation hurdles. Previous research has shown that friction can hinder follow-through and that individuals who live farther from COVID-19 vaccination sites are less likely to get vaccinated. However, the value of providing free round-trip transportation to vaccination sites is unknown. Here we show that offering people free round-trip Lyft rides to pharmacies has no benefit over and above sending them behaviourally informed text messages reminding them to get vaccinated. We determined this by running a megastudy with millions of CVS Pharmacy patients in the United States testing the effects of (1) free round-trip Lyft rides to CVS Pharmacies for vaccination appointments and (2) seven



different sets of behaviourally informed vaccine reminder messages. Our results suggest that offering previously vaccinated individuals free rides to vaccination sites is not a good investment in the United States, contrary to the high expectations of both expert and lay forecasters. Instead, people in the United States should be sent behaviourally informed COVID-19 vaccination reminders, which increased the 30-day COVID-19 booster uptake by 21% (1.05 percentage points) and spilled over to increase 30-day influenza vaccinations by 8% (0.34 percentage points) in our megastudy. More rigorous testing of interventions to promote vaccination is needed to ensure that evidence-based solutions are deployed widely and that ineffective but intuitively appealing tools are discontinued.

Circ Heart Fail. 2024 Jun 24:e011705. doi: 10.1161/ CIRCHEARTFAILURE.124.011705

Association of Patient Reported Outcomes
With Caregiver Burden in Older Patients With
Advanced Heart Failure: Insights From the
SUSTAIN-IT Study

Nguyen DD, Spertus JA, Benton MC, et al

BACKGROUND: Caregivers of patients with advanced heart failure may experience burden in providing care, but whether changes in patient health status are associated with caregiver burden is unknown.

METHODS: This observational study included older patients (60-80 years old) receiving advanced surgical heart failure therapies and their caregivers at 13 US sites. Patient health status was assessed using the 12-item Kansas City Cardiomyopathy Questionnaire (range, 0-100; higher scores are better). Caregiver burden was assessed using the Oberst Caregiving Burden Scale, which measures time on task (OCBS-time) and task difficulty (OCBS-difficulty; range, 1-5; lower scores are better). Measurements occurred before surgery and 12 months after in 3 advanced heart failure cohorts: patients receiving long-term left ventricular assist device support; heart transplantation with pretransplant left ventricular assist device support; and heart transplantation without pretransplant left ventricular assist device support. Multivariable linear regression was used to identify predictors of change in OCBS-time and OCBS-difficulty at 12 months.

RESULTS: Of 162 caregivers, the mean age was 61.0 ± 9.4 years, 139 (86%) were female, and 140 (86%) were the patient's spouse. At 12 months, 99 (61.1%) caregivers experienced improved OCBS-time, and 61 (37.7%) experienced improved OCBS-difficulty (versus no change or worse OCBS). A 10-point higher baseline 12-item Kansas City Cardiomyopathy Questionnaire predicted lower 12-month OCBS-time (β =-0.09 [95% CI, -0.14 to -0.03]; P<0.001) and OCBS-difficulty (β =-0.08 [95% CI, -0.12 to

-0.05]; P<0.001). Each 10-point improvement in the 12-item Kansas City Cardiomyopathy Questionnaire predicted lower 12-month OCBS-time (β=-0.07 [95% CI, -0.12 to -0.03]; P=0.002) and OCBS-difficulty (β=-0.09 [95% CI, -0.12 to -0.06]; P<0.001).

CONCLUSIONS: Among survivors at 12 months, baseline and change in patient health status were associated with subsequent caregiver time on task and task difficulty in dyads receiving advanced heart failure surgical therapies, highlighting the potential for serial 12-item Kansas City Cardiomyopathy Questionnaire assessments to identify caregivers at risk of increased burden.

J Hum Hypertens. 2024 Jun 26. doi: 10.1038/s41371-024-00919-0

Discrimination and Hypertension Among a
Diverse Sample of Racial and Sexual Minority
Men Living With HIV: Baseline Findings of a
Longitudinal Cohort Study

Gillespie A, Song R, Barile JP, et al

Racial and sexual orientation discrimination may exacerbate the double epidemic of hypertension (HTN) and HIV that affects men of color who have sex with men (MSM). This was a cross-sectional analysis of African American, Asian American, Native Hawaiian, or Pacific Islander (NHPI) MSM living with HIV (PLWH) cohort in Honolulu and Philadelphia. Racial and sexual orientation discrimination, stress, anxiety, and depression were measured with computer-assisted self-interview questionnaires (CASI). We examined the associations between racial and sexual orientation discrimination with hypertension measured both in the office and by 24-h ambulatory blood pressure monitoring (ABPM) using multivariable logistic regression. Sixty participants (60% African American, 18% Asian, and 22% NHPI) completed CASIs and 24-h ABPM. African American participants (80%) reported a higher rate of daily racial discrimination than Asian American (36%) and NHPI participants (17%, P < 0.001). Many participants (51%) reported daily sexual orientation discrimination. Sixty-six percent of participants had HTN by office measurement and 59% had HTN by 24-h ABPM measurement. Participants who experienced racial discrimination had greater odds of having office-measured HTN than those who did not, even after adjustment (Odds Ratio 5.0 (95% Confidence Interval [1.2-20.8], P = 0.03)). This association was not seen with 24-h ABPM. Hypertension was not associated with sexual orientation discrimination. In this cohort, MSM of color PLWH experience significant amounts of discrimination and HTN. Those who experienced racial discrimination had higher in-office blood pressure. This difference was not observed in 24-h APBM and future research is necessary to examine the long-term cardiovascular effects.



Clin Lung Cancer. 2024 May 29:S1525-7304(24)00082-2. doi: 10.1016/j.cllc.2024.05.003

Patients' Preferences for Adjuvant Osimertinib in Non-Small-Cell Lung Cancer After Complete Surgical Resection: What Makes It Worth It to Patients?

Awidi M, Mier-Hicks A, Perimbeti S, et al

BACKGROUND: The ADAURA trial confirmed adjuvant Osimertinib's efficacy in EGFR-mutated non-small-cell lung cancer (NSCLC), yet the limited mature overall survival (OS) data at approval poses a challenge. This study explores patient preferences in the absence of complete OS information, hypothesizing that disease-free survival (DFS) benefit alone may influence adjuvant Osimertinib pursuit.

METHODS: At Roswell Park Comprehensive Cancer Center (Jan-Dec 2021), patients assessed for adjuvant therapy received a survey probing OS and DFS preferences. Scenarios were (a) minimum OS justifying Osimertinib, (b) minimum DFS improvement justifying 3-years of adjuvant Osimertinib, (c) minimum 5-year DFS percent change, and (d) minimum OS justifying copay changes. Results were analyzed.

RESULTS: Of 524 NSCLC patients, 51 participated. Scenario 1 saw 56% requiring a 12-month OS benefit for Osimertinib justification. In scenario 2, 72% deemed a 12-month DFS benefit sufficient. Scenario 3 revealed 31% opting out despite a 10% OS increase. Scenario 4 showed varied willingness to pay, with 33% unwilling to any shoulder copayment even with a 10-year OS benefit.

CONCLUSION: This study explores patient preferences without complete OS data, revealing diverse thresholds. Factors include employment, education, and willingness to pay. Findings underscore shared decision-making importance. Limitations include sample size, potential biases, and regional focus; larger cohorts are needed for validation.

Clin Transplant. 2024 Jul;38(7):e15381. doi: 10.1111/ctr.15381

A Tailored Virtual Program for Alcohol Use
Disorder Treatment Among Liver Transplant
Candidates and Recipients Is Feasible and
Associated With Lower Post-Transplant Relapse

Goswami A, Weinberg E, Coraluzzi L, et al

BACKGROUND: Alcohol-associated liver disease (ALD) is a leading indication for liver transplant (LT) in the United States. Rates of early liver transplant (ELT) with less than 6 months of sobriety have increased substantially. Patients who receive ELT commonly have alcohol-associated hepatitis (AH) and are often too

ill to complete an intensive outpatient program (IOP) for alcohol use disorder (AUD) prior to LT. ELT recipients feel alienated from traditional IOPs.

METHODS: We implemented Total Recovery-LT, a tailored virtual outpatient IOP specific for patients under evaluation or waitlisted for LT who were too ill to attend community-based alcohol treatment programs. The 12-week program consisted of weekly group and individual counseling delivered by a master's level Certified Addiction Counselor trained in the basics of LT. Treatment consisted of 12-Step Facilitation, Motivational Interviewing, and Cognitive Behavioral Therapy. We report on program design, implementation, feasibility and early outcomes.

RESULTS: From March 2021 to September 2022, 42 patients (36% female, 23 in LT evaluation, 19 post-transplant) enrolled across five cohorts with 76% (32/42) completing the program. Alcohol relapse was more common among noncompleters versus those who completed the program (8/10, 80% vs. 7/32, 22%, P = 0.002). History of trauma or post-traumatic stress symptoms were associated with lower likelihood of completion. Patients' desire for continued engagement after completion led to the creation of a monthly alumni group.

CONCLUSIONS: Our integrated IOP model for patients with high-risk AUD in LT evaluation or post-transplant is well-received by patients and could be considered a model for LT programs.

Transplantation. 2024 Jul 1;108(7):1584-1592. Epub 2024 Feb 23. doi: 10.1097/TP.0000000000004953

The Lower Survival in Patients With Alcoholism and Hepatitis C Continues in the DAA Era

Thuluvath PJ, Amjad W, Russe-Russe J, Li F

BACKGROUND: Alcohol liver disease (ALD) may coexist with hepatitis C (HCV) in many transplant recipients (alcoholic cirrhosis with hepatitis C [AHC]). Our objective was to determine whether there were differences in postliver transplantation outcomes of patients with AHC when compared with those with alcoholic cirrhosis (AC) and/or alcoholic hepatitis (AH).

METHODS: Using UNOS explant data sets (2016-2020), the survival probabilities of AC, AH, and AHC were compared by Kaplan-Meier survival analysis. Cox proportional-hazard regression analysis was used to determine outcomes after adjusting for disease confounders. The outcomes were also compared with predirect antiviral agent (DAA) period.

RESULTS: During study period, 8369 biopsy-proven ALD liver transplant recipients were identified. Of those, 647 had AHC (HCV + alcohol), 353 had AH, and 7369 had AC. MELD-Na score (28.7 \pm 9.5 versus 23.8 \pm 10.7; P < 0.001) and presence of ACLF-3 (19% versus 11%; P < 0.001) were higher in AC + AH as compared



with AHC. AHC and AC+AH has similar adjusted mortality at 1-y, but 3-y (hazard ratios, 1.76; 95% confidence intervals, 1.32-2.35; P < 0.0001) and 5-y (hazard ratios, 1.64; 95% confidence intervals, 1.24-2.15; P = 0.0004) mortality rates were higher in AHC. Survival improved in the DAA era (2016-2020) compared with 2009 to 2013 in AHC, but remained worse in AHC group versus AC and/or AH. Malignancy-related mortality was higher in AHC (15% versus 9.3% in AC) in the DAA era.

CONCLUSIONS: AHC was associated with lower 3- and 5-y post-LT survival as compared with ALD without HCV and the worse outcomes in AHC group continued in the DAA era.

J Thorac Cardiovasc Surg. 2024 Jun 25:S0022-5223(24)00536-1. doi: 10.1016/j.jtcvs.2024.06.014

Influence of Air Quality on Lung Cancer in People Who Have Never Smoked

Hutchings H, Wang A, Grady S, Popoff A, Zhang Q, Okereke I

OBJECTIVE: Lung cancer is the leading cause of cancer-related death. The percentage of people who have never smoked with lung cancer has risen recently, but alternative risk factors require further study. Our goal was to determine the impact of air quality on incidence of lung cancer in people who have smoked or never

METHODS: The Cancer Registry from a large urban medical center was queried to include every new diagnosis of lung cancer from 2013 to 2021. Air quality and pollution data for the county were obtained from the United States Environmental Protection Agency from 1980 to 2018. Patient demographics, location of residence, smoking history and tumor stage were recorded. Bivariate comparison analyses were conducted in R.

RESULTS: A total of 2,223 new cases of lung cancer were identified. Mean age was 69.2 years. There was a nonsmoking rate of 8.1 percent. A total of 37% of patients identified as a racial minority. People who have never smoked were more likely to be diagnosed at an advanced stage. When analyzing geographic distribution, incidence of lung cancer among people who have never smoked was more closely associated with highly polluted areas. People who have never smoked with lung cancer had significantly higher exposure levels of multiple pollutants.

CONCLUSIONS: Newly diagnosed lung cancer appears to be more related to poor air quality among people who have never smoked than people who have smoked. Future studies are needed to examine the associations of specific pollutants with lung cancer incidence.



TABLE 5

EFFICACY ANALYSIS RESULTS IN COMBINED POPULATION AT WEEK 76^a

Clinical Endpoints	KISUNLA (N = 860)	Placebo (N = 876)
CDR-SB ^b		
Mean baseline	3.92	3.89
Adjusted mean change from baseline	1.72	2.42
Difference from placebo (%)d	-0.70 (29%) p<0.0001	-
ADAS-Cog ^{13c}		•
Mean baseline	28.53	29.16
Adjusted mean change from baseline	5.46	6.79
Difference from placebo (%)d	-1.33 (20%) p=0.0006	-
ADCS-iADL ^c		
Mean baseline	47.96	47.98
Adjusted mean change from baseline	-4.42	-6.13
Difference from placebo (%)d	1.70 (28%) p=0.0001	_

a Abbreviations: ADAS-Coq13 = Alzheimer's Disease Assessment Scale – 13-item Cognitive Subscale; ADCS-iADL = Alzheimer's Disease Cooperative Study – instrumental Activities of Daily Living subscale; CDR-SB = Clinical Dementia Rating Scale-Sum of Boxes; NCS2 = natural cubic spline with 2 degrees of freedom; MMRM = mixed model for repeated measures.

- b Assessed using MMRM analysis.
- c Assessed using NCS2 analysis.
- d Percent slowing of decline relative to placebo: difference of adjusted mean change from baseline between treatment groups divided by adjusted mean change from baseline of placebo group at Week 76.

slightly brown solution. KISUNLA is supplied in one vial per carton as follows:

• 350 mg/20 mL (17.5 mg/mL) single-dose vial: NDC 0002-9401-01.

Storage and Handling

Unopened Vial

- Store refrigerated at 2°C to 8°C (36°F to 46°F).
- Keep the vial in the outer carton to protect from light.
- Do not freeze or shake.
- If refrigeration is not available, may be stored at room temperature (20°C to 25°C [68°F to 77°F]) for up to 3 days.

Each 30-minute infusion would cost \$695.5 before insurance. For 12 months of treatment, the cost would be \$32,000. In clinical trials, 46% completed treatment in 12 months.

For full prescribing information, please see Product Insert. KISUNLA is manufactured by Eli Lilly and Company.



Navigating Remote Case Management continued from page 4

technologies to support remote case management. In addition to the electronic health record (EHR) and nurse helplines, there are now new telehealth patient portals. These portals support more timely responses to patient inquiries, escalation of a case requiring the direct involvement of a physician, specialist, or other professional, and reduction of unnecessary hospital emergency department, urgent care facility, or doctor office visits. This, in turn, helps contain health care costs, a core goal of today's value-based health care models. Additionally, mobile apps help case managers and their patients communicate on a regular basis. Some type of software records and stores vital statistics (eg, blood pressure, heart rate, oxygen level, glucose level, temperature) and conveys it to the case manager while also providing personalized patient education. Collaboration between remote nurse case managers and other clinicians is also enhanced and more convenient using today's medical technologies.

Challenges for Case Managers Serving Remotely

Remote case management is decidedly filling a dire need; however, for case managers, it is not without its challenges. As we know, traditional case management too has its challenges, but caring for a patient in a face-toface setting helps to build rapport, facilitate communications, and encourage engagement. Remote case management can be perceived as less warm and friendly, more distant, and for some patients, a bit intimidating. That is why it is very important to let your patients and their families/caregivers know that although you are not there in person with them, your dedication and commitment to their best health outcomes is not being compromised.

Patients are not the only ones who may be skeptical of remote case management. Despite the pain they are feeling from the nurse shortage, many health care providers are reluctant to go all-in with remote case management. The Medical Group Management Association data showed that in 2022, only 25% of medical practices offered remote patient monitoring. Among the reasons cited were resistant to change, information technology systems that were not advanced enough, cybersecurity concerns, and the burden of training. To combat these challenges, case managers must adopt best practices and approaches when providing remote case management.

Remote Case Management Best Practices

If you think remote case management might be for you, here are the qualifications needed:

- An AS or BS degree (In some programs, especially those with a highly specialized clinical focus, an MSN may be required.)
- An active RN license in the state of the potential employer(s)
- CCM designation (Commission for Case Manager certification)
- Computer literacy and BLS/ CPR (Basic Life Support/Cardiac Pulmonary Resuscitation) certifications
- Specialized experience in certain medical conditions is not a prerequisite (but it is valuable to have for some providers)

It is vital that you have the self-awareness to know you will find career fulfillment working remotely with your patients. Not all case managers are suited to managing their patients virtually and prefer direct human contact. Further, it is important to understand your responsibilities and what functions you will be expected to perform as a remote case manager.

These include the Medicare annual wellness process, prior authorizations, patient education, managing prescription refills, patient portal engagement, peer-to-peer review, review of lab results with patients, scheduling appointments and treatments, recommending treatment plan modifications when needed, triage (ie, physician and specialist referrals), and reviewing and returning of inbound/outbound calls). Just as any nurse case manager, a remote case manager is expected to be a strong patient advocate, helping patients access all of the medical, social, and community-based resources they need to better manage their health and support better outcomes.

Closing Comments

By leveraging today's advanced medical technologies, including AI and its predictive analytics, health care providers can rely on remote case management as a cost-effective, patient-centered care approach. It addresses providers nursing needs at a time when nursing and case manager shortages prevail and are not expected to improve in the near future. Additionally, it is a future-forward way of aligning human resources with capital resources for true value-based health care.

Enjoy the rest of your summer and give some thought to remote case management.

Catherine M. Mullahy

Catherine M. Mullahy, RN, BS, CRRN, CCM, FCM, Executive Editor cmullahy@academyccm.org

Readers

Have an idea for an article? Send your suggestions for editorial topics to:

cmullahy@academyccm.org.

Understanding and Managing Resistance: A Guide for Case Managers continued from page 22

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Case Management Fellows - Class of 2024; Explaining Case Management continued from page 2

application to using this fact sheet. I would suggest you provide a copy to every new patient and family in your case load. The fact sheet reinforces what you will explain to your patient and family, and it will give them something in writing to refer to. You can download the fact sheet at: cmsa.org/ case-management-at-a-glance/

The second is Fact Sheet: The Impact of Case Management on the Healthcare System, a multipaged fact sheet that defines case management, who professional case managers are, guiding principles followed by case

managers, various case management practice settings, populations served and services provided by case managers, factors that support the demand for case managers, the positive impact of case management on the health care system, and findings from research and models of evidence. It is a succinct but well explained fact sheet. This fact sheet could be distributed and discussed with others you work with, so the entire health care team has a better understanding of case management. It can be used to educate governing bodies and senior management to frontline staff. You can download a copy of this fact sheet at: cmsa. org/the-impact-of-case-managementon-the-healthcare-system-3/

These fact sheets are useful tools and references for you to use to improve your practice of professional case management. I would be interested in knowing what you think of the fact sheets and how you use them. Please let me know by sending an email to gwolfe@academyccm.org. I look forward to hearing from you.

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

ACCM: Improving Case Management Practice through Education

A Career Path into Disability Management: Advocating for Ill or Injured Employees in the **Workplace** continued from page 6

During the injured employee's hospitalization, the case manager at the hospital learned that the vehicle involved in the accident was the family's only car. This made it difficult for the employee's wife to come to the hospital and transport her three children. In addition, she was expecting her fourth child. After learning

of this transportation challenge, the case manager reached out to me as the disability manager working for the employer.

The case manager and I had already been working closely together and had established a good rapport. Because of this relationship, and with an understanding of both the statutory regulations and the employer's policies, I felt confident requesting that the employer release funds to enable the family to purchase a car.

In essence, advocacy comes down to

doing the right thing for all involved. That brings me back to my father's experience as a manager so many years ago and being unable to keep an employee on the job after they received treatment. He saw the unfairness in the employer's policies but was powerless to change them. Watching him, I became inspired to be part of the change that has occurred over the years, with workplace policies and benefits that I hope will continue to evolve with even greater fairness for all involved. CM

Case Management Society of America National Conference 2024 Recap continued from page 9

Kelley, Kevin Parry, and CMSA Past President, Cynthia Whitaker. We also recognized the loss of dear friends of CMSA, Edward Davis, Gil Lattimer, John Mullahy, and Tom Rasmussen.

For our Board of Directors recognition, we saluted 2 outgoing members, Laura Ostrowsky and Dr Samantha Walker, and welcomed incoming members, Cynthia Hopkins and Carolina Mosley. I was also thrilled to recognize the record number of volunteers working on committees to move the practice of case management forward. We were honored to have representatives of 2 affiliate partners in attendance (the American Association of Nurse Life Care Planners [AANLCP] and the Aging Life Care Association [ALCA]) to meet with through the week—they were having a great time!

CMSA also recognized outstanding contributions to the field of case management with its annual awards ceremony. Dr Melanie A Prince received the CMSA Lifetime Achievement Award; Joyace Ussin was honored with the CMSA Award of Service Excellence; and Chapter Excellence Awards were given to CMSA Chicago, CMSA Houston/Gulf

Coast, and the CMSA Midwest Coalition in recognition of their hard work and innovation in the past year. And we announced the retirement of Rebecca Perez, CMSA's longtime Education Manager. Becky, you will be missed!

Mindy Owen returned to the stage to announce the CMSA Fellow Class of 2024: Michele O'Brien, Laura Ostrowsky, Dr Lisa Simmons-Field, and Dr Samantha Walker. Congratulations to this esteemed group.

But what really took my breath away was the "Year in Review" video. I was in the middle of these incredible accomplishments through the year but seeing them put together really shows you what a determined group of people can do when they put their minds to it. From our 2 position papers, the launch of our DEIB Committee, and successful Hill Day, to working with the Centers for Medicare & Medicaid Services (CMS) on a member survey, working with the National Quality Forum (NQF) on 2 panels, publication of Case Management fact sheets (health care and consumer) and so much more...case management is well on its way to no longer being the best kept secret in health care. Kudos to all!

Speaking of recognition, we also announced a new program, "Rising Professionals in Case Management," to identify and acknowledge emerging leaders and innovators in case management practice. Stay tuned for more on this program.

And at the end of the final keynote, on June 7, 2024, I was honored to welcome CMSA's new president, Janet Coulter, MSN, MS, RN, CCM, FCM, to the stage to take her place as our president for 2024-2206. Congratulations, Janet! You are going to be awesome, and CMSA is in good hands. Janet's first order of business was announcing the location for CMSA 2025 National Conference, our 35th Anniversary event—deep in the heart of Texas. Dallas, here we come!

The CMSA National Conference 2024 was more than just an educational event; it was a catalyst for advancing the profession of case management. The discussions and connections made during the conference are expected to have a lasting impact on the attendees and the patients they serve. As the health care landscape continues to evolve, the role of case managers will become increasingly vital. The CMSA National Conference demonstrated that the case management community is ready to meet these challenges head-on, with a commitment to excellence, innovation, and patient-centered care.

See you at CMSA2025 in Dallas! CM

Case Managers Are...

continued from page 8

not all case managers are mental health specialists, all of us deal with the mental health of our clients at every interaction. We can recognize loneliness, anxiety, and grief in our clients without them putting these emotions into words. Our clients feel supported by us and often share things that are deeply personal. We communicate our clients' needs across a continuum of care, involving other specialists and professionals who can help.

While our client is always at the center of what we do, we understand the limitations of the systems that we work in. Case managers are pragmatists. We are monitoring for efficiencies and striving for the most direct route to care. We are constantly evaluating costs—not just monetary—but also the cost of frustration, time, and mental energy. We understand that what is saved on one client can be used to help another and that our efficiencies in case management make room for our work to grow.

Although my patients have never

met me in person, they recognize the work that I do. I have connected them to care when they've felt lost. I've provided education when they thought they had nothing more to learn. I've found gaps in their care and needs that sometimes even they were not aware of. The rewards of case management are immeasurable. Some days are incredibly challenging, but our small victories keep us going. As case managers, we step in and make a difference. After all, case managers are the glue and duct tape holding it all together.

Legal Updates continued from page 7

presence of visible weapons.

Below are some additional important actions for health care organizations to take that are based on UCHealth's SAFE Program:

- Staff members should STOP if they feel unsafe for any reason.
- Workers should pause to generally ASSESS their environments. Staff members should think about what has happened and observe what is currently occurring. Is there, for example, mounting frustration or anger?
- Staff should then FAMILIARIZE themselves with the room. Who is the patient? Where is the

patient? Are there any factors that might escalate behaviors? Staff members should also consider putting themselves in positions in which they have a route to escape, if necessary.

 Practitioners should also ENLIST help. Getting help may, for example, include pushing panic buttons on mobile devices.

Chief of Security at UCHealth said in Becker's Hospital Review on June 4, 2024:

"You can't just talk about the shrimp and [get] a good picture. We have to talk about the roux and the rice and everything else that goes into this for a good picture to be painted

so people have an understanding. We want to solve this with an electronic learning or a 15-minute huddle, but we can't. This is continuous and a persistent pursuit toward educating, communicating, recognizing, responding to, reporting, and recovering from workplace violence."

Every caregiver matters. The health care industry has lost caregivers to violence on the job in the past. Let's not repeat these terrible events.

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Beyond Binary: Ethical Considerations in Caring for Transgender Youth continued from page 18

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Vol. 30, No. 3, June/July 2024. CareManagement (ISSN #1531-037X) is published electronically six times a year, February, April, June, August, October, and December, and its contents are copyrighted by Academy of Certified Case Managers, Inc., 2740 SW Martin Downs Blvd. #330, Palm City, FL 34990;

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