CareManagement

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INSIDE THIS ISSUE

CONTINUING EDUCATION ARTICLES:

SPECIAL SECTIONS:

DEPARTMENTS:

Gary S. Wolfe

Transgender Health Care

There are approximately 1.4 million adults living in the United States who identify as transgender. You might think you don't know any transgender people, or you don't work with any. In reality, you probably don't really know if any of your coworkers and friends are transgender. The social and economic marginalization of transgender individuals is widespread, which leads to health care inequities and poorer health outcomes for this population. Transgender and gender diverse individuals face harassment, discrimination, and rejection within society. Lack of awareness, knowledge, and sensitivity as well as bias even from health care professionals leads to inadequate access to, underuse of, and inequities within the health care system for transgender patients. To reduce the inequities experienced by the transgender community, inclusive health care is essential.

Some of the issues transgender individuals face include:

- Harassment
- Discrimination
- Rejection
- Abuse
- Neglect and/or unfair treatment
- Bias from health care professionals and others
- Underuse of the health care system
- Barriers to medical care
- Lack of sensitivity including hostility and unsupportive care
- Untrained/uneducated health care providers/workers
- Lack of access to health insurance
- Finding providers knowledgeable in transgender or gender-diverse care
- Ethical issues of care
- Refusal of care

Be an advocate for the transgender individual and an example for others on how to care for transgender individuals.

As a result of these issues, some of the consequences transgender individuals suffer include:

- Denial of care
- Poor mental health including psychologic distress and suicide risk
- More chronic conditions than the general population
- Higher rates of health problems related to sexually transmitted infections, HIV/AIDS, substance misuse, seeking preventative health care and health care screenings less often than do other people, mental illness, sexual and physical violence, and higher prevalence and earlier onset of disabilities
- Overall elevated mortality rates compared to cisgender individuals
- Lower quality of life

It is well established that gender is a social construct and not a reality of biology, nor is it binary. This is contrasted with sex, which is generally defined as the biological characteristics (ie, reproductive, chromosomal, hormonal) of a person established at birth, and is in fact nonbinary, although it is most often characterized as male or female. Gender, however, is a social construct that may be cisgender male or female, but individuals may alternatively be identified as nonbinary, genderfluid, genderqueer, or transgender male or female among other identities. There are many unique terms used to describe

continues on page 34

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Catherine M. Mullahy

Patient Assessment and Self-Assessment–Important Considerations for Patients…and You!

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

Patient Assessment

Case managers understand that an essential component of the case management process is assessment. Its value and contribution assist in the determination and comprehensive understanding of the patient's health care and social needs, capabilities, and resources they have access to within their family and community. When conducting an assessment, it's also important to determine the barriers that might undermine or prevent achieving goals that have been established during the care management planning phase. Three primary objectives are:

1. Identifying the client's key problems to be addressed, as well as individual needs and interests
2. Determining the expected care goals and target outcomes
3. Developing a comprehensive case management plan that addresses those problems and needs while allowing you, as the case manager, to achieve the established care goals

When gathering information in the assessment phase, and to ensure that this is an objective process, it's often recommended that the case manager should speak with or meet the client personally, but also to hold discussions with their support system, treating physicians, and other members of their health care team to learn about the care they previously received and the types of services to which they best respond. An in-depth assessment also provides valuable information and insight concerning the individual's health care literacy and willingness to accept recommendations.

Just as assessment is essential in the intervention we provide for our patients, self-assessment is a critical component of performance evaluations for ourselves and any staff under our supervision.

Self-Assessment

While many case managers become adept in assessing their patients' needs, these professionals might find it extremely challenging to assess their own performance. Just as assessment is essential in the intervention we provide for our patients; self-assessment is a critical component of performance evaluations for ourselves and any staff under our supervision. When case managers struggle with this assessment, it can impact their professional growth and the quality of the services they provide. Just as there are strategies or steps in conducting our patient assessments, there are strategies that can be used for more effective self-assessments:

1. **Recognize Hurdles**: Understanding the barriers to effective self-assessment is the first step in overcoming them. Case managers may face a range of challenges, from a lack of confidence in their abilities and uncertainty about the criteria to use, to embarrassment about their possible deficiencies. For those in supervisory positions, coaching and training sessions in a nonthreatening manner that target the goals and benefits of self-assessment are beneficial. Creating a supportive environment will encourage an open exchange of information without fear of criticism.
2. **Set Clear Goals:** Clear, measurable goals are the foundation of effective self-assessment. Without them, case managers may struggle to evaluate their performance accurately. Goals should align with both the organization's mission as well as the case manager's personal career aspirations.
3. **Foster a Reflective Culture:** To promote a more effective environment for self-assessment, it's important to create a workplace culture where feedback is regularly exchanged, and where reflective practices are embedded into daily routines. Having team members share their successes and challenges creates the kind of collaborative and nonthreatening environment that promotes and normalizes self-assessment.
4. **Provide Tools:** Providing case managers with checklists or forms specifically designed for the case management professional is helpful on its own, but also serves another purpose. It communicates that their services warrant the creation of tools that encourage and simplify this process rather than a "one size fits all approach." These tools should guide the case managers through their evaluation and prompt them to consider various aspects of their

continues on page 34

The Momentum Continues

By Collen Morley, DNP, RN, CCM, CMAC, CMCN, ACM, RN, FCM

The year 2024 has only just started but it continues the momentum from 2023 for the Case Management Society of America (CMSA). The year 2023 was marked by significant achievements, the continuation of member-focused initiatives, and the strengthening of industry partnerships, which collectively underscore CMSA's commitment to advancing the practice of case management, advocating for the profession at both the national and local levels. In 2024, CMSA has already demonstrated continuing growth for the association overall. Let's take a look at what we've already accomplished in 2024 so far!

The open forum format has fostered a sense of community and collaboration, ensuring that the board's decisions reflect the diverse needs and aspirations of the case management professionals CMSA serves.

Quarterly Open Board Meetings Continue

To promote transparency and member engagement, CMSA held quarterly board meetings open to all members throughout 2023. These sessions provided valuable insights into the organization's strategic directions, operational updates, and opportunities for members to voice their ideas and concerns. The open forum format has fostered a sense of community and collaboration, ensuring that the board's decisions reflect the diverse needs and aspirations of the case management professionals CMSA serves, and this format will continue going forward. I encourage all members to attend and get involved.

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Launch of DEIB, Public Information, and Future Trends Committees

In response to the evolving landscape of health care and social services, CMSA launched several new committees this year, including those focused on Diversity, Equity, Inclusion, and Belonging (DEIB), Public Information, and Future Trends. These committees have been instrumental in guiding CMSA's efforts to embrace diversity within the profession, enhance public awareness of case management's value, and anticipate the future challenges and opportunities in health care. The DEIB committee, in particular, has made strides in promoting an inclusive environment that respects and values the unique contributions of all members. Calls for volunteers for each of these new committees were held, and I am proud to let you know that 100% of those who answered the call are slated to the committees of their choice, and all committees have begun their work!

Virtual Hill Day in March

One of the year's highlights was the Virtual Hill Day in March, which allowed CMSA members to engage directly with lawmakers and advocate for policies that support the case management profession and improve patient care. This virtual event provided a platform for members to discuss critical issues, such as health care access, quality of care, and the importance of case management services in achieving optimal health outcomes. The success of Virtual Hill Day has underscored the impact of collective advocacy and the importance of giving case managers a voice in the policy-making process.

Ongoing Collaborations

CMSA's commitment to building strong partnerships has been evident in its ongoing collaborations with like-minded organizations, such as the American College of Physician Advisors (ACPA), the American Association of Nurse Life Care Planners (AANLCP), and the National Association of Community Health

continues on page 35

Return-to-Work and Stay-at-Work: An Evolution in Practice and Attitudes

By Katherine Edwards, MEd, CCM, CDMS

Throughout my more than 3 decades of working in disability management, I've witnessed many significant changes in the field, particularly in acceptance of return-to-work and stay-at-work programs. As their names imply, return-to-work enables injured employees to return to the workplace while they are still healing, while stay-at-work programs help employees remain on the job as they recuperate. Both typically involve modified duties and other accommodations.

The success of these two approaches underscores the effectiveness of disability management, which seeks to minimize the impact of disability on both the employee and the employer. Consider the results of a study of US federal employees in the Office of Workers' Compensation Disability Management Program, which found that, after their first year in the program, 76% of injured workers returned to work. Overall, 82% of injured workers resumed working at some point during their time in the program.

Fortunately, as disability management has evolved, the value of having people at work in some capacity has become more widely recognized.

Today, return-to-work and stay-at-work are widely used by employers in both the public and private sectors. These programs are part of a wide variety of disability management services and solutions to help people with illnesses, injuries, and disabilities remain productive in the workplace.

Looking back, though, there has been an evolution in the disability management practice and the attitudes surrounding it. At the start of my career, I witnessed resistance on the part of some employers and employees to the idea that someone should be accommodated to do part of their job or work part of the day. Fortunately, as disability management has evolved, the value of having people at work in some capacity has become more widely recognized.

Today, return-to-work and stay-at-work programs support the individual needs of a variety of employees. Consider mature individuals who are working up to and past what has been the traditional retirement age. In health care, for example, we are seeing nurses "age out" of physically demanding tasks, such as lifting and moving patients. However, their clinical knowledge and expertise are valuable. Keeping them on the job in some capacity is crucial, particularly given the shortage of nurses, which also impacts the talent pipeline in case management as an advanced practice.

As manager of Return to Work and Injury Prevention at a large hospital system, I work collaboratively with a team dedicated to helping these valued employees return to the workplace, with the support and accommodation they need for a reasonable level of functioning. Being dually certified, as a Certified Case Manager (CCM) and a Certified Disability Management Specialist (CDMS), I have an appreciation for the entire process. Ideally, it should be seamless: from the provision of care immediately following an injury, through treatment and recuperation, and return to work.

It takes a personalized approach, seeing what the employee can do, rather than focusing on what they cannot. This is the common ground where we can work with employees and supervisors, to engage the people we serve. The basis is what we know to be true: it is far better for employees to maintain a connection to the workplace, preserve their earnings power, and find meaning in what they do. CM

References continued on page 35

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The Ole White Van

By Janet Coulter, MSN, MS, RN, CCM, FCM

The ole white van sitting in the hospital parking garage was getting more and more dusty. It became the topic of many of my families' conversations while my husband was hospitalized. We noticed the van while my husband was completing outpatient testing for a liver transplant. We would mention it in passing that the van was still parked there. But we didn't really pay much attention at the time. The hospital parking garage is huge so I always tried to park on the same level so it would be easier to remember and find my car. The ole white van was always there–in the same spot.

Then came the day that my husband received "the call" to receive a new liver. We rushed to the hospital and parked on the same level in the parking garage. The ole white van was there. When our family came to the hospital to visit, they would mention seeing the ole white van. Talking about the ole white van was a great distraction for my family. It would momentarily take our minds off our present situation—a welcome break from our current situation and a way to let our imaginations explore different ole white van scenarios.

They may present themselves as happy, confident, and successful. But underneath they may feel like the ole white van in the hospital parking lot—alone, no one to care for them, and waiting for someone to come along and help them.

The van was getting dustier and dustier. One tire started going flat. Someone wrote on the back window "wash me". The dust was getting so thick that other people started writing on the van. It was obvious the van had not been moved for a very long time.

As time passed, another tire went flat. My family and I had several discussions about the ole white van. Many scenarios were presented. Was the van stolen and hidden away in the hospital parking garage? That would be an odd place to hide a stolen van. Were there stolen goods in the van being hidden until the search for them cooled off? Was there a dead body in the van? (I watch too much TV! We looked through the windows but could not see much.) Did someone drive the van to the hospital to be seen in the emergency department? Were they admitted? Are they still an inpatient? Did they die? Did the van's owner go to a skilled nursing facility, rehab center, or nursing home, and leave their van in the parking garage? Will their family come and get the van? Does the family even know the van is there? Or was the van parked by a family member who has been staying with a loved one? That loved one must be very ill to be hospitalized for so long. Was the ole white van abandoned because the insurance lapsed, or maybe the car license expired? Maybe the van was going to be repossessed. There were so many questions!

At my husband's first post-transplant visit to the Transplant Clinic, the ole white van was gone. Did hospital security have it towed away? Did the patient or family retrieve the van? Did someone steal it? Was it repossessed? All we knew was that the van was gone…but the mystery remained! Where did it go?

This brings to mind that people also come into our lives with unexplained scenarios. We may never know what that person is going through. They may present themselves as happy, confident, and successful. But underneath they may feel like the ole white van in the hospital parking lot—alone, no one to care for them, and waiting for someone to come along and help them. There is a great lesson here. We as case managers provide guidance, support, and education for our clients. We may be that one person who comes alongside them to provide what they need. Sometimes a small gesture—like a phone call—can mean a lot.

continues on page 35

Janet Coulter, MSN, MS, RN, CCM, FCM, *is a transplant case manager with a wide variety of experiences including educator, administrator, team leader, and Director of Case Management. She was inducted as a Fellow of Case Management in 2022. Janet has published many articles in* CMSA Today, CareManagement, and the Professional Case Management Journal. *In addition, she recently published a chapter in* A Practical Guide to Acute Care Case Management: The Day to Day, *"How To Be An Acute Care Case Manager" Resource and a chapter in* Improving Lives Together: Case Managers Leading the Way.

General Compliance Guidance From the OIG, Part 2

By Elizabeth E. Hogue, Esq.

This is the second in a series of articles that will identify and provide information about key provisions of the General Compliance Guidance. Stay tuned for more on this topic.

The Office of Inspector General (OIG) of the US Department of Health and Human Services (HHS) is the primary enforcer of fraud and abuse prohibitions. The OIG periodically publishes guidance to help providers in their compliance efforts. The OIG has recently published additional General Compliance Guidance that applies to all health care providers, including private-duty home care agencies, that accept any funds from state or federal health care programs, including Medicaid/Medicaid waiver and the VA/TriCare. The OIG also announced that it will publish new guidance specific to segments of the health care industry in 2024. After new specific guidance is published, the General Compliance Guidance will still be effective.

The OIG emphasizes in new General Compliance Guidance that both general and specific guidance do not constitute model compliance programs. Rather, both general and specific guidance are for use as resources by health care providers. The OIG's Guidance is not intended to be one-size-fits-all, completely comprehensive, or all-inclusive of compliance considerations and fraud and abuse risks for every provider.

Remuneration includes anything of value including cash, in-kind, or other form.

The General Compliance Guidance includes an overview of the federal anti-kickback statute. According to the OIG, the overview is intended to help create awareness and provide tools and resources to aid compliance efforts to prevent violations and identify potential violations early on.

The federal anti-kickback statute prohibits providers involved in federal health care program business from engaging in practices that are common in other businesses, such as offering or receiving gifts to reward past or future referrals. In addition, the anti-kickback statute requires intent and is a criminal statute that prohibits remuneration—whether monetary, in-kind, or in other forms—in exchange for referrals of federal health care program business. The statute prohibits activities that occur directly or indirectly, as well as overtly or covertly. Remuneration includes anything of value including cash, in-kind, or other form.

Violation of the anti-kickback statute constitutes a felony punished by a maximum fine of $100,000 per violation, imprisonment up to 10 years, or both. Convictions may also result in mandatory exclusion from health care programs, including Medicare and Medicaid.

Congress has enacted several statutory exceptions to the anti-kickback statute. The OIG has also published exceptions to the statute in the form of safe harbor regulations. Compliance with exceptions or safe harbors will protect providers from liability under the statute.

When attempting to identify problematic arrangements under the anti-kickback statute, providers should address these key areas:

- Nature of the relationship between the parties
- Manner in which participants were selected
- Manner in which remuneration is determined
- Value of the remuneration
- Nature of items or services provided
- Federal program impact
- Clinical decision-making
- Steering
- Potential conflicts of interest
- Manner in which the arrangement is documented

When providers identify potentially problematic arrangements or practices, the OIG says that they can take steps to reduce or eliminate risks of violation

continues on page 35

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Beyond Boundaries: Unraveling the Ethical Challenges of Coordinated Transgender Health Care for Adults

By Chikita Mann, MSN, RN, CCM

Scenario: An individual transitioning from female to male is injured on the job and requests the board-certified case manager to address them by their preferred name. They also want their preferred name on all correspondence. Upon further investigation, the board-certified case manager realizes that the preferred name could hinder their ability to receive medical treatment due to the workers' compensation claim being in the previous name. Moreover, the individual had not undergone the legal transition process. How should the board-certified case manager handle this situation?

In the United States, there are over 1 million transgender individuals (Al-Hiraki et al., 2021). In providing comprehensive and affirming health care for transgender individuals, the role of care coordination emerges as a crucial and dynamic aspect of the patient experience. The field of transgender health is expanding but not fast enough for the health care demands of this population group. Limited access to health care and adverse health outcomes are experienced by transgender individuals, further exacerbated by instances of discrimination and mistreatment. Transgender care coordination goes beyond the traditional health care model, acknowledging the unique needs and challenges faced by individuals exploring gender-affirming care. This multifaceted approach involves orchestrating a seamless continuum of services, from initial assessments to ongoing support, ensuring that transgender clients receive holistic and patient-centered care.

As with any marginalized population, ethical dimensions of providing care for transgender clients have become increasingly significant. As awareness grows regarding the unique challenges faced by transgender individuals, health care professionals find themselves at the intersection of medical expertise and ethical responsibility. Lack of knowledge by health care professionals is a major barrier to transgendered individuals seeking medical treatment. This additionally contributes to the growing number of transgendered individuals who are not seeing health care for chronic conditions. Furthermore, research has shown that transgender individuals experience higher rates of sexually transmitted diseases, substance use, and psychiatric disorders. Another unfortunate plight of transgendered individuals is being refused necessary medical treatment (Juárez et al., 2023).

This article delves into the ethical considerations inherent in the care of transgender clients, emphasizing the need for sensitivity, respect, and cultural competence. From confidentiality and informed consent to advocacy for transgender rights, this exploration aims to shed light on the ethical complexities involved in delivering health care that not only address medical needs but also uphold the dignity and rights of transgender individuals. As we navigate this terrain, it becomes evident that ethical considerations play a pivotal role in fostering an inclusive and affirming health care environment for all.

Understanding Transgender Identity

To proficiently coordinate care for a marginalized individual, it is crucial to be cognizant of their distinct needs. In this article, the phrase *transgender and gender diverse* (TGD) will be used interchangeably with the term *transgender* to describe individuals whose current gender differs from the gender assigned at birth. Also, this article will focus on the transgender adult.

Defining Transgender

Gender, as a social construct, can encompass cisgender identities of male or female. Alternatively, individuals may identify as nonbinary, genderfluid, genderqueer, or transgender male or female, among various other identities.

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Gender identity is an internal self-perception that may or may not align with external factors such as attire, grooming, self-identification, or speech. Gender identity differs from sexual orientation, sex development, and outward expression of gender. The external representation of oneself, including clothing, hairstyle, voice, and behavior, is referred to as gender expression. Transgender individuals exist along a diverse gender spectrum, encompassing transgender men, transgender women, and nonbinary individuals (Feldman et al., 2021). See Table 1 for terms related to transgenderism.

TABLE 1 **TERMINOLOGY RELATED TO GENDER**
(Kelley, 2021; Bhatt et al., 2022)

Cisgender	Refers to individuals whose gender identity corresponds with the sex assigned to them at birth.
Genderfluid	An individual with a gender identity that is not rigid and varies on a daily, weekly, monthly, etc., basis. For instance, this person may identify as female one day and male the next, or as nonbinary on some days and male on others. Their identity and pronouns may similarly fluctuate.
Genderqueer	An encompassing term that describes a gender identity aligning with both male and female identities, neither exclusively male nor female, or somewhere along the spectrum between male and female. This term is occasionally viewed as an umbrella term that includes gender nonbinary, though definitions may vary.
Legal Transition	Altering the gender marker and name on legal documents and forms of identification.
Nonbinary	Refers to individuals whose gender identity extends beyond the binary categories of "woman" or "man."
Gender diverse	Refers to individuals whose gender identity or expression diverges from cultural expectations, regardless of whether they personally identify as trans or nonbinary.
Transgender	A comprehensive term encompassing individuals whose gender identity, expression, or behavior diverges from what is typically associated with the sex assigned to them at birth.
Transgender male	An individual identified as male, who prefers male or gender-neutral pronouns (e.g., he/him/his, they/them/theirs, etc.), despite being assigned female at birth (AFAB). This person's gender identity aligns with being male. May also be referred to using the terms "FTM".
Transgender female	An individual identified as female, who prefers female or gender neutral pronouns (e.g., she/her/hers, they/them/theirs, etc.), despite being assigned male at birth (AMAB). This person's gender identity aligns with being female. May also be referred to using the terms *MTF*.

Health Care Disparities

Transgender individuals represent an underserved and vulnerable population encountering numerous inequities, including obstacles in accessing and receiving sufficient health care. The primary concerns of transgender individuals are identified in this article as insurance coverage for transition-related care, accessibility to such care, and the education of health care clinicians about transgender patients and related issues (Tanenbaum & Holden, 2023). Health care disparities persistently affect transgender individuals, creating significant challenges in accessing inclusive and affirming health care. These disparities arise from various sources, including discrimination, lack of cultural competence among health care clinicians, and insufficient understanding of transgender health care needs. Transgender individuals often face barriers to gender-affirming care, such as hormone therapy and gender confirmation surgeries, due to systemic issues and inadequate insurance coverage. Additionally, the reluctance of some health care professionals to undergo transgender health care training further contributes to disparities, leading to suboptimal health care experiences for transgender individuals (Tanenbaum & Holden, 2023).

Hormone Therapy and Medical Interventions

Hormone therapy is a critical aspect of gender-affirming care for many transgender individuals. For those seeking to align their physical characteristics with their gender identity, hormone therapy can bring about significant changes such as the development of secondary sex characteristics. Transgender individuals may undergo hormone therapy to achieve a more congruent gender presentation, which can positively impact their mental well-being and overall quality of life (Ramsay & Safer, 2023).

In transgender women (assigned male at birth), hormone therapy typically involves the administration of estrogen and antiandrogen medications. These medications and hormones can lead to the development of breast tissue, a softer skin texture, and a reduction in facial and body hair. For transgender men (assigned female at birth), testosterone is commonly prescribed to induce changes like voice deepening, increased body hair, and muscle development (Ramsay & Safer, 2023).

Gender-Affirmation Surgery

Gender-affirmation surgery, also known as *gender-confirming* or *gender reassignment surgery*, is a medical procedure that helps align an individual's physical characteristics with their gender identity. This surgery is a crucial aspect of gender-affirming care for many transgender individuals, assisting them in achieving a body that better corresponds to their gender identity. The specific procedures involved in

Health care disparities persistently affect transgender individuals, creating significant challenges in accessing inclusive and affirming health care.

gender-affirmation surgery vary based on the individual's gender identity and the desired outcome. For transgender women (assigned male at birth), procedures may include vaginoplasty, breast augmentation, and facial feminization surgery. Transgender men (assigned female at birth) may undergo procedures such as chest masculinization (top surgery), hysterectomy, and phalloplasty or metoidioplasty (Coleman et al., 2022).

It's important to note that not all transgender individuals pursue gender-affirmation surgery, and the decision to undergo these procedures is highly personal. Factors such as individual preferences, health considerations, and cultural or religious beliefs influence these decisions. Access to gender-affirmation surgery can be impacted by various factors, including financial barriers, health care policies, and societal acceptance. Many health care professionals adhere to the guidelines of the World Professional Association for Transgender Health (WPATH) or other relevant standards to ensure that individuals seeking gender-affirmation surgery receive appropriate care. Gender-affirmation surgery is often considered one part of a broader gender-affirming care plan, which may also include hormone therapy, mental health support, and other services (Coleman et al., 2022).

Mental Health Considerations

The pervasive stigma and discrimination faced by transgender individuals significantly impact their mental health, contributing to a range of adverse psychological outcomes. The constant exposure to societal prejudices, biases, and discriminatory practices can lead to heightened levels of stress, anxiety, and depression (Al-Hiraki et al., 2021). Transgender individuals may grapple with feelings of isolation and rejection, exacerbating existing mental health challenges. Stigma can also manifest within health care settings, hindering access to gender-affirming care and discouraging individuals from seeking necessary medical support. Addressing the impact of stigma and discrimination on the mental health of transgender individuals requires a comprehensive approach, encompassing societal awareness, education, and the cultivation of inclusive health care environments.

Gender Dysphoria

Gender dysphoria is a psychological distress that may occur when an individual's gender identity differs from the sex they were assigned at birth. It is recognized as a medical diagnosis, and it is an essential concept in understanding the experiences of transgender individuals. The distress associated with gender dysphoria may manifest in various ways, including emotional distress, anxiety, and dissatisfaction with one's physical appearance or gendered characteristics (Coleman et al., 2022).

In the context of health care for transgender individuals, gender dysphoria can significantly affect the nature of care. It may drive individuals to seek gender-affirming interventions, such as hormone therapy or gender confirming surgeries, to alleviate the distress and align their physical characteristics with their gender identity (Coleman et al., 2022). Understanding and addressing gender dysphoria is crucial for health care clinicians to offer sensitive, effective, and patient-centered care.

Culturally competent and affirming care that acknowledges and respects the challenges associated with gender dysphoria is vital for promoting the well-being of transgender individuals. It involves a collaborative and holistic approach that addresses both the physical and mental health aspects of gender dysphoria, ensuring that individuals receive care that is respectful, inclusive, and aligned with their unique needs and goals.

Posttraumatic Stress Disorder

Posttraumatic stress disorder (PTSD) can significantly affect transgender individuals, particularly as they may experience unique stressors related to their gender identity. Transgender individuals may face discrimination, harassment, and violence, leading to a higher prevalence of trauma compared to the general population. Discrimination, social rejection, and stigma can contribute to a hostile environment, increasing the risk of traumatic experiences for transgender individuals. Instances of bullying, family rejection, and hate crimes are unfortunately common, further heightening the likelihood of developing PTSD. Additionally, transgender individuals may experience trauma related to gender dysphoria, the distress that arises when one's gender identity conflicts with their assigned sex at birth. Difficulties accessing gender-affirming care or facing barriers to social acceptance can exacerbate these challenges, contributing to the risk of PTSD (Simhoni, 2022).

It's important to note that not all transgender individuals pursue gender-affirmation surgery, and the decision to undergo these procedures is highly personal.

Ethics Associated With Care Coordination for Transgender Clients

For the Board-certified case manager (CCM), the Code of Professional Conduct for Case Managers and Certified Disability Management Specialists (CDMS) is a guide (Box 1) for ethical care coordination (CCMC®, 2015). But before we delve into the ethics associated with care coordination for the TGD individuals, we will need to address cultural competence and gender-affirming care.

BOX 1 PRINCIPLES OF THE CODE OF PROFESSIONAL CONDUCT FOR CASE MANAGERS

1. Board-certified case managers will place the public interest above their own at all times.
2. 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.
4. Board-certified case managers will act with integrity and fidelity with clients and others.
5. 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.

Cultural Competence

The presumption that being transgender is "abnormal" contributes to the erasure and invisibility of the transgender experience and identity. Cultural competence in care coordination for transgender adults is essential for providing effective and affirming health care. According to the National Academies of Sciences, Engineering, and Medicine, lack of cultural competence remains a source of concern for TGD individuals (Yu et al., 2023). Recognizing and understanding the diverse experiences within the transgender community is paramount as everyone's journey is unique. Care coordinators need to be well-versed in the intricacies of gender identity, expression, and the specific health care needs associated with transgender adults. This cultural competence extends beyond mere awareness to encompass respectful and inclusive practices that consider the lived experiences and challenges faced by transgender individuals.

A culturally competent care coordination approach involves sensitivity to preferred names and pronouns, creating a safe and nonjudgmental environment, and being attuned to the broader sociocultural factors that may affect transgender adults' health. By integrating cultural competence into care coordination, health care professionals can ensure that transgender adults receive care that is not only medically sound but also respectful, affirming, and aligned with their unique cultural context.

A Special Note About Intersectionality

Intersectionality is a crucial framework for understanding the complex and interconnected layers of identity and social categorizations that individuals experience. When applied to TGD minorities, intersectionality recognizes that their experiences are shaped not only by their transgender identity but also by other intersecting factors such as race, ethnicity, socioeconomic status, disability, and more. TGD minorities often face compounded challenges and discrimination due to the intersection of multiple marginalized identities. For instance, a TGD person of color may encounter distinct forms of discrimination that result from both their transgender identity and their racial or ethnic background. Intersectionality emphasizes the importance of considering the intersecting factors that contribute to the unique experiences and struggles of transgender minorities, ultimately advocating for more inclusive and tailored approaches to address their diverse needs within social, health care, and legal contexts (Coleman et al., 2022; Padrón & Pederson, 2022; Tanenbaum & Holden, 2023).

Gender-Affirming Care

The basis of care coordination for the transgender individual is gender-affirming care. The model of gender-affirming care embraces diversity in gender identity, supporting individuals in defining, exploring, and actualizing their gender identity. This approach fosters an environment of exploration free from judgments or assumptions. Individualized and centered on the unique needs of each person, gender-affirming

Gender dysphoria is a psychological distress that may occur when an individual's gender identity differs from the sex they were assigned at birth. It is recognized as a medical diagnosis, and it is an essential concept in understanding the experiences of transgender individuals.

care encompasses psychoeducation tailored to age and developmental level, parental and family support, social interventions, and gender-affirming medical interventions (Gender-affirming Care Saves Lives, 2022).

One significant obstacle hindering the provision of gender-affirming care is insufficient education for health care professionals. The lack of comprehensive training in transgender health care issues leaves health care clinicians ill-equipped to understand and address the unique needs of transgender individuals. This knowledge gap not only affects the quality of care but also contributes to systemic barriers, perpetuating misunderstandings and biases within health care systems. To overcome this barrier, it is imperative to prioritize education and training initiatives for health care professionals, fostering a more inclusive and culturally competent health care environment. By enhancing awareness and understanding of gender-affirming care, health care professionals can play a pivotal role in dismantling barriers and ensuring equitable access to health care for transgender individuals (Yu et al., 2023).

Another significant obstacle to gender-affirming care is countertransference. Countertransference pertains to both the conscious and unconscious responses of a clinician to a patient (Bhatt et al., 2022). Provision of gender-affirming care begins with the CCM's first encounter with the TGD individual. Should the CCM feel uneasy about interacting with the TGD individual, this discomfort will be perceptible to the individual and impede effective communication.

Ethical Considerations

The ethical principles that will be discussed are justice, advocacy, confidentiality and privacy, informed consent, and beneficence.

Justice

The ethical principle of justice plays a pivotal role in transgender care by emphasizing the importance of fairness, equity, and the elimination of discrimination. In the context of transgender health care, justice calls for equal access to quality and affirming care for all individuals, regardless of their gender identity. Transgender individuals have historically faced systemic barriers, discrimination, and disparities in health care. The principle of justice advocates for dismantling these barriers and ensuring that transgender individuals receive fair and equitable treatment. This includes access to gender-affirming interventions, mental health support, and other health care services that address their unique needs (Padrón & Pederson, 2022).

Health care clinicians must strive to create an inclusive and affirming environment that upholds justice by actively working against discrimination and stigmatization. This involves cultural competence training to understand the diverse experiences within the transgender community and advocating for policy changes that protect transgender individuals from discrimination. Justice in transgender care also encompasses issues related to health care affordability, insurance coverage, and legal protections. It calls for policies that recognize and address the specific health care needs of transgender individuals, ensuring that they are not disadvantaged or excluded from essential services (Padrón & Pederson, 2022).

Advocacy

Advocacy and cultural competence play integral roles in ensuring the well-being and equitable treatment of transgender individuals within health care settings. Cultural competence involves health care professionals understanding and respecting the diverse aspects of gender identity and expression. By being culturally competent, health care clinicians can create an environment that validates and acknowledges the unique experiences of transgender individuals. Additionally, advocacy goes hand in hand with cultural competence as it involves actively supporting and promoting the rights, dignity, and equal access to health care for transgender individuals. This includes challenging discriminatory practices, addressing systemic barriers, and advocating for policy changes that foster an inclusive and affirming health care environment. Together, cultural competence and advocacy contribute to a health care landscape where transgender individuals feel respected and supported and receive care that aligns with their unique needs and identities.

Confidentiality and Privacy

Confidentiality and privacy are of utmost importance for transgender individuals seeking health care due to the sensitive and personal nature of gender identity and expression. Respecting and safeguarding the confidentiality of

Informed consent is a crucial principle in transgender health care, emphasizing the autonomy and decision-making capacity of the individual seeking gender-affirming care. This concept recognizes that transgender individuals are the experts of their own experiences and allows them to make informed decisions about their health care without unnecessary gatekeeping.

transgender patients is crucial for fostering trust, ensuring their well-being, and upholding their dignity. Here are key reasons why confidentiality and privacy are vital in transgender health care:

1. **Disclosure Concerns:** Transgender individuals may face societal stigma, discrimination, or even rejection from family and friends. The fear of unintentional disclosure of their gender identity can be a significant barrier to seeking health care. Maintaining confidentiality helps create a safe space for individuals to disclose their gender identity without fear of repercussions.
2. **Trust and Clinician-Patient Relationship:** Trust is foundational in any health care relationship. For transgender individuals, who may have experienced discrimination or bias in the past, knowing that their health care clinician will protect their privacy fosters a trusting relationship. This, in turn, encourages open communication about their health care needs and concerns.
3. **Mental Health Considerations:** Many transgender individuals experience mental health challenges, such as anxiety or depression, related to their gender identity. Ensuring confidentiality enables them to discuss these issues openly with health care clinicians, facilitating proper mental health support and intervention.
4. **Legal and Social Concerns:** In some regions, legal protections for transgender individuals may be limited. Confidentiality becomes a critical safeguard against potential legal consequences or social stigma related to their gender identity. It also protects against potential discrimination in other aspects of life, such as employment or housing.
5. **Medical History and Gender-Affirming Care:** The need for privacy extends to medical history and the pursuit of gender-affirming care. Many transgender individuals undergo procedures such as hormone therapy or gender-affirming surgeries. Protecting their confidentiality ensures that these medical interventions are discussed and managed in a respectful and private manner.

Informed Consent

Informed consent is a crucial principle in transgender health care, emphasizing the autonomy and decision-making capacity of the individual seeking gender-affirming care. This concept recognizes that transgender individuals are the experts of their own experiences and allows them to make informed decisions about their health care without unnecessary gatekeeping. For transgender individuals, informed consent is particularly significant in the context of gender-confirming interventions such as hormone therapy or gender-confirmation surgeries. It ensures that individuals receive comprehensive information about the potential risks, benefits, and alternatives associated with these interventions, empowering them to make decisions aligned with their gender identity and overall well-being.

The importance of informed consent lies in fostering a collaborative and respectful health care relationship. It acknowledges the rights of transgender individuals to actively participate in decisions regarding their care, promoting transparency and open communication between health care clinicians and patients. This approach contrasts with historical practices that required extensive psychiatric evaluation or pathologized transgender identities before accessing gender-affirming treatments. Informed consent models help reduce barriers to care, increase accessibility, and affirm the dignity of transgender individuals. It contributes to a more patient-centered health care environment that respects diverse gender identities, promotes shared decision-making, and empowers individuals to shape their gender-affirming journeys according to their unique needs and preferences.

Beneficence

Beneficence, the ethical principle of promoting well-being and providing positive benefits, is crucial for transgender care coordination. Transgender care coordination aims to address the holistic well-being of individuals, encompassing not only medical needs but also mental health, social support, and overall quality of life. Beneficence ensures that care coordination efforts prioritize the positive impact on the transgender individual's health and life satisfaction. Beneficence in transgender care means providing affirmative and inclusive care that respects and affirms the individual's gender identity. This includes using correct names and pronouns, acknowledging diverse gender expressions, and promoting a health care environment that fosters a sense of

continues on page 31

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Addressing Social Determinants of Health: Are We There Yet?

By Rebecca Perez, MSN, RN, CCM

According to a 2014 article published in *Public Health Reports,* the public health community started to focus on what we now know as social determinants of health (SDOH), or social drivers of health, over 2 decades ago. We have and still do refer to clinical services as medical care rather than health and health care. (Braveman, 2014) Health is influenced by social policies not just clinical services. (Braveman, 2014). In this same article, the authors refer to the work of Scottish physician, Thomas McKeown who studied death records for England and Wales from the mid-19th Century through the 1960s. (Braveman, 2014) Interestingly, he noted a steady decline of deaths even before medical care advanced with treatments like antibiotics and improved critical care. (Braveman, 2014) He attributed the reasons for the decline to improved living conditions that included nutrition, sanitation, and clean water. Understanding the impact of SDOH and addressing them is not new, but there is a renewed focus to assess and address them.

The World Health Organization (WHO) defines social determinants as "the conditions in which people are born, grow, live, work, and age." (WHO, 2024) These determinants encompass (WHO, 2024):

- Income and social protection
- Education
- Unemployment and job security
- Working life conditions
- Food insecurity
- Housing, basic amenities, and the environment
- Early childhood development
- Social inclusion and nondiscrimination
- Structural conflict
- Access to affordable health services of decent quality

These determinants influence health equity or are contributors to health inequity. WHO states that social determinants are more important to health and health care than lifestyle choices (WHO, 2024). WHO cites numerous studies that suggest that social determinants impact 30% to 55% of health outcomes and that addressing social determinants is necessary to improve health and reduce inequities (WHO, 2024) Healthy People 2030 groups the SDOH into 5 domains (DHHS, n.d.):

1. Economic stability
2. Education access and quality
3. Health care access and quality
4. Neighborhood and built environment
5. Social and community context

Economic stability: One in 10 people in the United States lives in poverty. (DHHS, n.d.) As a result, many cannot afford healthy food, health care, and housing. When individuals have steady employment, they are less likely to live in poverty and are more likely to be healthy. However, it may be difficult for some to find and keep a job, especially if they are challenged with a disability or conditions that limit them in their ability to work. There are individuals who are steadily employed but still cannot afford the things they need to be healthy. Providing resources for career counseling and high-quality child care can help, but there is also need for policies that will help people pay for food, housing, health care, and education to reduce poverty and improve health and well-being. Healthy People 2030 has begun to address some of the issues related to social determinants. (DHHS, n.d.) Education access

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WHO states that social determinants are more important to health and health care than lifestyle choices.

and quality: People with higher levels of education are more likely to be healthy and live longer. (DHHS, n.d.) Children that live in poverty may have disabilities and or may routinely be exposed to discrimination. As a result, they are more likely to struggle in school. The stress of poverty alone can affect the development of a child's brain. Healthy People 2030 focuses on providing high-quality educational opportunities for children and adolescents. (DHHS, n.d.) This focus has resulted in improvements in fourth graders' math skills, an increase in the number of children with disabilities in regular education programs, and an increase in the number of high school students graduating in 4 years. (DHHS, n.d.) Health care access and quality: About 1 in 10 people in the United States do not have health insurance, and without insurance they are less likely to have a primary care provider, access the care they need, or obtain medications. (DHHS, n.d.) Another contributor to not accessing care is because the individual may live too far away from health care providers. There is a need to find strategies that result in increased health care coverage and access to providers whether in-person or remotely. Heathy People 2030 reports some improvement in the number of Americans with health and prescription drug coverage, but there is more to be done.

Neighborhood and built environment: Where people live has a major impact on their health and well-being. Many Americans live in areas with high violent crime rates and poor air and water quality. (DHHS, n.d.) Those most affected are ethnic minorities and people with low incomes. (DHHS, n.d.) Individuals living in these conditions are less likely to leave their homes for activities such as walking or biking because of safety concerns.

Social and community context: The presence or lack of relationships and interactions with family, friends, coworkers, and community members has an impact on health and well-being. (DHHS, n.d.) To reduce these impacts, individuals need positive relationships at home, at work, and in the community. The most vulnerable are children whose parent(s) are incarcerated, adolescents who are bullied, older people, and people with disabilities because there may be no support from loved ones. These individuals need interventions and services that will provide the support that is otherwise unavailable.

In May of 2023, the Centers for Medicare & Medicaid Services (CMS) released the results of the Accountable Health Communities Model, which included 29 organizations that implemented the model between 2018 and 2021. The model tested whether beneficiaries connected to community resources to address their health-related social needs (HRSN) improved health care utilization outcomes, and reduced cost. (CMS, 2023) CMS's term of health-related social needs can be used interchangeably with social determinants/drivers. The clinical community collaboration focused on screening of beneficiaries living in the community to ascertain if they had unmet health-related social needs. The identified beneficiaries were made aware of community services to address their needs along with assistance in navigating how to access the services. The model also encouraged the alignment of clinical and community services to ensure that the needs of the beneficiaries were met. The model created 2 tracks to accomplish these goals (CMS, 2023):

6. Assistance track: assistance was provided to beneficiaries to help them navigate and access the services needed
7. Alignment track: ensure that community partners were aligned with making services available and that they were responsive to beneficiaries' needs

Clinical delivery sites (physician practices, behavioral health providers, clinics, and hospitals) conducted health-related social needs screenings and referred beneficiaries to community service providers that could address the identified needs. (CMS, 2023) Beneficiaries were connected to the community service providers that had the capacity to address their specific social needs. (CMS, 2023) The model focused on 5 health-related social needs: housing, transportation, food insecurity, utility assistance, and interpersonal violence. (CMS, 2023) Food insecurity was the most prevalent and persistent need. (CMS, 2023) Seventy-seven percent of eligible beneficiaries accepted navigation but more than one-half had no needs resolved. (CMS, 2023) The key challenges to having their needs resolved were a lack of transportation, ineligibility for services, long wait lists, and a lack of resources such as housing vouchers and utility assistance. (CMS, 2023) CMS reported that the model reduced emergency department (ED) visits among Medicaid beneficiaries by 3% and fee-for-service (FFS) Medicare beneficiaries by 8%. (CMS, 2023) Avoidable ED (those deemed nonemergent) visits decreased by 9% due to better ambulatory care. (CMS, 2023) While not statistically significant, total expenditures and other hospital-based utilization outcomes showed reductions for Medicaid and FFS Medicare beneficiaries. (CMS, 2023) CMS developed

the Accountable Health Communities Health-Related Social Needs Screening Tool, which was used by the organizations that participated in the project. The tool is available for use outside the project. The core questions address (CMS, 2023):

1. Living situation: having a steady place to live, having a place to live but concerned about losing it in the future, and not having a steady place to live
2. Questions related to the place where they live: the presence of pests, mold, lead paint or pipes, lack of heat, oven or stove not working, smoke detectors not working or missing, and water leaks
3. Questions related to food: within the last 12 months was the beneficiary worried they would run out of food, or the food bought did not last
4. Questions related to transportation: within the last 12 months a lack of reliable transportation to medical appointments, meetings, work, or getting things for daily needs
5. Question related to utilities: within the last 12 months threats to shut off electricity, gas, oil, or water
6. Questions related to safety: how often does anyone including family and friends physically hurt them; how often does family and friends insult them; how often does anyone including family and friends threaten them with harm; how often does anyone including family and friends scream or curse at them?

The tool also includes supplemental questions that assess financial strain, employment, family and community support, education, physical activity, substance use, mental health, and disabilities. This tool has been vetted as part of the Accountable Health Communities innovation and is available for organizations to use, and it is the assessment tool recommended by CMS. For more information about the Accountable Health Communities screening tool please visit: cms.gov/priorities/innovation/media/document/ahcm-screeningtool-companion

The collection of data related to SDOH has been and continues to be an issue for organizations. The determinants are well-defined but collecting and analyzing the information has been challenging. As of January 1, 2024, CMS mandates that hospitals reporting to the Inpatient Quality Reporting program must submit the results of 2 new measures SDOH-1 and SDOH-2. The primary goal of these measures is to establish screening for social risk factors and provide a rate of inpatient populations identified as having 1 or more social risk factors. By requiring all hospitals to systematically collect patient-level data, collaboration between providers and community-based organizations will come to fruition. (Heilman, 2022) A second goal is to eventually use the data from these measures to stratify patient risk and hospital performance rates. (Heilman, 2022) Another benefit could be that the acknowledgement of patients' social needs would lead to reducing adverse health outcomes and enhancing patient-centered treatment resulting in easier discharge planning processes.

The following are more details about the measures. These determinants were prioritized based on the Accountable Health Communities project (Heilman, 2022):

SDOH-1 Social drivers of health: The screening assesses 5 domains:

1. **Food insecurity**
   a. Limited or uncertain access to adequate quality and quantity of food
2. **Housing instability**
   a. Inability to pay rent or mortgage
   b. Frequent changes in residence, temporary stays with friends or relatives
   c. Living in crowded conditions
   d. Lack of sheltered housing
3. **Transportation needs**
   a. Lack of or limitations in the ability to reach destinations required for daily living
4. **Utility difficulties**
   a. Inconsistent availability of electricity, water, oil, and gas
5. **Interpersonal safety**
   a. Exposure to intimate partner violence, child abuse, and elder abuse

The measure examines the total number of screenings conducted. The denominator is the number of patients over the age of 18 admitted to a hospital and the numerator is the number of patients screened for the 5 domains.

SDOH-2 social drivers of health: The measure assesses the number of patients screened who identified 1 or more social risk factor. The measure denominator is the number of patients 18 years or older screened for the 5 domains and the numerator is the number of patients who screened positive for 1 or more risk factor.

Up until January 1, 2024, screening for SDOH was voluntary. As screenings are now required, the collection period is January 1, 2024, through December 31, 2024, and submission deadline for the data is May 15, 2025.

A challenge to many organizations is deciding what tool to use and how to integrate the data into their electronic health record. These challenges go beyond health care organizations. The lack of a standardized way to collect data and interoperability also impacts social care services organizations. Because of these limitations, efforts to coordinate comprehensive care may be compromised. According to the US Playbook to Address Social Determinants of Health, there is growing interest in capturing health-related social needs and SDOH in a standardized format for integration into an

Healthy People 2030 groups the SDOH into 5 domains: economic stability, education access and quality, health care access and quality, neighborhood and built environment, and social and community context.

electronic health record and or exchange it to ensure social needs are met. (Domestic Policy Council, 2023) Improving data quality and management should enhance service delivery and is especially important to organizations serving underrepresented populations. (Domestic Policy Council 2023) The Biden/Harris Administration is working on the following initiatives to improve data sharing and analysis (Domestic Policy Council):

- Establish a centralized federal data working group: this will encompass a coalition of agencies headed by the Office of the Federal Chief Information Officer to establish a SDOH Working Group. The Working Group will recognize and establish best practices to incorporate interoperable SDOH data collection, incorporate into policy for development and implementation, and encourage public and private investment in health information technology (HIT).
- Improve responsible and protected exchange of individual sensitive health information across federal agencies. The Department of Health and Human Services (DHHS) will expand guidance and resources to assist the health care sector understand the laws and obligations administered by DHHS as they relate to privacy. DHHS will support data standards that enable privacy practices using HIT.
- Align federally administered programs to support SDOH information exchange and closed-loop referrals: DHHS will continue to encourage agencies and organizations to adopt data standards such as United State Core Data for Interoperability (USCDI) and promote the adoption of Health Level 7 (HL7) Fast Healthcare Interoperability Resource (FHIR) to drive innovation for capturing and exchanging SDOH data that will support person-centered, accessible health interventions.

An earlier attempt to collect data related to SDOH was the development of Z codes. These were introduced with the ICD Tenth Revision (ICD-10) in October of 2015. The codes were meant to capture encounters other than a disease or injury and provide a consistent collection of SDOH data. However, the use of Z codes has been meager, despite their potential. (Truong, 2020) The lack of adoption and limited use of Z codes can be attributed to several factors. The codes are not reimbursable, there is a lack of training on how to use the codes, and there is no financial incentive to use them. (Truong, 2020) Some larger hospital and physician groups crosswalk the codes against their care models and have started collaborations with payers to optimize their use. (Truong, 2020) Kaiser Permanente Northwest has incorporated the use of Z codes in their care model in an effort to standardize data and target specific community resources and process changes to better meet patient needs. (Truong, 2020) A leader in health data analysis, 3M corporation has considered developing a composite score that includes Z codes. (Truong, 2020) While Z codes may have potential for improving the measurement of SDOH and facilitating the development of programs to address them, it does not appear that there has been any recent adoption.

In 2022, the National Quality Forum's (NQF's) Leadership Consortium identified SODH data collection and utilization to improve health outcomes as a priority issue. NQF is a nonprofit, nonpartisan, membership-based organization that works to improve health care outcomes, safety, equity, and affordability. Their unique role is to bring all voices to the table to forge multistakeholder consensus on quality measurement and improvement standards and practices that achieve health improvements for all. (NQF, 2024) NQF's Leadership Consortium launched an Implementation Collaborative in which a subset of member organizations, or Implementers, identified lessons learned, barriers, and outcomes from their respective projects. The Implementers relied on their Leadership Consortium colleagues to provide feedback (NQF, 2024). Four Leadership Consortium members volunteered to be Implementers. The following is a list of the Implementers and their respective projects:

- Promoting Interoperability to Advance Community Partnerships (Veterans Health Administration)
- Improving Access to Housing and Nutrition with Case Management Intervention (Case Management Society of America)
- Texas Community Care Partnership for Health-Related Social Needs (Texas Health and Human Services Commission)
- Leveraging Digital Tools to Meet Patient's Social Resource Needs (Phreesia)
- Using SDOH and Patient Activation Measure (PAM) Data to Target Limited Community Health Worker Resources to High-Need Patients (Phreesia)

The projects addressed SDOH by examining how SDOH

The collection of data related to SDOH has been and continues to be an issue for organizations. The determinants are well-defined but collecting and analyzing the information has been challenging.

data is collected and used, promotion of interoperability using a standards-based approach, the use of the Patient Activation Measure (PAM) to collect patient activation data, and the Protocol for Responding to & Assessing Patients' Assets, Risks & Experiences (PRAPARE) was used to screen for social drivers. All data were collected digitally to identify and personalize the needs of patients with high social needs, to improve how community health workers address the needs of patients with high needs, identify additional community-based organizations to meet the needs of individuals stratified as high risk, and evaluate the impact of case management facilitation of food and housing resources for patients identified with needs on admission to acute care. (NQF, 2024) The Case Management Society of America (CMSA), a member of the Leadership Consortium and one of the volunteer project implementers, invited several CMSA member organizations to participate in the project. CMSA received interest and partnered with Marion County Health, an acute care facility in Marion, Indiana. Marion Health began assessing patients for social drivers well before the recent CMS requirement. They developed their own assessment tool and created a resource guide for patients identified as having needs. CMSA and Marion County Health communicated each quarter to examine the number of acute care admissions that were screened for and identified as having social needs. Additional measurements included follow-up postdischarge to see if the patients accessed the resources and if their needs were met. CMSA would then report this data to the NQF Leadership Consortium. The project began in early 2022 and concluded in December of 2022.

The process Marion County implemented did not conclude with providing patients with resources and scheduling follow-up visits with their primary care and specialty physicians at the time of discharge. The inpatient case managers followed up with discharged patients 10 to 14 days after discharge to see if they accessed the resources provided to them, if they received the help needed, and if they were satisfied with the process. Early in the project, the case managers had difficulty reaching many of the postdischarge patients. Initially, only 8% returned calls and accessed the resources provided, so they began using a secure texting program to increase postdischarge contact. (NQF, 2024) This resulted in some improvement in knowing if the patients accessed any resources. By the end of the project, their postdischarge contact increased by 50%, but only 20% actually accessed any resources. Of the 50% reached, all reported satisfaction with the process.

All of the implementers recognized barriers and promising practices. As the collection of SDOH data becomes part of everyday practice, the limitations of how to manage the data remain a challenge. (NQF, 2024) While many health care organizations want to experience fully integrated data systems, this has yet to be realized. (NQF, 2024) Contributing to these challenges is a lack of standardized documentation. There are variances in the use of screening codes like Logical Observation Identifiers Names and Codes (LOINC) and diagnosis codes such as Systemized Nomenclature of Medicine-Clinical Terminology (SNOMED CT), or International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10 CM and Z codes). (NQF, 2024) The use of different coding compounds the inability to achieve interoperability. Thus, there is a need to standardize both data collection and reporting to achieve interoperability and integration that will result in the ability to effectively address SDOH. (NQF, 2024) At the conclusion of these projects, the Leadership Consortium provided recommendations that include:

- Leveraging digital platforms to enhance real-time availability of information
- Leveraging existing infrastructures for efficient exchange of information
- Creating and maintaining relationships between health care institutions, community partners, and the broader health care community
- Developing roles and responsibilities to optimize the resolution of health-related social needs
- Developing multidirectional communication to increase awareness and transfer of health-related social needs information among and between health care services and referral sources
- Building meaningful relationships with experts in HIT, digital platforms, and artificial intelligence to streamline processes
- Strengthening interoperability through standardized processes

continues on page 32

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Understanding Clinical Trials (Part I)

By Gary Wolfe, RN, CCM, FCM

Part I of a 2-part series topic.

Clinical trials have advanced the treatment of diseases and health problems for centuries. For many patients, clinical trials have offered potential treatment when all approved treatment options have been exhausted. For others, they have provided altruistic opportunities to participate in advancing treatment options. Clinical trials are at the heart of improving treatment. Clinical trials look at new ways to prevent, detect, and treat disease. Clinical trials can study new drugs or combinations of drugs; new ways of performing surgery; new procedures; new medical devices; new ways to use existing treatments; new ways to change behavior.

What Is a Clinical Trial?

How do patients enroll in such trials? What safeguards and safety issues are in play? What is the role of the case manager in working with patients in clinical trials? This article will address those issues to provide case managers with knowledge to improve their professional practice of case management.

A clinical trial can be defined as a type of research that studies new medical, surgical, or behavioral interventions and evaluates their effects on human health outcomes. All clinical trial activities are an effort to improve the treatment and outcome for a specific health problem. The goal of a clinical trial is to determine if the prevention, treatment, or procedure is safe and effective.

History of Clinical Trials

The evolution of clinical trials traverses a long and fascinating journey from biblical times until the present. The first clinical trial is recorded in the *Book of Daniel* in *The Bible.* (Collier, 2009) This experiment was conducted by King Nebuchadnezzar, a military leader. During his rule in Babylon, Nebuchadnezzar ordered all people to eat only meat and drink only wine. The King believed this would keep his people healthy and in sound physical condition.

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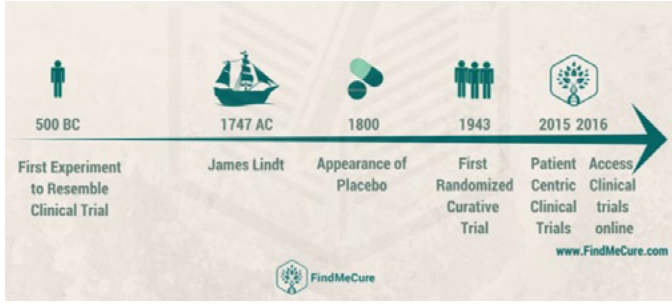
Several men who preferred to eat vegetables objected. The King allowed a group of men to eat legumes and water but only for 10 days. When the ten days had ended, it was determined that the men only eating legumes and vegetables and drinking water appeared better nourished than the meat eaters, so the King permitted the legume and vegetable eaters to continue (Figure 1).

Avicenna in 1025 AD described rules for the testing of drugs. (Bull, 1951) He suggested the clinical trial as a remedy should be used in the natural state in disease without complications. He recommended that trials have 2 treatments of contrary types, and a study be made of the time of action and the reproducibility of the effects. The first novel therapy clinical trial was conducted by Ambroise Pare in 1537 (Twyman, 2004); while serving in battle he was responsible for the treatment of battlefield wounded soldiers. The number of wounded was high, and he was in short supply of the conventional treatment, which was oil. Pare created a concoction of egg yolks, oil of roses, and turpentine. He found when he applied this treatment to wounds, the soldier had little pain, inflammation, and could sleep.

FIGURE 1 THE ABRIDGED VERSION OF CLINICAL TRIAL HISTORY



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The first recorded controlled clinical trial by a physician was conducted in 1747 by Dr. James Lind. (Dodgson, 2006) Dr. Lind was working on a ship and was appalled by the high mortality of scurvy amongst the sailors. In this study there were 12 sailors paired in groups of 2, each group with a different treatment. The treatment group receiving oranges and lemons recovered best and was fit for duty at the end of 6 days.

It took almost another century to report another milestone in the history of the modern clinical trial—the placebo.

The first clinical trial is recorded in the *Book of Daniel* in *The Bible*. (Collier, 2009) This experiment was conducted by King Nebuchadnezzar, a military leader.

The word placebo first appeared in the Hooper's Medical Dictionary in 1811. (Collier, 2009) It was in 1863 that Dr. Austin Flint conducted the first medical experiment in the United States comparing a placebo to an active treatment with 13 patients suffering from rheumatism using an herbal extract instead of an established treatment. This was a very important study because it emphasized the importance of a placebo in identifying the positive effects of active treatment.

The first double-blind controlled clinical trial was conducted by the Medical Research Council (MRC) of the United Kingdom in 1943 to 1944 to investigate patulin treatment (an extract of *Penicillium patulinum*) for the common cold. (Hart, 1999) The trial was rigorously controlled by keeping both the physician and the patient blinded to the treatment. Although the trial outcome did not show any protective effect of patulin, it established the fundamental rules concerning the double-blind process. The first randomized, controlled trial was of streptomycin in pulmonary tuberculosis in 1948 by the MRS of the United Kingdom. (Crofton, 2006) An important component of this trial was the randomization process over the alternation process because the allocation process was concealed at enrollment. Another significant feature was the use of objective measures such as interpretation of markers that were all blinded to the treatment assignment. (MRC, 1948)

The ethical framework for human subject protection has its origins in the ancient Hippocratic Oath, which focused and still focuses on the physician avoiding harming the patient. Although the Oath did not address human experimentation, the most advanced in human experimentation protection was a response to human abuses from World War II experiments. The first international guidance on the ethics of medical research was the Nuremberg Code, which was formulated in 1947. This informed consent for participation in trials was described in 1990; the Nuremberg Code stressed the essentiality of voluntariness of the consent. (Indian, 2006) In 1948, the Universal Declaration of Human Rights, which was adapted by the United National General Assembly, showed concern about rights of human beings being subjected to maltreatment. It was the thalidomide tragedy that helped pass the 1962 Kefauver-Harris amendments, which strengthened federal oversight of drug testing and included a requirement for informed consent. Thalidomide was a drug untested in pregnant women that was given as a sedative for morning sickness and caused severe deformities in infants. (Sparks, 2002) In 1964 the World Medical Association adapted the Helsinki Declaration with specific guidelines on use of human subjects in medical research. In 1966, the International Covenant on Civil and Political Rights stated, "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his consent to medical or scientific treatment." (Indian, 2006)

In parallel with the creation of ethical guidelines, clinical trials started to be addressed in regulation as government authorities began recognizing a need for controlling medical therapies in the early 20th century. The Food and Drug Administration (FDA) was founded in 1862 as a scientific institution and became law when the US Congress passed the Pure Food and Drugs Act in 1906. This legislation demanded greater accountability for marketing food and drugs, and the need for testing of drugs in clinical trial increased.

Since the scurvy trial, clinical trials have evolved into a standardized procedure, focusing on scientific assessment of efficacy and guarding patient safety. As clinical trials continue to evolve, there will always be a continuing need to balance medical progress and patient safety. New ethical and regulatory challenges will become apparent.

Why Are Clinical Trials Done?

Clinical trials are done for a variety of reasons but all in the interest of improving patient outcomes. Clinical trials are done to determine whether a new drug or device is safe and effective for use in people. A trial may be done to test a new combination of drugs. A trial may be done with an existing drug in a different population than was originally evaluated. A clinical trial may be done to study different ways to use a standardized treatment so it may be more effective and easier to use, or to decrease side effects. A clinical trial answers one or more of the following questions:

- Does the treatment work?
- Does it work better than what is currently being used?
- What side effects does it cause?
- Do the benefits of treatment outweigh the risks?
- Which patients or groups of patients are most likely to find this treatment helpful?

BOX 1

Clinical Trials: Inclusion and Exclusion

During drug development, researchers aim to include a broad range of patients who would likely use the product being studied. However, that aim has not always come to fruition. Those who are often left out of clinical trials are older patients, women, certain racial/ethnic groups, and children. In terms of children, the product being studied may not be appropriate for children during the initial trial phases. (US FDA, 2018)

Inclusion criteria define the patient population under study. The criteria may specify the stage of disease or particular pathophysiological characteristics of participants. Patients excluded may have other co-morbidities or be taking other medications that could mask the effect of the medication or device being studied. The ideal is to balance the desire to minimize heterogeneity, which may mask a finding of the drug's effect, with the need to generate data that are generalizable to a broad patient population. (US FDA, 2018)

Exclusion criteria can be based on potential risks for patient groups. Older adults and people with multiple chronic conditions may be excluded because of fear of potential adverse effects. Children, adolescents, and pregnant and lactating women are often excluded because of risks to pregnant women or fetus. Ethical considerations may exclude children and adolescents who cannot give informed consent. (US FDA, 2018) Other excluded groups are people with disabilities, which is discriminatory. Populations with disabilities who have been excluded include people with psychiatric disorders, those who abuse substances, people with visual or hearing problems, those with HIV or hepatitis, people in long-term care, those with speech and communication problems, and people who are not mobile. About 25% of the US population has one or more mobility, visual, hearing, cognitive, developmental, or intellectual impairment. (Plosky et al, 2022)

Older adults are often excluded because of polypharmacy, yet they are a population who may be likely to use the study drug when it is approved.

Other characteristics may also prevent groups of patients from participating. They may be geographically too distant, costs may be a financial burden, transportation and caregivers may be lacking, and health care fatigue can prevent patients from participating. (Plotsky et al, 2022)

What's more, there is a history of mistrust of clinical trials among some patient groups because of previous patient abuse, including forced sterilization, human radiation experiments, and experiments performed without informed consent. The Tuskegee Syphilis Study, in particular, is an enduring and salient example of such abuse and is often cited as contributing to significant suspicion of clinical research among African Americans. (US FDA, 2018)

One way to help alleviate a large barrier is to bring clinical sites to the hospitals, clinics, and doctors' offices in communities who are often not included. Doing so eliminates transportation and geographical barriers. Use research patient-facing organizers and staff who resemble (racially, ethnically, sociologically, and educationally) the people they are trying to recruit. Include in trial design numerical targets for enrolling participants from underrepresented group, especially those who might benefit from the treatment being studied. (Boyle, 2021)

"We want therapies to work for as many people as possible. The best way for that to happen is for all people to have access to participate in clinical research," says Namandje N. Bumpus, PhD, director of the Johns Hopkins Department of Pharmacology and Molecular Sciences. (Johns Hopkins Medicine, 2024)

A 2020 report from the US FDA details statistics about racial/ethnic participation in clinical trials (Johns Hopkins Medicine, 2024)

- **75% of participants are white, while White people are 60% of the US population**
- **8% of participants are African American/Black, while African Americans/Blacks are 13% of the US population**
- **11% of participants are Latinx/Hispanic, yet this group represents 18% of the US population**
- **6% of participants are Asian, and Asian Americans represent 6% of the US population**

Researchers are beginning to make changes in trial design. The importance of creating more inclusiveness in clinical trial participant are several (Johns Hopkins Medicine, 2024):

- **Race, disability and socioeconomic status, plus other demographic factors can affect a person's risk of developing certain conditions or responses to medical interventions**
- **Research participants must represent the people who are most** affect by the disease of condition being studied.

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It was in 1863 that Dr. Austin Flint conducted the first medical experiment in the United States comparing a placebo to an active treatment with 13 patients suffering from rheumatism using an herbal extract instead of an established treatment.

Who Conducts a Clinical Trial?

Clinical trials can be sponsored by organizations (such as a pharmaceutical company), federal offices and agencies (such as the National Institutes of Health [NIH] or the US Department of Veterans Affairs), or individuals (such as doctors or health care providers). The sponsor determines the location(s) of the trials, which are usually conducted at universities, medical centers, clinics, hospitals, and other federally or industry-funded research sites but may also be conducted in medical offices or by community organizations and other health entities. Some clinical trials are conducted in many settings including many countries simultaneously.

The Clinical Trial Process

The clinical trial process starts when a researcher, pharmaceutical company, or organization has an idea they want to test in human subjects to improve care and outcomes. Researchers can start this process in any number of ways. New insights into a disease process can allow researchers to design a new product that eradicates the effects of the disease. Tests can confirm that certain molecular compounds have beneficial results against certain diseases. Preexisting treatments can have unintended consequences. Researchers can develop novel technology, allowing medical interventions to target specific sites in the body or genetic material.

These thoughts and ideas are translated into a protocol which is a detailed plan of what the trial will study, the criteria of who can participate (see Box 1), the prescribed treatments, randomization, schedule of visits, reporting and recording requirements, the informed consent, the duration of the trial, and any compensation for the trial.

After development, researchers perform preclinical research, using good laboratory practices (GLP). Scientists do not perform these studies on humans, but the results should yield useful information about dosing and toxicity levels. Following the preclinical work, investigators perform the clinical research. The FDA monitors these clinical processes. They also oversee the succeeding steps in a drug's progress, including the drug review and the postmarket drug safety review for a minimum of 2 years (and, in some cases, longer) after a new treatment is released. The FDA may remove a treatment from the market anytime it discovers evidence that the treatment is a human safety risk. The FDA puts out regular updates and recalls treatments regularly. The agency is also developing a real-time surveillance system called Sentinel that supports adverse event reporting.

This marks the end of Part I of Clinical Trials. In the next issue, Gary will discuss types of clinical trials, phases, design, and more. Stay tuned. CM

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PharmaFacts for Case Managers

REZDIFFRA (resmetirom) tablets, for oral use

INDICATIONS AND USAGE

REZDIFFRA is indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).

This indication is approved under accelerated approval based on improvement of NASH and fibrosis. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Limitations of Use

Avoid use of REZDIFFRA in patients with decompensated cirrhosis.

DOSAGE AND ADMINISTRATION

Recommended Dosage and Administration

The recommended dosage of REZDIFFRA is based on actual body weight. For patients weighing:

- <100 kg, the recommended dosage is 80 mg orally once daily.
- ≥100 kg, the recommended dosage is 100 mg orally once daily.

Administer REZDIFFRA with or without food.

Dosage Modifications for CYP2C8 Inhibitors

Concomitant use of REZDIFFRA with strong CYP2C8 inhibitors (eg, gemfibrozil) is not recommended.

If REZDIFFRA is used concomitantly with a moderate CYP2C8 inhibitor (eg, clopidogrel) , reduce the dosage of REZDIFFRA:

- <100 kg, reduce the dosage of REZDIFFRA to 60 mg once daily.
- ≥100 kg, reduce the dosage of REZDIFFRA to 80 mg once daily.

DOSAGE FORMS AND STRENGTHS

REZDIFFRA Tablets:

- 60 mg: white oval-shaped film-coated tablets debossed with "P60" on one side and plain on the other side.
- 80 mg: yellow, oval-shaped, film-coated tablets debossed with "P80" on one side and plain on the other side.
- 100 mg: beige to pink, oval-shaped, film-coated tablets debossed with "P100" on one side and plain on the other side.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Hepatotoxicity

Hepatotoxicity has been observed with use of REZDIFFRA. One patient had normal alanine aminotransferase (ALT), aspartate aminotransferase (AST), and total bilirubin (TB) levels at baseline, who received REZDIFFRA 80 mg daily, developed substantial elevations of liver biochemistries that resolved when treatment was interrupted. After reinitiating REZDIFFRA, the patient had elevations of ALT, AST, and TB. Peak values observed were 58 x upper limit of normal (ULN) for ALT, 66 x ULN for AST, 15 x ULN for TB, with no elevation of alkaline phosphatase (ALP). Elevations in liver enzymes were accompanied by elevations in immunoglobulin G levels, suggesting drug-induced autoimmune-like hepatitis (DI-ALH). The liver tests returned to baseline following hospitalization and discontinuation of REZDIFFRA without any therapeutic intervention.

Monitor patients during treatment with REZDIFFRA for elevations in liver tests and for the development of liver-related adverse reactions. Monitor for symptoms and signs of hepatotoxicity (eg, fatigue, nausea, vomiting, right upper quadrant pain or tenderness, jaundice, fever, rash, and/or eosinophilia [>5%]). If hepatotoxicity is suspected, discontinue REZDIFFRA and continue to monitor the patient. If laboratory values return to baseline, weigh the potential risks against the benefits of restarting REZDIFFRA. If laboratory values do not return to baseline, consider DI-ALH or autoimmune liver disease in the evaluation of elevations in liver tests.

Gallbladder-Related Adverse Reactions

In clinical trials, cholelithiasis, acute cholecystitis, and obstructive pancreatitis (gallstone) were observed more often in REZDIFFRA-treated patients than in placebo-treated patients. If cholelithiasis is suspected, gallbladder diagnostic studies and appropriate clinical follow-up are indicated. If an acute gallbladder event is suspected, interrupt REZDIFFRA treatment until the event is resolved].

Drug Interaction with Certain Statins

An increase in exposure of atorvastatin, pravastatin, rosuvastatin and simvastatin was observed when concomitantly administered with REZDIFFRA , which may increase the risk of adverse reactions related to these drugs. Dosage adjustment for certain statins is recommended. Monitor for statin-related adverse reactions including but not limited to elevation of liver tests, myopathy, and rhabdomyolysis.

ADVERSE REACTIONS

The following clinically significant adverse reactions are:

- Hepatotoxicity
- Gallbladder-Related Adverse Reaction

Common Adverse Reactions

The table below displays EAIRs per 100 PY for the common adverse reactions that occurred in at least 5% of patients with F2 or F3 fibrosis treated in either drug arm with REZDIFFRA and were greater than that reported for placebo.

EXPOSURE-ADJUSTED INCIDENCE RATES (EAIR) OF COMMON ADVERSE REACTIONS REPORTED WITH REZDIFFRA IN ADULT PATIENTS WITH NONCIRRHOTIC NASH (TRIAL 1)[a, b, c]

Adverse Reaction	Placebo N=294 n (EAIR[d])	REZDIFFRA 80 mg Once Daily N=298 n (EAIR[d])	REZDIFFRA 100 mg Once Daily N=296 n (EAIR[d])
Diarrhea	52 (14)	78 (23)	98 (33)
Nausea	36 (9)	65 (18)	51 (15)
Pruritus	18 (4)	24 (6)	36 (10)
Vomiting	15 (4)	27 (7)	30 (8)
Constipation	18 (4)	20 (5)	28 (8)
Abdominal pain	18 (4)	22 (5)	27 (7)
Dizziness	6 (1)	17 (4)	17 (4)

a Population includes adult patients with noncirrhotic NASH with liver fibrosis (stages F2 and F3 at eligibility).

b Median exposure duration was 68 weeks for placebo, 74 weeks for REZDIFFRA 80 mg once daily, and 66 weeks for REZDIFFRA 100 mg once daily.

c EAIRs are per 100 person-years (PY) where total PYs were 435, 435, and 407 for placebo, 80 mg once daily, and 100 mg once daily arms, respectively.

d The EAIR per 100 PY can be interpreted as an estimated number of first occurrences of the adverse reaction of interest if 100 patients are treated for one year.

Abbreviations: EAIR, exposure-adjusted incidence rate; PY, person-years; NASH, nonalcoholic steatohepatitis

DRUG INTERACTIONS

Effects of Other Drugs on REZDIFFRA

The table below includes clinically significant drug interactions affecting REZDIFFRA.

CLINICALLY SIGNIFICANT INTERACTIONS AFFECTING REZDIFFRA

Strong or Moderate CYP2C8 Inhibitors	
Clinical Impact	Resmetirom is a CYP2C8 substrate. Concomitant use with a strong or moderate CYP2C8 inhibitor can increase resmetirom Cmax and AUC, which may increase the risk of REZDIFFRA adverse reactions.
Intervention	Concomitant use of REZDIFFRA with strong CYP2C8 inhibitors (e.g., gemfibrozil) is not recommended. Reduce REZDIFFRA dosage if used concomitantly with a moderate CYP2C8 inhibitor (e.g., clopidogrel) [see Dosage and Administration (2.2)].
Organic Anion-Transporting Polypeptides (OATP) 1B1 and OATP1B3 Inhibitors	
Clinical Impact	Resmetirom is an OATP1B1 and OATP1B3 substrate. Concomitant use with OATP1B1 and OATP1B3 inhibitors may increase resmetirom C_{max} and AUC, which may increase the risk of REZDIFFRA adverse reactions.
Intervention	Concomitant use of REZDIFFRA with OATP1B1 or OATP1B3 inhibitors (eg, cyclosporine) is not recommended.

Effects of REZDIFFRA on Other Drugs

The table below includes clinically significant drug interactions affecting other drugs.

CLINICALLY SIGNIFICANT INTERACTIONS AFFECTING OTHER DRUGS

Statins (Atorvastatin, Pravastatin, Rosuvastatin, or Simvastatin)	
Clinical Impact	REZDIFFRA increased plasma concentrations of some statins (atorvastatin, pravastatin, rosuvastatin and simvastatin), which may increase the risk of adverse reactions related to these drugs.
Intervention	Rosuvastatin and simvastatin: Limit daily statin dosage to 20 mg. Pravastatin and atorvastatin: Limit daily statin dosage to 40 mg.
CYP2C8 Substrates	
Clinical Impact	Resmetirom is a weak CYP2C8 inhibitor. Resmetirom increases exposure of CYP2C8 substrates, which may increase the risk of adverse reactions related to these substrates.
Intervention	Monitor patients more frequently for substrate-related adverse reactions if REZDIFFRA is co-administered with CYP2C8 substrates where minimal concentration changes may lead to serious adverse reactions.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no available data on REZDIFFRA use in pregnant women to evaluate for a drug- associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There are risks to the mother and fetus related to underlying NASH with liver fibrosis (see Clinical Considerations). In animal reproduction studies, adverse effects on embryo-fetal development occurred in pregnant rabbits treated with resmetirom at 3.5 times the maximum recommended dose during organogenesis. These effects were associated with maternal toxicity, whereas no embryo-fetal effects were observed at lower dose levels with better tolerance in pregnant rabbits. No embryo-fetal developmental effects occurred in pregnant rats treated with resmetirom or the metabolite MGL-3623. A pre- and postnatal development study in rats with maternal dosing of resmetirom during organogenesis through lactation showed a decrease in birthweight and increased incidence of stillbirths and mortality (postnatal days 1-4) at 37 times the maximum recommended dose. These effects were associated with marked suppression of maternal T4, T3, and TSH levels.

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

Report pregnancies to Madrigal Pharmaceuticals, Adverse Event reporting line at 1-800-905-0324 and madrigalpharma.com/contact/.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

There are risks to the mother and fetus related to underlying maternal NASH with liver fibrosis, such as increased risks of gestational diabetes, hypertensive complications, preterm birth, and postpartum hemorrhage.

Lactation

Risk Summary

There is no information regarding the presence of REZDIFFRA in human or animal milk, the effects on the breast-fed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for REZDIFFRA and any potential adverse effects on the breastfed infant from REZDIFFRA or from the underlying maternal condition.

Pediatric Use

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

Geriatric Use

In Trial 1, of the 594 patients with NASH who received at least one dose of REZDIFFRA, 149 (25%) were 65 years of age and older and 13 (2%) were 75 years of age and older. No overall differences in effectiveness but numerically higher incidence of adverse reactions have been observed in patients 65 years of age and older compared to younger adult patients.

Renal Impairment

The recommended dosage in patients with mild or moderate renal impairment is the same as in patients with normal kidney function. REZDIFFRA has not been studied in patients with severe renal impairment.

Hepatic Impairment

Avoid use of REZDIFFRA in patients with decompensated cirrhosis (consistent with moderate to severe hepatic impairment). Moderate or severe hepatic impairment (Child-Pugh Class B or C) increases resmetirom Cmax and AUC , which may increase the risk of adverse reactions.

No dosage adjustment is recommended for patients with mild hepatic impairment (Child-Pugh Class A).

The safety and effectiveness of REZDIFFRA have not been established in patients with NASH cirrhosis.

CLINICAL STUDIES

The efficacy of REZDIFFRA was evaluated based on an efficacy analysis at Month 12 in Trial 1 (NCT03900429), a 54-month, randomized, double-blind, placebo-controlled trial. Enrolled patients had metabolic risk factors and a baseline or recent liver biopsy showing NASH with fibrosis stage 2 or 3 and a NAFLD Activity Score (NAS) of at least 4. Efficacy determination was based on the effect of REZDIFFRA on resolution of steatohepatitis without worsening of fibrosis and one-stage improvement in fibrosis without worsening of steatohepatitis, on post-baseline liver biopsies collected at 12 months.

The Month 12 analysis included 888 F2 and F3 (at eligibility) patients randomized 1:1:1 to receive placebo (n = 294), REZDIFFRA 80 mg once daily (n = 298), or REZDIFFRA 100 mg once daily (n = 296), in addition to lifestyle counseling on nutrition and exercise. Patients were on stable doses of medications for diabetes, dyslipidemia, and hypertension.

Demographic and baseline characteristics were balanced between treatment and placebo groups. Overall, the median (Q1 to Q3) age of patients at baseline was 58 (51 to 65) years, 56% were female, 21% were Hispanic, 89% were White, 3% were Asian, and 2% were Black or African American.

Median (Q1 to Q3) body mass index (BMI) was 35 (31 to 40) kg/m^2 and median (Q1 to Q3) body weight was 99 (85 to 114) kg.

The table below presents the Month 12 histopathology results comparing REZDIFFRA with placebo on 1) the percentage of patients with resolution of steatohepatitis and no

worsening of liver fibrosis and 2) the percentage of patients with at least one stage improvement in liver fibrosis and no worsening of steatohepatitis. Two pathologists, Pathologist A and Pathologist B, independently read the liver biopsies for each patient. Both the 80 mg once daily and the 100 mg once daily dosages of REZDIFFRA demonstrated improvement on these histopathology endpoints at Month 12 compared to placebo. In a statistical analysis incorporating both pathologists' independent readings, REZDIFFRA achieved statistical significance on both histopathology endpoints for both doses.

Examination of age, gender, diabetes status (Yes or No), and fibrosis stage (F2 or F3) subgroups did not identify differences in response to REZDIFFRA among these subgroups. The majority of patients in the trial were white (89%); there were too few patients of other races to adequately assess differences in response by race.

EFFICACY RESULTS AT MONTH 12 IN ADULT PATIENTS WITH NONCIRRHOTIC NASH WITH STAGE 2 OR STAGE 3 FIBROSIS IN TRIAL 1

	Placebo N=294	REZDIFFRA 80 mg Once Daily N=298	REZDIFFRA 100 mg Once Daily N=296
Resolution of steatohepatitis and no worsening of liver fibrosis			
Response rate, Pathologist A (%)	13	27	36
Difference in response rate vs. placebo (95% CI)		14 (8, 20)	23 (16, 30)
Response rate, Pathologist B (%)	9	26	24
Difference in response rate vs. placebo (95% CI)		17 (11, 23)	15 (9, 21)
Improvement in liver fibrosis and no worsening of steatohepatitis			
Response rate, Pathologist A (%)	15	23	28
Difference in response rate vs. placebo (95% CI)		8 (2, 14)	13 (7, 20)
Response rate, Pathologist B (%)	13	23	24
Difference in response rate vs. placebo (95% CI)		11 (5, 17)	11 (5, 17)

Liver fibrosis was evaluated on the NASH Clinical Research Network (CRN) fibrosis score as 0 to 4. Resolution of steatohepatitis was defined as a score of 0–1 for inflammation, 0 for ballooning, and any value for steatosis. No worsening of steatohepatitis was defined as no increase in score for ballooning, inflammation, or steatosis. Estimated using the Mantel-Haenszel method stratified by baseline type 2 diabetes status (presence or absence) and fibrosis stage (F2 or F3). 95% stratified Newcombe confidence intervals (CIs) are provided. Patients with missing liver biopsy at Month 12 are considered a non-responder.

Starting at Month 3 and through Month 12, there was a trend of greater reductions from baseline in average ALT and AST in the REZDIFFRA groups as compared to the placebo group.

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

REZDIFFRA (resmetirom) tablets are packaged in white high-density polyethylene bottles closed with a child-resistant closure containing an induction seal.

60 mg Tablets: white oval-shaped film-coated tablets, debossed "P60" on one side and plain on the other side.

- 60 mg tablets (30 count)

80 mg Tablets: yellow, oval-shaped, film-coated tablets, debossed with "P80" on one side and plain on the other side.

- Bottle of 30 count
- Bottle of 90 count

100 mg Tablets: beige to pink, oval-shaped, film-coated tablets, debossed with "P100" on one side and plain on the other side.

- Bottle of 30 count
- Bottle of 90 count

STORAGE AND HANDLING

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

The company has priced the drug at an average wholesale price of $47,400.

For full prescribing information, please see Product Insert.

REZDIFFRA is manufactured by UPM Pharmaceuticals for Madrigal Pharmaceuticals.

Additional New Drug Approvals

- Duvyzat (givinostat) is a histone deacetylase inhibitor indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older.
- Tryvio (aprocitentan) is an endothelin receptor antagonist (ERA) for the combination treatment of hypertension that is not adequately controlled with other drugs.
- Lenmeldy (atidarsagene autotemcel) is an autologous hematopoietic stem cell (HSC) gene therapy for the treatment of children with metachromatic leukodystrophy (MLD).
- Tevimbra (tislelizumab-jsgr) is a programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor .
- Jubbonti (denosumab-bbdz) is a RANK ligand (RANKL) inhibitor interchangeable biosimilar to Prolia (denosumab) used in the treatment of osteoporosis.

continued on page 33

LitScan for Case Managers

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

AIDS Res Hum Retroviruses 2024 Mar 21. doi: 10.1089/AID.2023.0113. Online ahead of print.

Incident HIV-Associated Wasting/Low Weight Is Associated with Nearly Doubled Mortality Risk in the Modern ART Era

Michael B Wohlfeiler, Rachel Palmieri Weber, Laurence Brunet, et al.

HIV-associated wasting (HIVAW) is an underappreciated AIDS-defining illness, despite highly effective antiretroviral therapy (ART). We (a) assessed the association between incident HIVAW/low weight and all-cause mortality, and (b) described virologic outcomes after people with HIV (PWH) experienced HIVAW/low weight while on ART. In the Observational Pharmaco-Epidemiology Research & Analysis (OPERA®) cohort, PWH without prior HIVAW/low weight who were active in care in 2016 to 2020 were followed through the first of the following censoring events: death, loss to follow-up, or study end (October 31, 2021). HIVAW/low weight was a diagnosis of wasting or low body mass index (BMI)/underweight or a BMI measurement <20 kg/m2. Hazard ratios (HRs) and 95% confidence intervals (CIs) for the association between time-dependent HIVAW/low weight and mortality were estimated with extended Cox regression models. Over a median follow-up of 45 months (interquartile range: 27, 65), there were 4755 (8%) cases of HIVAW/low weight and 1354 (2%) deaths among 62,314 PWH. PWH who experienced HIVAW/low weight had a significantly higher risk of death than those who did not (HR: 1.96; 95% CI: 1.68, 2.27) after adjusting for age, race, ethnicity, and changes in viral load (VL) and Veterans Aging Cohort Study Mortality Index scores over follow-up. Among 4572 PWH on ART at HIVAW/low weight, 68% were suppressed (VL of <200 copies/mL); subsequent virologic failure was uncommon (7%). Among viremic PWH, 70% and 60% achieved suppression and undetectability (VL of <50 copies/mL), respectively, over follow-up. HIVAW remains a challenge for some PWH. Particular attention needs to be paid to HIVAW/low weight and virologic control to restore health and potentially reduce the risk of death.

J Acquir Immune Defic Syndr. 2024 Mar 7. doi: 10.1097/QAI.0000000000003410. Online ahead of print.

Do HIV Care Outcomes Differ by Provider Type?

Weiser J, Tiey Y, Crim SM, Riedel DJ, Shouse RL, Dasgupta S.

BACKGROUND: We compared HIV care outcomes by HIV provider type to inform efforts to strengthen the HIV provider workforce.°

SETTING: US

METHODS: We analyzed data from CDC's Medical Monitoring Project collected during June 2019 to May 2021 from 6323 adults receiving HIV medical care. Provider types were infectious disease physicians only (ID physicians), non-ID physicians only (non-ID physicians), nurse practitioners only (NPs), physician assistants only (PAs), and ID physicians plus NPs and PAs (mixed providers). We measured patient characteristics, social determinants of health (SDOH), and clinical outcomes including retention in care; antiretroviral therapy prescription; antiretroviral therapy adherence; viral suppression; gonorrhea, chlamydia, and syphilis testing; satisfaction with HIV care; and HIV provider trust.

RESULTS: Compared with patients of ID physicians, higher percentages of patients of other provider types had characteristics and SDOH associated with poor health outcomes and received HIV care at Ryan White HIV/AIDS Program–funded facilities. After accounting for these differences, most outcomes were not meaningfully different; however, higher percentages of patients of non-ID physicians, NPs, and mixed providers were retained in care (6.5%, 5.6%, and 12.7%, respectively) and had STI testing in the past 12 months, if sexually active (6.9%, 7.4%, and 13.5%, respectively).

CONCLUSION: Most HIV outcomes were equivalent across provider types. However, patients of non-ID physicians, NPs, and mixed providers were more likely to be retained in care and have recommended STI testing. Increasing delivery of comprehensive primary care by ID physicians and including primary care providers in ID practices could improve HIV primary care outcomes.

Clin Infect Dis. 2024 Mar 11:ciae132. doi: 10.1093/cid/ciae132. Online ahead of print.

Effectiveness of the 2023-2024 Formulation of the Coronavirus Disease 2019 mRNA Vaccine

Shrestha NK, Burke PC, Nowacki AS, Gordon SM

BACKGROUND: The purpose of this study was to evaluate whether the 2023-2024 formulation of the COVID-19 mRNA vaccine protects against COVID-19.

METHODS: Employees of Cleveland Clinic in employment when the 2023-2024 formulation of the COVID-19 mRNA vaccine became available to employees, were included. Cumulative incidence of COVID-19 over the following 17 weeks was examined prospectively. Protection provided by vaccination (analyzed as a time-dependent covariate) was evaluated using Cox proportional hazards regression, with time-dependent coefficients used to separate effects before and after the JN.1 lineage became dominant. The analysis was adjusted for the propensity to get tested, age, sex, pandemic phase when the last prior COVID-19 episode occurred, and the number of prior vaccine doses.

RESULTS: Among 48,210 employees, COVID-19 occurred in 2,462 (5.1%) during the 17 weeks of observation. In multivariable analysis, the 2023-2024 formula vaccinated state was associated with a significantly lower risk of COVID-19 before the JN.1 lineage became dominant (HR, .58; 95% CI, .49-.68, P< .001), and lower risk but one that did not reach statistical significance after (HR, .81; 95% CI, .65-1.01, P value 0.06). Estimated vaccine effectiveness (VE) was 42% (95% CI, 32%-51%) before the JN.1 lineage became dominant, and 19% (CI, -1%-35%) after. Risk of COVID-19 was lower among those previously infected with an XBB or more recent lineage and increased with the number of vaccine doses previously received.

CONCLUSIONS: The 2023-2024 formula COVID-19 vaccine given to working-aged adults afforded modest protection overall against COVID-19 before the JN.1 lineage became dominant and less protection after.

Int J Infect Dis. 2024 Feb 28:106990. doi: 10.1016/j.ijid.2024.106990. Online ahead of print.

Post COVID-19 condition imposes significant burden in patients with advanced chronic kidney disease: a nested case-control study

Bouwxmans P, Malahe RK, Messchendorp AL, et al; RECOVAC Consortium

BACKGROUND: The burden of post COVID-19 condition (PCC) is not well studied in patients with advanced kidney disease.

METHODS: A large prospective cohort of SARS-CoV-2 vaccinated patients with chronic kidney disease stages G4-G5 (CKD G4/5), on dialysis, and kidney transplant recipients (KTR) were included. Antibody levels were determined after vaccination. Presence of long-lasting symptoms was assessed in patients with and without prior COVID-19 and compared using logistic regression. In patients with prior COVID-19, PCC was defined according to the WHO definition.

RESULTS: 216 CKD G4/5 patients, 375 dialysis patients, and 2005 KTR were included. Long-lasting symptoms were reported in 204/853 (24%) patients with prior COVID-19 and in 297/1743 (17%) patients without prior COVID-19 (aOR: 1.45 (1.17-1.78)], P<0.001). PCC was prevalent in 29% of CKD G4/5 patients, 21% of dialysis patients, and 24% of KTR. In addition, 69% of patients with PCC reported (very) high symptom burden. Odds of PCC was lower per 10-fold increase in antibody level after vaccination (aOR 0.82 [0.70-0.96], P=0.01) and higher in case of COVID-19 related hospital admission (aOR 4.64 [2.61-8.25], P=0.003).

CONCLUSIONS: CKD G4/5 patients, dialysis patients, and KTR are at risk for PCC with high symptom burden after SARS-CoV-2 vaccination, especially if antibody levels are low and in case of hospitalization due to COVID-19.

Circulation. 2024 Mar 12;149(11):807-821. doi: 10.1161/CIRCULATIONAHA.123.067032. Epub 2023 Nov 6.

Nonischemic or dual cardiomyopathy in patients with coronary artery disease

Bawaskar P, Nicholas Thomas N, Ismail K, et al.

BACKGROUND: Randomized trials in obstructive coronary artery disease (CAD) have largely shown no prognostic benefit from coronary revascularization. Although there are several potential reasons for the lack of benefit, an underexplored possible reason is the presence of coincidental nonischemic cardiomyopathy (NICM). We investigated the prevalence and prognostic significance of NICM in patients with CAD (CAD-NICM).

METHODS: We conducted a registry study of consecutive patients with obstructive CAD on coronary angiography who underwent contrast-enhanced cardiovascular magnetic resonance imaging for the assessment of ventricular function and scar at 4 hospitals from 2004 to 2020. We identified the presence and cause of cardiomyopathy using cardiovascular magnetic resonance imaging and coronary angiography data, blinded to clinical outcomes. The primary outcome was a composite of all-cause death or heart failure hospitalization, and secondary outcomes were all-cause death, heart failure hospitalization, and cardiovascular death.

RESULTS: Among 3023 patients (median age, 66 years; 76% men), 18.2% had no cardiomyopathy, 64.8% had ischemic cardiomyopathy (CAD+ICM), 9.3% had CAD+NICM, and 7.7%

had dual cardiomyopathy (CAD+dualCM), defined as both ICM and NICM. Thus, 16.9% had CAD+NICM or dualCM. During a median follow-up of 4.8 years (interquartile range, 2.9, 7.6), 1116 patients experienced the primary outcome. In Cox multivariable analysis, CAD+NICM or dualCM was independently associated with a higher risk of the primary outcome compared with CAD+ICM (adjusted hazard ratio, 1.23 [95% CI, 1.06-1.43]; P=0.007) after adjustment for potential confounders. The risks of the secondary outcomes of all-cause death and heart failure hospitalization were also higher with CAD+NICM or dualCM (hazard ratio, 1.21 [95% CI, 1.02-1.43]; P=0.032; and hazard ratio, 1.37 [95% CI, 1.11-1.69]; P=0.003, respectively), whereas the risk of cardiovascular death did not differ from that of CAD+ICM (hazard ratio, 1.15 [95% CI, 0.89-1.48]; P=0.28).

CONCLUSIONS: In patients with CAD referred for clinical cardiovascular magnetic resonance imaging, NICM or dualCM was identified in 1 of every 6 patients and was associated with worse long-term outcomes compared with ICM. In patients with obstructive CAD, coincidental NICM or dualCM may contribute to the lack of prognostic benefit from coronary revascularization.

Clin Transplant. 2024 Mar;38(3):e15280. doi: 10.1111/ctr.15280

Does lung procurement and exposure to Perfadex impact heart transplantation outcomes?

Blitzer D, Baran DA, Lirette S, Copeland H.

INTRODUCTION: Some studies have shown increased incidence of primary graft dysfunction (PGD) after heart and lung procurement for heart transplant recipients. There have been limited investigations of the impact of lung procurement on heart procurement and the potential effects of the exposure to the type of lung preservation solution, the volume of the lung preservation solution and adequacy of decompression of the heart during heart and lung procurement and the impact on heart transplant outcomes.

METHODS: Adult heart transplant recipients in the UNOS database recorded from January 1, 2000, to June 30, 2022, formed the study cohort. Any heart that was procured with a lung team that utilized Perfadex preservation solution (XVIVO, Gothenburg, Sweden) was classified as exposed to Perfadex and otherwise classified as not exposed to Perfadex. Lung procurements performed with a preservation solution other than Perfadex or unknown were excluded (n = 2486). Simple comparisons were made with t-tests or chi-squared tests. Logistic regression models were used to predict 30-day and 1-year survival. Accelerated failure time models were employed to analyze time to death and time to rejection.

RESULTS: The cohort consisted of 34,192 heart transplants, of which 21,928 donors were not exposed to Perfadex (64.1%). There were statistically, but not clinically, significant differences in donor characteristics for these groups including in donor age (33.34 ± 11.01 not exposed vs. 30.70 ± 10.69 exposed; P < .001), diabetic donor (4% not exposed vs. 3% exposed; P = .004), and ischemic time (3.28 ± 1.09 h not exposed vs. 3.24 ± 1.05 h exposed; P = .002). In adjusted models, for all included donors, Perfadex exposure was associated with increased short-term mortality, but no long-term difference (1 year mortality OR 1.10, P = .014).

CONCLUSION: Perfadex exposure was associated with increased short-term mortality for heart transplant recipients. Mechanistic investigation is warranted.

Clin Transplant. 2024 Mar;38(3):e15270. doi: 10.1111/ctr.15270.

Use of induction therapy post–heart transplantation: clinical practice recommendations based on systematic review and network meta-analysis of evidence

Foroutan F, Guyatt G, Stehlik J, et al.

BACKGROUND: The use of induction therapy (IT) agents in the early post–heart transplant period remains controversial. The following recommendations aim to provide guidance on the use of IT agents, including Basiliximab and Thymoglobulin, as part of routine care in heart transplantation (HTx).

METHODS: We recruited an international, multidisciplinary panel of 15 stakeholders, including patient partners, transplant cardiologists and surgeons, nurse practitioners, pharmacists, and methodologists. We commissioned a systematic review on benefits and harms of IT on patient-important outcomes, and another on patients' values and preferences to inform our recommendations. We used the GRADE framework to summarize our findings, rate certainty in the evidence, and develop recommendations. The panel considered the balance between benefits and harms, certainty in the evidence, and patient's values and preferences, to make recommendations for or against the routine postoperative use of Thymoglobulin or Basiliximab.

RESULTS: The panel made recommendations on 3 major clinical problems in HTx: (1) We suggest against the routine postoperative use of Basiliximab compared to no IT, (2) we suggest against the routine use of Thymoglobulin compared to no IT, and (3) for those patients for whom IT is deemed desirable, we suggest for the use of Thymoglobulin as compared to Basiliximab.

CONCLUSION: This report highlights gaps in current knowledge and provides directions for clinical research in the future to better understand the clinical utility of IT agents in the early post heart transplant period, leading to improved management and care.

Cancer Cell. 2024 Mar 11;42(3):474-486.e12. doi: 10.1016/j.ccell.2024.01.013. Epub 2024 Feb 22.

Chronic stress increases metastasis via neutrophil-mediated changes to the microenvironment

He X-Y Gao Y, Ng D, et al.

Chronic stress is associated with increased risk of metastasis and poor survival in cancer patients, yet the reasons are unclear. We show that chronic stress increases lung metastasis from disseminated cancer cells 2- to 4-fold in mice. Chronic stress significantly alters the lung microenvironment, with fibronectin accumulation, reduced T cell infiltration, and increased neutrophil infiltration. Depleting neutrophils abolishes stress-induced metastasis. Chronic stress shifts normal circadian rhythm of neutrophils and causes increased neutrophil extracellular trap (NET) formation via glucocorticoid release. In mice with neutrophil-specific glucocorticoid receptor deletion, chronic stress fails to increase NETs and metastasis. Furthermore, digesting NETs with DNase I prevents chronic stress-induced metastasis. Together, our data show that glucocorticoids released during chronic stress cause NET formation and establish a metastasis-promoting microenvironment. Therefore, NETs could be targets for preventing metastatic recurrence in cancer patients, many of whom will experience chronic stress due to their disease.

Am Heart J. 2024 Mar 12:S0002-8703(24)00055-3. doi: 10.1016/j.ahj.2024.03.004. Online ahead of print.

Vascular health years after a hypertensive disorder of pregnancy: The EPOCH Study

Miller HE, Tierney S, Marcia L Stefanick ML, et al.

BACKGROUND: Preeclampsia is associated with a 2-fold increase in a woman's lifetime risk of developing atherosclerotic cardiovascular disease (ASCVD), but the reasons for this association are uncertain. The objective of this study was to examine the associations between vascular health and a hypertensive disorder of pregnancy among women ≥ 2 years postpartum.

METHODS: Premenopausal women with a history of either a hypertensive disorder of pregnancy (cases: preeclampsia or gestational hypertension) or a normotensive pregnancy (controls) were enrolled. Participants were assessed for standard ASCVD risk factors and underwent vascular testing, including measurements of blood pressure, endothelial function, and carotid artery ultrasound. The primary outcomes were blood pressure, ASCVD risk, reactive hyperemia index measured by EndoPAT and carotid intima-medial thickness. The secondary outcomes were augmentation index normalized to 75 beats per minute and pulse wave amplitude measured by EndoPAT, and carotid elastic modulus and carotid beta-stiffness measured by carotid ultrasound.

RESULTS: Participants had a mean age of 40.7 years and were 5.7 years since their last pregnancy. In bivariate analyses cases (N=68) were more likely than controls (N=71) to have hypertension (18% vs. 4%, P=0.034), higher calculated ASCVD risk (0.6 vs 0.4, P=0.02), higher blood pressures (systolic: 118.5 vs. 111.6 mm Hg, P=0.0004; diastolic: 75.2 vs 69.8 mm Hg, P=0.0004), and higher augmentation index values (7.7 vs. 2.3 P=0.03). They did not, however, differ significantly in carotid intima-media thickness (0.5 vs. 0.5, P=0.29) or reactive hyperemia index (2.1 vs 2.1, P=0.93), nor in pulse wave amplitude (416 vs 326, P=0.11), carotid elastic modulus (445 vs 426, P=0.36), or carotid beta stiffness (2.8 vs 2.8, P=0.86).

CONCLUSION: Women with a prior hypertensive disorder of pregnancy had higher ASCVD risk and blood pressures several years postpartum but did not have more endothelial dysfunction or subclinical atherosclerosis.

Am J Ind Med. 2024 Apr;67(4):321-333. doi: 10.1002/ajim.23568. Epub 2024 Feb 12.

Mortality and cancer incidence in perfluorooctanesulfonyl fluoride production workers

Alexander BH, Ryan A, Church TR, Kim H, Olsen GW, Logan PW

BACKGROUND: Exposure to per- and polyfluoroalkyl substances (PFAS) has been associated with several health outcomes, though few occupationally exposed populations have been studied. We evaluated mortality and cancer incidence in a cohort of perfluorooctanesulfonyl fluoride–based specialty chemical manufacturing workers.

METHODS: The cohort included any employee who ever worked at the facility from 1961 to 2010 (N = 4045), with a primary interest in those who had 365 cumulative days of employment (N = 2659). Vital status and mortality records were obtained through 2014 and the cohort was linked to state cancer registries to obtain incident cancer cases from 1995 to 2014. Cumulative exposure was derived from a comprehensive exposure reconstruction that estimated job-specific perfluorooctanesulfonate (PFOS)-equivalents (mg/m3) exposure. Overall and exposure-specific standardized mortality ratios (SMR) were estimated in reference to the US population. Hazard ratios (HRs) and 95% confidence interval (CI) for cumulative PFOS-equivalent exposure (log2 transformed) were estimated within the cohort for specific causes of death and incident cancers using a time-dependent Cox model.

RESULTS: Death rates were lower than expected except for cerebrovascular disease (SMR = 2.42, 95% CI = 1.25-4.22) and

continues on page 33

Beyond Boundaries: Unraveling the Ethical Challenges of Coordinated Transgender Health Care

continued from page 13

dignity and acceptance.

Beneficence is evident in facilitating access to gender-affirming interventions, such as hormone therapy or gender confirmation surgeries, when these are deemed necessary for the individual's well-being. Coordinating access to these interventions contributes to aligning the individual's physical characteristics with their gender identity. Beneficence plays a role in addressing health care disparities faced by transgender individuals. Care coordination efforts should actively work toward reducing disparities in health care access, quality, and outcomes, promoting positive health outcomes for transgender individuals.

Best Practices in Transgender Health Care

1. When obtaining the TGD individual's history, use person-centered care guidelines. A person-centered approach to transgender care involves actively including the individual in decision-making, respecting their gender identity, and providing information and options that align with their goals. It involves open communication, sensitivity to pronoun use and chosen names, and recognizing the impact of societal stigma on mental health.
2. Obtain a detailed medical history that includes past and present hormone use.
3. Confirm with the TGD individual their preferred pronouns and use these preferred pronouns in your documentation. It is paramount that the care manager is aware of language that is respectful and inclusive for the transgender individual. Be willing to provide your preferred pronouns as well.
4. Seek education regarding transgender health and rights. One resource is the World Professional Association for Transgender Health. Another is UCSF Center of Excellence for Transgender Health.
5. Approach individuals with gender dysphoria with empathy, recognizing the mental health aspect of their experiences. The CCM should also be willing to facilitate access to counseling and support services.
6. Ask the transgender individual about readiness to disclose their gender identity with family. Inquire into their support system. Their "family" may not be a blood-related relative(s).
7. Verify with the transgender individual which individuals they wish to disclose their health information to. This should also be documented for other health care professionals who are involved with care coordination.
8. Take cues from the patient in conversations about sexuality and gender identity.

Conclusion

How was the scenario resolved? The CCM explained to the transgender individual that since the claim was submitted in the previous name, they would have to continue with that name for billing purposes. Changing the name could also interfere with their receiving pay for being out of work. However, the CCM stated they would use the preferred name when communicating with the transgender individual. They would additionally inform other case parties of the preferred name. The transgender individual was very pleased with the CCM explaining why the name change could not be updated on all correspondence. They were additionally appreciative of the CCM being considerate to use their preferred name when communicating. CE1

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References continued on page 33

Addressing Social Determinants of Health: Are We There Yet? *continued from page 18*

- Building relationships with community leaders and agencies to facilitate social needs assessments and connect patients to resources while improving communications among all parties
- Developing methods to include social needs information with health care services referrals

However, these recommendations may undergo some changes based on feedback from the full Consortium.

NQF released the full report of this Leadership Consortium project on March 5, 2024. The project recognizes the challenges all of health care is facing as new developments and best practices are identified, but overcoming these challenges will require flexibility and compromise. To view the full report visit: https://www.qualityforum.org/NQF_Leadership_Consortium.aspx

In the meantime, individuals with health-related social needs will need to be identified and interventions to meet those needs found and coordinated. Referring back to the CMSA project with Marion County Health, efforts were made to follow up with patients' postdischarge to ensure their needs were met, but not all patients were reached. When a patient is difficult to reach, is there more that can or should be done? One intervention could be a warm hand-off from the discharging facility to a health plan or community case manager to continue to follow up with a patient to ensure their needs were met. Based on anecdotal observations from the Marion County Health acute care case managers, patients may be hesitant to access resources due to feelings of embarrassment or shame. This indicates a need to examine how screenings are done—whether they are conducted with empathy and lack of bias and whether patients are given information on how accessing resources for identified needs might actually help with their health condition management. This indicates a need for training in methods like motivational interviewing and perhaps even poverty training. We are not yet at a place where there is consistency in screening or follow-up, but once there, shouldn't there be an assessment of whether or not meeting nonmedical needs has resulted in health improvements?

As you have observed, the terms used to describe nonmedical social concerns are social determinants. social drivers, or health-related social needs and they translate the same: addressing issues and concerns outside of medical care that impact an individual's ability to manage their health. The journey has only begun, but many organizations already have processes in place to address the social drivers of health. The challenges outlined in this article should not deter health care and community stakeholders from continuing to find a way to gather, analyze, report, and act on the data. This first year of collecting data will set the stage for more cooperation and collaboration to achieve standardization. But what is really most important is that we meet the needs of those who are challenged with nonmedical issues and situations that impact their ability to manage their health and that there is follow-up to gauge if they actually did achieve health improvements. CE II

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continued from page 30

bladder cancer (SMR = 3.91, 95% CI = 1.07-10.02) in the highest exposure quartile. Within the cohort, the incidence of bladder, colorectal, and pancreatic cancer were positively associated with exposure; however, except for lung cancer (HR = 1.05, 95% CI = 1.00-1.11) the CIs did not exclude an HR of 1.

CONCLUSIONS: This study provides some evidence that occupational exposure to PFOS is associated with bladder and lung cancers and with cerebrovascular disease.

Am J Gastroenterol. 2024 Mar 14. doi: 10.14309/ajg.0000000000002756. Online ahead of print.

Non-Hispanic Black persons with nonalcoholic fatty liver disease have lower rates of advanced fibrosis, cirrhosis, and liver-related events even after controlling for clinical risk factors and PNPLA3 genotype

Samala N, Xin Y, Wilson LA, et al ; NASH Clinical Research Network

BACKGROUND AIMS: Nonalcoholic fatty liver disease (NAFLD) is less frequent in non-Hispanic persons (NHB), but there are knowledge gaps in our understanding of disease severity and outcomes of NAFLD in NHB. We compared liver histology and clinical outcomes of NAFLD in NHB and non-Hispanic White adults (NHW).

METHODS: We compared liver histology and outcomes of 109 NHB and 1910 NHW adults with biopsy proven NAFLD participating in the Nonalcoholic Steatohepatitis Clinical Research Network observational studies. The relationship between self-reported NHB race/ethnicity and advanced fibrosis was assessed via multivariable logistic regression after controlling for clinical co-variates and PNPLA3 genotype.

RESULTS: NHB and NHW with NAFLD had similar NAFLD activity scores (NAS, 4.4 vs 4.3, P=0.87) and proportions with definite NASH (59% vs 58%, P=1.0), but NHB had significantly lower rates of advanced fibrosis (22% vs 34%, p=0.01) or cirrhosis (4.6% vs 12.1%, P=0.010). Compared to NHW, NHB had significantly lower frequency of advanced fibrosis (OR: 0.48, 95% CI: .27-0.86, P=0.01). In a comparison between 24 NHB and 655 NHW with advanced fibrosis, the NAS (5.6 vs 4.9, P=0.01) and lobular inflammation grade (2.2 vs 1.7, P<0.002) were significantly higher among NHB with advanced fibrosis. One NHB and 23 NHW died during follow-up (0.30 vs 0.28 per 100 person-year follow-up). Seven and zero liver-related deaths occurred in NHW and NHB with NAFLD respectively.

CONCLUSION: The risk of advanced fibrosis in NHB with NAFLD is significantly lower, after controlling for clinical risk factors and PNPLA3 genotype. Although their risk for advanced fibrosis was low, NHB with NAFLD and advanced fibrosis had higher NAS and lobular inflammation, indicating a difference in their relationship between necroinflammation and fibrosis.

PharmaFacts for Case Managers

continued from page 26

- Tyenne (tocilizumab-aazg) is an interleukin-6 (IL-6) receptor antagonist biosimilar to Actemra used for treatment of rheumatoid arthritis, giant cell arteritis, polyarticular juvenile idiopathic arthritis, and systemic juvenile idiopathic arthritis.
- Letybo (letibotulinumtoxinA-wlbg) is an acetylcholine release inhibitor and a neuromuscular-blocking agent indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.
- Simlandi (adalimumab-ryvk) is a tumor necrosis factor (TNF) blocker interchangeable biosimilar to Humira, approved for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa, and uveitis.
- Amtagvi (lifileucel) is a tumor-derived autologous T cell immunotherapy used for the treatment of adult patients with unresectable or metastatic melanoma.

Beyond Boundaries: Unraveling the Ethical Challenges of Coordinated Transgender Health Care

continued from page 31

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Transgender Health Care
continued from page 2

gender, and it is incumbent upon the case manager to have a working knowledge of these terms and recognize which expression a patient wishes to use. The binary construct of gender is one of Western context and is not absolute.

It is essential for the case manager to understand the issues, consequences, and barriers to care for the transgender individual. All these issues are more pronounced for people of color.

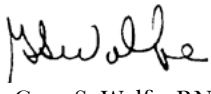
Key points to remember in care of the transgender individual:

- Being transgender or gender diverse is not rare and is no longer considered pathological; it represents an example of human dignity
- Scientific evidence supports biological underpinnings to gender identity development
- Gender-affirming care has clear physical and mental health benefits, some of which could be lifesaving

So, what can the case manager do to ensure that transgender individuals receive the ethical, safe and needed care they are seeking?

- Become educated: The first thing a case manager can do is to become educated about transgender issues. You can study, read, attend workshops, talk with transgender individuals, and in the process, you will develop some sensitivity and understanding of issues the transgender individual faces.
- Be nonjudgmental: Don't let your own bias or judgment enter your caring process. You don't have to agree or completely understand, or have all the answers, but you are obligated to provide safe, nonjudgmental care with all the ramifications of the Code of Professional Conduct.
- See the individual: Start by recognizing them by the name that they wish to be called including the pronouns. Document this information so others will know.
- Ensure they receive all the care including referrals that are appropriate and necessary for their care including preventative/screening care.
- Help make sure your coworkers have appropriate training for caring for the transgender individual.
- Be an advocate for the transgender individual.
- Be an example for others on how to care for transgender individuals.

Poor health care has been identified as one of the many factors that lower quality of life for transgender individuals. You, the case manager, can make a difference. Become educated. Set an example. Make a difference.



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ACCM: Improving Case Management Practice through Education

Note: Read *Beyond Boundaries: Unraveling the Ethical Challenges of Coordinated Transgender Health Care for Adults* by Chikita Mann, MSN, RN, CCM, in this issue.

Patient Assessment and Self-Assessment–Important Considerations for Patients…and You!
continued from page 3

work—from client interaction and time management to the decision-making process and effectiveness of their intervention.

5. **Offer Support:** Support from supervisors and mentors is crucial when case managers become frustrated with the self-assessment process. When conversations are encouraged, and constructive feedback is offered, case managers gain valuable perspective and a deeper understanding of how they can improve their performance.
6. **Encourage Growth:** Self-assessment shouldn't be a one and done process but rather a regular part of a case manager's professional journey. While this process is often aligned with a performance review by supervisors and possibly linked to increases in salary or a promotion, it should also be an opportunity to identify areas where further professional development, education, or mentoring would be beneficial.

The coming months will provide many opportunities for the kind of on-site educational programs at local case management chapters that we've missed due to the pandemic. The CMSA National Conference was held April 4–7, 2024, in Providence, Rhode Island. It provided opportunities to network with colleagues, visit exhibits and attend poster presentations that always provide food for thought. Attending this conference can renew your passion for case management. You can learn more about what happened at the conference at the website cmsa.societyconference.com

Of course, *CareManagement* welcomes you to contribute an article to share your expertise with your peers, and possibly add that contribution to your professional resume and your pursuit of career advancement.

Enjoy this Spring and the holidays that will allow you to spend time with family and friends.

Take some time for you as you make a difference for others…one patient at a time! Warm regards,

Catherine M. Mullahy, RN, BS, CRRN, CCM, FCM, *Executive Editor*
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Return-to-Work and Stay-at-Work: An Evolution in Practice and Attitudes *continued from page 5*

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The Ole White Van *continued from page 6*

Continue on, case managers! Provide a positive outcome for your clients! You are making a difference! CM

This work has been previously published by CMSA Chicago 2023 in Case Management: Creating Connections…Shaping Solutions – 5th Edition *and reprinted with permission by Eric Bergman and Colleen Morley, Editors and the author, Kathy Barrows.*

General Compliance Guidance From the OIG, Part 2 *continued from page 7*

of the anti-kickback statute, including an evaluation of whether an arrangement can be structured or restructured to meet the requirements of applicable exceptions or safe harbors. CM

The Momentum Continues *continued from page 4*

Workers (NACHW). These partnerships have facilitated the sharing of knowledge, resources, and best practices, enhancing the effectiveness of case management across different health care settings. The new (2024) collaboration with NACHW, in particular, has highlighted the critical role of community health workers in supporting case management efforts, especially in underserved communities. We continue to grow our networking outreach as well, with our LinkedIn page meeting an all time high of 7200 followers in February, 2024. If you're not following our LinkedIn page already, please do so and invite your friends/colleagues/connections as well.

Planning for the CMSA National Conference in Providence, RI

The planning for the CMSA National Conference, set to take place in Providence, RI, from June 4–7, 2024, has been a focal point of the year's activities. The conference is shaping up to be an unparalleled opportunity for professional development (79.5 continuing education credits available), networking, and collaboration among case management professionals. The theme for the CMSA 2024 conference is "The Future of Healthcare Powered by Case Management." This theme highlights the crucial role of case management in shaping the future of health care, focusing on how case management practices and professionals are integral to driving improvements in patient care, health care delivery, and outcomes in an ever-evolving health care landscape. The conference will feature a comprehensive program of educational sessions, workshops, and keynote presentations designed to enhance the skills and knowledge of attendees. The event will also include a robust exhibition hall, showcasing the latest products, services, and technologies in case management.

A Year of Growth and Impact

As we reflect on the first part of 2024, it is clear that CMSA has not only continued its tradition of excellence but has also expanded its reach and impact in new and meaningful ways. The launch of the DEIB, Public Information, and Future Trends committees, along with the successful Virtual Hill Day and ongoing collaborations with existing partners and the new collaborations we continue to seek out and foster, are testament to CMSA's dynamic approach to addressing the needs of its members and the broader case management community. The anticipation for the National Conference in Providence further amplifies the excitement surrounding CMSA's activities and its role in shaping the future of case management.

The 2024 year has already been a year of significant achievements for CMSA, marked by a deepened commitment to member engagement, advocacy, and professional development. As the organization moves forward, the continued success of its initiatives, including the eagerly awaited National Conference, will undoubtedly contribute to the advancement of the case management profession and the betterment of health care outcomes for patients across the nation.

Onward! CM

The Case Management Society of America *(CMSA) facilitates the growth and development of professional case managers across the full health care continuum, promoting high quality, ethical practice benefitting patients and their families. We strive for improved health outcomes by providing evidence-based resources, impacting health care policy and sustaining the CMSA-developed Standards of Practice for Case Management.* www.cmsa.org

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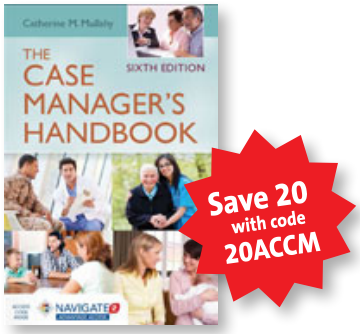
Here are just some of Mullahy & Associates' career-advancing resources:



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